UPDATE: Pathways to Prevention: Efficacy of Opioids for Chronic Pain

David Thomas, Ph.D.
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Prescription Opioid Overdose Deaths

Source: CDC Wonder

Heroin Overdose Deaths

Source: CDC Wonder
Nearly 80 percent of people who reported initiating heroin use in the past year had previously abused prescription pain medications...

About **100 million** Americans suffer from chronic pain
There is “not a consensus” on when opioids are safe and effective.
Pathways to Prevention:
Weighing the evidence. Identifying the research gaps. Determining next steps.
Pathways to Prevention Timeline

Proposal Review and Approval – 8 weeks
ODP Receives P2P Workshop Proposal
ODP Accepts P2P Workshop Proposal
Organizational Meeting
Working Group Meeting
Pathways to Prevention Workshop
Approval to Implementation – 12–14 months

Planning and Implementation – 9–12 months

Dissemination and Follow-Up – 1–9 months
Post-Workshop Dissemination
Federal Partners Meeting
Pathways to Prevention Process for “Efficacy of Opioids for Chronic Pain”

- NIH, FDA, CDC, SAMSA, OASH, AHRQ...
- NIH, FDA, CDC, SAMSA, OASH, AHRQ, Outside Gov’t stakeholders
- Pathways to Prevention Conference Natcher, NIH Main Campus

**Evaluation Panel vetting/formation**

- **NIH and FDA**
- **NIH, FDA, CDC, SAMSA, OASH, AHRQ...**
- **NIH, FDA, CDC, SAMSA, OASH, AHRQ, Outside Gov’t stakeholders**
- **Pathways to Prevention Conference Natcher, NIH Main Campus**

- **Sept. 2012**
- **Jan. 2013**
- **Aug. 2013**
- **Sept. 29 and 30th, 2014**
- **Jan., 2015**
- **Feb., 2016**

**White Paper:**
- Future Research Directions

**Cross-Gov’t Portfolio Analysis**

**Pathways to Prevention Federal Partners Meeting**
Pathways to Prevention Federal Partners Meeting

- Building on the workshop’s momentum
- Identifying actionable items from the report (e.g., meetings, Funding Opportunity Announcements [FOAs])
- Closing gaps in research
- Applying information to prevention strategies
Cross-Federal Government Pain Research Portfolio Analysis

• *What exists in current portfolio (IPRP database indispensable!)*
Beyond Federal Pain Research Portfolio??

**FDA-mandated post-market safety studies on opioids:**

2065-1 ... *risks of misuse, abuse, addiction, overdose, and death associated with long-term use of opioid analgesics for management of chronic pain*...

2065-2 *Develop and validate measures of the following opioid-related adverse events: ...*

2065-3 *Conduct a study to validate coded medical terminologies ...*

2065-4 *Conduct a study to define and validate “doctor/pharmacy shopping” ...*

2065-5 *Conduct a clinical trial to estimate the serious risk for the development of hyperalgesia following use of ER/LA opioid analgesics...*
Beyond Federal Pain Research Portfolio??

High Dose Opioids:  

Less Opioids:
National Institutes of Health Pathways to Prevention Workshop: The Role of Opioids in the Treatment of Chronic Pain

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This National Institutes of Health (NIH) workshop was cosponsored by the NIH Office of Disease Prevention (ODP), the NIH Pain Consortium, the National Institute on Drug Abuse, and the National Institute of Neurological Disorders and Stroke. A multidisciplinary working group developed the workshop agenda, and an evidence-based practice center prepared an evidence report through a contract with the Agency for Healthcare Research and Quality to facilitate the workshop discussion. During the 1.5 day workshop, invited experts discussed the body of evidence, and attendees had opportunities to provide comments during open discussion periods. After weighing evidence from the evidence report, expert presentations, and public comments, an unbiased, independent panel prepared a draft report that identified research gaps and future research priorities. The report was posted on the ODP Web site for 2 weeks for public comment. This article is an abridged version of the panel's full report, which is available at https://prevention.nih.gov/programs-events/pathways-to-prevention/workshops/opioids-chronic-pain/workshop-resources#final-report.

For author affiliations, see end of text. This article was published online first on Annals.org on 13 January 2015.

Chronic pain affects an estimated 100 million Americans, or one third of the U.S. population. Approximately 25 million have moderate to severe chronic pain that limits activities and diminishes quality of life. Pain is the primary reason that Americans receive disability insurance, and societal costs are estimated at between $560 billion and $620 billion per year due to missed workdays and medical expenses.

Although there are many treatments for chronic pain, an estimated 5 to 8 million Americans use opioids for long-term management. Opioid prescriptions and use have increased dramatically over the past 20 years; the number of opioid prescriptions for pain treatment was 76 million in 1991 but reached 219 million in 2011. This striking increase has paralleled increases in opioid overdoses and treatment for addiction to prescription painkillers. Yet, evidence also indicates that 40% to 70% of persons with chronic pain do not receive proper medical treatment, with concerns for both overtreatment and undertreatment. Together, the prevalence of chronic pain and the increasing use of opioids have created a “silent epidemic” of distress, disability, and danger to a large percentage of Americans. The overriding question is: Are we, as a nation, approaching management of chronic pain in the best possible manner that maximizes effectiveness and minimizes harm?

On 29 and 30 September 2014, the National Institutes of Health (NIH) convened a Pathways to Prevention workshop, “The Role of Opioids in the Treatment of Chronic Pain.” The workshop involved a panel of 7 experts, featured more than 20 speakers, and was informed by a systematic review conducted by the Pacific Northwest Evidence-based Practice Center (EPC) under contract to the Agency for Healthcare Research and Quality (1). The EPC review addressed evidence about the long-term effectiveness of opioids, the safety and harms of opioids, the effects of different opioid management strategies, and the effectiveness of risk mitigation strategies for opioid treatment.

See also:
Related article
1) Federal and nonfederal agencies should sponsor research to identify which types of pain, specific diseases, and patients are most likely to benefit and incur harm from opioids. Such studies could use a range of approaches and could include demographic, psychological, sociocultural, ecological, and biological characterizations of patients in combinations with clear and accepted definitions of chronic pain and well-characterized records for opioids and other pain medications.

2) Federal and nonfederal agencies should sponsor the development and evaluation of multidisciplinary pain interventions, including cost–benefit analyses and identification of barriers to dissemination.

3) Federal and nonfederal 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 to clinical settings.

4) Electronic health record vendors and health systems should incorporate decision support for pain management and facilitate export of clinical data to be combined with data from other health systems to better identify patients who benefit from or are harmed by opioid use.

5) Researchers on the effectiveness and harms of opioids should consider alternative designs (e.g., n-of-1 trials, qualitative studies, implementation science, secondary analysis, or phase 1 and 2 designs) in addition to randomized clinical trials.

6) Federal and nonfederal agencies should sponsor research on risk identification and mitigation strategies, including drug monitoring, before widespread integration of these into clinical care. This research should also assess how policy initiatives affect patient/public health outcomes.

7) Federal and nonfederal agencies and health care systems should sponsor research and quality improvement efforts to facilitate evidence-based decision making at every step of the clinical decision process.

8) In the absence of definitive evidence, clinicians and health care systems should follow current guidelines by professional societies about which patients and which types of pain should be treated with opioids and about how best to monitor patients and mitigate risk for harm.

9) The National Institutes of Health or other federal agencies should sponsor conferences to promote harmonization of guidelines of professional organizations to facilitate more consistent implementation of them in clinical care.
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