

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



*David Thomas, Ph.D.*

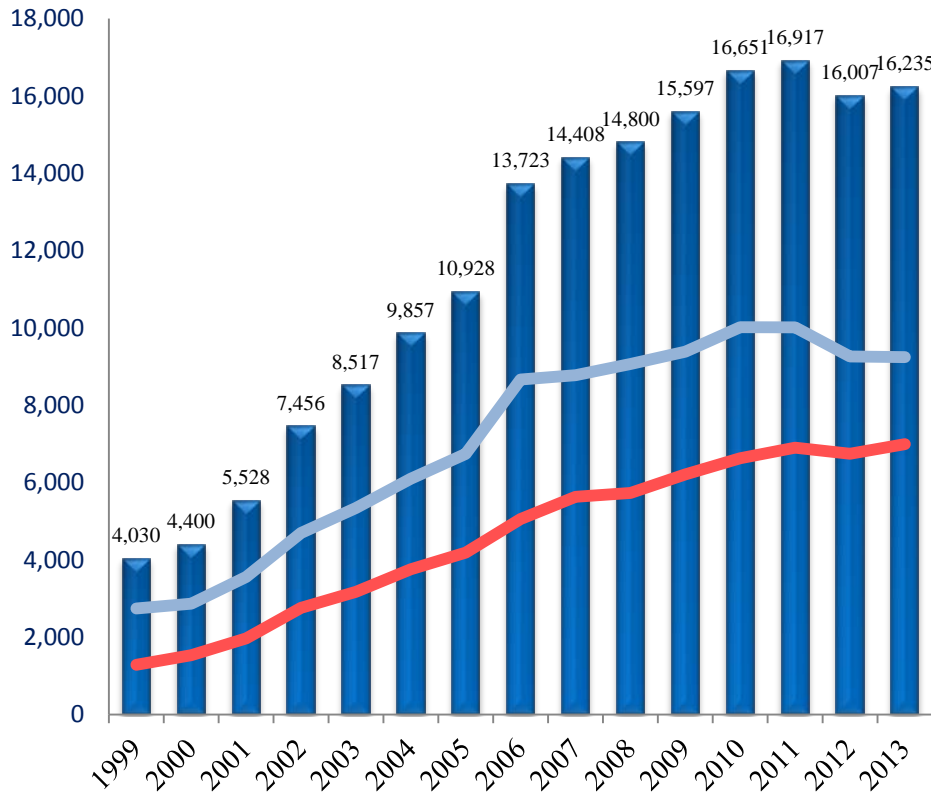
*National Institute on Drug Abuse/ NIH Pain Consortium*

# Overdose Death Data Updates

Source: CDC

## Prescription Opioid Overdose Deaths

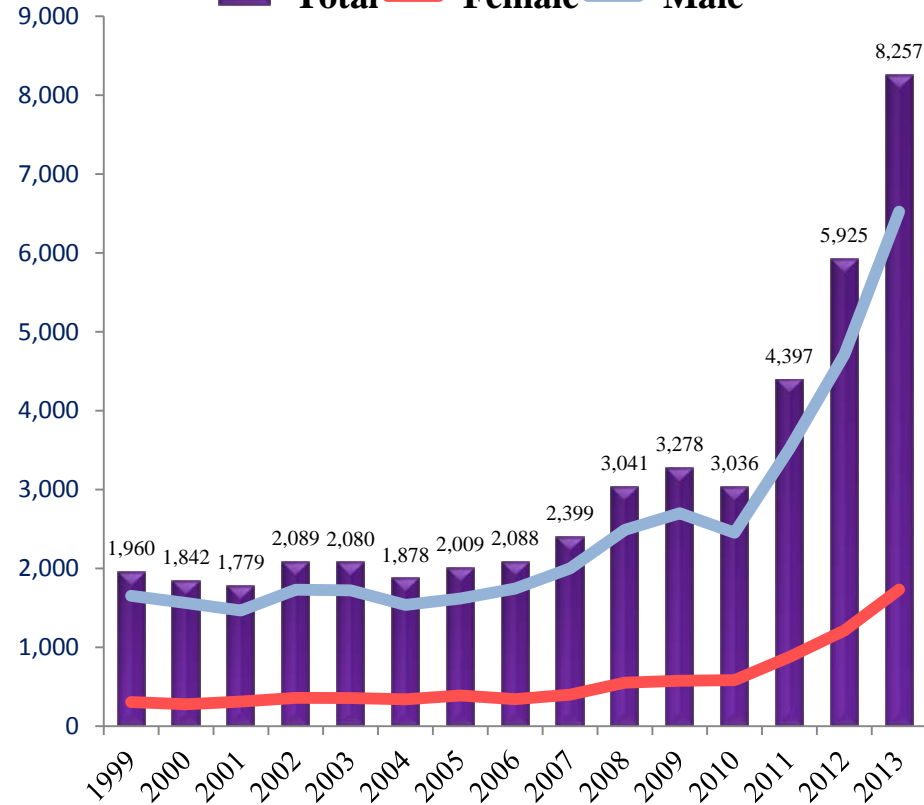
■ Total ■ Female ■ Male



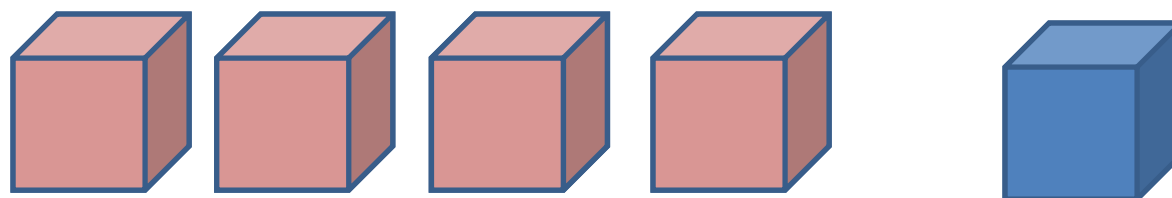
Source: CDC Wonder

## Heroin Overdose Deaths

■ Total ■ Female ■ Male

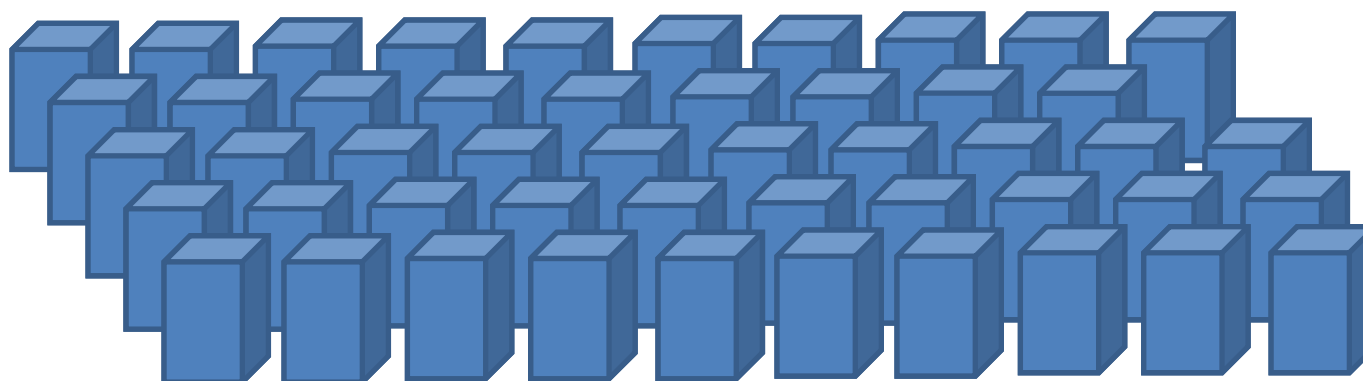


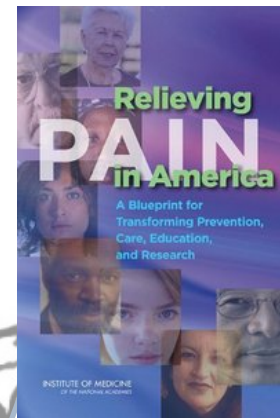
Source: CDC Wonder



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

Muhuri, P. et. al., *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*, CBHSQ Data Review (August 2013), retrieved from <http://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.htm>.





*About 100 million Americans suffer from chronic pain*

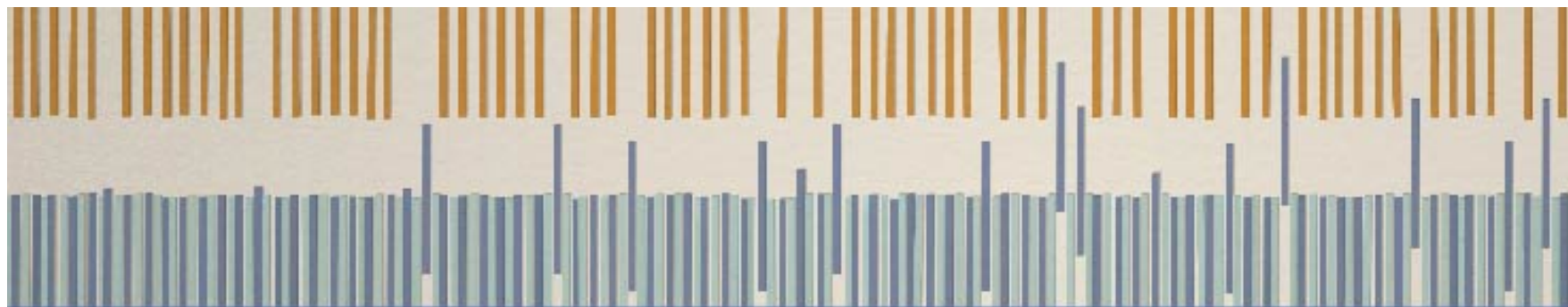
# *Problem*

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*There is “not a consensus” on when opioids are safe and effective.*



**National Institutes of Health**  
*Office of Disease Prevention*



## **Pathways to Prevention:**

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

# Pathways to Prevention Timeline





**Pathways to Prevention:  
The Role of Opioids in the Treatment of Chronic Pain**

September 29–30, 2014

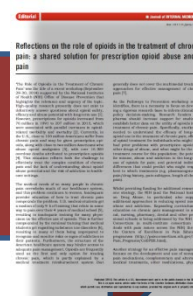
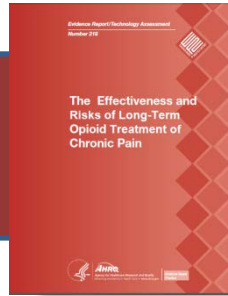


Back row, left to right: Takamaru Ashikaga, David C. Steffens, Christopher M. Callahan

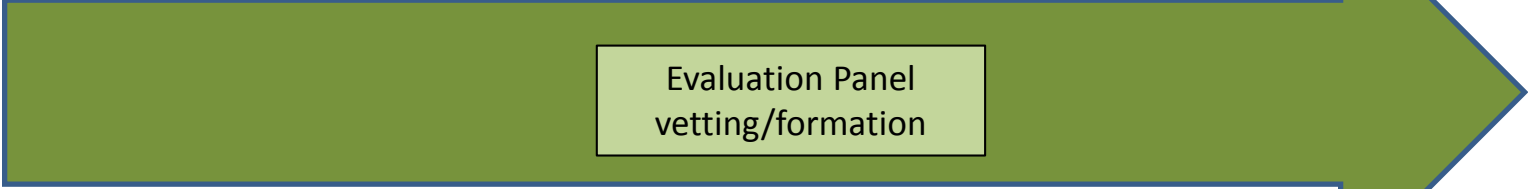
Front row, left to right: David M. Murray, David B. Reuben, G. Anne Bogat, Anika A.H. Alvanzo, Victoria Ruffing



# Pathways to Prevention Process for "Efficacy of Opioids for Chronic Pain"



White Paper:  
Future  
Research  
Directions



Evaluation Panel  
vetting/formation

Cross-Gov't  
Portfolio  
Analysis



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

Pathways to  
Prevention  
Federal  
Partners  
Meeting

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

# *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 ...*

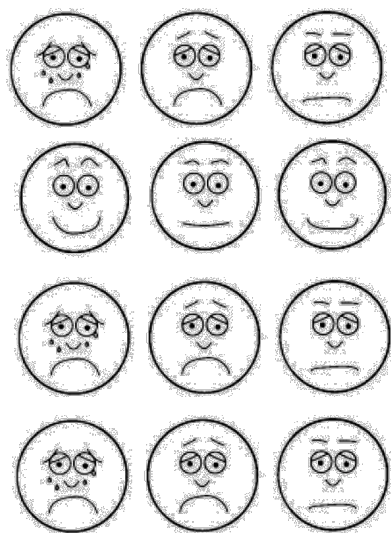
*2065-4 Conduct a study to define and validate “doctor/pharmacy shopping” ...*

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

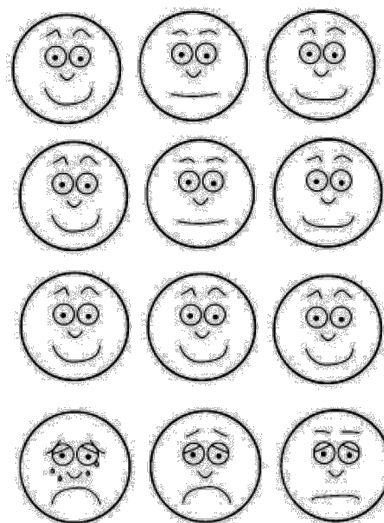


# Beyond Federal Pain Research Portfolio??

*High Dose Opioids:*



*Less Opioids:*



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

David B. Reuben, MD; Anika A.H. Alvanzo, MD, MS; Takamaru Ashikaga, PhD; G. Anne Bogat, PhD; Christopher M. Callahan, MD; Victoria Ruffing, RN, CCRP; and David C. Steffens, MD, MHS

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#finalreport>.

Ann Intern Med. doi:10.7326/M14-2775

[www.annals.org](http://www.annals.org)

For author affiliations, see end of text.

This article was published online first at [www.annals.org](http://www.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 \$630 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.

### CONTEXT

The expert panel considered in detail many contextual issues that affect understanding about the dilemma of opioid use and chronic pain (see the full report at <https://prevention.nih.gov/programs-events/pathways-to-prevention/workshops/opioids-chronic-pain/workshop-resources#finalreport>). Some of these are discussed in the following paragraphs.

The burden of dealing with unremitting pain can be devastating to a patient's psychological well-being and can negatively affect their ability to maintain gainful employment or achieve meaningful professional advancement. It can affect relationships with spouses and significant others; may limit engagement with friends and other social activities; and may induce fear, demoralization, anxiety, and depression.

Health care providers, who are often poorly trained in the management of chronic pain, are sometimes quick to label patients as "drug-seeking" or as "addicts" who overestimate their pain. Some physicians "fire" patients for increasing their dose or for merely voicing concerns about their pain management. These experiences may make patients feel stigmatized or feel as if others view them as criminals and may heighten fears that their pain-relieving medications will be taken away, leaving them in chronic, disabling pain.

Some patients who adhere to their prescriptions may believe that their pain is managed adequately, but others using opioids in the long term may continue to have moderate to severe pain and diminished quality of life. Although many physicians believe that opioid treatment can be valuable for patients, many also believe that patient expectations for pain relief may be

#### See also:


Related article ..... 1



- 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.



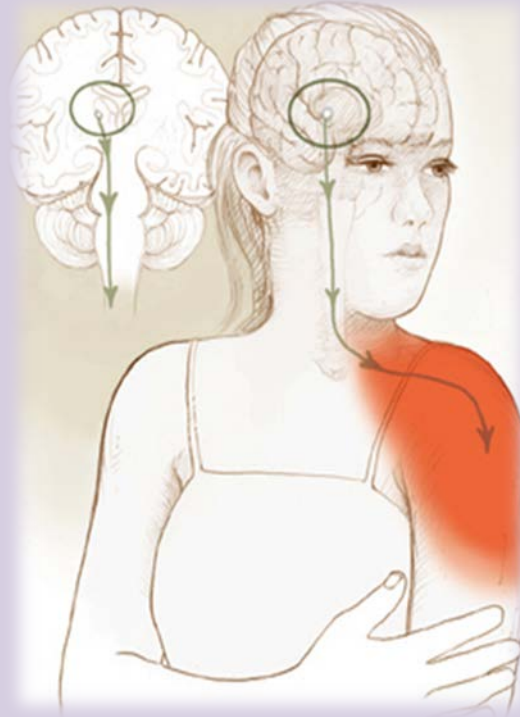
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3) Federal and nonfederal agencies should sponsor research to **develop and validate research measurement tools for identification of patient risk and outcomes** (including benefit and harm) related to long-term opioid use that can be adapted to clinical settings.

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