

Pathways to Prevention:

Weighing the evidence. Identifying the research gaps. Determining next steps.

A Report from the Federal Partners' Meeting of the National Institutes of Health Pathways to Prevention Workshop: The Role of Opioids in the Treatment of Chronic Pain

Wednesday, March 9, 2016

8:30 a.m. – 12:30 p.m.

Sponsored by:

National Institutes of Health (NIH) Office of Disease Prevention (ODP)

NIH Pain Consortium

National Institute on Drug Abuse (NIDA)

National Institute of Neurological Disorders and Stroke (NINDS)

Summary

On September 29–30, 2014, the National Institutes of Health (NIH) held the [Pathways to Prevention \(P2P\) Workshop: *The Role of Opioids in the Treatment of Chronic Pain*](#), as part of the NIH Office of Disease Prevention's (ODP) [P2P Program](#), whose goal is to gather experts to identify research gaps or methodological and scientific weaknesses in a scientific area and suggest research needs to move the field forward. The P2P workshop on opioids and chronic pain was co-sponsored by the ODP, the NIH Pain Consortium, the National Institute on Drug Abuse (NIDA), and the National Institute of Neurological Disorders and Stroke (NINDS).

As part of the P2P Program, senior representatives from federal government agencies (the Federal Partners) meet to identify strategies to address recommendations that come from the P2P workshops. This report summarizes the discussion at the March 9, 2016 Federal Partners' Meeting held after the P2P workshop on opioids and chronic pain, and reflects part of a concerted federal response to the epidemic of prescription opioid misuse and overdose in the United States. The Federal Partners identified research areas for potential collaboration, resources used by different federal agencies, and potential next steps to address some of the recommendations from the P2P Workshop: *The Role of Opioids in the Treatment of Chronic Pain* Final Report (Reuben et al., 2015).

Background

Pain is a complex condition affected by biological, psychological, and social factors. Analysis of data from the 2012 National Health Interview Survey (NHIS) estimates that 126 million adults in the U.S. report pain, with 25 million experiencing chronic pain and 14 million enduring severe or high pain levels (Nahin, 2015). Pain is also the primary reason Americans receive disability insurance, with an estimated cost from missed work and medical expenses of \$560 to \$635 billion per year (Committee on Advancing Pain Research, 2011). Despite the enormity of the societal costs, 40%–70% of people suffering from chronic pain in the United States do not receive proper medical treatment for it (Reuben et al., 2015).

Opioids represent one pain management strategy. Opioid prescriptions have increased dramatically in the last 20 years from 76 million in 1991 to 219 million in 2011, and five to eight million Americans use opioids for long-term management of chronic pain. Eighty percent of all opioid prescriptions in the developed world are written in the United States (Reuben et al., 2015).

These data highlight both the challenge of effectively treating chronic pain and the need for more knowledge about the appropriate use of opioid medications. Specifically, there is a critical need to understand the effectiveness, potential for abuse, risk of addiction, and potential role of opioids as part of a comprehensive pain management approach.

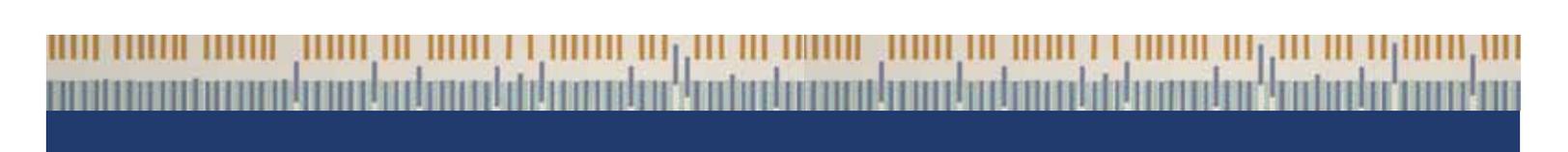
The P2P Workshop and Federal Partners Meeting

In response to this need, the NIH Pain Consortium, working with the ODP, NIDA, and NINDS, organized a P2P workshop to focus on the role of opioids in the treatment of chronic pain. The goal of the [P2P Program](#)

is to host workshops that identify research gaps in a selected scientific area, identify methodological and scientific weaknesses in that scientific area, suggest research needs, and move the field forward through an unbiased, evidence-based assessment of a complex public health issue. The P2P workshop focusing on the effectiveness of opioids for chronic pain was designed to address four key questions:

1. What is the long-term effectiveness of opioids for treating chronic pain?
2. What are the potential risks of opioid treatment in patients with chronic pain?
3. What are the effects of different opioid management strategies on outcomes related to addiction, abuse, misuse, pain, and quality of life?
4. What is the effectiveness of risk mitigation strategies for opioid treatment?

A multidisciplinary Content-Area Expert Group developed the workshop agenda, and an evidence report was prepared by an Evidence-based Practice Center through a contract with the Agency for Healthcare Research and Quality (AHRQ) to facilitate the workshop discussion (Chou et al., 2014). The P2P Workshop: *The Role of Opioids in the Treatment of Chronic Pain* was held on September 29–30, 2014. During the workshop, invited experts discussed the body of evidence and attendees had the opportunity to provide comments during open discussion periods. After weighing the data from the evidence report, expert presentations, and public comments, an unbiased, independent panel prepared a report summarizing the P2P workshop, which identified research gaps and future research priorities and made nine recommendations directed toward federal and non-federal agencies, pharmaceutical companies, health systems, and clinicians. (Reuben et al., 2015).



As part of the P2P Program, senior representatives from federal agencies involved in the planning process meet after each workshop to develop strategies to address the recommendations. On March 9, 2016, senior government representatives (the “Federal Partners” in the P2P Workshop: *The Role of Opioids in the Management of Chronic Pain*) met to develop strategies to address some of the recommendations outlined in the panel report. The objective of the Federal Partners’ Meeting was to encourage research in key areas, identify opportunities to leverage existing resources, and promote collaboration and synergy while reducing overlapping efforts across the federal agencies, with the ultimate goal of providing rigorous scientific evidence that can lead to improved pain management for patients and reduce prescription opioid abuse.

The present report summarizes the discussions from the **Federal Partners’ Meeting** (see pages 11–12 for a participant list), which focused on three of the panel’s recommendations:

1. Federal and non-federal agencies should sponsor research to identify which types of pain, specific diseases, and patients are most likely to benefit and incur harm from opioids.
2. Federal and non-federal agencies should sponsor the development and evaluation of multidisciplinary pain interventions, including cost-benefit analyses and identification of barriers to dissemination.
3. Federal and non-federal agencies should sponsor research to develop and validate research measurement tools for identification of patient risk and outcomes (including benefit and harm) related to long-term opioid use that can be adapted for clinical settings.

An analysis of research activities conducted or supported by the participating agencies relevant to these three recommendations identified gaps and opportunities. Participants discussed the research directions that might have the highest priority and the resources and collaborations that could be applied to address these areas.

Summary of Discussion of P2P Panel Recommendation I:

Sponsor research to identify which types of pain, diseases, and patients are most likely to benefit and incur harm from opioid usage

Background: A theme throughout the discussion was the importance of continuing to consider the use of opioids in the context of chronic pain management approaches. Clinicians take various factors into consideration when proposing the use of opioids, either alone or in combination with other approaches. The [Centers for Disease Control and Prevention \(CDC\) Guideline for Prescribing Opioids for Chronic Pain](#) recommends that clinicians consider opioid therapy only if expected benefits for pain and function are anticipated to outweigh risks to the patient (Dowell et al., 2016). However, as noted in the P2P Panel Report (Reuben et al., 2015), little research exists to indicate whether a given patient will benefit from or be harmed by using opioids for chronic pain management.

Specific Research Focus Areas: Clearly, better predictors in individual patients of potential benefit and harm from opioid use are needed. The following high priorities were identified:

- Conduct studies incorporating pharmacogenomics approaches that are designed to identify genetic predictors of benefits and harms.

- Identify predictors of who is likely to benefit or be harmed based on psychological tests and considering patient history, type of pain, race, sex, age, and other factors.
- Promote research that identifies relative risks that could be used in health care settings to inform clinical decision-making by health care providers in collaboration with the patient.
- Develop strategies to identify risks related to dependence, abuse, misuse, addiction, and overdose, including other types of risks and side effects.

Opportunities for Collaboration Among Federal Agencies, Resources and Next Steps

Potential opportunities include encouraging researchers to use common data elements and databases developed by federal agencies in their studies. For instance, various agencies could work together to expand pain registries and standardize assessment tools to determine those patients for whom opioid therapy is most appropriate, and those at risk for potential harm. Several tools have the capacity to provide consistent patient outcomes data and could be used for risk assessment:

1. NIH Patient Reported Outcomes Measurement Information System (PROMIS®) (Cella et al., 2010)
2. The Pain Assessment Screening Tool and Outcomes Registry (PASTOR) (Cook et al., 2014)
3. The Collaborative Health Outcomes Information Registry (CHOIR) (Sturgeon et al., 2015).

PROMIS® instruments administer questions using computer adaptive testing that allows for precision with the fewest possible number of questions. PASTOR capitalizes on this computer adaptive testing through a short (20 to 30 minute) PROMIS® survey instrument

that captures demographic information and an anatomical map of pain areas. This information is compiled into one longitudinal dataset to create a comprehensive, three-page report of a patient’s pain that can be tracked over time to show improvements or declines. CHOIR, which uses a set of open-source tools to assess patient-reported health outcomes (e.g. PROMIS®), encompasses a subset of the Stanford-NIH Open Source Health Registry that collects longitudinal data in clinical settings using set measures. These downloadable, open-source tools can easily be adapted to specific research questions.

Other pain assessment tools include:

[The Orofacial Pain: Prospective Evaluation and Risk Assessment](#) (OPPERA), developed by the National Institute of Dental and Craniofacial Research; [The MAPP study \(Multidisciplinary Approach to the Study of Chronic Pelvic Pain\)](#); and [PhenX](#), a toolkit to standardize phenotyping for conditions of interest. Electronic health records are another potential resource, especially at the Department of Veterans Affairs, where individual records are often held for years and contain retrospective, as well as prospective data.

These data sets could be used to identify sub-groups of pain patients that may be at risk of harm or those who would most likely benefit from opioid therapies, and under what kinds of conditions.

To address this recommendation, research development could also focus on identifying who would respond best to certain kinds of drugs and who would be at risk for addiction using individualized pharmacogenomics techniques; refining “brain-in-a-dish” models to study the effects of drugs in cultured human brain tissues (Geha et al., 2016); and encouraging patient-centered outcomes research projects.

A currently-funded federal government resource, the [NIH Health Care Systems Research Collaboratory](#), was

identified as an existing research infrastructure that could be used to learn more about the types of pain, conditions, and patients most likely to benefit, or incur harm, from opioid use.

Summary of Discussion of P2P Panel Recommendation II:

Sponsor the evaluation of multidisciplinary pain interventions, including cost-benefit analyses and identification of barriers to dissemination

Background: The past 20 years have seen a surge in opioid prescribing, so much so that opioids are often used as a replacement for comprehensive pain treatment. The CDC released the [Guideline for Prescribing Opioids for Chronic Pain](#) (Dowell et al., 2016) on March 15, 2016, and the [National Pain Strategy](#) (Interagency Pain Research Coordinating Committee, 2016) was released by the Department of Health and Human Services (HHS) later that same week; both documents promote the use of integrated, comprehensive treatments for chronic pain with considerably less reliance on opioids.

Specific Research Focus Areas: While there is heightened awareness of the need to move away from sole reliance on prescription opioids and toward more integrated, multidisciplinary pain management, there also is a lack of recent evidence identifying the approaches (and perhaps, in what combination) that improve pain management and function, and the types of patients with chronic pain who benefit most. In order to inform treatment decisions, and also to help inform reimbursement policies, the Federal Partners identified the following top research priorities:

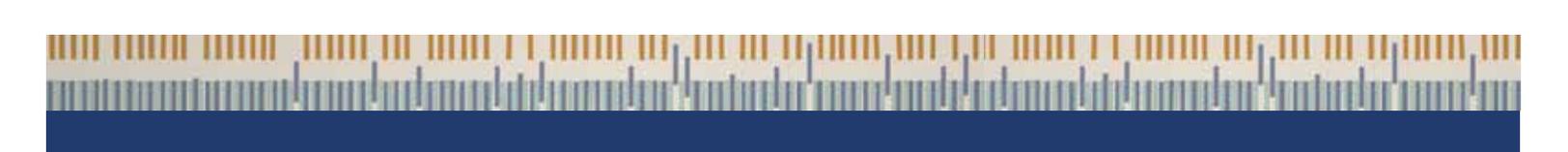
- Conduct studies that examine the effectiveness of comprehensive, integrated pain management models.
- Examine how combinations of treatments work based on patient characteristics.

- Examine how combinations of treatments work based on the type of chronic pain being treated.
- Assess the circumstances under which opioids are effective as a component of a more comprehensive pain treatment approach. For example, are low-dose short-acting opioids effective for breakthrough pain that may occur, and if so, under what circumstances and for whom?

Opportunities for Collaboration Among Federal Agencies, Resources and Next Steps

Developing integrated approaches that incorporate a multidisciplinary team are likely to be essential for effective pain management strategies. A team approach focuses not only on pain management but also includes goals for increasing quality of life and improving function for a person experiencing chronic pain. For example, as part of emphasizing a multidisciplinary approach to pain management, the Department of Defense (DOD) has developed innovative approaches for promoting access to complementary strategies to manage pain. The importance of certain modalities from complementary approaches such as mindfulness training, hypnosis, and acupuncture in management of chronic pain was discussed; the NIH National Center for Complementary and Integrative Health (NCCIH) is a possible resource for facilitating collaborations related to studying the potential role and contributions of integrative medicine in pain management.

Other models of multidisciplinary care include those that offer a menu system of modalities that patients experiencing pain can try until they find the combination that works best for them, or a decision tree that guides providers in identifying management approaches that can be used by providers.



Due to the dearth of recent data on multidisciplinary approaches to managing chronic pain, the Federal Partners identified this topic for a comprehensive analysis to inform research priorities. As a first step, the Federal Partners propose a workshop to bring together scientists and clinicians with expertise in multidisciplinary team approaches to pain management to inform research priorities and help identify the most significant gaps in our knowledge base. The Federal Partners may then explore the development of funding initiatives to address key research gaps identified at such a workshop.

Summary of Discussion of P2P Panel Recommendation III:

Sponsor research to develop and validate research measurement tools for identification of patient risk and outcomes related to long-term opioid use

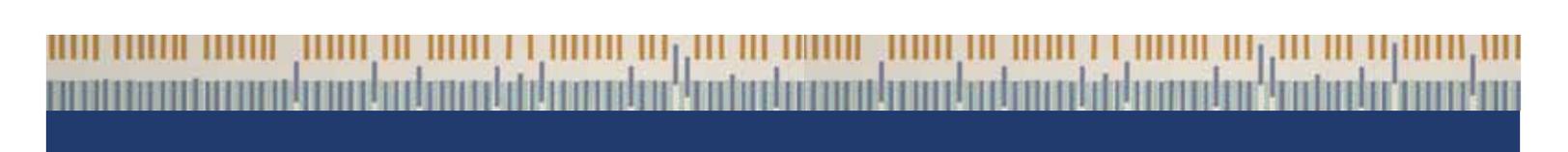
Background: Pain is a phenomenon with a biological substrate that appears to be substantial and widespread, and chronic pain is associated with changes in many parts of the body and brain. Furthermore, patients' pain experiences exist on many levels, including the psychological, behavioral, emotional, and social levels, and are often tied to other co-occurring conditions, including depression, anxiety, and insomnia. Chronic pain also impacts function and quality of life. Unfortunately, pain treatment and research have been complicated by the lack of specific objective means for measuring different types of pain and enabling comparisons between individuals. However, with the introduction of rigorous scientific measures, such as the NIH-supported PROMIS® (Cella et al., 2010) and PASTOR (Cook et al., 2014), it is becoming possible to compare subjective pain experience across different conditions and diseases.

Specific Areas of Research Focus: For comprehensive pain measurement assessments, researchers need to include both the affective and intensity dimensions of pain, and identify patterns or clusters of phenomena that group in various chronic pain states. The group identified the following research priorities:

- Study brain mechanisms of chronic pain, as chronic pain appears to be associated with changes in the brain that increase sensitivity and reactivity to pain.
- Study the impact of various pain treatments (including opioids) on brain changes associated with chronic pain.
- Examine the effectiveness of pain treatments based on the particular pattern of changes contributing to an individual's chronic pain.
- Explore how screening tools could be informed by other research. For example, one available screening tool is Screener and Opioid Assessment for Patients in Pain (SOAPP®). This tool could be further informed by results from pharmacogenomic studies, behavioral analyses, and phenotyping efforts.

Opportunities for Collaboration Among Federal Agencies, Resources and Next Steps

One possible collaboration would involve using an approach similar to that of the Alzheimer's Disease Neuroimaging Initiative (ADNI), a longitudinal, multisite observational study of elderly people with Alzheimer's Disease, those with mild cognitive impairment, and healthy individuals (<http://adni.loni.usc.edu/>). This project assesses the rate of change in cognition, function, brain structure, and biomarkers during aging. A pain research-focused collaboration



similar to the ADNI could include public-private partnerships with a variety of organizations and be further enhanced by partnering with organizations such as the Patient-Centered Outcomes Research Institute (PCORI) that ensure that pain patients are involved in the process. Assessment tools such as NIH PROMIS® (Cella et al., 2010), PASTOR (Cook et al., 2014), and CHOIR (Sturgeon et al., 2015) could also be used to link data and to gain a deeper understanding of pain beyond commonly-used self-report rating scales (i.e., one type of assessment that involves assigning a score of 1 to 10 to quantify the extent of pain).

These P2P activities are intended to continue to help inform researchers, policy makers, clinicians and other stakeholders who share the goal of promoting effective pain treatment while combating prescription drug misuse.

Conclusions and Next Steps

This federal partners' report from [Pathways to Prevention \(P2P\) *The Role of Opioids in the Treatment of Chronic Pain*](#) represents the final step of the NIH Office of Disease Prevention's [P2P Program](#). Initiated by the NIH Pain Consortium, this process included input from federal agencies, academia, professional organizations, patient advocates, and the general public. This unbiased approach encompasses a best effort to understand the potential role of opioids in treating chronic pain.

While this P2P Program activity is closed, our efforts to improve pain treatment and reduce prescription opioid abuse should continue in a significant and coordinated way. This federal partners' meeting report is key to aiding that effort. The report will be publicly available, and also will be distributed to key stakeholders across the federal government. The NIH Pain Consortium, which coordinates much of the pain research at the NIH, will receive copies and be briefed on the report. The Interagency Pain Research Coordinating Committee, which is mandated to help coordinate pain research across the federal government, will also receive this report and be briefed.

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Appendix: Tools and Resources:

CHOIR—Collaborative Health Outcomes Information Registry

Stanford developed and implemented this open-source, open-standard, free data-collection software in partnership with the NIH. CHOIR streamlines collection of qualitative information on an individual's pain in a safe, secure, and easy-to-use platform. Doctors access this information to better treat individuals through tools that show how a patient responds to treatment over time. Data from multiple patients can be analyzed to better understand pain conditions and develop more effective treatments. There are approximately 15,000 unique patients, 64,000 visits, and 40,000 follow-up visits and Medical Centers across the country use CHOIR in clinical practice and in biomedical research.

CDC Guideline for Prescribing Opioids for Chronic Pain

The Centers for Disease Control and Prevention released this report in March 2016 that calls for an integrated approach that leads to lower incidence of opioid prescriptions.

IMMPACT—Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials

IMMPACT is a multidisciplinary initiative comprised of invited representatives from federal agencies, academia, advocacy groups, consumer support and industry. During IMMPACT meetings, these diverse participants develop consensus recommendations for improving the design, execution, and interpretation of clinical trials of treatments for pain.

MAPP—Multidisciplinary Approach to the Study of Chronic Pelvic Pain Research Network

MAPP Research Network is a collaborative research network specializing in understanding the causes of chronic urological pelvic pain in interstitial cystitis/painful bladder syndrome and chronic prostatitis/chronic pelvic pain syndrome. Members of the MAPP Research Network conduct multidisciplinary studies from a systemic perspective that incorporate varied and complementary approaches and involve researchers from varied disciplines.

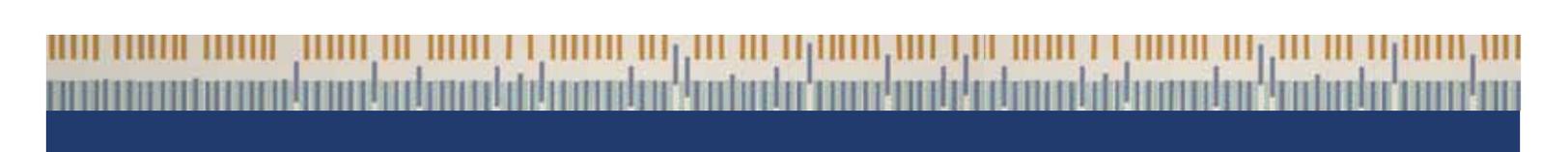
National Pain Strategy

The Department of Health and Human Services released the National Pain Strategy, a strategic plan from the Interagency Pain Research Consortium in March 2016 that promotes an integrated, comprehensive treatment plan for chronic pain with reduced reliance on opioids.

NIH Common Data Elements

cLBP—Chronic Low Back Pain Common Data Elements: A task force from the NIH Pain Consortium developed these public domain standards for assessing chronic low back pain. These elements are based on the IMMPACT recommendations for core domains from clinical trials devoted to chronic pain and use PROMIS instruments for assessing the core domains.

PhenX—consensus measures for Phenotypes and eXposures: The PhenX Toolkit consists of well-established, reproducible measures that are broadly applicable and provide a low burden to investigators and study participants. These measures can be used in genome-wide association studies and other large-scale genomic and epidemiologic research efforts to integrate genetic and epidemiological research,



PROMIS®—Patient Reported Outcomes Measurement Information System: PROMIS®

is used to measure patient-reported health status for physical, mental and social well-being by measuring what patients can do and assessing their feelings about answering questions. These measures can be used as primary and secondary endpoints in clinical trials, as well as across a wide variety of medical conditions and in the general population. These tools can be used by clinicians and patients to manage chronic conditions through improved communication.

OPPERA—Orofacial Pain Prospective Evaluation and Risk Assessment Study

This large, prospective clinical study funded by the National Institute of Dental and Craniofacial Research at the NIH is designed to identify individual risk factors that increase the risk of developing temporomandibular joint and muscle disorders.

PASTOR—Pain Assessment Screening Tool and Outcomes Registry

PASTOR is a survey tool based on PROMIS® measures designed to give clinicians a comprehensive overview of any patient's pain. Developed at the Department of Defense, PASTOR will be available for civilian use.

EHR—Electronic Health Records

EHRs can be used to assess long-term outcomes and efficacy of treatments. Closed systems, such as those used by the Department of Defense, Department of Veterans Affairs, and Kaiser Permanente could prove to be valuable sources of information on treatments, efficacy, outcomes, and cost-effectiveness.

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