THE PILL & THE PENDULUM:
An Evidence-based Approach to Avoid Opioid Overprescribing for Acute Pain
Objectives

At the conclusion of the presentation, the learner will be able to:

• Name at least 3 factors, which led to the rise of opioid overprescribing in the United States since the 1990s.

• Use recent evidence-based studies showing limited efficacy, poor risk/benefit ratio and delayed recovery when considering prescribing opioids for acute musculoskeletal pain

• Compare and contrast the Prescription Drug Monitoring Programs found in each of the meeting component states (New York, New Jersey, Pennsylvania and Maryland)
Factors Which Led to the Rise of Opioid Prescribing

1. Pain Advocacy Groups - undertreatment of pain
2. Physicians - Medical literature; Pill mills
3. Federal & State Regulators
4. Big Pharma
5. Managed Care/Insurance Reimbursement Rates
6. Our Patients
The Roots of Pain Advocacy

1970s - St. Christopher's Hospice - London
Dame Cicely Saunders (RN)
“dying in pain is inhumane - addiction doesn’t matter”

1980 - WHO Ladder
Stjernsward/Ventafridda
“Freedom from pain is a universal human right”

1980s - Palliative Care
Foley/Portnoy
Sloan Kettering Institute (NYC)
“Opiates should not be confined to just cancer patients but also to chronic non-cancer pain.”

1996 - Pain as the 5th Vital Sign
Dr. James Campbell
“If pain were assessed with the same zeal as other vital signs are, it would have a much better chance of being treated properly. We need to train doctors and nurses to treat pain as a vital sign”.

Quinones, Dreamland.
Portnoy’s Complaint

“These drugs [opioids] have certain characteristics, which, when interacting with a certain kind of brain, can lead to bad outcomes; but it’s not inherent in the pill such that everybody given that pill becomes an addict”

Sam Quinones. Dreamland, p. 92.
Portnoy’s Complaint

“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.”

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.
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Boston University Medical Center

Waltham, MA 02154

1995

FDA approves OxyContin - Time-released Oxycodone

- Believed that it was less addictive - fewer surges of euphoria/depression
- Allowed Purdue to claim that OxyContin had a lower potential for abuse than other oxycodone products due to time-release formula - cornerstone of company marketing strategy
- Label warned patients not to crush tablets because that would release “a potentially toxic amount of the drug” - an invitation to a junkie
- Didn’t realize OxyContin could be dissolved in water and injected
- Supervisor of FDA’s team that reviewed application later left and joined Purdue

Sam Quinones, Dreamland
OxyContin Marketing

- Emphasize small chance of addiction (<1%)
- Personalize patient’s stories - “I got my life back”
- Concentrate on heavy opiate physician prescribers
- Visit RNs, pharmacists, hospices, hospitals and nursing homes
- Incentivize sales force - bonuses
- Oxy Swag
- Pain Management/Speaker Training Seminars
- CME - helped fund > 20K education programs
- Funded Pain Societies and websites

Sam Quinones, Dreamland
Dollars Spent Marketing OxyContin (1996-2001)

Figure 1: Promotional Spending for Three Opioid Analgesics in First 6 Years of Sales

Pill Mills

• Physician
  – DEA license to prescribe schedule II drugs
  – Rx’s written every month ($250 for visit)
• Low Overhead- rent a building with a few offices/waiting rooms and hire staff
  – Dr. David Proctor- “The Godfather of the Pill Mill”
  – Dr. Frederick Cohn- saw up to 146 patients/day for 3 minutes each; 2.7 MM pills in 1 year
  – Dr. Fortune Williams- 2.3 MM pills in 9 months

Sam Quinones, Dreamland
The Oxy Economy

• “Patient” gets #90 OxyContin 80 mg; #120 Oxycodone 30 mg and #90 Xanax bars
  – Split 50/50 with sponsor who drove them around to clinics and paid the $250 for clinic visit
• Medicaid card pays for drugs ($800- $1200)
• Cost- $250 for doctor visit and $3 co-pay for meds

Sam Quinones, Dreamland
“Tenderizing the Terrain”
Sam Quinones- Dreamland

• Factors which led to the “Opioid Epidemic”
  – Economic Factors
    • Loss of blue collar jobs
  – Unscrupulous Physicians
    • Pill Mills
  – Missionary zeal of pain treatment advocates
    • Pain is undertreated
    • You can’t become addicted
  – Criminal Pharma Marketing
Mexican Black Tar Heroin
Figure 1. Number of Injury Deaths by Drug Poisoning, Suicide, Homicide, Firearms, and Motor Vehicle Crashes in the United States, 1999-2014\textsuperscript{a,b}

Source: Centers for Disease Control Prevention
Some states have more painkiller prescriptions per person than others.

Age-adjusted rate of drug overdose deaths, by state — 2010 and 2015

http://dx.doi.org/10.15585/mmwr.mm655051e1. (MMWR)
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<th>Cost (in BB $)</th>
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<td>Health Care Costs &amp; Substance Abuse Treatment</td>
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<td>Productivity (includes decreased productive hours &amp; lost productivity for incarcerated individuals)</td>
<td>---------------</td>
<td>20.4</td>
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<tr>
<td>Fatal Overdoses</td>
<td>---------------</td>
<td>21.5</td>
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<tr>
<td>Criminal Justice Costs</td>
<td>Costs borne by state and local governments</td>
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<tr>
<td>Total Economic Burden of Rx Opioid OD, Abuse and Dependence</td>
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<td>78.5</td>
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Where Are We Today?

• It is estimated that 1 out of 5 patients with a non-cancer pain diagnosis is prescribed opioids in office-based settings with primary care providers accounting for about half of all opioid pain relievers dispensed.

Daubresse M, Medical Care 2013.
The art of medicine consists in amusing the patient while nature cures the disease.

(Voltaire)
Why Use Opioids for Acute Pain?

• Opioids provide superior analgesia to other medications.
• Opioid safety profile is no worse than other medications.
• You can’t get addicted to opioids given for non-cancer pain.
• Opioids reduce pain effectively, thereby getting the employee back to work faster.
Opioids Provide Superior Analgesia to Other Medications.
ACOEM Practice Guidelines: Opioids and Safety-Sensitive Work (Hegmann, JOEM 2014)

There were four quality trials of acute pain patients treated with opioids compared with placebo, with a small overall magnitude of benefit, whereas the adverse effects profile was high.

- Among trials for treatment of acute pain, **Ibuprofen** was reportedly superior to **Codeine** or acetaminophen for acute injuries including fractures.
- **Diflunisal** was equivalent to **Codeine** for sprains, strains, and mild to moderate LBP. **Diflunisal** was also superior to **Codeine/APAP** for LBP.
- **Valdecoxib** was better-tolerated and trended toward greater pain relief than **Tramadol** for ankle sprains. **Valdecoxib** was equivalent to **Oxycodone** as assessed by pain ratings, but trended toward less rescue medication use and had fewer adverse effects among patients with spine and extremity pain.
- **Ketorolac** was equivalent for pain relief, but superior to **Meperidine (Demerol)** regarding adverse effects for treating severe LBP. Ketorolac was also superior to codeine/acetaminophen for acute LBP treated in emergency departments.
Opioid Safety Profile Is No Worse Than Other Medications.
Ibuprofen Tablets, USP

Cardiovascular Risk

- NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk (see WARNINGS).

- MOTRIN tablets are contraindicated for treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery (see WARNINGS).

Gastrointestinal Risk

- NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events (see WARNINGS).
Acetaminophen

Liver warning: This product contains acetaminophen. Severe liver damage may occur if:

- Adult takes more than 12 caplets in 24 hours, which is the maximum dose
- Taken with other drugs which contain acetaminophen

Ask a doctor before use if the user has liver disease
Opioids- Adverse Reactions

- GI- constipation, nausea/vomiting
- Somnolence
- Insomnia
- Sexual Dysfunction
- Hyperalgesia
- Tolerance/Addiction
- Respiratory Depression
You Can’t get Addicted to Opioids Given for Non-cancer Pain

Would you give your child HEROIN to remove a wisdom tooth?

Ask Your Dentist How Prescription Drugs Can Lead to Heroin Abuse

Partnership for a Drug-Free New Jersey in Cooperation with the Governor’s Council on Alcoholism and Drug Abuse and the NJ Dept. of Human Services

BEFORE THEY PRESCRIBE - YOU DECIDE. drugfreenj.org
Initiation Into Prescription Opioid Misuse Among Young Injection Drug Users (IDUs)

• 50 IDUs (volunteers) in NYC and LA
• Mean age- 21; 70% male; 72% white; 48% did not complete HS; 66% currently homeless; 90% w/ hx of jail time; 75% w/ hx of Psych Dx
• Type of Opioid Misused First: Vicodin > Oxycontin > Percocet
• Mode of Administration:
  – Swallowing: 82%
  – Snorting: 16%
  – Injecting: 2%
Initiation Into Prescription Opioid Misuse Among Young Injection Drug Users (IDUs)

Age of Initiation (in years):

– Marijuana- 12.5
– Alcohol- 12.8
– Opioids- 14.5
– Heroin- 16.6
Initiation Into Prescription Opioid Misuse Among Young Injection Drug Users (IDUs)

Misuse of own Opioid Prescription:

– 72% had been prescribed an opioid in their lifetime (often for sports injuries or dental procedures)

– 40% of the above respondents reported their own prescription as the source of first opioid misuse (15 years old)

I was taking it as prescribed but I still got a high feeling. It wasn’t intentional—doing it to actually get high. Then I told all my friends that I was getting pain pills and they’re like “Get ‘em and we’ll buy ‘em”. So when we went back to the doctor, I lied and said “Yes, it still hurts”. They prescribed me a lower dose and I traded some off and got Oxy”
In Their Own Words

• Heroin is better “high” than Rx Opioids (98%)
• Ease of Inhalation/Injection (32%)
• Heroin is cheaper and easier to obtain than Rx Opioids

“It [OxyContin] was getting harder and harder to get the pills that you could use in a needle, most of them would just gel-up. And it was cheaper and easier to get the heroin, which was much stronger and would get you higher than Oxycodone”
Percentage of the Total Heroin-Dependent Sample That Used Heroin or a Prescription Opioid as Their First Opioid of Abuse Data are plotted as a function of the decade in which respondents initiated their opioid abuse.
Opioid-Prescribing Patterns of Emergency Physicians and Risk of Long-term Use (NEJM, Feb 2017)

Methods

– retrospective analysis/ 2008-2011
– 375 K Medicare patients (characteristics were similar, including dx); opioid-free within 6 month before the visit
– ED providers- quartiles based on relative opioid prescribing rates
– Compared rates of “long-term” opioid use (6 months of days supplied)

Results

– 215 K patients received tx from “low intensity” ED prescribers
– 162 K patients received tx from “high intensity” ED prescribers
Figure 1. Prescribing Rates and Adjusted Odds Ratios for Long-Term Opioid Use, According to Quartile of Physician Opioid Prescribing.

Panel A shows rates of opioid prescribing by emergency physicians according to within-hospital quartile. I bars represent 95% confidence intervals. Panel B shows the adjusted odds ratios and corresponding 95% confidence intervals for rates of long-term opioid use, according to quartile of physician opioid prescribing. Physicians in each quartile were compared with those in the lowest prescribing quartile. Odds ratios were estimated with the use of logistic-regression models.
“Although causality cannot be established from this observational study, if our results represent a causal relationship, for every 48 patients prescribed a new opioid in the emergency department who might not otherwise use opioids, one will become a long-term user”

Barnett ML. NEJM, 2017
• 10% sample IMS Lifelink + database from 2006-15
• Patients were ≥ 18 years of age and had not received an opioid prescription for 6 months prior to receiving 1st opioid prescription.
• Patients were followed from the date of their first opioid prescription until loss of insurance, study end date or discontinuation of opioids (≥ 180 days without opioid use).
• Patients excluded- any diagnosis of cancer (except non-melanoma skin CA), substance abuse disorder within 6 months of 1st opioid prescription or whose first opioid prescription was for Buprenorphine

1.3 MM participants- 33,548 (2.6%) continued opioid therapy for 1 year- more likely to be:
• Older (49.6 years)
• Female (56%)
• Have a pain dx before initiation of opioid
• Initiated on higher doses of opioids
Characteristics of Initial Prescription Episodes and Likelihood of Long-term Opioid Use- US, 2006-15
(MMWR, Mar 2017)
Characteristics of Initial Prescription Episodes and Likelihood of Long-term Opioid Use- US, 2006-15
(MMWR, Mar 2017)

The Highest Probabilities of Continued Opioid Use at 1 year were observed among patients that initiated treatment with:

- Long-acting opioid: 27.3%
- Tramadol: 13.7%
- Schedule II short-acting opioid (Other): 8.9%
- Hydrocodone (short-acting): 5.1% → 18.7%
- Oxycodone (short-acting): 4.7%
Opioids, Prolonged Disability and Cost of Treatment

• **Busse, BMJ 2015**

  – Use of an opioid in the 1\textsuperscript{st} four weeks of a claim is associated with a longer claim duration

    • 6665 random claims (Ontario Workplace Safety and Insurance Board) for acute, low back strains (2005)
      – Excluded:
        » Cases w/o lost time
        » Cases ended < 4 weeks

    • 1442 of which remained OOW at 4 weeks
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<th>Table 2</th>
<th>Baseline characteristics of WSIB low back pain claims (n=1442)</th>
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<td>Age in years, mean (SD)</td>
<td>41.3 (10.5)</td>
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<td>Gender, n (%)</td>
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<td>Female</td>
<td>552 (38.3)</td>
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<td>Male</td>
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<td>First language, n (%)</td>
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<td>English</td>
<td>1372 (95.1)</td>
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<tr>
<td>Other</td>
<td>70 (4.9)</td>
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<td>Predisability income (dollars/week) mean (SD)</td>
<td>731.4 (332.5)</td>
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<td>Opioid prescription reimbursed by WSIB in the first 4 weeks of claim, n (%)</td>
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<td>Yes</td>
<td>136 (9.4)</td>
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<td>No</td>
<td>1306 (90.6)</td>
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<td>Prior WSIB claim, n (%)</td>
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<td>Yes</td>
<td>1091 (75.7)</td>
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<td>No</td>
<td>351 (24.3)</td>
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<td>Union membership, n (%)</td>
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<td>Yes</td>
<td>610 (42.3)</td>
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<td>656 (45.5)</td>
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<td>Employer RTW programme, n (%)</td>
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<td>Employer doubts work-relatedness of injury, n (%)</td>
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<td>Yes</td>
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<td>1051 (72.9)</td>
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<td>196 (13.6)</td>
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<td>Chiropractic care reimbursed by WSIB during claim, n (%)</td>
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<td>Early Chiropractic care (≥3 treatments received within the first 28 days), n (%)</td>
<td>247 (17.1)</td>
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<td>Physiotherapy reimbursed by WSIB during claim, n (%)</td>
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<tr>
<td>Early Physiotherapy (≥3 treatments received within the first 28 days), n (%)</td>
<td>388 (26.9)</td>
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</table>

RTW, return to work; WSIB, Workplace Safety and Insurance Board.

Figure 2: Kaplan-Meier curve for early reimbursement for opioid prescription.

Busse, BJM 2015
**Figure 5** The association between early opioid use/prescription and claim duration.
Opioids, Prolonged Disability and Cost of Treatment

• Vollin, Pain 2009
  – Individuals using opioids are 6x more likely than those not using opioids to experience “chronic” lost work time
  – Treatment costs for individuals using opioids was almost $20 K > than those not using opioids (3 years post-injury)
Opioids, Prolonged Disability and Cost of Treatment

• **Franklin, Spine 2008**
  - Prescription of opioids for more than 7 days for workers with acute back injuries is a risk factor for long term disability (1 year), after adjustment for pain, function and injury severity
  - The receipt of more than 1 opioid prescription is associated significantly with work disability at 1 year
Controlling the epidemic:

• **Prevent** new cases of opioid addiction.

• **Treatment** for people who are already addicted

• **Supply control** - Medical board & law enforcement efforts to reduce over-prescribing and black-market availability.
Nobody becomes a chronic pain patient without going through the acute pain phase first.
Opioid Prescribing Recommendations for Acute, Non-cancer Pain

Opioids are not the first-line choice for treatment of acute musculoskeletal pain.

- If opioid use is being considered (post-surgery/fracture; NSAID failure; severe pain) use a short-acting opioid at the lowest effective dose for the shortest period of time (less than 1 week and preferably 2-3 days).
- Maximum daily oral dose ➔ 50 MME (Hegmann 2014)
Opioid Prescribing Recommendations for Acute, Non-cancer Pain

Screen all individuals for risk of opioid abuse and obtain an opioid treatment agreement.
This tool should be administered to patients upon an initial visit prior to beginning opioid therapy for pain management. A score of 3 or lower indicates low risk for future opioid abuse, a score of 4 to 7 indicates moderate risk for opioid abuse, and a score of 8 or higher indicates a high risk for opioid abuse.

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<th>Male</th>
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<td>Rx drugs</td>
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<td><strong>Personal history of substance abuse</strong></td>
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<td>Age between 16—45 years</td>
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<td>History of preadolescent sexual abuse</td>
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<td><strong>Scoring totals</strong></td>
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Opioid Prescribing Recommendations
for Acute, Non-cancer Pain

Consult PDMP data, perform pill counts and obtain random urine drug testing to detect aberrant opioid drug-seeking behavior.
Opioid Prescribing Recommendations for Acute, Non-cancer Pain

Use functional improvement as a guide to continue opioids.
Opioid Prescribing Recommendations for Acute, Non-cancer Pain

Consider further testing (imaging studies, nerve conduction testing) or specialist referral should function and pain fail to improve within 3-4 weeks.
Population Health Approaches

- Prescription Drug Monitoring Programs (PDMP)
- Drug Formularies
Comparing State Opioid Prescribing Guidelines

<table>
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<tr>
<th>State</th>
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<th>NJ</th>
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<td>- What</td>
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<td>CME (hrs.)</td>
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<td>Effective Date</td>
<td>12/2013</td>
<td>5/2017</td>
<td>8/2013</td>
<td>1/2017</td>
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Interstate Sharing of Prescription Monitoring Database Information

1Oregon will only allow direct access to practitioners in California, Idaho, and Washington.

From: National Alliance for Model State Drug Laws, May 2016
PDMPs Can:

• Identify major sources of drug diversion:
  – Doctor shopping
  – Prescription fraud/ forgery
  – Improper Prescribing/ Dispensing

• Provide cost savings to healthcare systems

• Reduce Opioid Overdose Deaths

From PDMP Center of Excellence- Brandeis Univ; Sept 2014
PDMPs Can:

• Improve Clinical Decision-making and patient care
• Improve Health Outcomes

From PDMP Center of Excellence- Brandeis Univ; Sept 2014
STATE SUCCESSES: Decreases in Opioid Prescribing

Average Morphine Milligram Equivalents (MME)* per person decreased in most counties in Florida, Ohio, and Kentucky from 2010 to 2015.

These states have regulated pain clinics and set requirements for their state’s PDMP.

PDMP, Prescription Drug Monitoring Program, is a state-run electronic database used to track the prescribing and dispensing of controlled prescription drugs to patients.

- **Florida**: 80% of counties decreased
- **Ohio**: 85% of counties decreased
- **Kentucky**: 62% of counties decreased

*MME is a way to calculate the amount of opioids, accounting for differences in opioid drug type and strength.

www.cdc.gov/vitalsigns/opioids
New laws and enforcement reverse trends in oxycodone prescribing and related deaths in Florida.

- Oxycodone prescriptions fell by 24%.
- Deaths fell by 52% after years of increases.

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<th>Drug Class</th>
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<td>Opioids</td>
<td>Hydrocodone/acetamin</td>
<td>Lortab®</td>
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<td>Vicoprofen®</td>
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<td>Dilaudid®</td>
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<td>Hydromorphone ER</td>
<td>Exalgo</td>
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<td>Opioids</td>
<td>Levorphanol</td>
<td>Levo-Dromoran®</td>
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</table>
# Risks and Benefits of Drug Formularies

**Risks (Possible)**
- Increased administrative costs
- Decreased medication compliance
- Increased provider time burden
- Medical decision may not be patient-focused

**Benefits (Probable)**
- Reduced Administrative Costs
- Improved Clinical Outcomes - better medical practice - providers using EBM and prescribing more effective medications and non-pharmacologic treatments
- Reduction in direct drug costs - opioids, compounded topical medications and non-generic meds
Primum Non Nocere
First, Do No Harm

Why Screw it Up?
References


CDC Vital Signs, July 2014. cdc.gov/vitalsigns


References


https://www.cdc.gov/mmwr/volumes/66/wr/mm6610a1.htm
