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

Applicant Town Hall Session

July 15, 2016
11:00 a.m. -12:00 p.m. ET
Agenda

1. Welcome
2. Background on PCORI and the Funding Announcement
3. Eligibility
4. Application Timeline
5. Preparing Letter of Intent
6. Questions

Submitting Questions:

Submit questions via the chat function in Meeting Bridge.

Ask a question via phone (an operator will standby to take your questions).
Welcome to the Town Hall

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Improving Healthcare Systems

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Senior Program Officer,  
Communication and Dissemination Research
PCORI

• An independent, non-profit [501-(c)(1)] research institute authorized by Congress in 2010 and governed by a 21-member Board of Governors representing the entire healthcare community
PCORI helps people make informed healthcare decisions, and improves healthcare delivery and outcomes, by producing and promoting high-integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader healthcare community.
We Fund Comparative Clinical Effectiveness Research

- Generates and synthesizes evidence comparing benefits and harms of at least two different methods to prevent, diagnose, treat, and monitor a clinical condition or improve care delivery
- Measures benefits in real-world populations
- Describes results in subgroups of people
- Helps consumers, clinicians, purchasers, and policy makers make informed decisions that will improve care for individuals and populations
- Informs a specific clinical or policy decision

*Note: We do not fund cost-effectiveness research*

Adapted from *Initial National Priorities for Comparative Effectiveness Research*, Institute of Medicine of the National Academies
Targeted PCORI Funding Announcement (tPFA) Goals

To generate evidence to:

• Prevent unsafe opioid prescribing while ensuring adequate pain management using either of two related intervention strategies:
  • payer or health system strategies
  • patient and provider communication interventions addressing benefits and harms of various treatments
Why is this topic important to patients and other key stakeholders?

• Opioid abuse resulted in more than 18,000 deaths from prescription opioids in 2014 (NIH, 2015)
• Pain advocacy community has expressed concerns about the unintended harms to pain sufferers that may occur by restricting access to opioids

Any policies in this area must strike a balance between our desire to minimize abuse of prescription drugs and the need to ensure access for their legitimate use.

• What stakeholder groups have identified this as an important question?
  – Payers, particularly the National Association of State Medicaid Directors
  – Friends and family members who lost someone to prescription opioid abuse;
  – Patients with chronic pain;
  – Worker’s compensation organizations;
  – State and federal policymakers
Abundance of Evidence Gaps

- Wide variation among states in opioid prescribing rates; indicating a lack of consensus about when to prescribe opioids (CDC, 2016)

- Little evidence exists on how to prevent unsafe prescribing of opioids; research focus largely on patients on chronic opioid therapy (Dy et al, 2016)
  
  - No systematic reviews, RCTs, or controlled observational studies addressing the effects of opioid prescribing policies on clinical outcomes (Chou et al., 2009)
  
  - A number of strategies targeted to providers and/or patients to promote safe opioid prescribing have been developed but not rigorously evaluated (HHS, 2014)
  
  - Strategies that have proven successful in managing chronic pain and reducing the risk of opioid misuse for chronic pain have not been tested to promote safer initiation of opioids (Chang, et al. 2015)

- Guidelines recommend use only when alternatives are ineffective (CDC, 2016; Dy et al., 2016)
Clinical Strategies for Managing and Reducing Long-term Opioid Use for Chronic Non-Cancer Pain Targeted PFA

- Among patients with chronic non-cancer pain on moderate/high-dose long-term opioid therapy, what is the comparative effectiveness of strategies for reducing/eliminating opioid use while managing pain?
- Among patients with chronic non-cancer pain on moderate/low-dose long-term opioid therapy, what is comparative effectiveness and harms of strategies used to limit dose escalation?

- $40 million for up to 4 awards
- Awards anticipated July 2016
- This proposed announcement is complementary
Two Research Questions for Targeted PFA

**Question 1:** 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?

**Question 2:** What is the comparative effectiveness of different patient- and provider-facing interventions that facilitate improved knowledge, communication and/or shared decision making about the harms and benefits of opioids and alternative treatments on prevention of unsafe prescribing and improved patient outcomes?
Research Question 1: Payer/Health System Strategies

- **Research Question:** 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?

- **Population:** Potential new users of opioids or patients who have **used opioids for < 3 months** with **either acute or chronic pain**. Outside of end-of-life care. Does not include treatment for active cancer.
  - Patients with risk factors for dependence, abuse, and harm
  - Conditions where safer alternatives may be as or more effective
  - Conditions at risk of becoming chronic (e.g., nonstructural low back pain)

- **Interventions:** Must include interventions to prevent unsafe prescribing while ensuring adequate or improved pain management. Interventions must be evidence based or in widespread use.
Outcomes:
- **Primary**: Pain, quality of life, functional outcomes, reduction in unsafe prescribing
- **Examples of Secondary Outcomes**: Anxiety/depression, sleep, disability, harms (tolerance, dependence, addiction/opioid use disorder, overdose, death), provider satisfaction, provider self-efficacy, emergency department utilization

Study Design: Cluster RCT (encourage two active comparators plus usual care arm); or large, prospective observational study; encourage mixed methods

Setting: Primary care, broadly defined to include primary care practices, emergency departments, dentists offices, urgent care centers

Time: 3 years

Proposed Research Commitment: Up to 3 studies, up to $15M (total costs)
Research Question 2: Improved Knowledge, Communication and/or Shared Decision Making

- **Research Question:** What is the comparative effectiveness of different patient- and provider-facing interventions that facilitate improved knowledge, communication and/or shared decision making about the harms and benefits of opioids and alternative treatments on prevention of unsafe prescribing and improved patient outcomes?

- **Population:** Potential new users of opioids or patients who have **used opioids for < 3 months** with either **acute or chronic pain**. Outside of end-of-life care. Does not include treatment for active cancer.
  - Patients with risk factors for dependence, abuse, and harm
  - Conditions where safer alternatives may be as or more effective
  - Conditions at risk of becoming chronic (e.g., nonstructural low back pain)
Interventions:
- Must include interventions to prevent unsafe prescribing while ensuring adequate or improved pain management
- Must be evidence based or in widespread use
- May include combinations of patient and provider education, psychological management strategies, and/or self-management strategies
- Encourage two active comparators but dependent on interventions selected

Outcomes:

<table>
<thead>
<tr>
<th>Primary Outcomes</th>
<th>Examples of Secondary Outcomes</th>
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<tbody>
<tr>
<td><strong>Patient</strong></td>
<td></td>
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<tr>
<td>- Knowledge</td>
<td>- Decisional regret</td>
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<td>- Patient anxiety (from potential health outcomes)</td>
<td>- Satisfaction</td>
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<tr>
<td>- Quality of life (including pain control)</td>
<td>- Patient involvement preference</td>
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<tr>
<td>- Functional outcomes</td>
<td>- Harms (tolerance, dependence, addition/opioid use disorder, overdose, death)</td>
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<tr>
<td><strong>Provider</strong></td>
<td></td>
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<tr>
<td>- Rate of opioid initiation</td>
<td>- Satisfaction</td>
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<tr>
<td>- Reduction in unsafe prescribing</td>
<td>- Length of visit</td>
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<td>- Repeat opioid prescriptions</td>
<td>- Confidence and self-efficacy</td>
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<tr>
<td>- Knowledge</td>
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Research Question 2 (cont.)

- **Study Design:** RCT or cluster RCT

- **Setting:** Primary care, broadly defined to include primary care practices, emergency departments, dentist offices, urgent care centers

- **Time:** 3 years

- **Proposed Research Commitment:** 3-5 studies, up to $15M (total costs)
Applications should…

- Focus on patient populations who are potentially new users of opioids or patients who have used opioids for less than three months, with either acute or chronic pain. All chronic pain disorders outside of cancer pain at end of life are considered chronic non-cancer pain. Studies focusing on chronic opioid users will be non-responsive.

- Include interventions intended to prevent unsafe prescribing while ensuring adequate or improved pain management.

- Target primary care, broadly defined to include primary care practices, emergency departments, dentist offices, or urgent care centers. Applicants will need to further delineate and justify the setting for the proposed research within this broad area of primary care.

- Have a sufficiently large study population to enable precise estimates of effect sizes and to support evaluations of potential differences in intervention effectiveness in patient subgroups. The research may focus on either acute or chronic pain or both, if there is adequate attention to subgroups.

- Address clinical and healthcare delivery choices faced by patients, caregivers, clinicians, and delivery systems.
Timeline

- **Full Announcement Released:** August 15, 2016
- **Online System Opens:** August 15, 2016
- **Letter of Intent (LOI) Deadline:** September 14, 2016
- **Application Deadline:** December 19, 2016
- **Merit Review:** March 2017
- **Awards Announced:** June 2017
- **Earliest Start Date:** August 2017
Eligibility to Submit a Letter of Intent

- Any private sector (non-profit or for-profit) research organization.
- Any public sector research organization (university or college hospital or healthcare system, laboratory or manufacturer, unit of local, state, or federal government).
- Non-domestic components of organizations based in the US and foreign organizations may apply, as long as there is demonstrable benefit to the US healthcare system and US efforts in the area of patient-centered research can be clearly shown.
- Individuals are not permitted to apply.
Complete a Letter of Intent (LOI)

- Refer to the PCORI Online User Manual: Submitting a Letter of Intent
- Pre-Screen Questionnaire
- PI and Contact Information
- Project Information
- Templates and Uploads
- Refer to the PFA-specific LOI Template to address the areas of interest
- Please make sure to address all required sections of the LOI template
- Please refer to the specific PFA for this announcement as each announcement has its own unique characteristics and requirements
Letter of Intent (LOI)

- A LOI is required and must be submitted prior to the deadline.

- To submit a LOI, download the **Letter of Intent Template specifically for the Strategies to Prevent Unsafe Opioid Prescribing in Primary Care among Patients with Acute or Chronic Non-Cancer Pain - Cycle 3** from the Funding Center to begin your LOI.

- You must answer all questions.

- Do not upload additional documents as part of your LOI. Letters of endorsements or support are not accepted at this stage.

- Only those LOIs deemed most responsive (programmatically and administratively) to this PFA will be invited to submit a full application.

- Please refer to the PFA, Application Guidelines, and PCORI Online User Manuals in the Funding Center.
Funds Available and Project Duration

Available Funds: up to: $30 million

Total Cost Per Project: $5 million

Maximum Project Period: 3 years
Applicant Resources: Where Can I Find Help?

Visit pcori.org/apply
- Application Guidelines
- FAQs
- PCORI Online User Manuals
- Sample Engagement Plans

Schedule a Call with a Program Officer
- Submit a request at pcori.org/content/research-inquiry
- Call 202-627-1884 (programmatic inquiries)
- E-mail sciencequestions@pcori.org

Contact our Helpdesk
- E-mail pfa@pcori.org
- Call 202-627-1885 (administrative and technical inquiries)
Q&A

Ask a question via the chat function in Meeting Bridge.

Ask a question via phone (an operator will standby to take your questions).

If we are unable to address your question during this time, e-mail the Helpdesk at pfa@pcori.org.
Adjournment