Systems for Musculoskeletal Pain:
Questions submitted for consideration by workshop participants

Prioritizing Comparative Effectiveness Research Questions:
PCORI Stakeholder Workshops

June 9, 2015

Patient-Centered Outcomes Research Institute
1828 L St., NW, Suite 900
Washington, DC 20036
info@pcori.org
www.pcori.org
(202) 827-7700

1. What are the comparative benefits (in pain and disability outcomes) and risks of chiropractic care and a multidisciplinary panel including chiropractors and medical doctors for adults with chronic low back pain

2. What are the comparative benefits (in pain and disability outcomes) and risks of chiropractic care and a multidisciplinary panel including chiropractors and medical doctors for adults with chronic neck pain?

3. What are the comparative effectiveness of Patient-Centered Medical Homes, other multidisciplinary pain management programs, internet-based self-management programs, and single provider based treatment of adults with chronic musculoskeletal pain?

4. PEOPLE: Adults of all ages/ethnicities/gender with chronic musculoskeletal pain. OPTIONS: Patient-Centered Medical Home; Multidisciplinary Pain Management Programs; Internet-based self-management programs; Single-provider based treatment. OUTCOMES: Identify which system of treatment provides the best treatment outcomes: decreased need for opioid use, decreased morbidity (i.e. increased ability to perform ADL's, decreased adverse effects of treatment), and increased ability to successfully work/attend school. Reason for question: Millions of Americans suffer from chronic musculoskeletal pain, and these patients lose hundreds of thousands of work days, and generate billions of dollars in health care costs each year. Pharmacologic and surgical treatment options have significant risks. Many studies outside of the US have shown that multi-disciplinary team approaches may yield better outcomes. Given the fragmentation of care that is common to the US, such a study might help promote the use of such team approaches in our country.

5. When is the ideal time for referral of a patient with CLBP from a primary care physician to a specialist? [ideal would be defined as the period of time when outcomes are most improved]

6. Does implementation of the eCPQ (electronic Chronic Pain Questions) into a health system's EMR (electronic medical records) in a family practice or primary care setting result in better chronic pain care in patients with CLBP, OA, fibromyalgia or MSK compared to standard of care?

7. Does immediate intervention with appropriate therapy for condition (based on symptoms re- eCPQ) result in less chronification of back pain moving forward?

8. For patients with chronic LBP/MSD already established on COT, are more intensive specialty-based interdisciplinary services superior for reducing patients' reliance on opioids and facilitating improvements in functioning/QOL when compared to evidence-based multimodal services that can be feasibly delivered in closer connection with primary care clinics/clinicians?

9. Compared with no motivational intervention, can pain and functioning be improved in patients with low back pain and musculoskeletal pain with motivational interventions, (e.g., motivational enhancement treatment (MET) or compliance-enhancing interventions), that improve engagement in multidisciplinary treatment protocol? Outcome: Enhanced motivational factors, less pain intensity, improved physical functions, and increased exercise compliance.

10. For patients with CLBP, what is the comparative effectiveness of pain clinic care as compared with a comprehensive, primary care-based, patient-centered approach in improving physical function, reducing pain, and optimizing quality of life?

11. For older adults with chronic musculoskeletal pain (including CLBP), what is the comparative effectiveness of pain clinic care as compared with geriatrician-directed care for optimizing physical function and patient/caregiver quality of life?

12. For patients with chronic myofascial pain, what is the comparative effectiveness of interdisciplinary pain management as compared with acupuncturist-delivered intramuscular electrical stimulation plus self-management in reducing pain, improving function, and optimizing quality of life?

13. Study to define best practice standards and guidelines used in the treatment of chronic pain patients. Topics needed to identify include: number of long term opioid and non-opioid treated patients, patient centered strategies (education, Owestry index forms used, patient engagement in own care, patient self-assessments, clinician assessments of patients. …), Risk Mitigation Strategies, all non-opioid therapies (medication and other in-house or referred), opioid therapy guidelines, opioid tapering strategies, opioid titration strategies, all tools in use not described herein found to be effective in care of chronic pain patients (any unique tools should be sent with form or example to study team) and associated certifications achieved. Facilities eager to use advanced best practices of care will be eager to participate and most likely have data requested available. Target group(s) is same as 6). Common best practices used can be identified as well as unique tools to be considered for use universally in the care of chronic pain patients.

14. Observational Study of efficacy of implementation of "Universal Precautions" practices in opioid prescribing. Recommended prescribing practices, including risk assessment, treatment agreements, accessing the PDMP (Prescription Drug Monitoring Program), dose reduction strategies and routine Urine Drug Testing can seem overwhelming to the busy primary care practitioner. A study demonstrating the effectiveness of these practices in decreasing the known complications of opioid therapy in patients who are candidates for opioid therapy based on clinical presentation and pain pathophysiology (see 1 above) could provide the required evidence.

15. Opioid risk reduction in persons initiating opioids for chronic non-cancer pain

    a. Population: Patients with musculoskeletal pain who meet eligibility criteria for initiating opioid therapy (e.g, failed alternatives such as PT, non-opioid drugs, injections). This project must include vulnerable populations who are more likely to be undertreated for pain but who suffer disproportionately from pain (NHANES) including minorities and low income groups.

    b. Patient-centered medical home structure that takes advantage of an EMR support package and case management to offer support and insure high quality care. The EMR must offer tools to evaluate risk of OAs (ORT) and monitor of total opioid dose/daily dose as well as concurrent treatment with potentially risky drugs such as psychotherapeutics (e.g. benzodiazepines, hypnotics), antidepressants. EMR prompts about consideration of complementary lower risk alternatives (e.g., topical therapies) and

generates reminders for urine drug screening at intervals based on ORT. The EMR offers ready connection to state prescription monitoring programs (obtained by staff at each visit) well as monitors the frequency of requests for refills and visits. Patients complete an opioid agreement that includes expectations to pursue agreed upon non-drug therapies and clinician agreement to refill agreed upon opioid treatment based on assessment of patient functional goals. Physicians receive education about use of EMR to monitor/guide opioid and other pain therapies. Case managers educate about stretching and other non-drug alternative management strategies plus educational materials to give patients.

c. Option 2: low opioid dose therapy and referral to a practice-based pain champion – MD, PA, RN – who has received advanced training in an evidence based pain management program, Patient visits the clinic specialist at least every 6 months (to supplement care from a primary care physician). This arm offers basic EMR support (ORT, OA agreement) Both arms offer collaborative care with appropriate specialists (PT, pain experts). Outcomes: Opioid dose, functional measures (6 min speed walk, 50ft speed walk, 5x sit to stand), mental health(PHQ 9) /mental functioning (symbol digit test) measures, pt satisfaction, measures of opioid misuse (early refill requests, dose escalation).

16. What are the comparative benefits and risks of pain contracts vs no pain contract for individuals with chronic low back pain utilizing chronic opiate therapy?

17. Can chronic pain patient efficacy and involvement as part of their own chronic pain care team lead to reductions over time of opioid use levels and improvements to quality of life? Positive study results could have an impact for physician impetus to share and effectively communicate chronic pain care details with the patient and make the patient take a more responsible role in their own treatment.

18. More research is needed on how to support and foster a mutually positive and enduring doctor-patient relationship during opioid taper/discontinuation, which is an emotionally stressful endeavor for both patients and their doctors. Examples of support to be studied might include an interdisciplinary team approach, a weekly phone call with an expert for the prescribing doctor to talk through difficult cases, a group education/psychosocial intervention for patients going through the detoxification process, etc. This research would help us learn which forms of health care delivery lead to better outcomes not just for patients (pain ,quality of life, function), but also for doctors (quality of professional life and professional function) and the doctor-patient relationship (trust, affection, loyalty, compliance, patient satisfaction).

19. As the Topic Briefs attached have so nicely summarized, there are many individual patient characteristics, many different interventions, and many variations of the different interventions. For example, a big issue that came up in the report on Non-invasive treatments for low back pain is which combination of therapies with different pharmacological or nonpharmacological treatments is associated with incremental benefits versus the individual components of the combination therapy, and which combinations and sequences of therapy are the most effective. Similarly, in the Spinal injections report there are different techniques and approaches (caudal vs. transforaminal etc.) for the injections. Complicating this is a question of the role of imaging during the procedure and even more complicated, a question of skill of the provider in outcomes. However, studying each of these variations two at a time in head to head comparisons is probably not going to lead to clarity for the complex multi-step management of these patients. I suggest that what is needed is to harness “big data” and supplement with Patient related Outcomes information to collect

detailed data on patient characteristics, intervention characteristics, outcomes across time, including repeat interventions, multiple interventions (drugs, physical therapy, noninvasive treatments, surgery etc.) given simultaneously or sequentially etc. This data can be analyzed to answer the following questions:

a. Are there patterns of specific patient characteristics, intervention characteristics etc. that consistently get better outcomes?

b. Are there patterns of specific patient characteristics, intervention characteristics etc. that consistently get worse outcomes or harms from treatments?

c. Using this information, very targeted head to head comparisons could be designed to test hypotheses generated from the data.

20. What is the comparative effectiveness of number-based pain scales (eg 0-10) vs functional-based pain scales in patient-specific rating of pain for individuals with chronic low back and MSK pain?

21. POPULATION: Patients with knee pain and radiologic findings of moderate knee OA (Kellgren Lawrence Grade II and III).OPTIONS: PT+NSAIDs+injections (cortisone/HA) vs total knee arthroplasty. OUTCOMES: Oswestry, SF36 at 18 months. POPULATION: Patients diagnosed with fibromyalgia. OPTIONS: Medications vs exercise/sleep training/CBT/MBSR (some combination of therapies). OUTCOMES: VAS, FIQ (Fibromyalgia Impact Questionnaire) at 1 year. The common theme running though the comments we received on the reports on Non-invasive treatment for Low back pain and The long term benefits and safety of opioids for chronic pain (not just low back pain), we offer another question:

    a. For patients with chronic low back pain (with regular risk or high risk for co-morbidities), what are the long-term effectiveness and harms of opioids compared to other non-invasive treatment options on patient centered outcomes such as quality of life and ability to return to work?

22. Identify effective tobacco cessation strategies for smokers with chronic spinal pain.

23. In older adults with lower extremity osteoarthritis (hip and/or knee), does a comprehensive physical therapy program of manual therapy, exercise and education produce greater improvements in function and disability compared to usual care? Usual care defined as advice, medications and intra-articular injections (CSI or hyaluronate). Outcomes would be function and disability levels.

24. How effective is long term opioid therapy for chronic back pain? Should quality of life measures be included before and after commencement of long term opioid therapy?

25. What are the comparative benefits and risks of the use of agreements (also called “opioid contracts”) when managing pain in the person with cancer?

26. What are the benefits in pain and function for adults with low back pain who participate in Pain Coping Skills Training versus Pain Coping Skills Training + Motivational Intervention versus usual care?

27. What are the comparative benefits and risks of a combined approach using yoga, mind body practice and non opioid analgesics versus long term opioid analgesics in patients with chronic generalized pain? Outcome measures include QOL indices (better mobility, sleep, mood, function) and pain reduction.

28. What are the long-term effects of oral or transdermal opioids compared to other available treatment options on pain, function, safety, and addiction (and withdrawal) in people with chronic non-cancer pain conditions, such as osteoarthritis and chronic low back pain?

29. If we administer FDA approved & treatment guideline recommended medicines in patients diagnosed with chronic pain including OA, CLBP, and musculoskeletal (MSK) pain, are outcomes (decreased disability, improved productivity) improved compared to subjects who receive treatment that is non-FDA approved and not in the treatment guidelines?

30. I was a bit concerned about the planned separation of sessions into a clinical interventions and systems approaches subgroups as my understanding is that almost all available evidence suggests that a multi-modal approach is likely indicated for treatment of chronic LBP and musculoskeletal disorders (MSD) more generally and suspect the outcomes of the discussion would be most useful if participants could discuss the full spectrum of questions/potential intervention approaches. I understand that a group of 30 could be somewhat unwieldy but wonder if the benefits of meeting as a larger group might outweigh the limitations.

31. The question of primary outcome(s) is critical. Recent consensus on appropriate outcomes emphasizes the important of functioning rather than pain severity as the primary outcome of importance (i.e., recent National Pain Strategy Draft Report http://iprcc.nih.gov/docs/DraftHHSNationalPainStrategy.pdf). Perhaps leading off the workshop with some clarity about prioritized outcomes could provide a helpful framework for the ensuing discussion as I suspect resulting suggested research questions may be influenced by relative prioritization of outcomes. In the topic briefs, more of the review of the research to date is organized around pain relief for the clinical interventions brief while the broader set of functional measures is emphasized in the systems approach brief. I realized that PCORI by design prioritizes those outcomes of high importance to patients so specifying this a priori may not be possible but the most relevant CER questions may be related to outcomes under consideration.

32. Might an ensuing RFP in this topic domain be a good place to encourage the use of sequential, multiple assignment, randomized trial (SMART) designs (e.g., Collins, Murphy, & Strecher, Am J Prev Med, 2007) that allow for an efficient examination of a number of modalities alone and in combination that might best inform for whom under what conditions particular components/interventions are most effective?

33. What is the role of active vs. passive treatments in helping patients manage chronic LBP and MSD and maintain optimal functioning/QOL and minimize adverse events? That is, are patients for whom interventions are focused on skills training (coping skills including activity rest cycling, cognitive restructuring, emotional regulation, distraction) and lifestyle based interventions (e.g., increasing physical activity) better or worse off than those who use more passive treatments (pharmacotherapy, injections, surgery)?

34. What is the benefit of chronic opioid treatment (COT) compared to supported self-care management for patients with chronic LBP or MSD for whom primary care providers are considering initiating COT? Using a 2x2 factorial design would allow one to examine both these as individual modalities as well as their combination with a usual care comparison.

35. Do provider delivered CAM services (chiropractic care, acupuncture) when combined with supported self-care enhance patients with chronic LBP/MSD long term functioning/QOL when compared with independently provided self-management or independent CAM services? This question is pertinent based on the large number of patients that self-report utilizing CAM modalities for management of chronic LBP/MSD (often w/o knowledge of or coordination with conventional medical providers/services) and more recent research suggesting that utilization of CAM modalities with some evidence of reducing pain severity may improve patients' uptake of and adherence to the subsequent use of self-care modalities for pain management.

36. Can integrative/CAM treatment protocols (e.g., mindfulness-based stress reduction, acupuncture, structural integration) for patients with spinal disorders improve musculoskeletal chronic pain without surgery? Outcome: Preventing needless surgeries (less invasive treatments).

37. What are the identifiable risk factors in children that can lead to chronic pain as adults and how can those factors be addressed during childhood to help prevent the development of chronic pain later in life? What types of chronic pain prevention programs instigated in at-risk youth (those with pain, obesity, sports injuries and children of parents with chronic pain) can prevent chronic pain as they age? Outcome: Reduced incidence of chronic pain as adults.

38. Do chronic musculoskeletal pain patients have more success managing their pain and improving their function when they are treated by physicians who have had more than the average 10 hours of pain education taught in medical schools? Compare the outcomes of patients treated by multiple physicians who have varying degrees of pain education.

    a. Outcome: Changing the medical education curriculum would -

        i. improve patient outcomes including a higher quality of life for patients;

        ii. improve patient reported satisfaction with care;

        iii. improve efficiency of care.

39. In patients with neurological conditions of the spine, would medications, surgery or rehabilitation programs that improve the neurological condition of the spine also improve coexisting musculoskeletal pain? Outcome: improved quality of life for patients, and reduction of the number of people with chronic musculoskeletal pain.

    1) Improving long-term function and pain in opioid-using persons with chronic pain

i. Population: Patients with chronic non-cancer musculoskeletal pain. (3+ months) prescribed >1 month opioid therapy (consider a minimum dose such as >20 morphine equivalent)

ii. Option 1: Non-pharmacologic, evidence-based interventions (stretching/massage group education) in primary care clinic with case management to facilitate and promote engagement and long-term maintenance of activities at home

iii. Option 2: Similar curriculum/support offered by a community-based organizations several times weekly such as the YMCA. This program must be at no or low cost. Peer coach support to encourage engagement and maintenance of activities along with an incentive/competition for completion. Outcomes – Function (e.g., 6 min walk test, sit to stand 5x) QoL, patient satisfaction, mental health (PHQ9, anxiety), pain (10 pt scale), change in dose of opioid repeated measures at 3,6, 12 mos. Study must involve a multidisciplinary team (primary care, pain specialty, PT, kinesiology, psychology/psychiatry) to insure that the interventions offer high levels of motivation and patient self-management education while coordinating closely with the primary care provider."

40. Cognitive behavioral therapy. Population: Patient with chronic noncancer pain >3 months without achievement of functional goals

    a. Option 1: individual CBT directed by primary care clinic-based counselor (e.g. case manager trained in a pain management program – consider a refinement of the general CBT model such as the Acceptance and Com¬mitment Therapy (ACT) 1) provided in person counseling biweekly alternating with phone call updates - supplemented by education/practice with meditation and stress management techniques in group therapy programs. Case manager collaborates closely with the primary care physician in developing a drug treatment program plan and encouraging adherence

    b. Option 2: patient referred to psychologist for CBT with informational support for meditation and stress management approaches

    c. In both arms patients are provided educational materials informing them that opioids are only one component of a pain treatment program that require other nondrug approaches to improve function.

    d. Similar to outcomes above but focus on empowerment, satisfaction, mental health conditions (e.g. PHQ9)

41. From my perspective, if we are to make real progress in developing an evidence base that can be useful in clinical decision making, most importantly, there are several underlying issues/factors that need to be addressed in study design and execution irrespective of the treatment or clinical approach being studied. Failure to do so, I'm afraid, will result in 'more of the same' evidence that currently exists. I've outlined a few of some of the most important below for your review and consideration. This may be further down the road in the process, but nonetheless, I consider this the most important contribution I can make in this process.

42. Factors that may moderate treatment efficacy in individuals with chronic low back and musculoskeletal pain and crucial to address in CER and pragmatic trial design and execution:

    a. Pain Comorbidities: Many patients with these conditions suffer concurrently with other pain disorders, such as headache disorders, chronic pelvic pain, fibromyalgia and temporomandibular disorders. Growing evidence suggests that those with multi-site pain are more recalcitrant to treatment, have poorer outcomes and increased disability. However, most studies only address the pain condition of primary interest and fail to take into account the impact of other pain disorders on treatment efficacy. Further, a patient-centered holistic treatment approach is to treat pain in the whole person versus fragmented medical care by different specialists for pain in different body sites.

    b. Other Comorbidities and Contributing Factors: Many chronic low back pain patients also experience non-pain comorbidities and contributing factors, such as sleep disturbance, altered mood, fatigue and decreased physical function, which can serve as moderators of the pain itself. As such, the pain field has advanced to understand that it is insufficient to simply measure pain severity/inference in any clinical study, as multiple domains of health and quality of life, such as those listed above. Further, during the course of treatment, these factors may improve prior to a patient's pain severity or interference improving. Contributing factors are individual to each patient; one patient may experience significant sleep disturbance, while another has altered mood and fatigue. A patient-centered approach to treatment would be a personalized medicine approach that assesses and treats all contributing domains of health and quality of life, in addition to chronic pain. [Recommendations for core domains to be measured in clinical pain research have been put forth by IMMPACT (Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials) and others.]

    c. Heterogeneity: Countless studies in multiple chronic pain populations have demonstrated that heterogeneity – both phenotypic clustering within a given pain diagnosis (chronic low back pain, chronic musculoskeletal pain) as well as heterogeneity in treatment response – is imperative to address, irrespective of the treatment(s) being studied to identify biological and other predictors of treatment success and failure, as well those more likely to experience adverse effects from a particular treatment(s).

43. Improve function for Native Americans with Myofascial Pain living in New Mexico and the Navajo Nation. Identify 3 Federally Qualified Health Care Centers in Rural New Mexico and the Navajo Reservation; follow patients with myofascial pain with designated outcomes measures (BPI, QOL, etc).Pre and Post Measures after group exercise program, PT, Trigger point injection, etc

44. To Increase the Self Efficacy for Primary Care Clinicians treating Native Americans with Myofascial Pain. Bring Primary care clinicians to University of New Mexico for 2 days Hands On Myofascial Trigger point training course, followed by weekly 60-90 minute remote UNM ECHO Pain telementoring conference to gain knowledge and self efficacy in pain (and myofascial pain) and safe opioid prescribing. Measure pre-post self-efficacy and knowledge for Primary care clinicians. Measure the effectiveness of a combination of synchronous (UNM ECHO Pain) videotelementoring and 2 day live training vs. "treatment" as usual for Primary Care clinicians.