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Management of Opioid Use Disorder
Update on the Changing Clinical and Regulatory Landscape

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Disclosures

Dr. Gandhi, faculty for this activity, has no relevant financial relationship(s) to disclose. None of the planners for this activity have relevant financial relationships to disclose.

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Learning Objectives

After participating in this session, attendees will be able to:

1. Describe the current status of the opioid epidemic and opioid overdose deaths.
2. Recognize the changes in illicit opioid supply and their impact on the clinical management of patients with opioid use disorder (OUD).
3. Identify medications to utilize for treatment of OUD in general medical settings in light of the recent federal regulatory changes.

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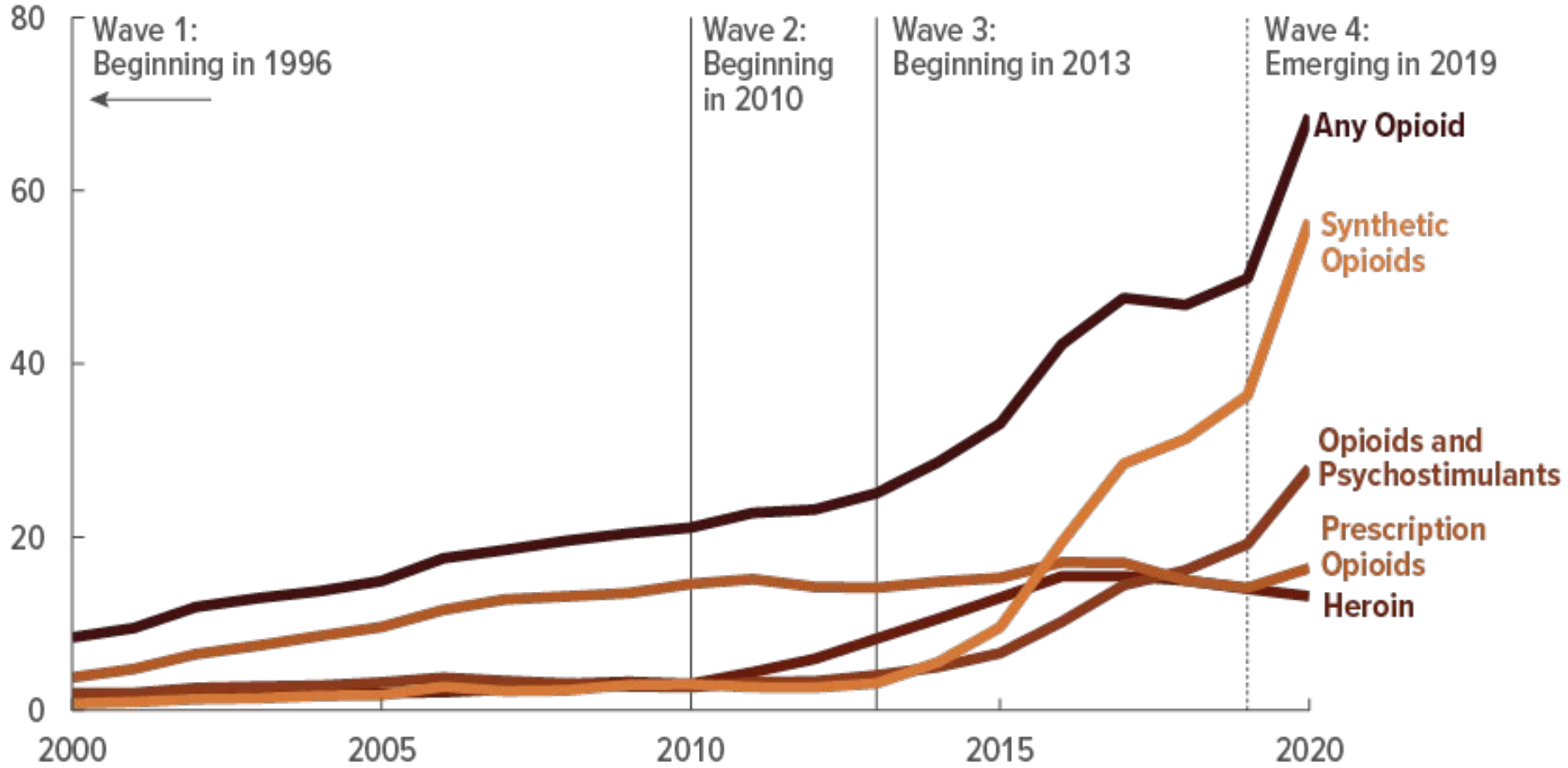
STATUS OF THE OPIOID EPIDEMIC

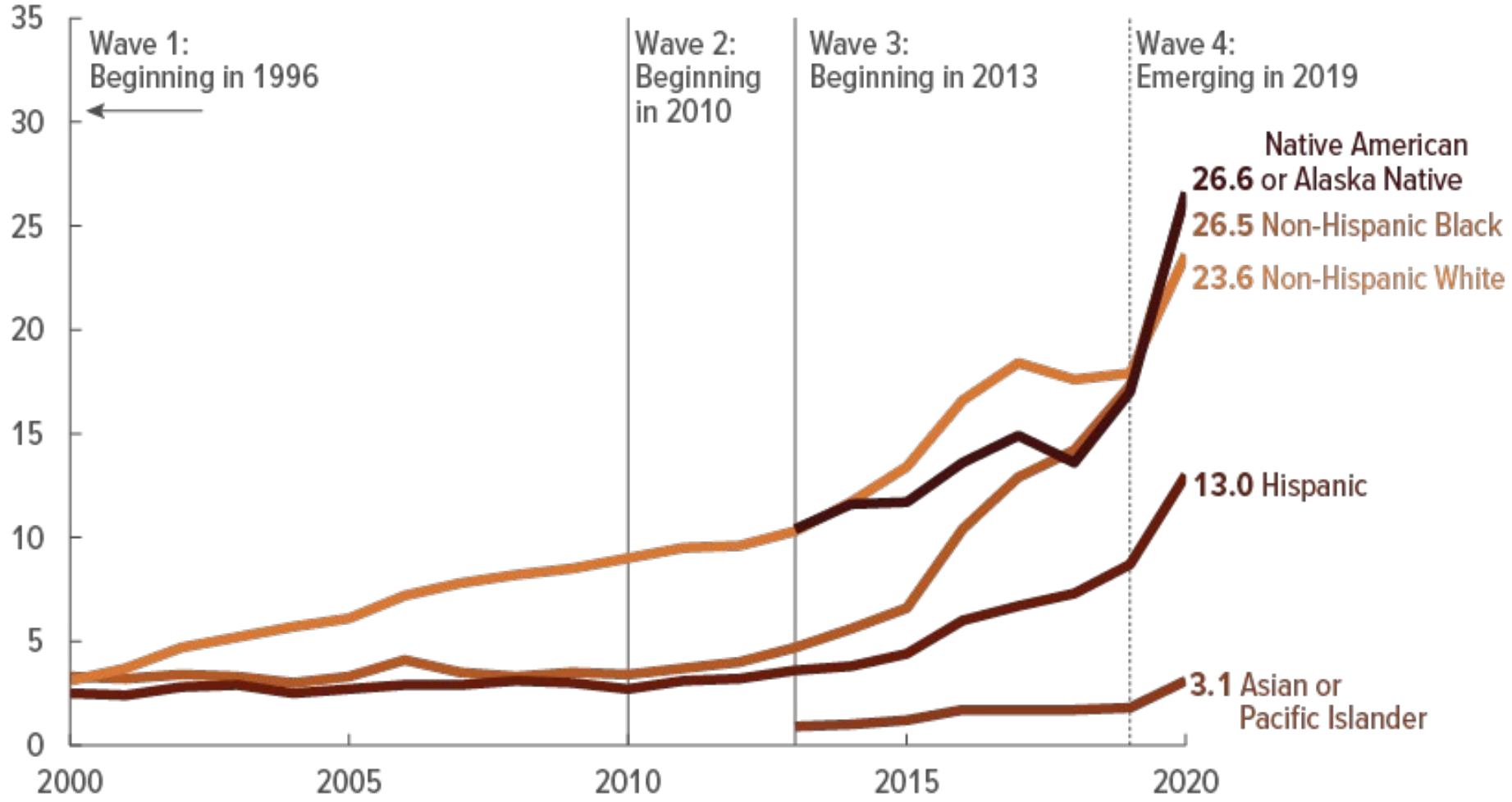
Overdose Deaths Involving Opioids, by Type of Opioid

Thousands of Deaths



https://www.cbo.gov/publication/58532

Overdose Deaths Involving Opioids, by Race and Ethnicity: Deaths per 100,000 People

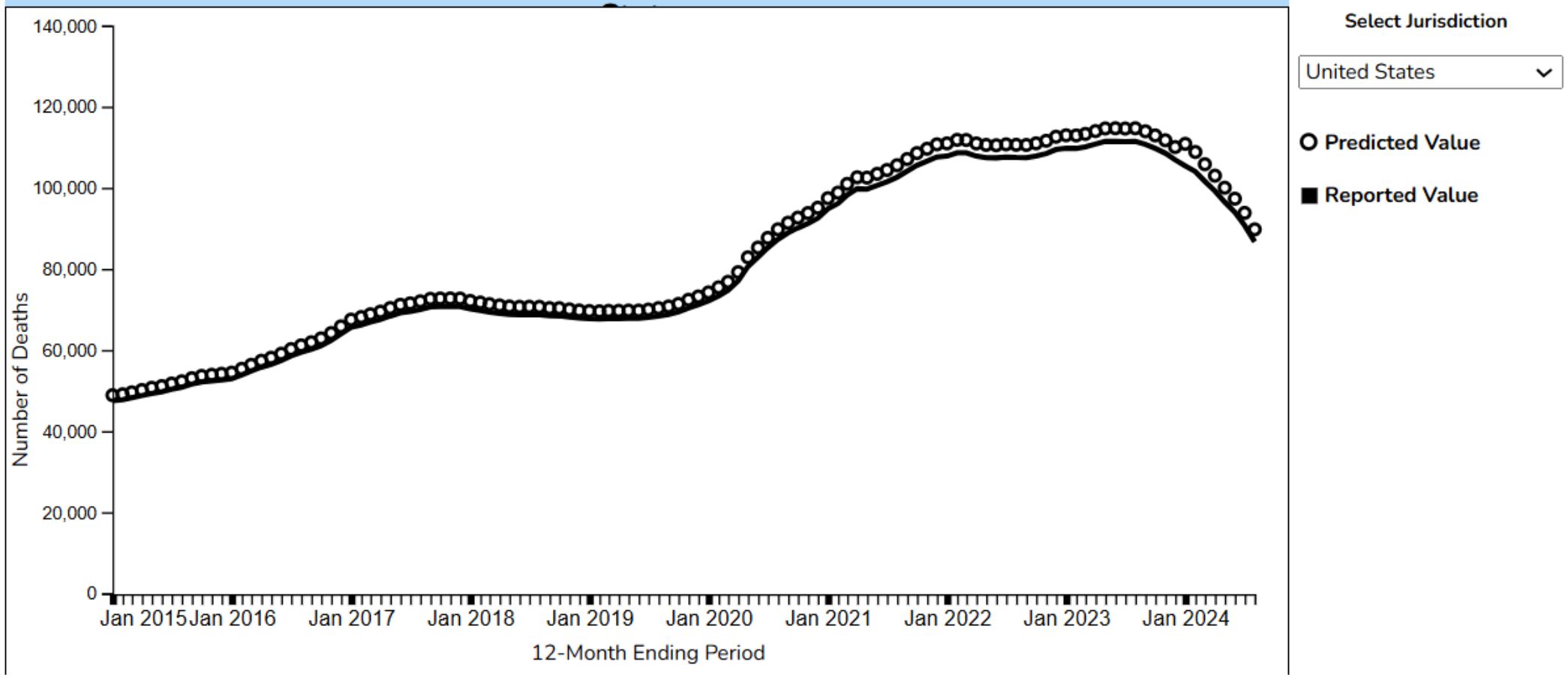


https://www.cbo.gov/publication/58532

12 Month-ending Provisional Number and Percent Change of Drug Overdose Deaths

Based on data available for analysis on: January 5, 2025

Figure 1a. 12 Month-ending Provisional Counts of Drug Overdose Deaths: United



Source: https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

12 Month-ending Provisional Number of Drug Overdose Deaths by Drug or Drug Class

Based on data available for analysis on: January 5, 2025

*After opening the **drug class dropdown**, click the top of the dropdown menu again to make the checkboxes disappear.*

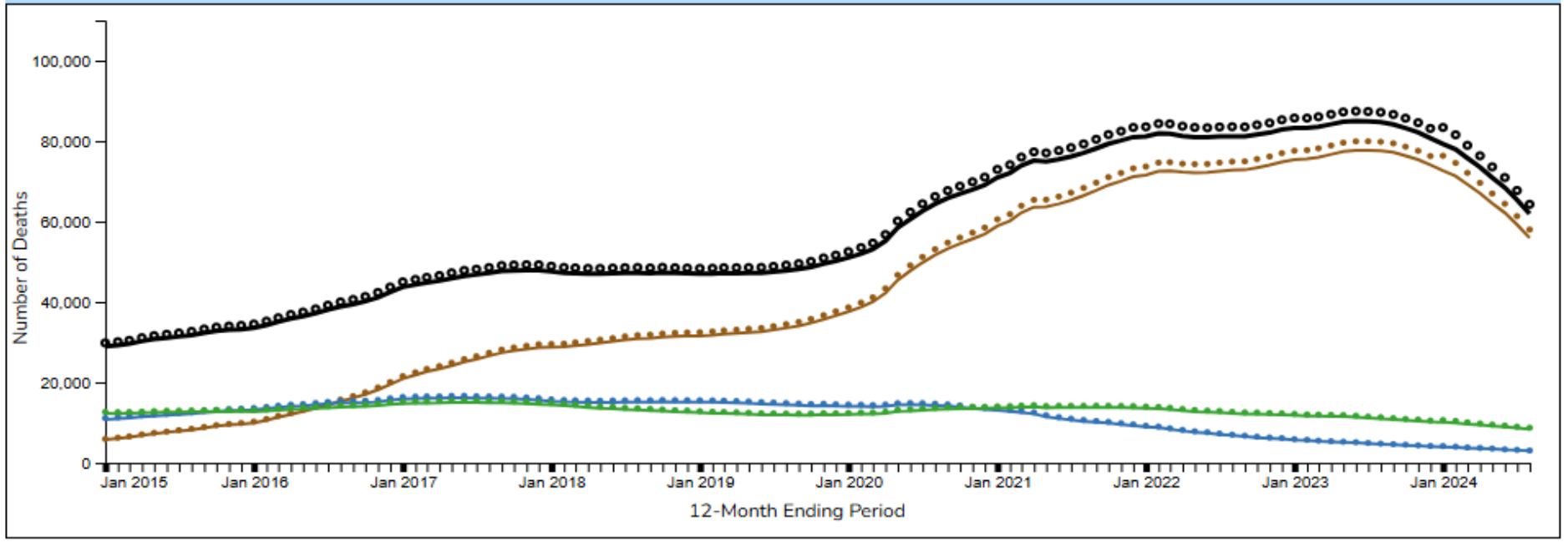
Select Jurisdiction

United States

Select specific drugs or drug classes

Select drug class

Figure 2. 12 Month-ending Provisional Number of Drug Overdose Deaths by Drug or Drug Class: United States



Legend for Drug or Drug Class

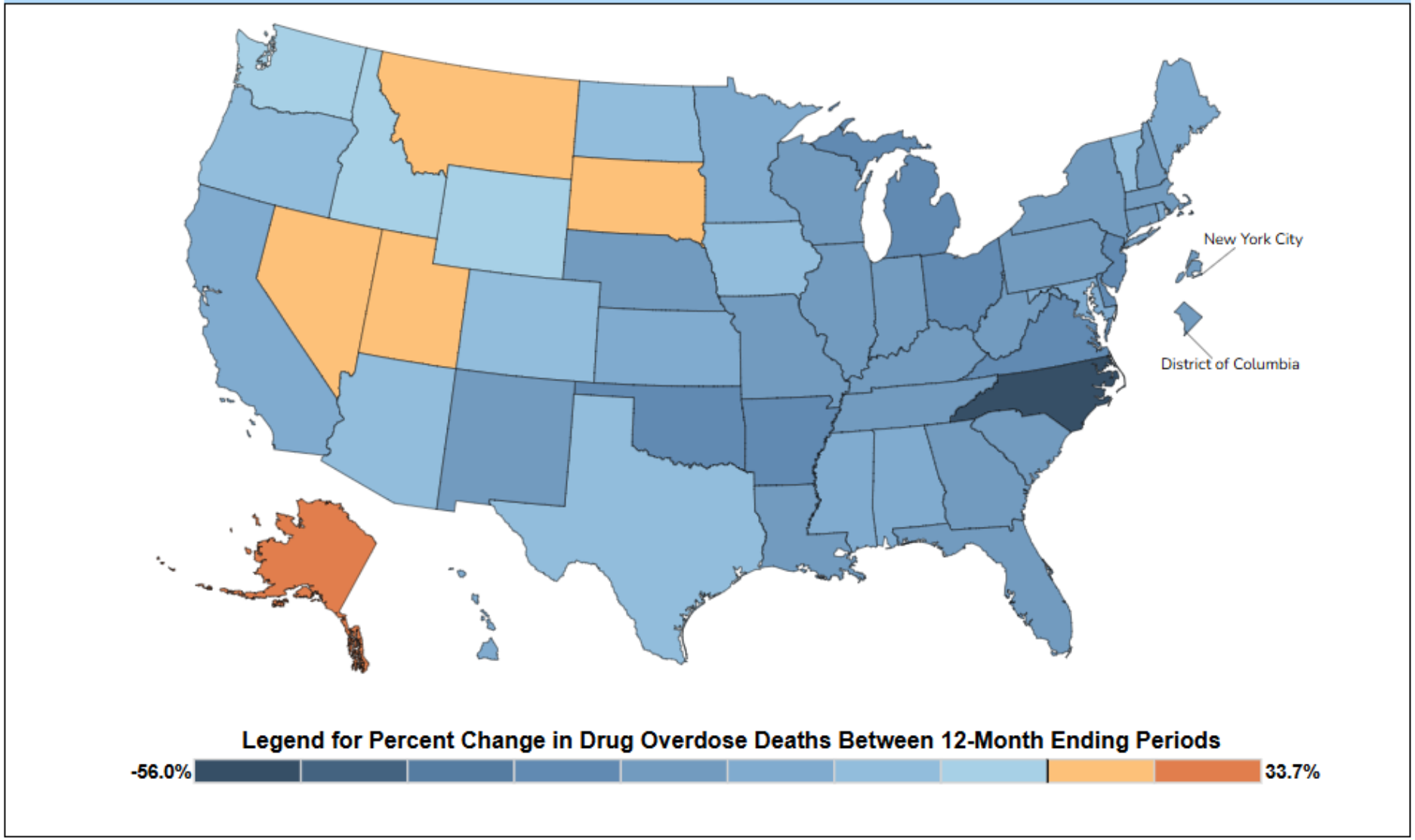
- Heroin (T40.1)
- Natural & semi-synthetic opioids (T40.2)
- Opioids (T40.0-T40.4,T40.6)
- Synthetic opioids, excl. methadone (T40.4)

---- Reported Value

O Predicted Value

Source: https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

Figure 1b. Percent Change in Reported 12 Month-ending Count of Drug Overdose Deaths, by Jurisdiction: August 2023 to August 2024



Source: https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

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RECENT CHANGES IMPACTING PRACTICE

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Quick Recap of MOUD

- 3 FDA approved medications for opioid use disorder:
  - Methadone: full mu opioid receptor agonist
  - Buprenorphine: partial mu agonist
  - Naltrexone: mu antagonist
- All 3 are highly effective, but naltrexone is less widely used because of difficulty with initiation and adherence
- Methadone and buprenorphine: decrease or eliminate non-prescribed opioid use (NNT=2 for relapse prevention*)
- Decrease HIV/Hep C transmission, criminal activity, increase employment, improve quality of life**
- Decrease overdose mortality by >50%***

*Epstein DH, Heilig M, Shaham Y. Science-Based Actions Can Help Address the Opioid Crisis. Trends Pharmacol Sci. 2018 Nov;39(11):911-916. doi: 10.1016/j.tips.2018.06.002. PMID: 30343726.

**Garcia-Portilla MP, et al. Long term outcomes of pharmacological treatments for opioid dependence: does methadone still lead the pack? Br J Clin Pharmacol. 2014 Feb;77(2):272-84. doi: 10.1111/bcp.12031. PMID: 23145768; PMCID: PMC4014027

*** Burns M, et al. Duration of medication treatment for opioid-use disorder and risk of overdose among Medicaid enrollees in 11 states: a retrospective cohort study. Addiction. 2022 Dec;117(12):3079-3088. doi: 10.1111/add.15959. Epub 2022 Jun 13. PMID: 35652681; PMCID: PMC10683938.

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Fentanyl and Precipitated Withdrawal

Traditional vs Micro/Macro-dosing in Buprenorphine Initiation

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Fentanyl Complicates Buprenorphine Initiation

- Initiation of buprenorphine presents considerable challenges due to the risk of precipitated withdrawal (PW)
- Particularly true when transitioning from full mu opioid receptor (MOR) agonists with prolonged action (e.g., methadone/fentanyl) to buprenorphine
- PW occurs because of buprenorphine's low intrinsic activity (i.e., ***partial agonist*** action) at the MOR, combined with its capacity to displace full agonists from the MOR (i.e., ***high affinity***)

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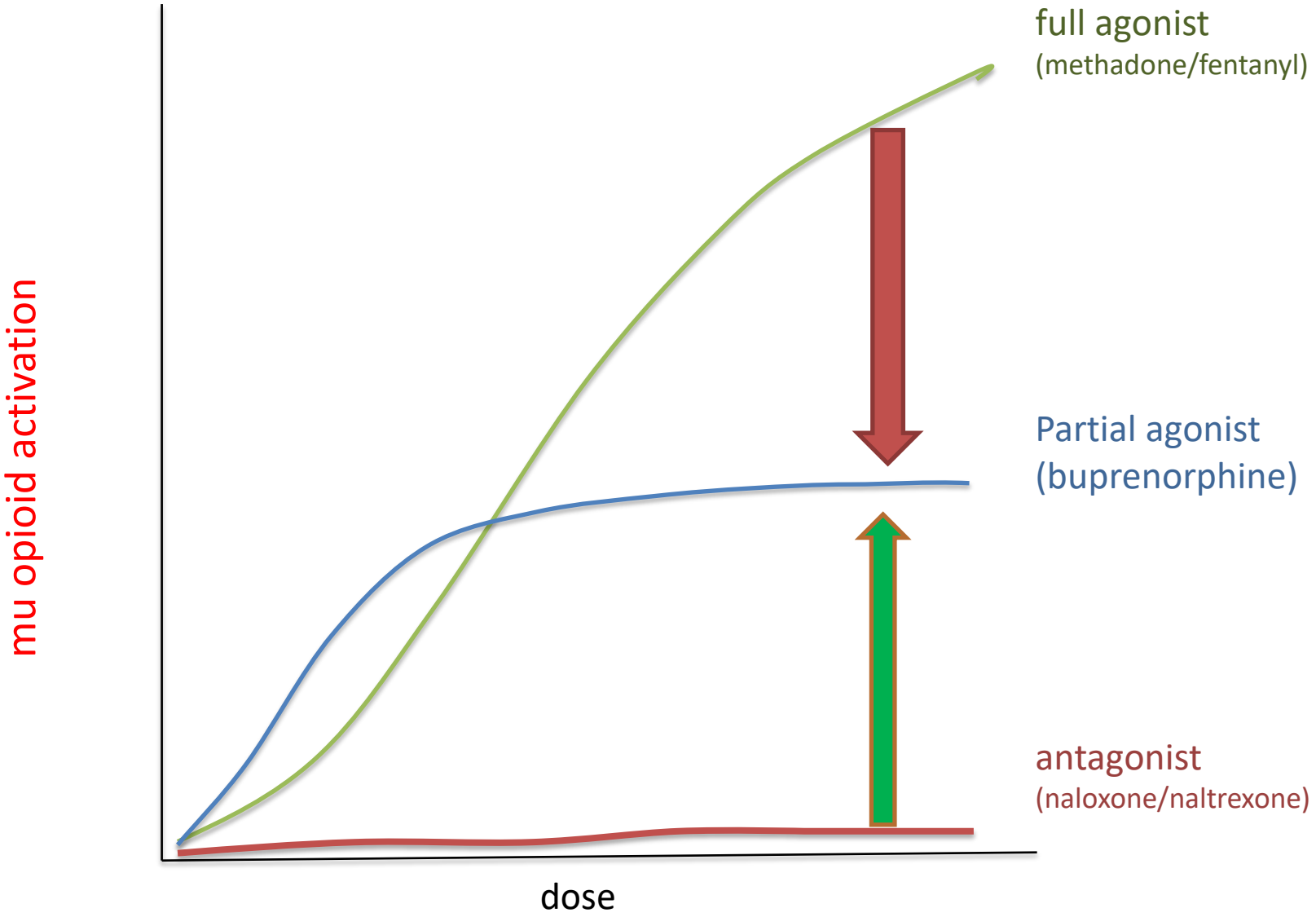

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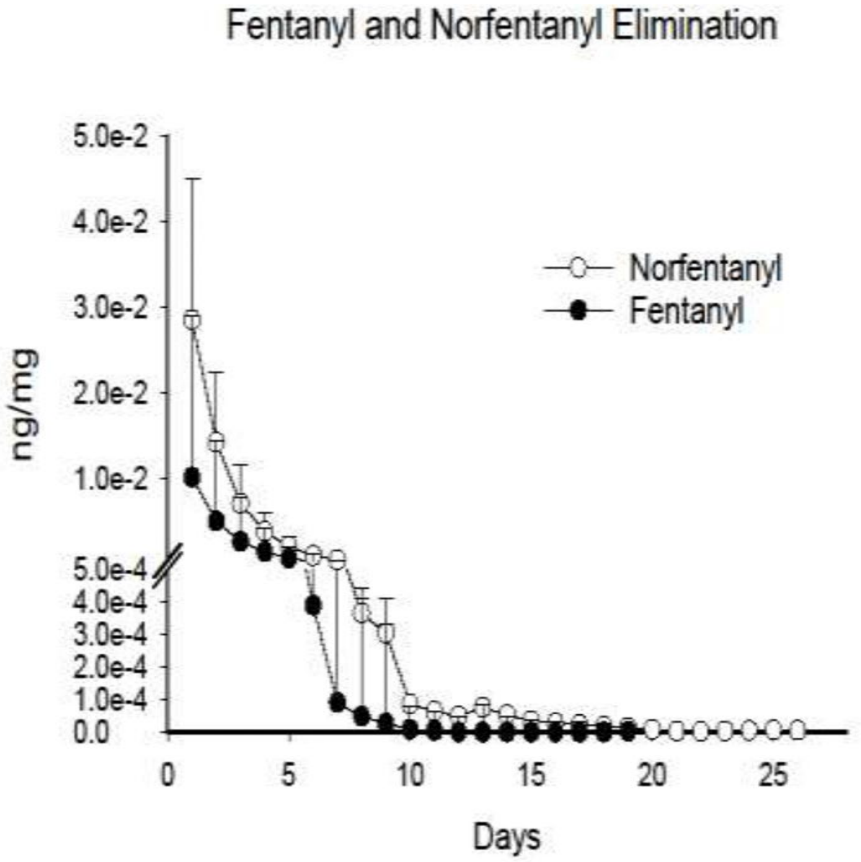
Fentanyl Pharmacology

- Distinct pharmacological profile vs other opioids
  - –high potency (100x morphine)
  - –high lipophilicity
  - –sequestration and gradual release from lipid tissue
  - –extended elimination half-life*
  - –long window of risk for PW
  - –extended positivity on fentanyl drug tests



*Mean time for fentanyl and norfentanyl clearance was 7.3 (4.9) and 13.3 (6.9) days, respectively. One participant continued to test positive for fentanyl for 19 days and norfentanyl for 26 days

*Huhn AS, Hobelmann JG, Oyler GA, Strain EC. Protracted renal clearance of fentanyl in persons with opioid use disorder. Drug Alcohol Depend. 2020 Sep 1;214:108147. doi: 10.1016/j.drugalcdep.2020.108147. PMID: 32650192; PMCID: PMC7594258.

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The Old Approach to PW Prevention

- Old guidelines are based primarily on methadone to buprenorphine transitions
- Recommend tapering methadone to less than 30mg, discontinuing it for 1-2 days and then starting buprenorphine at a low dose (2mg SL)*
- Many patients experience PW even after following the recommended protocol
- PW while starting buprenorphine has become more common since the advent of non-pharmaceutical fentanyl
- Low/High Dose Buprenorphine Initiation offers alternative ways to reduce the risk of PW by initiating bup using smaller (“micro”), or higher (“macro”) doses

*Substance Abuse and Mental Health Services Administration. *Medications for Opioid Use Disorder*. Treatment Improvement Protocol (TIP) Series 63 Publication No. PEP21-02-01-002. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2021.

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What is Low-dose Buprenorphine Initiation?*

- Involves starting buprenorphine at a lower than usual dose- typically 0.25-1 mg initially
- In contrast to traditional initiation, patients may continue their use of full opioid agonists (e.g., methadone or fentanyl), until a therapeutic dose of buprenorphine is achieved
- At that point, the full opioid agonist is discontinued, without the need for a slow taper
- Typically, this process takes place over a 3- to 10-day period
- Although it is now being applied widely, evidence for its effectiveness is preliminary, limited to case reports/series, utilizing disparate protocols and transition time-frames

*De Aquino JP, Parida S, Sofuoglu M. The Pharmacology of Buprenorphine Microinduction for Opioid Use Disorder. Clin Drug Investig. 2021 May;41(5):425-436. doi: 10.1007/s40261-021-01032-7.

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Example of a Microdose Protocol*

Table 2. Outpatient Microinduction Protocol Using Sublingual 2 mg Buprenorphine/Naloxone Tablets or Films

Day	Bup/Nlx Dose and Frequency	Full Agonist Opioid
1	0.5 mg daily (1/4 tablet or film)	No change
2	0.5 mg BID	No change
3	1 mg BID (half-tablet or film)	No change
4	2 mg BID	No change
5	2 mg TID	No change
6	4 mg TID	No change
7 and beyond	Per provider discretion	Taper by 25% weekly

Bup, Buprenorphine; Nlx, naloxone; BID, twice a day; TID, twice a day.

*Robbins JL, Englander H, Gregg J. Buprenorphine Microdose Induction for the Management of Prescription Opioid Dependence. J Am Board Fam Med. 2021 Feb;34(Suppl):S141-S146.

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High Dose Buprenorphine Initiation ("Macrodosing")

- Approaches buprenorphine initiation with higher than typical doses- 8-16mg as the 1st dose, going up to 32mg on Day 1
- Is more convenient for use in ER/inpatient settings, where rapid stabilization and discharge are high priorities, with ability to monitor the patient closely
- Evidence is limited to large uncontrolled case series and case reports, with good results and low frequency of precipitated withdrawal*

* Herring AA, Vet al. High-Dose Buprenorphine Induction in the Emergency Department for Treatment of Opioid Use Disorder. JAMA Netw Open. 2021 Jul 1;4(7):e2117128. doi: 10.1001/jamanetworkopen.2021.17128. PMID: 34264326; PMCID: PMC8283555.

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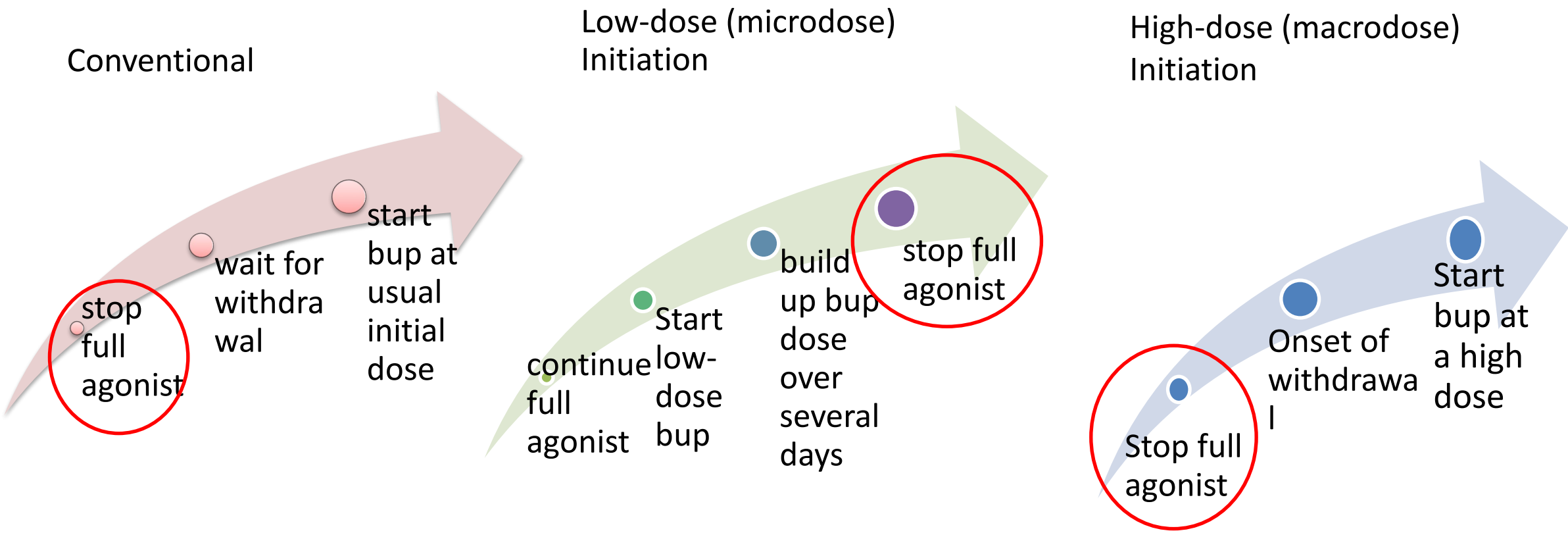
Conventional vs Micro- vs Macro- Approach



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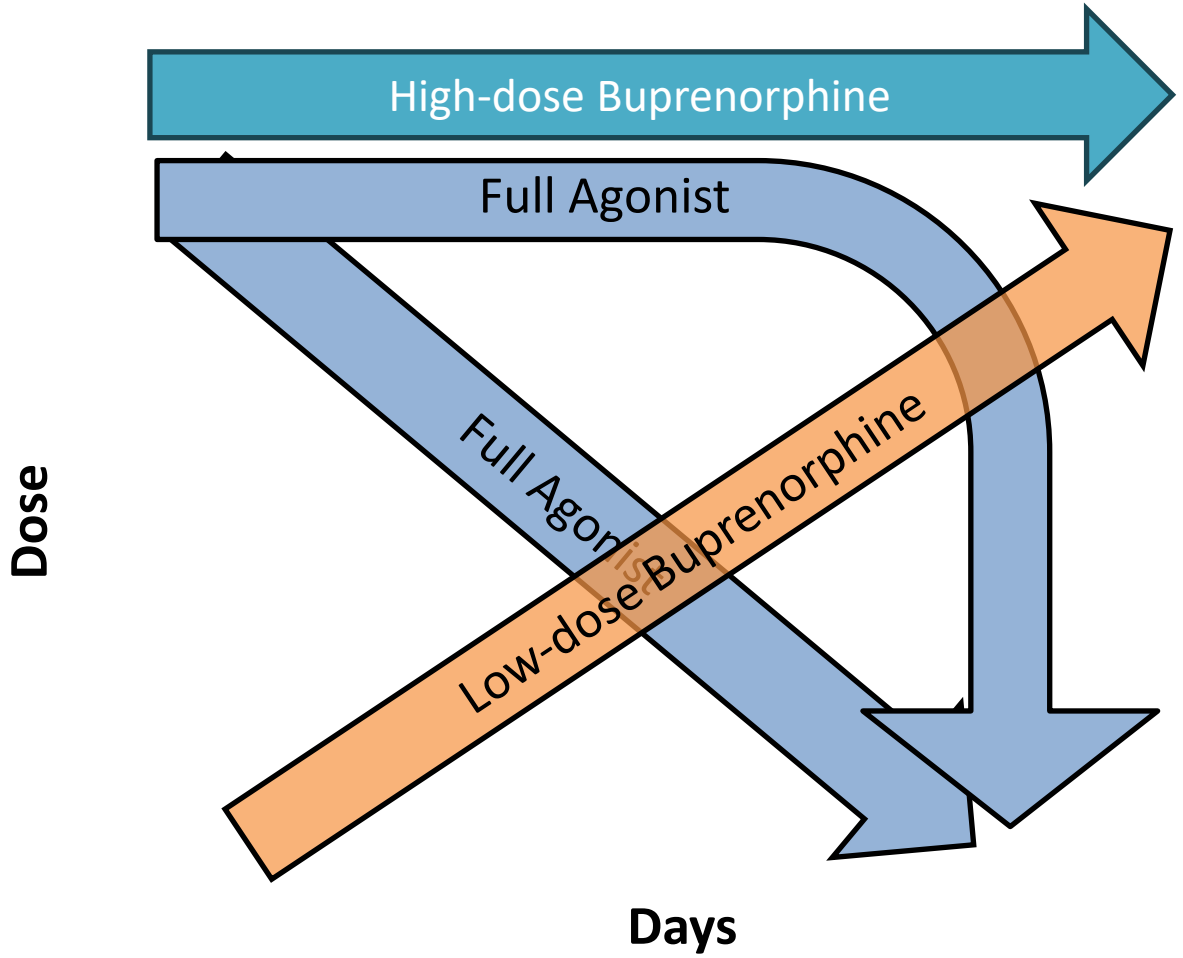
How it Works

With microdosing, the goal is to gradually sneak buprenorphine on to the mu receptors, avoiding a catastrophic displacement of the full agonist which would trigger precipitated withdrawal



With macrodosing, the strategy is to give a high enough dose of the partial agonist to produce sufficient agonistic effect at the mu receptors to mitigate the risk of precipitated withdrawal

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Traditional vs LD vs HD Buprenorphine Initiation

	Traditional	Low-dose	High-dose
Starting dose	2-4mg SL	0.25-1mg SL (no FDA approved formulations available at these doses)	8-16mg SL
Day 1 total dose	8-12mg	0.5-1mg	8-32mg
Time to therapeutic dose	2-7 days	3-10 days	1 day
Risk of precipitated withdrawal (in pts using fentanyl)	Elevated	Low	Low
Cessation of full agonist before initial dose	>24h before initial dose	Not necessary	Long enough for moderate withdrawal

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Impact of Fentanyl on Methadone Treatment

- Higher level of physical dependence among fentanyl-exposed patients
- Starting methadone doses have been trending up, with several recent studies suggesting that higher initial doses and more rapid dose escalation* are safe and effective**
- Patients also need higher doses to stabilize now than in the pre-fentanyl era*
- Fentanyl does not appear to impact retention and outcomes of methadone treatment.***

*Guerra-Alejos BC, et al. Prescribing practices in opioid agonist treatment and changes in compliance to clinical dosing guidelines in British Columbia, Canada. Addiction. 2024 Aug;119(8):1453-1459. doi: 10.1111/add.16491. Epub 2024 Apr 7. PMID: 38584294.

**Racha S, et al. Safety of rapid inpatient methadone initiation protocol: A retrospective cohort study. J Subst Use Addict Treat. 2023 May;148:209004. doi: 10.1016/j.josat.2023.209004. Epub 2023 Mar 15. PMID: 36931605.

*** Stone AC, et al. One year of methadone maintenance treatment in a fentanyl endemic area: Safety, repeated exposure, retention, and remission. J Subst Abuse Treat. 2020 Aug;115:108031.

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ADULTERANTS IN DRUG SUPPLY

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Rapid Analysis of Drugs (RAD) Database

- NIST-based GCMS checking of submitted nonmedical drug samples
- Of late, “heroin” contains
  - Fentanyl, fentanyl precursors, and fentanyl analogues
    - Phenethyl 4-ANPP and 4-ANPP
  - Nitazenes (eg isotonitazene, metonitazene)
  - Xylazine & medetomidine
  - Synthetic cathinones
  - Quinine, mannitol, caffeine, acetaminophen
  - Nonpharmaceutical BZDs (etizolam, flualprazolam,
  - bromazolam, flubromazolam)
  - **Virtually no diacetylmorphine (heroin)**

Slide courtesy: Aaron Greenblatt, MD

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Xylazine and Fentanyl

- Xylazine
  - Serves as a diluent or bulking agent because fentanyl is a highly potent respiratory depressant
  - Increasing the concentration of xylazine enables reducing the quantity of fentanyl mitigating risk of fatal overdoses
  - Extends fentanyl's sedative effect, with less impact on breathing
  - It is legal and cheaper than fentanyl

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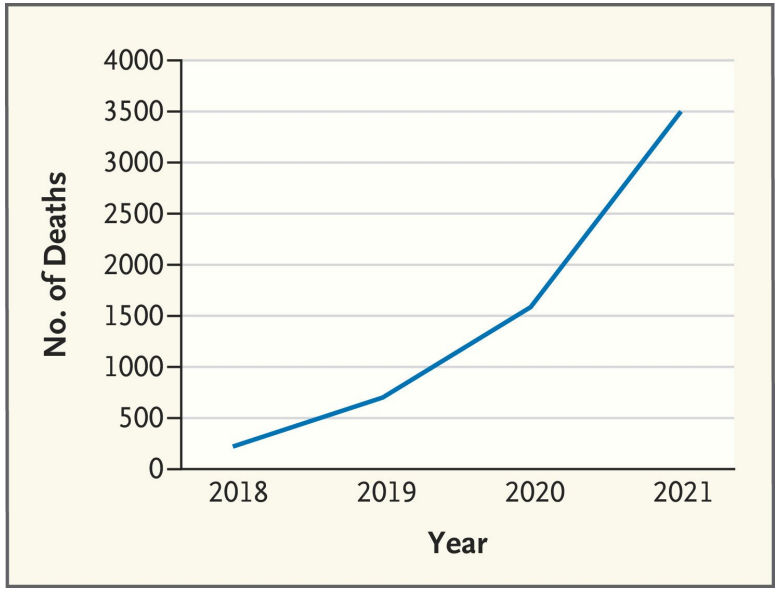
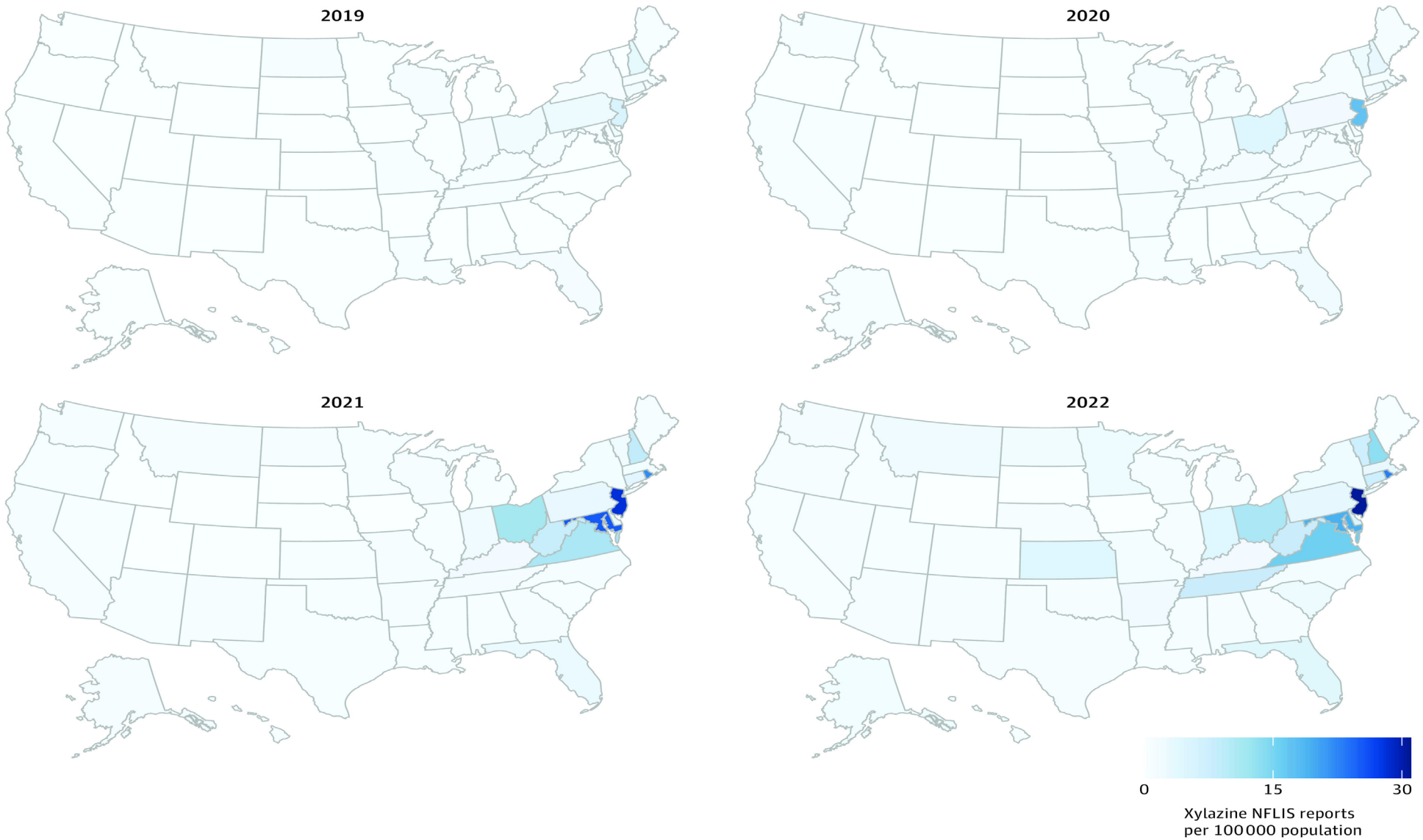
Xylazine across US & Maryland

- DEA has seized xylazine and fentanyl mixtures in 48 of 50 States.
- Deaths in the United States involving xylazine grew from 260 in 2018 to 3480 in 2021, an increase of 1238%, with the highest numbers reported in Pennsylvania, Maryland, New York, and Connecticut*
- Among 364 samples of drug paraphernalia tested in Maryland November 2021–August 2022 that were positive for fentanyl or fentanyl analogs, 80% also contained xylazine**



*Gupta R, Holtgrave DR, Ashburn MA. Xylazine - Medical and Public Health Imperatives. N Engl J Med. 2023 Jun 15;388(24):2209-2212. doi: 10.1056/NEJMp2303120. Epub 2023 Apr 26. PMID: 37099338.

**Russell E, et al. Rapid Analysis of Drugs: A Pilot Surveillance System To Detect Changes in the Illicit Drug Supply To Guide Timely Harm Reduction Responses - Eight Syringe Services Programs, Maryland, November 2021-August 2022. MMWR 2023 Apr 28;72(17):458-462. doi: 10.15585/mmwr.mm7217a2. PMID: 37104171.



Cano M, Daniulaityte R, Marsiglia F. Xylazine in Overdose Deaths and Forensic Drug Reports in US States, 2019-2022. JAMA Netw Open. 2024 Jan 2;7(1):e2350630. doi: 10.1001/jamanetworkopen.2023.50630. PMID: 38180756; PMCID: PMC10770774.

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Xylazine Pharmacology

- Xylazine is a non-opioid sedative/tranquilizer approved for use in veterinary practice (“Tranq”)
- It is an alpha-2 adrenergic agonist
- It inhibits presynaptic norepinephrine release
- Xylazine is structurally related to clonidine, can cause CNS depressant effects (sedation) and cardiovascular side effects (bradycardia, hypotension, and cardiac arrest)
- May be taken orally, subcutaneously, intravenously, intramuscularly, or through inhalation

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Clinical Effects

Xylazine can cause:

- Sedation
- Respiratory depression
- Hypotension
- Bradycardia
- Pupillary constriction
- Hyperglycemia
- Wounds
- Withdrawal symptoms
- Death

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Management: Acute intoxication

- Naloxone is ineffective in relieving the physiological effects caused by xylazine, but should still be used as most xylazine intoxications also involve an opioid
- No FDA approved reversal agents for xylazine in humans
- Treatment is mainly supportive, involving management of the physiological effects of xylazine
- May include supplemental oxygen/intubation, and medications to raise the heart rate and BP in severe cases

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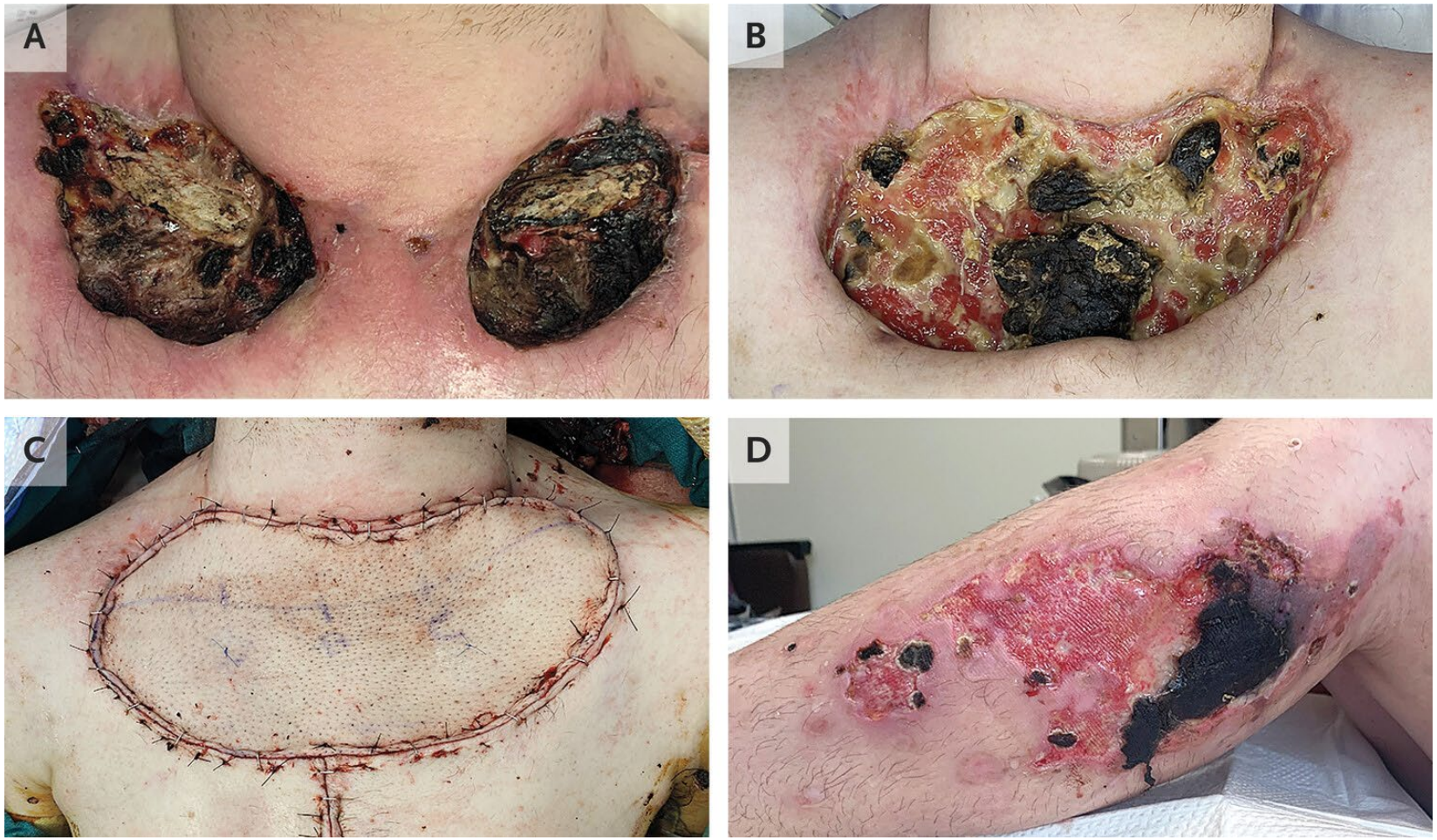
Xylazine Skin Wounds*

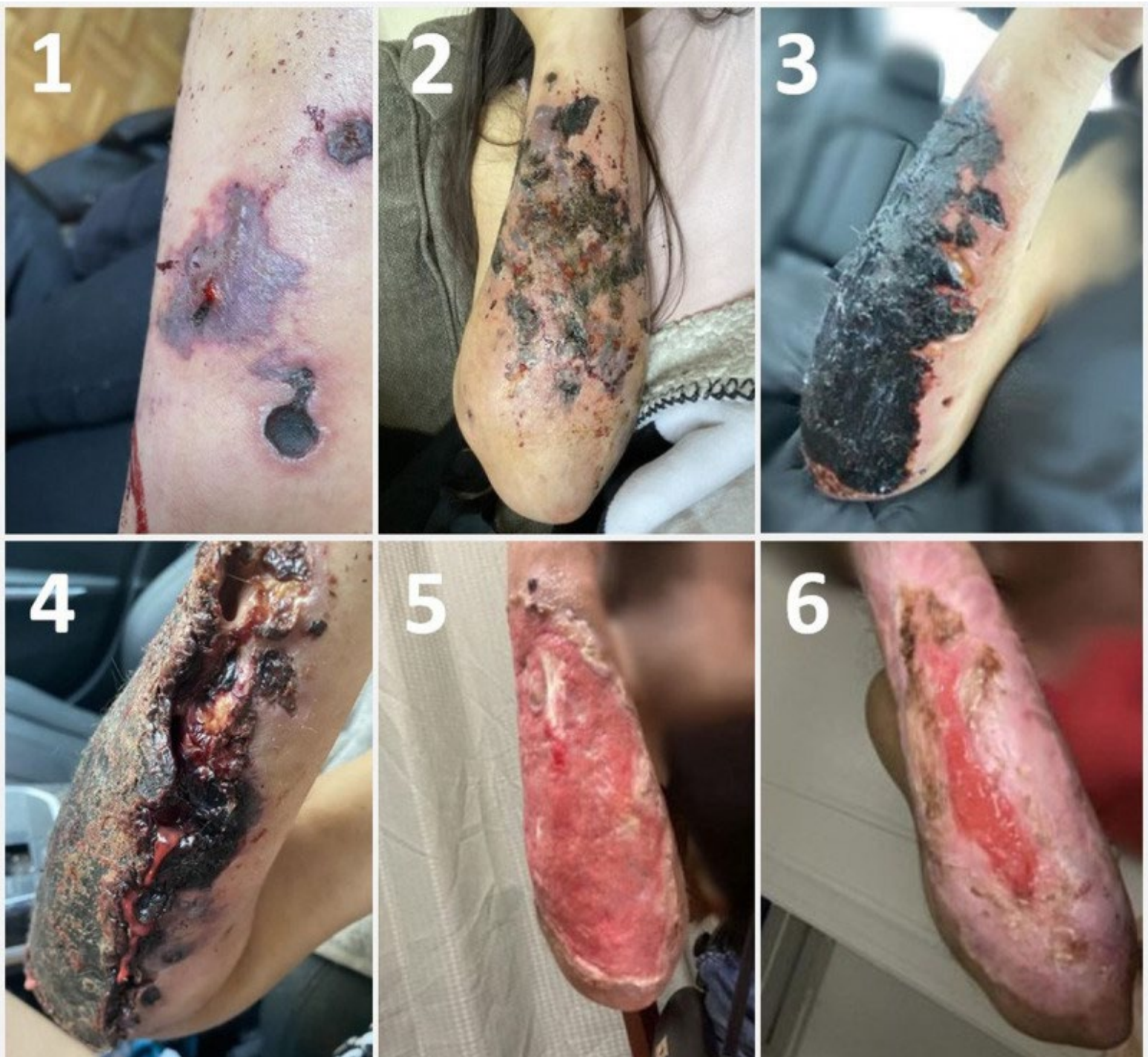
- Not limited to injection use or injection sites
- Unclear mechanism
- Patients may avoid hospital-based care due to fears of stigmatizing treatment, unmanaged pain and withdrawal, and previous traumatic health care encounters
- Discriminatory practices are common- denial of surgical debridement, SNF admission, residential SUD treatment, inadequate management of withdrawal/pain, etc.
- Good, low barrier, compassionate wound care can improve outcomes and prevent complications, including the risk of amputations

*McFadden R, et al. Xylazine-associated Wounds: Clinical Experience From a Low-barrier Wound Care Clinic in Philadelphia. J Addict Med. 2024 Jan-Feb 01;18(1):9-12. doi: 10.1097/ADM.0000000000001245. Epub 2023 Nov 29. PMID: 38019592; PMCID: PMC10967264.

Xylazine Associated Skin Injury



Source: O'Neil J, Kovach S. Xylazine-Associated Skin Injury. N Engl J Med. 2023 Jun 15;388(24):2274. doi: 10.1056/NEJMicm2303601. PMID: 37314708.



Panels 1–4 depict the progression of a xylazine-associated wound… Some PWUDs and hospital-based wound specialists have noted similarities between these wounds and chemical burns. Panels 5–6 show healing in the same wound after surgical debridement during a hospitalization followed by ongoing community-based wound care

Source: McFadden R, et al. Xylazine-associated Wounds: Clinical Experience From a Low-barrier Wound Care Clinic in Philadelphia. J Addict Med. 2024 Jan-Feb 01;18(1):9-12. doi: 10.1097/ADM.0000000000001245. Epub 2023 Nov 29. PMID: 38019592; PMCID: PMC10967264.

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Buprenorphine: Perioperative Management

- Previously, it was recommended that buprenorphine should be discontinued 2-7 days before planned surgery
- This would expose patients to the discomfort of opioid withdrawal and cravings, and risk of relapse
- It is now recommended that buprenorphine should be continued* and a full agonist opioid may be added, if necessary, for pain control

*Kohan L, et al. Buprenorphine management in the perioperative period: educational review and recommendations from a multisociety expert panel. Reg Anesth Pain Med. 2021 Oct;46(10):840-859. doi: 10.1136/rapm-2021-103007. Epub 2021 Aug 12. PMID: 34385292.

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New Medications/Formulations

- Availability of new long-acting injectable buprenorphine formulations:
  - Sublocade – q 4 weeks
  - Brixadi- q 1 week, q 4 weeks
- New naloxone formulations: 8mg (Kloxxado) nasal spray
- OTC naloxone sprays: RiVive 3mg, Narcan 4mg, generic 4mg
- New opioid antagonist: nalmefene (Opvee -2.7mg nasal spray)- with a longer duration of action

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New Developments in Service Delivery

- Initiation of buprenorphine in ERs
- Starting LAI buprenorphine in ERs
- Initiation of buprenorphine in the field by EMS
- Expansion of inpatient SUD consultation-liaison services and availability of peer support specialists in hospitals
- Expansion of access via telemedicine
- Increasing emphasis on harm reduction, e.g., syringe services, overdose education/naloxone distribution programs, safe consumption facilities

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Regulatory Changes Impacting Clinical Practice

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MOUD and Regulations

- A long history of tension between patient-centered care vs regulatory structure driven largely by concern over diversion
- Regulations made 'normal' life difficult while on MOUD, esp methadone, limiting access
- The Opioid Epidemic, especially the advent of fentanyl in the drug supply, combined with pandemic-enforced natural experiment in flexible regulatory environment became catalysts for dramatic changes to the treatment landscape

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MAT (Mainstreaming Addiction Treatment) Act

- *Removed the waiver requirement to prescribe buprenorphine for opioid use disorder, e*ffective 12/29/2022:
  - there are no limits on the number of patients a prescriber may treat for OUD with buprenorphine
  - separate tracking is no longer required for prescribing buprenorphine
  - pharmacy staff can fill buprenorphine prescriptions using the prescriber's regular DEA number

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MATE (Medication Access and Training Expansion) Act

- *Requires prescribers of controlled substances to complete an 8-hour SUD training upon renewing or receiving their DEA license* (effective June 27, 2023)
  - One time requirement
  - Previous waiver training to prescribe buprenorphine counts towards this requirement; those certified in addiction psychiatry/addiction medicine are exempt; some recent graduates from medical/APN/PA schools are also exempt if their curriculum met this requirement
  - Training hours do not have to be completed in one session and can be virtual
  - Training providers must meet some requirements

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42 CFR Part 8 Final Rule

HIGHLIGHTS

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Impact of Pandemic-era Flexibilities*

- Patients perceived increased take-homes as a positive change
- Diversion was rare
- Providers thought that take-home flexibilities allowed them to provide more patient-centered care, though some expressed concern that less frequent contact with patients could be destabilizing
- There were no significant increases in methadone overdoses
- Findings on changes in illicit substance use during the pandemic were mixed
- There were modest improvements in retention

*Krawczyk N, Rivera BD, Levin E, Dooling BCE. Synthesising evidence of the effects of COVID-19 regulatory changes on methadone treatment for opioid use disorder: implications for policy. Lancet Public Health. 2023 Mar;8(3):e238-e246. PMID: 36841564; PMCID: PMC9949855.

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Methadone Treatment Admission Criteria

- Moderate/Severe OUD, OUD in remission, or high risk of relapse. No minimum 1 year of continuous use requirement
- Under 18s must have consent from parents/legal guardians unless state law allows them to consent independently

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Telehealth

- The screening and full examination may be completed via telehealth for those patients being admitted for treatment
- For treatment with schedule II medications (such as methadone), audio-visual telehealth platforms must be used
- For treatment with schedule III medications (such as buprenorphine) or medications not classified as a controlled medication (such as naltrexone), audio-visual or audio only platforms may be used

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Initial Dose

- ".. of methadone shall be individually determined and shall include consideration of the type(s) of opioid(s) involved in the patient's opioid use disorder, other medications or substances being taken, medical history, and severity of opioid withdrawal.
- "The total dose for the first day should not exceed 50 milligrams unless the practitioner finds sufficient medical rationale, including but not limited to if the patient is transferring from another OTP on a higher dose that has been verified, and documents in the patient's record that a higher dose was clinically indicated".

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Take-home Doses

OTPs may provide unsupervised take-home doses of methadone in accordance with the following time-in-treatment standards:

- In treatment 0-14 days, up to 7 unsupervised take-home doses of methadone may be provided to the patient
- Treatment days 15-30, up to 14 unsupervised take-home doses of methadone may be provided to the patient
- From 31 days in treatment, up to 28 unsupervised take-home doses of methadone may be provided to the patient.
  - In all instances, it is within the clinical judgement of the OTP practitioner to determine the actual number of take-home doses within these ranges.

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Long-term Care Facilities

- Certification as an OTP is not required for the initiation or continuity of medication treatment or withdrawal management of a patient who is admitted to a hospital, long-term care facility, or correctional facility, that is registered with the Drug Enforcement Administration as a hospital/clinic.

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Modernizing Opioid Treatment Access (MOTA) Act

If enacted

- Will allow board-certified addiction medicine physicians and addiction psychiatrists to *prescribe* methadone (for OUD treatment)
- Will allow pharmacies to dispense methadone

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Assessment Questions

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Question 1

Select the correct response:

The "4th wave" of the opioid epidemic is characterized by:

A. Increased deaths due to overdose with psychostimulants combined with opioids.

B. Increased deaths due to methadone overdose.

C. Increased deaths due to prescription opioid overdose.

D. Increased deaths due to heroin overdose.

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Answer to Question 1

The "4th wave" of the opioid epidemic is characterized by:

A. Increased deaths due to overdose with stimulants combined with opioids.

B. Increased deaths due to methadone overdose.

C. Increased deaths due to prescription opioid overdose.

D. Increased deaths due to heroin overdose.

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Question 2

Select the best response:

Which of the following statements is not true with regard to opioid precipitated withdrawal (PW)?

A. There is an increased risk of PW when initiating buprenorphine in individuals using fentanyl.
B. PW occurs when there is an abrupt decrease in mu opioid receptor activation.
C. There is a high risk of PW when initiating methadone in individuals using fentanyl.
D. Risk of PW may be decreased by initiating buprenorphine at either very low or high doses compared to conventional doses.

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Answer to Question 2

Which of the following statements is not correct with regard to opioid precipitated withdrawal (PW)?

A. There is an increased risk of PW when initiating buprenorphine in individuals using high potency synthetic opioids.
B. PW occurs when there is an abrupt decrease in mu opioid receptor activation.
C. There is a high risk of PW when initiating methadone in individuals using fentanyl.
D. Risk of PW may be decreased by initiating buprenorphine at either very low or high doses compared to conventional doses.

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Question 3: Select the best response

You are seeing a patient via audio-visual telemedicine. Based on your assessment you diagnose OUD and would like to initiate MOUD. Under current regulations, which of the following options are available to you as an outpatient family practitioner?

A. Prescribe buprenorphine
B. Prescribe naltrexone
C. Prescribe methadone
D. A + B
E. A + C
F. B + C

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Answer to Question 3

You are seeing a new patient via audio-visual telemedicine. Based on your assessment you diagnose OUD and would like to initiate MOUD. Under current regulations, which of the following options are available to you as an outpatient family practitioner?

A. Prescribe buprenorphine
B. Prescribe naltrexone
C. Prescribe methadone
D. A + B
E. A + C
F. B + C