Board of Governors Meeting

Via Teleconference/Webinar

June 18, 2019
12:00 PM – 1:30 PM ET

pcori
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome and Introductions

Grayson Norquist, MD, MSPH

Chairperson, Board of Governors

Joe Selby, MD, MPH

Executive Director

Agenda

12:00 PM	**Call to Order, Roll Call, and Welcome**
12:00 – 12:05	**Consider for Approval:** Minutes of the May 13, 2019 Board Meeting
12:05 – 12:20	**FY2019 Mid-Year Financial Review**
12:20 – 1:00	**Research Portfolio Exploration Series:** Focus on Opioids Portfolio
1:00 PM	**Wrap Up and Adjournment**

Board Vote

Call for a Motion to:	• **Approve** the Minutes of the May 13, 2019 Board Meeting
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

FY2019 Mid-Year Financial Review

(As of 3/31/2019)

Russell Howerton, MD

Vice Chair, Finance and Administration Committee

Regina Yan, MA

Chief Operating Officer

Estimated Revenue and Expenditures

$2.754 billion will be committed by FY2021; expenses will continue through FY2024 until all research projects are completed.

	In Millions	% of Total Expenditures
Revenue	**$ 3,341**	
Program Services (thru FY2024)	**2,993**	**89.6%**
Award Payments	*2,754*	*82.4%*
Other Direct Program Costs	*239*	*7.2%*
Program Support (thru FY2024)	**127**	**3.8%**
Admin Support (thru FY2024)	**221**	**6.6%**
Total Expenditures (thru FY2024)	**$ 3,341**	**100%**

Award Payments are costs associated with Research, PCORnet, Engagement, Dissemination, and AHRQ Workforce Training awards.

Other Direct Program Costs are costs associated with the direct delivery of each program area. These costs may include personnel, professional services, and meeting & conferences associated with the Science, Research Infrastructure, Engagement, and Dissemination departments, as well as the Methodology Committee.

Program Support are costs associated with supporting program delivery and evaluation across all program areas. These costs may include personnel, professional services, and meeting & conferences associated with the Evaluation & Analysis, Communications, and Program Support & Information Management departments.

Admin Support are costs associated with general institutional support (such as the Board, administrative staff, rent, IT system infrastructure, human resources, finance, etc.).

FY2019 Revenue
(10/1/2018 – 3/31/2019)

REVENUE	*$ in millions*
From PCOR Trust Fund	
PCOR Fee	$ 274.5
Federal Appropriation	112.6
CMS Transfers from FHI/FSMI Trust Funds	109.2
Interest	0.3
From Interest (U.S. Treasury Securities)	15.9
Total Revenue	**$ 512.5**

Cash Balance and Outstanding Award Obligations
(As of 3/31/2019)

CASH BALANCE	*$ in millions*	
Cash -- PCOR Trust Fund	$	0.0
Cash -- Operating Account		17.5
U.S. Treasury Securities		1,445.0
Total	**$**	**1,462.5**

OUTSTANDING AWARD OBLIGATIONS	*$ in millions*	
Cumulative Funding Commitments*	$	2,415.0
Outstanding Award Obligations**	$	1,069.0

* Includes Research, PCORnet, Engagement, Dissemination, and AHRQ Workforce Training funding commitments.

** Outstanding award obligations are amounts of contracts awarded that will require payments during a future period. These amounts will become due and payable as research progresses over time through FY2024.

FY2019 Actual vs. Budget by Broad Categories
(As of 3/31/19)

	FY2019 YTD ACTUAL (through 3/31/19)	% of Total Actual	FY2019 YTD BUDGET (through 3/31/19)	% of Total Budget	FY2019 YTD VARIANCE (through 3/31/19)	
PROGRAM SERVICES	$ 164,153,360	88%	$ 162,138,051	87%	$ (2,015,309)	(1.2) %
PROGRAM SUPPORT	7,807,054	4%	8,216,396	4%	409,342	5.0 %
ADMINISTRATIVE EXPENSES	14,843,628	8%	15,870,660	9%	1,027,032	6.5 %
TOTAL	$ 186,804,042	100%	$ 186,225,107	100%	$ (578,935)	(0.3) %

PCORI's Opioid Portfolio:
A Multipronged Approach to Addressing the Opioid Epidemic

Layla Lavasani, PhD

Associate Director, Clinical Effectiveness and Decision Science

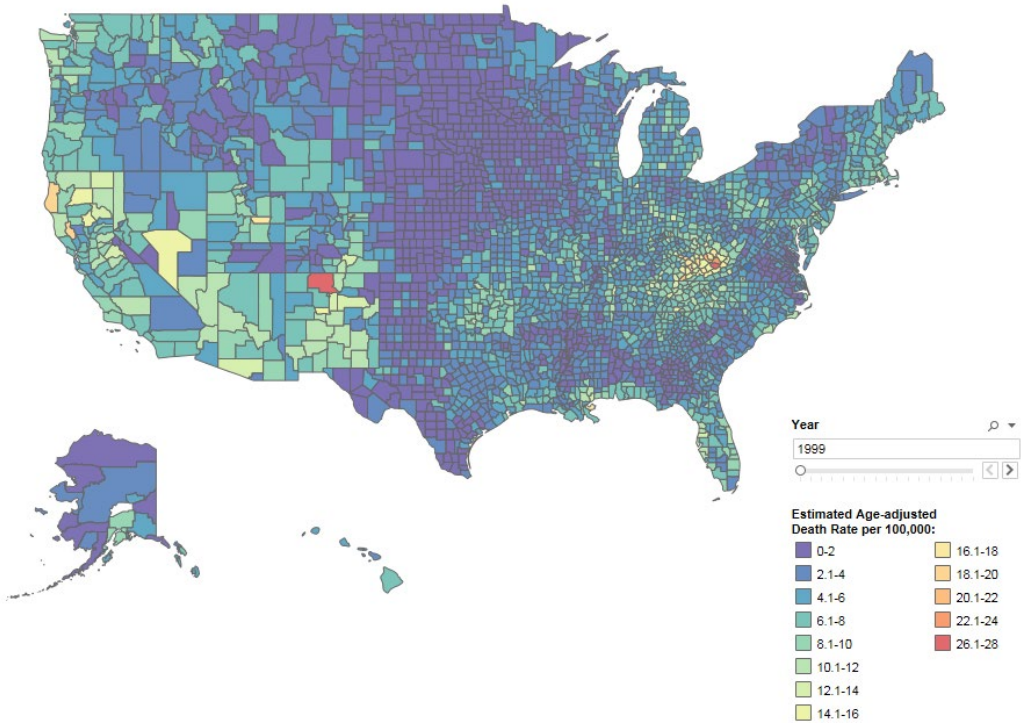
Els Houtsmuller, PhD

Associate Director, Healthcare Delivery and Disparities Research

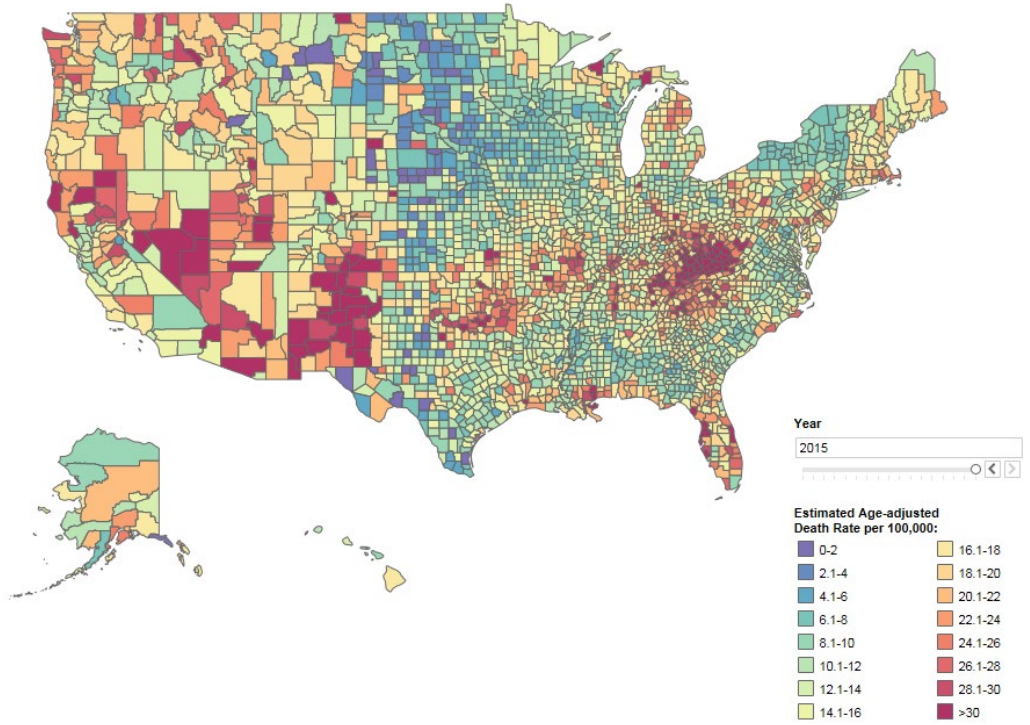
The Opioid Epidemic

Drug Overdose Death Rates

1999



2015



Source: CDC/NCHS, National Vital Statistics System, Mortality

PCORI's Stakeholder-Driven Process for CER

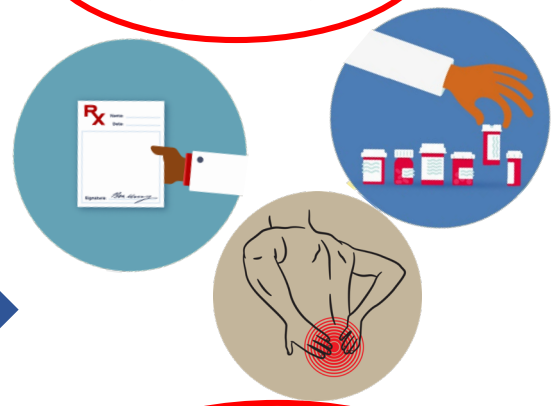
Board Priority Area: Chronic Pain & Opioid Crisis

Stakeholder Interviews & Workshops

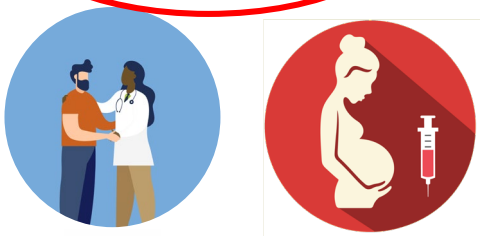
Background Research & Literature Reviews

CER Focus

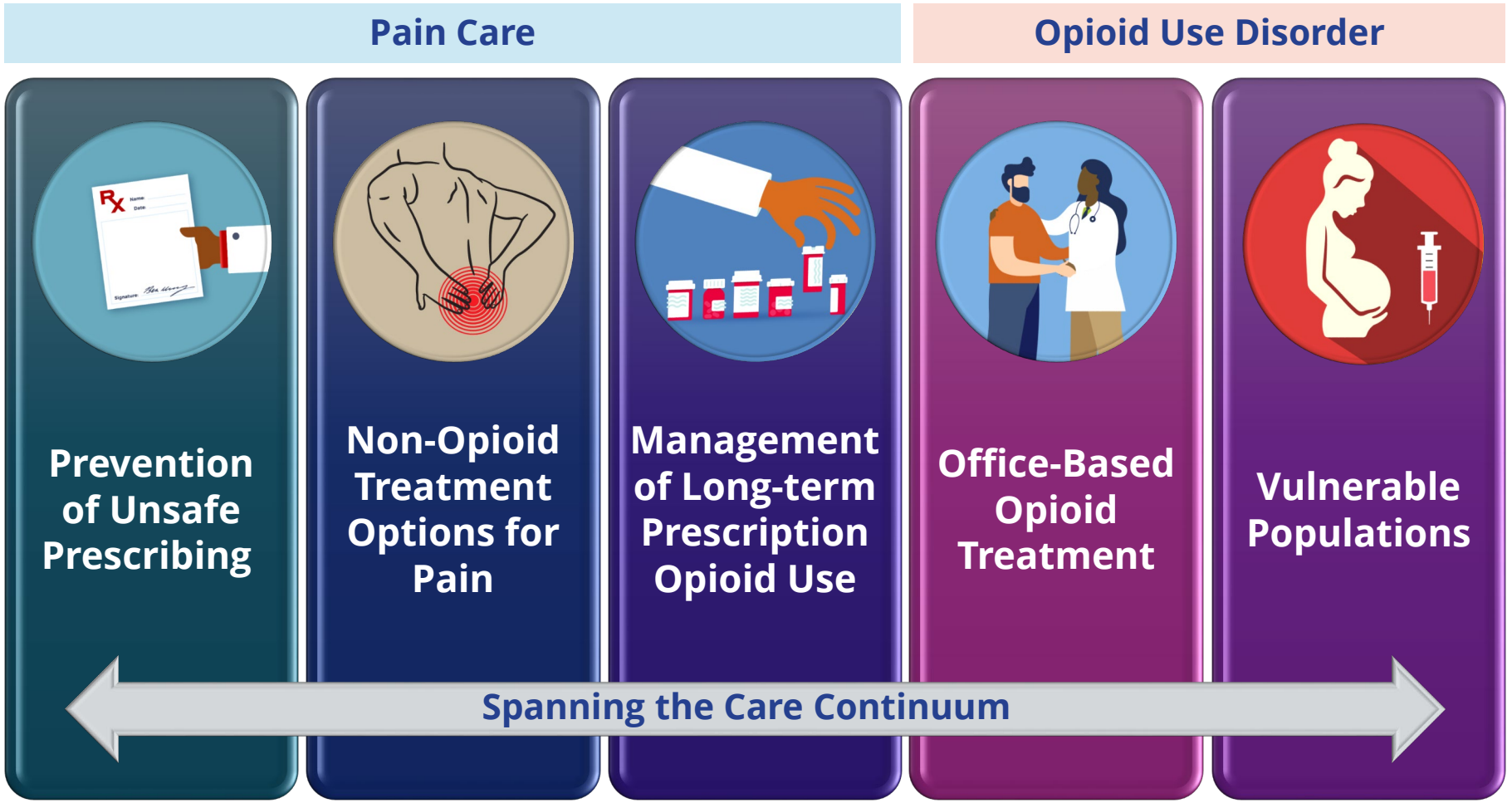
Pain Treatment



Opioid Use Disorder



A Patient-Centered Multipronged Approach to Addressing the Opioid Epidemic



PCORI's Rapid Response to the Crisis

Board Priority Area: Chronic Pain/ Opioid Crisis

Management of Chronic Opioid Pain Therapy

Reissue: **Management of Chronic Opioid Pain Therapy**

Unsafe Opioid Prescribing

Reissue: **Unsafe Opioid Prescribing**

MAT Delivery for Pregnant Women

Reissue: **MAT Delivery for Pregnant Women**

Psychosocial Interventions for OUD

2015 | 2016 | 2017 | 2018

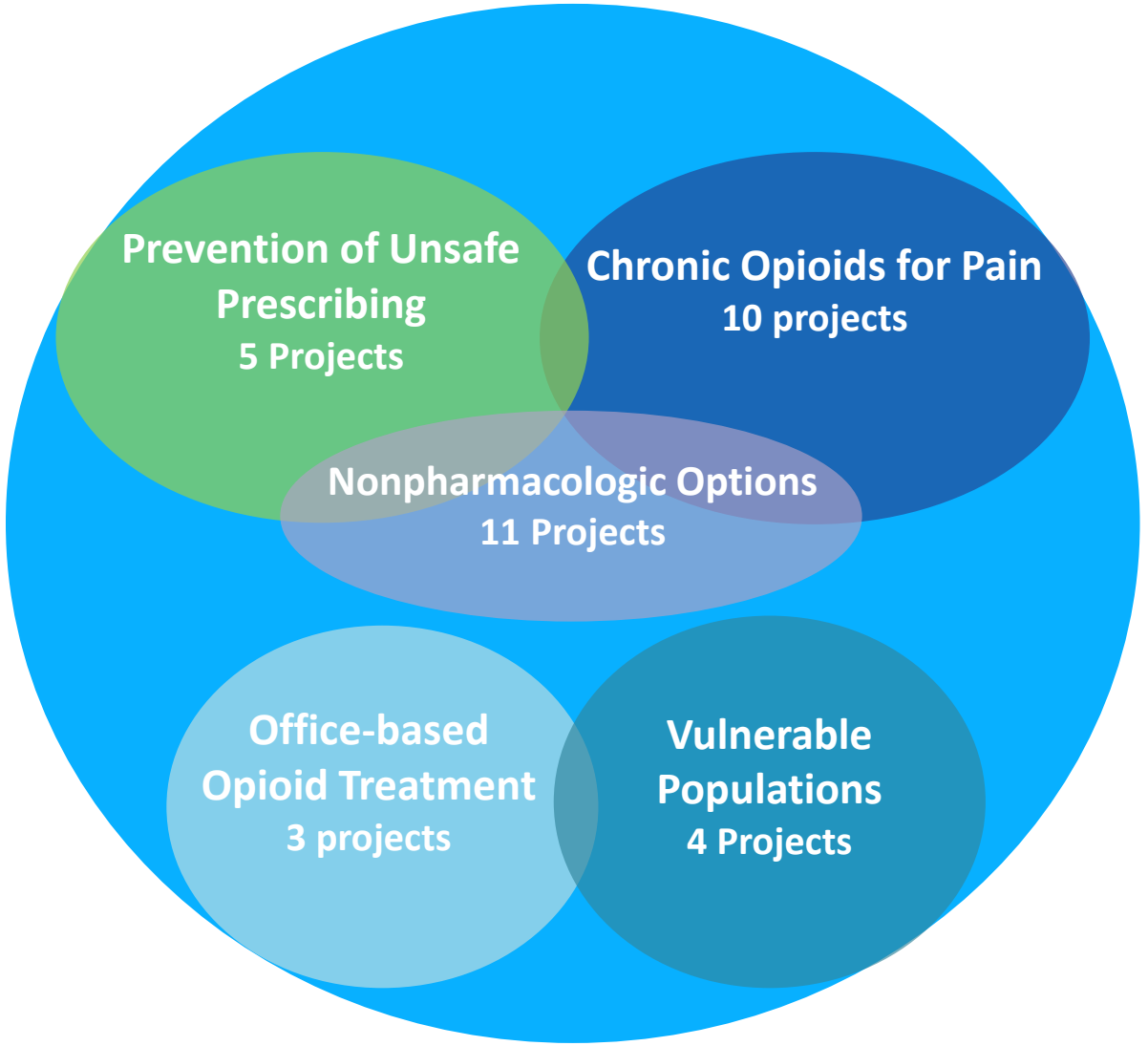
Oct 2017: HHS Declares National Crisis

PCORI's Opioid Portfolio: A Multipronged Approach

$128 MILLION

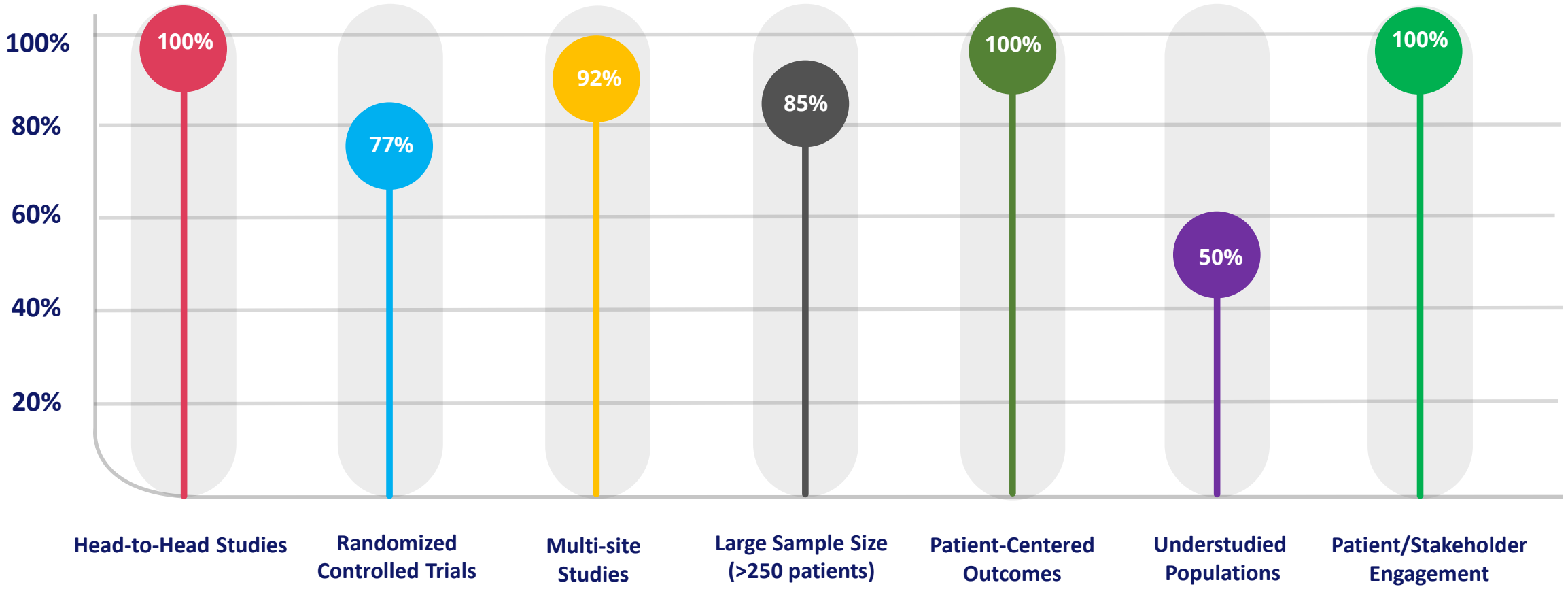
SUPPORTING 26

CER STUDIES ON OPIOID USE



As of June 2019
Categories are not mutually exclusive

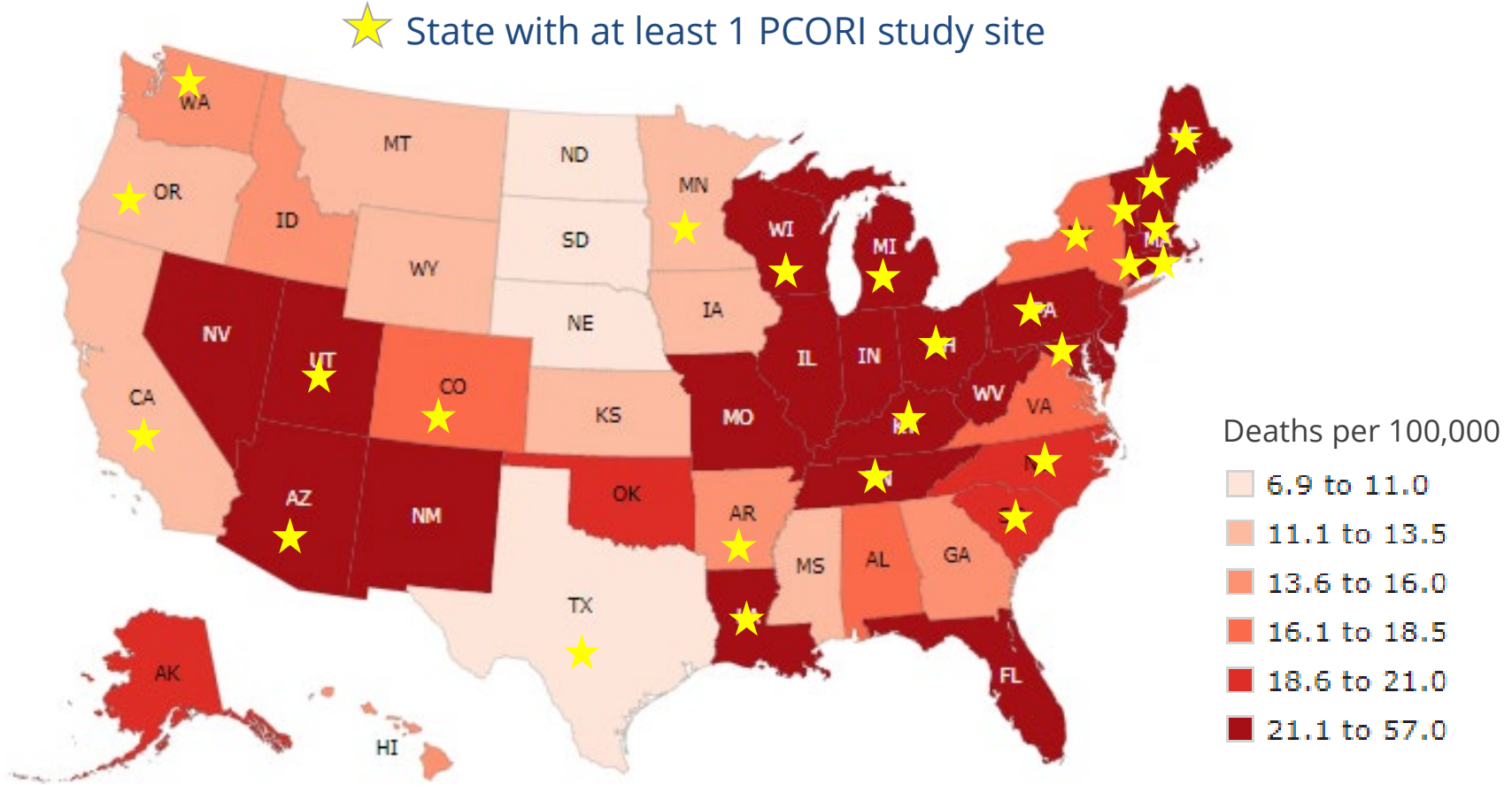
Key Portfolio Strengths



N = 26 studies

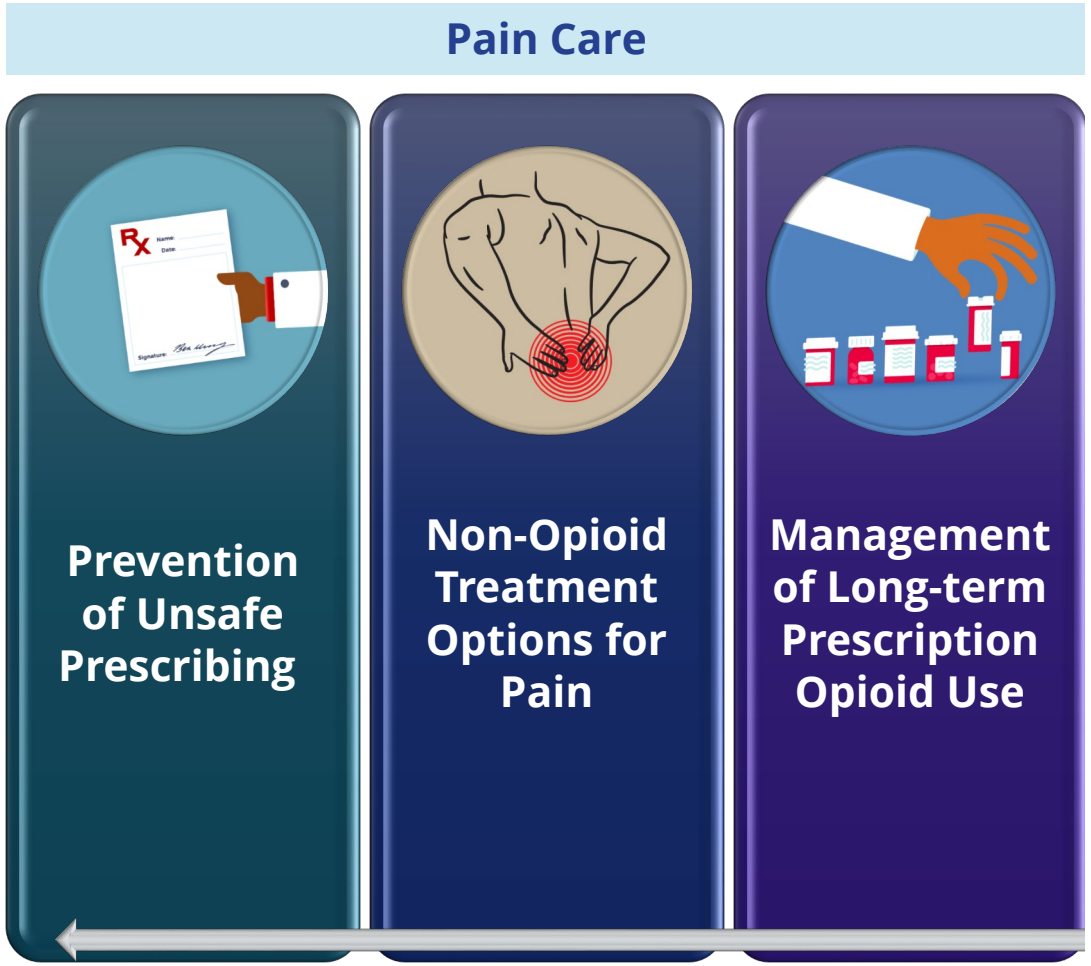
PCORI Studies in Key Opioid Epidemic Areas

2017 Drug Overdose Death Rates by State



SOURCE: CDC/NCHS, National Vital Statistics System, Mortality

Opioid-Related Studies: A Focus on Improved Pain Management



Improving Pain Management While Reducing Patient Risk

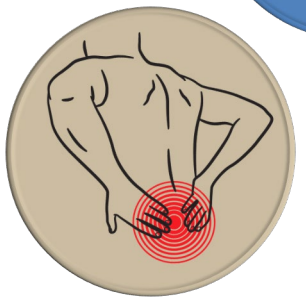
> The ongoing opioid crisis lies at the intersection of two substantial public health challenges – reducing the burden of suffering from pain and containing the rising toll of the harms that can result from the use of opioid medications.

Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use; National Academies of Sciences, Engineering, and Medicine, 2017.

Improving Pain Management: Key Evidence Gaps

- **Insufficient evidence on interventions to improve safe prescribing:**
  - No RCTs or observational studies examining the effects of opioid prescribing policies or provider-level interventions on clinical and patient-centered outcomes

- **Lack of long-term effectiveness data for treatment options:**
  - Insufficient comparative effectiveness for nonopioid therapies and sequencing of treatment options
  - Little evidence on comparative effectiveness of opioids plus nonopioid options
  - Sparse evidence on the effectiveness of dose reduction/tapering strategies and impact on patient-centered outcomes

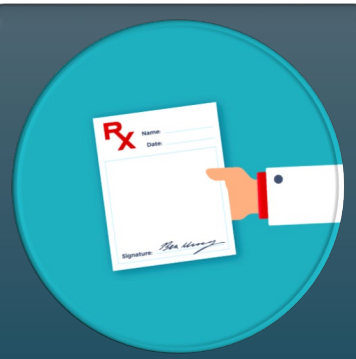


Improving Pain Management: Portfolio Highlights

- Head-to-Head Comparisons:
  - Studies include system, provider, and patient-level interventions
- Measurement of Patient-Centered Outcomes:
  - Pain, Function, Quality of Life
- Sample size and Follow-up:
  - Large sample sizes
  - Longer-term (1 year follow-up) pragmatic clinical trials
- Diverse patient populations:
  - Patients with comorbidities including mental health disorders and substance use disorders

Highlights: Prevention of Unsafe Prescribing

5
Studies
$19 million



Prevention of Unsafe Prescribing

Comparisons:

- Payer- or system-level strategies to improve safe prescribing
  - Provider nudges/EHR reminders
  - Changes in state-level Medicaid policies
- Provider- or patient-facing interventions to improve shared decision-making

Outcomes:

- Safe Prescribing, Opioid Prescriptions, Opioid Dose
- Pain, Function, Quality of Life, Opioid-related Harms

Highlights: Management of Long-term Opioids

10
Studies
$65 million

Management of Long-term Prescription Opioid Use

Comparisons:

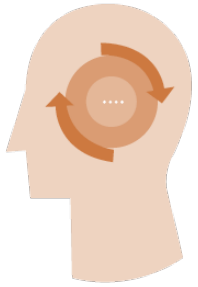
- Strategies for limiting/reducing opioid dose while improving pain management through non-opioid options
- Nonpharmacological therapies for specific pain conditions
- Sequencing of nonpharmacological therapies

Outcomes:

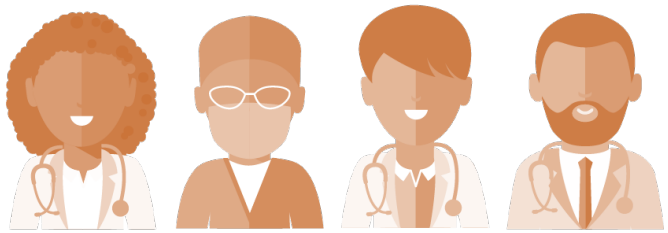
- Pain, Function, Quality of Life
- Opioid Dose, Opioid-Related Harms

Highlights: Nonopioid Therapies

11 Studies

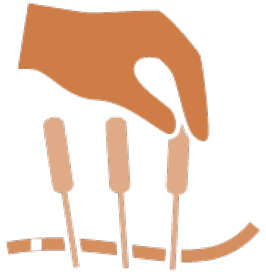


Cognitive Behavioral Therapy
4 Studies



Collaborative Care (Systems)
2 Studies

Physical Therapy
1 Study



Acupuncture
1 Study

Mindfulness Meditation
3 Studies

Patient Education/Activation
3 Studies

Categories not mutually exclusive

STUDY PROFILE

Pain-Cognitive Behavioral Therapy and Chronic Pain Self-Management Within the Context of Opioid Reduction

What This Study Does

- The project examines a patient-centered approach to voluntary opioid reduction in combination with nonpharmacologic behavioral treatments to improve pain management

Comparators

- Cognitive Behavioral Therapy for pain (pain-CBT)
- The Chronic Pain Self-Management Program (CPSMP)
- Usual care

Design

- Multisite RCT to test the comparative effectiveness of two behavioral treatment strategies, accounting for patient preference to taper or contain their opioid dose (n=865)

Key Outcomes

- Treatment success at 12 months as measured by pain and opioid use

Engagement

- The Patient Advisory Committee informed the selection of the comparators and study design and will be meaningfully engaged throughout the research project

Why It Matters

Each year millions of new prescriptions are initiated for patients. Many patients despair at not knowing how to reduce their long term opioids due to fear of experiencing distress, and physicians lack information to help them.

PI: Beth Darnall, PhD
Stanford University School of Medicine

Results Available: February 2024

The Opioids Portfolio: Treatment for OUD

2.1 million people
with Opioid Use Disorder

>130 people/day
died of an opioid overdose

Source: CDC Opioids Portal, Accessed June 14, 2019

Providing Evidence-Based Treatment for Opioid Use Disorder

> As the United States confronts the devastating opioid crisis, why are clinicians, treatment centers, and individuals who help address OUD not utilizing these evidence-based, proven solutions?

Leshner and Dzau, Medication-Based Treatment to Address Opioid Use Disorder JAMA. 2019;321(21):2071-2072

Evidence-based Treatment for Opioid Use Disorder

- Medication-Assisted Treatment: medication + psychosocial interventions
  - In primary care: Office-Based Opioid Treatment (OBOT)

- Shortage of providers
  - Requirement to offer or refer to psychosocial services
    - Barrier: Providers do not offer; Evidence mixed, unclear

- Treatment retention, illicit opiate use challenges w/ OBOT
  - Psychosocial interventions may improve

Treatment for Opioid Use Disorder: Evidence Gaps

- Office-Based Opioid Treatment: Effectiveness of Psychosocial Interventions
  - Which interventions work for which patients?
  - For which patients is medication only sufficient?

Highlights: Psychosocial Interventions for Office-Based Opioid Treatment

3
Studies
$15 million

Office-Based Opioid Treatment

Total number of patients: 1315

Comparisons

- Medication management (MM)
- MM + Community Reinforcement and Family Training (CRAFT)
- MM + Remotely-delivered Contingency Management
- MM + Cognitive Behavioral Therapy (CBT)
- MM + Peer Support by Certified Recovery Specialists (CRSs)
- MM + CBT + CRSs

Highlights: Psychosocial Interventions for Office-Based Opioid Treatment

3
Studies
$15 million

Office-Based Opioid Treatment

Outcomes

- Buprenorphine adherence, Opioid abstinence
- Diversion, Overdose, Psychosocial functioning, Quality of Life

Harmonized study features

- Medication only study arm (total n= 485)
- Outcomes and Assessment times
- Duration Intervention and Follow-up

STUDY PROFILE

Identifying Optimal Psychosocial Interventions for Patients Receiving Office-Based Buprenorphine

What This Study Does

- This study will determine comparative effectiveness of two widely used psychosocial interventions within the context of office-based buprenorphine treatment. The study compares these models for specific subgroups.

Comparators

- Medical Management (MM)
- MM + Cognitive Behavioral Therapy (CBT)
- MM + Certified Recovery Specialists (CRS)
- MM + CBT + CRS

Design

- Randomized control trial (n=440)

Key Outcomes

- Opioid abstinence
- Retention in OBOT; QoL; treatment satisfaction; ED utilization

Engagement

- Study team includes patient investigator. Study Advisory Committee consists of local and national advocacy and policy organizations, CBT leaders, behavioral/mental health and substance use service agencies, and policy makers
- Community Advisory Board consists of former patients currently in recovery. CAB members contribute as project advisors

Why It Matters

CBT and CRSs are used clinically with medication for Opioid Use Disorder. This study will assess their relative, as well as the combined, effectiveness for different patient subgroups.

PI: David S. Festinger , PhD
Philadelphia College of Osteopathic Medicine

Results Available January 2024

Treatment for Opioid Use Disorder: Evidence Gaps

- Treatment for Vulnerable Populations
  - Treatment setting and delivery for pregnant women
  - Treatment strategies for people re-entering society

Highlights:
Vulnerable Populations- Pregnant Women

3
Studies
$16 million

Vulnerable Populations

Total number of patients: 3,369

Comparisons:

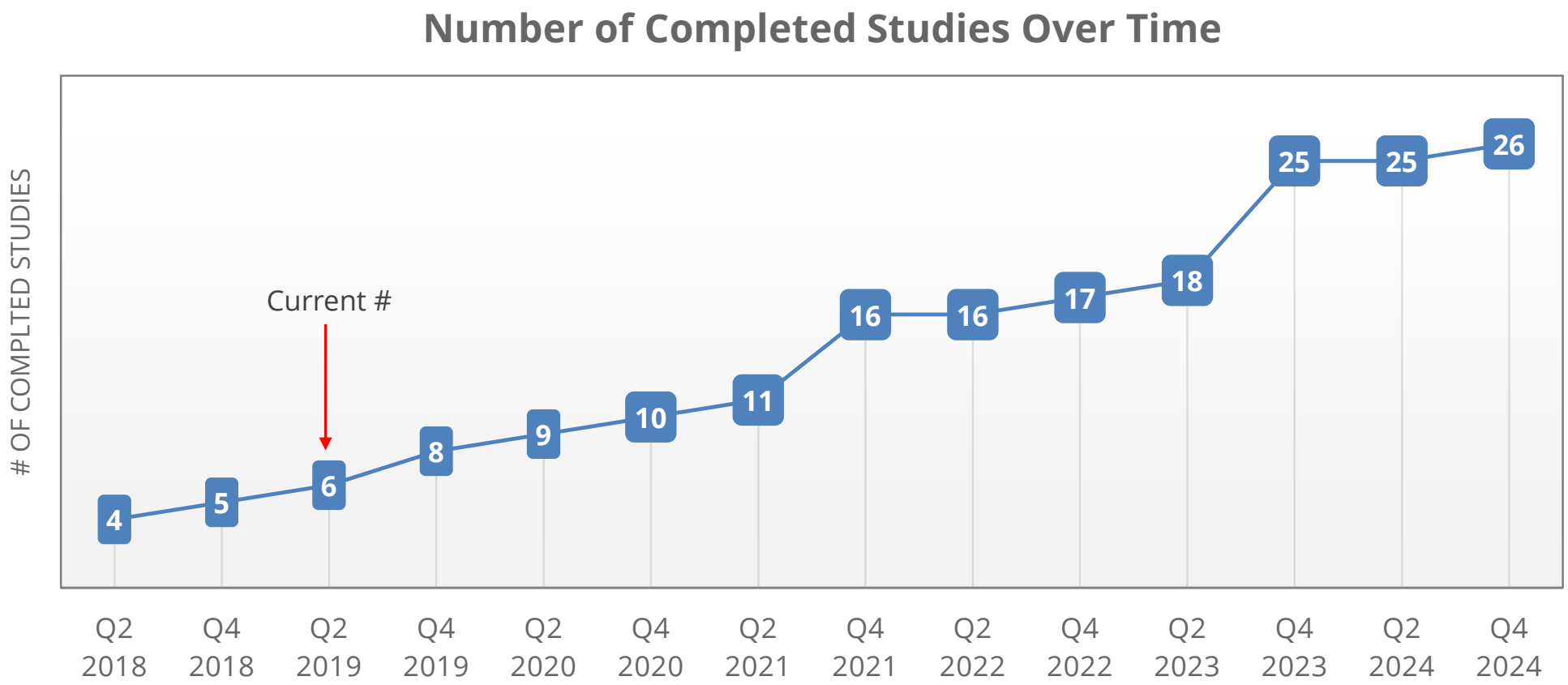
- Integrated prenatal and OUD care vs Prenatal care and referral to OUD care
- Care program at academic center vs group session care in rural area
- Provider support: Collaborative Care vs Tele-support (Project ECHO)

Outcomes:

- Buprenorphine adherence, Opioid abstinence, Perinatal complications
- Provider burden, Custody status, Patient- provider relationship, Quality of Life

Harmonized study features

When Will Results from Studies Be Available?



Additional Opioid-Related Activities

PCORnet Rapid Cycle Research:

- Descriptive study to evaluate and demonstrate the use of PCORnet for surveillance of the opioid epidemic

Engagement Awards:

- 4 Awards totaling almost $1 million focused on community-engaged PCOR in opioids
  - Creating a Community with Mothers with Mental Illness Using Opioids
  - Patients Lead: Identifying Meaningful Outcomes to Drive Substance Use Disorders Research and Care
  - Rapid Engagement of the Opioid Research Consortium of Central Appalachia (ORCA)
  - Engaging Patients and Clinicians to Improve Patient-Centered Treatment Outcomes: SSURTIE

Annual Meeting:

- Opioid Sessions highlighting PCORI work for the last 4 years (2016-2019)

Looking Ahead

PCORI responded rapidly to the opioid epidemic and remains committed to addressing the public health crisis with strong stakeholder-driven CER.

Upcoming:

- Continuing to identify and explore important evidence gaps in opioid-related research
- 2019 Annual Meeting Opioid session: Nonpharmacological Pain Treatment Approaches

Questions?

Wrap Up and Adjournment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