National Opioid Epidemic

Joshua D. Lenchus, DO, RPh, FACP, SFHM
Associate Professor of Medicine, Anesthesiology, and Radiology
University of Miami Miller School of Medicine
Disclosure

- No financial or other material conflicts of interest
- Not representative of any institution or organization
Definitions

- Opiate
- Opioid
- Narcotic
- Controlled substance
Morpheus: God of Dreams

- Winged creature
- Many siblings
- Communicator
- Dream: human form
- Hypnos
- “In the arms of Morpheus”
Mechanism of action

http://flipper.diff.org/app/items/6280
# Receptor activity

<table>
<thead>
<tr>
<th>Mu</th>
<th>Delta</th>
<th>Kappa</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analgesia</td>
<td>Analgesia with fewer adverse effects</td>
<td>Mild analgesia</td>
</tr>
<tr>
<td>Sedation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Euphoria</td>
<td></td>
<td>Dysphoria</td>
</tr>
<tr>
<td>Respiratory depression</td>
<td></td>
<td>Less respiratory depression</td>
</tr>
<tr>
<td>Constipation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical dependence</td>
<td></td>
<td>Decreased dependence</td>
</tr>
</tbody>
</table>
# Opioid classification

<table>
<thead>
<tr>
<th>Full agonist</th>
<th>Partial agonist</th>
<th>Agonist-antagonist</th>
<th>Antagonist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine</td>
<td>Buprenorphine</td>
<td>Pentazocine</td>
<td>Naloxone</td>
</tr>
<tr>
<td>Fentanyl</td>
<td></td>
<td>Butorphanol</td>
<td>Naltrexone</td>
</tr>
<tr>
<td>Oxycodone</td>
<td></td>
<td>Nalbuphine</td>
<td></td>
</tr>
<tr>
<td>Hydrocodone</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methadone</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication</td>
<td>Onset</td>
<td>Duration</td>
<td>Equianalgesic dose</td>
</tr>
<tr>
<td>------------------</td>
<td>----------------</td>
<td>-----------</td>
<td>--------------------</td>
</tr>
<tr>
<td>Fentanyl patch</td>
<td>12-24 hrs</td>
<td>72 hrs/patch</td>
<td></td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>15-30 mins</td>
<td>4-6 hrs</td>
<td>7.5mg po</td>
</tr>
<tr>
<td>Methadone</td>
<td>30-60 mins</td>
<td>&gt; 8 hrs</td>
<td></td>
</tr>
<tr>
<td>Morphine IR</td>
<td>30-60 mins</td>
<td>3-6 hrs</td>
<td>30mg po</td>
</tr>
<tr>
<td>MS Contin®</td>
<td>30-90 mins</td>
<td>8-12 hrs</td>
<td>30mg po</td>
</tr>
<tr>
<td>Kadian®</td>
<td>30-90 mins</td>
<td>12-24 hrs</td>
<td>30mg po</td>
</tr>
<tr>
<td>Oxycodone IR</td>
<td>10-15 mins</td>
<td>4-6 hrs</td>
<td>20mg po</td>
</tr>
<tr>
<td>Oxycodone CR</td>
<td>1 hr</td>
<td>12 hrs</td>
<td>20mg po</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>30-60 mins</td>
<td>4-6 hrs</td>
<td>30mg po</td>
</tr>
<tr>
<td>Codeine</td>
<td>30-60 mins</td>
<td>4-6 hrs</td>
<td>200mg po</td>
</tr>
<tr>
<td>Meperidine</td>
<td>10-15 mins</td>
<td>2-4 hrs</td>
<td>300mg po</td>
</tr>
</tbody>
</table>
# Opioid allergy

<table>
<thead>
<tr>
<th>Phenanthrenes</th>
<th>Piperidine/phenylpiperadine</th>
<th>Deiphenylheptanes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine</td>
<td>Fentanyl*</td>
<td>Methadone*</td>
</tr>
<tr>
<td>Hydromorphone*</td>
<td>Meperidine</td>
<td>Propoxyphene</td>
</tr>
<tr>
<td>Oxymorphone*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Codeine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydrocodone</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxycodone*</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Why are we talking about this?

- Statistics
- Leading cause of injury death
- Headlines
- Legislation
From 1999 to 2013, the amount of prescription opioid pain relievers prescribed & sold in the U.S. nearly QUADRUPLED.

Yet there has not been an overall change in the amount of pain that Americans report.
ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients, Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER
Hershel Jick, M.D.
Boston Collaborative Drug Surveillance Program
Waltham, MA 02154

Boston University Medical Center


Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases

Russell K. Portenoy and Kathleen M. Foley

Pain Service, Department of Neurology, Memorial Sloan-Kettering Cancer Center, and Department of Neurology, Cornell University Medical College, New York, NY 10021 (U.S.A.)

(Received 10 June 1985, accepted 28 October 1985)

Summary

Thirty-eight patients maintained on opioid analgesics for non-malignant pain were retrospectively evaluated to determine the indications, course, safety and efficacy of this therapy. Oxycodone was used by 12 patients, methadone by 7, and levorphanol by 5; others were treated with propoxyphene, meperidine, codeine, pentazocine, or some combination of these drugs. Nineteen patients were treated for four or more years at the time of evaluation, while 6 were maintained for more than 7 years. Two-thirds required less than 20 morphine equivalent mg/day and only 4 took more than 40 mg/day. Patients occasionally required escalation of dose and/or hospitalization for exacerbation of pain; doses usually returned to a stable baseline afterward. Twenty-four patients described partial but acceptable or fully adequate relief of pain, while 14 reported inadequate relief. No patient underwent a surgical procedure for pain management while receiving therapy. Few substantial gains in employment or social function could be attributed to the institution of opioid therapy. No toxicity was reported and management became a problem in only 2 patients, both with a history of prior drug abuse. A critical review of patient characteristics, including data from the 16 Personality Factor Questionnaire in 24 patients, the Minnesota Multiphasic Personality Inventory in 23, and detailed psychiatric evaluation in 6, failed to disclose psychological or social variables capable of explaining the success of long-term management. We conclude that opioid maintenance therapy can be a safe, salutary and more humane alternative to the options of surgery or no treatment in those patients with intractable non-malignant pain and no history of drug abuse.
How did we get here?

- 1980s: opioids for non-malignant pain
- 1996: the 5th vital sign; OxyContin released
- 1998: FSMB protection
- 2001: TJC weighs in
- 2004: failure to treat is punishable
- 2007: Purdue is guilty of misbranding

Multiple Contributing Elements

- Annual volume of opioid prescriptions steadily on the rise throughout the 1990's
- Aggressive marketing by opioid manufacturers
- Rise of internet sales
- Birth of pill mills
- Low prescriber awareness / low public awareness
- Initially weak regulatory environment
- Pain as a vital sign
- HCAHPS pain question
Some states have more opioid prescriptions per person than others

Number of opioid prescriptions per 100 people, 2016

Source of Rx opioids, non-medical use

- Given by a friend or relative for free
- Prescribed by ≥1 physicians
- Stolen from a friend or relative
- Bought from a friend or relative
- Bought from a drug dealer or other stranger
- Other

**Notes:**
- Obtained from the US National Survey on Drug Use and Health, 2008 through 2011. 5
- Estimate is statistically significantly different from that for highest-frequency users (200-365 days) (P<.05).
- Includes written fake prescriptions and those opioids stolen from a physician’s office, clinic, hospital, or pharmacy; purchases on the Internet; and obtained some other way.

Source of pain relievers for non-medical use, users aged 12 or older: 2012-2013

Image from SAMHSA, as cited in Tetrault and Butner, 2015.
Primary non-heroin opiates/synthetics admission rates, by State (per 100,000 population aged 12 and over)

1999 (range 1 - 50)

< 8  15 - 18  45 or more  8 - 14  19 - 44

Incomplete data

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.
Primary non-heroin opiates/synthetics admission rates, by State (per 100,000 population aged 12 and over)

2001 (range 1 – 71)

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.
Primary non-heroin opiates/synthetics admission rates, by State (per 100,000 population aged 12 and over)

2003
(range 2 - 139)

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.
Primary non-heroin opiates/synthetics admission rates, by State (per 100,000 population aged 12 and over)

2005
(range 0 – 214)

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.
Primary non-heroin opiates/synthetics admission rates, by State (per 100,000 population aged 12 and over)

2009
(range 1 – 379)

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.
NUMBER OF BABIES DIAGNOSED WITH NEONATAL ABSTINENCE SYNDROME (NAS)

Source: Reuters analysis of U.S. Department of Health and Human Services data
# Drug overdose deaths

<table>
<thead>
<tr>
<th>USA</th>
<th>Jan 2016</th>
<th>Jan 2017</th>
<th>% change</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>52,898</td>
<td>64,070</td>
<td>21</td>
</tr>
<tr>
<td>Florida</td>
<td>3,324</td>
<td>5,167</td>
<td>55</td>
</tr>
</tbody>
</table>

**USA Jan 2016 Jan 2017 % change**

<table>
<thead>
<tr>
<th>USA</th>
<th>Jan 2016</th>
<th>Jan 2017</th>
<th>% change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heroin</td>
<td>13,219</td>
<td>15,446</td>
<td>17</td>
</tr>
<tr>
<td>Semi-synthetic opioids</td>
<td>12,726</td>
<td>14,427</td>
<td>13</td>
</tr>
<tr>
<td>Methadone</td>
<td>3,276</td>
<td>3,314</td>
<td>1</td>
</tr>
<tr>
<td>Synthetic opioids</td>
<td>9,945</td>
<td>20,145</td>
<td>103</td>
</tr>
<tr>
<td>Cocaine</td>
<td>6,986</td>
<td>10,619</td>
<td>52</td>
</tr>
<tr>
<td>Psychostimulants</td>
<td>5,922</td>
<td>7,663</td>
<td>29</td>
</tr>
</tbody>
</table>

CDC, National Center for Health Statistics, National Vital Statistics System, as of 8/6/2017
Painkiller Sales and Overdose Deaths

The nation’s rising overdose death rate from painkillers such as Vicodin, Percocet and OxyContin closely parallels an increase in opioid prescription sales over the past 15 years.

Sales (kg per 10,000) — Deaths (per 100,000)

Source: U.S. Drug Enforcement Administration and Centers for Disease Control and Prevention
© 2016 The Pew Charitable Trusts
Relationship Between Opioid Prescribing and Drug Overdose Death Rates

Source: Death rate, 2008, CDC/NVSS. Opioid pain reliever sales rate, 2010, DEA’s ARCOS
Number of Deaths from Prescription Opioid Pain Relievers

USA

Source: National Center for Health Statistics, CDC Wonder
Opioid overdose deaths have quadrupled since 1999, and continues to increase in the US.
Economic burden of opioid abuse

- Nonmedical use of opioid pain relievers cost insurance companies up to $72.5 billion annually in health-care cost

- Social & economical consequences
  - Cost of prevention and treatment
  - Increased incidences of opioid overdose deaths
  - Safety risk to the public due to drug affected driving
  - Environmental contamination due to inappropriate disposal and illicit cultivation
  - Loss of productivity at work
  - Neonatal abstinence syndrome

Risks of Opioid Therapy

- **Mortality** (of all-causes)
  - Hazard ratio (HR) 1.64 for long acting opioids for non-cancer pain

- **Overdose deaths** (unintentional)
  - HR 7.18-8.9 for MED > 100 mg/d

- **Opioid use disorder**
  For patients on long-term opioids (> 90 days)
  - HR 15 for 1-36 mg/d MED
  - HR 29 for 36-120 mg/d MED
  - HR 122 for > 120 mg/d MED

*MED=Morphine Equivalent Daily Dose (in mg/d)
Consequences

- Opioid use disorder
- Addiction
- Addiction treatment
- Withdrawal
- Toxicity/overdose
- Overdose treatment
# DSM-5 Criteria for OUD (Rx opioids)

(2 or more criteria)

<table>
<thead>
<tr>
<th>DSM-5 Criteria</th>
<th>Example behaviors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Craving or strong desire to use opioids</td>
<td>Describes constantly thinking about opioids</td>
</tr>
<tr>
<td>Recurrent use in hazardous situations</td>
<td>Repeatedly driving under the influence</td>
</tr>
<tr>
<td>Using more opioids than intended</td>
<td>Repeated requests for early refills</td>
</tr>
<tr>
<td>Persistent desire/unable to cut down or control opioid use</td>
<td>Unable to taper opioids despite safety concern or family’s concern</td>
</tr>
<tr>
<td>Great deal of time spent obtaining, using or recovering from the effects</td>
<td>Spending time going to different doctor’s offices and pharmacies to obtain opioids</td>
</tr>
<tr>
<td>Continued opioid use despite persistent opioid-related social problems</td>
<td>Marital/family problems or divorce due to concern about opioid use</td>
</tr>
<tr>
<td>Continued opioid use despite opioid-related medical/psychological problem</td>
<td>Insistence on continuing opioids despite significant sedation</td>
</tr>
<tr>
<td>Failure to fulfill role obligations</td>
<td>Poor job/school performance; declining home/social function</td>
</tr>
<tr>
<td>Important activities given up</td>
<td>No longer active in sports/leisure activities</td>
</tr>
</tbody>
</table>
Physical dependence vs. addiction

Physical Dependence

- Body is used to having a high level of opioid
- Abrupt discontinuation will result in withdrawal symptoms (nausea & vomiting, anxiety, etc.)

Addiction

- Uncontrollable craving and compulsive use, inability to control drug use
- There is no addiction without craving

• Addiction is a chronic, progressive brain disease due to altered brain structure and function

Addiction

- Definition
  - Tolerance
  - Withdrawal
  - Abuse
  - Helplessness
  - Compulsion
  - Isolation
  - Vicious circle of devastation

- Dependence

- Hyperalgesia


Addiction treatment

- Inpatient
  - Short term
  - Long term
- Outpatient
- Medication-assisted
  - Methadone
  - Buprenorphine:
    - http://www.samhsa.gov/medication-assisted-treatment
MAT

- Component of comprehensive treatment
- Methadone
- Buprenorphine
- Naltrexone/naloxone?
<table>
<thead>
<tr>
<th><strong>Treatment setting</strong></th>
<th>Buprenorphine/Naloxone*</th>
<th>Methadone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office-based</td>
<td></td>
<td>Specially licensed OTP</td>
</tr>
<tr>
<td><strong>MOA</strong></td>
<td>Partial opioid agonist*</td>
<td>Opioid agonist</td>
</tr>
<tr>
<td><strong>FDA-approved?</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Reduces cravings?</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>OUD classification?</strong></td>
<td>Mild—Moderate</td>
<td>Mild/Moderate/Severe</td>
</tr>
<tr>
<td><strong>Candidates</strong></td>
<td>None/few failed attempts</td>
<td>Many failed attempts</td>
</tr>
<tr>
<td><strong>Recommended for those using ongoing short-acting opioids?</strong></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Psychosocial intervention recommendations</strong></td>
<td>Addiction-focused MM</td>
<td>Individual counseling and/or contingency management</td>
</tr>
</tbody>
</table>

http://buprenorphine.samhsa.gov/
http://www.opioidprescribing.com/naloxone_module_1-landing
http://www.pcssmat.org
https://www.samhsa.gov/medication-assisted-treatment
Withdrawal

- Rhinorrhea
- Diarrhea
- Yawning
- Anxiety
- Mydriasis
- Lacrimation
- Vomiting
- Hyperventilation
- Hostility
Toxicity/overdose

- Coma
- Miosis
- Bradypnea/hypoventilation
Overdose treatment

- BLS
- Naloxone
- Active monitoring
Regulatory/Agency Actions

- 2014-17: Approval of a new formulations of naloxone for community use, including autoinjector and intranasal products

- Development of abuse deterrent (AD) opioid formulations

- Much more…
■ Jun 10, 2015 – FL HB751, Emergency Treatment and Recovery Act


■ Mar 16, 2016 – CDC Guideline for Prescribing Opioids for Chronic Pain

■ Jul 7, 2016 – National Governors Association: Finding Solutions to the Prescription Opioid and Heroin Crisis: A Roadmap for States

■ Jul 22, 2016 – US S.524, Comprehensive Addiction and Recovery Act

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm
http://www.cdc.gov/drugoverdose/prescribing/guideline.html
WHY GUIDELINES FOR PRIMARY CARE PROVIDERS?

Primary care providers account for approximately 50% of prescription opioids dispensed.

Nearly 2 million Americans, aged 12 or older, either abused or were dependent on prescription opioids in 2014.

- An estimated 11% of adults experience daily pain
- Millions of Americans are treated with prescription opioids for chronic pain
- Primary care providers are concerned about patient addiction and report insufficient training in prescribing opioids

**MYTH VS TRUTH**

1. Opioids are effective long-term treatments for chronic pain

   - While evidence supports short-term effectiveness of opioids, there is insufficient evidence that opioids control chronic pain effectively over the long term, and there is evidence that other treatments can be effective with less harm.

2. There is no unsafe dose of opioids as long as opioids are titrated slowly

   - Daily opioid dosages close to or greater than 90 MME/day are associated with significant risks, and lower dosages are safer.

3. The risk of addiction is minimal

   - Up to one quarter of patients receiving prescription opioids long term in a primary care setting struggle with addiction. Certain risk factors increase susceptibility to opioid-associated harms: history of overdose, history of substance use disorder, higher opioid dosages, or concurrent benzodiazepine use.

**WHAT CAN PROVIDERS DO?**

First, do no harm. Long term opioid use has uncertain benefits but known serious risks. CDC’s Guideline for Prescribing Opioids for Chronic Pain will support informed clinical decision making, improved communication between patients and providers, and appropriate prescribing.

**PRACTICES AND ACTIONS**

**USE NONOPIOID TREATMENT**

Opioids are not first line or routine therapy for chronic pain (Recommendation #1).

In a systematic review, opioids did not offer more analgesia for chronic pain, and nonopioid medications were better tolerated, with greater improvements in physical function.

**START LOW AND GO SLOW**

When opioids are started, prescribe them at the lowest effective doses (Recommendation #5).

Studies show that high-dosage opioids are associated with a 4-6 times the risk of overdose compared to <60 MME/day.

**REVIEW PDMP**

Check prescription drug monitoring program data for high dosages and prescriptions from other providers (Recommendation #9).

A study showed patients with one or more risk factors (i.e., more prescriptions, 4 or more pharmacies, or dosage ≥130 MME/day) accounted for 55% of all overdose deaths.

**AVOID CONCURRENT PRESCRIBING**

Avoid prescribing opioids and benzodiazepines concurrently whenever possible (Recommendation #13).

A study showed concurrent prescribing is associated with a more than doubling of risk for overdose deaths compared with opioid prescription alone.

**OFFER TREATMENT FOR OPIOID USE DISORDER**

Offer or arrange evidence-based treatment (e.g., medication-assisted treatment and behavioral therapies) for patients with opioid use disorder (Recommendation #10).

A study showed patients prescribed long-acting opioids long term had 11-fold increase in the risk of opioid use disorder compared to patients not prescribed opioids.

**LEARN MORE**

www.cdc.gov/drugoverdose/prescribing/guideline.html
2016 CDC guidelines

- 18yoa+, chronic pain treatment (3mos+)
- Use non-opioid therapies
  - Nonpharmacological therapies
  - Non-opiate treatments
- Start low and go slow
- Follow up

http://www.cdc.gov/drugoverdose/prescribing/guideline.html
Opioid Prescribing Recommendations:
Summary of 2016 CDC Guidelines

**Determining when to initiate or continue opioids for chronic pain**
- Opioids are not first-line or routine therapy
- Establish treatment goals before starting opioid therapy and a plan if therapy is discontinued
- Only continue opioid if there is clinically meaningful improvement in pain and function
- Discuss risks, benefits and responsibilities for managing therapy before starting and during treatment

**Opioid selection, dosage, duration, follow-up and discontinuation**
- Use immediate-release (IR) opioids when starting therapy
- Prescribe the lowest effective dose
- When using opioids for acute pain, provide no more than needed for the condition
- Follow up and review benefits and risks before starting and during therapy
- If benefits do not outweigh harms, consider tapering opioids to lower doses or taper and discontinue

**Assessing risk and addressing harms of opioid use**
- Offer risk mitigation strategies, including naloxone for patients at risk for overdose
- Review PDMP* data at least every 3 months and perform UDT** at least annually***
- Avoid prescribing opioid and benzodiazepines concurrently when possible
- Clinicians should offer or arrange MAT**** for patients with OUD†

*Prescription drug monitoring program
**Urine drug testing
***Some VA facilities may require more frequent testing
****Medication-assisted treatment
†Opioid use disorder
- Determine when to initiate/continue opioids
  - Non-Rx and non-opioid tx is preferred
  - Establish tx goals; discuss realistic risks and benefits

- Opioid logistics
  - Rx IR instead of ER/LA
  - Begin w/ lowest effective dose; consider quantity and duration
  - Monitor

- Assessing risk & addressing harms
  - Consider risk mitigation
  - Consult PDMP
  - Urine drug screen
  - Avoid opiate/BZD combos
  - Treat opioid use disorder

http://www.cdc.gov/drugoverdose/prescribing/guideline.html
Treatment

- Non-pharmacological
  - Heat/cold
  - Exercise
  - *Behavioral counseling

- Pharmacological
  - Anticonvulsants/Antidepressants
  - Naltrexone
  - Methadone
  - Buprenorphine
  - Naloxone

http://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine
**STEP 2** Develop and Select Policies

**PREVENTING OPIOID MISUSE AND OVERDOSE**

**HEALTH CARE STRATEGIES FOR PREVENTION AND EARLY IDENTIFICATION**

- Develop and update guidelines for all opioid prescribers.
- Limit new opioid prescriptions for acute pain, with exceptions for certain patients.
- Adopt a comprehensive opioid management program in Medicaid and other state-run health programs.
- Remove methadone for managing pain from Medicaid preferred drug lists.
- Expand access to non-opioid therapies for pain management.
- Enhance education and training for all opioid prescribers.
- Maximize the use and effectiveness of state prescription drug monitoring programs.
- Use public health and law enforcement data to monitor trends and strengthen prevention efforts.
- Enact legislation that increases oversight of pain management clinics to reduce “pill mills.”
- Raise public awareness about the dangers of prescription opioids and heroin.

**RESPONDING TO OPIOID MISUSE AND OVERDOSE**

**HEALTH CARE STRATEGIES FOR TREATMENT AND RECOVERY**

- Change payment policies to expand access to evidence-based MAT and recovery services.
- Increase access to naloxone.
- Expand and strengthen the workforce and infrastructure for providing evidence-based MAT and recovery services.
- Create new linkages to evidence-based MAT and recovery services.
- Consider authorizing and providing support to syringe service programs.
- Reduce stigma by changing the public’s understanding of substance use disorder.

In The News…

- **Aug 2016**: influx of fentanyl-laced counterfeit pills and toxic compounds further increases risk of fentanyl-related ODs and fatalities

- **Sep 2016**: FDA adds boxed warnings to Rx opioids and BZDs
  - DEA issues carfentanil warning
Open letter to all Medical Providers:
“Years from now, I want us to look back and know that, in the face of a crisis that threatened our nation, it was our profession that stepped up and led the way.”

TurnTheTideRx.org website
Launched Aug. 8, 2016
Platform with resources
For physicians and their patients

http://turnthetiderx.org/
The White House
Office of the Press Secretary

For Immediate Release

September 16, 2016

Presidential Proclamation --
Prescription Opioid and Heroin
Epidemic Awareness Week, 2016

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim September 18 through September 24, 2016, as Prescription Opioid and Heroin Epidemic Awareness Week. I call upon all Americans to observe this week with appropriate programs, ceremonies, and activities that raise awareness about the prescription opioid and heroin epidemic.

IN WITNESS WHEREOF, I have hereunto set my hand this sixteenth day of September, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and forty-first.

BARACK OBAMA

Assessing and monitoring

- **SBIRT**

- “Universal Precautions” when prescribing opioids in chronic non-cancer pain (CNCP)

- **ORT** = Opioid Risk Tool

- **PDMB** = Florida’s Prescription Drug Monitoring Program
10 steps of “Universal Precautions”

- Make a diagnosis with appropriate differential.
- Perform a psychological assessment, including risk of addictive disorders.
- Obtain informed consent.
- Use a treatment agreement.
- Conduct assessments of pain level and function before and after the intervention.
- Begin an appropriate trial of opioid therapy with or without adjunctive medications and therapies.
- Reassess pain score and level of function.
- Regularly assess the “4As” of pain medication (analgesia, ADLs, adverse events, aberrant drug-related behaviors).
- Periodically review pain diagnosis and co-occurring conditions, including addictive disorders.
- Document initial evaluation and follow-up visits.

Adapted from Gourlay et al., 2005. (SAMHSA TIP 54, page 49)
Regulatory Actions: Spurring Development of Abuse-Deterrent (AD) Opioids

- Incentivize the development of opioid medications with progressively better AD properties and support their widespread use
  - Guidance for Industry-Abuse-Deterrent Opioids-Evaluation and Labeling

- Assure appropriate development and availability of generics, reflecting their importance in U.S. healthcare
  - Generic drugs play a critical role in U.S. healthcare, including important role in controlling costs and expanding access
  - Draft Guidance for Industry-General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products
    - Expect to publish final guidance this year
**Results: Development of AD Formulations of Opioids**

- **Ten** opioids approved with AD labeling claims (latest April, 2017), one of which is the first IR AD formulation:
  - (OxyContin, Targiniq ER, Embeda, Hysingla ER, MorphaBond ER, Xtampza ER, Troxyca ER, Arymo ER, Vantrela ER, Roxybond)
  - Work to date has often focused on use of crush/extraction-resistant, inclusion of an antagonist, and aversion technologies but some new approaches being explored
  - More than 30 active investigational new drug applications (INDs) being discussed for AD formulations
    - New technologies being explored (e.g., pro-drugs that require activation to prevent IV abuse and snorting)
- **FDA is requiring post-approval studies to measure real-world effects of these new formulations**
In the news…

- **Aug 2017**: As of Jan 2018, GA docs will be required to take 3hrs of CME on opioid prescribing before license renewal
- **Sep 2017**: FDA requires 74 opioid manufacturers to develop physician training
- **States and cities sue opioid manufacturers and distributors**
Gov. Scott’s opioid legislation

- $50M budgetary proposal
- 3d limit on Rx opioid duration
  - 7d in exceptional cases w/ documentation
- Participate in PDMP
- Fight unlicensed pain mgmt. clinics
- CME requirement
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Source: State Pain Policy Advocacy Network

(Greg Cross/Bulletin graphic)
Opioid prescribing limits

At least 25 states have considered legislation over the past two years to limit initial prescriptions of opioid medications to a certain number of days.

Limit on initial prescription:
- 15 days
- 10 days
- 7 days
- 5 days
- 3 days

Source: State Pain Policy Advocacy Network (Greg Cross/Bulletin graphic)
Controlled substance disposal

- Small amounts
- Secure safely

Safe disposal options

- Veterans Health Administration
- Return to pharmacist or prescriber?
Medication disposal per FDA

- **Take-back programs**
  - [https://apps.deadiversion.usdoj.gov/NTBI/NTBI-PUB.pub;jsessionid=9FAB89C880077FD9090F8C29528755BE?_flowExecutionKey=_c7F1409E9-1531-886A-1583-C384A7490D0A_k43E06DBB-5972-1222-92F3-32981A599F0B](https://apps.deadiversion.usdoj.gov/NTBI/NTBI-PUB.pub;jsessionid=9FAB89C880077FD9090F8C29528755BE?_flowExecutionKey=_c7F1409E9-1531-886A-1583-C384A7490D0A_k43E06DBB-5972-1222-92F3-32981A599F0B)

- **DEA-authorized collectors**
  - [https://apps.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e1s1](https://apps.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e1s1)
  - DEA Office of Diversion Control’s Registration Call Center: 1-800-882-9539

- **Household trash**

- **Flushing:**
The opioid epidemic

33,000 Americans killed in 2015 by opioids, including prescription drugs and heroin—more than any previous year.

91 daily U.S. deaths from opioid overdose, including prescription drugs and heroin.

183,000 U.S. deaths from overdoses related to prescription opioids, 1999-2015.

6 out of 10 portion of total U.S. deaths by drug overdose that involve an opioid.

15,000 deaths in 2015 from overdoses involving such prescriptions.

2 million Americans in 2014 who abused or were dependent on prescription opioids.

25 to 54 age range for most U.S. deaths by overdose of a prescription opioid, 1999-2014.

13,000 number of U.S. deaths by heroin overdose in 2015.

20.6 percentage increase from 2014 to 2015 in deaths by heroin overdose.

Source: Centers for Disease Control and Prevention

DailySignal.com
Thank you

Joshua D. Lenchus, DO, RPh, FACP, SFHM
jlenchus@med.miami.edu
305-243-1960 (off)
Additional references

- National Institute on Drug Abuse (NIDA) [https://www.drugabuse.gov/]
- Drug disposal: [https://www.deadiversion.usdoj.gov/drug_disposal/index.html]
- Annual cost of treating Rx opioid use and abuse > $50B/yr
- OD deaths per capita rose twice as much on average 2013-15 in states that expanded Medicaid than those that did not
- Opioid-related inpatient hospital stays nationwide that were paid for by Medicaid increased by ~40% Q42012 – Q42014, 4x the rate of growth in Medicaid enrollment
- Medicaid patients are twice as likely to be Rx opioids than privately insured patients
- State Medicaid programs favor generics over more expensive branded agents with abuse-deterrent formulas
Clinically meaningful improvement

- 30%+ improvement
- Assess and document
- Validated tools

- What is not CMI?
- Rx – CMI = inappropriate care
Rates of Opioid Sales, OD Deaths, and Treatment, 1999–2010

CDC. MMWR 2011
Treatment options

• Best treatment option is **PREVENTION!**

• **Counseling & Behavioral Therapies**
  - Individual and group counseling
  - Inpatient and residential treatment
  - Intensive outpatient treatment
  - Case or care management
  - Recovery support services
  - 12-step fellowship
  - Peer supports

• **Medication Assisted Treatment**
  - Buprenorphine
  - Methadone
  - Naltrexone