Webcast Wednesday: Outpatient OUD Treatment

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12/2/2020

UNC SCHOOL OF MEDICINE

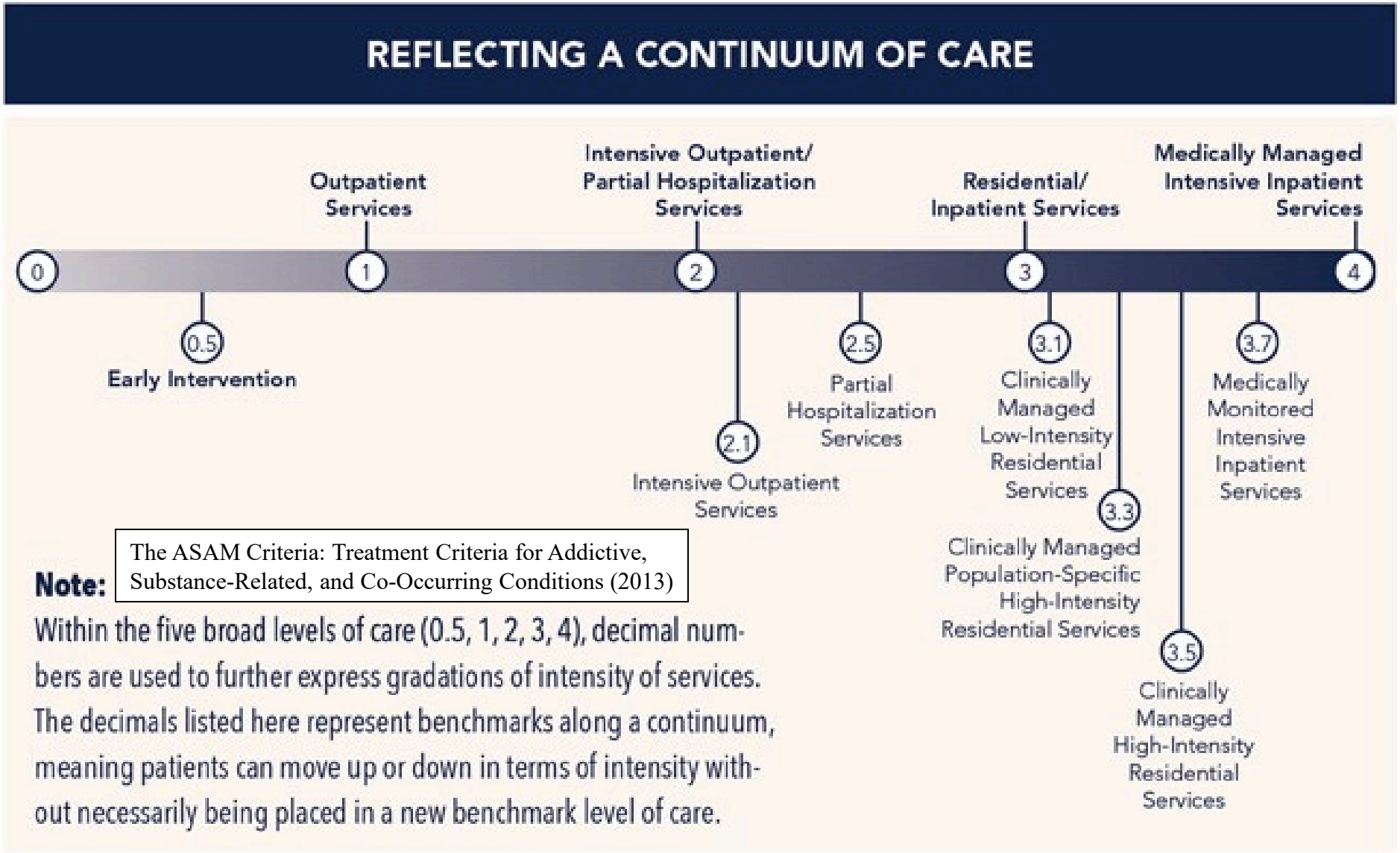
Disclosure/Conflict of Interest

I have no actual or potential conflicts of interest in relation to this program and no disclosures.

Objectives:

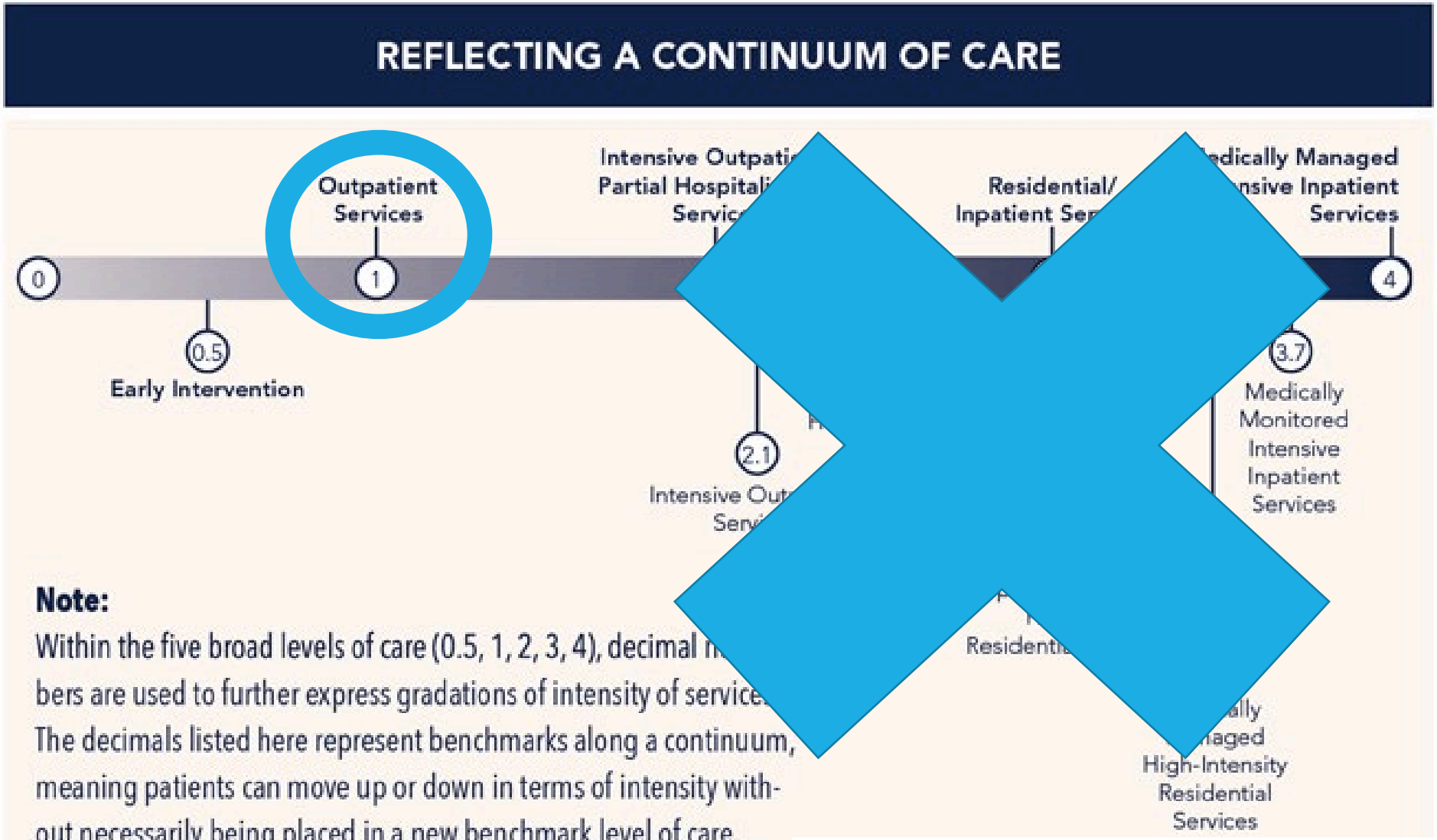
- Describe the epidemiology of opioid use and addiction at the national and state levels, highlighting impact of COVID-19
- Review key principles of addiction medicine including definitions, the brain disease model and SUD diagnostic criteria
- Discuss three FDA approved treatment options for OUD, with a focus on various buprenorphine formulations.
- Review important adjunct medications to providing care to individuals with OUD including PrEP, PEP and Naloxone
- Describe the recent expansion of Tele-BH treatment for OUD

Treatment of OUD: ASAM Placement Criteria



The ASAM Criteria: Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions (2013)

Treatment of OUD: ASAM Placement Criteria



The ASAM Criteria: Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions (2013)

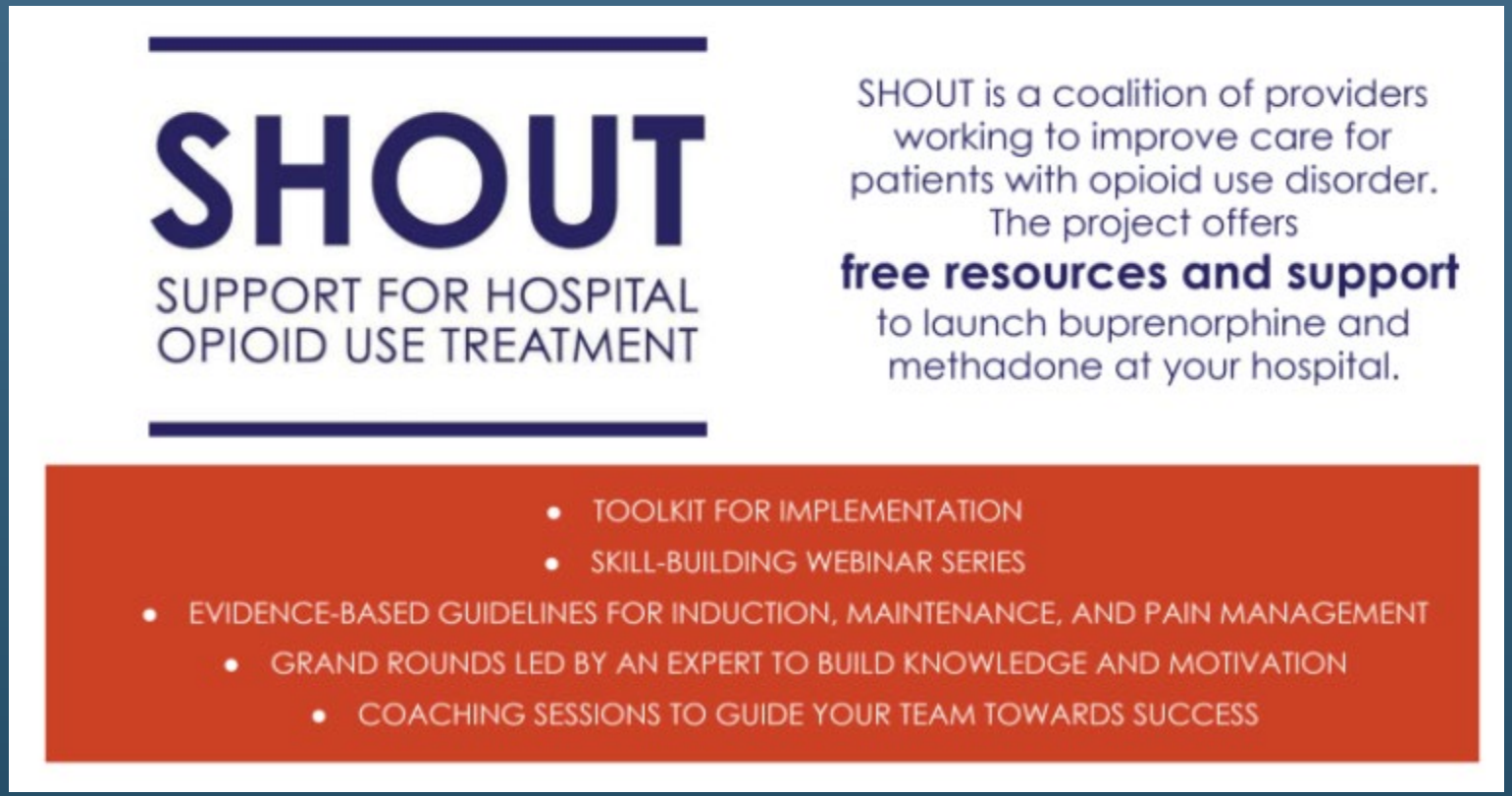
Inpatient OUD Treatment

Inpatient OUD Treatment

Detox ≠ Evidence-Based Treatment

Inpatient OUD Treatment

Project SHOUT - Inpatient MOUD



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Case

- 34 yo G2P1102 F with hx opioid and tobacco use disorders who presents to your clinic to establish care.

- She reports using intranasal heroin daily and smokes 1 pack of cigarettes daily.

Case

- 34 yo G2P1102 F with hx opioid and tobacco use disorders who presents to your clinic to establish care.
- She reports using intranasal heroin daily and smokes 1 pack of cigarettes daily.
- Reports hx overdoses and has not received formal treatment in the past. ROS+ for insomnia, nausea, intermittent diarrhea, increased anxiety, anhedonia, irritability.
- **What are your next steps?…**

Definition of Addiction

Addiction is a primary, **chronic** and **relapsing brain disease** characterized by an individual pathologically pursuing reward and/or relief by substance use and other behaviors despite adverse consequences.

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"All things are poison, and nothing is without poison. Solely the **dose** determines that a thing is not a poison."

–**Paracelsus 1500s**

What are Opioids?

- "**Natural**," referred to as **Opiates**
  - Morphine, codeine, opium

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- Synthetic referred to as Opioids
  - Semisynthetic: heroin, oxycodone, buprenorphine
  - Fully Synthetic: fentanyl, tramadol, methadone

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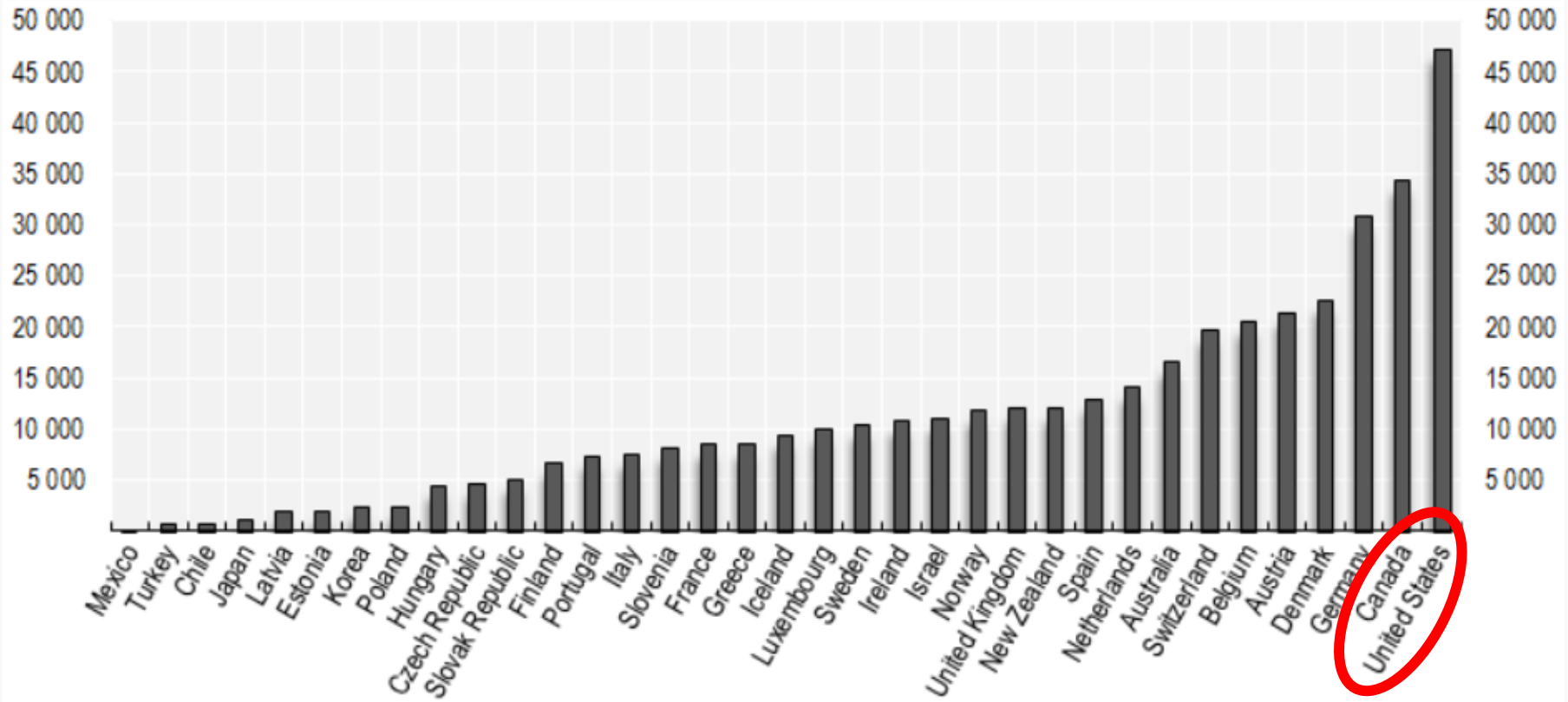
- **Opioids = "Natural" + Synthetic**

Global Perspective

BACKGROUND INFORMATION - THE UNITED STATES

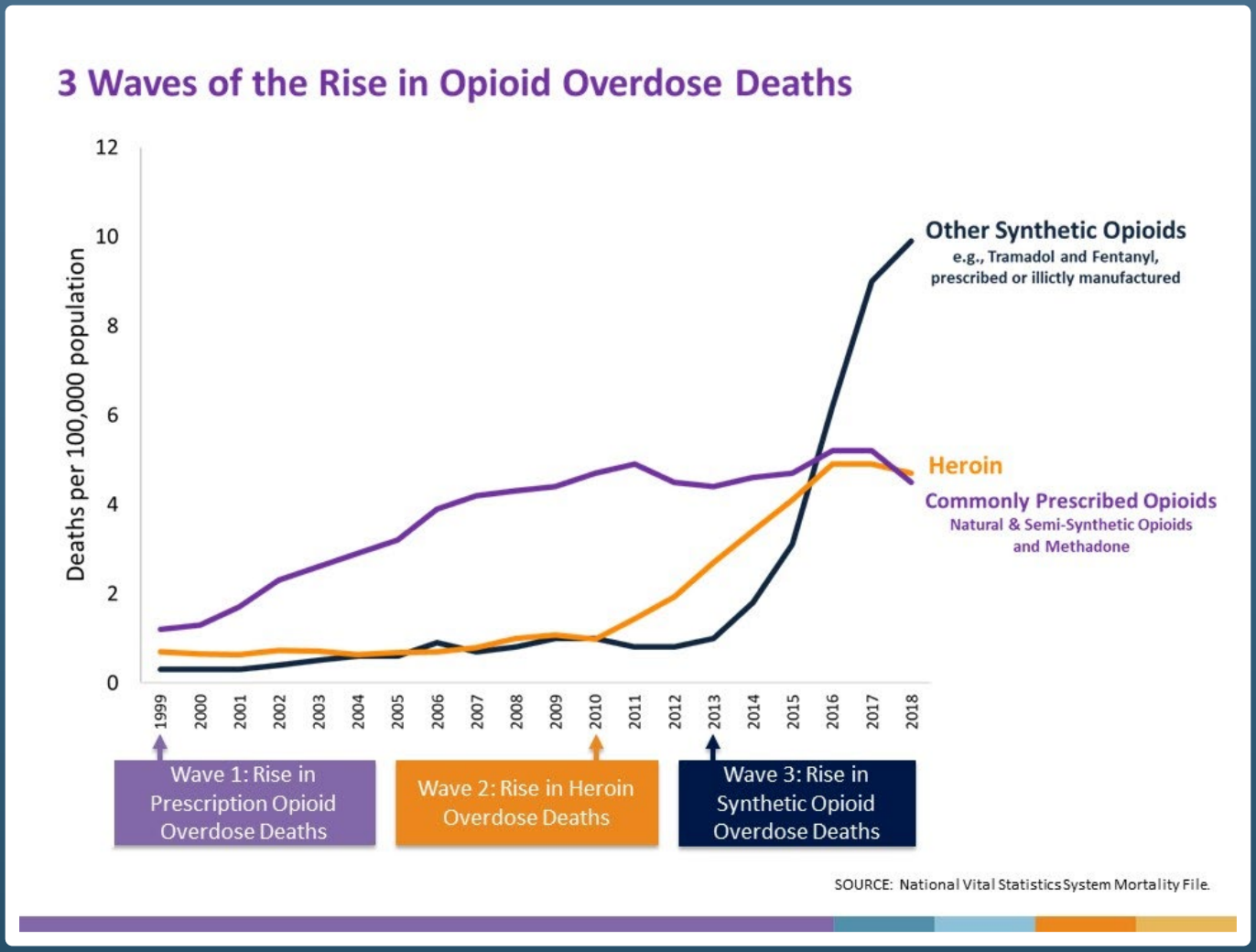
The prescription of opioids per capita is significantly higher in the United States than elsewhere in the OECD

Per million

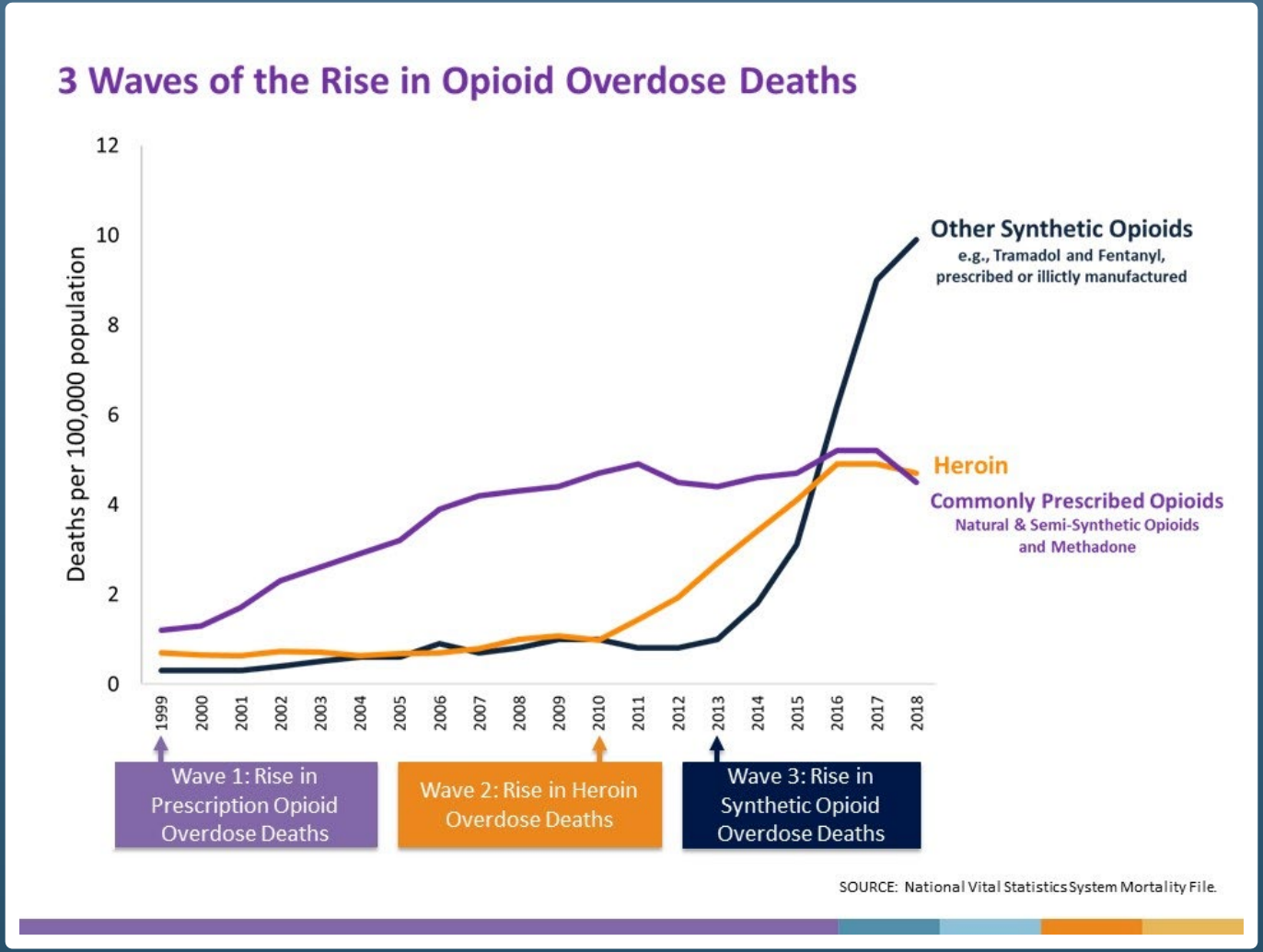


Source: OECD (2018), OECD Economic Surveys: United States 2018, OECD Publishing.

"Triple Wave"


3 Waves of the Rise in Opioid Overdose Deaths
Deaths per 100,000 population
0
2
4
6
8
10
12
1999
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
Other Synthetic Opioids
e.g., Tramadol and Fentanyl, prescribed or illictly manufactured
Heroin
Commonly Prescribed Opioids
Natural & Semi-Synthetic Opioids and Methadone
Wave 1: Rise in Prescription Opioid Overdose Deaths
Wave 2: Rise in Heroin Overdose Deaths
Wave 3: Rise in Synthetic Opioid Overdose Deaths
SOURCE: National Vital Statistics System Mortality File.

"Triple Wave"



"Fourth Wave" -> Methamphetamines

Deaths/year in US Related to Drug Use

>480,000

95,000

50,042

10,724

14,666

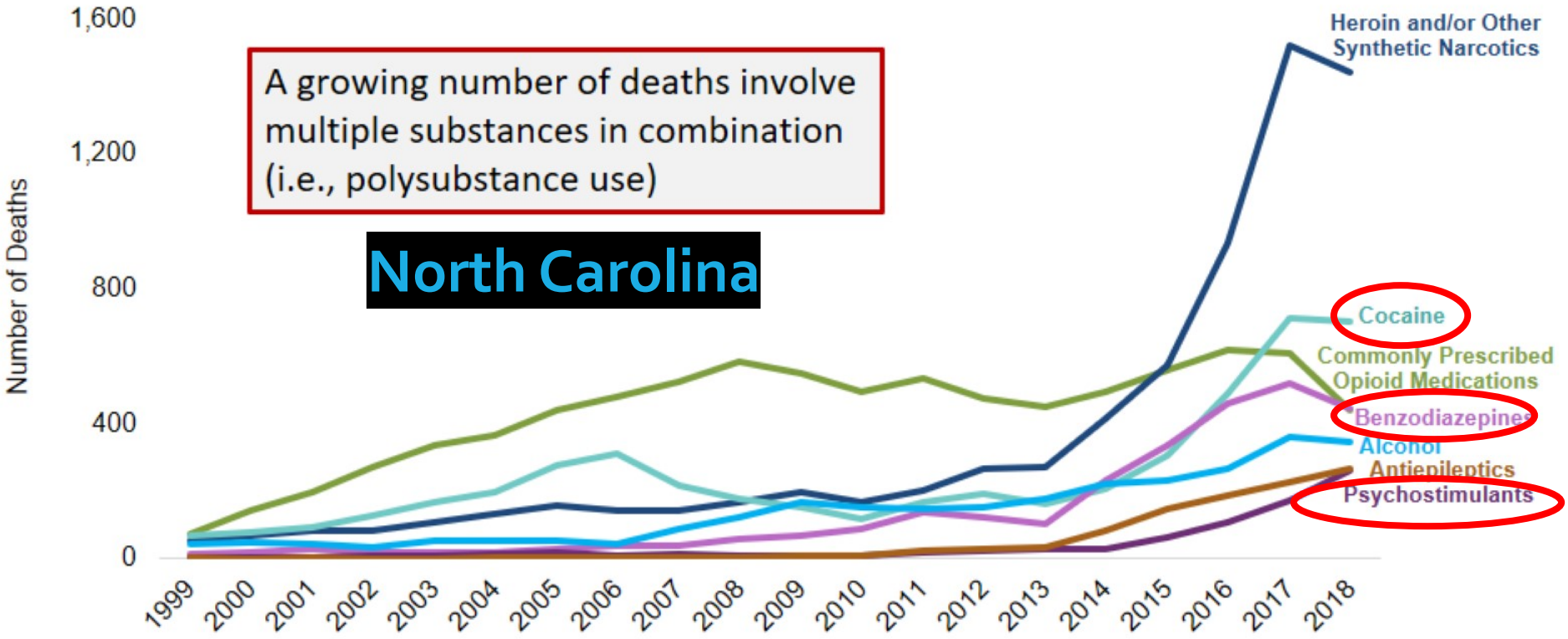
Deaths/year in US Related to Drug Use

	PRE-COVID-19	POST-COVID-19
• Tobacco	>480,000	
• Alcohol	95,000	
• **Opioid OD**	**50,042**	???
• Benzodiazepine OD	10,724	
• Cocaine OD	14,666	

Opioids represent OD deaths from all opioids: analgesics, heroin, illicit synthetics.

Reported by US CDC: Alcohol (2011-2015), tobacco (2014) cocaine/benzodiazepines (2018), opioids (2019)

Unintentional overdose deaths involving illicit opioids* decreased from 2017 to 2018 while deaths involving stimulants increased



*Heroin and/or Other Synthetic Narcotics (mainly illicitly manufactured fentanyl and fentanyl analogues)

Technical Notes: These counts are not mutually exclusive; If the death involved multiple substances it can be counted on multiple lines; Unintentional medication, drug, alcohol poisoning: X40-X45 with any mention of specific T-codes by drug type; limited to N.C. residents

Source: Deaths-N.C. State Center for Health Statistics, Vital Statistics, 1999-2018
Analysis by Injury Epidemiology and Surveillance Unit

COVID-19 & OUD

- Compromised lung conditions (tobacco, vaping, opioids)
- Exacerbation of existing racial inequity in US Healthcare System
- Harm Reduction Efforts w/ Physical Distancing
  - Likely decrease in observed overdoses
  - Distribution and subsequent reversal with naloxone may be less likely
- Treatment
  - Limited social supports/isolation (mutual help groups, restricted travel)
  - Barriers to obtaining medications

COVID-19 & SUD & Racial Disparities

Volkow et al., Molecular Psychiatry, 2020

- People w/ SUDs -> higher risk of contracting + worse consequences from COVID-19 (African Americans **13.8%** vs. **8.6%** for whites)

- Opioids = 10.2x "more likely than those w/o SUD to have COVID"
- Tobacco= 8.2x
- Alcohol= 7.8x
- Cocaine= 6.5x
- Cannabis=5.3x

Volkow Blog

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Volkow et al., Molecular Psychiatry, 2020

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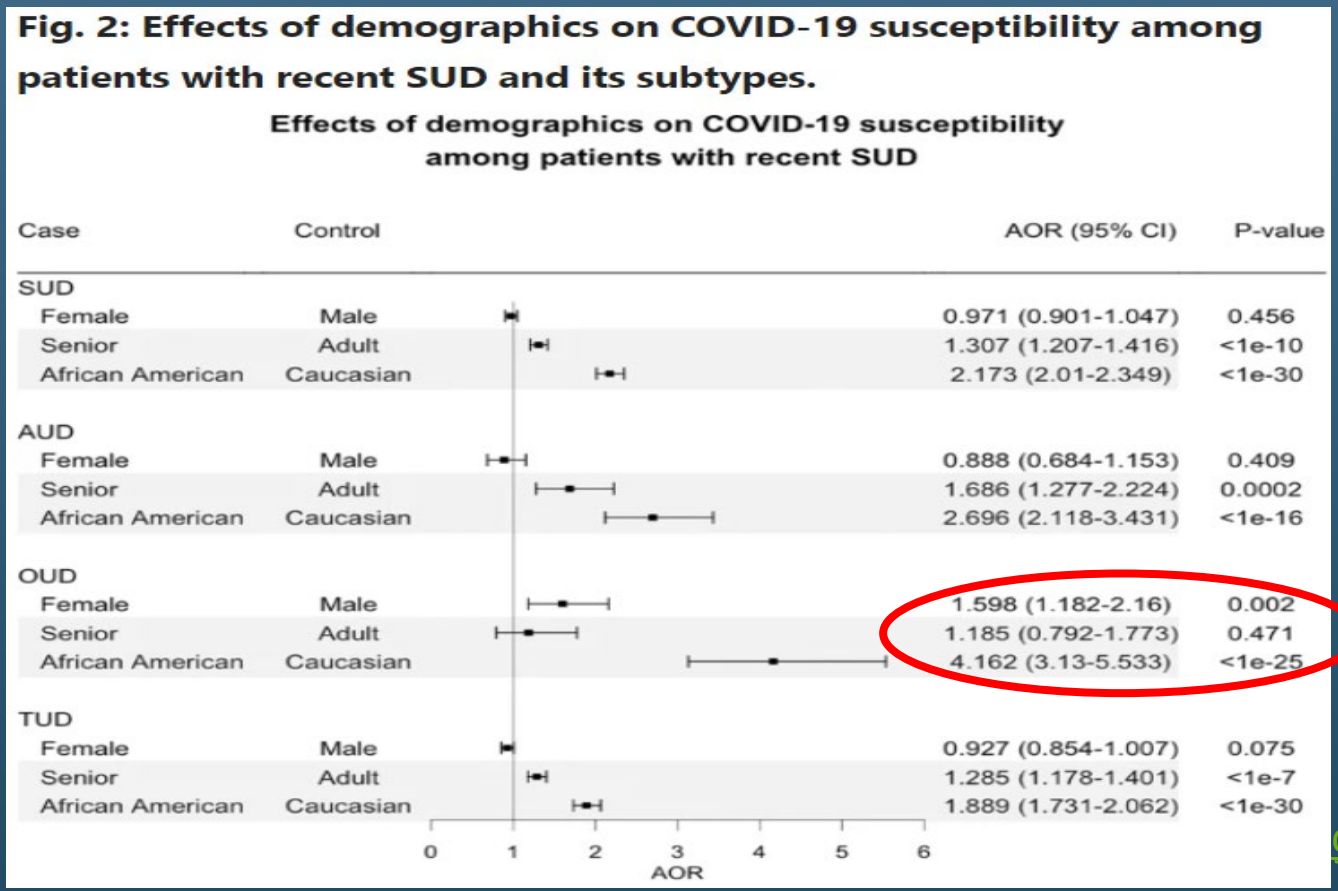
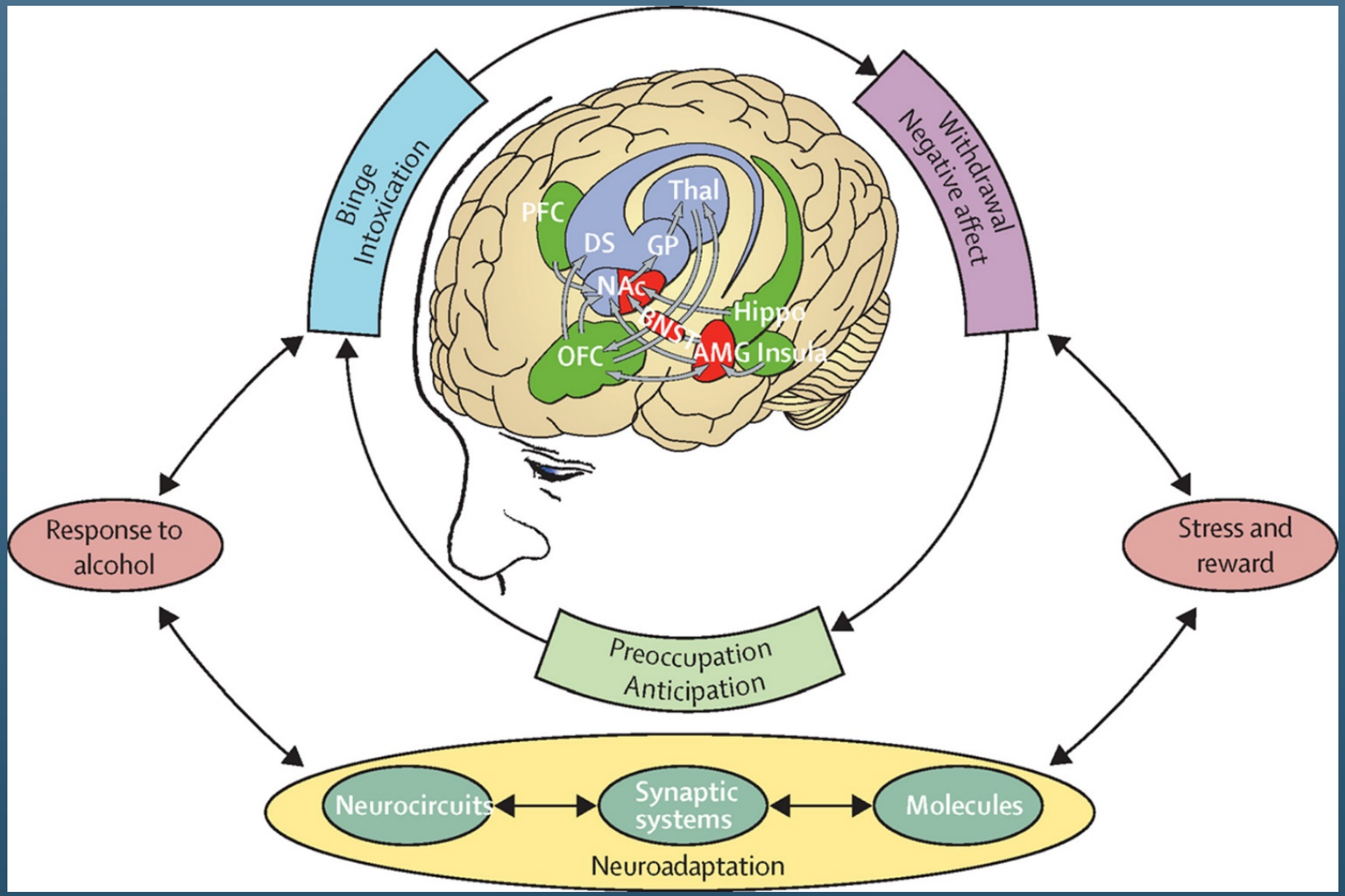
Fig. 2: Effects of demographics on COVID-19 susceptibility among patients with recent SUD and its subtypes.

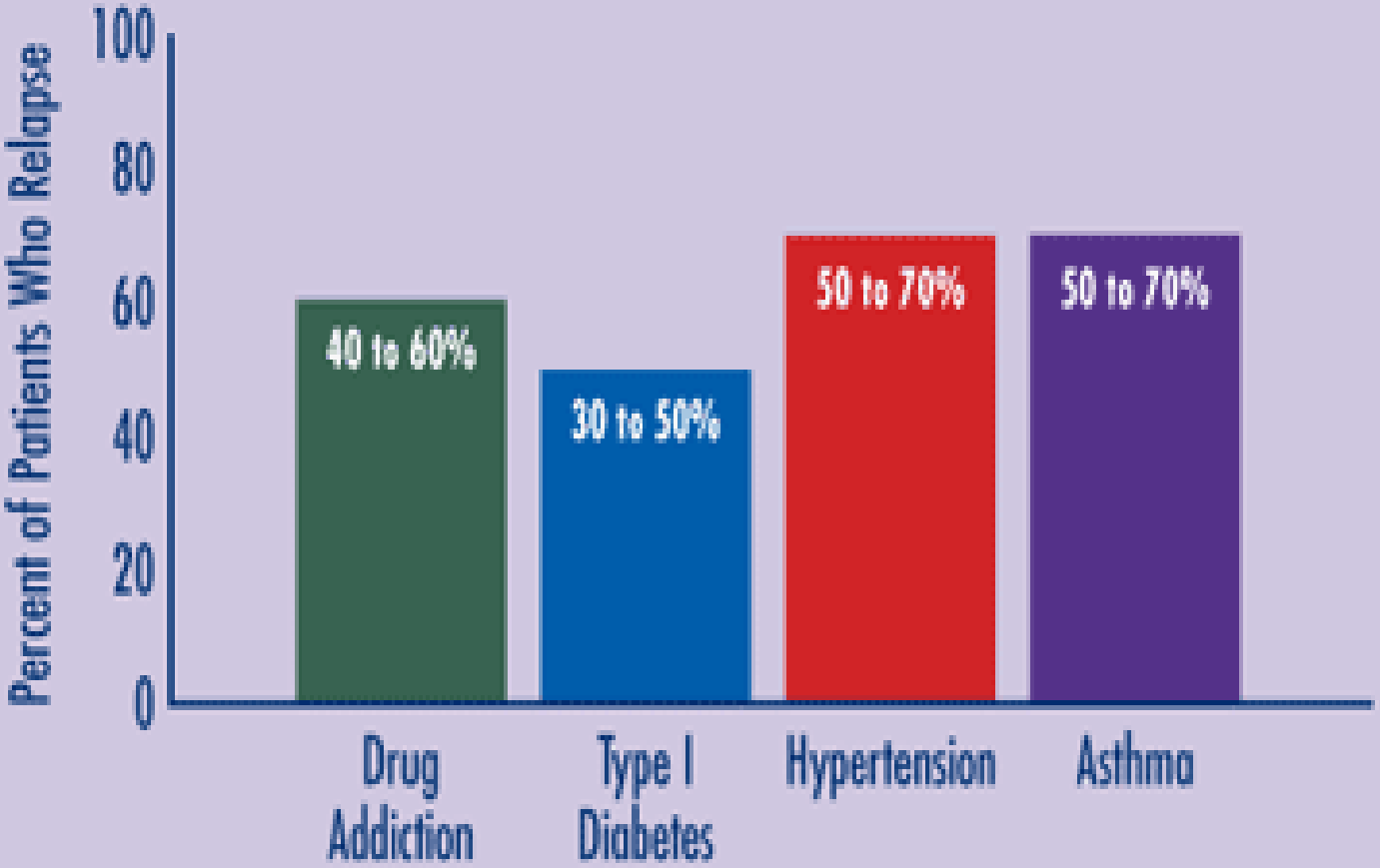


Neurobiology of Addiction



Volkow and Koob, The Lancet, 2015

COMPARISON OF RELAPSE RATES BETWEEN DRUG ADDICTION AND OTHER CHRONIC ILLNESSES



JAMA, 284:1689-1695, 2000

Comparison of Chronic Diseases

	Diabetes Mellitus	Addiction
Relapse Rates	30-50%	40-60%
Medication Adherence	30-50%	40-60%
Screening/Monitoring	A1C	Urine Drug Screens
Access to Treatment	++++	+
Behavioral Interventions	Nutritionist/DM educator	Individual Counseling/Groups
Pharmacotherapy	Multiple formulations	Multiple Formulations
Refractory to Treatment	Endocrinology	Addiction Medicine/Psychiatry
HealthCare Stigma	+	++++

DSM-5 Criteria for OUD

Substance use disorders are defined as a pattern of use that results in marked distress and/or impairment, with two or more of the following symptoms over the course of a 12-month period:

1. Using the substance in larger amounts or over a longer period of time than intended
2. Unsuccessful attempts or persistent desire to reduce use
3. Too much time spent on obtaining, using, and/or recovering from the effects of the substance
4. A strong craving for the substance
5. Significant interference with roles at work, school, or home
6. Continued use despite recurrent social or interpersonal consequences
7. Reducing or giving up important social, occupational, or recreational activities because of the substance use
8. Substance use in situations in which it may be physically hazardous
9. Substance use despite recurrent or persistent physical or psychological consequences
10. Tolerance of the substance
11. Withdrawal from the substance

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Loss of Control

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Use Despite Neg Consequences

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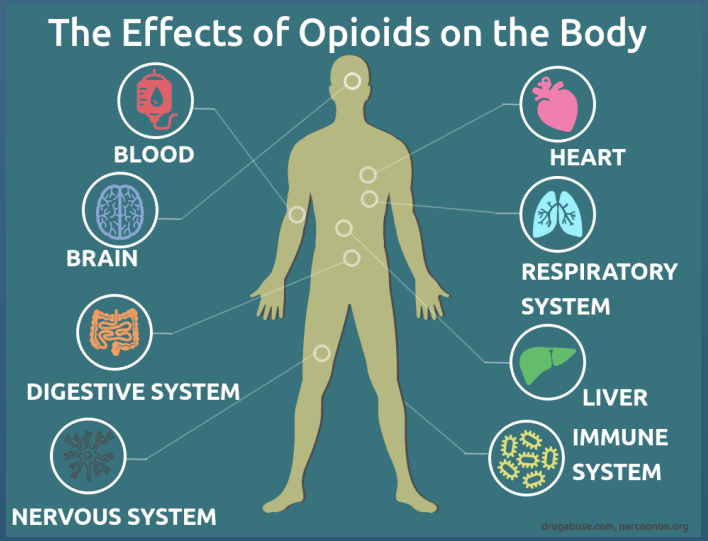
Loss of Control
Use Despite Neg Consequences
Physiologic Changes

Mild = 3
Moderate = 4-5
Severe ≥ 6

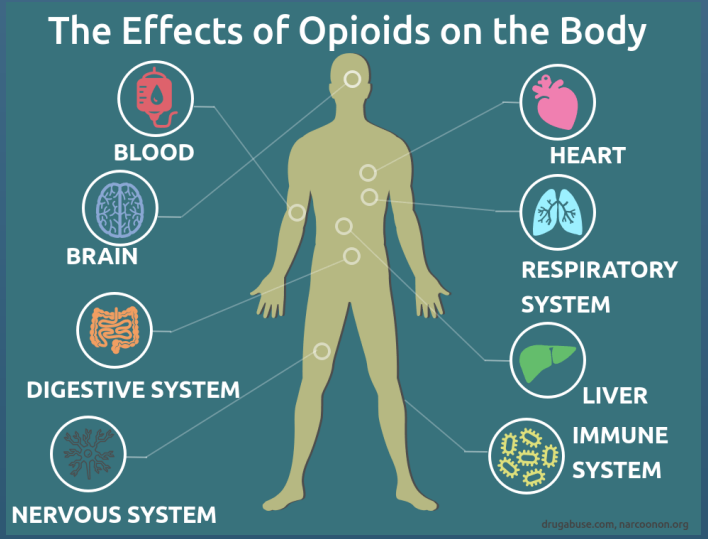
How do Medications for OUD Treatment Work?

- Provides **physiological** and **psychological** stabilization that can allow recovery to take place
  - **Reduce/prevent withdrawal**
  - **Diminish/eliminate cravings**



How do Medications for OUD Treatment Work?

- Provides **physiological** and **psychological** stabilization that can allow recovery to take place
  - **Reduce/prevent withdrawal**
  - **Diminish/eliminate cravings**
  - **Block the euphoric effect**
  - **Restore physiological function**



Opioid Use Disorder (OUD)

Most effective treatment is

Medication Assisted Treatment (MAT)

Opioid Use Disorder (OUD)

Most effective treatment is

~~Medication Assisted Treatment (MAT)~~

Medication for OUD (MOUD)

Is MOUD Effective for Opioid Addiction?

Decreases:

- Illicit use, death rate[1]
- HIV, Hep C infections[2-4]
- Crime[5]

Increases:

- Social functioning and retention in treatment[6-7]

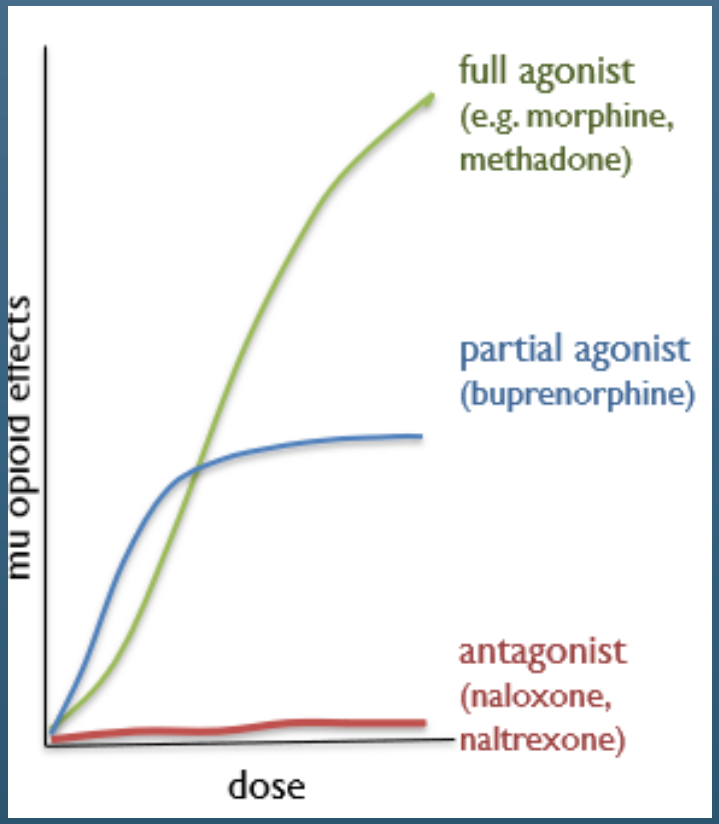
1.Kreek J, SubstAbuse Treatment 2002
2.MacArthur, BMJ, 2012
3.Metzgar, Public Health Reports 1998
4. K Page, JAMA IM, 2014
5.Gerstein DR et al, CALDATA General Report, CA Dept of Alcohol and Drug Programs, 1994
6. Mattick RP et al, Cochrane Database of Systematic Reviews, 2009
7. Mattick RP et al, Cochrane Database of Systematic Reviews, 2014

Special Populations

- Neonates (NOWS)
- Adolescents/Young Adults
- Pregnancy
- Veterans
- Older Adults
- Justice Involved
- Healthcare Providers (NCPHPs)

FDA Approved MOUD for Opioid Use Disorder

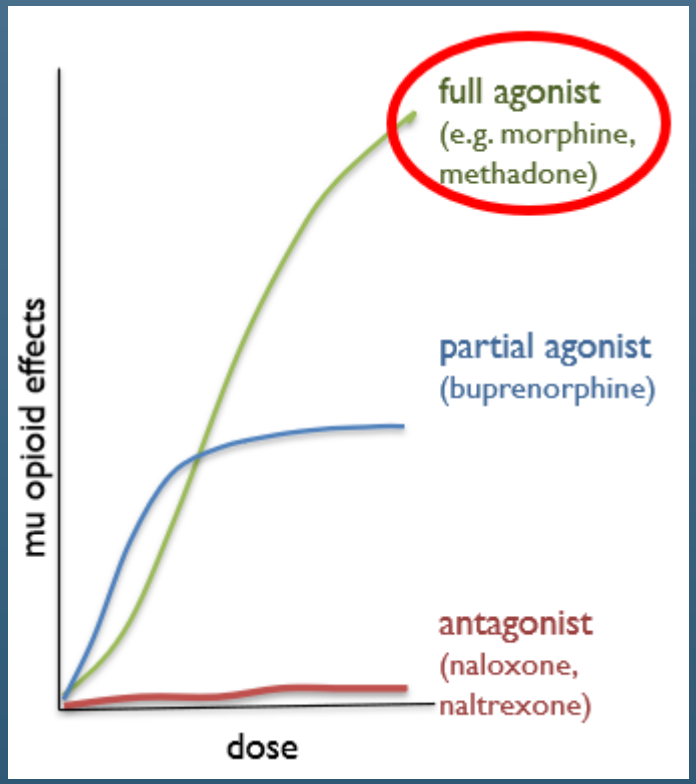
- Methadone
- Buprenorphine
- Naltrexone (*PO, IM)



SAMHSA, TIP Series 63, 2018

Methadone

- Long-acting, half-life 15-60 hrs
- Full agonist



21 CFR 1306.07 (c)

Methadone

- Long-acting, half-life 15-60 hrs
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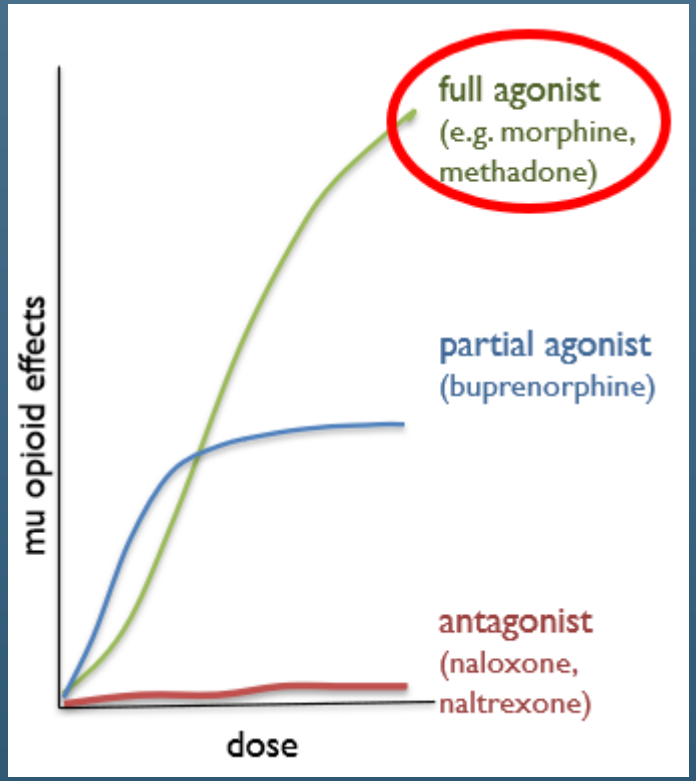
- Generally 80-120 mg/day
- Dangerous in overdose with polysubstance
  - QT prolongation



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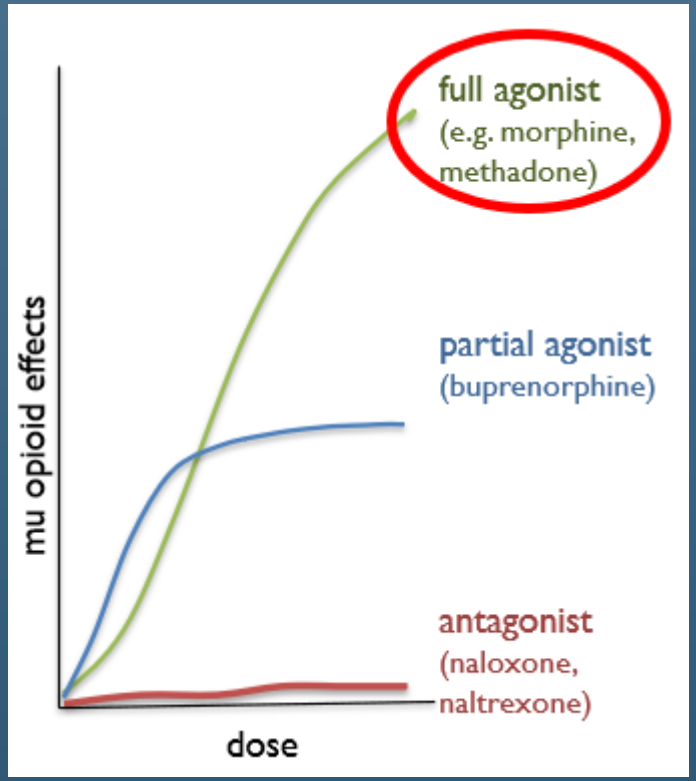
Methadone

- Long-acting, half-life 15-60 hrs
- Full agonist

- Generally 80-120 mg/day
- Dangerous in overdose with polysubstance
  - QT prolongation

- Can <u>continue</u> methadone for maintenance while inpatient
- If admitted for reason other than OUD, can <u>initiate</u> while inpatient



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Opioid Treatment Programs (OTPs)

- Methadone can only be prescribed in a federally-regulated OTP when used for treatment of addiction
- Most common approach used worldwide

Salsitz, Mt Sinai J of Medicine, 2000

Opioid Treatment Programs (OTPs)

- Methadone can only be prescribed in a federally-regulated OTP when used for treatment of addiction
- Most common approach used worldwide

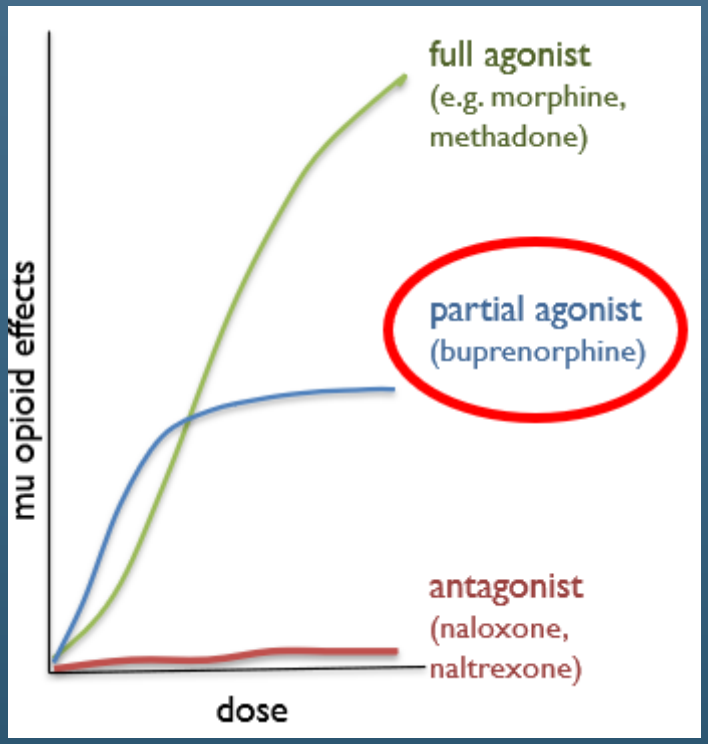
- Daily, directly observed therapy
  - Can obtain take home doses

- Not reported in PDMP
- Not referred to as "Methadone clinics"

Salsitz, Mt Sinai J of Medicine, 2000

Buprenorphine

- Partial mu-opioid agonist
- Kappa-opioid antagonist
- Half-life ~24-36 hrs



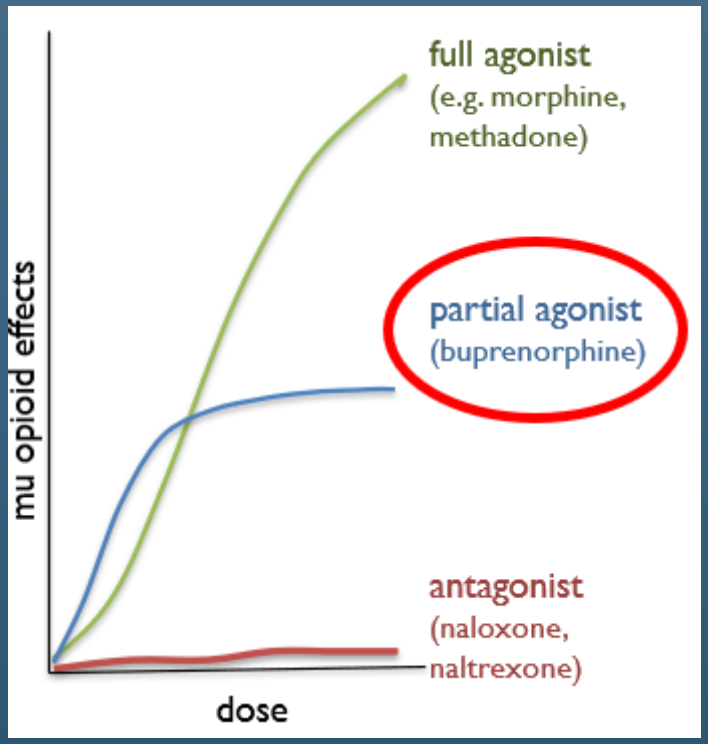
SAMHSA, 2018
Orman & Keating, 2009

Buprenorphine

- Partial mu-opioid agonist
- Kappa-opioid antagonist
- Half-life ~24-36 hrs

- 20-40x more potent than morphine

- Highest affinity for opioid receptor
  - Blocks/displaces other opioids
  - Can precipitate withdrawal

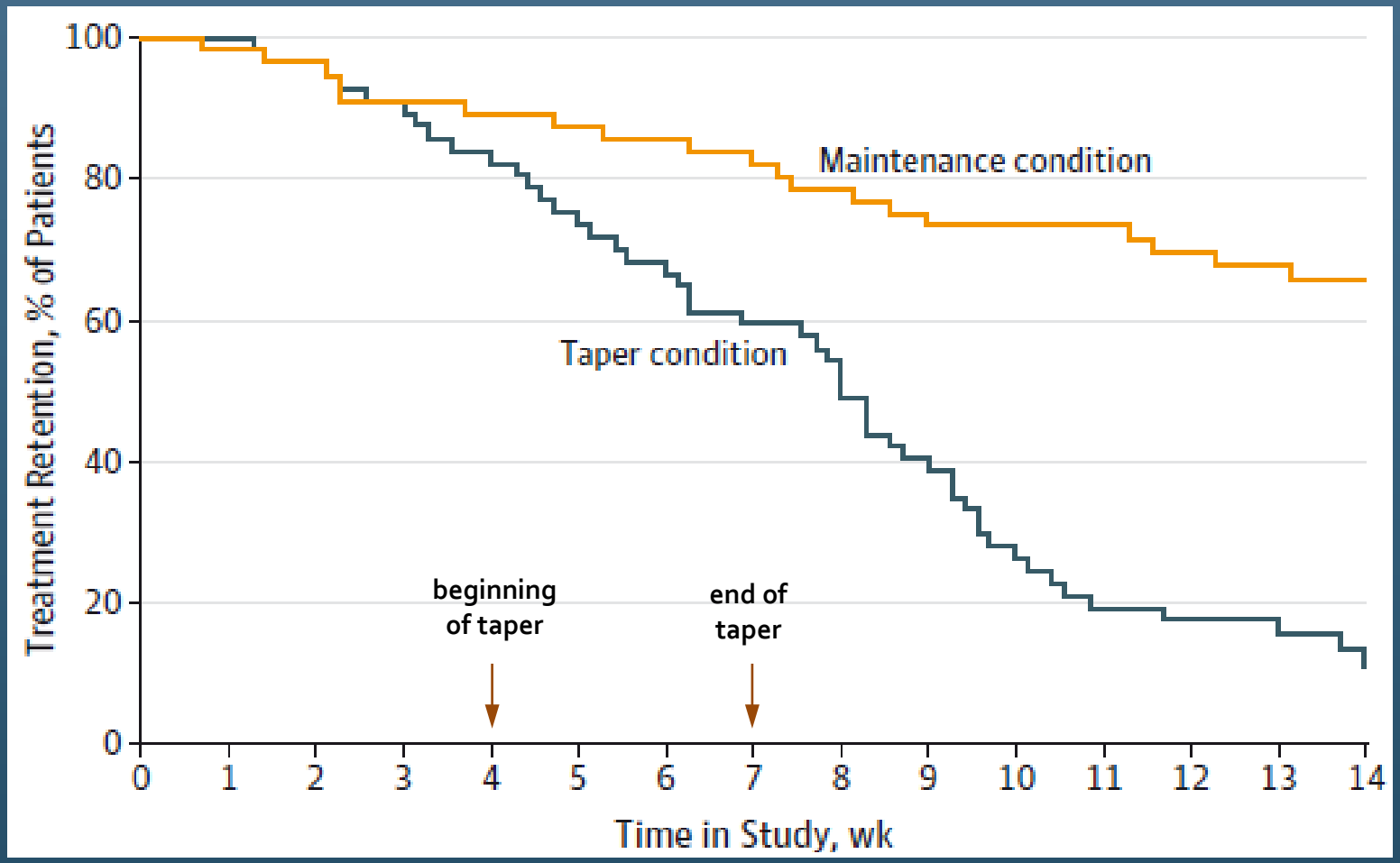


SAMHSA, 2018
Orman & Keating, 2009

Buprenorphine Formulations

	Route	Product Name
Buprenorphine With Naloxone (combo product)	SL	Suboxone® (film/tablet)
	SL	Zubsolv® (tablet)
	Buccal	Bunavail® (film)
Buprenorphine Without Naloxone (mono product)	SL	Subutex® (tablet) - generic
	Implant – q6 mo	Probuphine®
	SC injection – q 30d	Sublocade®
FDA Approved - Pain	IV	Buprenex®
	Transdermal – q7 days	BuTrans®
	Buccal	Belbuca® (film)

Buprenorphine: Maintenance vs. Taper (Prescription Opioid Dependence)



Fiellin et al., 2014

Office-Based Outpatient Treatment (OBOT)

- DATA 2000 -> physicians prescribe Buprenorphine for OUD in an office setting
  - 8 hrs of training, DEA assigns X license #
  - 1st year = 30 pts; request increase to 100 pts

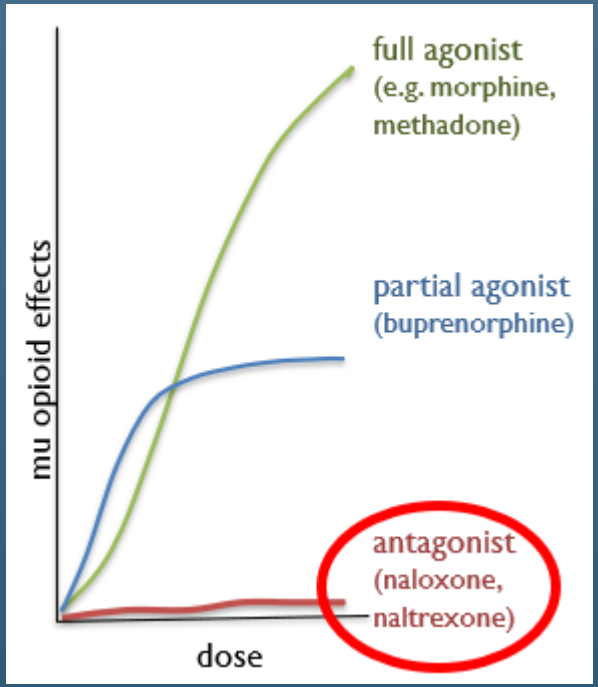
Office-Based Outpatient Treatment (OBOT)

- DATA 2000 -> physicians prescribe Buprenorphine for OUD in an office setting
  - 8 hrs of training, DEA assigns X license #
  - 1st year = 30 pts; request increase to 100 pts
- Comprehensive Addiction Recovery Act (CARA) 2016
  - Authorizes NPs + PAs to obtain DEA X license
  - 24 hrs of training
- SUPPORT Act 2018
  - 11/2/2020 – permanently allowing NP + PAs to be considered qualifying practitioner
  - Clinical Nurse Specialist, Certified RN Anesthetist, Certified Nurse Midwife
    - Temporarily includes these individuals as "qualifying practitioners"

Naltrexone

- Full Antagonist

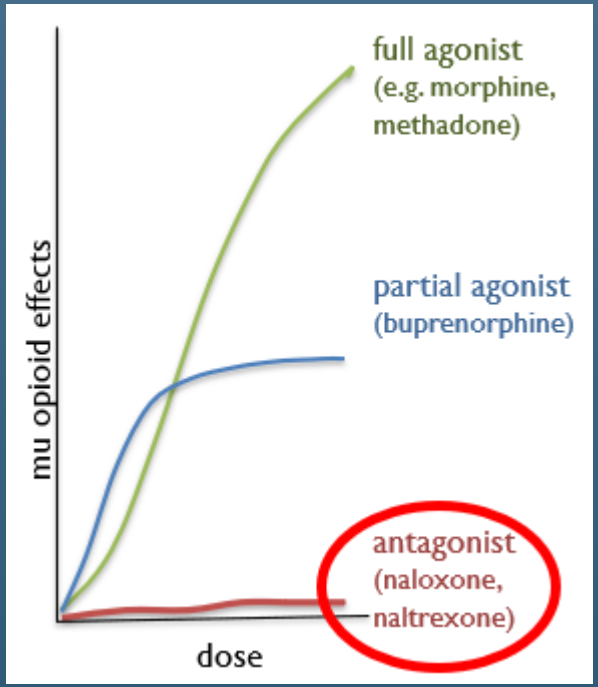
- Formulations
  - Tablets: Revia®: FDA approved in 1984
  - Extended-Release intramuscular injection: Vivitrol®: FDA approved in 2010



SAMHSA, 2018
Orman & Keating, 2009

Naltrexone

- Full Antagonist
- Formulations
  - Tablets: Revia®: FDA approved in 1984
  - Extended-Release intramuscular injection: Vivitrol®: FDA approved in 2010
- Administration
  - Abstain from opioids:
    - > 7 days (short-acting) vs. 10-14 (long-acting)
  - Difficulty initiating inpatient/outpatient



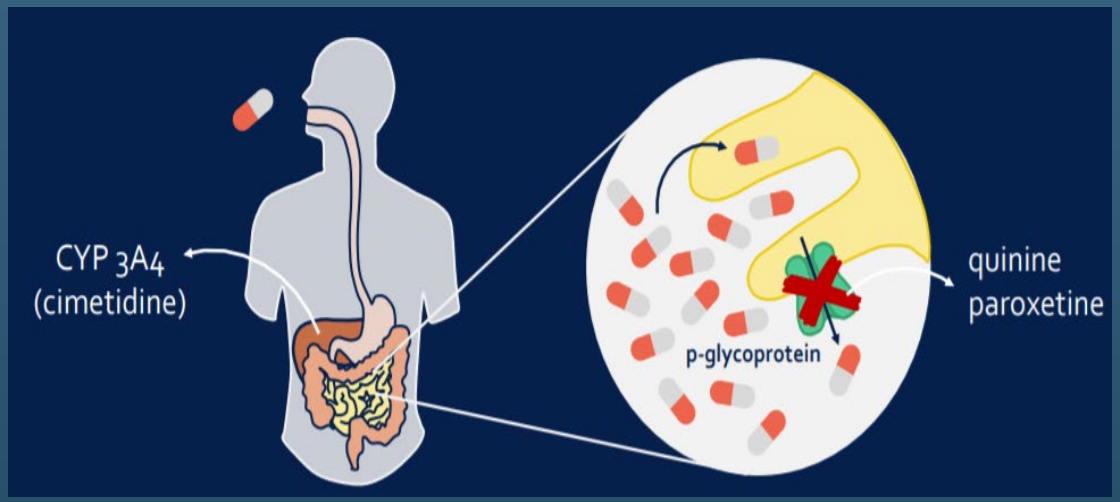
SAMHSA, 2018
Orman & Keating, 2009

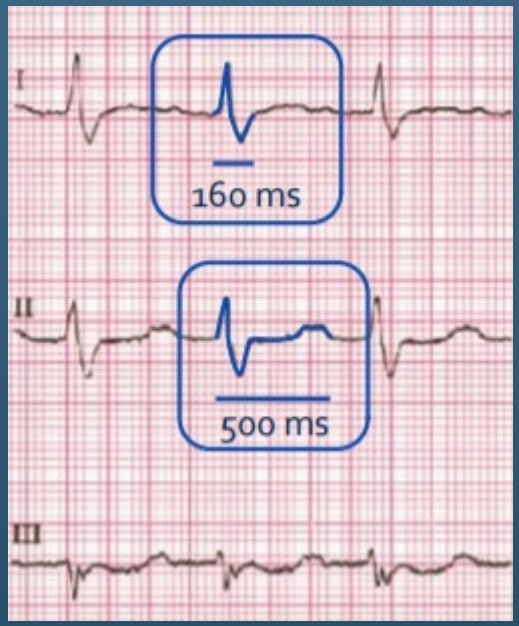
Mitragyna speciosa

- Major alkaloid: Mitragynine
  - Low dose -> Stimulant-like effect (≤ 5 g)
  - Higher doses -> Opioid-like effect (~15 g)
- Withdrawal – onset 12-18 hrs, several days
  - No controlled trials, similar to other opioids
- Treatment for Kratom Use Disorder?

Loperamide for Opioid Withdrawal?

- "Poor Man's Methadone," "Lope-Dope"
- Euphoria, Withdrawal Mgmt
- Blocks Na+ & HERG K+ Channels

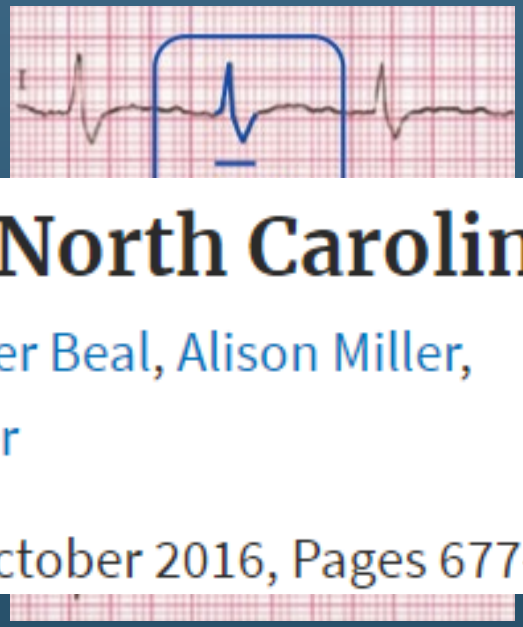




Wu P and Juurlink D (Ann Emerg Med 2017)

Loperamide for Opioid Withdrawal?

- "Poor Man's Methadone," "Lope-Dope"
- Euphoria, Withdrawal Mgmt
- Blocks Na+ & HERG K+ Channels



Loperamide-Related Deaths in North Carolina

Sandra C. Bishop-Freeman ✉, Marc S. Feaster, Jennifer Beal, Alison Miller, Robert L. Hargrove, Justin O. Brower, Ruth E. Winecker

Journal of Analytical Toxicology, Volume 40, Issue 8, October 2016, Pages 677–686,

Wu P and Juurlink D (Ann Emerg Med 2017)

Adjunct Treatment

Opioid Use Disorder

HIV Prevention: PrEP/PEP

- Prophylactic daily antiretroviral
  - Truvada® (Tenofovir disproxil fumarate/Emtricitabine)
  - Descovy® (Tenofovir alafenamide/Emtricitabine)
    - Excludes: risk involving receptive vaginal intercourse
- **CDC Recommendation** for PWID
  - Based on a single RCT in Bangkok

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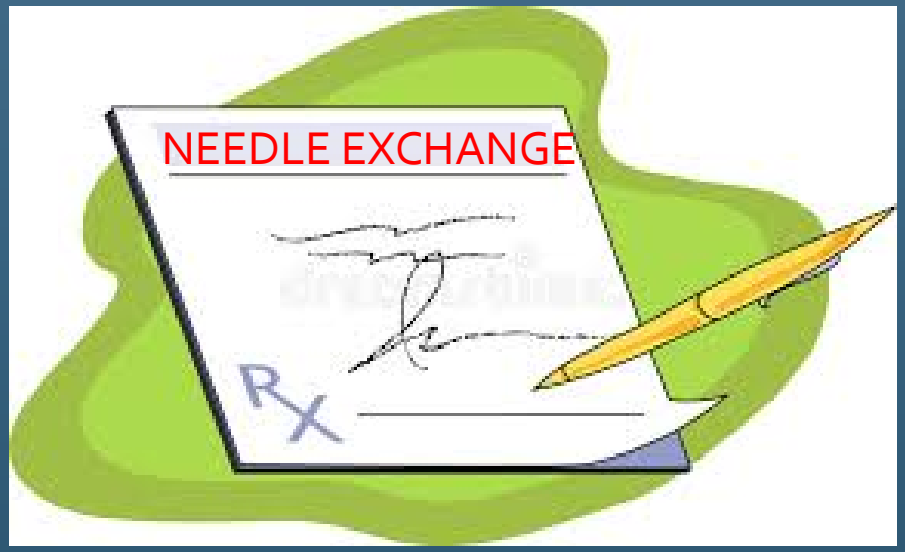
- **CDC Recommendation** for PWID
  - Based on a single RCT in Bangkok
- Challenging in real-world practice
  - Requires regular engagement in care
- **PEP** (post-exposure prophylaxis)

Adjunct Treatments

- Pharmacotherapy
  - Hepatitis C
  - Co-occurring mental illness
  - Tobacco/Nicotine use
- Vaccinations
  - Hep A
  - Hep B
  - PSV23
  - Tdap
  - Influenza
  - COVID-19?…

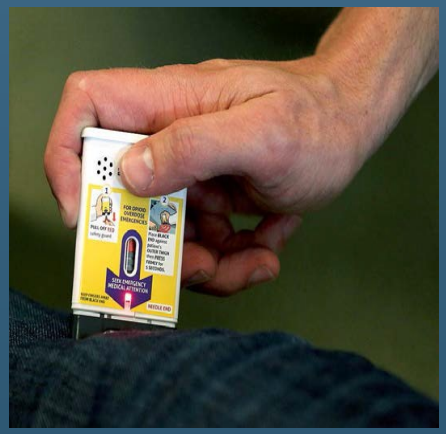


Naloxone

- No effect other than blocking opioids
- No potential for abuse
- Naloxone ≠ MAT!!
- Increased shelf life for Narcan®! (Aug 2020)

Narcan®
Nasal Spray

Adapt Pharma



Auto-injector
Evzio® (generic)

Kaleo Inc.

Intramuscular
Injection

Various Companies

Urine Drug Testing

- Rationale for testing
  - Frequency, types of testing, cross check PDMP
- Screening vs. confirmation
- Positive result…
- Negative result…
- POC Testing?

	Ref Range & Units	11/4/20 1558
Amphetamine Screen, Ur	Not Applicable	<500 ng/mL
Barbiturate Screen, Ur	Not Applicable	<200 ng/mL
Benzodiazepine Screen, Urine	Not Applicable	<200 ng/mL
Cannabinoid Scrn, Ur	Not Applicable	<20 ng/mL
Methadone Screen, Urine	Not Applicable	<300 ng/mL
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Resulting Agency		UNCH MCL

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Buprenorphine, Urine	Cutoff: 5.0 ng/mL	605.0
Norbuprenorphine, Urine	Cutoff: 2.5 ng/mL	1219.8

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	Ref Range & Units	11/3/20 1211
Amphetamine Confirm	Cutoff: 25 ng/mL	5682
Phentermine	Cutoff: 25 ng/mL	Negative
Methamphetamine Confirm, Ur	Cutoff: 25 ng/mL	5452
Pseudoephedrine	Cutoff: 25 ng/mL	Negative
MDA	Cutoff: 25 ng/mL	Negative
MDMA Confirm	Cutoff: 25 ng/mL	Negative
Amphet Interp, Urine		Positive.

Behavioral Treatment to Facilitate Recovery

Studies of MAT efficacy all in combination with behavioral treatment;
MAT outcomes best when integrated with behavioral interventions

Mutual support/self-help groups
- AA, NA, Smart Recovery, Women for Sobriety

Psychosocial and non-pharmacologic treatments
- Cognitive Behavioral Therapy
- Dialectical Behavioral Therapy
- Motivational Enhancement Therapy
- Contingency or Incentive Based Therapy
- Community Reinforcement and Couples Based Therapies

Behavioral Health's Role in OUD Treatment

- **Optional** psychosocial treatment should be offered in conjunction with pharmacotherapy.

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- A decision to refuse psychosocial treatment/absence of available treatment should **not** preclude or delay MAT.
- Refusing psychosocial services should **not** generally be used as rationale for discontinuing current MAT.

What can/should I do at an Outpatient Visit?

Enhancing likelihood of long-term recovery:

- Check State Prescription Drug Monitoring Program
- Introduce UDS if not done previously
- Collaborative Care: Integrated BH care (IMPACT model)
- Infectious disease evaluation (PrEP, PEP, Vaccines)
- Assess for IPV/housing/sexual health
- Harm reduction (needle exchange, naloxone)
- Safe storage of medications
- Assess tobacco/nicotine use

"Case Management"
Adapting Treatment Based on Outcome

Based on ongoing assessment, consider need to:

- Increase level of care
- Improve recovery environment
  - Joblessness / Homelessness
  - Substance use in the living environment

- Assess/access treatment for co-morbid psychiatric problems
- Assess and integrate primary care
- Is there now a need for MOUD?
- If on MOUD, how is adherence? Can it be improved?

Tele-BH for OUD

Expansion of Services During COVID-19:

- Initially audio/video only for MOUD prescribing
- DHHS, DEA, SAMSHA – 3/31/2020
    - Buprenorphine induction via telephone
- Low threshold treatment access/Reach Vulnerable populations
    - Not well studied
- Relaxation of Requirements for OTPs
- Changes in reimbursement for Tele-BH services

Words Matter!

What we say and how we say it makes a difference to our patients with substance use disorder(s).

Stigmatizing Language	Non- Stigmatizing Language
Addict, drunk, junkie	
Drug habit Abuse Drug problem	
Clean	
Clean or dirty drug screen	

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Clean	Person in recovery Abstinent Not drinking or taking drugs
Clean or dirty drug screen	Positive or negative (toxicology screen results)

Case Follow Up

- 34 yo G2P1102 F with hx opioid and tobacco use disorders who presented to your clinic to establish care.
- Stabilized cravings/withdrawal on Buprenorphine/naloxone 8/2 mg SL tablet BID.
- Engaged pt using motivational interviewing for tobacco use, stopped smoking after ~12 months. Pt requested IUD for contraception and eventually would like to start counseling for past hx trauma.

Summary Points

- Addiction is a chronic disease and primarily involves the rewarding effects of dopamine.
- Pharmacotherapy is strongly evidence-based for opioid use disorder, consistently demonstrating better long-term outcomes than no MOUD (detox/medically supervised withdrawal).
- Consider adjunct pharmacotherapies (PrEP, PEP, Naloxone) when working with individuals with opioid use disorder.
- Tele-behavioral health services allow for buprenorphine prescribing, increasing access to treatment.

SE AETC MOUD ECHO (Telementoring)

KY - https://krhio.org/project-echo/

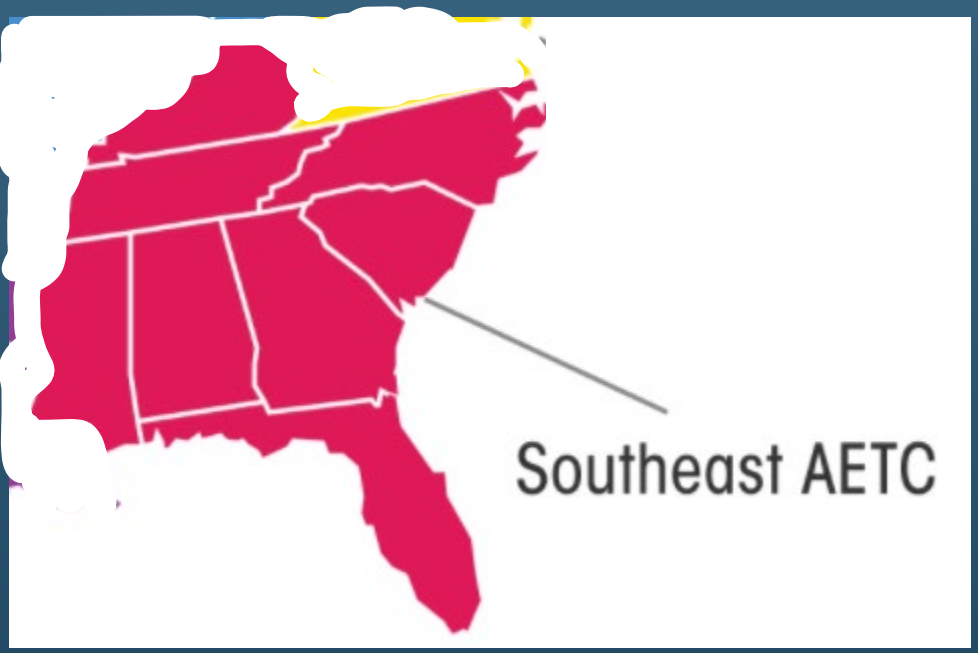
TN - https://www.etsu.edu/com/cme/project_echo_main.php

NC - www.echo.unc.edu | https://mahec.net/event/58626

SC - https://scmataccess.org/

AL - https://www.uabmedicine.org/web/medicalprofessionals/project-echo

GA, FL, MS-?



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Thank you!
Questions?

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https://www.cdc.gov/drugoverdose/resources/hhs.html
https://www.samhsa.gov/medication-assisted-treatment
https://www.asam.org/resources/publications
https://www.hhs.gov/about/agencies/iea/partnerships/opioidtoolkit/index.html
https://www.asam.org/membership/state-chapters