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Overview of opioid use disorder with Focus on Buprenorphine Suboxone vs Sublocade

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Disclosures

- I have no relevant financial relationships with commercial interests.
- I have no actual or potential conflicts of interest in relation to this presentation

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Learning objectives

Brief review of opioid usage including overdose deaths

Examine risk factors and clinical presentation of Opioid use disorders

Review the DSM 5 criteria for OUD

Review harm reduction in SUD and the paradigm shift in addiction treatment

Review FDA approved medications utilized for Opioid use disorders (MOUD) with focus on transmucosal vs. injectable buprenorphine.

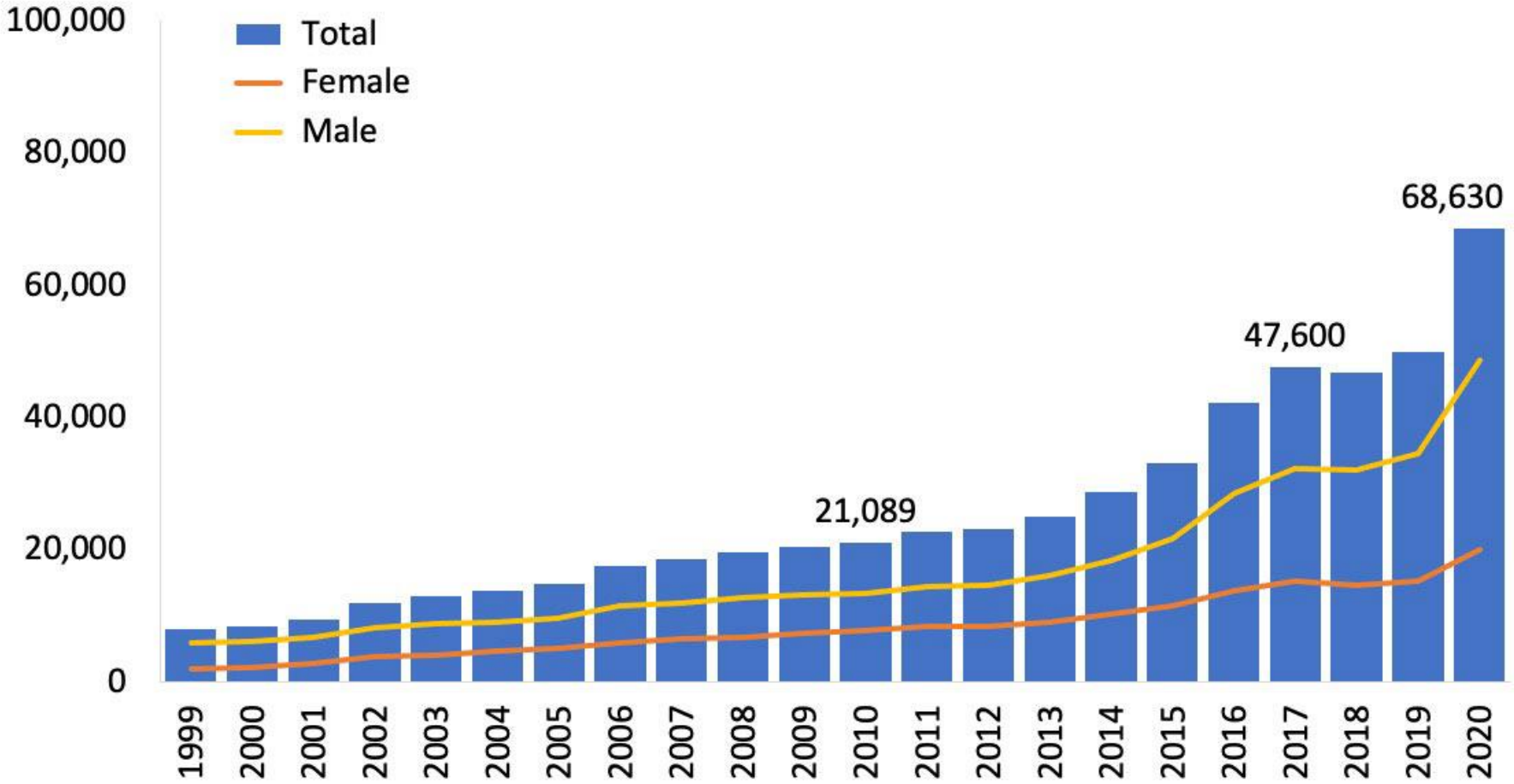
Review requirements for prescribing MOUD medications with emphasis on Buprenorphine products

Deeper dive into Buprenorphine products and compare oral vs injectable forms

Opioids are uniquely problematic

- Pain is subjective There isn't any data to measure outcomes.
- Patients often have an unrealistic expectation to feel no pain. Clinicians are incentivized to provide opioids to keep patients happy and provide excellent survey results
- Unlike other medications, opioids typically do not have a maximum dosage
- Opioid hyperalgesia = ongoing or worsening pain
- Must have opioid analgesics since they have legitimate uses with no substitution
- Many physicians do not understand addiction and opioids are prescribed across many specialties

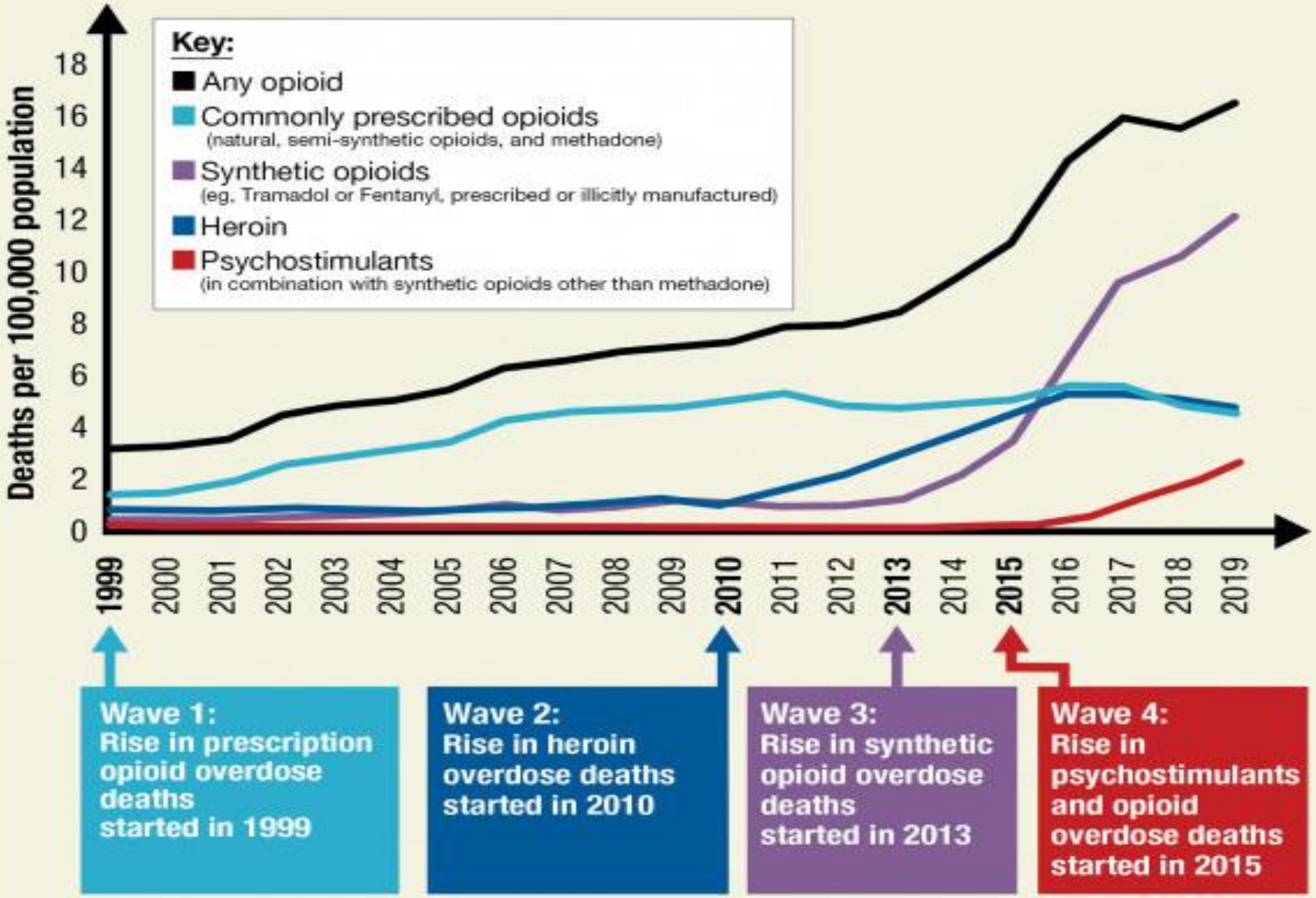
Figure 3. National Overdose Deaths Involving Any Opioid, Number Among All Ages, by Gender, 1999-2020



*Among deaths with drug overdose as the underlying cause, the any opioid subcategory was determined by the following ICD-10 multiple cause-of-death codes: natural and semi-synthetic opioids (T40.2), methadone (T40.3), other synthetic opioids (other than methadone) (T40.4), or heroin (T40.1). Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2020 on CDC WONDER Online Database, released 12/2021.

FIGURE 1

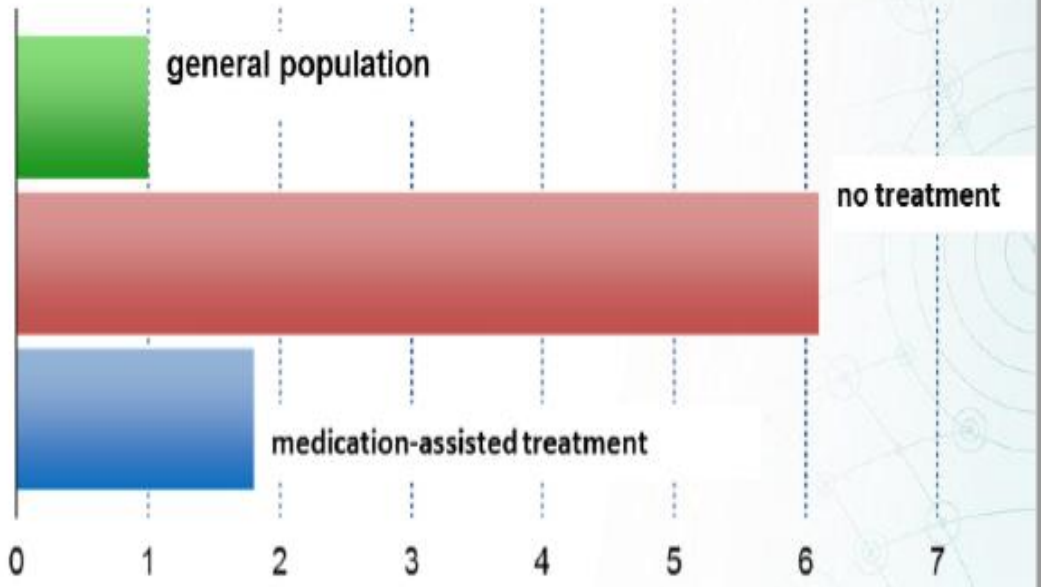
Timeline of Opioid-related Overdose Deaths



Source: National Vital Statistics Systems Mortality File and the National Institute on Drug Abuse.

Benefits of MOUD: Decreased Mortality

Death rates:



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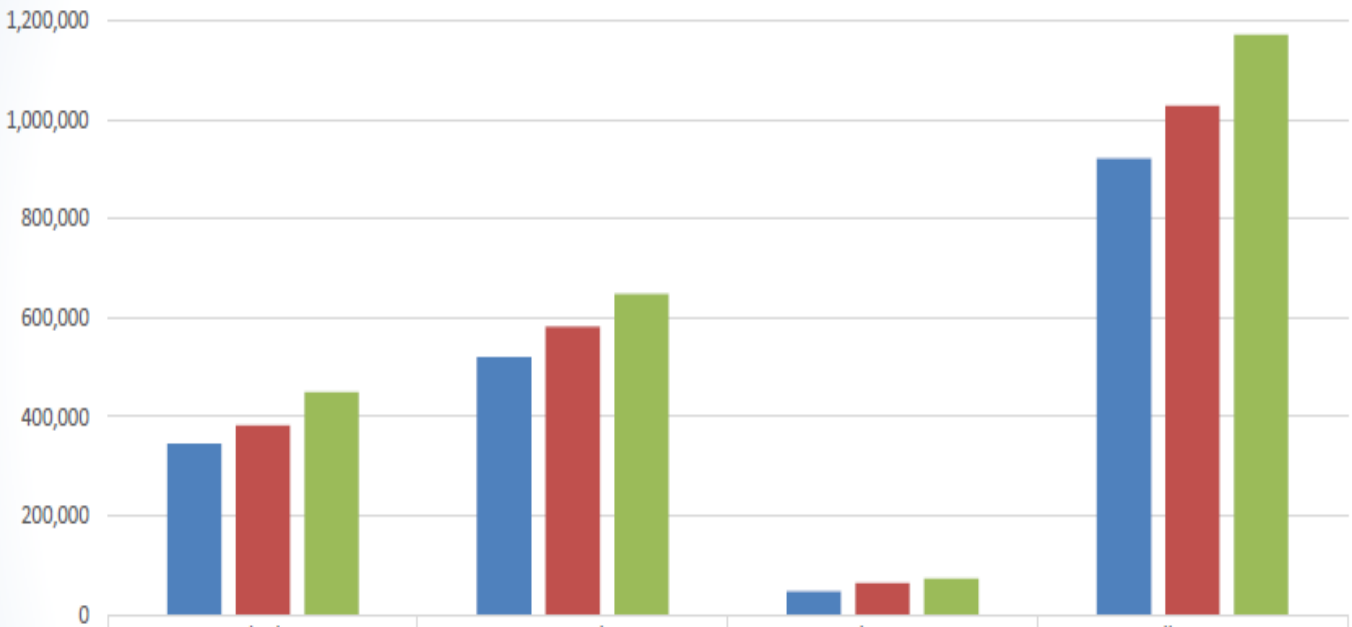
Individuals Receiving MOUDs by Year



	Methadone	Buprenorphine	Naltrexone	All MOUD
2016	345,443	520,398	46,860	921,692
2017	382,867	581,613	64,020	1,028,500
2018	450,247	648,864	73,260	1,172,371

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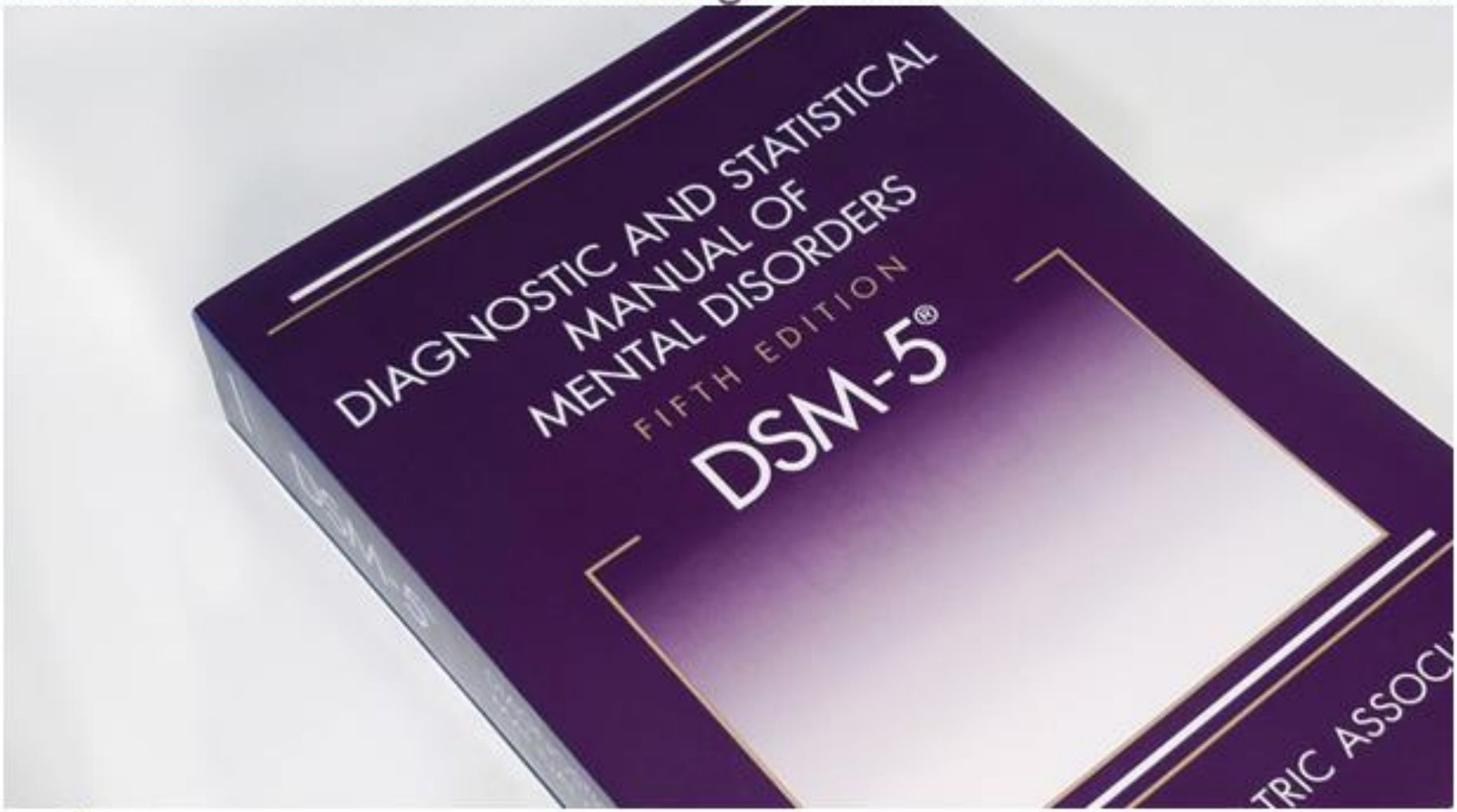
Fentanyl 100 x more potent than morphine and 50 x more potent than heroin

FENTANYL
HAS TAKEN THE LIVES OF AT LEAST 434 PEOPLE IN RIVERSIDE COUNTY SINCE 2016. IT TAKES LESS THAN 1/5TH OF A SINGLE TEASPOON TO CAUSE 434 DEATHS.

2 MILLIGRAMS
1/2500 TEASPOON
1 LETHAL OVERDOSE

Diagnosing SUD



DSM-5 Opioid Use Disorder

- Taking the opioid in larger amounts and for longer than intended
- Wanting to cut down or quit but not being able to do it
- Spending a lot of time obtaining the opioid
- Craving or a strong desire to use opioids
- Repeatedly unable to carry out major obligations at work, school, or home due to opioid
- Continued use despite persistent or recurring social or interpersonal problems caused or made worse by opioid use
- Stopping or reducing important social, occupational, or recreational activities due to opioid
- Recurrent use of opioids in physically hazardous situations
- Consistent use of opioids despite acknowledgment of persistent or recurrent physical or psychological difficulties from using opioids
- *Tolerance as defined by either a need for markedly increased amounts to achieve intoxication or desired effect or markedly diminished effect with continued use of the same amount. (Does not apply for diminished effect when used appropriately under medical supervision)
- *Withdrawal manifesting as either characteristic syndrome or the substance is used to avoid withdrawal (Does not apply when used appropriately under medical supervision)

Mild = 2-3 criteria; Moderate = 4-5 criteria; Severe = 6+ criteria

Risk factors for OUD

- Chronic opioid use with chronic pain syndrome
- Untreated Psychiatric disorders including ADHD, anxiety and depression
- History of Benzodiazepine and/or Alcohol use disorder
- Early use especially adolescents. Group most vulnerable 25-34
- Exposure to sexual, physical or emotional abuse
- Growing up in a household that normalized drug use
- Incarceration
- Genetic predisposition
- Occupational exposure

Some complications of opioid use disorder

- Overdose
- Increased mortality (6-20x higher than general population)
- Infections
  - Cellulitis/abscess
  - Osteomyelitis
  - Septic emboli
  - Endophthalmitis
  - Endocarditis
  - HIV
  - HCV
    - 32% become positive for HCV within 1 year of IDU
    - 53% positive within 5 years

Harm reduction…. Paradigm change in addiction treatment

- Meets people “where they are” but doesn’t leave them there.

Applies evidence-based interventions to reduce negative consequences:

- **Medication Assisted Treatment**
- Naloxone rescue kits
- Syringe exchange programs
- PrEP (Pre-exposure prophylaxis for HIV)
- PEP (Post-exposure prophylaxis for HIV)
- Fentanyl test strips
- HEP C testing /HIV testing & education on prevention/treatment

- Works to elicit **ANY POSITIVE CHANGE** based on individual patient need, circumstance, and readiness to change.

MAT components: focus on OUD

1. Medication management with **FDA approved agents**
   - Opioid full agonists → **methadone**
   - Opioid partial agonists → **buprenorphine**
   - Opioid antagonists → **naltrexone**

2. Evidence-based **psychosocial treatments**
   - Motivational Interviewing
   - Manualized therapies (e.g. Seeking Safety)
   - Harm reduction psychotherapy

3. Treat **co-occurring psychiatric disorders** and address comorbid medical illness whenever possible

MAT/MOUD

Evidence-based:

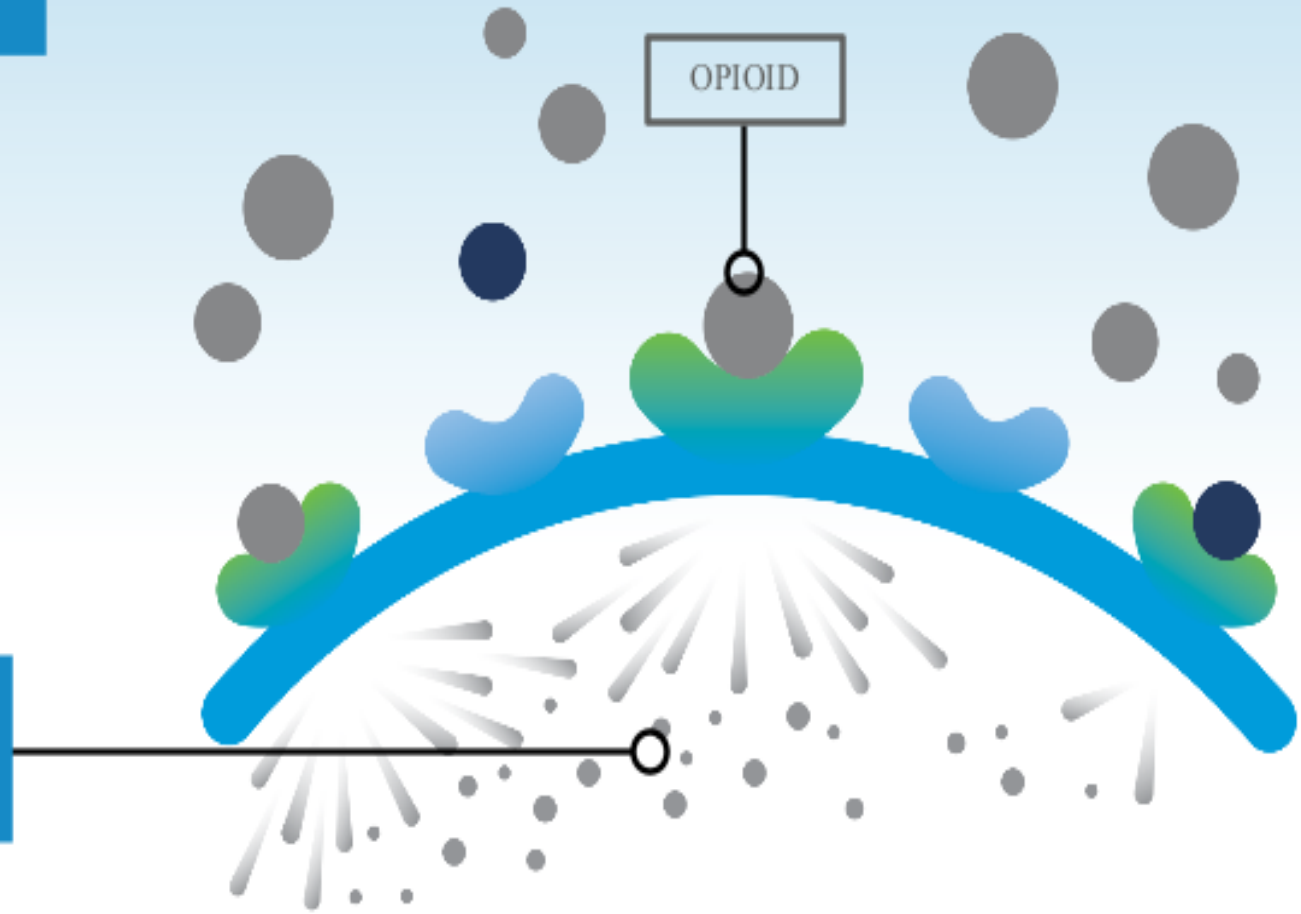
- Decrease illicit opioid use
- Reduce transmission of Hepatitis C and HIV
- Decrease criminal behavior
- Reduce sexual risk behaviors (e.g., trading sex for money/drugs)
- Improve social functioning
- Retain people in treatment
- Decrease overdose and death
- Increase employment
- Decrease in domestic violence

THE BRAIN & OPIOID USE

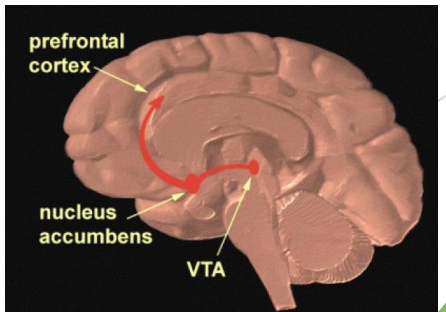
Understanding the Effects of Opioids

● = Endogenous Opioid

● = Opioid (e.g., Heroin and Pain Relievers)



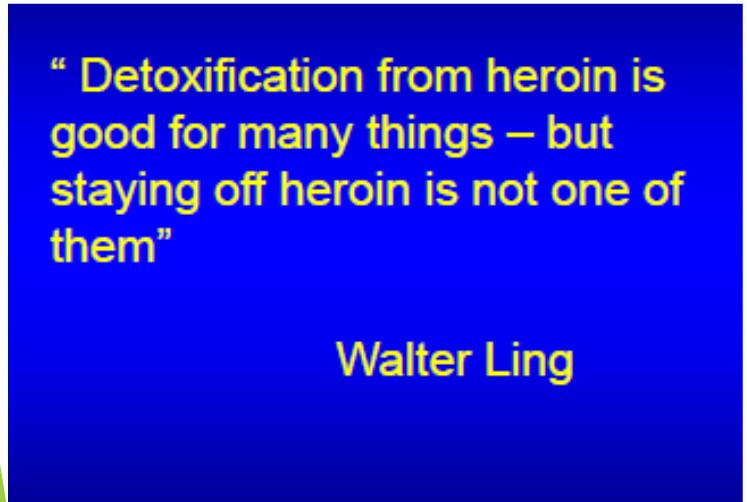
References: 1. Kosten TR et al. *Sci Pract Perspect.* 2002;1(1):13–20. **2.** Drugs, Brains, and Behavior: the Science of Addiction | National Institute on Drug Abuse (NIDA). https://www.drugabuse.gov/publications/drugs-brains-behavior-science-addiction/preface. Accessed November 17, 2016. **3.** Meyer JS, Quenzer LF. The opioids. In: *Psychopharmacology: Drugs, the Brain, and Behavior*. 2nd ed. Sunderland, MA: Sinauer Associates, Inc; 2013.



MOUD

- Use as long as the Benefits outweigh the Risk similar to other chronic diseases
- Long term maintenance therapy

  (minimum 18 months)
- Detox: is not treatment, (medical management of withdrawal)



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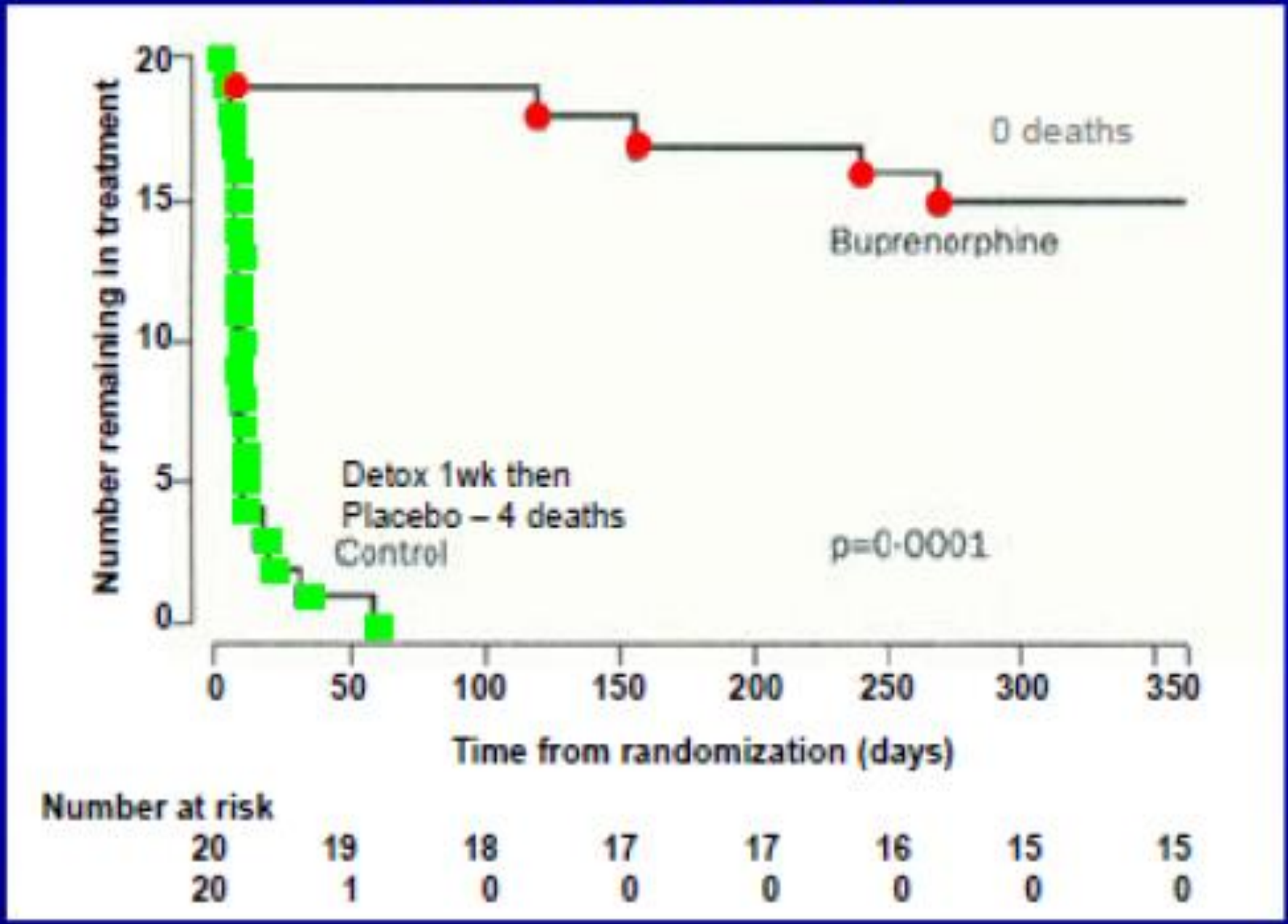
Buprenorphine Maintenance vs Detox. RCT of cumulative retention in treatment

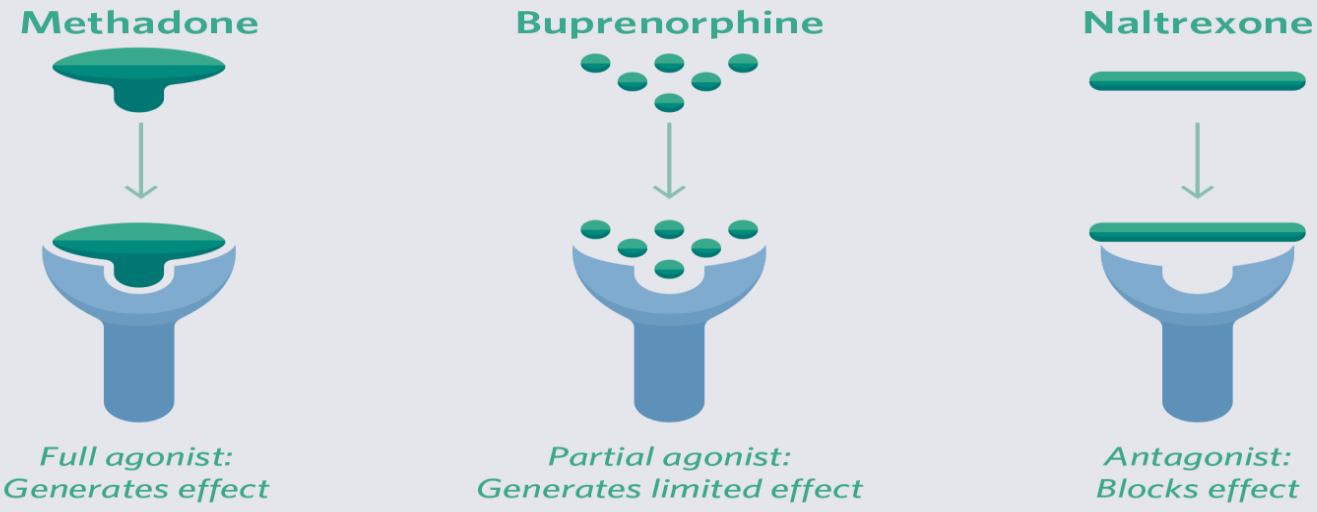


Co-prescribe Narcan

- Naloxone – short acting medication to remove opioid from opioid receptor, reverses opioid overdose
- Co-Prescribing naloxone (NARCAN) is a best practice
- Train Patient, care givers on use of naloxone to reverse overdose

Figure 1

How OUD Medications Work in the Brain



Methadone (schedule 2 controlled substance)

- Synthetic, slow acting full mu-opioid receptor agonist
  - Half-life 24-36 hours
  - Blocks euphoric effects of self administered opioids
  - Eliminates or strongly reduces cravings for opioids
- Used for treatment of substance use disorder since 1960's. Officially approved for MAT 1972
- Only available through licensed Opioid Treatment Programs (OTP) approved and accredited by SAMHSA/HHS
- Dispensed @ OTP daily initially
  - Patients can progress to receiving "take-home doses"
  - Average 80 to 120mg/day

Cardiac concerns related to QT interval especially with overdose

Naltrexone/ANTAGONIST

- Oral agent Revia . ASAM does NOT recommend it routine use for MAT except in select groups where you can ensure compliance.(50mg once daily)
- Monthly Injection of 380mg IM (Vivitrol) Currently approx. $1500 dollars a month.
- ***Must be completely withdrawn from Opioids*** . No use for 7-14 days depending on the half life of the drug used
- Can induce withdrawal if using opioids
- Blocks opioid receptors (high affinity)
- If stop using Naltrexone, would have lost opioid tolerance putting them at risk for Overdose
- Will have to use alternatives to opioids for pain management
- If patient is successful at overcoming the receptor blockade , they are at high risk for overdose
- Not a controlled substance
- No abuse potential
- ***Works for opioids and alcohol***

Naltrexone patient selection

- Patients not able to be on agonist (buprenorphine or methadone)
  - High motivation for abstinence
  - Profession where treatment with agonist controversial
- Patients successful on agonist but want to try abstinence
- Failed prior treatment with agonist
- Abstinent, but at risk for relapse
- Patients for whom relapse would be disastrous
- Patient with less severe form of disorder
  - Short history of use, lower level of use

Buprenorphine/PARTIAL AGONIST

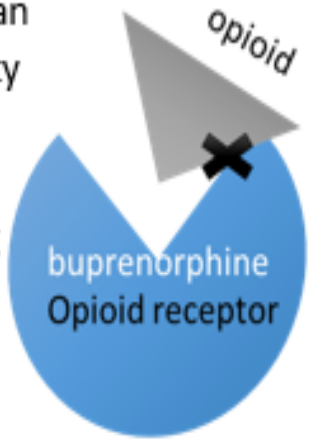
Regulation: certified and specially trained clinician; patient limits in treatment (DEA X Waiver) , CIII, can be prescribed by in clinic, dispensed by community pharmacy

Benefits: Detox and maintenance therapy, craving reduction, combined with naloxone to prevent misuse, good efficacy in opioid use disorder

Several dosage forms including daily oral (tabs, films, SL), long-acting implant, long acting injectable. Some mixed with naloxone

Risks:

Must initiate brief withdrawal (4-12 hours), misuse risk, street value due to withdrawal aid, dependence



PARTIAL AGONIST: partial activation, partial blockade

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Buprenorphine Has a "Ceiling Effect"

Once a certain dosage threshold is passed, the opioid effects plateau even when an individual takes more of the medication. This "ceiling effect" **helps reduce the risk of misuse as well as side effects.**

Buprenorphine/partial agonist

schedule 3 controlled substance Requires an X-Waiver

- No need for detoxification . Process of induction
- Oral sublingual or mucosal films now available in generic. Injectable is expensive (currently about $1500) (sublocade)
- Now can be induced in a clinic, hospital or even through telemedicine while at home
- Companies now providing services via telemedicine platform including UDS and coaching/therapy
- Begin induction when the patient feels mildly or moderately "drug sick" (can base off of COWS score or modified COWS score > 12) Potential for induced withdrawal if start too soon. ***"precipitated withdrawal"***

Buprenorphine/partial agonist

Start slow typically 2 mg up to 8 -12mg day one. Sweet spot is between 16-24 mg a day once completely induced. Over 24mg not supported ***however short term use up to 32 mg is sometimes used***

- Government loosening of requirements to prescribe to meet the needs
- If a patient on buprenorphine has pain, may need to split the dosage. Pain effects only last about 6-8 hours
- Can take 5-25 min to dissolve , best if mucosa is wet, avoid talking, smoking or swallowing
- ***Micro-induction or macro-induction with fentanyl***
- *Cannot take orally due to first pass metabolism*
- Can test for norbuprenorphine to assess compliance if concern for diversion
- Buprenorphine Quick Start Guide - SAMHSA

https://www.samhsa.gov › sites › default › files

ASAM

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- Both office-based and **home-based initiation of buprenorphine** are **considered safe and effective** when starting buprenorphine treatment.

- Consider the patient's past experience with buprenorphine and assessment of their ability to manage initiation at home.

Rationale:
Home-based buprenorphine initiation has become increasingly common in recent years and is considered. safe and effective under appropriate circumstances

Buprenorphine prescribing requirements

Buprenorphine waiver application with SAMHSA (a division of HHS) after completion of training

OR

Must file a NOTICE OF INTENT with SAMHSA

OR

Must work in a certified Opioid treatment program

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Buprenorphine prescribing

When prescribing buprenorphine to treat OUD **outside of an OTP** , provider must have a DATA 2000 Waiver, also called an "X-DEA number" →*EXCEPTION if using buprenorphine in hospital setting in accordance with the opioid withdrawal facility approved order set/ notification of intent*

- DATA 2000 Waiver can be obtained by any physician who takes an 8-hour online course (DEA X Waiver)
- DATA 2000 Waiver can be obtained by a PA or APN after 24 hours of training
- Upon approval by SAMHSA a provider will obtain permission to have a case load of 30 patients
- 2nd year can apply to increase to 100
- 3rd year can apply to increase to 275
- Can apply for increase sooner if become board certified in addiction medicine

Exemption from the traditional x-Waiver

- A practitioner may seek a waiver from this registration requirement by submitting a ***notice of intent (NOI),*** with specific statutorily required certifications, to the Substance Abuse and Mental Health Services Administration (SAMHSA) within HHS. *Id.* at § 823(g)(2)(B). Once SAMHSA approves the exemption request and notifies the Drug Enforcement Administration (DEA) of that approval, DEA issues an X-waiver identification number authorizing that practitioner to treat OUD patients with buprenorphine.
- Can then treat up to 30 patients at any one time
- ***This cannot be increased annually and not be applied toward waiver increase***

3 Day DEA Rule

- Can prescribe Buprenorphine or Methadone for no more than 72 hours to “bridge” a patient if you don’t have an X-waiver or work in an OTP
- Cant give more than 24 hour supply at one time
- Cannot be renewed, must be < 72 hours

- The three-day rule **permits practitioners to administer no more than one day's medication at a time for a maximum of three days, which cannot be renewed or extended**

BUPRENORPHINE FORMULATIONS

Generic Name	Route of Administration (Dosing)	Brand Names	For the Treatment of	Formulation Considerations
Buprenorphine (monoproduct)	Sublingual Tablets (Daily)	Generic versions available similar to Subutex*	Opioid withdrawal and opioid use disorder	Some risk for diversion or misuse; Requires daily Compliance
Buprenorphine and naloxone	Sublingual tablets and film (Daily)	Generic versions available in addition to Suboxone, Cassipa^, Zubsolv, Bunavail	Opioid withdrawal and opioid use disorder	Lower potential for misuse and diversion (compared to monoproduct); Requires daily compliance
Buprenorphine extended-release	Extended-release Injection (Monthly)	Sublocade^	Moderate to severe opioid use disorder in patients who have initiated treatment with transmucosal buprenorphine followed by dose adjustment for a minimum of 7 days	No risk for patient diversion or misuse; Requires patients to be on a stable dose of transmucosal buprenorphine for at least 7 days; Monthly instead of daily medication compliance; Less fluctuation in buprenorphine levels (compared to daily doses)

**Subutex was discontinued. ^ New/tentative FDA approval (since 2015 Guideline release)*
Some patients may experience withdrawal/cravings when switched to a different formulation.
Table content was derived from FDA labels. Labels and label updates can be accessed at https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm.

BUPRENORPHINE FORMULATIONS CONT'D

Generic Name	Route of Administration (Dosing)	Brand Names	For the Treatment of	Formulation Considerations
Buprenorphine extended-release	Extended-release Injection (Weekly or Monthly)	Brixadi^	Moderate to severe opioid use disorder in patients who have initiated treatment with a single dose of transmucosal buprenorphine or who are already being treated with buprenorphine	Tentative approval from FDA (not eligible for marketing in the U.S. until November 30, 2020). No risk for patient diversion or misuse; only a single prior dose of transmucosal buprenorphine required prior to initiation; Weekly or Monthly instead of daily medication compliance; Less fluctuation in buprenorphine levels (compared to daily doses)
Buprenorphine hydrochloride	Subcutaneous Implant (Every 6 months)	Probuphine Implant^	Treatment of opioid use disorder in patients who have achieved and sustained prolonged clinical stability on low-to-moderate doses of a transmucosal buprenorphine (i.e., no more than 8 mg per day)	Requires prolonged stability on 8 mg per day or less transmucosal buprenorphine; No risk for patient diversion or misuse; Healthcare provider training required for implant insertion and removal; Insertion site should be examined one week after insertion; Implant must be removed after 6 months; Risks associated with improper insertion and removal; Currently only FDA approved for a total treatment duration of one year (one insertion per arm); Less fluctuation in buprenorphine levels (compared to daily doses)

**Subutex was discontinued. ^ New/tentative FDA approval (since 2015 Guideline release)*
Some patients may experience withdrawal/cravings when switched to a different formulation.
Table content was derived from FDA labels. Labels and label updates can be accessed at https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm.


Sublocade™
(buprenorphine extended-release)
injection for subcutaneous use
300 mg
NDC 12496-0300-1
WARNING: SERIOUS HARM OR DEATH
COULD RESULT IF INJECTED INTRAVENOUSLY
Rx only
Sterile
Single dose only
To be administered by a healthcare provider only.
CARTON CONTENTS
One pouch with sterile prefilled syringe containing 300 mg/1.5 mL (200 mg/mL) of
buprenorphine in the ATRIGEL® Delivery System (poly DL-lactide-co-glycolide and
N-methyl-2-pyrrolidone) and one oxygen absorber.
One sterile 19 G 5/8" safety needle.

WARNING: RISK OF SERIOUS HARM OR DEATH WITH INTRAVENOUS ADMINISTRATION; SUBLOCADE RISK EVALUATION AND MITIGATION STRATEGY

- Serious harm or death could result if administered intravenously. SUBLOCADE forms a solid mass upon contact with body fluids and may cause occlusion, local tissue damage, and thrombo-embolic events, including life threatening pulmonary emboli, if administered intravenously.

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- Because of the risk of serious harm or death that could result from intravenous self-administration, SUBLOCADE is only available through a restricted program called the SUBLOCADE REMS Program. Healthcare settings and pharmacies that order and dispense SUBLOCADE must be certified in this program and comply with the REMS requirements.

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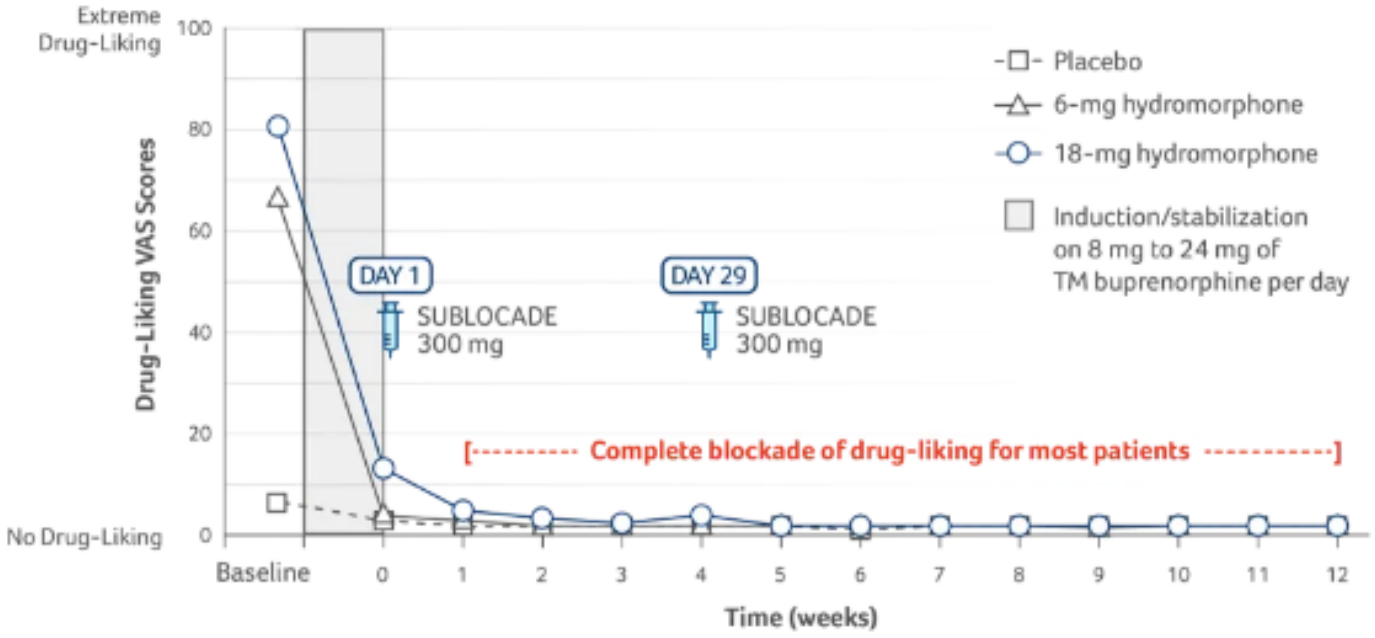
Median Peak Drug-Liking VAS Scores[1,2]



SUBLOCADE comes in 2 doses: 300 mg and 100 mg. (same price) The subcutaneous dosage is given **once a month** (with at least 26 days between doses). The injections start with 300 mg to help the medication reach an effective level. After 2 months of 300mg, many patients will receive a lower dose of 100 mg monthly.

A patient must be induced and stabilized on transmucosal buprenorphine prior to given a subQ injection

*****Sublocade must be obtained and administered by a REMS certified facility**

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Pros with sublocade

- Once monthly dosing
- Little to no diversion potential
- Little compliance concern
- If a patient stops the injections, the taper will be slow

Sublocade Cons

- Expensive (however covered by many insurance companies and Medicaid)
- Can be painful (large needle)
- Bump can stay around for months
- Injection site reaction
- First month can be rough and may need supplemental buprenorphine (especially weeks 2-4)
- Must be given at a REMS certified clinic.
- Dangerous if given into the blood stream

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Sublocade Side Effects

There are side effects that can occur with Sublocade injection. Sublocade side effects include:

- Constipation
- Vomiting
- Headache
- Nausea
- Increase in liver enzymes
- Pain at the injection site
- Vomiting
- Fatigue
- Itching at the injection site

What is the SUBLOCADE REMS (Risk Evaluation and Mitigation Strategy) Program?

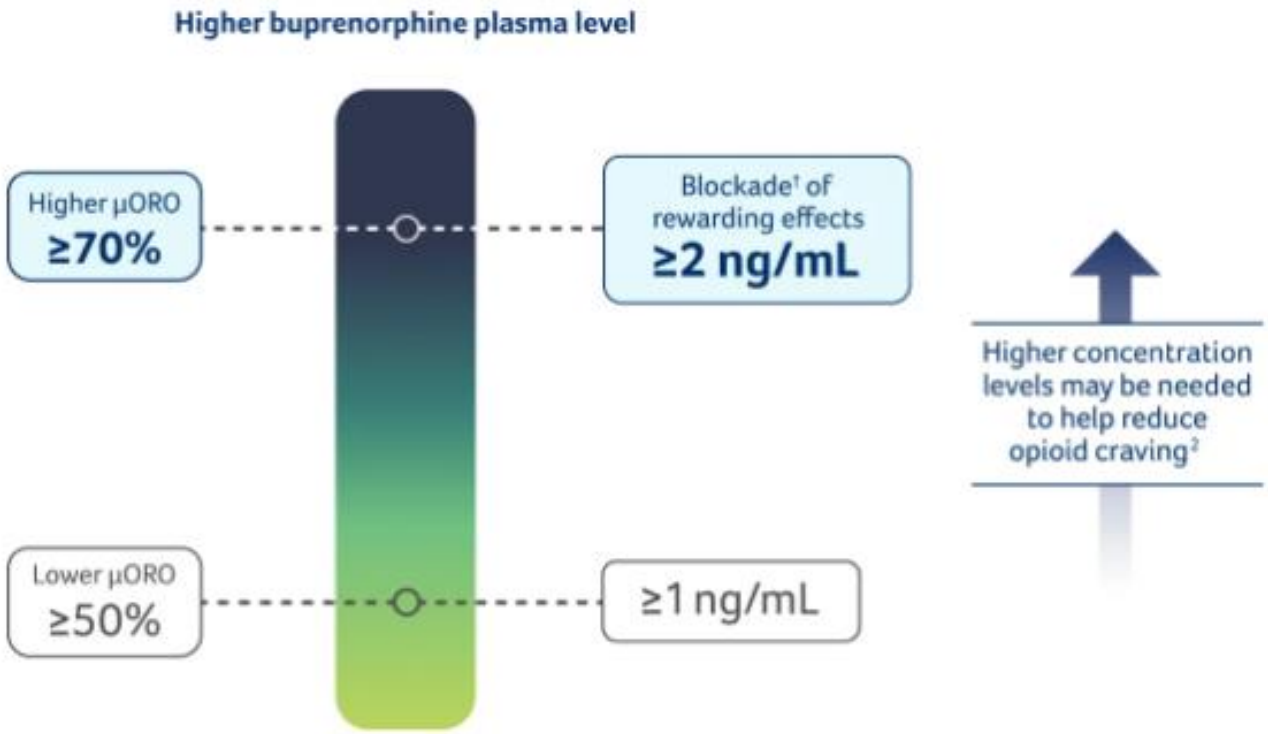
A REMS is a strategy to manage known or potential risks associated with a drug, and is required by the Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks. **SUBLOCADE is intended for abdominal subcutaneous injection only by a healthcare provider.** SUBLOCADE is available only through a restricted distribution program called the SUBLOCADE REMS Program because of the risk of **serious harm or death that could result from intravenous self-administration.**

What are the SUBLOCADE REMS program requirements?

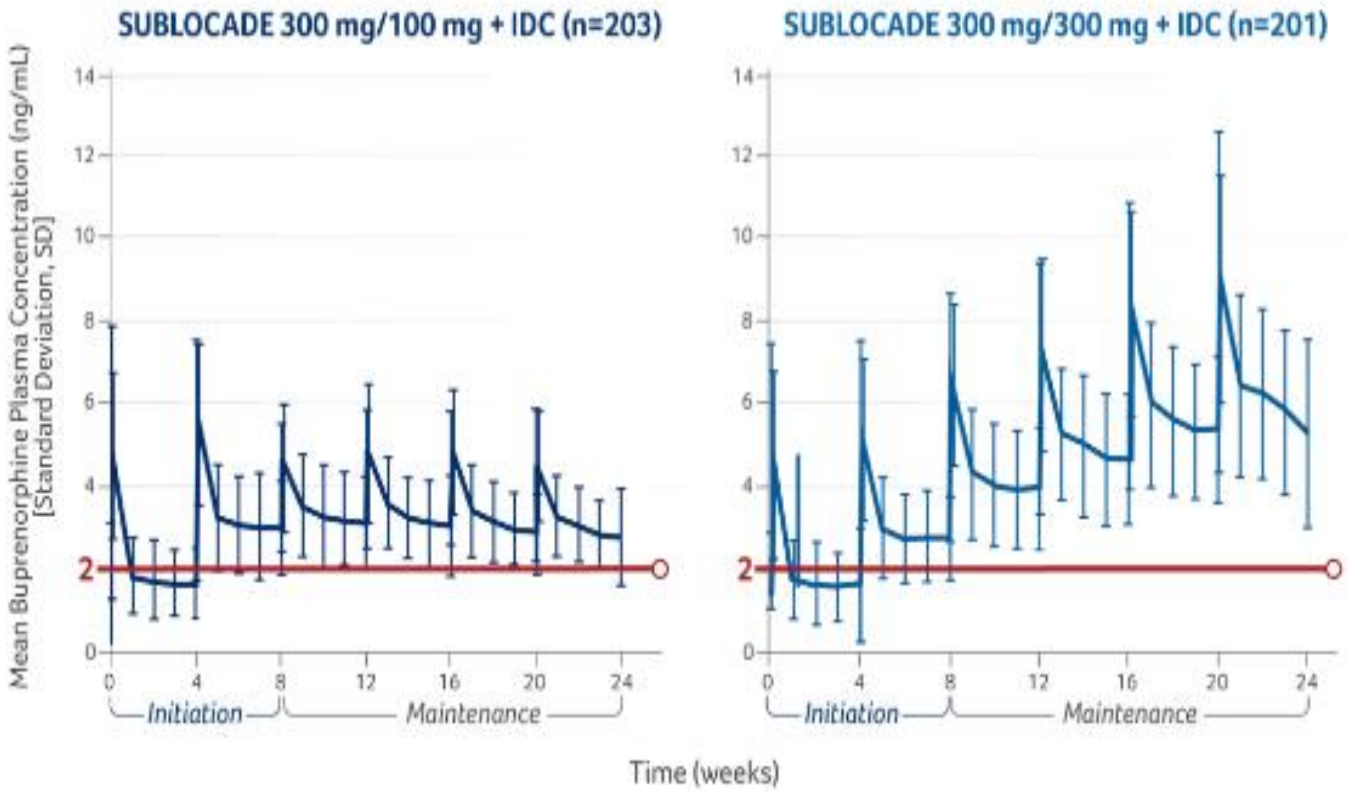
- All healthcare settings and pharmacies that dispense SUBLOCADE must be certified in the SUBLOCADE REMS program
- Healthcare providers, healthcare settings, and pharmacies must obtain SUBLOCADE through a restricted distribution program
- **SUBLOCADE should never be dispensed directly to a patient.**

Which healthcare settings MUST BE certified in the SUBLOCADE REMS program?

All healthcare settings and pharmacies that dispense SUBLOCADE must be certified. Examples of healthcare settings include: group practice, independent practice, institution, Department of Defense (DoD) facility, outpatient clinic, hospital, Veterans Administration (VA) facility, opioid treatment program (OTP), closed healthcare system, other healthcare setting.


Higher buprenorphine plasma level
Higher μORO
≥70%
Blockade[1] of rewarding effects
≥2 ng/mL
Higher concentration levels may be needed to help reduce opioid craving[2]
Lower μORO
≥50%
≥1 ng/mL

Mean weekly buprenorphine concentration levels[3]



Sublocade

- 300mg sub Q roughly equal to 24mg/day (after steady state)
- 100mg sub Q roughly equal to 16mg/day (after steady state)
- Can test positive for along time after stopping the injection (some over a year)
- May need to supplement weeks 2-4 with transmucosal

- ***AT LEAST 70% μOR OCCUPANCY (μORO) BY BUPRENORPHINE WAS NEEDED TO BLOCK THE REWARDING EFFECTS OF OPIOIDS***[1]

Independent studies showed that buprenorphine plasma levels and μORO are highly correlated[2-4]

1 | SUBLOCADE Administration[1]

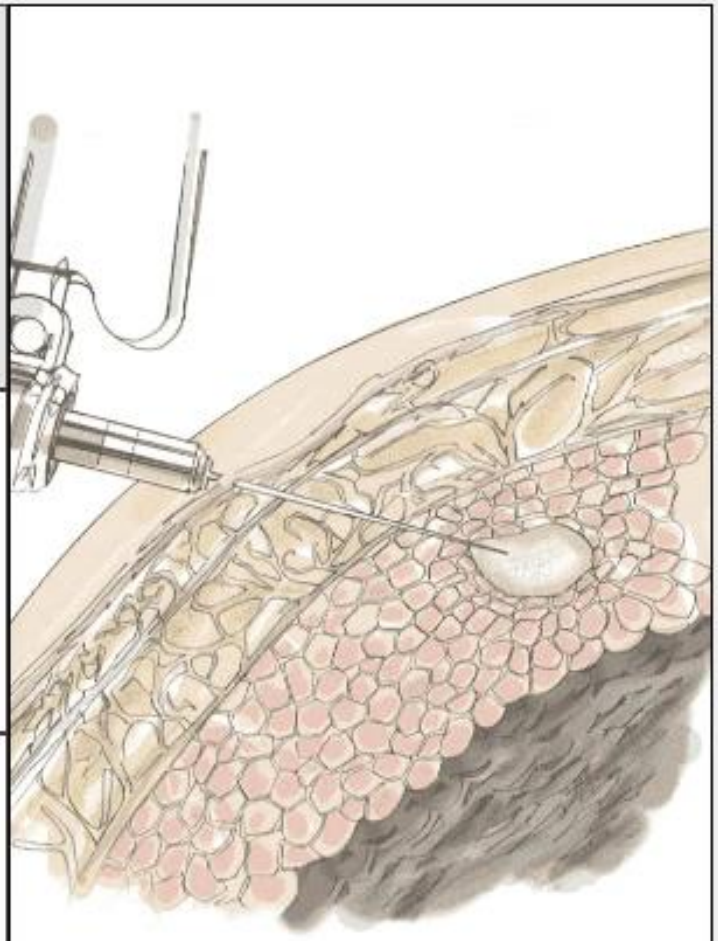
SUBLOCADE is administered as an injection into the abdominal subcutaneous tissue (total volume: 0.5 mL for 100 mg and 1.5 mL for 300 mg)

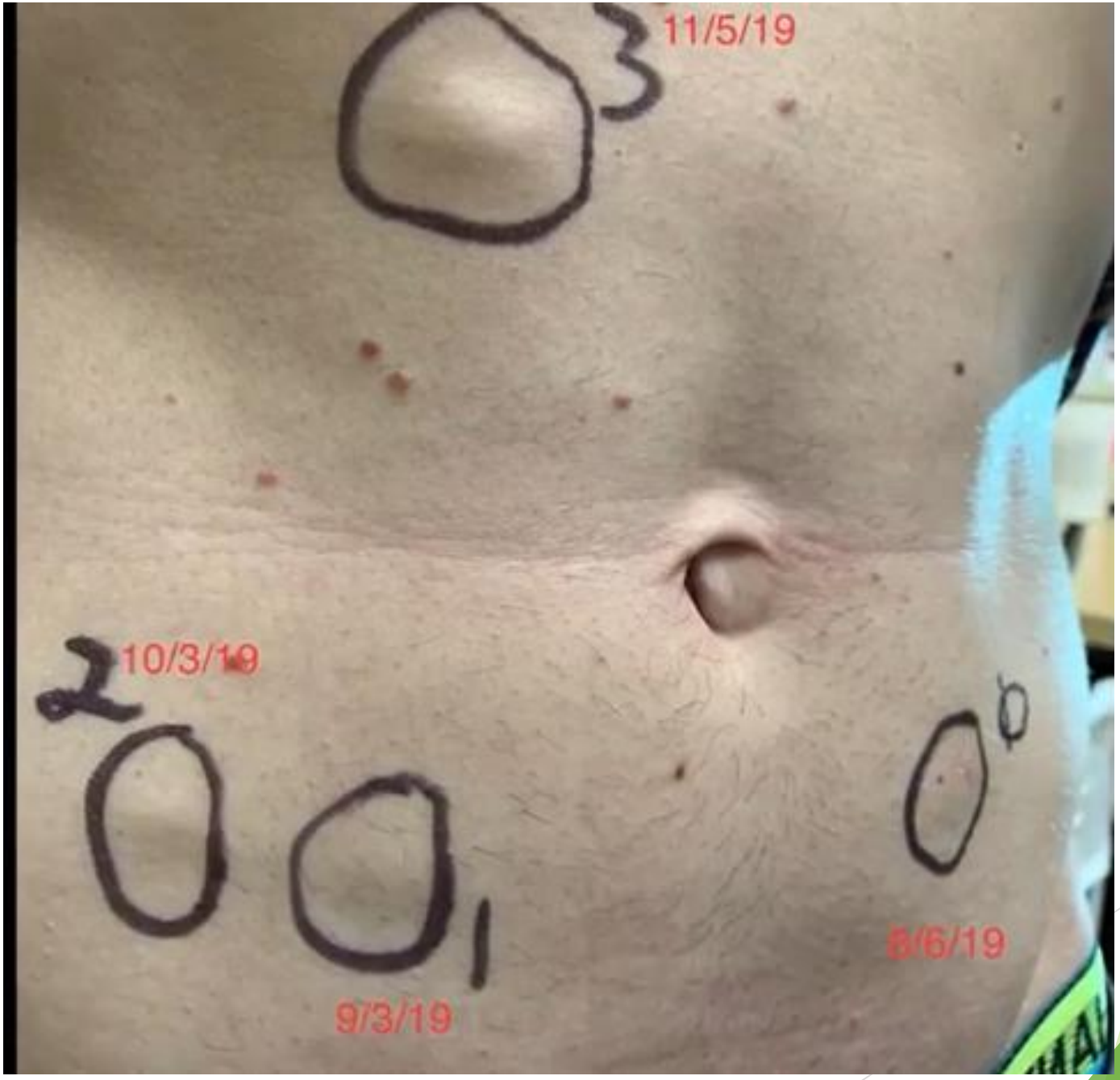
2 | Depot Formation[1]

SUBLOCADE is injected as a liquid, and upon contact with body fluids, the ATRIGEL® delivery system forms a solid depot containing buprenorphine

3 | Continuous Release[1]

After initial formation of the depot, buprenorphine is released via diffusion from, and the biodegradation of, the depot

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1
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Suboxone vs. Sublocade

Suboxone

Given sublingually as a tablet or film

Available in generic

Potential for diversion

Can be prescribed using many platforms including telemedicine

Often frequent visits to the pharmacy

Once induce and titrate, will stay on dosage

Sublocade

Given monthly subcutaneously as an injection

Expensive but covered by many insurance companies

Little risk of diversion

Must be prescribed and the injection given in a REMS facility

Present to clinic monthly for injection

Will need to be induced and be stable on transmucosal product first

A patient's decision to decline psychosocial treatment or the absence of available psychosocial treatment should not preclude or delay pharmacological treatment of opioid use disorder, with appropriate medication management.

Motivational interviewing or enhancement can be used to encourage patients to engage in psychosocial treatment.

Patients should be offered or referred to psychosocial treatment, based on their individual needs.

Rationale:

- Requirements for psychosocial treatment can present barriers to access to treatment for some patients
- Research has shown that methadone and buprenorphine treatment reduce mortality even without psychosocial treatment.

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Resources/References

- Medication-Assisted Treatment of Opioid Use Disorder Pocket Guide

  https://store.samhsa.gov/system/files/sma16-4892pg.pdf

  ▶ASAM practice guideline

  ▶Buprenorphine Waiver Management (X Waiver or DATA 2000)

  https://www.samhsa.gov/programs-campaigns/medication-assisted-treatment/training-materials-resources/buprenorphine-waiver

  Prescribe to Prevent

  https://prescribetoprevent.org/

1. Tanum L, Solli KK, Latif ZE, et al. Effectiveness of Injectable Extended-Release Naltrexone vs Daily Buprenorphine-Naloxone for Opioid Dependence: A Randomized Clinical Noninferiority Trial. JAMA Psychiatry 2017; 74:1197.
2. Fischer G, Gombas W, Eder H, et al. Buprenorphine versus methadone maintenance for the treatment of opioid dependence. Addiction 1999; 94:1337.
3. Sublocate package insert

Waiver training

- https://pcssnow.org/

(Can link through SAMHSA)

- American Psychiatric Association (APA)
- American Osteopathic Academy of Addiction Medicine (AOAAM)
- American Psychiatric Nurses association (APNA)
- American Society of Addiction Medicine (ASAM)
- American Academy of Physicians Assistants (AAPA)
- Others……

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THANK YOU
for your
ATTENTION!

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