Preventing Opioid Misuse in the Management of Pain Workgroup Meeting Summary

March 2016

Overview

On March 7, 2016, PCORI convened a multi-stakeholder workgroup to explore opportunities to fund comparative effectiveness research (CER) that would compare effective strategies for reducing inappropriate initiation of opioids while improving patient outcomes and reducing patient harms when managing non-cancer pain in primary care. The patient population of interest includes those who are potentially new or repeat users of opioids.

Workgroup members included patients, patient advocates, state and federal officials, clinicians, manufacturers, representatives of public and private payers, and researchers from universities and federal agencies. The meeting was open to the public via webinar.

Before the meeting, PCORI staff conducted informational interviews with stakeholders to identify evidence gaps, areas of research where PCORI could have an impact, and potential comparative effectiveness research (CER) questions. In addition, each participant was asked to identify two to three comparative effectiveness research questions pertaining to alternative strategies to decrease the initiation of opioids among primary care providers for patients with chronic, non-cancer pain that also would improve patient outcomes. Approximately 60 questions were submitted. During the meeting, the participants voted on their first, second, and third preferences for priority research questions for PCORI to consider for a future funding announcement. These were selected from a set of questions that came out of small group discussions.

Related Information

- Workgroup: Preventing Opioid Misuse in the Management of Pain
- Orientation to PCORI's Research Prioritization
- Comparative Effectiveness of Alternative Strategies for Decreasing Initiation of Opioids for Managing Chronic Pain Topic Brief
- Submitted Stakeholder Questions
- Workgroup Chair & Facilitator Biographies
- Preventing Opioid Misuse in the Management of Pain Workgroup Presentation
- Breakout Group Questions
- Archived Teleconference Audio Recordings

The Patient-Centered Outcomes Research Institute (PCORI) is an independent organization created to help people make informed healthcare decisions.

1828 L St., NW, Suite 900
Washington, DC 20036
Phone: (202) 827-7700
Fax: (202) 355-9558
Email: info@pcori.org
Follow us on Twitter: @PCORI

Introduction

PCORI recognizes the need to balance reducing inappropriate opioid use against not limiting patients' access for those who need them, and also improving access to non-opioid pain management alternatives with the goal of improving patient outcomes. Several federal initiatives are introducing programs to prevent prescription drug abuse and overdose. PCORI has a unique role to play in funding patient-centered outcomes research that examines strategies to reduce potential harm from opioids in the context of better use of evidence-based approaches to comprehensive pain management. PCORI convened the Preventing Opioid Misuse in the Management of Pain Workgroup to identify and refine questions that will potentially inform the development of a targeted funding announcement in this area.

The day began with presentations by National Institute on Neurological Disorders and Stroke (NINDS) Program Director Linda Porter, and Senior Program Officer Penny Mohr, from the Improving Healthcare Systems (IHS) Program at PCORI. Dr. Linda Porter, Chair of the Workgroup, discussed the importance of conducting further research on prevention of opioid misuse and PCORI's initiative set in the context of other federal initiatives. Penny Mohr presented the goals for the day and set the stage for the discussion on alternative strategies in primary care for preventing inappropriate initiation of opioids, for new or repeat patients. She noted that this workgroup complemented a previous PCORI initiative that solicited comparative effectiveness research on Clinical Strategies for Managing and Reducing Long-term Opioid Use for Chronic Pain. In order to not overlap with that earlier initiative, this workshop would not discuss research questions related to ways to better manage patients on long-term (more than three months) opioid use.

Participants were then organized by their interests and expertise into four breakout groups across three topic areas: 1) provider/patient-level communication and dissemination strategies; 2) comprehensive system-level opioid and pain management strategies; and 3) payer strategies—which met to formulate and prioritize research questions. Due to an overflow of interest, the second topic area was split into two separate groups. All participants then reconvened to summarize and discuss the results of the breakout sessions and rank a narrowed set of questions that they recommended PCORI to target.

Breakout Sessions

PCORI staff refined stakeholders' input and drafted three to four representative questions in each category. In each of the four breakout sessions, participants spent about two hours discussing each question using the Population, Interventions, Comparators, Outcomes, Timing, Setting (PICOTS) framework[1], identifying the intervention and comparators, target populations, and outcomes of interest—and revising and formulating potential comparative effectiveness research (CER) questions that were aligned with PCORI's mission and the most compelling in terms of their potential impact on practice. Participants also discussed potential challenges to conducting research on the proposed questions and how the challenges might be addressed. They were instructed to come back to the full group with one to two refined questions they recommended as priority research for PCORI.

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[1] Thompson M, Tiwari A, Fu R, et al. A Framework to Facilitate the Use of Systematic Reviews and Meta-Analyses in the Design of Primary Research Studies [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2012 Jan. Results available from: http://www.ncbi.nlm.nih.gov/books/NBK83626/

Provider/Patient-Level Communication and Dissemination Strategies

The Provider/Patient-level Communication and Dissemination Strategies breakout group focused its discussion on four broad areas for potential research (Box A). After discussion of each of the four research questions, the group elected to advance questions 1 and 2 because they focus more on support for the patient and provider. The group discussed the potential of putting the questions together; however, they decided that it would be best to keep them as two, equally strong, complementary research questions. They underscored the need for *educating both the patient and the physician.* The population of focus was deemed any new user of opioids with either chronic or acute pain. The setting of care included primary care or the emergency department. Stakeholders in this breakout group also noted that challenges and important considerations for provider-patient educational strategies are the increased time burden placed on the provider and the lack of reimbursement for shared decision making. They also noted that these interventions may be largely untested, although they have often been adopted by health systems. A recommendation was to compare some untested interventions that are in common use in some health systems and need to be compared. Outcomes that were identified as important to study for these questions included reduction of opioids, patient satisfaction, and provider satisfaction.

Box A

1. Does PCP telehealth (e.g., video-mentoring by specialists using the TelePain/ECHO model) improve the application of best practices (e.g., opioid initiation criteria), PCP self-efficacy, reduce patient inconvenience (e.g., travel time), and improve patient outcomes when compared with mandated Continuing Medical Education?

2. What is the comparative effectiveness of different strategies of shared decision making to educate patients about the relative risks and benefits of opioids and alternative treatments on opioid initiation and patient outcomes?

3. For patients with nonmalignant pain being considered for opioids, what is the comparative effectiveness of various screening/risk assessment tools on reducing rates of inappropriate provider initiation of opioids and reducing patient harms?

4. What is the comparative effectiveness of different clinical decision support tools integrated into EHRs and online portals to enhance pain management on opioid prescribing and patient outcomes?

Comprehensive System-Level Opioid and Pain Management Strategies

The two breakout groups examining Comprehensive System-Level Opioid and Pain Management Strategies took quite different approaches to their assignment. They both began with four target questions (Box B). One breakout group focused largely on refining the wording of the first question. The other breakout group focused on ranking the questions and identified additional strategies that might be compared. Both noted that relevant to the aim of reducing inappropriate prescribing, "inappropriate" was difficult to define. The first group suggested altering this to the more neutral language of "changing prescribing behavior." They agreed that guidelines (e.g., Centers for Disease Control, or Association for Community Affiliated Plans) could serve as a foundation for defining appropriate prescribing noted as "guideline concordant care." A research question would not require researchers to adhere to a specific set of guidelines, but investigators would have to describe and justify the proposed standard of care. The target population was defined as new users of opioids or patients who have used opioids for less than three months, which could include both chronic and acute pain patients. In the second group, the target population was more narrowly defined to get at the concept of inappropriate prescribing. The group recommended focusing research on patients at risk for ineffective opioid treatments (e.g., fibromyalgia, headache, lower back pain). The target population also would include patients at higher risk for conversion from acute to chronic pain (e.g., nonstructural back pain).

Box B

1. What is the comparative effectiveness of health system opioid strategies that include elements of prescription monitoring and physician feedback combined with expanding access to alternative methods for pain management (e.g., physical rehabilitation/conditioning, mental health and counseling support, meditation, cognitive behavioral therapy, or biofeedback)?

2. What is the comparative effectiveness of physical therapist-assisted pain management services versus cognitive-behavioral therapy (coping skills) approach versus usual care for reducing the inappropriate initiation of opioids for pain management?

3. What is the comparative effectiveness of early initiation of behavioral and/or multidisciplinary rehabilitation versus usual care for non-malignant pain on reducing the inappropriate initiation of opioids and improving patient functioning?

4. What is the comparative effectiveness of alternative medication management plus case management to connect patients with relevant services for pain management versus expanding access to alternative nonpharmacologic therapies at the point of care (e.g., embedded acupuncture services, CBT, PT/exercise therapy, yoga?)

A wide range of health system strategies were discussed in the first group, including: connection of providers within health systems with Prescription Drug Monitoring Programs, prescriber monitoring and feedback, expanding access to non-opioid pharmacological and nonpharmacological strategies, case management, clinician education, patient education, structured clinical assessments, and shared decision-making approaches. In the second group, question 4 (Box B) was of particular interest. Another intervention of interest that was not on the original list of questions was the mandatory use of patient-reported assessment tools coupled with physician feedback at every clinical encounter to avoid high-risk prescribing. The latter could leverage electronic health records and access team-based care and case management through telemedicine. Notably, participants in both groups spoke about the challenges of limited available evidence for many of the potential health systems interventions. They agreed that it is critical to look at strategies to change and improve provider behavior, AND strategies that offer alternative approaches to patients that meet their needs.

The primary outcomes that were identified by the first group as important to study included quality of life (QOL), patient functioning (including control), and ability to cope. Secondary outcomes included pain intensity, reduced inappropriate prescribing, pain, disability, harms (e.g., tolerance, dependence, addiction/opioid use disorder, overdose, death), patient access to medications, provider self-efficacy, number of days on opioids, guideline concordant care, emergency department patient utilization, referrals to recommend therapy, and informed consent. Additional outcomes identified by the second group included mood, patient knowledge, and self-efficacy.

Payer Strategies

The Payer Strategies breakout group discussed insurer-based opioid strategies that include formulary limitations on opioid use, elements of prescription monitoring and physician feedback combined with better coverage of alternative methods for pain management. Thethree specific research questions discussed are shown in Box C. Several participants raised concerns about the first question, mentioning a high level of provider fatigue for provider profiling and the feedback received across so many disease areas already. Most participants were interested in the other two questions, which were then further refined.

In discussing the target population, one participant noted there is ongoing research suggesting opioids are less likely to be effective in patients presenting with pain of a more centralized nature (fibromyalgia-like), and centralized pain prediction tools in development could form the basis for defining inappropriate prescribing.[2] Patient advocates commented that the focus on non-cancer pain was not helpful in thinking about therapies. Participants ultimately agreed the target population for both of these questions should be defined as new users of opioids with acute pain who are at high risk for abuse or misuse, or for progressing to chronic therapy. An example of this population was persons with non-structural back pain.

Box C

1. For patients with non-cancer pain who are new, or repeat users of opioids, what is the comparative effectiveness of prescription monitoring and physician feedback examining their prescription patterns to their peers compared with general physician education on standards and guidelines for use of opioids compared with usual care on reducing rates of inappropriate provider initiation of opioids in primary care for pain and improving patient outcomes?

2. For patients with non-cancer pain who are new, or repeat users of opioids, what is the comparative effectiveness of improving access to alternative non-pharmacological treatment modalities like biofeedback, cognitive behavioral therapy, or yoga in primary care on reducing rates of inappropriate provider initiation of opioids for pain and improving patient outcomes?

3. What is the comparative effectiveness of changing the reimbursement/incentive structure for opioids versus nonpharmacologic options plus increasing access to alternative (non-opioid) pain management services versus usual care?

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[2] Clauw D. The Development of Treatments for Pain. Presentation at the FDA Science Advisory Board, March 1, 2016. Available at: http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/ScienceBoardtotheFoodandDrugAdministration/UCM489203.pdf

Participants discussed a variety of evidence-based alternatives to opioids that might be addressed by payers, including expanding reimbursement for multidisciplinary pain management programs. One patient participant remarked about the importance of social support, and payer strategies to facilitate online support or access to support groups among a community of chronic pain patients could be very beneficial. Gabapentin or combined medication therapy are relevant alternatives for patients presenting with an acute flare of a more central nervous system pathophysiology of pain, such as fibromyalgia, and payers may have prior authorization policies directing providers to use these treatments before prescribing opioids. It was noted that many of these strategies discussed by participants, and most complementary and alternative therapies listed in question 2 (including cognitive behavioral therapy, acupuncture, biofeedback, mindfulness training) would likely not be relevant alternatives to opioids for patients presenting with acute pain. Therapies such as physical therapy, NSAIDs, and movement therapy are relevant alternative evidence-based pain management interventions for patients with some types of acute nociceptive pain, such as non-structural low back pain. Stakeholders noted the notion that payers are not paying for such therapies may be inaccurate, and that service availability does not necessarily ensure access or practice change. Participants also noted that providers should receive more training on the evidence base about the benefits and harms of non-opioid alternative therapies as a first step to improving patient outcomes.

Rather than suggesting comparison of specific reimbursement/incentive strategies across payers for question 3, the group developed a broad list of tools in use by insurers. These include: copays, formulary design, prior authorization, limitations on days' supply, pharmacy lock-in programs, mandatory use of PDMPs for scripts exceeding three days' supply, mandatory patient informed consent for prescribing that exceeds 30 days, expanded coverage and reduced copays or co-location for complementary and alternative medicine. Important outcomes to study for both questions were similar to those identified by the "organizational strategies" group, but also included anxiety/depression, sleep, and provider satisfaction.

Research Questions Rank Results and General Discussion

During the report-back session, participants presented the resulting seven refined research questions (see Table 1). After review and discussion of all breakout group questions, participants ranked the seven questions according to their first, second, and third choices. The three top-ranking questions were:

1. What is the comparative effectiveness of different health system strategies that aim to change opioid prescribing behavior and/or expand access to non-opioid methods for pain management with the goal of improving patient function and quality-of-life outcomes while reducing patient harm? [14 first preference votes]

2. For patients with acute pain who are new or repeat users of opioids, what is the comparative effectiveness of improving access to non-pharmacological treatment modalities (like physical therapy, biofeedback, cognitive behavioral therapy [CBT], or yoga) in primary care on reducing rates of inappropriate provider initiation of opioids for pain and improving patient outcomes? [13 first preference votes]

3. What is the comparative effectiveness of different strategies of shared decision making to educate patients about the relative risks and benefits of opioids and alternative treatments on opioid initiation and patient outcomes? [13 first preference votes]

Next Steps

To conclude the day, Program Director of IHS at PCORI, Steve Clauser, thanked participants for their input and noted that PCORI intends to continue to conduct further analyses and refinement of the questions put forth by the workgroup. Prioritized questions and deliberations from the workshop will be shared with PCORI leadership and PCORI governance will determine the next steps.

Table 1. Displays the frequency of each question that stakeholders ranked according to participants' first, second, and third choices.