Preventing Opioid Misuse in the Management of Pain: Questions submitted for consideration by workshop participants

Prioritizing Comparative Effectiveness Research Questions: PCORI Stakeholder Workshops

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1. What are the comparative effectiveness of using various screening tools prior to the initiation of opioid therapy to predict risk of opioid addiction in patients presenting to primary care for chronic, non-malignant pain?

2. What is the comparative effectiveness of provider audit-feedback versus no feedback on prescription writing patterns for reducing the rate of treating chronic, non-malignant chronic pain?

3. What is the comparative effectiveness of using clinical pathways versus traditional opioid therapy for chronic, non-malignant pain in primary care?

4. Physician/Patient-level Strategy: What is the comparative effectiveness of various primary care physicians and use of an Opioid Risk Tool when treating newly identified/diagnosed patients with chronic non-cancer being considered for pain treatment on reducing rates of provider initiation of opioids for chronic pain and improving patient outcomes?

5. For patients with chronic non-cancer pain who are new, or repeat users of opioids, what is the comparative effectiveness of insurer-based Opioid Risk Tool at time of opioid prescription fill that include feedback assessment results to physician and naloxone co-rx with opioid on reducing patient harms (e.g., opioid misuse, abuse, overdose)?

6. For patients with chronic non-cancer pain who are new, or repeat users of opioids, what is the comparative effectiveness of prescription monitoring and physician feedback comparing 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 provider initiation of opioids in primary care for chronic pain and improving patient outcomes?

7. For patients with chronic non-cancer pain who are new, or repeat users of opioids, what is the comparative effectiveness of alternative non-pharmacological treatment modalities like Biofeedback, Cognitive Behavioral Therapy, (CBT), or Yoga in primary care on reducing rates of provider initiation of opioids for chronic pain and improving patient outcomes?

8. For physician considering new start of opioids for chronic pain, what is the impact of providing case management services to provide information about and help patients transition to alternative therapy programs?

9. In adult patients (age 18-65) receiving chronic opioid therapy ,does the finding of marijuana on a random urine drug screen in a patient otherwise compliant with the terms of his/her treatment contract indicate an increased risk of overdose compared to matched controls without the finding of marijuana in their drug screen?

10. In adult patients (age 18-65) receiving chronic opioid therapy, judged to be stable on their medication regimen, is there any difference in their rates of overdose, misuse when seen for office follow-up at one month versus three months versus six months?

11. In adult patients (age 18- 65) with documented chronic low back pain secondary to lumbar disc disease, does the use of opioid pain relievers improve function and lessen disability compared to nonopioid therapies?

12. What are the comparative outcomes (pain, function, mood, opioid use) of an on-line program of a) relaxation / meditation / guided imagery audio, b) back pain education video, and c) exercise instructions versus standard care with muscle relaxants and simple analgesics in adult primary care patients with acute low back pain?

13. What are the comparative benefits (pain, function, mood, opioid use) of an on-line program of a) educational video regarding chronic pain biology, b) relaxation / meditation / guided imagery audio, c) back pain education video, and d) exercise instructions versus standard care in adult primary care patients with chronic low back pain?

14. What are the results at 6 months (pain, function, mood, opioid use) of an educational video regarding the risks and benefits of opioid treatment provided prior to the physician visit in opioid-free adults with low back pain or fibromyalgia as compared with patients not shown the video?

15. If PCPs are educated about how to identify the type of pain generator, will they be more likely to initiate mechanism directed therapy than opioids for chronic pain? Does education regarding the alternative treatments facilitate earlier transition off of opioids for acute pain, to more mechanistic medications and treatments for chronic management?

16. Does educating PCPs regarding the treatments available through chronic pain management specialists improve the likelihood of referral for consultation prior to starting chronic opioids? Does it decrease the likelihood of needing chronic opioids? If started, does it decrease the daily dose?

17. Does improving access to adjuvant care modalities through better insurance coverage (psychological services including cognitive behavioral training, physical therapy, stress management, nutrition, addiction, etc) decrease the likelihood of PCPs initiating opioids for chronic pain?

18. Would working with the educational system to create certified pain management nurses to work with physicians to educate the chronic pain patient on alternative methods of treating chronic pain and the need for necessary lifestyle changes, make a difference in the number of opioid prescriptions written each year compared to the number written to the patient who has not received the benefit of pain management education from his physician working with the new nurse specialty People: Population of Interest. The educated chronic pain patient who might require less opioid therapy. The uneducated chronic pain patient who might require more opioid therapy. Certified Pain Management Nurses: To educate the chronic pain patient in the importance of exercise, nutrition, adequate sleep, relaxation skills (i.e. diaphragmatic breathing, progressive muscle relaxation, acupressure, hot and cold modalities, pacing and prioritizing your daily life, guided imagery, goal-setting and etc.) Also, to educate the patient on alternative medicine practices to manage pain: (i.e. acupuncture, hypnotherapy, biofeedback, meditation, Tai Chi, yoga, and etc.) Physicians with chronic pain patients who are considering using opioid therapy for them. Options: Nursing Schools, Colleges, and Universities adding the required education for nurses to be certified in pain management, which would be tantamount in education to the current certified diabetic nurse specialist, who fills the gap between the physician and the nurse to increase care for the diabetic patient. Pain management educators would furnish brochures, pamphlets, and etc. on pain management skills, alternative medicine, and the necessary life style changes to the all physicians who are currently considering opioid therapy to their chronic pain patients OUTCOME: Chronic pain management education by certified pain management nurses early in the stages of treatment for the patient with chronic pain, after the primary care physician's and/or pain management physician's recommendations for treatment

which may consist of one or more of the following: physical therapy, electrical stimulation as with a TENS unit, an invasive treatment with stimulators to block the transmit of the pain signal to the brain, pain blocks with steroids, nerve ablations and etc., may prevent the escalation of chronic pain and undo patient suffering, ergo to the point where it is so detrimental to the patients, rendering them unable to function in life physically, psychologically, and socially (i.e. unable to work, family interaction is effected, the patient's independence is threatened, and there is a decrease of socialization and depression may follow), because of the intensity of the pain without the administration of opioids. To recapitulate, certified pain management nurses may have a positive effect on decreasing the number of opioid prescription written each year by physicians who are attempting to alleviate undo patient suffering by creating an educated chronic pain patient who is unaware of other strategies to manage their chronic pain. The following may not be included in my research question, if you feel that it is not appropriate, due to the mention of government funding. Thank you for your consideration of my question. GOAL ACHIEVEMENT: This would be achieved by the government helping to fund the education at nursing colleges, universities, and etc. The government would have Medicare and other insurers accept coverage for the . Certified Pain Management Nurse. State Community Colleges: Federal Government financial aid to State Community Colleges for non-credit courses in pain management education, since many have had to cut out many of their non-credit courses, due to State budget cuts (Arizona community colleges).

19. Physician/Patient Strategies: In patients being considered for opioids for chronic non-malignant pain, how effective is the opioid risk tool compared to usual care in reducing rates of provider initiation of opioids for chronic pain?

20. Comprehensive system level opioid and pain management strategies: Does early initiation of behavioral and /or multidisciplinary rehabilitation for chronic non-malignant pain vs. usual care result in reduced initiation of opioids for chronic pain and improved functioning?

21. What is the comparative effectiveness of a pre-operative, web-based, psychosocial intervention combining cognitive-behavioral therapy and acceptance-based mindfulness approaches and standard patient pre-operative teaching to reduce the use of opioids in orthopedic post-operative pain management? (Prevention / Harm Reduction)?

22. What is the comparative effectiveness of a web-based, psychosocial intervention combining cognitive-behavioral therapy and acceptance-based mindfulness approaches and standardized patient education print materials on management of chronic (noncancer) back pain in reducing reliance on opioid pain management in primary care?

23. What is the comparative effectiveness and financial impact of a payer capitated, time limited, multidisciplinary Pain Rehabilitation program (including psychological evaluation and counseling, physical rehabilitation, osteopathic manipulation, pharmaceutical and interventional management, case managers, and chronic pain education) being completed prior to prescribing opioids for chronic non-malignant pain versus usual care in patients under the age of 65?

24. What is the comparative effectiveness of payer coverage for up to one year of mindfulness movement therapy based courses (yoga, Tai Chi, and similar) versus usual care on reducing the prescribing of opioids for patients with chronic non-malignant pain?

25. What is the impact on decrease in total number of opioid prescriptions written after the primary care provider completes a structured course on common chronic pain complaints and treatments (similar in structure to the University of Washington's TelePain Case Conference series)?

26. 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 which may include the following: Strategies to improve physical rehabilitation/conditioning Strategies that address mental health issues and/or incorporate counseling, meditation, CBT, biofeedback Strategies that incorporate non pharmacologic modalities eg acupuncture, TENS, strategies that incorporate injections and or nerve blocks to help reduce pain and to facilitate physical rehabilitation/conditioning Strategies that incorporate multimodal analgesics (non opioid) …..compared with usual care for patients with chronic, non cancer pain who are new or repeat users of opioids on reducing rates of provider initiation of opioids for chronic pain and improving patient outcomes?

27. 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 which may include the following: Strategies to improve physical rehabilitation/conditioning Strategies that address mental health issues and/or incorporate counseling, meditation, CBT, biofeedback?

28. What is the comparative effectiveness of provider audit-feedback versus no feedback on prescription writing patterns for reducing the rate of treating chronic, non-malignant pain with opioids?

29. What is the comparative effectiveness of pharmacy-level, primary care-level, patient- and caregiver-level communication and dissemination strategies to promote guideline concordant care for managing patients with chronic noncancer pain who are new, or repeat users of opioids on reducing rates of provider initiation of opioids for chronic pain, limiting the time of exposure to opioid analgesics, and improving patient outcomes?

30. What is the comparative effectiveness of offering prescribed naloxone by primary care physicians and by pharmacists at initiation of opioid therapy for patients with chronic noncancer pain as compared to as a risk mitigation strategy for patients receiving opioids for chronic pain, on improving patient outcomes and reducing opioid-related morbidity and mortality?

31. Comprehensive system-level opioid and pain management strategies
    What is the comparative effectiveness of health system opioid strategies that include elements of naloxone co-prescription, pharmacist medication reconciliation and physician feedback from pharmacist, and physician feedback based on prescription monitoring review compared with usual care (voluntary prescription monitoring checks) for patients with chronic, non-cancer pain who are new, or repeat users of opioids in primary care on reducing rates of opioid-related injury, reducing benzodiazepine-opioid coprescription, and improving patient outcomes?

32. What happens when you initiate different types of abuse deterrent formulations (ADFs) vs. non-ADF vs. non-opioid in improving patient outcomes and reducing patient harms? Specifically, what is the comparative effectiveness of different types of ADFs (e.g. physical/chemical methods, naloxone) in improving patient outcomes and reducing patient harms?

33. What is the comparative effectiveness of different strategies to reduce misuse and abuse, including restricting the number of tablets per prescription, patient agreements, provider education programs (REMS?), PMDPs, etc.?

34. What is the comparative effectiveness of various treatments for chronic pain? Opioid alternatives for chronic noncancer pain (e.g., functional restoration, rehabilitation, behavioral therapy) have very different time courses for their treatment effects compared to opioids. What methodological approaches need to be applied to make the comparison between these interventions possible? These approaches must be intuitive to primary care providers if the results of such research is going to be persuasive enough to impact their behavior.

35. Physician-patient strategies -- There has been an untested assumption that regulation of access to long-term opioids for common chronic pain conditions needs to be balanced against patient needs for effective pain control with opioid analgesics. The long-term effectiveness of opioids for managing common chronic pain conditions has never been tested, and is increasingly questioned. If PCORI could support research that evaluated whether opioids sustain their effectiveness for controlling pain and improving function over the long-term (say two years of follow-up) for low back pain, fibromyalgia, OA, headache and other common chronic pain conditions, this would directly influence decisions of clinicians and patients whether long-term opioid use should be initiated.

    A controlled study of this might be possible by comparing the outcomes of patients seeking care for chronic pain in physician practices which rarely prescribe opioids for long-term use for common chronic pain conditions to outcomes of comparable patients in practices that frequently prescribe opioids long-term for these conditions. It is well established that there is enormous variation in how often opioids are prescribed long-term in different geographic areas and among different clinical settings and clinicians. A study of two cohorts of patients, one exposed to physicians who rarely if ever prescribe opioids long-term and the other cohort exposed to physicians who frequently prescribe opioids long-term might be able to efficiently answer the question regarding long-term effectiveness. It might also be used to understand differences among clinicians who frequently and rarely prescribe opioids long-term in how they care for patients with common chronic pain conditions.

36. On the payer side: Would covering things like acupuncture, chiropractic, exercise classes, etc reduce the use of opioids?

37. What are alternate options to prescribing opioids for chronic pain - mind body classes, pain management classes, online EMMIs?

38. On the patient - clinician side: Is there data that using tools like the SOAPP, ORT, opioid agreement letters, UDS, checking the CURES data base for diversion actually improve patient outcomes - less addiction, overdoses and death?

39. Do chronic pain patients have more success managing their chronic pain illness with non-opioid treatments if they feel their doctor's believe them about their pain? Compare the outcomes of patients treated by two different physicians or physician groups. Physician/Physician Group "A" would use protocols based on Johns Hopkins Health Review below to demonstrate to patients that their pain illness is real and is being treated seriously. Physician/Physician Group "B" would do nothing special to validate their patients' pain and illness. Both groups of patients would have access to the same treatments to be

determined - ideally a multidiscipline approach including non-opioid medications, massage, exercise, sleep hygiene education and possible medical intervention, and nutrition counseling.
Possible Outcomes:
Reduce acute pain from becoming chronic
Shared-decision making (patient-reported, provider-reported)
Patient satisfaction with decision process
Less patient reported depression and anxiety
Source:
Keiger, Dale. (Spring /Summer 2015). Pain, pain, go away. Johns Hopkins Health Review, Volume 2, Issue 1. Retrieved March 03, 2016, from http://www.johnshopkinshealthreview.com/issues/springsummer-2015/articles/pain-pain-go-away
National Pain Report, National Pain Report Fibromyalgia Survey Results. Retrieved March 03, 2016, from http://nationalpainreport.com/national-pain-report-fibromyalgia-survey-results

40. Do chronic pain patients have more success managing their chronic pain illness with non-opioid treatments if they are mentored by a veteran chronic pain patient? Compare the outcomes of patients treated by two different physicians or physician groups. Physician/Physician Group "A" would refer patients for mentoring to a trained veteran chronic pain patient. Mentors would be trained in selfmanagement and coping skills. Physician/Physician Group "B" would not utilize mentors. Both groups of patients would have access to the same treatments from both Physician Groups A and B to be determined - ideally a multidiscipline approach including non-opioid medications, massage, exercise, sleep hygiene education and possible medical intervention, and nutrition counseling.
Possible Outcomes:
Patient satisfaction with decision process
Improved patient disease self management and coping capacity which could lead to less physician appointments and decreased anxiety
Shared-decision making (patient-reported, provider-reported)
Sources:
R. (2016, February 20). Mentoring may help teens cope with chronic pain. Retrieved March 03, 2016, from http://www.deccanchronicle.com/lifestyle/health-and-wellbeing/200216/mentoring-may-help-teenscope-with-chronic-pain.html
Walters et al. (2013), Effects of telephone health mentoring in community-recruited chronic obstructive pulmonary disease on self-management capacity, quality of life and psychological morbidity: a randomised controlled trial. Retrieved March 03, 2016, from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3773640/

41. Do chronic pain patients have more success managing their chronic pain illness with non-opioid treatments if physicians ask about their sleep quality and address a potential sleep disorder? Compare the symptoms, quality of life and functional ability of chronic pain patients receiving treatment for their sleep disorders to chronic pain patients who are not being treated.
Possible Outcomes: Quality of life, Less pain and fatigue, and improved function
Sources & references:
Rosenfeld, V., MD. (2011, May 31). Sleep Apnea in Patients With Fibromyalgia: A Growing Concern. Retrieved March 03, 2016, from http://www.practicalpainmanagement.com/pain/myofascial/fibromyalgia/sleep-apnea-patients-fibromyalgia-growing-concern?page=0,1 Michigan Technological University

(2008, September 7). What A Sleep Study Can Reveal About Fibromyalgia. Retrieved March 03, 2016, from https://www.sciencedaily.com/releases/2008/09/080903134311.htm
According to the 1996 NSF Gallup poll, more women (58%) suffer from nighttime pain than men (48%). In the 2000 NSF Sleep in America poll, one in four women reported that pain or physical discomfort interrupted their sleep three nights a week or more.

42. To compare whether patient education on opioids couple with share decision making (risk/benefit) of treatment selection as a way to reduce over prescription of opioids

43. To compare with or without urine screening before prescribing opioids as a way to prevent opioid misuse

44. To compare whether frequent remote monitoring (e.g. mobile tools) as early detection may prevent opioid misuse or abuse.

45. What is the comparative effectiveness of mandatory vs optional PDMP checking and at what frequency on reducing rates of provider initiation of opioids for chronic pain and improving patient outcomes, especially overdose?

46. What is the comparative effectiveness of mandatory vs optional prescriber training on the new CDC guidelines for reducing rates of provider initiation of opioids for chronic pain and improving patient outcomes, especially overdose?

47. What is the comparative effectiveness of payer system adoption of CDC guidelines on dose, urine testing frequency, PDMP checking vs more frequent or more intense patient monitoring requirements for reducing rates of provider initiation of opioids for chronic pain and improving patient outcomes, especially overdose?

48. What is the effectiveness of changing EHR default opioid prescribing amounts on prescribing behavior and guideline adherence?

49. What are the comparative benefits or risks of changing EHR default opioid prescribing amounts for patient with acute pain?

50. What are the comparative benefits or risks of changing EHR default opioid prescribing amounts for patient with chronic non-cancer pain?

51. What are the comparative benefits (amount and duration of opioid use) of provider (physician) education regarding effectiveness of opioids vs. non-opioid pain management approaches to patients with non-cancer pain?

52. alternative medication management + triage/case management to connect patients with relevant services for pain management and addressing medical and mental health comorbidities that impact pain and functioning vs. alternative to medication management to reduce pain severity at point of care (e.g., embedded acupuncture serves) coupled with ready access to evidence-based approaches for improving functioning (e.g., CBT, PT/exercise therapy, yoga – note some of these more focused on improving physical functioning while others

target coping/psychosocial functioning although most represent some hybrid of both)

53. change in reimbursement/incentive structure + increasing access to alternative (non-opioid) pain management services vs. usual care

54. Physical therapist assisted pain management services vs. cognitive-behavioral therapy (coping skills) approach (keeping usual care as a third arm for robust assessment of secular-related changes related to national focus on reductions in opioids for chronic pain management.

55. Topic: Education--Background: It is not clear whether mandated Continuing Medical Education (CME) has been able to significantly change prescription practices among primary care physicians (PCP's) (AAFPstatement. Ann Fam Med 2012; 10:474-475). On the other hand, specialist video-mentoring has been shown to increase PCP self-efficacy and enhance safer care by de-monopolizing specialty. Does PCP video-mentoring by specialists (using the TelePain/ECHO model) improve application of best practices (e.g. opioid initiation criteria), self-efficacy (e.g. confident to deliver comprehensive care) and reduce patient inconvenience (e.g. travel, ER use), when compared to CME?

56. Practice/Policy--Background: Multiple guidelines recommend primary care physicians (PCP's) to use brief screening and patient-reported assessment tools before initiating opioids (Johns Hopkins/Clinton Foundation report 2015, CDC guidelines 2016). Would the mandatory use of brief screening and patient-reported assessment tools (e.g. PEG,PHQ4, sleep, PROMIS social, ORT) at every clinical encounter improve best practices (e.g. opioid initiation criteria) when compared to voluntary use?

57. Physician-patient strategies -- There has been an untested assumption that regulation of access to long-term opioids for common chronic pain conditions needs to be balanced against patient needs for effective pain control with opioid analgesics. The long-term effectiveness of opioids for managing common chronic pain conditions has never been tested, and is increasingly questioned. If PCORI could support research that evaluated whether opioids sustain their effectiveness for controlling pain and improving function over the long-term (say two years of follow-up) for low back pain, fibromyalgia, OA, headache and other common chronic pain conditions, this would directly influence decisions of clinicians and patients whether long-term opioid use should be initiated. A controlled study of this might be possible by comparing the outcomes of patients seeking care for chronic pain in physician practices which rarely prescribe opioids for long-term use for common chronic pain conditions to outcomes of comparable patients in practices that frequently prescribe opioids long-term for these conditions. It is well established that there is enormous variation in how often opioids are prescribed long-term in different geographic areas and among different clinical settings and clinicians. A study of two cohorts of patients, one exposed to physicians who rarely if ever prescribe opioids long-term and the other cohort exposed to physicians who frequently prescribe opioids long-term might be able to efficiently answer the question regarding long-term effectiveness. It might also be used to understand differences among clinicians who frequently and rarely prescribe opioids long-term in how they care for patients with common chronic pain conditions.

58. Session Two: System level opioid and pain management strategies: There are innovative approaches to improving management of chronic pain that may be cost-effective employing personnel already treating chronic pain patients--such as the "StartBack" model of assessing prognostic risk of low back pain patients and providing psychologically informed physical therapy for patients at high risk of an unfavorable functional outcome, while

offering reassurance and short-term palliative care with non-opioid analgesics to patients likely to have a favorable outcome. Implementing a "StartBack" model intervention could be paired with discouraging the initiation of long-term opioids for low back pain. Clinics might be randomized to either usual care chronic low back pain (including continued prescribing of long-term opioids) or to the StartBack model coupled with avoiding initiation of long-term opioid use. The evaluation would assess which set of clinics had more favorable long-term pain and functional outcomes among their chronic low back pain patients.

59. Session Three: Payer strategies: We propose an evaluation of a payer strategy the requires documented informed consent before opioids are prescribed for longer than three days. The following policy could be implemented on a randomized basis in different health plans. There is substantial evidence that many patients initiate long-term opioid use by refilling prescriptions that were for short-term management of pain (e.g. post-procedure pain, an acute flare-up of an ongoing chronic pain condition) with discussion of whether long-term use of opioids is likely to be safe and effective, and without informed consent regarding risks.

60. What are the comparative benefits and risks of medication assisted treatment (MAT)) for opioid, alcohol and tobacco use disorder; and recovery support being offered concurrently with pain management to persons with history of substance use disorder?

61. What are the comparative benefits and risks of screening for substance use disorder and the results of the screening being associated in how the pain is managed?

62. What is the comparative effectiveness of organizational strategies to increase use of guideline-recommended pain management approaches for improving pain outcomes and reducing opioid use in patients with acute and chronic pain conditions for which opioids are not recommended?

63. What is the comparative effectiveness of organizational strategies to reduce high-risk opioid prescribing practices (e.g., long-acting opioids, excessive opioid quantities, opioid-sedative co-prescribing) in acute, post-operative, or post-hospital discharge settings?