



ADVANCED RECOVERY

S Y S T E M S

an advanced approach to patient care

The Current State of Opioid Pain Management in 2017: Where we have been, Where we are at, Where are we going?

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Learning Objectives

- To understand the time line of opioid prescribing for chronic pain and how it impacts the current opioid epidemic
- To understand the impact of the new opioid guidelines on pain care
- To understand non opioid approaches to pain
- To understand the approach to the patient currently on opioid therapy for pain

Do. Or do not. There is no try –
Yoda



Where we have been:

Opioid Timeline

- Morphine was first isolated between 1803 and 1805 by Friedrich Serturmer. Named after Morpheus the Greek God of dreams.
- 1853: The hypodermic syringe is invented. Inventor's wife is first to die of injected drug overdose.
- 1898: Bayer chemist invents diacetylmorphine, names it heroin. Touted as the antidote to morphine addiction
- 1914: U.S. Congress passes Harrison Narcotics Tax Act.
- 1928: What eventually becomes known as the Committee on the Problems of Drug Dependence forms to organize research in pursuit of the Holy Grail: a nonaddictive pain killer.



Opioid Timeline

- 1951: Arthur Sackler revolutionizes drug advertising with campaign for antibiotic Terramycin. Pharmaceutical detailing begins
- 1952: Arthur, Raymond, and Mortimer Sackler buy Purdue Frederick.
- 1960: Arthur Sackler's campaign for Valium makes it the industry's first \$ 100 million drug.
- 1980: The New England Journal of Medicine publishes letter to editor from Jane Porter and Herschel Jick. Short term in patient study indicating that opioids for pain are not addicting

Opioid Timeline

- Early 1980s: First Xalisco migrants set up heroin trafficking businesses in the San Fernando Valley of Los Angeles.
- 1984: Purdue releases MS Contin, a timed-release morphine painkiller marketed to cancer patients.
- 1986: Drs. Kathleen Foley and Russell Portenoy publish paper in the journal Pain, opening a debate about use of opiate painkillers for wider variety of pain. They use the Porter and Jick paper as proof that opioids are not addicting

Timeline

- Early 1990-2 Xalisco Boys heroin cells begin expanding beyond San Fernando Valley to cities across western United States. Their pizza-delivery-style system evolves.
- 1996: Purdue releases OxyContin, timed-released oxycodone, marketed largely for chronic-pain patients.
- 1996: President of American Pain Society urges doctors to treat pain as a vital sign.
- 1996 AAPM issued a consensus statement supporting LTOT Stating that the risk for de novo addiction was low, respiratory depression induced by opioids was short lived and was antagonized by pain, tolerance was not common and efforts to control diversion should not limit opioid prescribing



"It's the only treatment option he has under his current health plan."

Timeline

- Late 1990s: Xalisco Boys heroin cells begin to spread to numerous cities and suburbs east of the Mississippi River.
- 1998– 99: Veterans Administration and JCAHO adopt idea of pain as fifth vital sign.
- 2001: Injured workers covered under Washington State's workers' comp system start dying of opiate overdoses.
- 2004: Washington State Department of Labor & Industries Drs. Gary Franklin and Jaymie Mai publish findings on deaths of injured workers due to overdoses on opiate painkillers

**EXCLUSIVE
EXCERPT**

McVEIGH'S CHILLING DEATH ROW TESTIMONY



Newsweek

April 9, 2001 : \$3.50

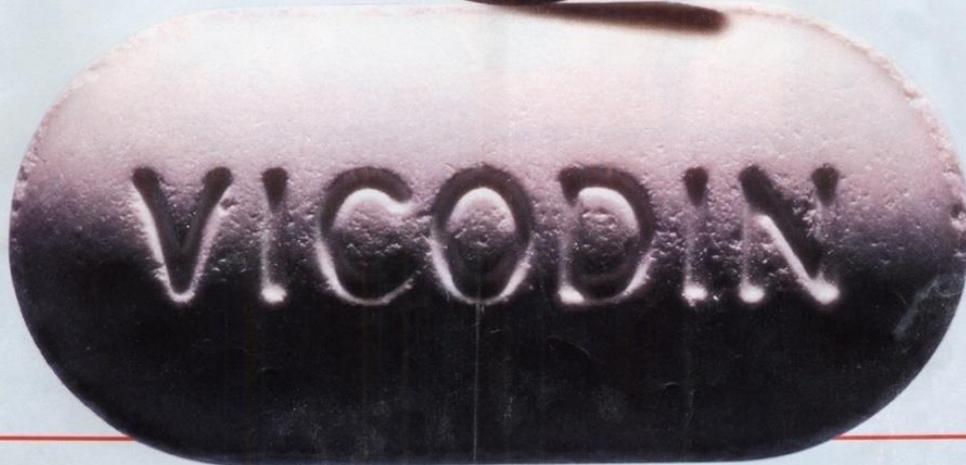
newsweek.msnbc.com

PainKillers

**Vicodin and
OxyContin:
Hot Drugs
That Offer
Relief—And
Danger**



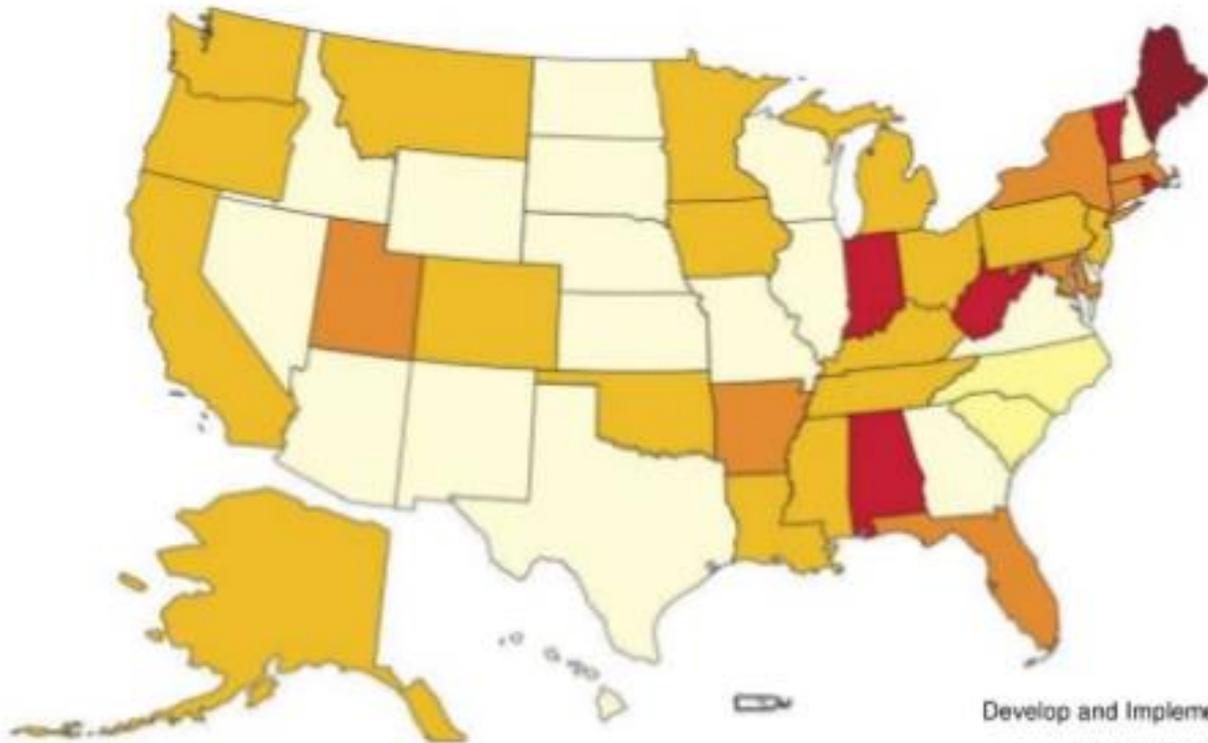
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Opioid Timeline

- Mid-2000s: Xalisco black tar heroin cells are now in at least seventeen states. Portsmouth, Ohio, has more pill mills per capita than any U.S. town. Florida's lax regulations make it another center of illicit pill supply.
- 2007: Purdue and three executives plead guilty to misdemeanor charges of false branding of OxyContin; fined \$ 634 million.
- 2008: Drug overdoses, mostly from opiates, surpass auto fatalities as leading cause of accidental death in the United States.
- 2010: NEJM Flood of Opioids, Rising Tide of Deaths NEJM
- 2011: Ohio passes House Bill 93, regulating pain clinics.

Primary non-heroin opiates/synthetics admission rates, by State (per 100,000 population aged 12 and over)



1999
(range 1 - 50)



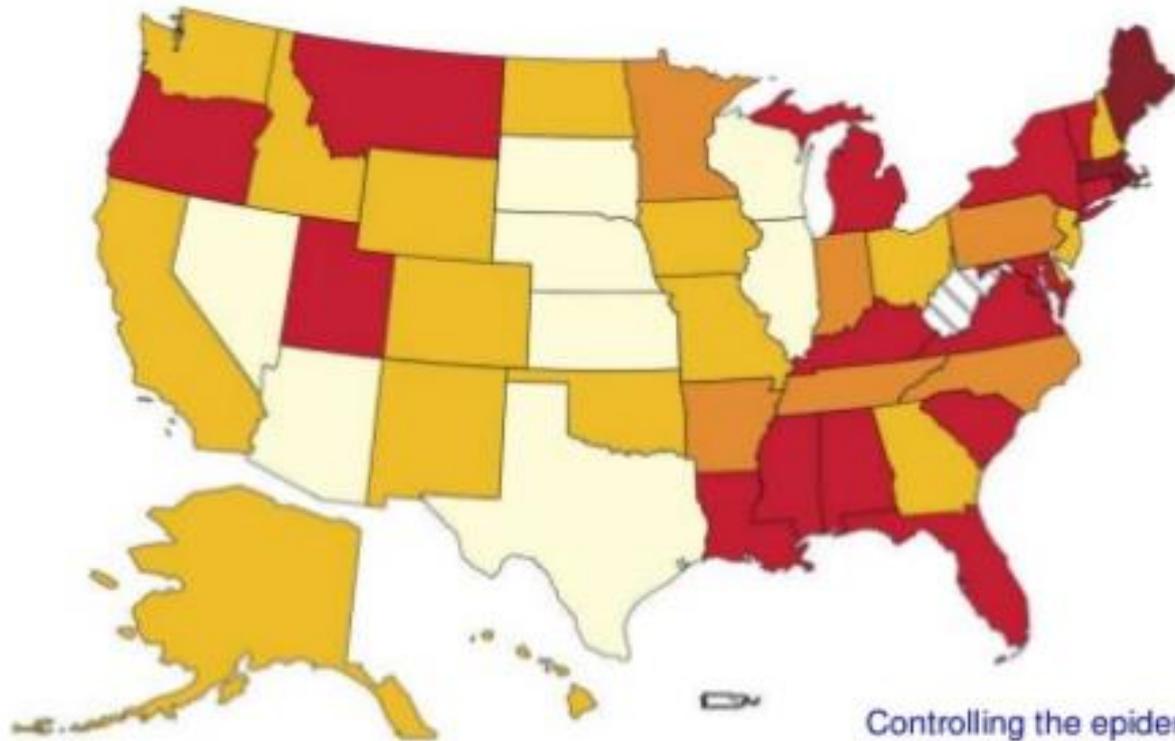
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Develop and Implement a Standard of Care

Opoid Prescribing in 2012: The Wild West



Primary non-heroin opiates/synthetics admission rates, by State (per 100,000 population aged 12 and over)



2001
(range 1 – 71)

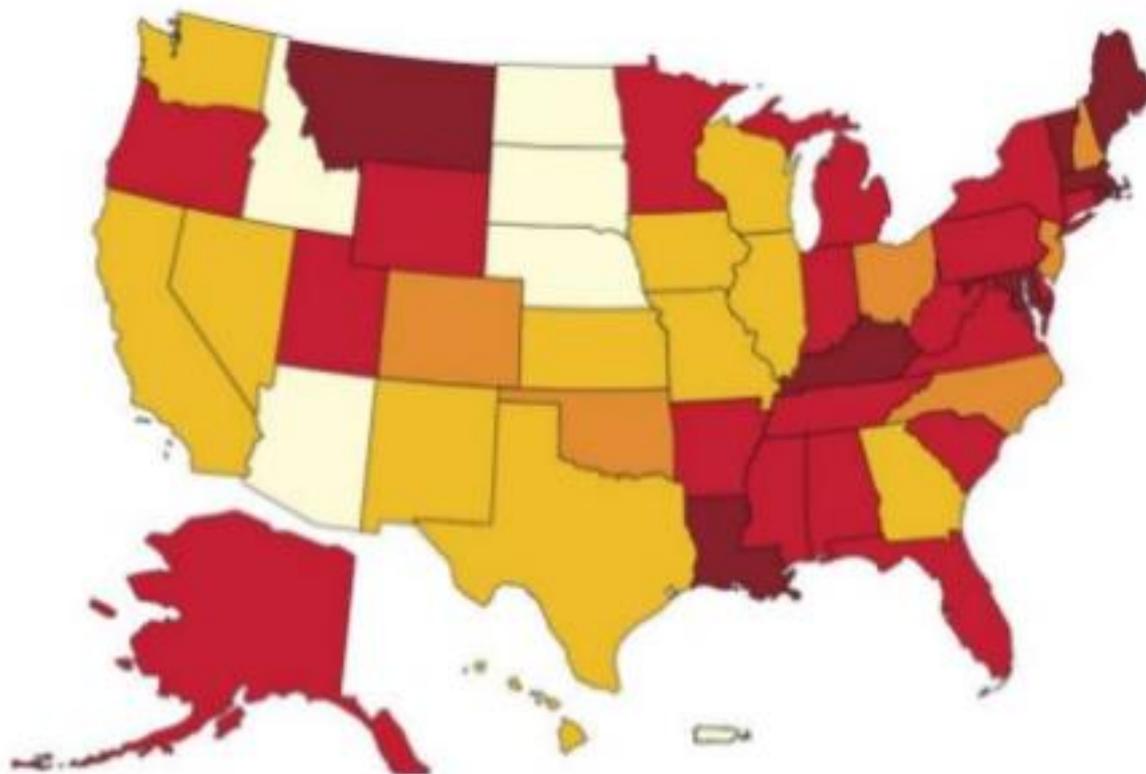


Controlling the epidemic: *A Three-pronged Approach*

- Primary Prevention- prevent new cases of opioid addiction.
- Secondary Prevention- provide people who are addicted with effective treatment.
- Supply control- Efforts by medical boards and law enforcement agencies to reduce over-prescribing and black market availability.

Statistics
I Health
Data
10.

Primary non-heroin opiates/synthetics admission rates, by State (per 100,000 population aged 12 and over)



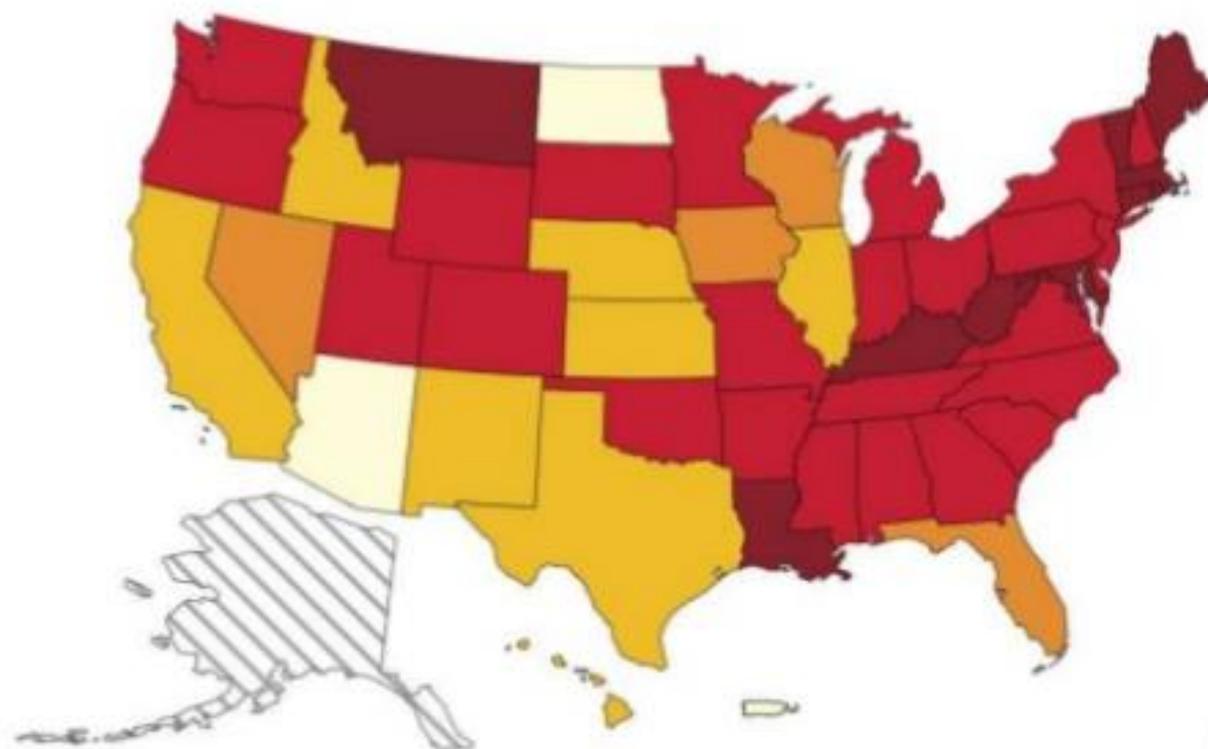
2003

(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)



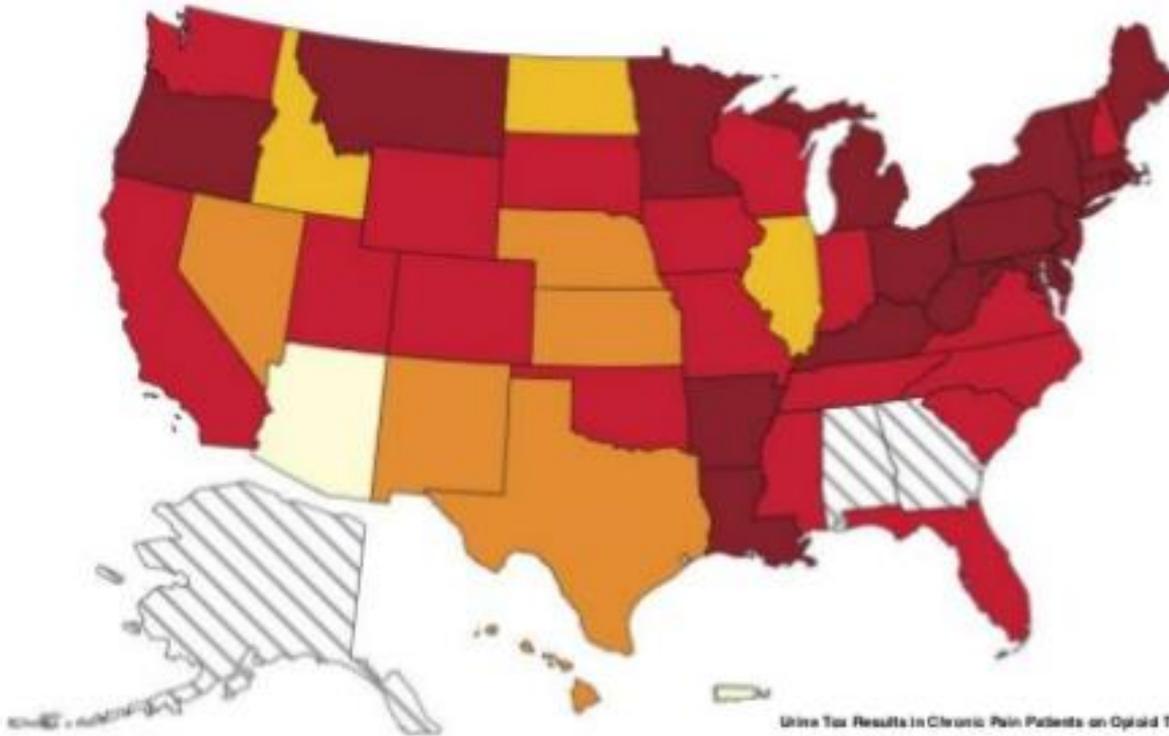
2005

(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.

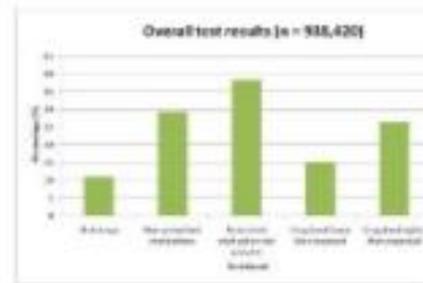
Primary non-heroin opiates/synthetics admission rates, by State (per 100,000 population aged 12 and over)



2007
(range 1 – 340)



Urine Test Results in Chronic Pain Patients on Opioid Therapy



Source: Institute of Medicine (IOM), 2007. <http://www.nationalacademies.org/pain/painreport/>

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.

Opioid Timeline

- 2013: The College on the Problems of Drug Dependence turns seventy-five without finding the Holy Grail of a nonaddictive painkiller.
- 2014: Actor Philip Seymour Hoffman dies, focusing widespread attention for the first time on the United States' opiate-abuse epidemic and the transition from pills to heroin in particular.
- 2014: The FDA approves Zohydro, a timed-release hydrocodone painkiller with no abuse deterrent. It also approves Purdue's Targiniq ER, combining timed-release oxycodone with naloxone, the opiate-overdose antidote.
- 2015 Increased Risk of OUD related to Prescription Opioid Studies Released
- 2016 CDC Guidelines
- Increasing death rates due to increase in illicit fentanyl
- 2017 VA/DoD Guidelines

Prince Rogers Nelson, died April 21 at age 57, after being found unresponsive in an elevator at Paisley Park, his home and recording studio in Chanhassen, Minnesota.



The Scope of the Problem: Where We Are

- In the 1960s, 80% of people entering treatment for heroin use started using heroin as their first opioid, while in the 2000s, 75% of people entering treatment for heroin use started using prescription opioids as their first opioid.
- Since 1999, the number of overdose deaths involving opioids quadrupled.
- 91 Americans die every day from an opioid overdose.
- Since 1999, the amount of prescription opioids sold in the U.S. nearly quadrupled, yet there has not been an overall change in the amount of pain that Americans report. Deaths from prescription opioids—drugs like oxycodone, hydrocodone, and methadone—have more than quadrupled since 1999.



Fentanyl

- Fentanyl, a powerful synthetic opioid, poses an increasing public health threat.
- Low production costs encourage suppliers to “cut” heroin with the drug, particularly white powder heroin sold in the eastern United States.
- Fentanyl also appears as a prevalent active ingredient in counterfeit OxyContin (oxycodone) tablets.
- It poses a serious overdose risk because it can rapidly suppress respiration and cause death more quickly than do other opioids.
- It is estimated that 41% of the roughly 7100 heroin-related deaths during this period involved fentanyl.

Fentanyl

- Many people who die from fentanyl overdose appear to have been unaware that they were using the drug.
- In addition to being mixed with heroin, fentanyl is sometimes sold as methylenedioxymethamphetamine (MDMA), or ecstasy.
- From 2012 through 2014, the number of reported deaths involving fentanyl more than doubled, from 2628 to 5544
- Recent analysis in Canada showed that fentanyl was present in 89% of seized counterfeit OxyContin tablets.
- In the US recent fatalities have also been attributed to fentanyl in counterfeit Xanax (alprazolam), Norco (acetaminophen–hydrocodone), and other medications.

Fentanyl

- Even with declining prices, heroin costs about \$65,000 per kilogram wholesale, whereas illicit fentanyl is available at roughly \$3,500 per kilogram.
- Drug dealers thus face strong incentives to mix fentanyl with heroin and other street drugs.
- The drug appears to significantly reduce market prices of illicit opioids (and some other substances), while dramatically increasing risk.
- Producing precise fentanyl doses also requires specialized equipment and knowledge.
- Street-drug suppliers who are unwilling or unable to provide precise dosing create especially acute overdose risks.

Beyond Fentanyl

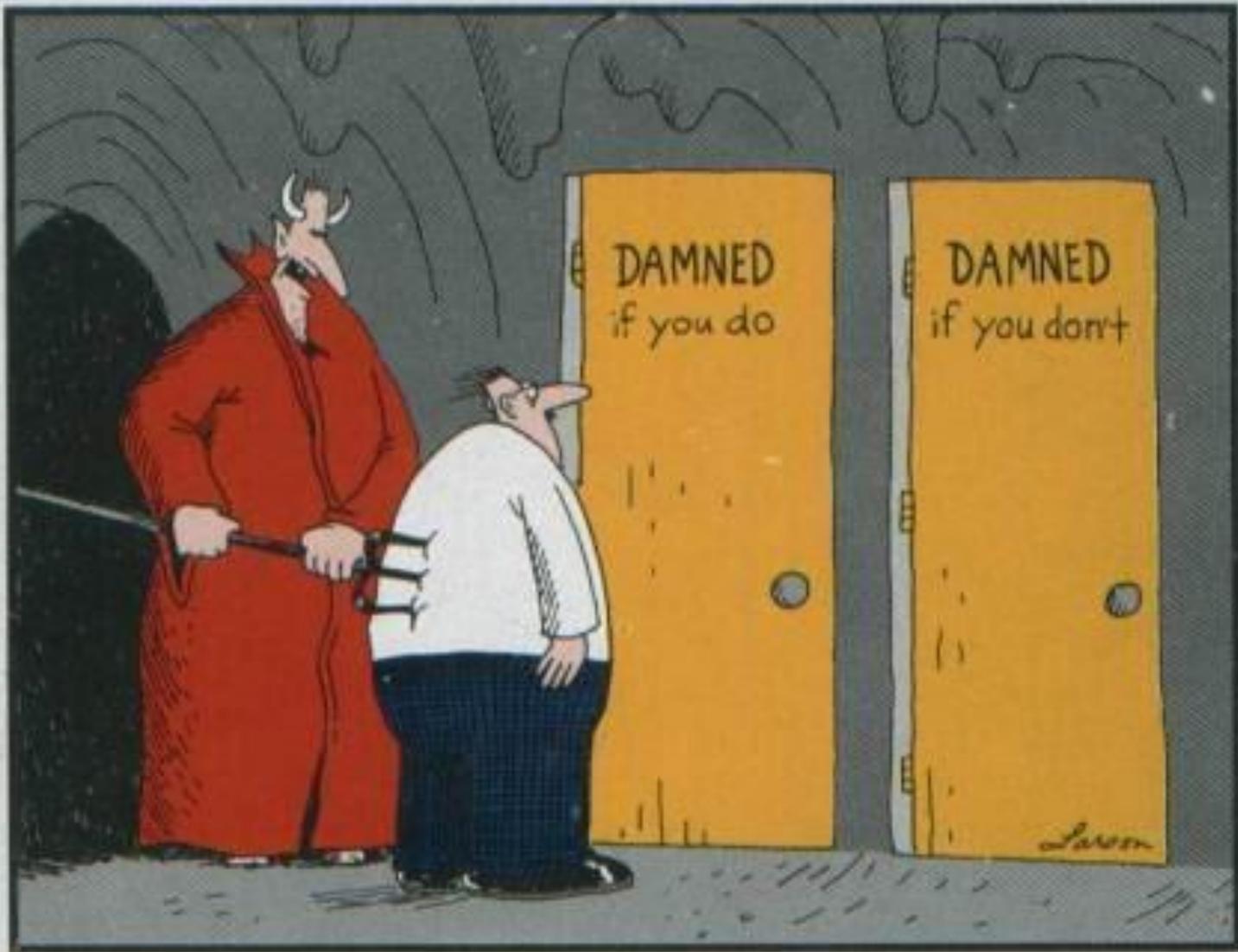
- Sufentanil 1000 x Morphine
- Carfentanil 10,000 x Morphine
- W-18 30,000 x Morphine

EVIDENCE ABOUT OPIOID THERAPY

- Benefits of long-term opioid therapy for chronic pain not well supported by evidence.
- Short-term benefits small to moderate for pain; inconsistent for function.

Evidence For Harm

- Overdose
- Development of OUD – Risks increase with acute therapy and increase further with chronic therapy, especially with increased dose
- Increased all cause mortality
- Increased risk of hospital acquired pneumonia
- Significant side effects even when taken as directed



“C’mon, c’mon — it’s either one or the other.”

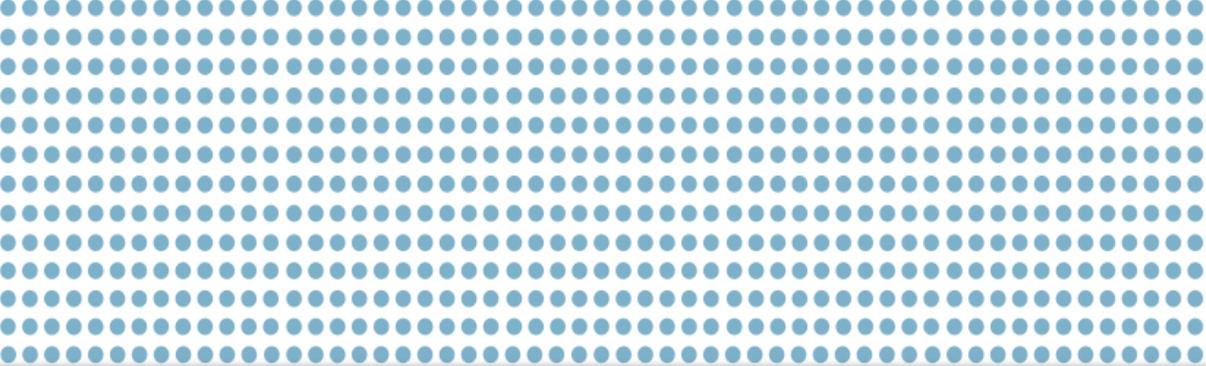
For every **1** death there are...



 **10** treatment admissions for abuse⁹

 **32** emergency dept visits for misuse or abuse⁶

 **130** people who abuse or are dependent⁷

 **825** nonmedical users⁷

Heroin use is part of a larger substance abuse problem.

Nearly all people who used heroin also used at least 1 other drug.

Most used at least **3** other drugs.

Heroin is a highly addictive opioid drug with a high risk of overdose and **death** for users.

People who are addicted to...



ALCOHOL

are

2x



MARIJUANA

are

3x



COCAINE

are

15x



Rx OPIOID PAINKILLERS

are

40x

...more likely to be addicted to heroin.

SOURCE: National Survey on Drug Use and Health (NSDUH), 2011-2013.

Opioid Costs in the US

- ED – Cases in which an opioid other than heroin was cited as a reason for an ED visit
 - 2004 - 299,498
 - 2011- 885,348
- Average Workman's Comp Costs
 - Without Opioids - \$13,000
 - With Short Acting Opioids - \$39,000
 - With Long Acting Opioids - \$117,000
- Between 2001 and 2008, opioid prescriptions as a share of all drugs used to treat workplace injuries jumped 63 percent
- In California, workplace insurers spent \$252 million on opioids in 2010, which represented about 30 percent of all prescription costs; in 2002, opioids accounted for 15 percent of drug expenditures

Opioids and ED visits

- There were an estimated 135,971 opioid related ED visits in the US in 2010.
- Of all visits, prescription opioids (including methadone) were involved in 68%, heroin in 16%, multiple opioids in 2.7%, and unidentified opioids in 13%.
- Benzodiazepine intoxication co-occurred in 22% of opioid overdoses.
- Among the 45% of patients who were treated and released from the emergency department (ED), the mean charge was \$3397; conversely, the mean charge for a hospitalized patient was \$29,807 with a mean length of stay of 3.8 days.
- 1.4% of patients died before hospital discharge.
- Total charges for opioid overdose-related visits amounted to \$2.3 billion in 2010.

Opioid-Prescribing Patterns of Emergency Physicians and Risk of Long-Term Use

- Wide variation in rates of opioid prescribing existed among physicians practicing within the same emergency department, and rates of long-term opioid use were increased among patients who had not previously received opioids and received treatment from high-intensity opioid prescribers

Opioid Use Disorder and Prescription Opioids

- Using electronic records from a large US health care system, we identified outpatients receiving five or more prescription orders for opioid therapy in the past 12 months for noncancer pain. In 2008, we completed diagnostic interviews with 705 of these patients using the DSM-4 criteria. In the current study, we reassessed these results using the final DSM-5 criteria.
- **Lifetime prevalence of “any” prescription opioid-use disorder in this cohort was 41.3%**
- The best predictors were age less than 65 years, current pain impairment, trouble sleeping, suicidal thoughts, anxiety disorders, illicit drug use, and history of substance abuse treatment.

Boscarino et al

Substance Abuse and Rehabilitation 2015;6 83–91

- An odds ratio (OR) is a measure of association between an exposure and an outcome. The OR represents the odds that an outcome will occur given a particular exposure, compared to the odds of the outcome occurring in the absence of that exposure.
- a = Number of exposed cases
- b = Number of exposed non-cases
- c = Number of unexposed cases
- d = Number of unexposed non-cases
- $OR = \frac{a/c}{b/d} = \frac{ad}{bc}$
- OR=1 Exposure does not affect odds of outcome
- OR>1 Exposure associated with higher odds of outcome
- OR<1 Exposure associated with lower odds of outcome

Opioid Prescribing and OUD

- Patients with CNCP prescribed opioids had significantly higher rates of OUDs compared to those not prescribed opioids. Effects varied by average daily dose and days supply:
 - low dose, acute OR=3.03
 - low dose, chronic OR=14.92
 - medium dose, acute OR =2.80
 - medium dose, chronic OR=28.69
 - high dose, acute OR=3.10
 - high dose, chronic OR=122.45
- Among individuals with a new CNCP episode, prescription opioid exposure was a strong risk factor for incident OUDs; magnitudes of effects were large. Duration of opioid therapy was more important than daily dose in determining OUD risk.
- Edlund et al *Clin J Pain*. 2014 July ; 30(7): 557–564

Opioid Dependence vs Addiction

A Distinction Without a Difference?

- Dependence on opioid pain treatment is not, as we once believed, easily reversible
- it is a complex physical and psychological state that may require therapy similar to addiction treatment, consisting of structure, monitoring, and counseling, and possibly continued prescription of opioid agonists.
- Whether or not it is called addiction, complex persistent opioid dependence is a serious consequence of long-term pain treatment that requires consideration when deciding whether to embark on long-term opioid pain therapy as well as during the course of such therapy.

Characteristics of Patients Who are at Higher Risk for Over Sedation and Respiratory Depression

- Sleep apnea or sleep disorder diagnosis
- Morbid obesity with high risk of sleep apnea
- Snoring
- Older age; risk is
 - 2.8 times higher for individuals aged 61-70
 - 5.4 times higher for age 71-80
 - 8.7 times higher for those over age 80
- No recent opioid use
- Post-surgery, particularly if upper abdominal or thoracic surgery
- Increased opioid dose requirement or opioid habituation
- Longer length of time receiving
- General anesthesia during surgery
- Receiving other sedating drugs, such as benzodiazepines, antihistamines, diphenhydramine, sedatives, or other central nervous system depressants
- Preexisting pulmonary or cardiac disease or dysfunction or major organ failure
- Thoracic or other surgical incisions that may impair breathing
- Smoker

Potential Risks for All Patients – Even Those Perceived to be at Low Risk

- Endocrinopathies – Hypogonadism, Alterations in Growth Hormone
- Hyperalgesia
- Sleep Apnea
- Constipation
- Decline in Cognition
- Immunosuppression
- Respiratory Depression
- Increased risk of symptoms of depression, PTSD, anxiety
- Decline in functional Improvement
- Increased risk of falls
- Increased risk for accidents
- Chronic Dry Mouth with Increased Risk of Dental Disease
- Osteoporosis

Opioids, The 800lb Gorilla in Pain Care



CDC and VA/DoD Opioid Guidelines: Where We Are Going



CDC - Determining When to Initiate or Continue

Opioids for Chronic Pain

- **1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain.** Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.
- **2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks.** Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.
- **3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.**

VA/DoD Guidelines

Version 3.0 – Feb. 2017

Recommend against:

Initiating long-term opioid therapy (LOT) for chronic pain, particularly in the following patient populations due to increased risk of adverse events with OT:

- untreated substance use disorder (SUD),
- concurrent benzodiazepine use,
- less than 30 years of age

CDC - Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation

- 4. **When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids**
- 5. **When opioids are started, clinicians should prescribe the lowest effective dosage.** Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage **to ≥ 50 morphine milligram equivalents (MME)/day**, and should **avoid increasing dosage to ≥ 90 MME/day or carefully justify a decision to titrate dosage to ≥ 90 MME/day**
- 6. **Long-term opioid use often begins with treatment of acute pain.** When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe **no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed**
- 7. **Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation.** Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids

VA/DoD

- **Recommend:**
- A short duration (consideration of OT ≥ 90 days requires re-evaluation and discussion with patient)
- The lowest dose indicated, as there is no safe dose and risk increases with dose
- Informed consent discussion of risks and benefits of OT and alternative therapies upon initiation
- Ongoing risk mitigation, including random urine drug testing (and appropriate confirmatory testing), checking state prescription drug monitoring programs, monitoring for overdose potential and suicidality, providing overdose education, prescribing of naloxone rescue and accompanying education, and suicide risk assessment (and intervening if necessary)

CDC Assessing Risk and Addressing Harms of Opioid Use

- **8. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms.** Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥ 50 MME/day), or concurrent benzodiazepine use, are present. Offer Naloxone to Patients When Factors That Increase Risk for Opioid-Related Harms Are Present
- High Risk Patient Populations Include
 - Patients with Sleep-Disordered Breathing, Including Sleep Apnea
 - Pregnant Women
 - Patients with Renal or Hepatic Insufficiency
 - Patients Aged ≥ 65 Years
 - Patients with Mental Health Conditions
 - Patients with Substance Use Disorder
 - Patients with Prior Nonfatal Overdose

VA/DoD

- **Recommend:**
- Evaluation of risks and benefits at least every three months and more frequently as dose increases
- Tapering OT to reduced dose or to discontinuation when risks of LOT outweigh benefits (avoid abrupt discontinuation unless required for immediate safety concerns; individualize tapering)
- Interdisciplinary care (addressing pain, SUD, and/or mental health problems) for patients presenting with high risk and/or aberrant behavior

VA/DoD

- **Recommend:**
- Ongoing risk mitigation, assessment for opioid use disorder (OUD) and suicide, and consideration for tapering
- For patients with evidence of untreated SUD, close monitoring, SUD treatment, and tapering
- For patients with concurrent use of OT and benzodiazepines, tapering one or both medications
- For patients taking >90 mg MEDD, evaluation for tapering to reduced dose or to discontinuation
- **For patients with chronic pain and OUD, medication assisted treatment of OUD**

CDC - Assessing Risk and Addressing Harms of Opioid Use

- **9. Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months**
- **10. When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs**
- **11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible**
- **12. Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder**

ORT

- Opioid Risk Tool 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.

Mark each box that applies	Female	Male
Family history of substance abuse		
Alcohol	1	3
Illegal drugs	2	3
Rx drugs	4	4
Personal history of substance abuse		
Alcohol	3	3
Illegal drugs	4	4
Rx drugs	5	5
Age between 16—45 years	1	1
History of preadolescent sexual abuse	3	0
Psychological disease		
ADD, OCD, bipolar, schizophrenia	2	2
Depression	1	1
Scoring totals		

SOAPP-R (The Screener and Opioid Assessment for Patients with Pain)

- 1. The goal to address the limitations of the SOAPP v.1, have less transparent items to reduce overt patient deception.**
- 2. Alpha version of the SOAPP-R was developed with 142 questions.**
- 3. Beta version with 97 questions was administered to 283 chronic pain patients on long-term opioid therapy. Items were evaluated based on data collected at follow-up, including correlation with the Aberrant Drug Behavior Index (ADBI), derived from interview data, physician ratings, and urine toxicology screens.**
- 4. Twenty-four items were retained and comprise the final SOAPP-R.**

Never 0, Seldom 1, Sometimes 2, Often 3, Very Often 4

- 1. How often do you have mood swings?**
- 2. How often have you felt a need for higher doses of medication to treat your pain?**
- 3. How often have you felt impatient with your doctors?**
- 4. How often have you felt that things are just too overwhelming that you can't handle them?**
- 5. How often is there tension in the home?**
- 6. How often have you counted pain pills to see how many are remaining?**
- 7. How often have you been concerned that people will judge you for taking pain medication?**
- 8. How often do you feel bored?**
- 9. How often have you taken more pain medication than you were supposed to?**
- 10. How often have you worried about being left alone?**
- 11. How often have you felt a craving for medication?**
- 12. How often have others expressed a concern over your use of medication?**

- 13.** How often have any of your close friends had a problem with alcohol or drugs?
- 14.** How often have others told you that you had a bad temper?
- 15.** How often have you felt consumed by the need to get pain medication?
- 16.** How often have you run out of pain medication early?
- 17.** How often have others kept you from getting what you deserve?
- 18.** How often, in your lifetime, have you had legal problems or been arrested?
- 19.** How often have you attended an AA or NA meeting?
- 20.** How often have you been in an argument that was so out of control that someone got hurt?
- 21.** How often have you been sexually abused?
- 22.** How often have others suggested that you have a drug or alcohol problem?
- 23.** How often have you had to borrow pain medications from your family or friends?
- 24.** How often have you been treated for an alcohol or drug problem?

Current Opioid Misuse Measure (COMM)

**Development and Validation of the Current Opioid Misuse Measure,
Stephen F. Butler, Simon H. Budman, Kathrine C. Fernandez, Brian Houle,
Christine Benoit, Nathaniel Katz, and Robert N. Jamison**

- 1. An initial pool of 177 items from 26 pain management and addiction specialists.**
- 2. Concept mapping identified six primary concepts underlying medication misuse**
- 3. Twenty-two pain and addiction specialists rated the items on importance and relevance, resulting in a 40-item alpha COMM**
- 4. Final item selection was based on 227 patients taking opioids for CNCP, using the alpha version of the COMM, the Prescription Drug Use Questionnaire (PDUQ) interview, and urine toxicology screening. From the 40 items alpha COMM, 17 items appeared to adequately measure aberrant behavior, demonstrating excellent internal consistency and test-retest reliability.**

Never 0, Seldom 1, Sometimes 2, Often 3, Very Often 4

- 1. How often have you had trouble with thinking clearly or had memory problems?**
- 2. How often do people complain that you are not completing necessary tasks? (i.e. doing things that need to be done, such as going to class, work, or appointments)**
- 3. How often have you had to go to someone other than your prescribing physician to get sufficient pain relief from your medications. (i.e. another doctor, the Emergency Room)**
- 4. How often have you taken your medications differently from how they are prescribed?**
- 5. How often have you seriously thought about hurting yourself?**
- 6. How much of your time was spent thinking about opioid medications? (having enough, taking them, dosing schedules, etc.)**
- 7. How often have you been in an argument?**
- 8. How often have you had trouble controlling your anger? (e.g. road rage, screaming, etc.)**

- 9.** How often have you needed to take pain medications belonging to someone else?
- 10.** How often have you been worried about how you're handling your medication?
- 11.** How often have others been worried about how you're handling your medications?
- 12.** How often have you had to make an emergency phone call or show up at the clinic without an appointment?
- 13.** How often have you gotten angry with people?
- 14.** How often have you had to take more of your medications than prescribed?
- 15.** How often have you borrowed pain medication from someone else?
- 16.** How often have you used your pain medication for symptoms other than for pain? (e.g. to help you sleep, improve your mood, or relieve stress)
- 17.** How often have you had to visit the Emergency Room?

VA/DoD Acute Pain

- **Recommend:**
 - Alternatives to opioids for mild-to-moderate acute pain
 - If opioids are prescribed, immediate-release opioids at lowest effective dose with reassessment no later than 3-5 days to determine if adjustments or continuation of OT is indicated
- **We suggest:**
 - Use of multimodal pain care when opioids are used (should also offer patient education about opioid risks and alternatives to OT)

Key Concerns

- No evidence shows a long-term benefit of opioids in pain and function for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials <6 weeks in duration).
- Extensive evidence shows the possible harms of opioids (including abuse and dependence, overdose, myocardial infarction, motor vehicle crashes).
- Extensive evidence suggests benefits of alternative treatments compared with long-term opioid therapy, including nonpharmacologic therapy and nonopioid pharmacologic therapy, with less harm.

Some Adjuncts and Alternatives to Opioid Therapy are All Options for Patients

- Antidepressants
- Anticonvulsants
- Acetaminophen
- Medications for sleep –
Non benzodiazepine
- Topical Agents
- NSAIDS
- Heat
- Physical therapy
- Exercise
- Cognitive-behavioral
therapy
- TENS Unit
- Mindful Meditation
- Yoga
- Acupuncture

The Current Conundrum. Patients Already on Long Term Opioid Therapy

- Tapering options
- Diagnosis and Treatment of OUD
- Treat Comorbidities
- Overdose Education and Naloxone
- Maximizing Non opioid therapy for pain



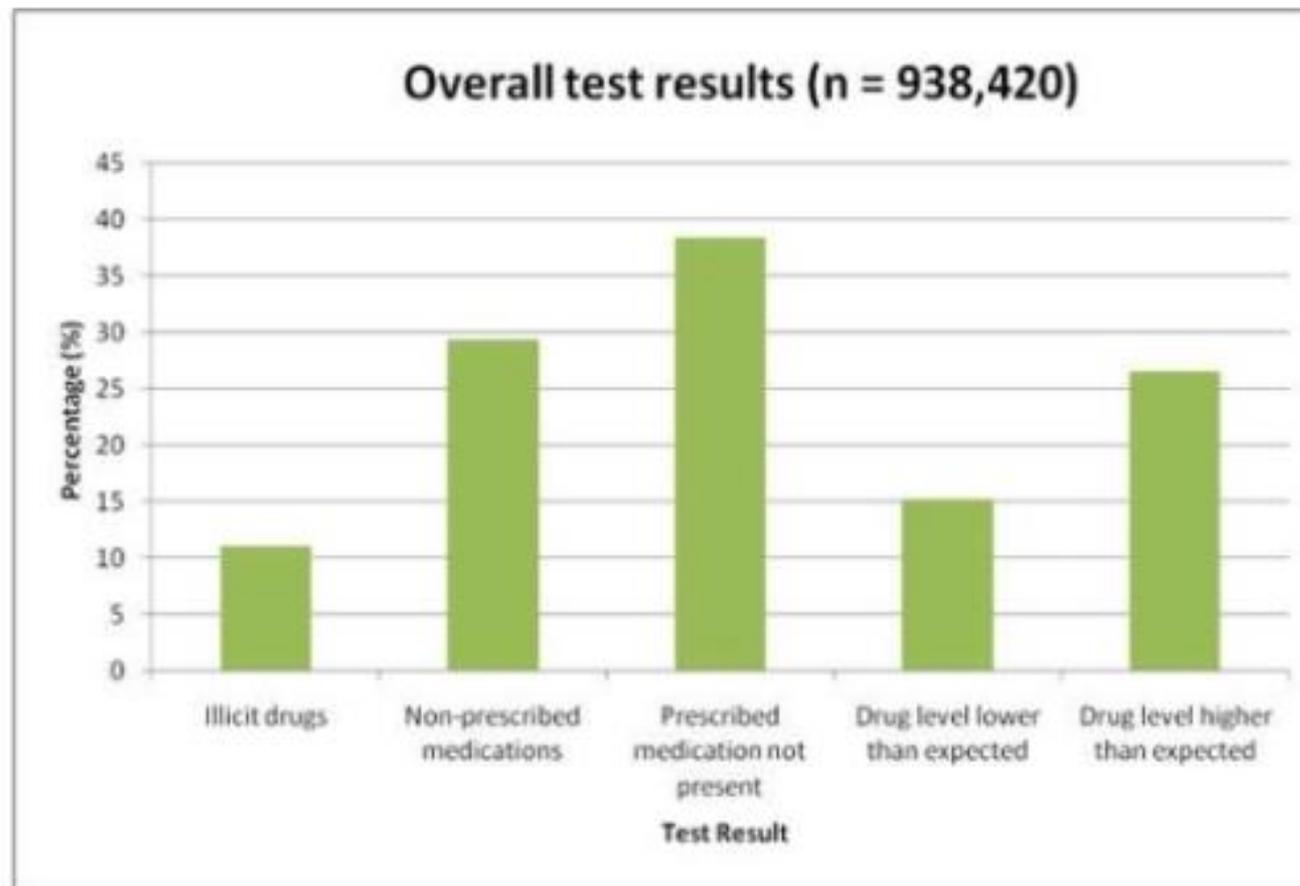
Reasons for Opioid Tapering

- No pain reduction, no improvement in function or patient requests to discontinue therapy
- Severe unmanageable adverse effects (e.g., drowsiness, constipation, cognitive impairment)
- Dosage indicates high risk of adverse events (e.g., doses of 90 MEDD and higher)
- Non-adherence to the treatment plan or unsafe behaviors (e.g., early refills, lost/stolen prescription, buying or borrowing opioids, failure to obtain or aberrant UDT)

Reasons for Opioid Tapering

- Concerns related to an increased risk of SUD (e.g., behaviors, age < 30, family history, personal history of SUD)
- Overdose event involving opioids
- Medical comorbidities that can increase risk (e.g., lung disease, sleep apnea, liver disease, renal disease, fall risk, advanced age)
- Concomitant use of medications that increase risk (e.g., benzodiazepines)
- Mental health comorbidities that can worsen with opioid therapy (e.g., PTSD, depression, anxiety)

Urine Tox Results in Chronic Pain Patients on Opioid Therapy



Source: Couto JE, Goldfarb NI, Leider HL, Romney MC, Sharma S. High rates of inappropriate drug use in the chronic pain population. *Popul Health Manag.* 2009;12(4):185–190.

Dose and Overdose Risk

- Dasgupta et al. (2015) compared residents of North Carolina who had received an opioid prescription in the last year to residents who had not
- Of 629 individuals with an opioid overdose death, 151 (24%) had no record of having been dispensed an opioid
- Of the 478 patients who died from an opioid overdose who were prescribed opioids, 235 (49%) had been prescribed <80 mg MEDD
- Overdose incidence rate ratios (IRRs) doubled each time the MEDD ranges increase from 60.0-79.9 mg to 80.0-99.9 mg (IRR 2.9 to 6.2), then to 120-139.9 mg (IRR 14.1), 160-179.9 mg (IRR 29.5), and 350-399.9 mg (IRR 63.2)

- Incidence rate ratio (IRR) - Incidence rate ratio is the ratio of two incidence rates. The incidence rate is defined as number of events divided by the person-time at risk. To calculate the IRR, the incidence rate among the exposed portion of the population, divided by the incidence rate in the unexposed portion of the population, gives a relative measure (IRR) of the effect of a given exposure and approximates the relative risk or the odds ratio if the occurrences are rare

Subgroups at Higher Risk

- Each 50 mg increase in MEDD nearly doubled the odds while each 100 mg MEDD increase tripled the risk for OUD.
- Concurrent prescribing of sedative-hypnotics and benzodiazepines increases risk of fatal or non-fatal opioid overdose 2-10 fold across opioid dose ranges
- In patients receiving LOT, moderate quality evidence indicated that men are 50% more likely to escalate to high-dose opioids (defined as >200 mg MEDD) and twice as likely to experience an opioid-related death compared to women

Subgroups at Higher Risk

- Risk of prescription opioid overdose is elevated across MEDD dosage levels in patients with co-occurring depression
- A history of or active SUD increases risk for serious prescription opioid-related toxicity or overdose across opioid dosages
- A retrospective cohort review of patients with CNCP receiving LOT at least five days per week for 90 days determined that those with a history of non-opioid SUD had 28 times the odds of developing OUD

Opioid Taper

- **Strongly caution patients that it takes as little as a week to lose tolerance to their prior opioid dose and that they are at risk of an overdose if they resume their prior dose.**
- Clinicians should also educate the patient/family about acute and protracted opioid withdrawal symptoms and provide treatment strategies to mitigate these symptoms as appropriate
- To foster patient engagement with the taper plan, clear written and verbal instructions should be given to the patient/family regarding the tapering protocol, strategies to mitigate withdrawal symptoms, and additional non-opioid treatments for the patient's pain condition
- Regardless of the initial speed of taper, the rate of taper may need to be adjusted during the course of lowering the opioid dose
- The pace of taper should be reevaluated after each dose change

Rate of Taper

- The rate of taper takes into account many factors that include initial dose, formulations available, and risk factors that increase harm.
- A gradual taper over months or even years for patients starting on very high opioid doses involves reducing by 5-20% every four weeks.
- In some patients, a faster taper may be needed when risks are too high to consider a gradual taper; consider tapering the dose by 5-20% per week in this patient population.
- When it is determined that patient risks are significantly high to warrant a rapid taper over a period of days or weeks, then specialty consultation should be obtained to determine the rate of taper and resources needed.
- These patients will need frequent follow-up and reevaluation of SUD, mental health, and/or co-occurring medical conditions with every dose change.

Naloxone

- Overdose education should be provided and naloxone should be offered as an antidote to all patients at risk for an opioid overdose including those who are in the process of tapering.
- During and following an opioid taper, patients may still be using opioids from other sources such as saved opioids, other prescribers, friends and family, as well as illicit sources.
- Continued surveillance for OUD and assessment for naloxone is suggested in patients who are no longer on opioids but who remain at risk for opioid use from unknown sources.

OUD

- It is important to recognize that some patients who are undergoing an opioid taper may experience symptoms of OUD that were not present or had not been previously identified prior to the taper.
- Opioid prescribers and the treatment team should remain vigilant for signs and symptoms of OUD for patients receiving LOT; particular attention is warranted during the tapering process.
- When there is concern for OUD or other SUD in a patient undergoing opioid tapering, clinicians should recommend SUD assessment and treatment to the patient in a setting that corresponds to the patient's level of risk and availability of services, while considering patient preferences
- The possibility exists that some patients may be able to be seen in the primary care setting while others may be more appropriate for specialty care.

OUD and Mental Health

- Patients on LOT with OUD are at increased risk of overdose when opioids are either continued or discontinued without appropriate treatment for OUD.
- We recommend MAT for OUD (e.g., MAT using methadone, buprenorphine/naloxone, or ER injectable naltrexone)
- Underlying mental health disorders may be exacerbated by opioid use and/or opioid tapering and may require ongoing interdisciplinary care that includes mental health services

Opioid Guidelines

- Reflect review of the data that indicates significant risks with no evidence of long term benefit
- Risks include higher risks of overdose and the development of opioid use disorder than previously recognized
- Initiation of opioid therapy is discouraged in both the CDC and VA/DoD Guidelines
- Addressing OUD and Opioid dependence during the tapering process will be needed moving forward
- A biopsychosocial Assessment, Self care techniques, non pharmacologic and non opioid pharmacologic therapies are the mainstay of chronic pain evaluation and treatment.

Sometimes Innovation Requires Taking a Deep Breath and Moving On

