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CME Outfitters

Thinking Outside the Box: Novel Strategies to Improve Outcomes in Opioid Use Disorder (OUD)

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2016-2025: Projected Opioid Death Toll

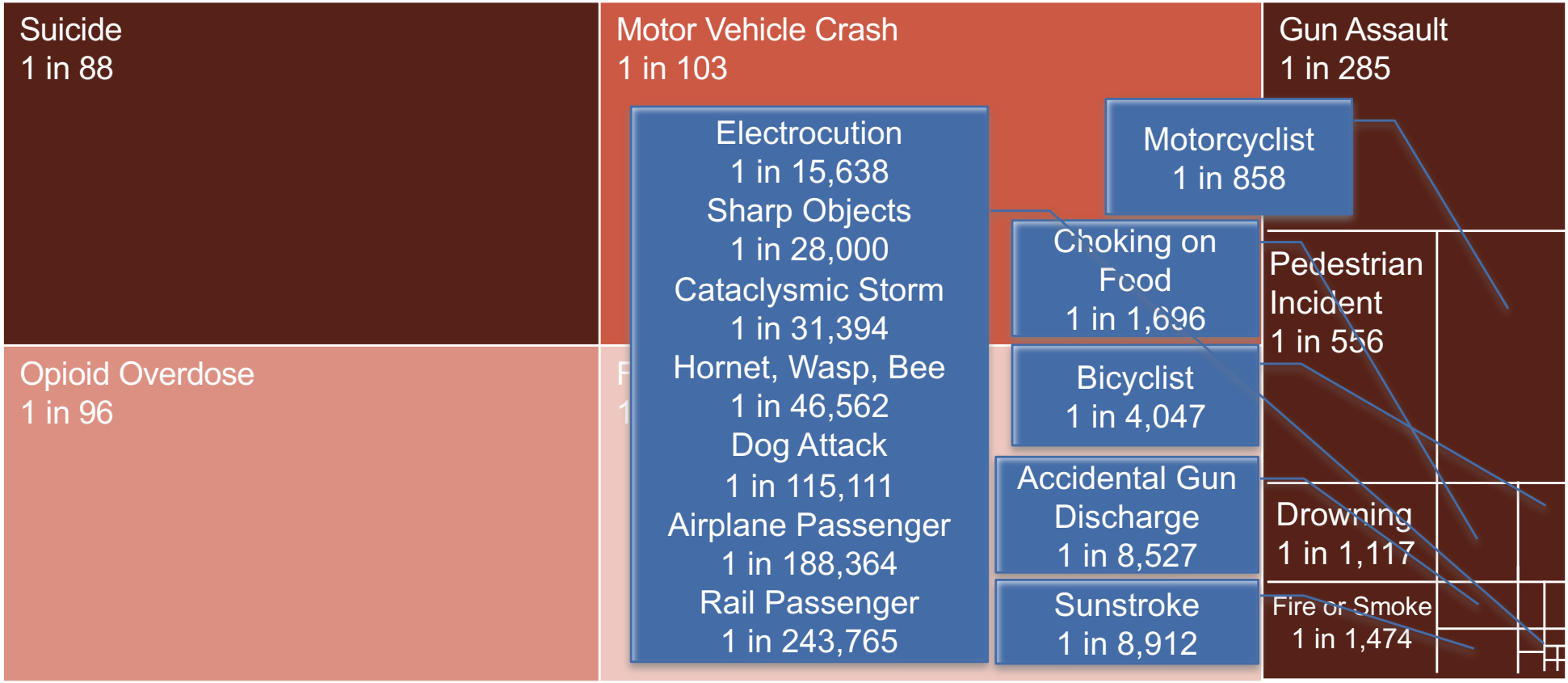
510,000

Deaths if we do nothing

- No single policy is likely to substantially reduce deaths over 5 to 10 years
  - Wider availability of naloxone could reduce opioid-related deaths by 21,200 over 10 years
  - Medication-based treatments for opioid addiction like buprenorphine and methadone would reduce deaths by 12,500
  - Reductions in painkiller prescribing for acute pain would reduce deaths by 8,000

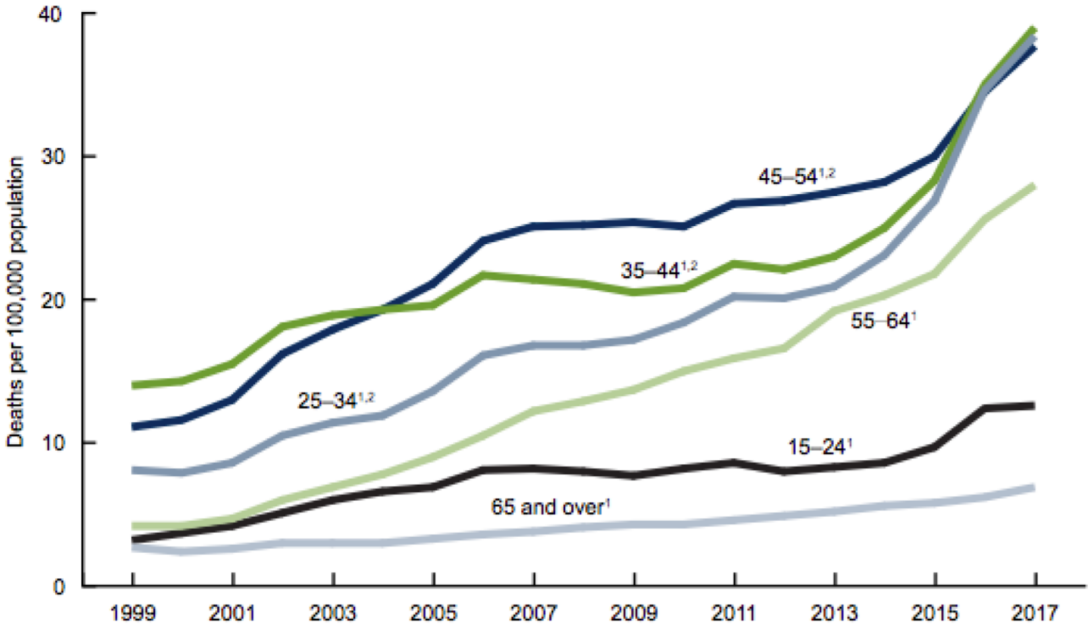
Pitt AL, et al. Am *J Public Health*. 2018;108(10):1394-1400.

Lifetime Odds Of Dying for Selected Causes US, 2017



National Center for Health Statistics. Mortality data for 2017 as compiled from data provided from the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. 2018 National Safety Council. Available at www.injuryfacts.nsc.org. Accessed January 15, 2019.

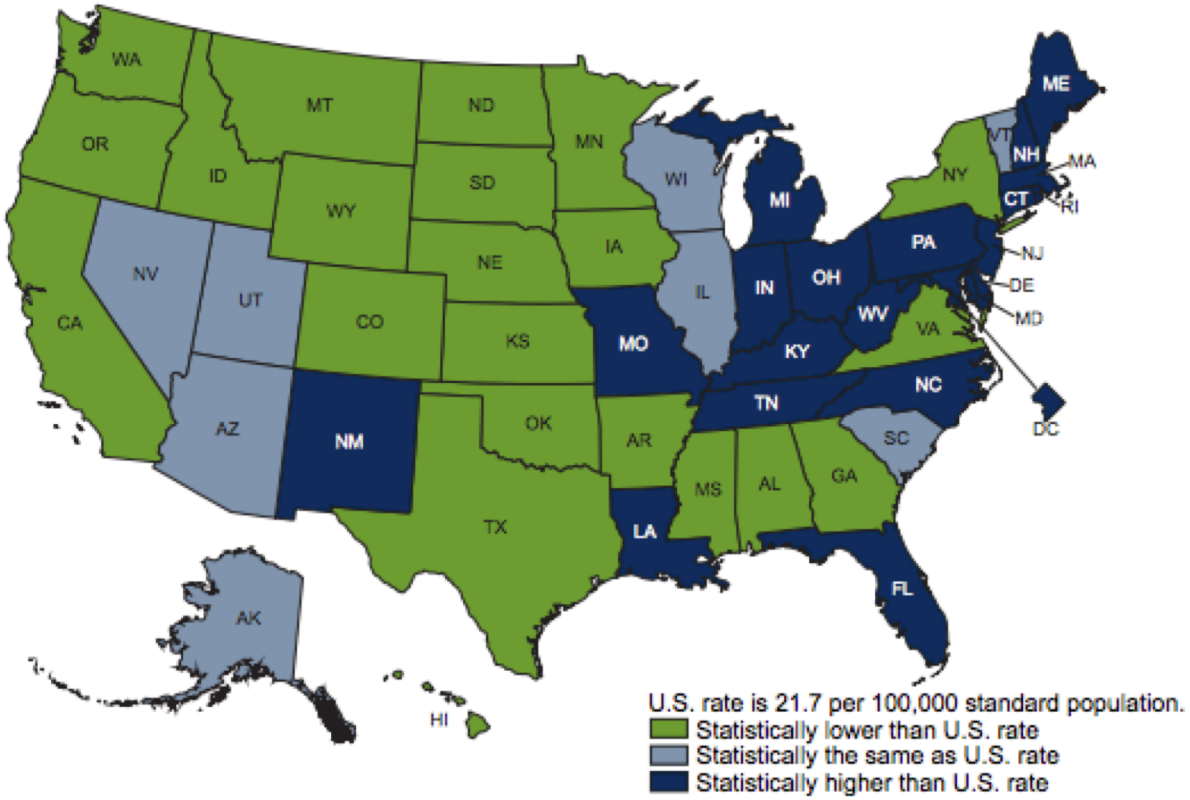
Drug Overdose Death Rates, by Selected Age Group: United States, 1999–2017



- In 2017, rates were significantly higher for age groups 25-34 (38.4 per 100,000), 35-44 (39.0), and 45-54 (37.7) than for those aged 15-24 (12.6), 55-64 (28.0), & 65+ (6.9)
- From 1999 to 2017, the greatest % change in drug overdose death rates occurred among adults aged 55–64, increasing from 4.2 per 100,000 in 1999 to 28.0 in 2017, a more than 6-fold increase

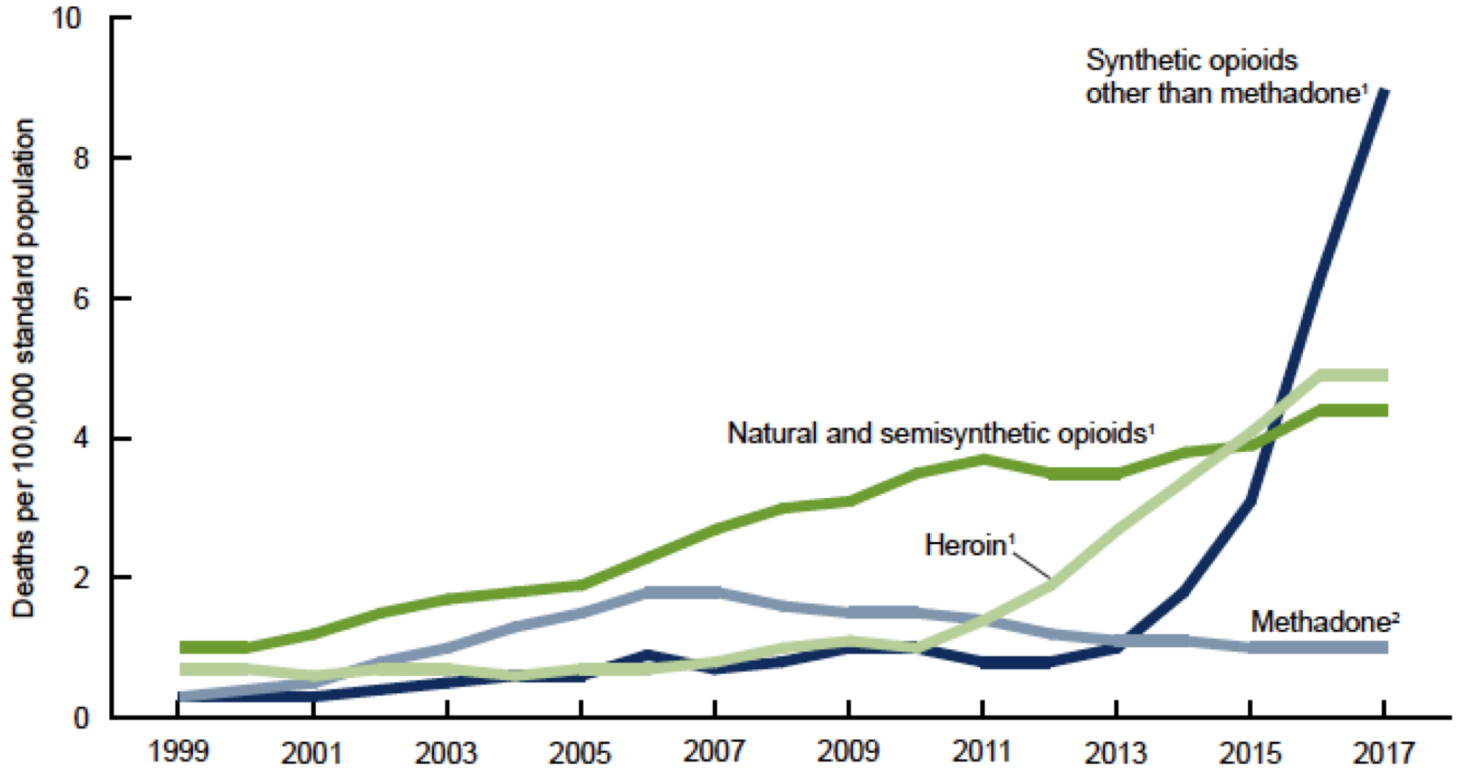
https://www.cdc.gov/nchs/data/databriefs/db329_tables-508.pdf#2.

2017 Age-Adjusted Overdose Death Rates by State



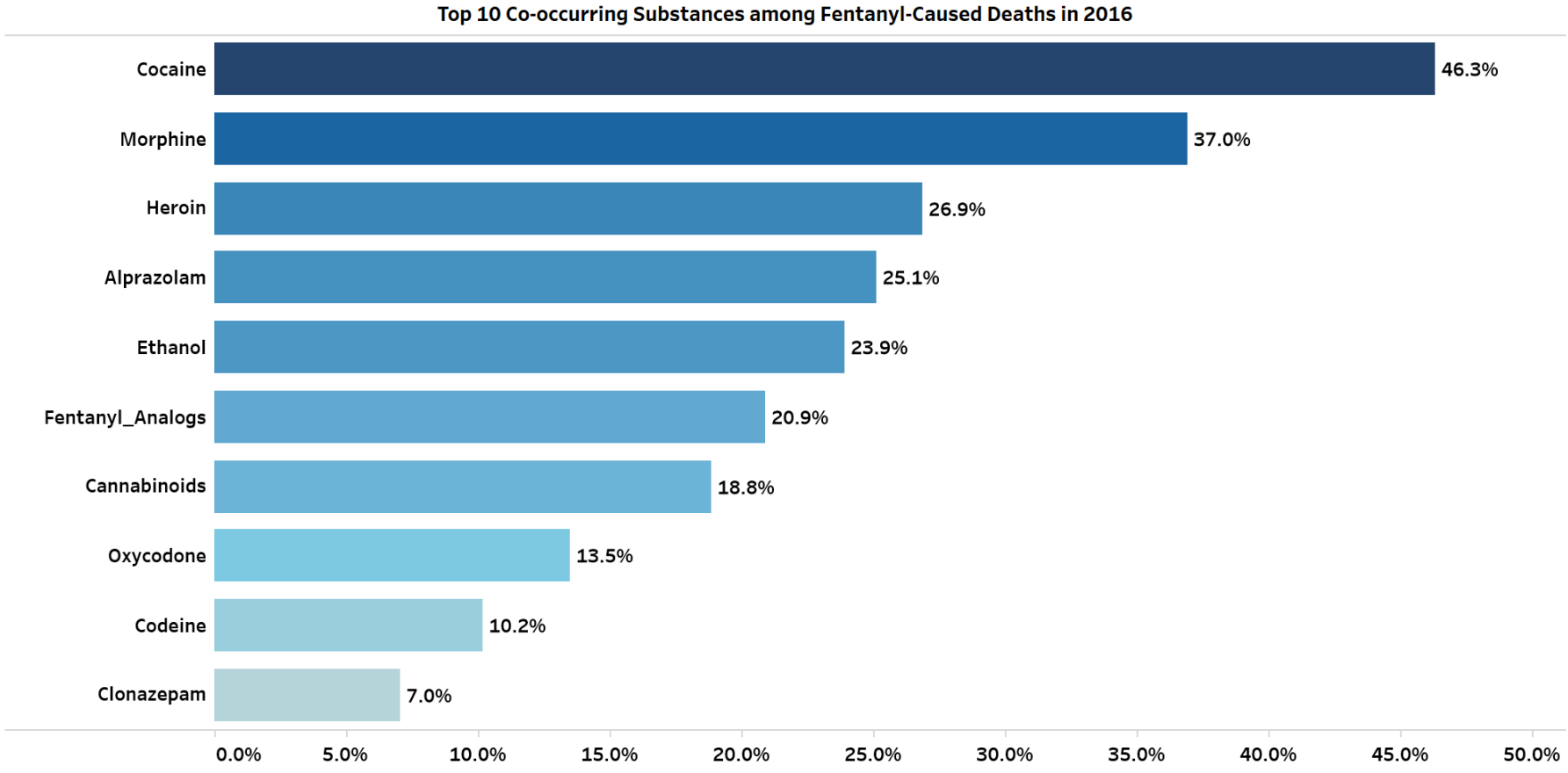
https://www.cdc.gov/nchs/data/databriefs/db329_tables-508.pdf#3.

Age-Adjusted Deaths by Opioid Category



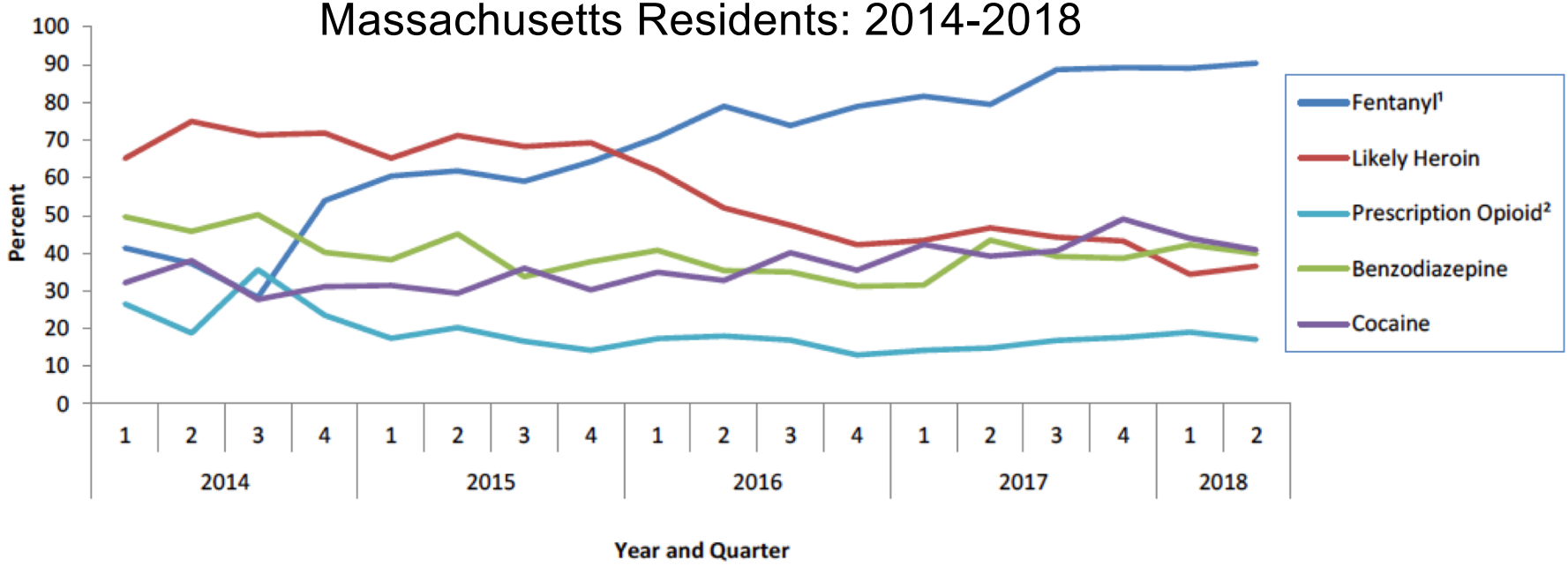
https://www.cdc.gov/nchs/data/databriefs/db329_tables-508.pdf#4.

State of Florida Fentanyl-Related Deaths (N = 1391)



Data courtesy of Bruce Goldberger, PhD

Percent of Opioid-Related Overdose Deaths with Specific Drugs Present



- Among 962 opioid-related overdose deaths in 2018 where a toxicology screen was available, 863 (90%) had a positive screen for fentanyl

https://www.mass.gov/files/documents/2018/11/16/Opioid-related-Overdose-Deaths-among-MA-Residents-November-2018.pdf

The Fentanyl Pipeline

- The Zheng drug trafficking organization was hardly clandestine.
- Shanghai-based network sold synthetic narcotics, including deadly fentanyl, on websites posted in 35 languages, from Arabic and English to Icelandic and Uzbek.
- Chinese syndicate bragged that its laboratory could “synthesize nearly any” drug and that it churned out 16 tons of illicit chemicals/month. The group was so adept at smuggling, and so brazen in its marketing, that it offered a money-back guarantee to buyers if its goods were seized by U.S. or other customs agents.

Infectious Disease Consequences

Viral hepatitis is increasing at concerning rates: new hepatitis B infections **rose 20%** from 2014-2015, and new hepatitis C infections **increased 233%** from 2010-2016

1 of every 10 new HIV infections is among people who inject drugs

The rate of **infants born to hepatitis C-infected mothers increased by 68%** nationally from 2011-2014, primarily due to the nation's opioid crisis

People who inject drugs are at elevated risk for unsafe sexual practices, such as having sex without a condom, having sex partners who are injection drug users, or engaging in sex work. Such high-risk sex behavior puts injectable drug users at elevated risk for acquiring a sexually transmitted disease (STD) and for transmitting an STD to their sexual network

$100 MILLION IN MEDICAL COSTS

the result of a 2015 outbreak of diseases linked to opioid use in Indiana

225 people were diagnosed with HIV
>90% were co-infected with hepatitis C

Addressing the Infectious Consequences of the U.S. Opioid Crisis. Centers for Disease Control. Available at https://www.cdc.gov/nchhstp/budget/infographics/opioids.html. Accessed January 15, 2019.

Collateral Damage of OUD

- Families, friends, coworkers, and communities
- Foster care system experiencing dramatic increase in the number of children in the system[1]
  - Over 2 million children live in households in which at least one parent has an illicit drug use disorder[2]
- Economic impact of lost productivity, lower discretionary income is estimated to be in the tens of billions/year[3]

1. Simon S. *NPR*. https://www.npr.org/2017/12/23/573021632/the-foster-care-system-is-flooded-with-children-of-the-opioid-epidemic. December 23, 2017. Accessed September 17, 2018.; 2. Lipari RN, Van Horn SL. *CBHSQ Report.* August 2017.; 3. Kolhatkar S. *New Yorker*. Published August 24, 2017. Accessed September 17, 2018.

Critical Themes for Combating the Opioid Crisis

Treatment Focused

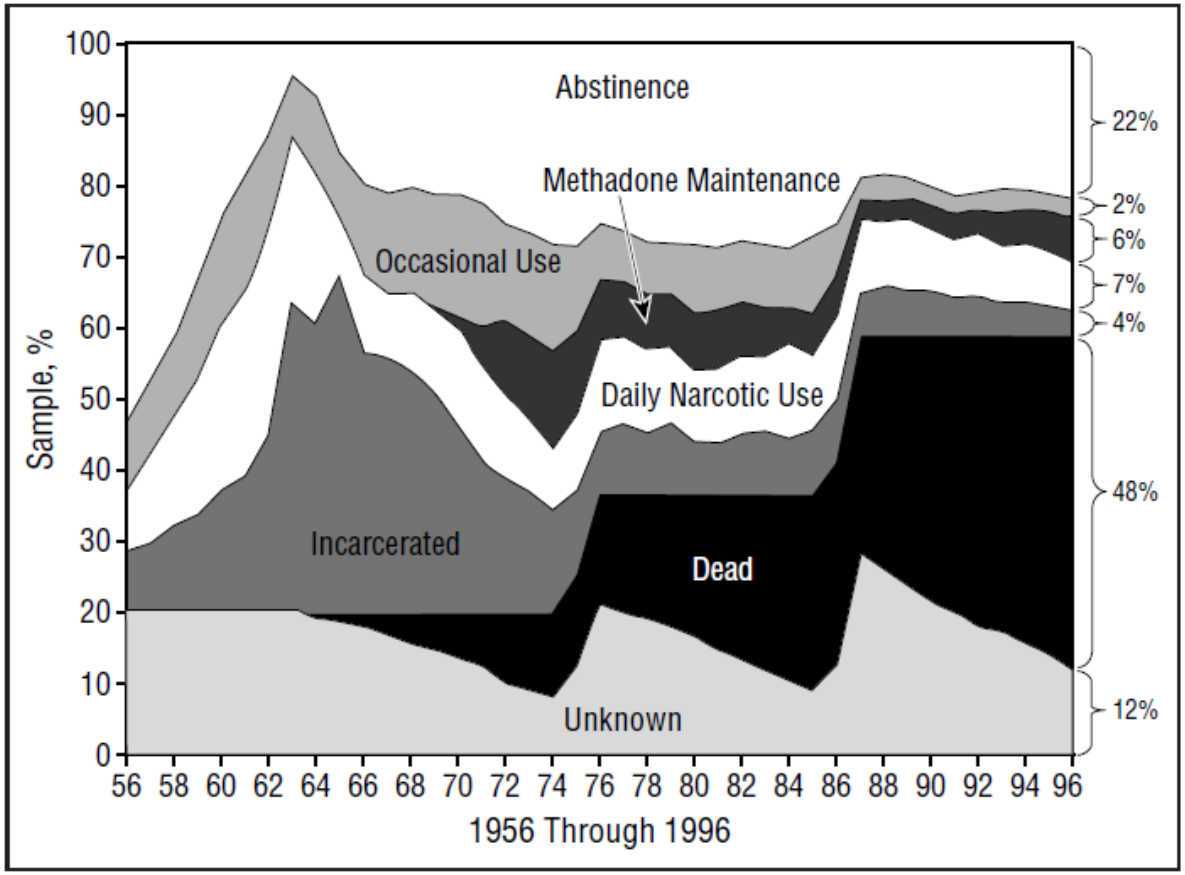
- Increase naloxone availability
- Increase MAT capacity and match to individuals with best chance of success
- Increase coordination between behavioral health, substance abuse, MAT and physical HCPs
- Law enforcement collaboration with healthcare stakeholders
- Shift correctional system from a source of the problem to part of the solution

Charumilind S, et al. https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/why-we-need-bolder-action-to-combat-the-opioid-epidemic#0. Accessed January 17, 2019.

Learning Objective 1

Increase screening to identify OUD and initiate an appropriate level of intervention in vulnerable patients.

Long-Term Outcomes of Opioid Use Disorder



Hser YI, et al. *Arch Gen Psychiatry*. 2001;58(5):503-508.

Rapid Opioids Dependence Screen (RODS) Aligned to *DSM-IV*

DSM-IV Criteria for Substance Dependence	Corresponding RODS Question
Tolerance (marked increase in amount; marked increase in effect	**Did you ever need to use more opioids to get the same high as when you first started using drugs?**
Characteristic withdrawal symptoms; substance taken to relieve withdrawal	**In the morning, did you ever use opioids to keep from feeling dope sick or did you ever feel dope sick?**
Substance taken in larger amount and for longer period than intended	**Did you ever need to use more opioids to get the same high as when you first started using drugs?**
Persistent desire or repeated unsuccessful attempt to quit	**Did you find it difficult to stop or not use opioids?**
Much time/activity to obtain, use, recover	**Did you ever need to spend a lot of time/energy on finding opioids or recovering from feeling high?**
Important social, occupational, or recreational activities given up or reduced	**Did you ever miss important things like doctors' appts., family/friend activities or other things because of opioids?**
Use continues despite knowledge of adverse consequences	**Did the idea of missing a fix ever make you anxious or worried?**
Clinical experience question	**Did you worry about your use of opioids?**

Wickersham JA, et al. *J Correct Health Care.* 2015;21(1):12-26.

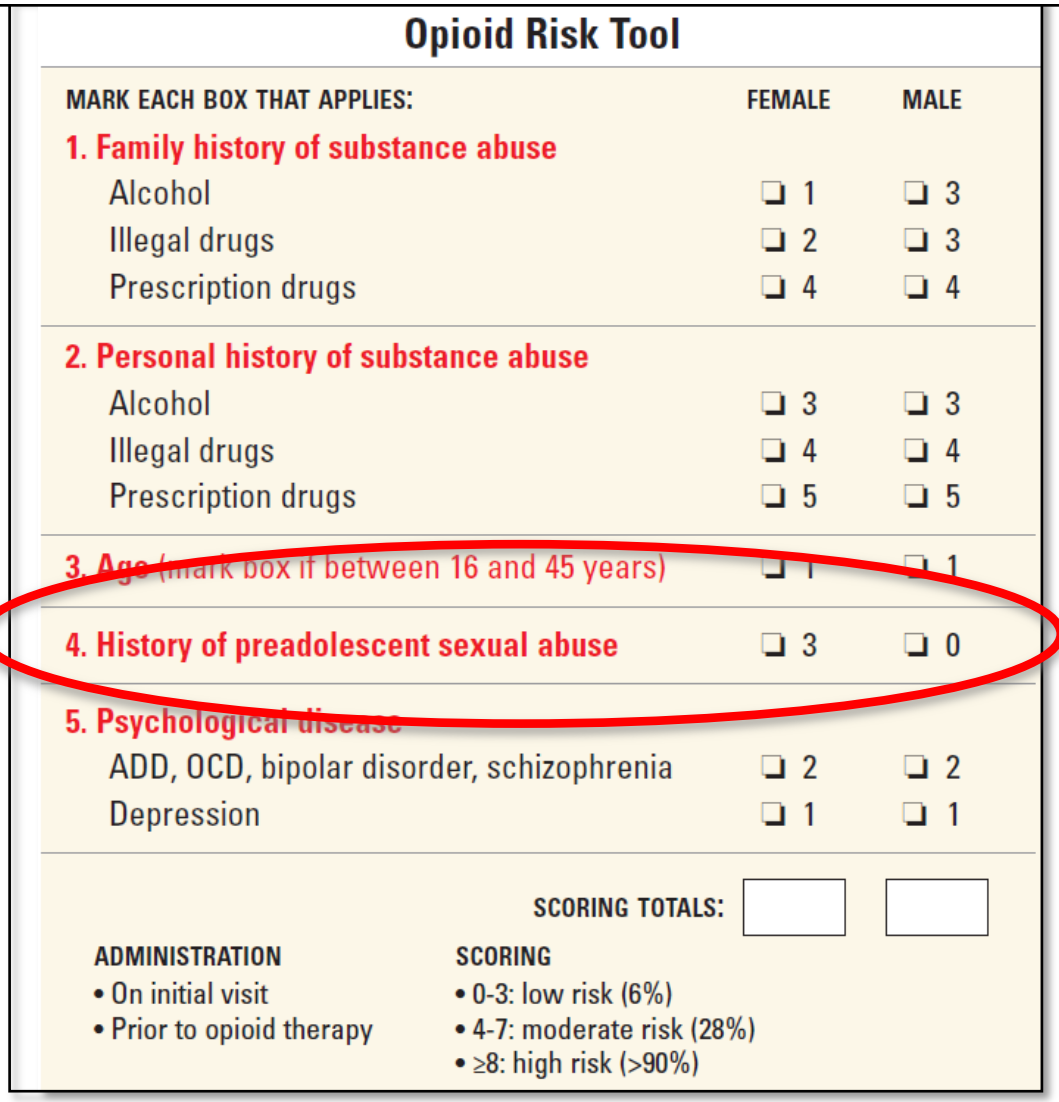
Emergency Department's Role in Screening and Initiating Treatment for OUD

- Emergency departments (ED) charged with screening and identifying the appropriate level of care for many chronic diseases have been reluctant to initiate treatment for OUD[1]
- Randomized trail conducted at Yale School of Medicine demonstrated the feasibility and efficacy of ED-initiated buprenorphine treatment in patients with OUD
  - 34% in ED seeking treatment
  - 66% were identified by screening, including 9% after an overdose
- Patients assigned to brief psychosocial intervention, started on buprenorphine, and linked to the hospital's primary care center for 10 wks of continued treatment were **2x** as likely to be engaged in formal addiction treatment at 30 days as those given a referral to treatment alone or brief psychosocial intervention and referral to treatment[2]
- ED initiated treatment also found to be cost-effective.[3]

1. D'Onofrio G, et al. *N Engl J Med*. 2018;379(26):2487-2490.; 2. D'Onofrio G, et al. *JAMA.* 2015:313:1636-1644.; 3. Busch SH, et al. *Addiction.* 2017;112:2002-2010.

Use Risk Assessment Tool[1]

A study of 295 patients in an outpatient treatment setting for substance use disorders or depression, substance use was **4x higher among victims of emotional and sexual abuse** than those in the control group.[2]



Opioid Risk Tool

MARK EACH BOX THAT APPLIES:	FEMALE	MALE
1. Family history of substance abuse		
Alcohol	❑ 1	❑ 3
Illegal drugs	❑ 2	❑ 3
Prescription drugs	❑ 4	❑ 4
2. Personal history of substance abuse		
Alcohol	❑ 3	❑ 3
Illegal drugs	❑ 4	❑ 4
Prescription drugs	❑ 5	❑ 5
3. Age (mark box if between 16 and 45 years)	❑ 1	❑ 1
4. History of preadolescent sexual abuse	❑ 3	❑ 0
5. Psychological disease		
ADD, OCD, bipolar disorder, schizophrenia	❑ 2	❑ 2
Depression	❑ 1	❑ 1
SCORING TOTALS:		

ADMINISTRATION
- On initial visit
- Prior to opioid therapy

SCORING
- 0-3: low risk (6%)
- 4-7: moderate risk (28%)
- ≥8: high risk (>90%)

1. Webster LR, Webster RM. *Pain Med* 2005;6:432-442
2. Tucci AM, et al. *Child Abuse & Neglect*. 2010;34:95-104.

Learning Objective 2

Utilize recent clinical updates on the safety and efficacy of current therapies for OUD to overcome barriers to integration in practice.

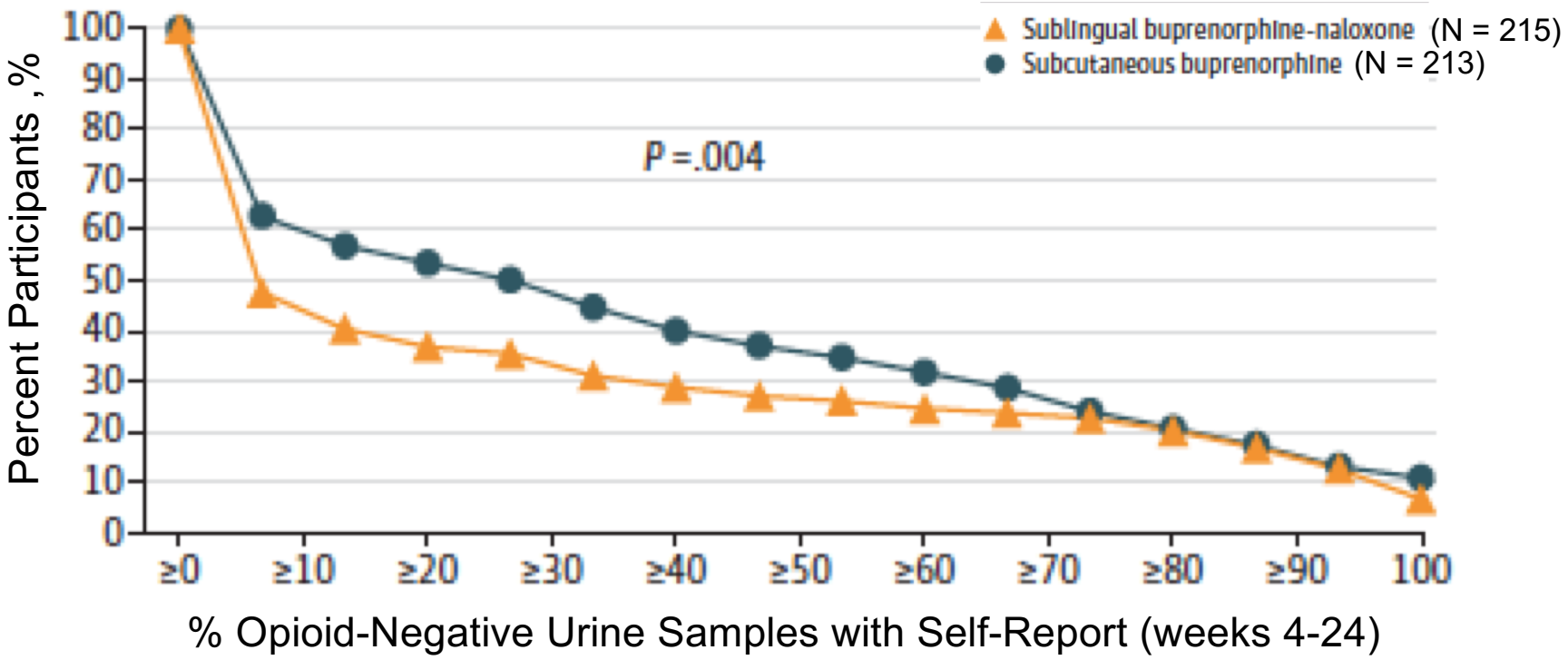
FDA-Approved Medications to Treat OUD

Medication	Receptor Pharmacology	Formulation
Methadone	Full mu opioid agonist	• Oral solution, liquid concentrate, tablet/diskette, powder
Buprenorphine	Partial mu opioid agonist	• Once monthly injection for subcutaneous use
Buprenorphine-naloxone	Partial mu opioid agonist/mu antagonist	• Sublingual film
Naltrexone	Mu opioid antagonist	• Extended release injectable suspension

Prescribing information available at https://www.accessdata.fda.gov

Center for Substance Abuse Treatment. Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs. Rockville (MD): SAMSHA (US); 2005. (Treatment Improvement Protocol (TIP) Series, No. 43.) Chapter 3. Pharmacology of Medications Used to Treat Opioid Addiction. Available from: https://www.ncbi.nlm.nih.gov/books/NBK64158/

Subcutaneous Buprenorphine vs. Sublingual Buprenorphine-Naloxone: Percentage Opioid-Negative Urine Samples Over 24 Weeks



Weeks 1-12: Weekly injections; Weeks 12-24: Monthly injection

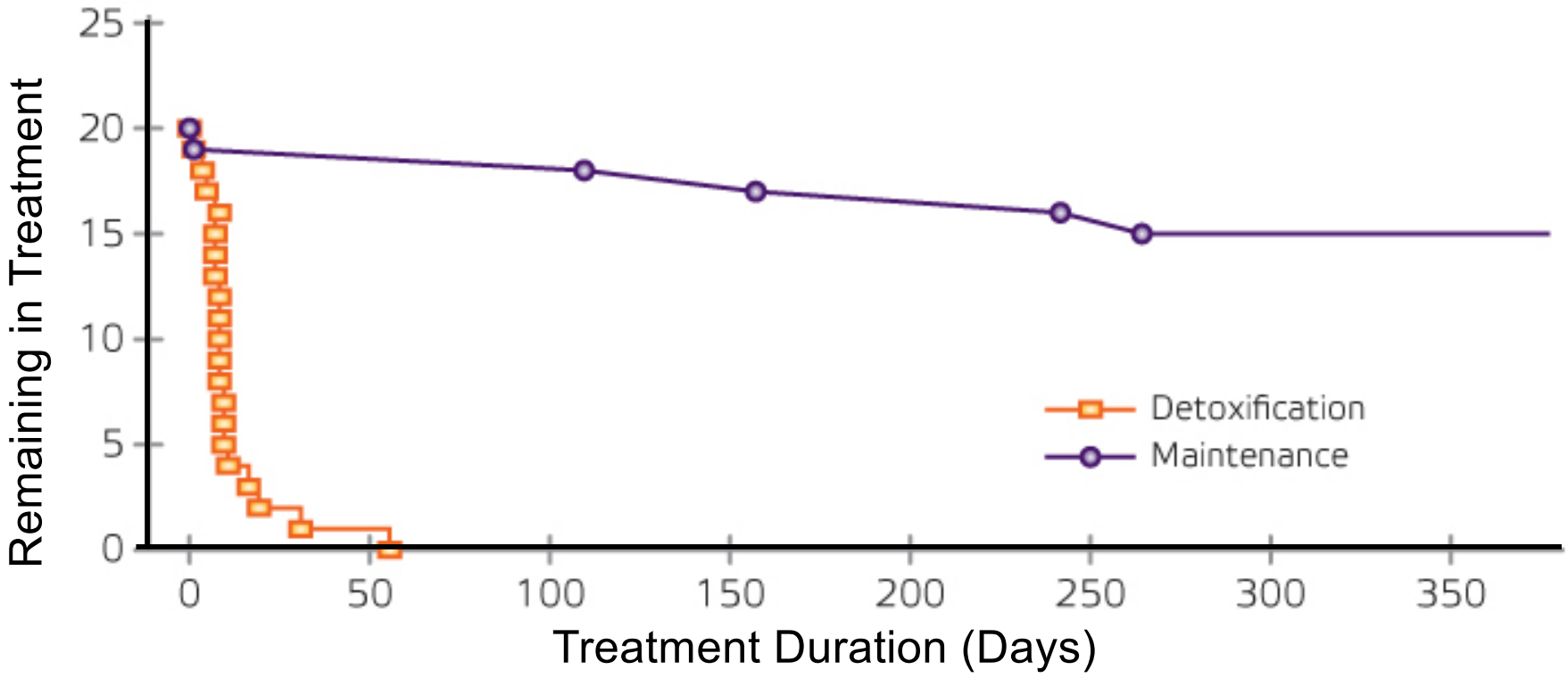
Lofwall MR, et al. *JAMA Intern Med*. 2018;178(6):764-773.

Comparative Effectiveness of Extended-Release Naltrexone vs Sublingual Buprenorphine for Opioid Relapse Prevention (X:BOT)

- 24 wk, open-label, randomized controlled, comparative effectiveness trial in outpatients after inpatient induction
  - Monthly extended-release naltrexone injections (XR-NTX) vs. daily sublingual buprenorphine (BUP-NX) film
  - Fewer participants successfully initiated XR-NTX than BUP-NX: 72% VS 94%; $p < .0001$
    - At 24 wks, among participants that were successfully initiated, both medications were equally safe and effective
    - Study treatment retention for 24 wks was between 43% and 47%
  - During treatment outcomes were better for BUP-NX than XR-NTX

Lee JD, et al. *Lancet* 2018;391(10118):309-318.

Detoxification vs. Maintenance Medication



All patients (n = 40) participated in cognitive-behavioral group therapy, received weekly individual counseling sessions, and submitted 3x weekly urine samples

Kakko J, et al. *Lancet* 2003;361(9358):662-668.

Psychiatric ER: VA Connecticut

- Dedicated and locked, 24/7/365
- One of only several nationally at a VA
- Capacity of 14, able to provide extended observation
- Mostly voluntary patients
- Staffed by ~30 MDs, all required to have a buprenorphine waiver

Initiation of Buprenorphine

Evaluation	Hold in PER, full history and physical exam, urinary drug screening (UDS), Clinical Opiate Withdrawal Score (COWS)	
Buprenorphine initiation	2-4 mg driven by patient history or COWS	Up to 8 mg on day 1 and 16 mg on day 2
Stabilization	Patients typically stabilized by day 2, often in PER, even if it takes 2-3 days	Contracted “detox” facility does not detox patients with OUD, instead initiates and stabilizes
Next steps	Refer to buprenorphine clinic with ambulatory detox team to bridge the gap if needed	Recommend inpatient treatment or the substance abuse day program

Reaching Out into the Community to Address OUD

- In San Francisco, opioid addiction treatment offered on the streets
- Some hospital emergency departments are giving people medicine for withdrawal, plugging a hole in a system that too often fails to provide immediate treatment
- Others meeting homeless where they live to provide naltrexone injections

Naloxone

- Not a “cure” but reverses the dangers of an opioid overdose allowing medical treatment and hopefully prevent death
- Three FDA approved formulations of naloxone[1]
  - Injectable
  - Autoinjectable
    - Prefilled autoinjection device
    - Once activated, device provides verbal instructions to the user
  - Prepackaged nasal spray
    - Prefilled, needle-free device requiring no assembly
    - Sprayed into one nostril while patients lay on their back
- Access to naloxone is expanding
- SAMHSA Opioid Overdose Prevention Toolkit[2]

1. https://www.drugabuse.gov/related-topics/opioid-overdose-reversal-naloxone-narcan-evzio.;
2. https://store.samhsa.gov/shin/content//SMA18-4742/SMA18-4742.pdf

Intentional (Suicide) vs. Unintentional (Accidental) Overdose Deaths

- Epidemiological data indicate that over 50% of individuals with OUD meet criteria for concurrent major depressive disorder[1]
- Yet, most strategies to address overdose do not include screening for suicide or the need to tailor interventions for suicidal persons[2]
- Diagnosis and assessment of psychiatric comorbidity and monitoring of depressive symptoms is essential[1]

1. Srivastava BA, Gold MS. *Mayo Clin Proc*. 2018:93(3):269-272.
2. Oquendo MA, Volkow N. *N Engl J Med*. 2018;378(17):1567-1569.

Learning Objective 3

Demonstrate how collaborative care strategies can be optimized to facilitate the delivery of evidence-based treatment for OUD.

Comprehensive Opioid Addiction Treatment (COAT) Program

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Director of Addictions
Department of Behavioral Medicine and Psychiatry
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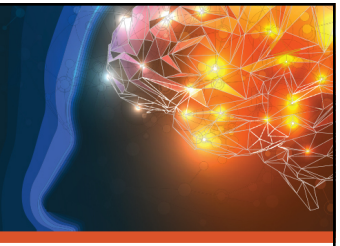
Comprehensive Opioid Addiction Treatment (COAT) Program



- West Virginia University started using buprenorphine in 2004 (treated ~2500 patients)
  - Group Based: Medical Management directly followed by Group Therapy
  - Step Based: Advance through 4 treatment phases
  - Varied Groups: Male only, female only, mixed gender, pregnant
- Currently treat ~500 patients in 53 groups at Morgantown, WV site
- Training environment: medical students, medical residents, social workers, nurses, pharmacists, peer recovery coaches
- Expanding in West Virginia via ECHO and Hub-Spoke

COAT Clinic Phases

Beginner	Intermediate	Advanced	Maintenance
1-90 days abstinence	91-365 days abstinence	> 365 days abstinence	> 3 years abstinence
Weekly group therapy (8-12 patients)	Bi-weekly group therapy (8-12 patients)	Monthly group therapy (8-12 patients)	Every other month medication management session
Signed peer meeting lists (4 hours/week)	Written report/no signatures required for peer meetings	Mandatory peer meetings no longer required	
Monthly individual therapy	Monthly individual therapy	Monthly individual therapy no longer required	

- Infectious disease screening
- Referral for psychiatric services if necessary
- Referral for other medical conditions if necessary

Current Outcomes of COAT

Retention

- Weekly groups
  - 49%-50%
- Beyond weekly groups
  - 65% - 84%

Abstinence* (n = 499)

- 71% have attained 90 days continuous
- 207 pts > 1 yr continuous
- 123 pts > 3 yrs continuous
- 16 pts > 10 yrs continuous

* Abstinence defined as using MAT as prescribed and no use of any intoxicating substance (including THC or ETOH)

West Virginia COAT Model

Guiding Principles

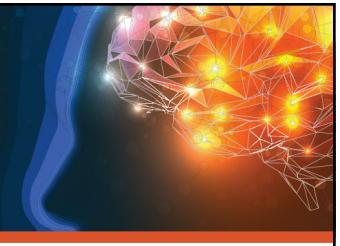
- Medication alone is not sufficient
- Group therapy and psycho-education is efficient and effective
- Med management and therapy should be linked together
- Require regular participation in 12-step/peer recovery groups
- Encourage abstinence from all intoxicating substances
- Goal is to increase quality of life and decrease mortality

Benefits

- Address bio-psycho-social domains
- Build cohesion and create healthy culture
- Shared learning environment
- Maximize structure while being financially sustainable
- Reward and sense of accomplishment
- Increase access
- Minimize provider burnout
- Multidisciplinary training opportunities
- Replicable (e.g. Private office, FQHC, tele-health)

SMART Goals

Specific, Measurable, Attainable, Relevant, Timely



- Decreasing opioid prescribing alone is not enough. Individuals with OUD need to be matched with the appropriate treatment and psychosocial intervention to give them the best chance of success
- Screen individuals comorbid psychiatric disorders for OUD
- Seek out novel programs, learn from successes, and share best practices in your community

Questions & Answers

Don’t forget to fill out your evaluations to collect your credit.