Strong States, Strong Nation

POLICY OPTIONS TO DECREASE RISKS FROM THE USE OF METHADONE AS A PAIN RELIEVER

NATIONAL CONFERENCE of STATE LEGISLATURES

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Today's Speakers

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- Delegate Don Perdue, RPh, West Virginia House of Delegates

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THE PEW CHARITABLE TRUSTS

Policy Options to Decrease Risks from the Use of Methadone as a Pain Reliever

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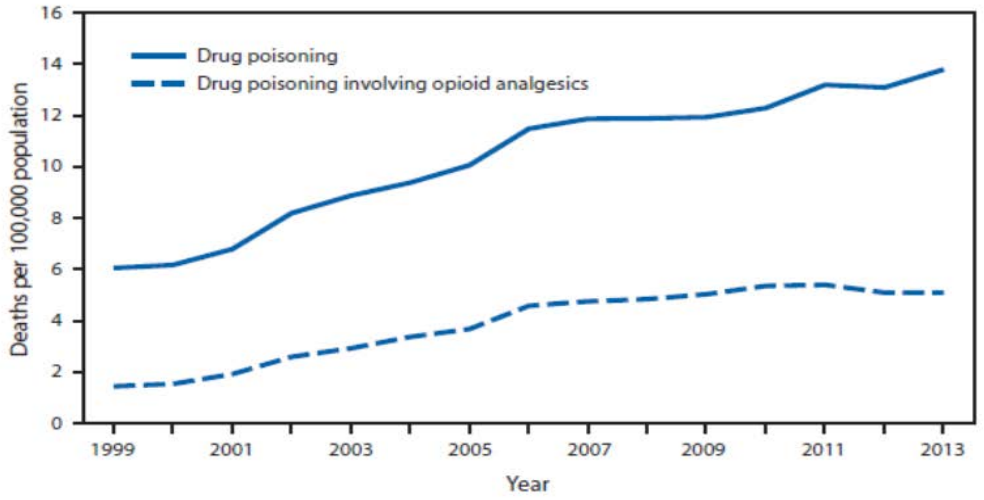
Overview—Prescription Drug Abuse

More than 16,000 people in the United States die each year from opioid-related prescription drug overdoses.

Rates* of Deaths from Drug Poisoning† and Drug Poisoning Involving Opioid Analgesics§ — United States, 1999–2013

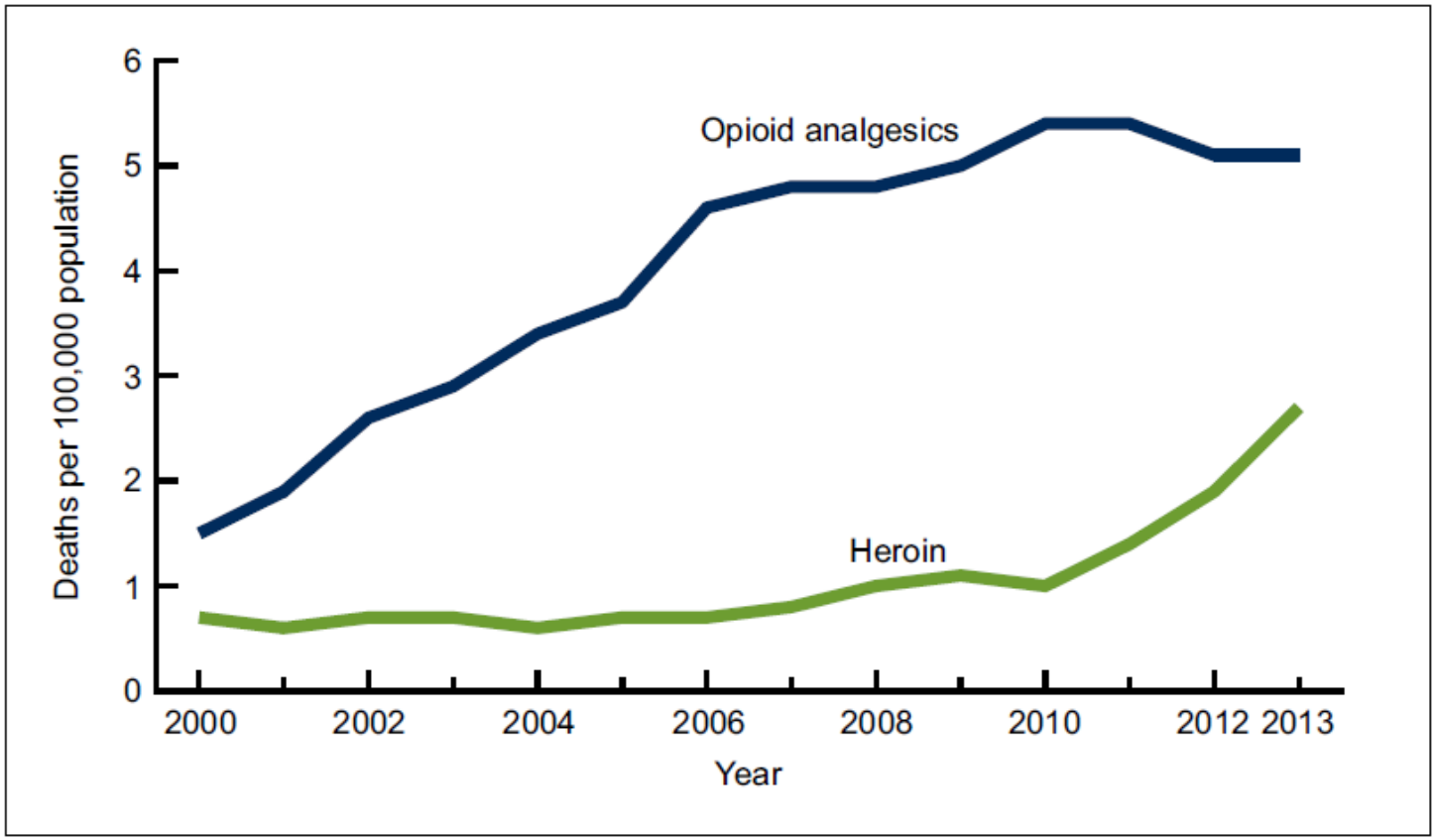


* Per 100,000 population, age-adjusted to the 2000 U.S. standard population.
† Drug poisoning deaths can result from taking an overdose of a drug, being given the wrong drug, taking a drug in error, or taking a drug inadvertently. Drug poisoning deaths include all intents (i.e., unintentional, suicide, homicide, and undetermined intent).
§ Drug poisoning deaths are identified using the *International Classification of Diseases, Tenth Revision (ICD-10)* underlying cause of death codes X40–X44, X60–X64, X85, and Y10–Y14. Drug poisoning deaths involving opioid analgesics are the subset of drug poisoning deaths with a multiple cause of death code of T40.2–T40.4.

Centers for Disease Control and Prevention, "QuickStats: Rates of Deaths From Drug Poisoning and Drug Poisoning Involving Opioid Analgesics—United States, 1999–2013," *Morbidity and Mortality Weekly Report* 64, no. 1 (2015): 32, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6401a10.htm?s_cid=mm6401a10_e

Overview: Prescription Drug and Heroin Abuse

Figure 1. Age-adjusted rates for drug-poisoning deaths, by type of drug: United States, 2000–2013



Hedegaard H, "Drug-poisoning Deaths Involving Heroin: United States, 2000–2013," *NCHS Data Brief,* No. 190, (2015), http://www.cdc.gov/nchs/data/databriefs/db190.pdf

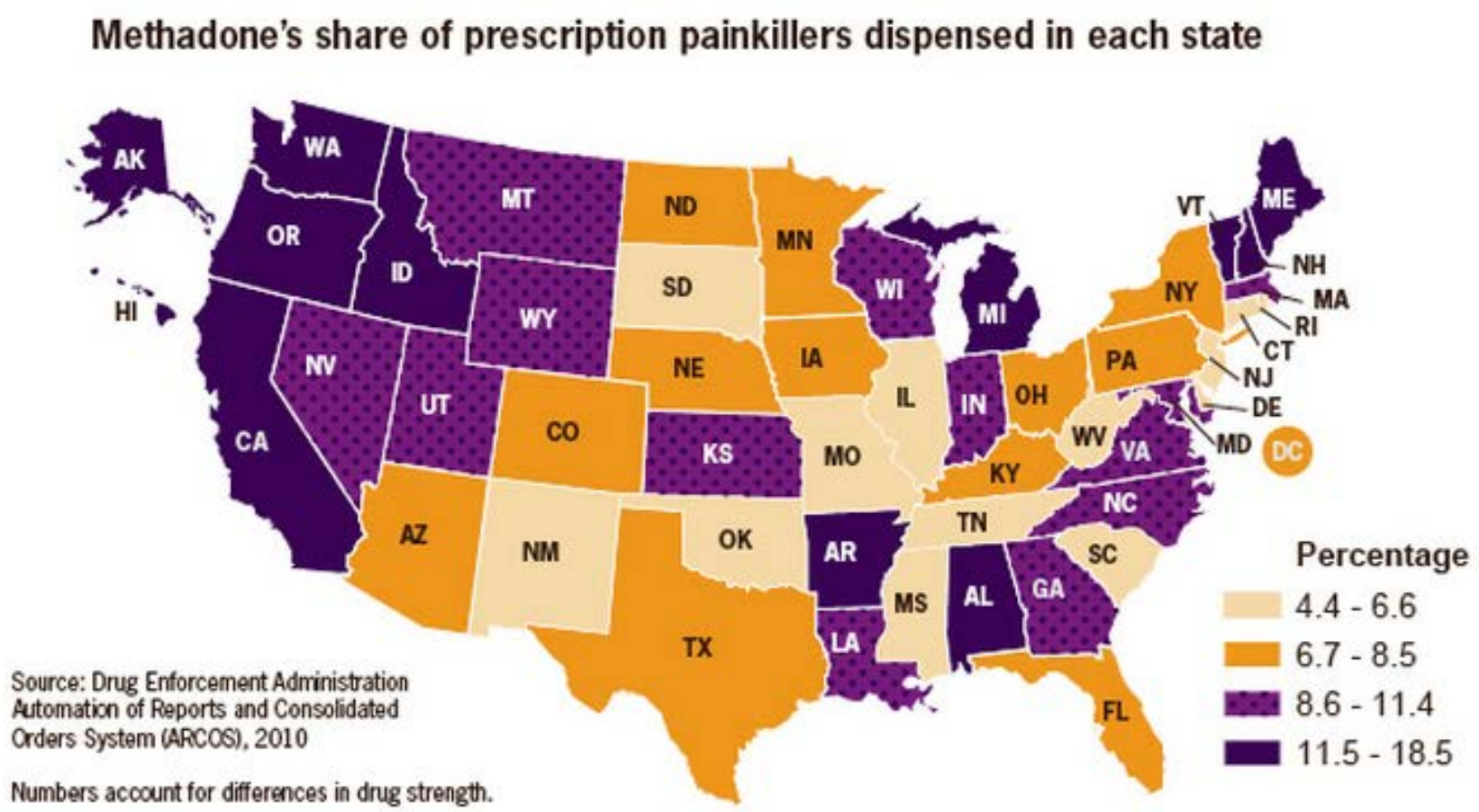
Methadone

- A synthetic opioid that has been used since the 1960s to treat heroin addiction by mitigating withdrawal symptoms[1]
- In the mid-1990s, methadone began to be increasingly prescribed for the treatment of chronic noncancer pain[1]
- Accounts for just two percent of opioid pain reliever prescriptions, yet is responsible for nearly one third of these deaths[2]

[1] Centers for Disease Control and Prevention, "Vital Signs: Risk for Overdose from Methadone Used for Pain Relief – United States, 1999–2010," *Morbidity and Mortality Weekly Report* 61, no. 26 (2012): 493-497, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6126a5.htm

[2] Centers for Disease Control and Prevention, "Vital Signs: Prescription Painkiller Overdoses: Use and Abuse of Methadone as a Painkiller," http://www.cdc.gov/vitalsigns/pdf/2012-07-vitalsigns.pdf

Methadone Use by State

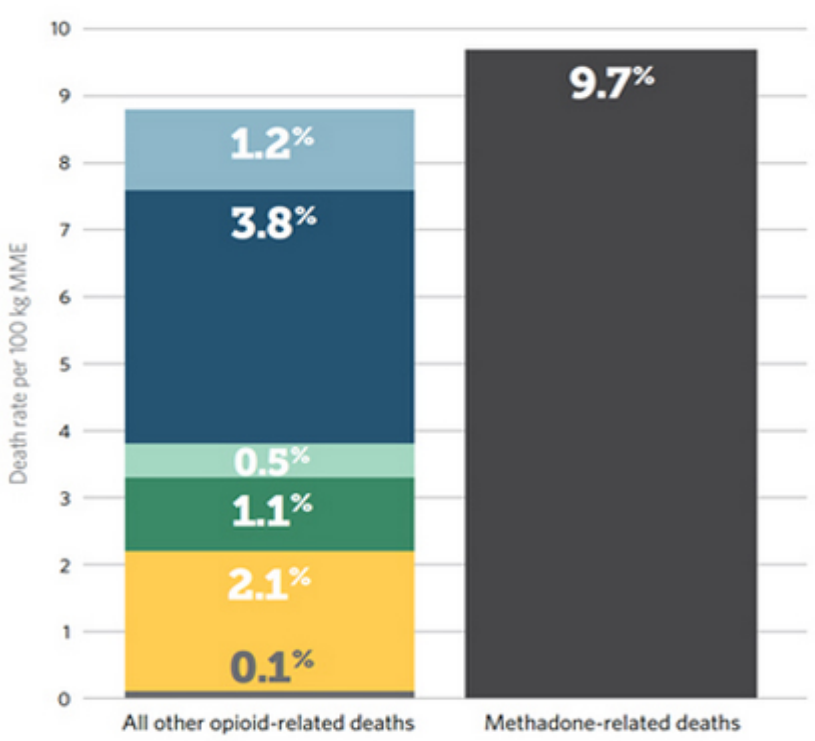


Centers for Disease Control and Prevention, "Vital Signs: Prescription Painkiller Overdoses: Use and Abuse of Methadone as a Painkiller," http://www.cdc.gov/vitalsigns/pdf/2012-07-vitalsigns.pdf

Methadone-related Deaths

Figure 1

Single-drug Related Deaths by Type of Opioid in 13 States, 2009 (n = 748)*



Methadone
Buprenorphine
Fentanyl
Hydrocodone
Hydromorphone
Morphine
Oxycodone

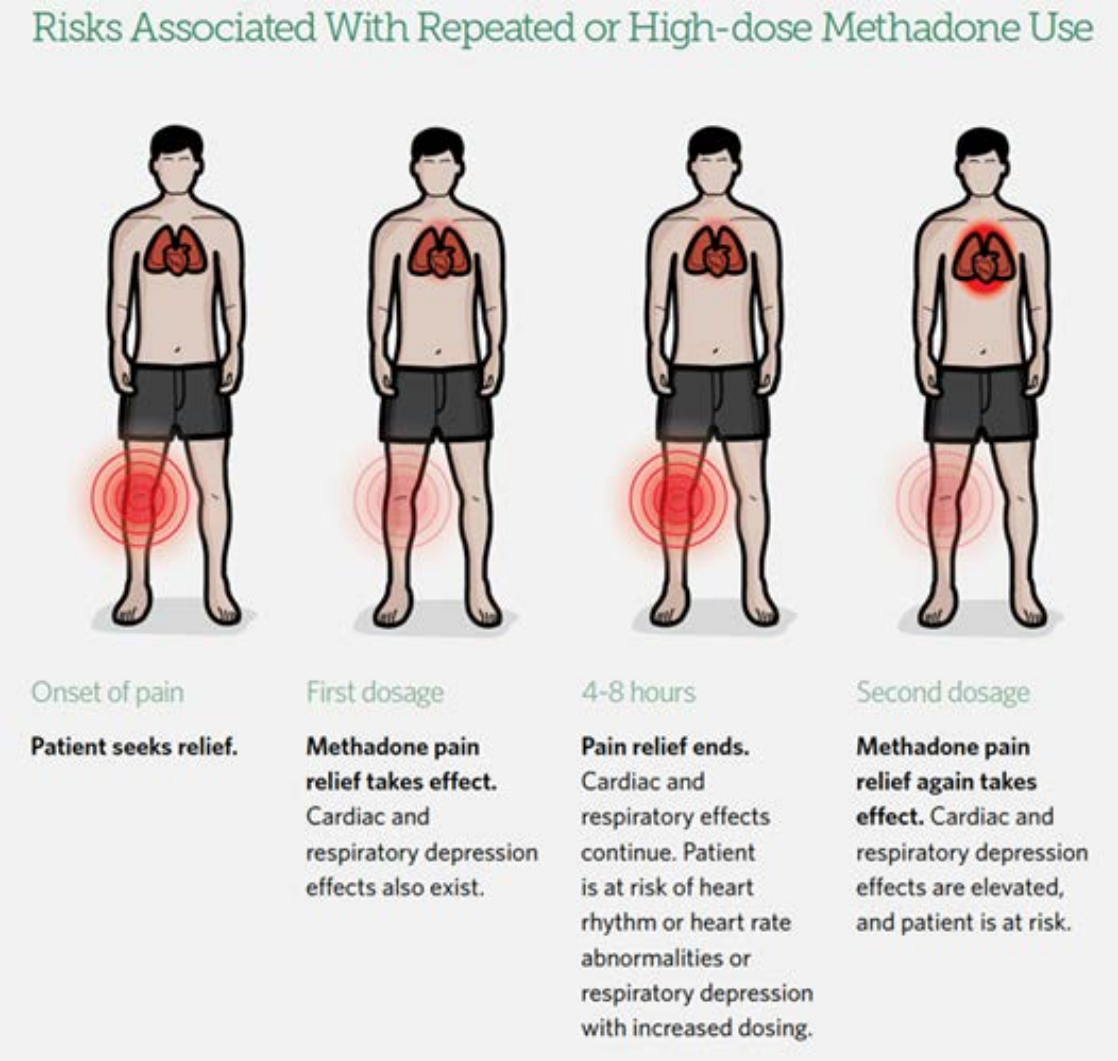
Note:

* Methadone deaths may include events from its use for pain and addiction treatment.

Source: Centers for Disease Control and Prevention

The Pew Charitable Trusts, "Prescription Drug Abuse Epidemic: Methadone," (2014), http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2014/08/prescription-drug-abuse-epidemic

Risks of Methadone Used for Pain



The Pew Charitable Trusts, “Prescription Drug Abuse Epidemic: Methadone,“ (2014), http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2014/08/prescription-drug-abuse-epidemic

Stakeholder Viewpoints

- In 2006, FDA issued a public health advisory regarding the use of methadone for pain control and added a “black box” warning about the drug’s risks on its labeling:[1]
  - Reserve methadone for use in patients for whom alternative analgesic treatment options are ineffective, not tolerated, or otherwise provide inadequate pain management
- Also increased the recommended dosing interval from every 3-4 hours to every 8-12 hours[2]

[1] Food and Drug Administration, “Methadone Hydrochloride Approved Label 4/14/2014,” accessed June 22, 2015, http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/090707Orig1s003lbl.pdf

[2] Food and Drug Administration, “Public Health Advisory: Methadone Use for Pain Control May Result in Death and Life-Threatening Changes in Breathing and Heart Beat” (2006), accessed June 22, 2015, http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm124346.htm

Stakeholder Viewpoints (continued)

- In 2008, DEA asked drug manufacturers to restrict distribution of the largest formulation of methadone pills (40 mg), which is not approved for the treatment of pain, to authorized opioid addiction treatment programs and hospitals.[1]
- In 2012, CDC recommended that:
  - Insurance formularies not list methadone as a preferred drug for the treatment of noncancer pain
  - Methadone be reserved for use in selected circumstances (e.g., for cancer pain or palliative care), by prescribers with substantial experience in its use. [2]

[1] Drug Enforcement Administration, "Methadone Hydrochloride Tablets USP 40 mg (Dispersible)," (2008), http://www.deadiversion.usdoj.gov/pubs/advisories/methadone_advisory.htm

[2] Centers for Disease Control and Prevention, "Vital Signs: Risk for Overdose from Methadone Used for Pain Relief – United States, 1999–2010," *Morbidity and Mortality Weekly Report* 61, no. 26 (2012): 493-497, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6126a5.htm

Stakeholder Viewpoints (continued)

- In 2012, the American Academy of Pain Medicine (AAPM)[1] and the American Society of Interventional Pain Physicians (ASIPP)[2] also recommended that methadone not be used as a first-line therapy for chronic pain:
  - AAPM: “Payers should not designate methadone as preferred,” and if it is to be used, “all methadone prescribers should complete an education program specific to the medication.”
  - ASIPP: “Methadone is recommended for use in late stages after failure of other opioid therapy and only by clinicians with specific training in the risks and uses.”

[1] The American Academy of Pain Medicine, “The Evidence Against Methadone as a ‘Preferred’ Analgesic: A Position Statement From the American Academy of Pain Medicine” (2014), accessed June 22, 2015, http://www.painmed.org/files/the-evidence-against-methadone-as-a-preferred-analgesic.pdf
[2] American Society of Interventional Pain Physicians, “Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 2—Guidance” Pain Physician Journal 15 (2012): S67–S116, http://www.painphysicianjournal.com/2012/july/2012;%2015;S67-S116.pdf

Harms Associated with Methadone Use

- A retrospective analysis of TennCare patients' medical records from 1997 to 2010 found those receiving methadone for pain had a 46 percent increased risk of overdose death as compared to those who received an alternative therapy (sustained release morphine).[1]
- In 2007, almost a third of unintentional overdose deaths in the Medicaid population in North Carolina were attributed to methadone.[2]
- Methadone was involved in 64 percent of prescription opioid overdose deaths in Washington State between 2004 to 2007.[3]

[1] Ray W, et al., "Out-of-Hospital Mortality Among Patients Receiving Methadone for Noncancer Pain." *JAMA Intern Med*. 2015;175(3):420-7.
[2] Whitmire JT and Adams GW, "Unintentional Overdose Deaths in the North Carolina Medicaid Population: Prevalence, Prescription Drug Use, and Medical Care Services," State Center for Health Statistics Studies, no. 162 (2010),http://www.schs.state.nc.us/SCHS/pdf/SCHS_162_WEB_081310.pdf
[3] Centers for Disease Control and Prevention, "Overdose Deaths Involving Prescription Opioids Among Medicaid Enrollees—Washington, 2004-2007," Morbidity and Mortality Weekly Report 58 no. 42 (2009): 1171–75,http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5842a1.htm

Why Is Methadone Still Prescribed for Pain?

- Factors that may be driving use include:[1,2,3]
  - Long duration of action
  - Effective treatment for refractive pain
  - Cost differential
- Methadone is a preferred pain reliever for most state Medicaid programs.[4]
  - 30 states currently list methadone as a preferred analgesic for pain[5]

[1] Food and Drug Administration, "Methadone Hydrochloride Approved Label 4/14/2014," http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/090707Orig1s003lbl.pdf

[2] The American Academy of Pain Medicine, "The Evidence Against Methadone as a 'Preferred' Analgesic: A Position Statement From the American Academy of Pain Medicine," http://www.painmed.org/files/the-evidence-against-methadone-as-a-preferred-analgesic.pdf

[3] CDC,"Overdose Deaths Involving Prescription Opioids Among Medicaid Enrollees—Washington, 2004-2007," *MMWR,* 58, no 42 (2009):1171-5

[4] CDC, "Vital Signs: Prescription Painkiller Overdoses: Use and Abuse of Methadone as a Painkiller," http://www.cdc.gov/vitalsigns/pdf/2012-07-vitalsigns.pdf

[5] The Pew Charitable Trusts, in-house research on state Medicaid fee-for-service preferred drug lists

Strategies Used by State Medicaid Programs to Address Safety Concerns

- Remove methadone from the preferred drug list (PDL)
  - In 2013, North Carolina became the first state to remove methadone from its PDL[1]
  - D.C.[2] and 10 other states followed
- Give methadone a status of non-preferred
  - Examples: Alaska,[3] Minnesota,[4] Nevada,[5] Tennessee,[6] West Virginia[7]

[1] Vestal C, "Most States List Deadly Methadone as a 'Preferred Drug,'" *Stateline*, Apr. 23, 2015, http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2015/4/23/most-states-list-deadly-methadone-as-a-preferred-drug
[2] District of Columbia. Medicaid Preferred Drug List, Available at https://dc.fhsc.com/downloads/providers/DCRx_PDL_listing.pdf
[3] Alaska Medicaid Preferred Drug List, Available at http://dhss.alaska.gov/dhcs/Documents/pdl/PDF/2015-PDL-DRAFT.pdf
[4] Minnesota Medicaid Preferred Drug List, Available at http://www.dhs.state.mn.us/main/idcplg?IdcService=GET_FILE&RevisionSelectionMethod=LatestReleased&Rendition=Primary&allowInterrupt=1&noSaveAs=1&dDocName=dhs_id_016922
[5] Nevada Medicaid Preferred Drug List, Available at https://www.medicaid.nv.gov/Downloads/provider/NV_PDL_20150101.pdf
[6] Tennessee Medicaid Preferred Drug List, Available at https://tenncare.magellanhealth.com/static/docs/Preferred_Drug_List_and_Drug_Criteria/TennCare_PDL.pdf
[7] West Virginia Medicaid Preferred Drug List, Available at http://www.dhhr.wv.gov/bms3/Pharmacy/Documents/WV%20PDL01282015%20v2015%202e.pdf

Strategies Used by State Medicaid Programs to Address Safety Concerns (continued)

- Implement prior authorizations
  - Examples: Massachusetts[1] & Delaware[2]
- Introduce stepped therapy
  - Examples: Ohio[3]
- Provide education to improve use
  - Example: Washington State conducted outreach—warning letters and office visits to educate top prescribers about pharmacology.[4]

[1] Massachusetts Medicaid Preferred Drug List, Available at https://masshealthdruglist.ehs.state.ma.us/MHDL/pubdownloadpdfcurrent.do?id=45
[2] Delaware Medicaid Preferred Drug List, Available at http://www.dmap.state.de.us/information/Pharmacy/DEM%20PDL.pdf
[3] Ohio Medicaid Preferred Drug List, Available at: http://medicaid.ohio.gov/Portals/0/Providers/ProviderTypes/MedicaidDrugProgram/PharmacyandTherapeuticsCommittee/2014-07-29-PDLrevised.pdf
[4] Vestal C, "Most States List Deadly Methadone as a 'Preferred Drug,'" *Stateline*, Apr. 23, 2015, http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2015/4/23/most-states-list-deadly-methadone-as-a-preferred-drug

National Spotlight on the Use of Methadone of Pain

- This issue was highlighted by the White House as part of an event held on October 21, 2015
  - President Obama announced commitments by federal, state, local governments and the private sector to address the prescription drug abuse and heroin epidemic
- As part of that effort, CMS will issue guidance to state Medicaid programs by the end of 2015 that will:
  - Outline steps to reduce risk of overdose through PDLs and utilization management
  - Recommend that programs consider removing methadone for pain from their PDLs

https://www.whitehouse.gov/the-press-office/2015/10/21/fact-sheet-obama-administration-announces-public-and-private-sector

Pew Activities to Improve the Safety of Methadone for Pain

- Describe the extent of prescribing of methadone and alternative therapies for pain in Medicaid
- Characterize patient harms (e.g., overdose rates, emergency room visits, and hospitalizations)
- Illustrate opportunities for change through case studies
- Advocate for drug-use policies that improve the safety of methadone for pain

A fact sheet from THE PEW CHARITABLE TRUSTS | Aug 2014

Prescription Drug Abuse Epidemic

Spotlight on Methadone

Overview

More than 16,500 people in the United States die each year from opioid-related prescription drug overdoses.[1] Methadone, which accounts for just 2 percent of opioid pain reliever prescriptions, is responsible for nearly one-third of these deaths.[2]

Methadone is a synthetic opioid, or narcotic pain reliever, that has been used since the 1960s to treat heroin addiction by mitigating withdrawal symptoms. In the mid-1990s, it began to be increasingly prescribed for the treatment of noncancer pain. Methadone, which is available in a low-cost generic form, is also a preferred pain reliever for most state Medicaid programs.

Growing public health concerns

In the early 2000s, as methadone prescriptions for pain control increased across the nation, so did the number of overdose deaths involving the drug. According to an analysis of data from 2009 in selected states, methadone was implicated in 40 percent of deaths that involved only one opioid—more than double the deaths attributed to other drugs in its class.[3] (See Figure 1.) When taken in combination with other drugs, it was involved in 31 percent of all opioid-related deaths. In addition, emergency department visits and deaths linked to methadone have increased nationwide.

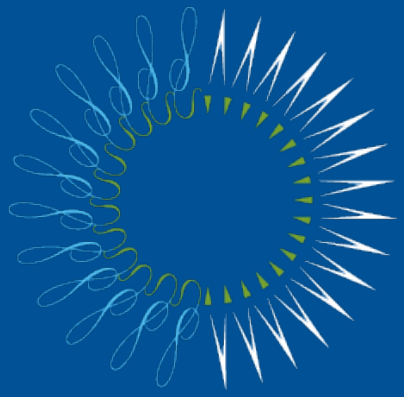
In response, the U.S. Food and Drug Administration in 2006 issued a public health advisory regarding the use of methadone for pain control and added a "black box" warning about the drug's risks on its labeling.[4] The agency also increased the recommended dosing interval from every 3-4 hours to every 8-12 hours.[5] As is the case with other extended-release and long-acting opioids, the current labeling for methadone states that it should be used by patients for whom nonopioid analgesics or immediate-release opioids, such as morphine, have failed, are not tolerated, or would otherwise be inadequate.[6]

In 2008, the Drug Enforcement Administration asked drug manufacturers to restrict distribution of the largest formulation of methadone pills (40 mg), which is not approved for the treatment of pain, to authorized opioid addiction treatment programs and hospitals.

Data from the Centers for Disease Control and Prevention (CDC) show that methadone deaths increased nearly sixfold in 11 years, jumping from 784 deaths in 1999 to 4,577 deaths in 2010.[7] These deaths coincided with growing U.S. pharmacy purchasing rates. The amount of methadone distributed to pharmacies increased more than 230 percent from 2001 to 2010.[8]

The problem with methadone

Methadone's unique properties distinguish it from other opioid drugs. Pain relief from methadone lasts four to eight hours, but its effects on other organs, such as the lungs and heart, can continue for eight to 59 hours.[9]



THE PEW CHARITABLE TRUSTS

Thank You

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Lessons from West Virginia

- Delegate Don Perdue, RPh, West Virginia House of Delegates
- Delegate Matthew Rorhbach, MD, West Virginia House of Delegates

Drug epidemic in West Virginia

- West Virginia has highest rate of drug overdose fatalities with 28.9 per 100,000 people suffering (Healthy Americans, 2013).
- West Virginia's drug overdose death rate was more than double the national average. The national average was 13.4.
- Majority of these are prescription drugs. Outnumber heroin and cocaine overdoses.
- Per the CDC July 2014 Vital Signs Report, West Virginia ranks third in nation for highest # of painkiller prescription rates per person.

Drug epidemic in West Virginia

- Prescription drug misuse, abuse, and overdose are three of the top public policy problems facing West Virginia.
- As a legislature, we're are aggressively addressing the issue.
- Bipartisan issue effecting all districts (especially rural areas).
- The state is not sweeping it under the table.

Methadone as Pain Medicine

- States have given so much attention to oxycodone and heroin, I fear we are overlooking what is possibly an even more dangerous drug…methadone

Methadone as Pain Medicine

- Prescription drugs accounted for more than half of the roughly 44,000 overdose deaths in the U.S. in 2013.
- From 1997-2005 nationally, prescriptions increased 700 percent for OxyContin, 300 percent for hydrocodone **and 1,000 percent for methadone.**

Methadone as Pain Medicine

- Methadone prescribed responsibly is a safe medication and it's effective.
- But what is responsible prescribing when it so easily gets to "the street" and people die?

West Virginia Actions

- Addressed “Pill Mills”
- Methadone is a non-preferred, long-acting analgesic for Medicaid patients in West Virginia.
- Unique method: the WV Medicaid P&T committee removed the drug. It did not require legislation. Authorizing bodies in Nevada and Oregon also removed methadone as a preferred drug for pain management from the state Medicaid program’s PDL.
- Methadone actions part of larger strategy to address prescription drug abuse

West Virginia, Future …

- Removing “street” Methadone
- Improving treatment options
- Other considerations

Questions and Comments

Thank you!

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