Opioids

John Barsanti, MD
Medical Director Commonwealth Spine and Pain Specialists
Almost 218,000 Americans died from overdoses related to Rx opioids from 1999 to 2017.

www.cdc.gov
Opioids

• How did we get here? Is it all Purdue’s fault?

• What are we doing about it? Guidelines and more guidelines.

• Opioids in Workers Comp.

• The Pendulum
March 24 (UPI) -- Hundreds of cities, counties and Native American tribe filed a lawsuit against members of the Sackler family for creating the opioid crisis through their ownership of the company that manufactures the painkiller OxyContin.
The maker of OxyContin and the company's controlling family agreed Tuesday to pay a groundbreaking $270 million to Oklahoma to settle allegations they helped create the nation's deadly opioid crisis with their aggressive marketing of the powerful painkiller.
How did we get here?

- Opium poppy plant is the source of all opiates
- Cultivation dates back to Mesopotamia, approximately 3,400 BC
- Opium derived from the milky sap of the opium poppy flower
- 1803 German scientist Friedrich Serturner isolated Morphine from Opium
- Morphine is a precursor to codeine, fentanyl, methadone, hydrocodone, hydromorphone, demerol and oxycodone
How did we get here?

- Morphine was widely used in the civil war
- It is estimated that 400,000 soldiers became addicted
- 1874 English chemist Alder Wright refined Heroin from a Morphine base
- It was intended to be a safer alternative to morphine
How did we get here?

• 1890’s Bayer marketed heroin as a morphine substitute and cough suppressant.

• Bayer promoted heroin use for children suffering from cough and colds

• Early 1900’s heroin addiction skyrocketed

• In 1908, President Theodore Roosevelt appointed Dr. Hamilton Wright as Opium Commissioner of the United States.

• In The New York Times in 1911, Wright was quoted as saying, “Of all the nations of the world, the United States consumes the most habit-forming drugs per capita.”
How did we get here?

• In response, the Harrison Narcotics Tax Act of 1914—the first major piece of U.S. legislation to control the sale and use of opiates—was passed. The act passed restrictions on the distribution and sale of heroin and opium, as well as cocaine.

• Ten years later, Congress made it illegal to make, import or sell heroin when it passed the Anti-Heroin Act of 1924.
How did we get here?

- World War II required the use of opioids on a large scale to treat injured soldiers
- Methadone created by German scientists due to a shortage of morphine
- 1950’s and 1960’s pain clinics opened
  - Focused on chronic pain as an illness
  - Used nerve blocks to help to determine the physiological source of pain and treat pain with methods other than surgery
How did we get here?

- 1970’s drug use escalates in US, Gerald Ford sets up a task force, with greater attention to heroin.
- Mid to late 70’s Percocet and Vicodin
- Letter discounts concerns of using opiates in chronic pain
How did we get here?

- Porter and Jick looked at 11,882 patients treated with narcotics.
- They opined that “the development of addiction is rare in medical patients with no history of addiction.”
- Jick told the Washington Post in 1977 that less than 1% of patients he studied died from a reaction to the drugs.
- Terminal illness and chronic pain began to be treated more with prescription opiates.
How did we get here?

- Six years later Russell Portenoy chronicled 38 patients on chronic opioids, two became addicted.
- He felt opioid maintenance can be safe and more humane compared with surgery or withholding treatment.
- 1990’s the thinking changed about the use of opioids.
How did we get here?

- Pain as the fifth vital sign
- There is no maximum dose of opioids
- Oxycodone introduced in 1996
- Marketed to primary care doctors
- Law suits if you did not treat pain
How did we get here?

- Oxycontin
  - early 90’s pain prescriptions increased by 2-3 million per year
  - after Oxycontin, prescriptions jumped to 8 million more per year
  - after Purdue video opioid pain prescriptions jumped by 11 million
  - 2007 three Purdue executives pleaded guilty for misbranding the drug and downplaying addiction
  - Purdue settled with US government for $635 million
How we got here?

- Joint Commission in 2001
  - Pain must be assessed in all patients, doctors required to examine their patient’s pain.
  - Commission printed a book, sponsored by Purdue, as part of a required continuing education program.
  - The book claims “there is no evidence that addiction is a significant issue when persons are given opioids for pain control” Doctors concerns about addiction are inaccurate and exaggerated.
How did we get here?

- “There is no doubt that the widely held belief that short-term use of opioids had low risk of addiction was an important contributor to inappropriate prescribing patterns for opioids and the subsequent opioid epidemic”

- 2009 Joint commission removed its standard to assess pain in all patients

  - Dr. James W. Baker, the Joint Commission’s executive vice president for health care quality evaluation.
How did we get here?

- August 2010
- study by JEJM
  - survey of more than 2,500 people who used oxycontin before and after abuse deterrent.
  - Before abuse deterrent 35.6% admitted to abusing the drug
  - After deterrent number dropped to 12.8%
  - 24% surveyed said they still found ways to alter the tamper resistant properties.
How did we get here?

• “Most people I know don’t use oxycontin to get high anymore, they have moved on to heroin because it is easier to use, much cheaper and easily available.”
How did we get here?

- 2011
  - Dr. Portenooy
    - “What I was trying to do was create a narrative so that the primary care audience would feel more comfortable about opioids in a way they hadn’t before. In essence, this was education to destigmatize, we often left evidence behind”
    - “Clearly if I had an inkling of what I know now then, I wouldn’t have spoken in the way that I spoke. It was clearly the wrong thing to do.”
THE OPIOID EPIDEMIC BY THE NUMBERS

130+ People died every day from opioid-related drug overdoses (estimated)

11.4 m People misused prescription opioids

47,600 People died from overdosing on opioids

2.1 million People had an opioid use disorder

81,000 People used heroin for the first time

2 million People misused prescription opioids for the first time

28,466 Deaths attributed to overdosing on synthetic opioids other than methadone

886,000 People used heroin

15,482 Deaths attributed to overdosing on heroin

SOURCES
2. NCHS Data Brief No. 293, December 2017
48.5 million Americans have used illicit drugs or misused Rx drugs.
• From 1999 to 2017, more than 700,000 people have died from a drug overdose.
• Around 68% of the more than 70,200 drug overdose deaths in 2017 involved an opioid.
• In 2017, the number of overdose deaths involving opioids (including prescription opioids and illegal opioids like heroin and illicitly manufactured fentanyl) was 6 times higher than in 1999.
3 Waves of the Rise in Opioid Overdose Deaths

- **Other Synthetic Opioids**: e.g., Tramadol and Fentanyl, prescribed or illicitly manufactured
- **Commonly Prescribed Opioids**: Natural & Semi-Synthetic Opioids and Methadone
- **Heroin**

Deaths per 100,000 population

Wave 1: Rise in Prescription Opioid Overdose Deaths
Wave 2: Rise in Heroin Overdose Deaths
Wave 3: Rise in Synthetic Opioid Overdose Deaths

Statistics

- Roughly 21-29% of patients prescribed opioids for chronic pain misuse them.
- Between 8 and 12 percent develop an opioid use disorder.
- An estimated 4-6 percent who misuse prescription opioids transition to heroin.
- About 80% of people who use heroin first misused prescription opioids.

National Institute on Drug Abuse
Guidelines

• Federation of State Medical Boards and local state boards adopted guidelines in the early 2000’s

• CDC GUIDELINES FOR PRESCRIBING OPIOIDS
Guidelines

• In 2016, the Centers for Disease Control and Prevention (CDC) introduced guidelines for prescribing opioids to chronic pain patients. These guidelines apply to physicians treating patients outside the context of cancer, palliative, and end-of-life care. The goal of the guidelines was to reduce the number of people who misuse or abuse opioids, while still ensuring that patients have access to safe and effective treatment for chronic pain.
Guidelines

- **OPIOIDS ARE NOT FIRST LINE THERAPY**

- Non-pharmacologic and non-opioid pharmacologic therapy is preferable when treating chronic pain. Opioids should only be prescribed if the benefits outweigh the risks.

- If opioids are used, they should be used with other treatments such as non-steroidal anti-inflammatory drugs (NSAIDs), physical therapy, cognitive behavioral therapy, and interventions.
Guidelines

• ESTABLISH GOALS FOR PAIN AND FUNCTION

• Set realistic treatment goals for patients who are prescribed opioids. Treatment should be continued only if there is meaningful improvement in pain and function that outweighs the risks.
• **DISCUSS RISKS AND BENEFITS**

  The risks and benefits should be discussed with the patient before starting opioids and during treatment. Be explicit and realistic in telling patients that complete relief of pain is unlikely and there is no good evidence that long-term opioid use improves pain or function.

• All the risks of opioid use should be discussed, including the most serious ones, such as fatal respiratory depression and lifelong opioid use disorder.
Guidelines

• USE IMMEDIATE RELEASE OPIOIDS INITIALLY

• The CDC recommends initiating opioid treatment with immediate-release prescriptions as opposed to extended release. Clinical evidence shows that there is a higher chance of overdose if patients are started on long-acting opioids.
Guidelines

• CONSIDER THE LOWEST EFFECTIVE DOSE

• The CDC recommends starting an opioid prescription with the lowest effective dose.

• The CDC also recommends evaluating the risks and benefits if the dosage is greater than 50 MME/day (morphine milligram equivalents/day), and avoiding dosages greater than 90 MME/day without careful justification.
Guidelines

• PRESCRIBE SHORT DURATIONS FOR ACUTE PAIN

• Because long-term opioid use often starts with treatment for acute pain, the CDC suggests only prescribing the lowest effective dose, immediate release, and in no greater quantity than needed for the expected duration of the pain.
Guidelines

• EVALUATE THE BENEFITS AND RISKS FREQUENTLY

• CDC recommendations include evaluating the benefits and risks within one to four weeks of starting opioid treatment. These risks and benefits should be re-evaluated every three months, at minimum. If the benefits fail to outweigh the risks, the CDC suggests introducing other therapies and tapering the opioids to lower doses or until they are discontinued.
Guidelines

- MITIGATE RISK

- Opioid management should include mitigation of risks and offering naloxone when there is an increased risk of overdose, such as a patient history of overdose, a history of substance abuse, high opioid dosages over 50 MME/day, or concurrent benzodiazepine use. Continue to evaluate your patient’s risks going forward.
Guidelines

- REVIEW PMP DATA

- Physicians should review the patient’s prescription drug monitoring program data (PDMP) to determine if he or she is receiving opioids from other health care professionals. The PDMP should be checked when starting opioids and at least every three months while still prescribing.
Guidelines

- USE URINE DRUG TESTING

- Consider testing the patient’s urine for opioid use before initiating a treatment plan using opioids. Test annually, at minimum, while still prescribing opioids to the patient.
Guidelines

• AVOID CONCURRENT BENZODIAZEPINE USE

• Avoid prescribing opioids with benzodiazepines whenever possible.
Guidelines

• **OFFER TREATMENT FOR OPIOID USE DISORDER**

• Offer or arrange treatment for a patient if he or she develops opioid use disorder.
Guidelines Va Board

Acute Pain

• Treatment with opioids for acute pain must be with short-acting opioids, and for a seven-day supply or less (unless extenuating circumstances are clearly documented in the medical record).

• Treatment with opioids as part of treatment for a surgical procedure must be for a fourteen-day supply or less (unless extenuating circumstances are clearly documented in the medical record).

• An appropriate history and examination must be performed, including a check of the PMP in accordance with state law.

• Morphine Milligram Equivalent (MME) should be considered, and naloxone must be co-prescribed if the MME exceeds 120 MME/day.
Chronic Pain

An appropriate history and examination must be performed, as detailed in the regulations.

The practitioner must discuss risks, benefits, proper storage and disposal with the patient.

Naloxone must be prescribed for any patient when one or more of the following risk factors is present: prior overdose, substance abuse, doses in excess of 120 MME/day, or concomitant benzodiazepine.

Urine drug screen or serum medication levels shall be conducted at the initiation of chronic pain management and at least every three months for the first year of treatment and at least every six months thereafter.
Guidelines

- CMS publishes a roadmap in June 2018
  - Prevention
  - Treatment
  - Data
Guidelines

• New policies for Medicare drug plans starting January 1, 2019

• New safety alerts at pharmacies
  • limit initial dispensing to 7 days for opioid naive. (no opioids Rx in past 60 days)

• MME greater than 90
Guidelines

- CMS
  - Drug management programs
      - limits access to certain drugs deemed frequently abused, for patients considered to be at risk. In 2019, Opioids and benzo’s considered frequently abused.
      - Patient can be limited to using a specified provider and pharmacy
      - At risk patients identified as using multiple doctors and pharmacies.
      - Doctor will be contacted by CMS.
        - Are drugs necessary, safe, is pt at risk of misuse, would other non drug modalities be better
Opioids in Workers Comp

- The number of opioid prescriptions per workers’ compensation claim in the United States has climbed considerably since 2006.
- Persistent opioid use is linked with more costly claims and led to overall loss of work productivity.
Opioids in Workers
Comp

• Study of 9,596 workers comp claimants initially treated with an opioid. Total number of cases, 100,312
  • 30% continued to fill opioids beyond 90 days 10% beyond 365 days
  • Baseline characteristics include
    • increased age
    • claims adjudicated as permanent total disability
    • pre injury income greater than 60K
    • crush, sprain and strain vs soft tissue or contusions
    • back pain 46% more likely to have persistent opioid use
    • concomitant diagnosis of chronic joint pain or other chronic pain, such as fibromyalgia or migraines

• Jama Network, “Factors Associated With Persistent Opioid Use Among Injured Workers’ Compensation Claimants”
Opioids in Workers Comp

- Take away
  - high proportion of persistent use of opioids
  - identified those factors which lead to persistent use
  - since severity of injury did not correlate with persistent use, limit use of opioids in non severe injuries

- Jama Network, “Factors Associated With Persistent Opioid Use Among Injured Workers’ Compensation Claimants”
Opioids in Workers Comp

- Opioids delay return to work
  - workers with low back pain given long term opioids take significantly longer to return to work.
  - Long term defined as opioids given within the first three months of injury with at least three filled between the seventh and 12th months
  - workers with long term opioids received temporary disability benefits 251 percent longer than workers treated for low-back injuries without opioids
  - Recommendation against long term opioids for non surgical low back pain.

- Safety +Health April 4, 2018
Opioids in Workers Comp

- Ohio Bureau of Workers Compensation BWC
  - 2011 73% of injured WC patients received an opioid, 8,000 injured patients dependent on opioids
  - BWC implemented a closed pharmacy in 2011 controlling which opioids would be dispensed
    - 53% fewer workers received opioids
  - 2015 expanded coverage to include narcan and permitted treatment of opioid dependence
  - 2016 introduced opioid prescribing rule into the Ohio Administrative code, limits when and what can be prescribed
  - 2016 BWC reduced by 50% the number of dependent WC patients.
  - 2017 28% less pt’s received opioids
Opioids in Workers Comp

- Can WC payer be liable if patient switches to heroin and they drop coverage?
- Ohio ensuring addiction treatment and limiting amount of opioids given.
- Monitor MED (morphine equivalent dose) or MME (morphine mg equivalents) to catch aberrant behavior and treat before heroin is started.
Could CDC Guidelines Be Driving Some Opioid Patients to Suicide?

In a letter to the CDC, a group of doctors and advocates said the agency’s opioid prescription guidelines are having alarming consequences. But in the midst of an epidemic, where should doctors draw the line?

EJ Dickson  •  March 9, 2019 10:00AM ET
Pendulum

- Have we gone too far?
- Do we know maximum MME?
- Are we harming pain patients?
- What about elderly patients?
- What about “legacy” pain patients?
- Are we creating heroin addicts?
- Is dependence that bad?
- Prescription opioids account for 36% of overdose deaths
Pendulum

- Limitations of guidelines
- How effective really is Tylenol and Cognitive Behavior Therapy?
- How available are alternate modalities?
- How affordable are alternate modalities?
November 2018

- AMA passed resolutions critical of CDC
- expressed support of dosages of opioids greater than 90 MME in some patients. “such care can be medically necessary and appropriate”
- resolved that physicians should not be disciplined, lose their license, prosecuted or lose privileges if they prescribe above CDC thresholds.

December 2018 federal advisory panel criticized the CDC guidelines. “it was not intended to be model legislation for state legislators to enact”

- Same panel recommended revisions to CDC, more scientific evidence and more focus on the needs of older adults.
Pendulum

- Despite data showing majority of overdose deaths are not from prescription drugs, federal enforcement efforts are focused on opioid prescribing.
- Goal to lower prescriptions by one third in three years.
- DEA announced intention to decrease 2019 manufacturing quotas by 10% for the six most frequently abused opioids. Jeff Sessions suggested aspirin might be a reasonable substitute for opioids.
Pendulum

- Lower production
- Increased scrutiny by Federal agents
- Fear of losing license
- Restrictions by payer
NIH launches Helping to End Addiction Long Term, (HEAL) in 2018

- Funding to develop safe, effective, and nonaddictive, device based technologies for focal diagnosis, rehabilitation, and therapy of chronic pain
Pendulum

- Food and Drug Administration will require drug companies to study effectiveness of opioids in chronic pain and whether they cause hyperalgesia.

- Research scarce, some studies report no benefit beyond 12 weeks, and tolerance leads to addiction.

- Studies could lead to barriers to use of opioids or prohibit use all together.

- Richmond Times Dispatch March 25, 2019
Summary

• How did we get here? Is it all Purdue’s fault?

• What are we doing about it? Guidelines and more guidelines.

• Opioids in Workers Comp.

• The Pendulum
Summary

- Two things can be true at the same time
- We didn’t appreciate the addictive properties of opiates
- AND
- Opiates still play an important role in the treatment of both cancer and chronic non-cancer pain
Opioids

• Questions?