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The Time Has Come:
**Identification and Treatment of
OPIOID USE
DISORDER**

Tuesday, September 12, 2017

San Antonio, TX

Activity Chair

Brent Boyett, DMD, DO, FAAFP, ABAM

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Opioid Use Disorder: A Growing Problem

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Medical Director
NBA/NBPA Player Assistance/Anti-Drug Program
Birmingham, AL

The Opioid Crisis: An Epidemic in Three Stages...



Stage One

Prescription Opioids: Doctor as Drug Dealer



Physician Given Second Chance Gets 10 Years on Opioid Charges
medscape.com



Office of Public Affairs

FOR IMMEDIATE RELEASE Monday, January 30, 2017

Ohio Doctor Pleads Guilty to Running South Side Medical Center as Drug Premises and Evading More Than \$3.5 Million in Taxes

Government seizes more than \$29 million in proceeds

Today the government unsealed a plea agreement with the owner and operator of Columbus Southern Medical Center, which provided unlawful prescriptions of controlled substances to addicts throughout the Midwest and who engaged in a series of schemes to evade more than \$3.5 million in taxes, announced Acting Deputy Assistant Attorney General Stuart M. Goldberg of the Justice Department's Tax Division and U.S. Attorney Benjamin C. Glassman for the Southern District of Ohio.

Kevin B. Lake, 50, of New Albany, Ohio, pleaded guilty to drug, tax and fraud charges and agreed to the forfeiture of what remains from the \$29 million in seized funds earned from the clinic's illegal activities, after restitution is paid from the funds.

Prescription Opioids

- Highly addictive
 - Kill pain
 - Incredible euphoria
 - Relieve anxiety
- Lethal in overdose

Opioids Have Consequences

- Diversion
- Misuse
- Non-medical use
- Addiction
- Overdose
- Overdose death
- Psychomotor (small effects)
- Hypogonadism in men
- Drowsiness
- Falls/Fractures
- Depression
- Opioid Bowel Dysfunction

Opioid Efficacy: Overrated?

- Acute/postop pain: Well established for short-term use
 - Analgesic and functional improvement¹⁻³
 - Non-opioids sometimes as good or better^{4,5}
 - Amounts prescribed often more than what is needed⁶
- Long-term use for chronic pain: Uncertain⁷
 - Evidence is weak, mixed
 - Evidence is insufficient
 - Disconnect between guidelines and actual practice

1. Deyo RA, et al. *BMJ*. 2015;350:g6380.

2. American Society of Anesthesiologists. *Anesthesiology*. 2012;116:248-273.

3. American College of Emergency Physicians. Prescribing opioids in the Emergency Department. 2012. Available at: https://www.acep.org/MobileArticle.aspx?id=88136&coll_id=618&parentid=740. Accessed 9/8/17.

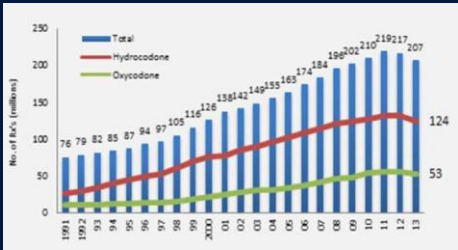
4. Moore PA, et al. *J Am Dent Assoc*. 2013;144(8):898-908.

5. Derry S, et al. *Cochrane Database Syst Rev*. 2013;6:CD010289.

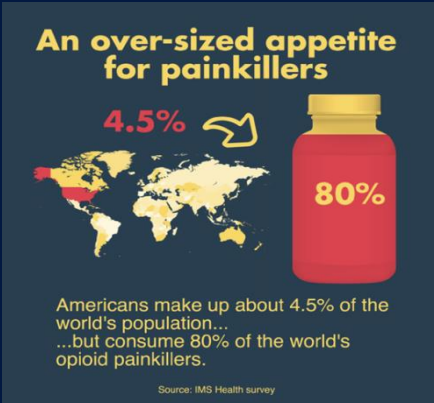
6. Maughan BC, et al. *Drug Alcohol Depend*. 2016;168:328-334.

7. Chou R, et al. *J Pain*. 2009;10(2):147-159.

Epidemiology of The Growing Opioid Epidemic



Opioid Prescriptions Dispensed by US Retail Pharmacies IMS Health, Vector One: National, years 1991-1996, Data Extracted 2011. IMS Health, National Prescription Audit, years 1997-2013, Data Extracted 2014.



Epidemiology of The Growing Opioid Epidemic

- US 5% of world population
80% of world's opioids, 99% of world's hydrocodone¹
- Shopping 0.7% patients prescribed opioids are doctor shoppers²
- Diversion Strong association with OD deaths³
- Misuse 20% of those prescribed^{4,5} ↓ from 2003-2013⁶
Health care costs ↑ close to 9x > general population⁵
33% ↑ misuse if opioid started before 12th grade⁷
- Addiction Prescription opioids: ↑ to 2 million Heroin: ↑ to 0.5 million^{6,8}
Societal costs: \$56 billion Health care costs: \$25 billion⁹

1. Manchikanti L, et al. *Pain Physician*. 2010;13:401-435.

2. McDonald DC, et al. *PLoS One*. 2013;8:e69241.

3. Hall AJ, et al. *JAMA*. 2008;300:2613-2620.

4. Sullivan MD, et al. *Pain*. 2010;150:332-339.

5. Ruetsch C. *J Manag Care Pharm*. 2010;16(1 Suppl B):S9-13.

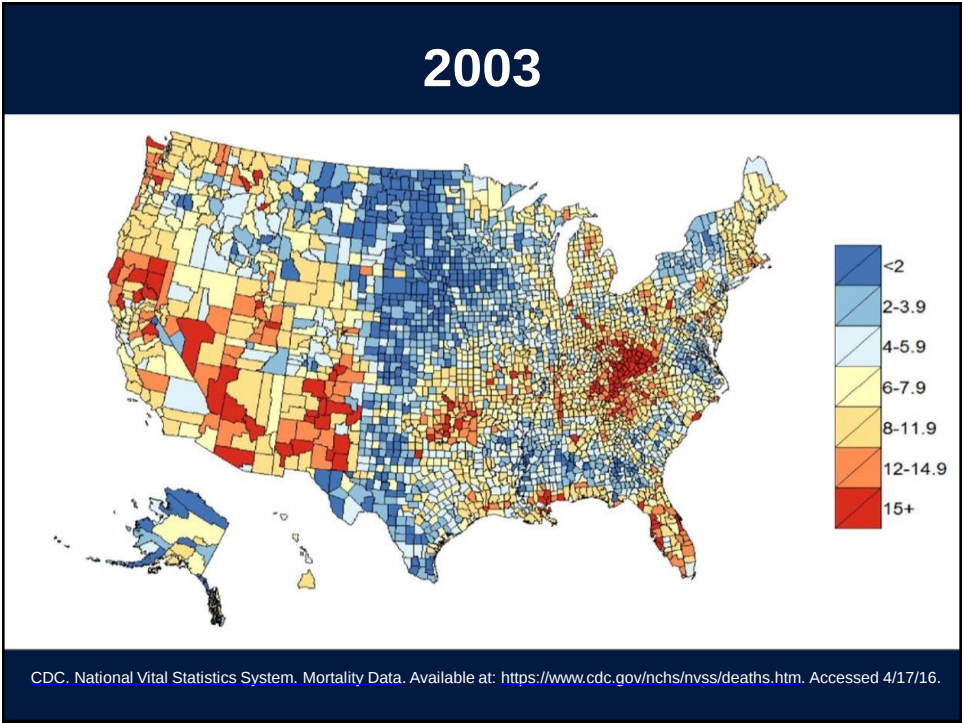
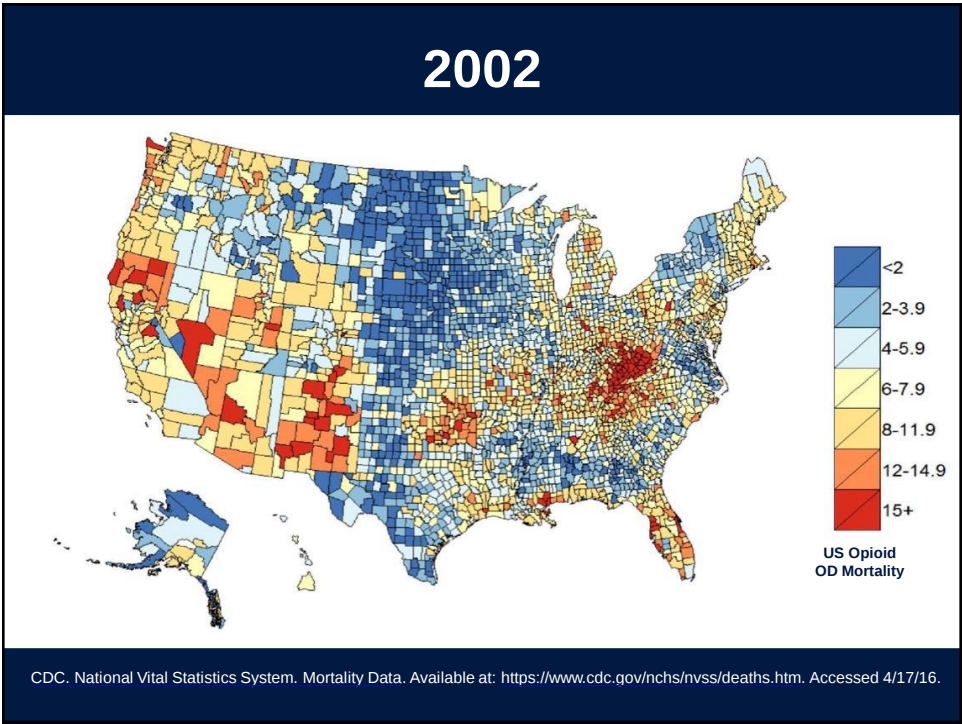
6. Han B, et al. *JAMA*. 2015;314:1468-1478.

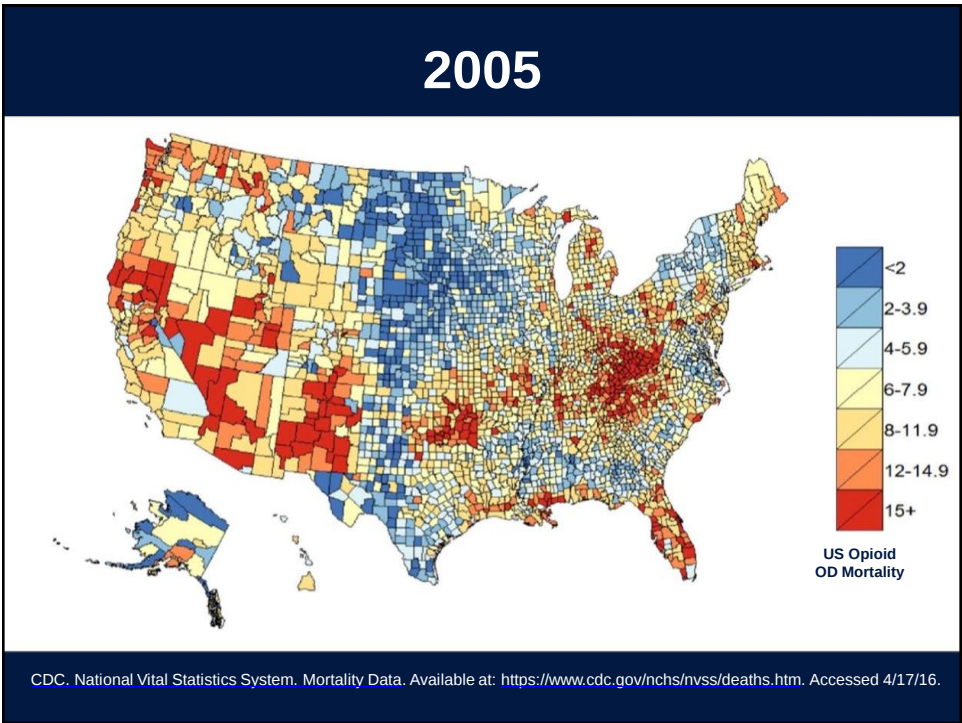
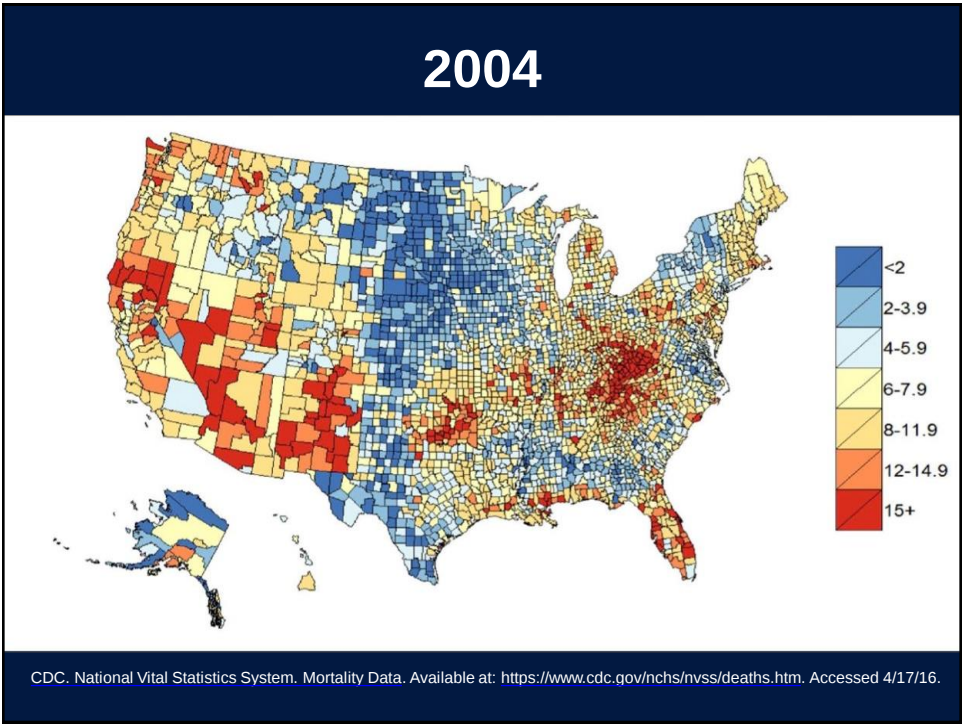
7. Miech R, et al. *Pediatrics*. 2015;136(5):e1169-e1177.

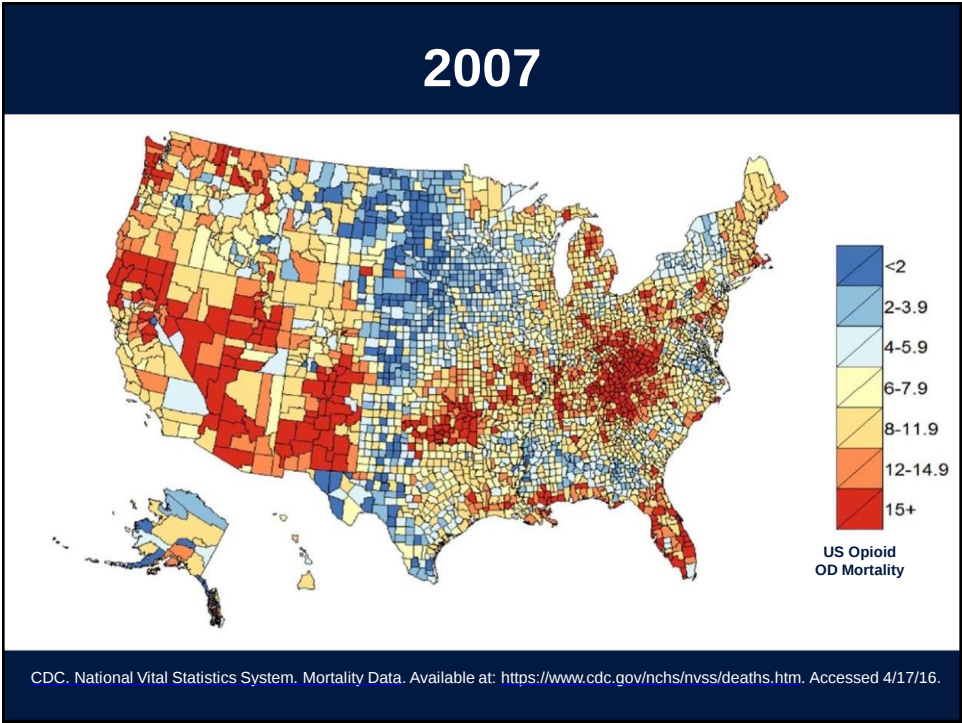
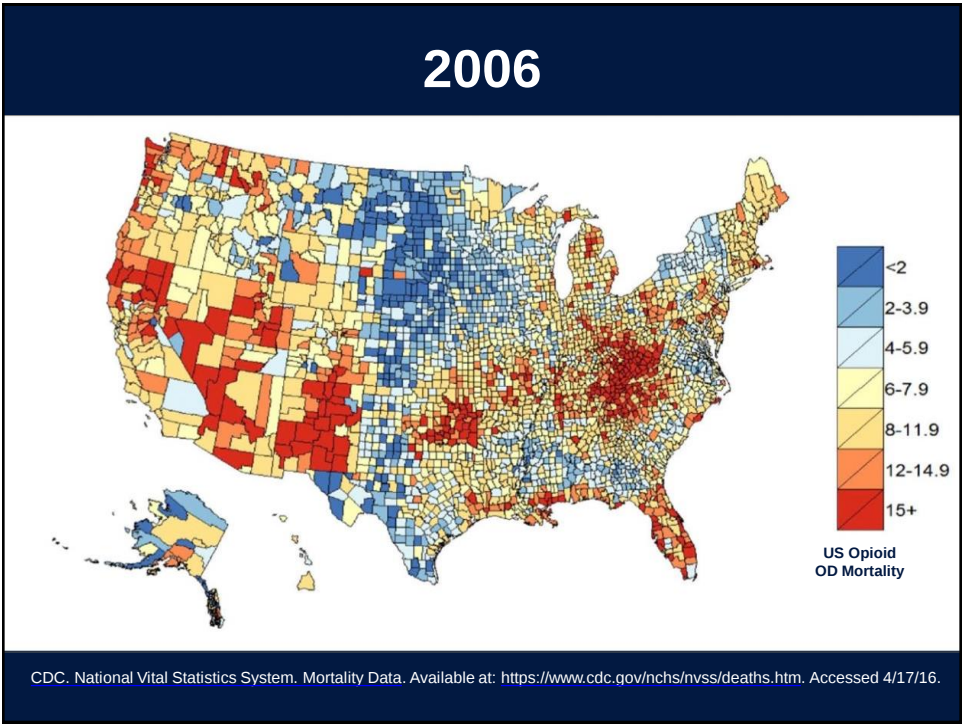
8. SAMHSA. Results from the 2013 National Survey on Drug Use and Health. Available at:

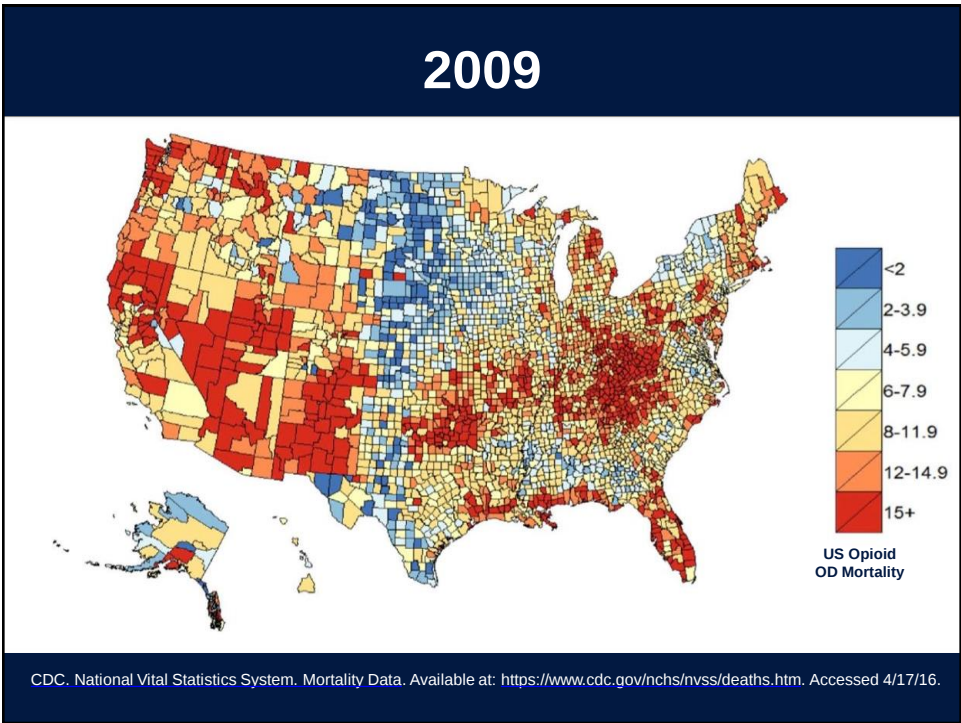
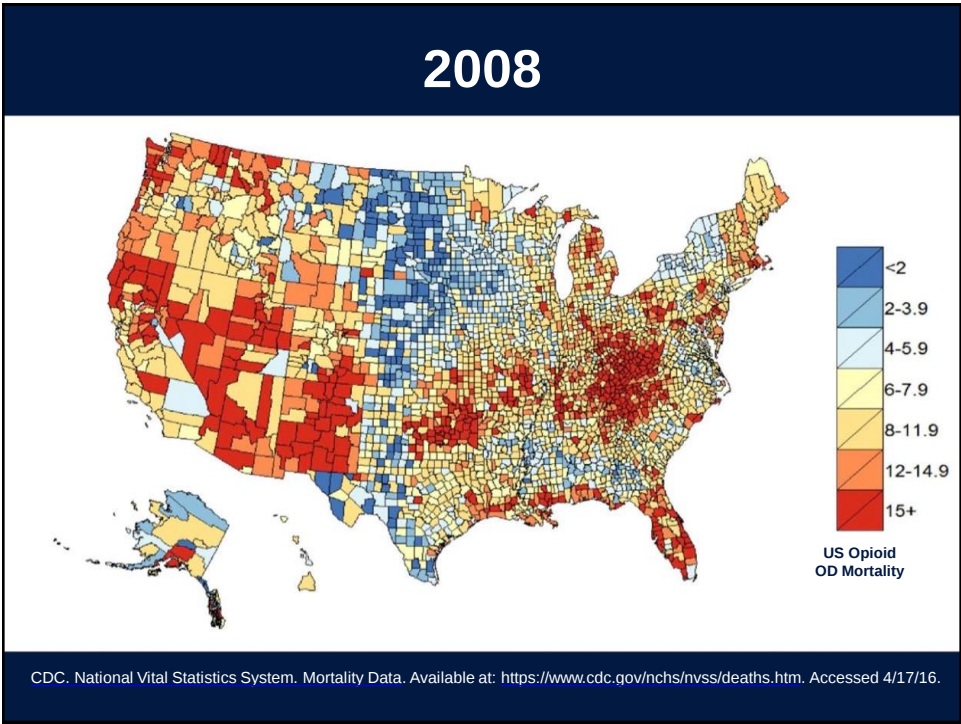
<https://www.samhsa.gov/data/sites/default/files/NSDUHresultsPDEWHTML2013/Web/NSDUHresults2013.pdf>. Accessed 4/3/26.

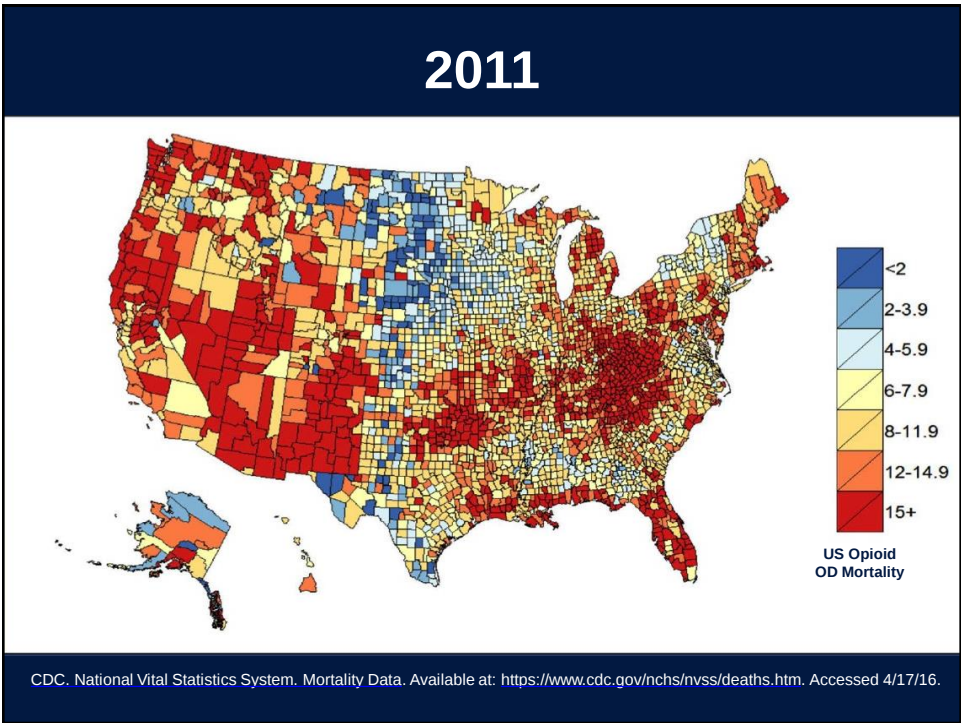
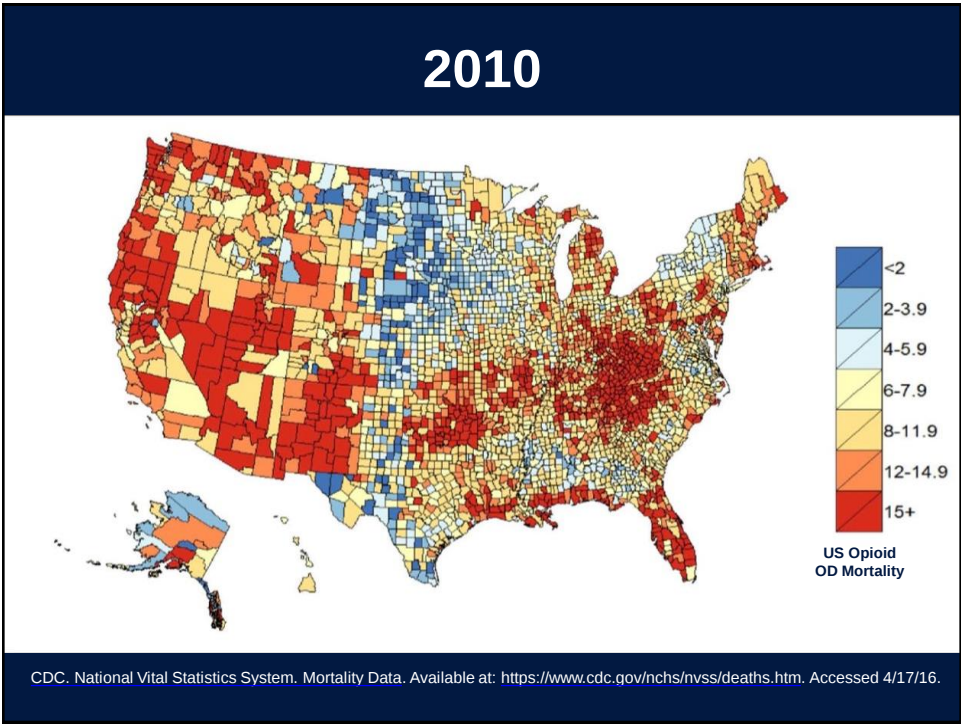
9. Birnbaum HG, et al. *Pain Med*. 2011;12(4):657-667.

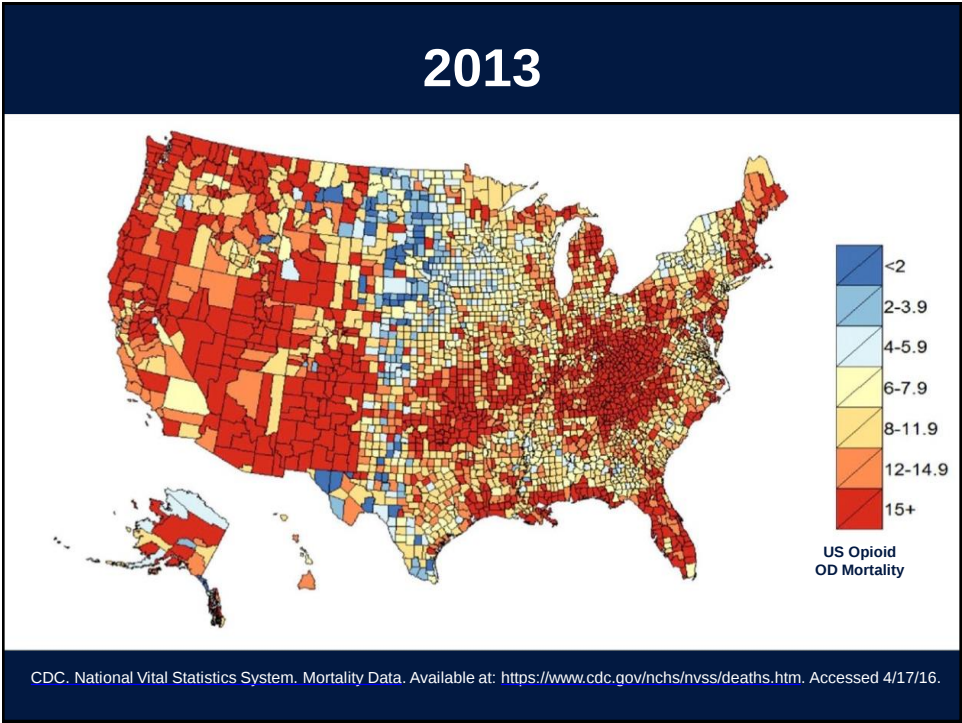
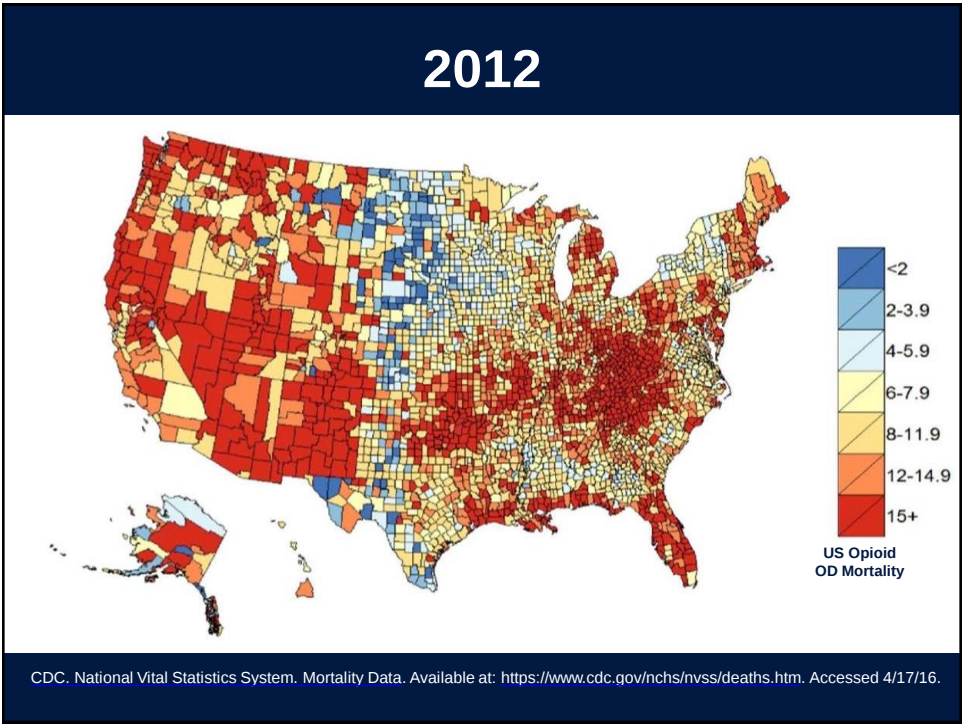












Opioid Overdose Risk Factors Provider-Related

- Prescribing opioids after non-fatal OD
- 91% patients represcribed opioids → 17% repeat OD¹
- Prescribing long-acting opioids^{2,3}
- Co-prescribing respiratory depressants notably benzodiazepines²⁻⁶
- Related to absence of risk monitoring?
 - Not studied

1. Larochelle MR, et al. *Ann Intern Med.* 2016;164:1-9.

2. Manchikanti L, et al. *Pain Physician.* 2012;15(3 Suppl):S1-S65.

3. Zedler B, et al. *Pain Med.* 2014;15:1911-1929.

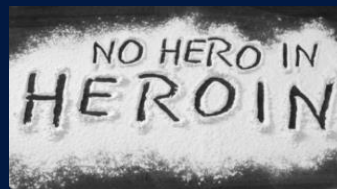
4. Jann M, et al. *J Pharm Pract.* 2014;27:5-16.

5. Shah NA, et al. *Am J Addict.* 2012;21 Suppl 1:S27-S34.

6. Park TW, et al. *BMJ.* 2015;350:h2698.

Stage Two Heroin: An “Unintended Consequence?”

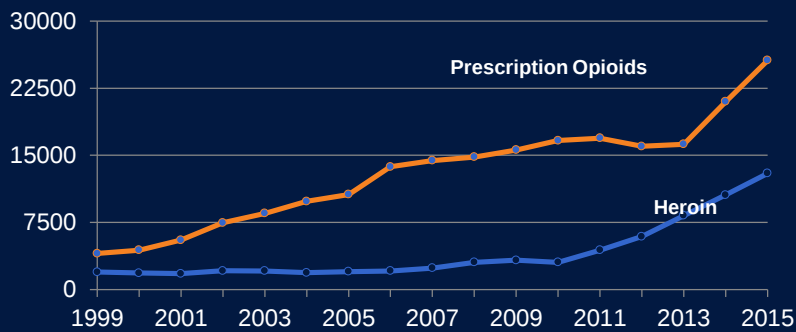
- Nationwide, drug overdoses overall are killing more people than car accidents
- In 2013, ~44,000 people died from drug overdoses — including ~25,000 from opioid painkillers and heroin — while ~30,000 people died in car crashes
- The Centers for Disease Control and Prevention counted 8,257 heroin overdose deaths in 2013, which represents nearly a quadrupling of the heroin death rate from 2000 to 2013, with most of the increase occurring after 2010



<https://www.cdc.gov/nchs/data/databriefs/db190.pdf>

<https://www.fars.nhtsa.dot.gov/Main/index.aspx>

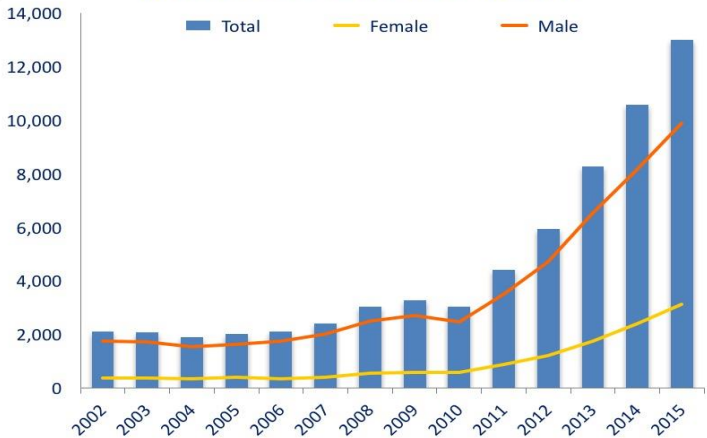
US Opioid Overdose Death



1. Adapted from CDC: Deaths Involving Opioid Analgesics, Heroin. Available at: <https://www.cdc.gov/drugoverdose/data/analysis.html>. Accessed 7/12/16.
2. Rudd RA, et al. *MMWR Morb Mortal Wkly Rep.* 2016;64:1378-1382.



National Overdose Deaths Number of Deaths from Heroin



Source: National Center for Health Statistics, CDC Wonder

Available at: <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates>. Accessed 9/10/17

Stage Three

Fentanyl and Its Analogues: Unprecedented Devastation



Fentanyl Abuse

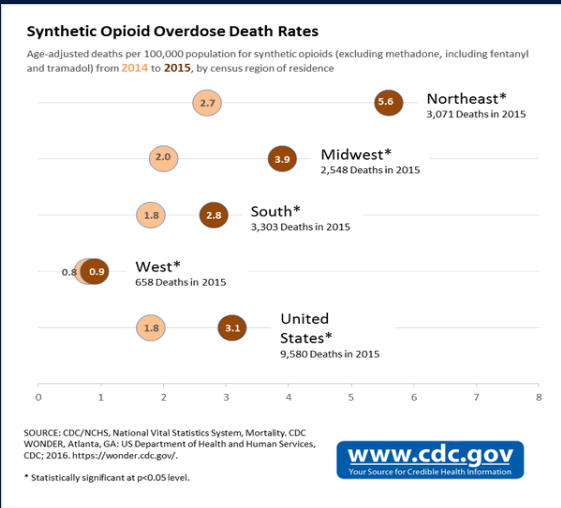
- Fentanyl is a synthetic (man-made) opioid that is 50x more potent than heroin and 100x more potent than morphine.
- The death rate of synthetic opioids other than methadone, which includes drugs such as tramadol and fentanyl, increased by 72.2% from 2014 to 2015.¹
 - Deaths increased across all demographics, regions, and numerous states.
 - Deaths are being driven by increases in fentanyl-involved overdose deaths, which are likely due to illicitly-manufactured fentanyl.^{2,3}

1. Rudd RA, et al. *MMWR Morb Mortal Wkly Rep.* 2016;65(50-51):1445–1452.
2. Gladden RM, et al. *MMWR Morb Mortal Wkly Rep.* 2016;65(33):837-43.
3. Peterson AB, et al. *MMWR Morb Mortal Wkly Rep.* 2016;65(33):844-9.

Synthetic Opioid Death Rates

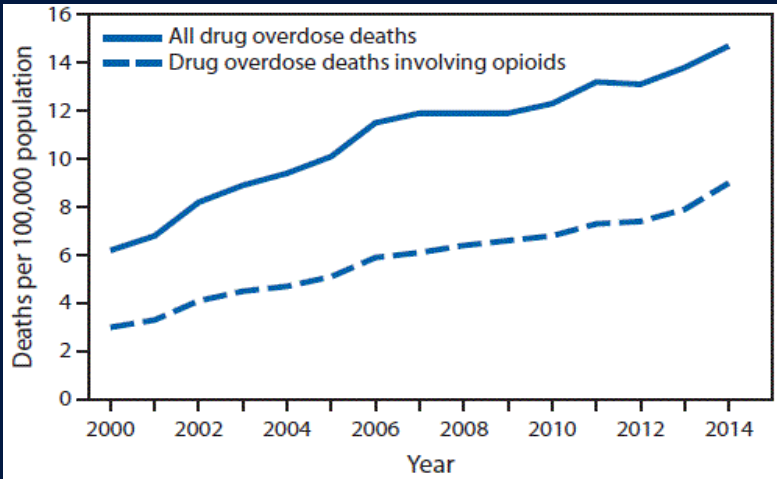
Synthetic opioid death rates increased in all US regions from 2014 to 2015¹ —

- 107.4% in Northeast
- 95% in Midwest
- 55.6% in South
- 12.5% in West



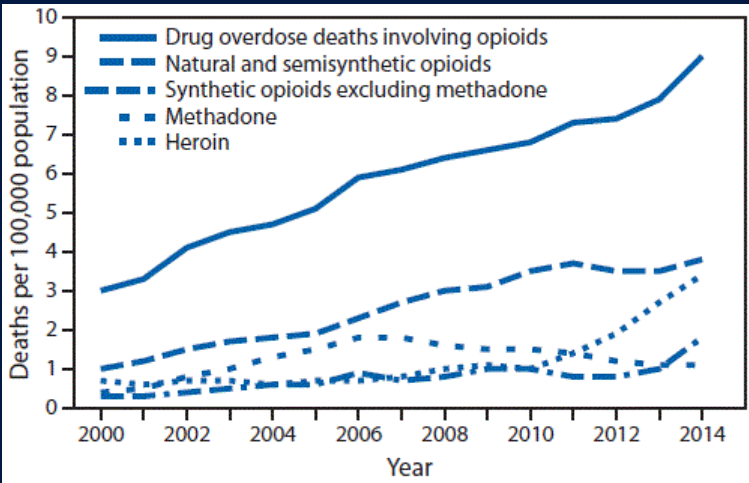
1. Rudd RA, et al. *MMWR Morb Mortal Wkly Rep.* 2016;65(50-51):1445–1452.

Age-adjusted US Drug Overdose Deaths and Drug Overdose Deaths Involving Opioids — 2000–2014



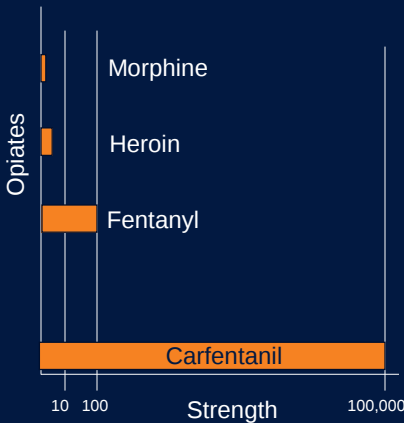
National Vital Statistics System, Mortality File, CDC, *MMWR*, January 1, 2016 / 64(50):1378-82, <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm>

Drug Overdose Deaths Involving Opioids, By Type of Opioid, in the United States During 2000-2014

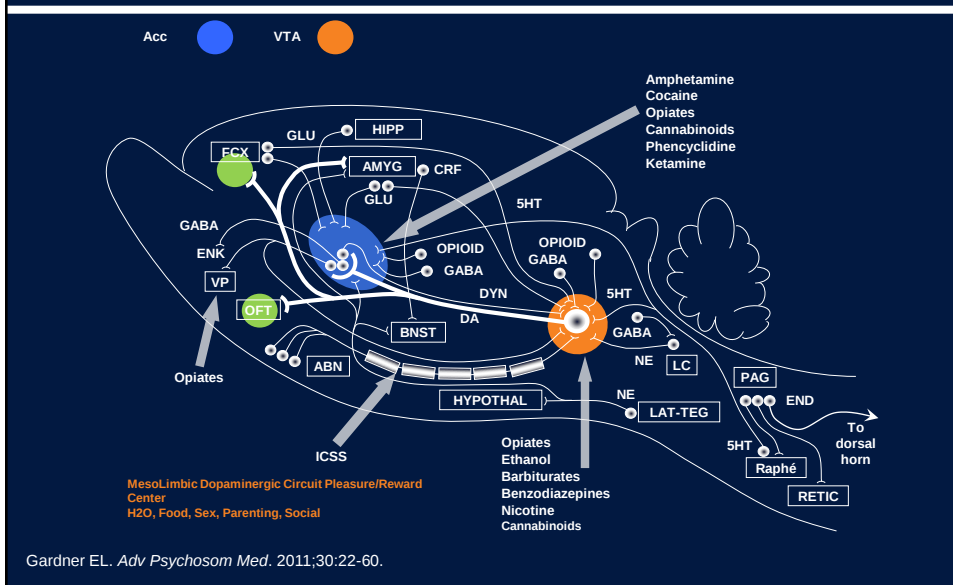


National Vital Statistics System, Mortality File, CDC, MMWR, January 1, 2016 / 64(50):1378-82, <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm>

Fentanyl Analogues: It's Still Getting Worse



Neurobiology of Addiction: Brain Reward Circuitry



2011 ASAM Definition of Addiction

- **Short Definition of Addiction:**
 - Addiction is a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors.
 - Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death.

Adopted by the ASAM Board of Directors April 19, 2011

Available at: <https://www.asam.org/docs/pressreleases/asam-definition-of-addiction-2011-08-15.pdf?sfvrsn=6>. Accessed 9/8/17.

A “User-Friendly” Definition of Addiction

- Addiction is a primary, chronic, relapsing brain disease characterized by:
 - Loss of control over one’s use of a drug
 - Continued use of the drug despite adverse consequences of that drug use
 - Obsessive desire and/or compulsive seeking for the drug
- Its onset is usually in adolescence
- It is treatable and controllable but not usually curable

Risk Factors for Adolescent Addiction Disorders

1. Family History (Genetics and Environment)
 - #1 risk factor → addiction in parent
2. Early Initiation
 - Youths who initiated alcohol use before age 15 → 4x more likely to develop alcohol dependence than those who started after age 20
 - Early patterns more likely to reflect environment; later patterns more likely to reflect genetics¹
3. Spectrum of Externalizing Disorders
 - Genetic risk for youth alcohol and drug problems may be related to the entire spectrum of “externalizing” disorders (e.g., ADHD, “Conduct Disorder,” etc.)
4. Gene-Environment Interaction
 - Childhood stressors (emotional, physical, sexual abuse)
 - Availability and access
 - Peer-group behavior
 - Parental attitudes/monitoring
 - Religiosity (alcohol use among females)

1. Kendler KS, et al. *Arch Gen Psychiatry*. 2008;65(6):674–682.

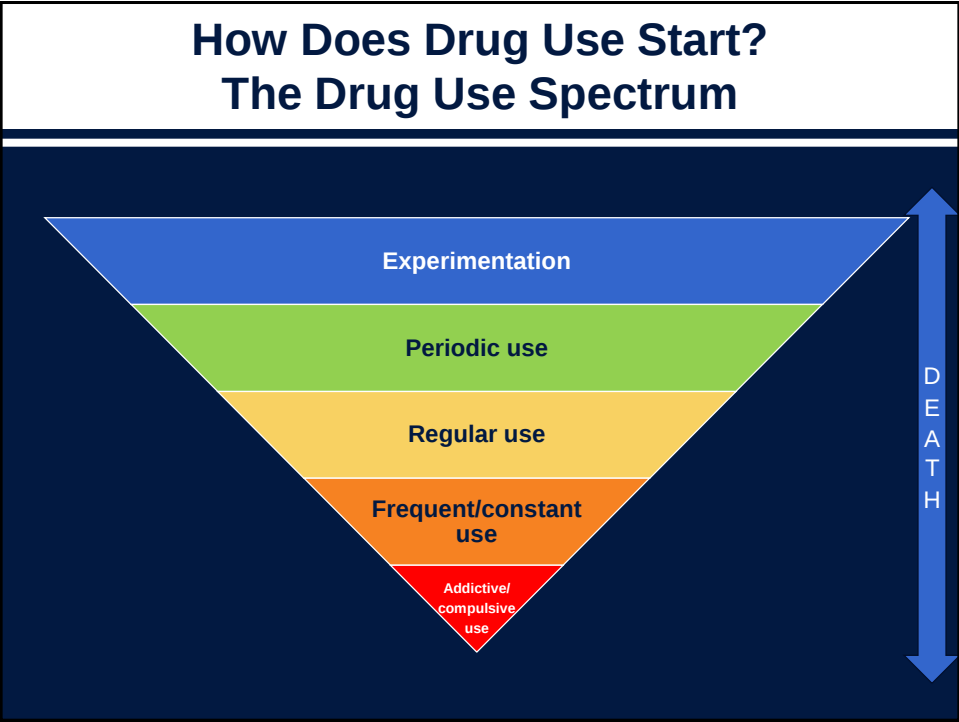
Warning Signs of Teen Drug Use

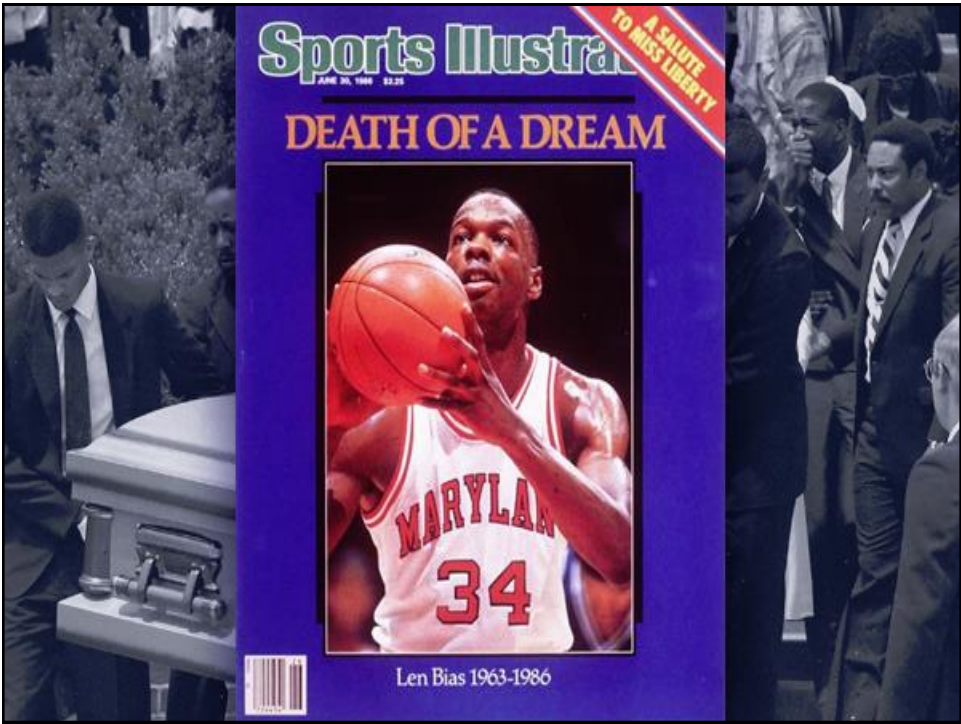
- Physical
 - Fatigue, repeated health complaints, red and glazed eyes, lasting cough
- Emotional
 - Personality change, sudden mood changes, irritability, irresponsible behavior, low self-esteem, poor judgment, depression, general lack of interest
- Family
 - Starting arguments, breaking rules, withdrawing from the family
- School
 - Decreased interest, negative attitude, drop in grades, many absences, truancy, discipline problems
- Social
 - New friends, less interested in “preppie” activities, problems with law, change in style

Chart of Evidence-based Screening Tools for Adults and Adolescents

Screening Tool	Substance Type		Patient Age		How Tool Is Administered	
	Alcohol	Drugs	Adults	Adolescents	Self-administered	Clinician-Administered
PreScreen						
NIDA Drug Use Screening Tool: Quick Screen	X	X	X	See APA Adapted NM ASSIST tools	See APA Adapted NM ASSIST tools	X
CRAFFT (Part A)	X	X		X	X	X
Alcohol Use Disorders Identification Test – C (AUDIT-C)	X		X		X	X
Opioid Risk Tool		X	X		X	
Full Screens						
NIDA Drug Use Screening Tool	X	X	X			X
Alcohol Use Disorders Identification Test (AUDIT)	X		X			X
CAGE-AID	X	X	X			X
CAGE	X		X			X
Drug Abuse Screening Test (DAST-10)		X	X		X	X
CRAFFT	X	X		X	X	X
DAST-20: Adolescent Version		X		X	X	X

<https://www.drugabuse.gov/nidamed-medical-health-professionals/tool-resources-your-practice/screening-assessment-drug-testing-resources/chart-evidence-based-screening-tools-adults>





A High Index of Suspicion, A Low Threshold for Action

Making a difference

Reply all |
Fri 9/16, 8:46 PM

+7 more

... we have received great feedback on the panel presentation at the high school this week. And, wow, what a nice-sized crowd!

Today I spoke to a mother who attended. About a year ago, they became aware of some alcohol & pot use by their teenage son. Since, she said, they have been concerned, but had no evidence of ongoing problems. As a result of attending the panel, she and her husband decided to search his backpack. They found evidence of ongoing and more serious drug use. They spoke to him, he admitted to it, and he's going to get treatment.

Language Matters

- “Abuse” pejorative¹ → Prefer “Nonmedical use”
- “Dependence” ambiguous² → Prefer “Addiction”
- Physical dependence = Tolerance / Withdrawal³
- Person-first language⁴
 - Person with pain ... Not pain patient
 - Person with addiction ... Not addiction patient / addict

1. Saitz R. *J Addict Med*. 2016;10:1-2.

2. Savage SR, et al. *J Pain Symptom Manage*. 2003;26:655-667.

3. WHO. Lexicon of alcohol and drug terms. Available at: http://www.who.int/substance_abuse/terminology/who_ladt/en/. Accessed 4/2/16.

4. CDC. Communicating with and about people with disabilities. Available at: https://www.cdc.gov/ncbddd/disabilityandhealth/pdf/disabilityposter_photos.pdf. Accessed 5/7/16.

The Time Has Come: Identification and Treatment of **OPIOID USE DISORDER**

CASE PRESENTATION

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Addiction, Pseudoaddiction, or Physical Dependence?

Brent Boyett, DMD, DO, FAAFP, ABAM

Founder and Owner
Boyett Health Services
Hamilton, AL
Chief Medical Officer
Pathway Healthcare
Dallas, TX

Case Discussion 1

- 53-year-old male
- 4 years hx of back pain: degenerative disc disease
- 4 years hx of hydrocodone/acetaminophen 7.5/325 mg TID
- Currently on oxycodone/acetaminophen 10/325 mg every 6 hours
 - States “medication just does not work like it used to”
 - Frequently takes 2 at a time for last few months and runs out of meds early
- Tried to convince family doctor to “prescribe something stronger”
- Recently, his doctor sent him a letter of dismissal because of repeated requests for early refills

Case Discussion 1 (cont.)

- Married and owns his own construction company
- Smokes a pack of cigarettes per day
- History of heavy alcohol use in his twenties with one DUI which resulted in the loss of his job
 - No longer uses alcohol
- Does not buy drugs from the street, crush and snort, or inject his opioids
- PDMP Web Search reveals that he has received prescriptions for alprazolam and oxycodone from two separate providers within past six months
- Drug tests positive for opioids and benzodiazepines

The Time Has Come:
**Identification and Treatment of
OPIOID USE
DISORDER**

**PANEL
DISCUSSION**

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Breaking the Barriers to Effective Treatment of OUD

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Medical Director

Mountain Medical Care

Denver, CO

Objectives

- Assess the barriers to treatment of patients with Opioid Use Disorder (OUD) and strategies to improve patients' ability to receive Medication Assisted Treatment (MAT)
- Evaluate current and emerging therapies for OUD based on evidence of safety and efficacy

Types of Barriers

- Treatment system barriers
- Medical provider barriers
- Patient barriers

Treatment System/ Medical Provider Barriers

- Stigma/bias
- Legal/regulatory
- Limited addiction therapy access
 - Workforce adequacy
 - Available service array
 - Lack of parity
 - Cost/coverage
- Limited evidence-based knowledge/application of knowledge
 - Reflecting chronic disease model, outcomes, collaboration, integration, mutual respect
 - Reflecting person-centered, recovery-oriented, cultural, trauma-informed principles
 - Addressing current ethnic/socioeconomic/gender/geographic disparities
 - Role of MAT
 - Focus on safety

Patient Barriers to Treatment

- Stigma/bias
- Feeling or fear of being stigmatized
- Fear of job, relationship losses, or discrimination
- Denial/shame
- Limited understanding of
 - Chronic disease model
 - Recovery-oriented approach
 - Multimodal approach, including the role of MAT
- Access to treatment
 - Availability
 - Cost/coverage

The Physician's Role

- *Not* as sole authorities
- *Part* of multimodal, multidisciplinary treatment
 - Coordination - Collaboration - Communication
 - As a team or coordinated network
 - Preferably integrated with behavioral health
- Active involvement of patients
 - Person-centered treatment
 - Participation and empowerment, not compliance
 - Focused on recovery, safety, quality of life
- Prescriber role is unique

Opioid Use Disorder Treatment

- Mutual help programs
- Addiction therapy
- Medication management

Patient Oriented
NOT
Program Oriented

Opioid Use Disorder Treatment

- Mutual Help Programs
- Addiction therapy*
- Medication management*

Patient Oriented
NOT
Program Oriented

* Addiction treatment services are those provided professionally
American Society of Addiction Medicine. Public Policy Statement on Treatment for Alcohol and Other Drug Addiction. 2010.
Available at: <https://www.asam.org/docs/default-source/public-policy-statements/1treatment-4-aod-1-10.pdf>. Accessed 7/16/16.

Mutual Help Programs

- Not *self* help but rather *mutual* help
- 12-step or other formats
- Peer recovery coaching¹
 - Narcotics Anonymous
 - Pills Anonymous or Prescriptions Anonymous
 - Alcoholics Anonymous
 - Effective²⁻¹³
 - Accessible
 - Minimum dose: Weekly⁹⁻¹¹
 - Inexpensive

Professional Role:
12-step Facilitation

1. SAMHSA. What are peer recovery support services? 2009. Available at: <https://store.samhsa.gov/shin/content/SMA09-4454/SMA09-4454.pdf>. Accessed 7/19/16.

2. Gossop NA. *Addiction*. 2008;103:119-125.

3. Humphreys K, et al. *Alcohol Clin Exp Res*. 2007;31:64-68.

4. Kelly JF, et al. *Drug Alcohol Depend*. 2013;129:151-157.

5. Kelly JF, et al. *Drug Alcohol Depend*. 2010;110:117-125.

6. Vederhus JK, et al. *BMC Psychiatry*. 2006;6:35.

7. Kaskutas LA. *J Addict Dis*. 2009;28:145-157.

8. Krentzman AR, et al. *Alcohol Treat Q*. 2010;29:75-84.

9. Hoffman NG, et al. *Psychiatr Clin North Am*. 1993;16:127-140.

10. Witbrodt J, et al. *J Sub Abuse Treat*. 2012;43:30-43.

11. Humphreys K, et al. *J Subst Abuse Treat*. 2004;26:151-158.

12. Cloud RN, et al. *Recent Dev Alcohol*. 2008;18:283-301.

13. Monterosso J, et al. *Drug Alcohol Depend*. 2007;90 Suppl 1:S100-S111.

Addiction Therapy

- Motivational Enhancement Therapy (MET)
- Cognitive Behavioral Therapy (CBT)
- Supportive-Expressive Therapy
- Contingency Management
- Trigger Management
- Network Therapy
- Peer Coaching
- Social Support
- Drug Court

Addiction Therapy Efficacy

- 2 RCTs for OUD: Beneficial results^{1,2}
- RCTs for “substance” or “drug” abuse: Beneficial results³⁻¹⁰
- Meta-analyses: Effect size varies
 - Very strong⁴ Meaningful⁵ Small^{6,7}
 - Benefit tends to ↓ over time⁵
 - Moderators of benefit uncertain⁷
- Guideline supported with reservation^{11,12}

1. McAuliffe WE. *J Psychoactive Drugs*. 1990;22:197-209.

2. Bickel WK, et al. *J Consult Clin Psychol*. 1997;65:803-810.

3. Azrin NH, et al. *Behav Res Ther*. 1994;32(8):857-866.

4. Windsor LC, et al. *Cultur Divers Ethnic Minor Psych*. 2015;21(2):300-313.

5. Waldron HB, et al. *Addiction*. 2004;99 Suppl 2:93-105.

6. Magill M, et al. *J Stud Alcohol Drugs*. 2009;70(4):516-527.

7. Blodgett JC, et al. *J Sub Abuse Treat*. 2014;46(2):87-97.

8. Schumacher JE. *J Ment Health Policy Econ*. 2002;5(1):33-42.

9. Woody GE. *Arch Gen Psychiatry*. 1983;40(6):639-645.

10. Kaminer Y. *Curr Psychiatry Rep*. 2002;4(5):397-401.

11. National Institute for Health Care and Excellence (NICE). Drug misuse in over 16s: psychosocial interventions. 2007. Available at: <https://www.nice.org.uk/guidance/cg51>. Accessed 7/16/16.

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Medication Management

- Withdrawal meds: Preparation for treatment
 - Adjunctive symptom meds: Post-acute withdrawal
 - Anti-craving meds: Primary medication management
- Medication Assisted Treatment (MAT)**

Medication Management Opioid Withdrawal

- Opioid withdrawal (WD) symptoms^{1,2}
 - Yawning, shakes, sweats, rhinorrhea
 - Pain: Generalized, abdomen, back
 - GI: Nausea, vomiting, diarrhea
 - Restlessness, anxiety, insomnia
 - ↑ pupils, HR, BP
- Opioid WD using opioids
 - Opioid initiated → tapered off
 - Methadone⁵⁻⁹
 - Buprenorphine⁷⁻¹³
 - Tramadol^{6,9,13}
- Adults: Feels life-threatening, almost never is
- Neonates: Can be life-threatening, death rare^{3,4}

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Medication Management Opioid Withdrawal

- Supported abrupt withdrawal - **Tapering unlikely to work if addicted**
- Monitor severity with Clinical Opioid Withdrawal Scale (COWS)^{1,2}
- Withdrawal meds given PRN; symptoms expected over 5 days³⁻⁵
 - Up to 3 weeks for buprenorphine and methadone
 - **Avoid benzodiazepines**

Pain	<u>Naproxen</u>	220 mg	PO	#20
Back spasm	<u>Cyclobenzaprine</u>	10 mg	PO	#20
Abdominal cramps	<u>Hyoscyamine</u>	0.0125 mg	SL	#20
Shakes/sweats	<u>Clonidine</u> ⁵⁻⁸	0.1 mg	PO	#20

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2. Wesson DR, et al. *J Psychoactive Drugs*. 2003;35(2):253-259.

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FDA-Approved Medications for MAT

- Methadone Full mu-opioid agonist
- Buprenorphine Partial mu-opioid agonist
- Naltrexone Mu-opioid antagonist
- Buprenorphine/naloxone combination

Methadone

- Schedule II
- Full mu-opioid agonist¹
- Long duration of clinical action for opioid addiction
- Approved for opioid addiction²
 - Supervised oral administration²
- Requires SAMHSA certification as Opioid Treatment Program (OTP)^{2,3}
 - Cannot prescribe for opioid addiction unless from within OTP
- Locate Methadone Opioid Treatment Program

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3. SAMHSA. Application for OTP certification. <https://www.samhsa.gov/medication-assisted-treatment/opioid-treatment-programs/apply>. Accessed 7/22/16.

Methadone for Opioid Addiction

- Effective¹⁻⁹ and guideline supported¹⁰⁻¹⁵
- Initiation: Progressively increased supervised PO QD dosing¹³⁻¹⁶
- Maintenance: 60 mg to 100 mg PO QD, sometimes higher¹⁵⁻¹⁹
- Duration of use: Indefinite individualized²⁰
- Discontinuation: By tapering over months^{20,21}
 - Abrupt withdrawal: WD symptoms last 3 to 4 weeks

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use and substance use disorders in pregnancy. 2014. Available at:

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17. Eap CB, et al. *Clin Pharmacokinet*. 2002;41(14):1153-1193.

18. Fared A, et al. *J Addict Dis*. 2010;29(1):1-14.

19. Farré M, et al. *Drug Alcohol Depend*. 2002;65(3):283-290.

20. Winstock AR, et al. *Int J Drug Policy*. 2011;22(1):77-81.

21. Senay EC, et al. *Arch Gen Psych*. 1977;34:361-367.

Methadone Adverse Reactions

- GI: Nausea, vomiting, abdominal pain, constipation¹
- Overdose death high, ↑ with CNS depressants²⁻⁸
- Respiratory depression⁹⁻¹¹
 - ↑ with CNS depressants
 - Resuscitate with naloxone by bolus
- QT ↑ → Torsades de Pointes, raised with other meds¹²⁻¹⁴

1. Pergolizzi JV Jr. *Pain Med News*. August 27, 2015.

2. CDC. *MMWR Morb Mortal Wkly Rep*. 2012;61:493-497.

3. Rudd RA, et al. *MMWR Morb Mortal Wkly Rep*. 2016;64:1378-1382.

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12. Chou R, et al. *J Pain*. 2014;15(4):338-365.

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Methadone Adverse Reactions

- CNS: HA, dizziness, confusion, dyscognition, psychomotor¹⁻⁴
- More than 50 drug-to-drug interactions^{5,6} in part related to:
 - Concurrent sedating meds like benzodiazepines
 - 90% protein binding
 - P450 metabolism: 8 enzymatic sites
- Nonmedical use: Addiction, diversion⁷⁻⁹
- Neonatal abstinence syndrome¹⁰⁻¹²
- Accidental childhood ingestion¹³

Partial
List

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2. Loeber S, et al. *Am J Drug Abuse*. 2008;34(5):584-593.
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8. Surrat H, et al. Street prices of Rx opioids. Pain Week Abstracts. 2012. Available at: <https://www.painweek.org/assets/documents/general/572-painweek2012abstracts.pdf>.
9. Maxwell JC, et al. *Am J Addict*. 2010;19(1):73-88.
10. Minozzi S, et al. *Cochrane Database Syst Rev*. 2013;12:CD006318.
11. Lund IO, et al. *Subst Abuse*. 2013;7:61-74.
12. Bagley SM, et al. *Addict Sci Clin Pract*. 2014;9(1):19.
13. Martin TC, et al. *Curr Drug Saf*. 2011;6(1):12-16.

Buprenorphine

- Schedule III¹
- Partial mu agonist: High affinity, slow dissociation, low intrinsic activity^{2,3}
- Long duration of clinical action for addiction^{2,4-7}
- Approved for opioid addiction as:
 - Single agent: Sublingual “mono” tablet or implant
 - Combination (4:1 buprenorphine/naloxone): Oral mucosal tablet or film^{2,7}
 - Induction and maintenance treatment
- Requires FDA waiver to prescribe⁸
- Locate physicians waived to prescribe or waived + providing implant

1. Drug Enforcement Administration (DEA). *Fed Regist*. 2002;67(194):62354-62370.
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Buprenorphine for Opioid Addiction

- Effective¹⁻⁹ and guideline supported¹⁰⁻¹⁴
- Initiation: Induction of the patient in withdrawal ^{12,15-17}
- Maintenance: Transmucosal 2 to 24 mg QD^{12,15,16} or implant¹⁸⁻²⁰
- Duration of use: Individualized, indefinite^{15,21,22}
- Discontinuation: By taper over months²²⁻²⁴
 - Abrupt withdrawal: WD symptoms over 3 to 4 weeks

1. Jasinski DR, et al. *Arch Gen Psychiatry*. 1978;35(4):501-516.
2. Mattick RP, et al. *Cochrane Database Syst Rev*. 2014;2:CD0002207.
3. Minozzi S, et al. *Cochrane Database Syst Rev*. 2013;12:CD006318.
4. Nielsen S, et al. *Cochrane Database Syst Rev*. 2016;5:CD011117.
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7. Clay E, et al. *J Med Econ*. 2014;17(9):626-636.
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13. Farmer CM, et al. *Subst Abuse*. 2015;36:209-216.
14. Donaher PA, et al. *Am Fam Physician*. 2006;73:1573-1578.
15. Ling W. *Pain Manag*. 2012;2:345-350.
16. Nielsen S. *J Subst Abuse Treat*. 2015;48:70-76.
17. Khemiri A, et al. *Postgrad Med*. 2014;126:113-120.
18. Rosenthal RN, et al. *JAMA*. 2016;316:282-290.
19. Ling W, et al. *JAMA*. 2010;304:1576-1583.
20. Weiss RD. *Drug Alcohol Depend*. 2014;140:118-122.
21. Bentley BS, et al. *J Sub Abuse Treat*. 2015;52:48-57.
22. Sigmon SC, et al. *JAMA Psychiatry*. 2013;70:1347-1354.
23. Dunn KE, et al. *Drug Alcohol Depend*. 2011;119:1-9.
24. Marinelli P, et al. *Drug Alcohol Depend*. 2014;138:83-88.

Buprenorphine: Transmucosal

- Buprenorphine
 - 30% to 60% bioavailable¹
 - Reduces opioid withdrawal and craving²
 - Blocks effects of other opioids used while on buprenorphine^{3,4}
 - Precipitates withdrawal if on other opioids when started⁵
 - Produces physical dependence⁶
- Naloxone in combination product
 - 7% bioavailable⁷
 - Without altering buprenorphine effect^{2,4,7,8}
 - 100% bioavailable if injected⁷
 - To deter abuse - not FDA-labeled as abuse deterrent^{2,4,7,8}

1. Kuhlman JJ Jr, et al. *J Anal Toxicol*. 1996;20:369-378.
2. Ling W. *Pain Manag*. 2012;2:345-350.
3. Walsh SL, et al. *J Pharm Exp Ther*. 1995;274:361-372.
4. Strain EC, et al. *Psychopharmacology (Berlin)*. 2002;159:161-166.

5. Rosado J, et al. *Drug Alcohol Depend*. 2007;90:261-269.
6. Eissenberg T. *J Pharmacol Exp Ther*. 1996;276(2):449-459.
7. Orman JS, et al. *Drugs*. 2009;69(5):577-607.
8. Harris DS, et al. *Clin Pharmacokinet*. 2004;43:329-340.

Buprenorphine Adverse Reactions

- GI: Nausea, vomiting, abdominal pain, constipation¹
- Overdose death rare: ↑ with CNS depressants^{2,4}
- Respiratory: ↓ despite ceiling effect⁵⁻¹¹
 - ↑ with CNS depressants
 - Resuscitate by naloxone by continuous infusion⁵
- QT ↑ not clinically significant^{1,12}

1. Ling W. *Pain Manag.* 2012;2:345-350.
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10. DeVido J, et al. *J Opioid Manag.* 2015;11:363-366.
11. Lee SC, et al. *Drug Alcohol Depend.* 2014;138:118-123.
12. Poole SA, et al. *J Addict Med.* 2016;10:26-33.

Buprenorphine Adverse Reactions

- CNS: Headache, dizziness, confusion, dyscognition, psychomotor¹⁻⁵
- Drug-to-drug interactions^{1,6} in part related to:
 - Concurrent sedating meds
 - 90% protein binding
 - P450 metabolism: 3A4
- Nonmedical use - Addiction, diversion⁷⁻¹²
- Neonatal abstinence program^{13,15}
- Accidental childhood ingestion¹⁶⁻¹⁸

Partial
List

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2. Loeber S, et al. *Am J Drug Abuse.* 2008;34(5):584-593.
3. Soyka M, et al. *J Clin Psychopharmacol.* 2008;28(6):699-703.
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6. McCance-Katz EF, et al. *Am J Addict.* 2010;19:4-16.
7. Lofwall MR, et al. *J Addict Med.* 2014;5:315-326.
8. Middleton LS, et al. *Addiction.* 2011;106:1460-1473.
9. Larance B, et al. *Drug Alcohol Depend.* 2014;136:21-27.

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17. Laronas EJ, et al. *J Pediatr.* 2013;163:1377-1383.
18. Hayes BD, et al. *Pediatrics.* 2008;121(4):e782-e786.

Naltrexone

- Not scheduled
- Competitive mu-opioid antagonist
- Long duration of clinical action for addiction
- Approved for addiction
 - Oral naltrexone for alcohol addiction^{1,2}
 - Depot IM naltrexone for alcohol^{3,4} and opioid addiction^{5,6}
- Locate physicians who can provide

1. Oslin DW, et al. *JAMA Psychiatry*. 2015;72:430-437.

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4. Pettinati HM, et al. *Alcohol Clin Exp Res*. 2011;35:1804-1811.

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6. Krupitsky E, et al. *Addiction*. 2013;108:1628-1637.

Naltrexone for Opioid Addiction

- Oral form: Mixed results^{1,2} Meta-analysis: Ineffective³
- IM depot form effective⁴⁻⁹ Guideline supported¹⁰
- Initiation: Only after opioid withdrawal complete
- Maintenance: Monthly IM depot injection
- Dose: Deep IM gluteal injection 380 mg
- Duration of use: Individualized, indefinite
- Abrupt discontinuation: Not associated with WD

1. Mannelli P, et al. *J Clin Psychopharmacol*. 2007;27(5):468-474.

2. Azarian A, et al. *J Addict Dis*. 1994;13:35-52.

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2015. Available at:

<https://www.healthquality.va.gov/guidelines/MH/sud/VADoDSUDCPGRevised22216.pdf>.

Accessed 7/16/16.

Naltrexone Adverse Events

- Not associated with euphoria, nonmedical use, addiction, OD death, respiratory depression, or accidental childhood exposure
- Precipitates withdrawal if on opioids
- GI: Nausea, vomiting, abdominal pain, constipation, hepatic impairment
- Fatigue, somnolence, sedation, dizziness
- Depression, anxiety, suicidality
- Injection site reactions
- Headaches, myalgias

Partial
List

Comer SD. *Arch Gen Psychiatry*. 2006;63:210-218.
Krupitsky E, et al. *Addiction*. 2013;108:1628-1637.
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Syed YY, et al. *CNS Drugs*. 2013;27:851-861.
Gastfriend DR. *Ann N Y Acad Sci*. 2011;1216:144-166.

OUD Treatment Med Comparisons

- OUD efficacy
 - Methadone = buprenorphine overall¹⁻⁶
 - No studies: Naltrexone versus methadone or buprenorphine
- Adverse events: Methadone > buprenorphine
 - Respiratory depression/overdose⁷
 - Neonatal Abstinence Syndrome^{3,4,8}
 - Cognitive, psychomotor dysfunction⁹⁻¹¹
 - Nonmedical use

Naltrexone without
these adverse events

1. Connock M, et al. *Health Technol Assess*. 2007;11:1-171, iii-iv.
2. Nielsen S, et al. *Cochrane Database Syst Rev*. 2016;5:CD011117.
3. Minozzi S, et al. *Cochrane Database Syst Rev*. 2013;12:CD006318.
4. Lund IO, et al. *Subst Abuse*. 2013;7:61-74.
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10. Soyka M, et al. *J Clin Psychopharmacol*. 2005;25:490-493.
11. Mintzer MZ. *Heroin Addict Relat Clin Probl*. 2007;9:5-24.

OUD Initial Medication Selection

- Consider access, coverage, cost, preference, prior success
- If QTc > 450 → avoid methadone
- If CV instability in WD → consider methadone
- If unable to be abstinent 7 to 10 days → avoid naltrexone
- If severe xerostomia → avoid buprenorphine
- If another SUD co-occurs with OUD → consider naltrexone
 - *Amphetamines^{1,2} *Gambling^{1,3} *Nicotine¹ Alcohol^{1,4}

* Not FDA approved

1. Aboujaoude E, et al. *CNS Drugs*. 2016;30:719-733.

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3. Piquet-Pessôa M, et al. *Expert Opin Pharmacother*. 2016;17:835-844.

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OUD Medication Prescribing Requirements

- Methadone – Patient education
 - DEA registration for Schedule II
 - Federally qualified opioid treatment program
- Naltrexone – Patient education
 - Refrigerator
 - Capacity to inject
- Buprenorphine – Patient education
 - DEA registration for Schedule III
 - FDA waiver for MAT
 - Certification to perform implants, if providing

Buprenorphine: FDA Waiver

- Required to prescribe approved Schedule III, IV, V opioids for addiction¹⁻³
- Requirements⁴
 - State medical license
 - DEA certification to prescribe Schedule III substances
 - Capacity to refer for counseling
 - Record keeping
- Training requirements
 - Physician: 8 hours approved training⁵⁻⁷
 - OR addiction board certification
 - NP/PA: 24 hours approved training
- Patient number limitations
 - 1st year: 30 patients¹
 - 2nd year: 100 patients^{1,8}
 - Thereafter: 275 patients^{1,8}

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Practice Recommendations: OUD Treatment

- Recommend patient involvement in mutual help programs (SORT A)
- Recommend professional addiction therapy (SORT A)
- Treat with methadone, naltrexone, or buprenorphine (SORT A)
- Provide overdose rescue education and naloxone¹⁻⁸ (SORT A)
- Collaborate, co-locate, and integrate with addiction therapy team⁹⁻¹¹ (SORT A)
- Monitor for and respond to continued opioid use (SORT A)

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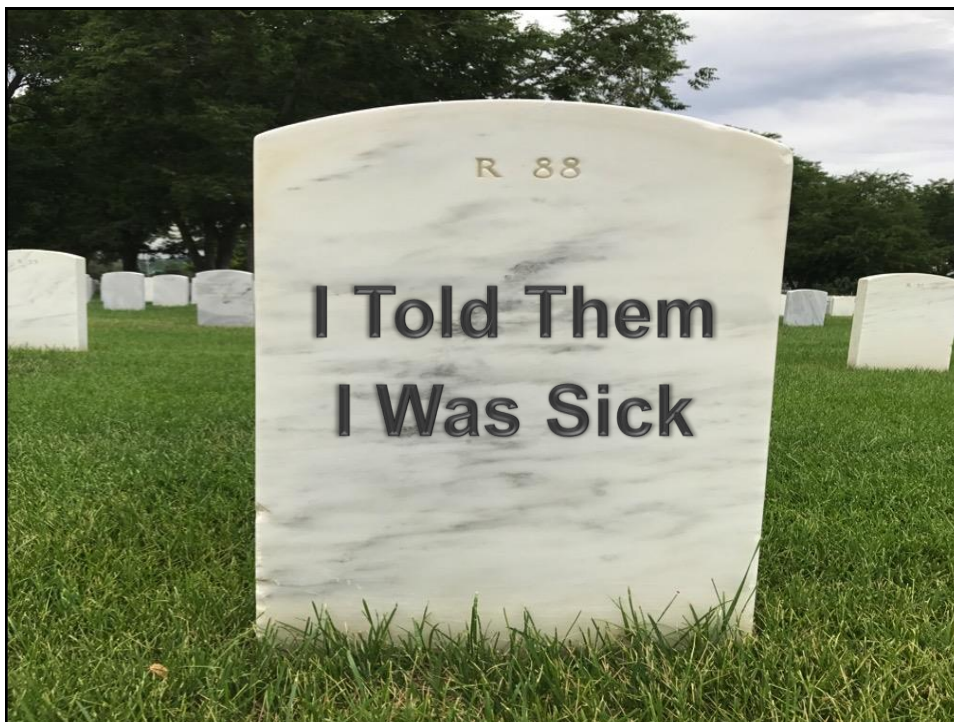
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The Time Has Come:
**Identification and Treatment of
OPIOID USE
DISORDER**

**CASE
PRESENTATION**

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Treatment of OUD

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Case Discussion 2

- 28-year-old female
- Presents with her friend after being rescued from a drug overdose in the ED 3 days ago
- Started using methamphetamine in her early twenties then added prescription pain pills
 - Stopped methamphetamine use after 1 year
 - Continued to use opioid pain medication with increasing dose
 - Began injecting heroin 3 months ago
- When she runs out of opioids, she experiences severe cravings and withdrawal symptoms

Case Discussion 2 (cont.)

- Smokes marijuana frequently to help control cravings when heroin is not available
- Smokes 1 pack per day
 - Smoked her first cigarette at age 13
- No activity on the PDMP
- History of binge drinking as a teenager
 - Now drinks infrequently
 - Has not had more than 3 drinks at a time in over a year
- Physical exam:
 - HR 105
 - BP 132/84
 - Fresh needle tracks in the antecubital area of the left arm
 - Oral exam reveals multiple dental caries and poor oral hygiene
 - Evidence of nicotine stomatitis in the area of her hard palate

The Time Has Come:
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**PANEL
DISCUSSION**

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