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This menu allows you to **control**:

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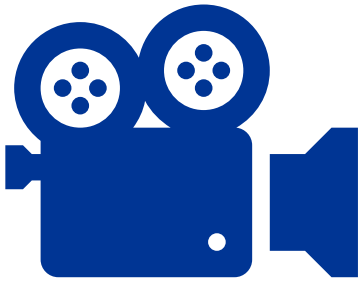

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Pose questions in the chat to **All Participants**

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Mutual Agreement

- Everyone on every PERU webinar is **valued**. Everyone has an expectation of **mutual, positive regard** for everyone else that respects the **diversity** of everyone on the webinar.
- We operate from a **strength-based, empathetic, and supportive** framework – with the people we serve, and with each other on PERU webinars.
- We encourage the use of **affirming language** that is not discriminatory or stigmatizing.
- We treat others as **they** would like to be treated and, therefore, avoid argumentative, disruptive, and/or aggressive language.

Mutual Agreement (continued)

- We strive to **listen** to each person, avoid interrupting others, and seek to **understand** each other through the Learning Network as we work toward the highest quality services for COE clients.
- Information presented in Learning Network sessions has been vetted. We recognize that people have different opinions, and those **diverse perspectives** are welcomed and valued. Questions and comments should be framed as **constructive feedback**.
- The Learning Network format is **not conducive to debate**. If something happens that concerns you, please send a chat during the session to the panelists and we will attempt to make room to address it either during the session or by scheduling time outside of the session to process and understand it. Alternatively, you can reach out offline to your PERU point of contact.

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Acknowledgements

- The Centers of Excellence is a partnership of the University of Pittsburgh's Program Evaluation and Research Unit and the Pennsylvania Department of Human Services; and is funded by the Pennsylvania Department of Human Services, grant number 601747.

- COE vision: The Centers of Excellence will ensure care coordination, increase access to medication-assisted treatment and integrate physical and behavioral health for individuals with opioid use disorder.

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Overview of Medications for Opioid Use Disorder

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By the end of this module, you will be able to do the following:

- Describe how opioid use disorder (OUD) can develop as a result of changes in the brain
- Discuss the efficacy of medications for opioid use disorder (MOUD) for improving OUD treatment engagement, retention, and outcomes
- List the general treatment phases for treating OUD with MOUD
- List at least two factors that help determine which MOUD is best for a patient
- Describe strategies for monitoring treatment, including ensuring treatment adherence and minimizing misuse/diversion

OUD Development

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The Reward (Mesolimbic) Pathway

- Neural pathway connecting **dopamine-releasing neurons**[1]
- The release of dopamine regulates response to **rewarding stimuli**[1]
- This **facilitates reinforcement** and motivation to engage in rewarding behavior[1]

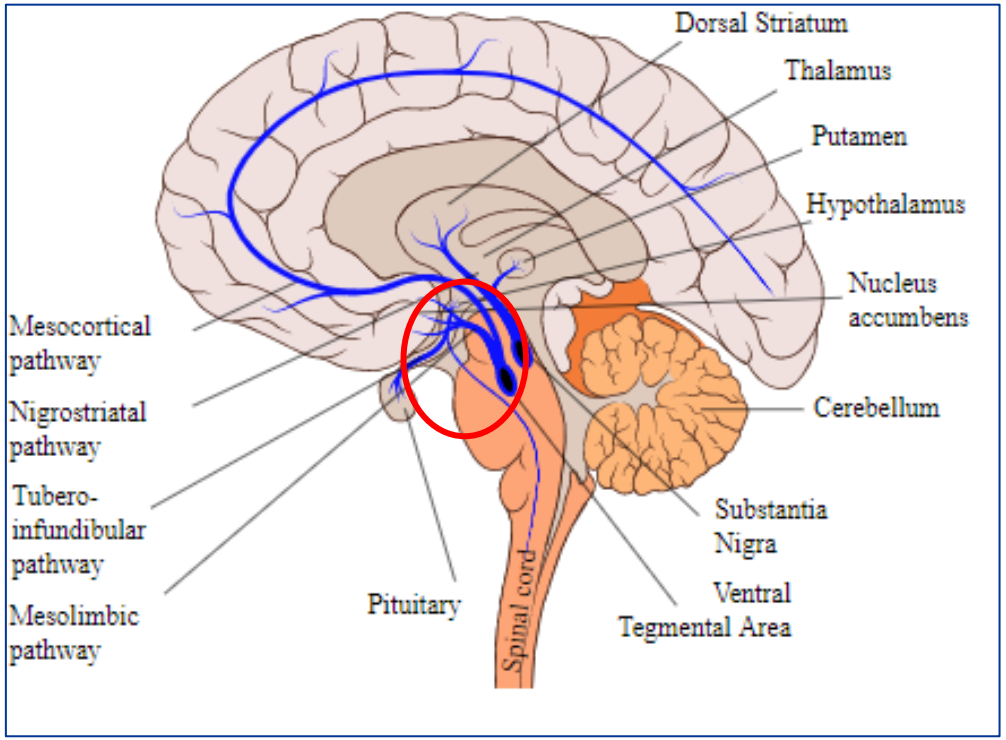

Figure 1: Dopaminergic Pathways[2]

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([1]Icahn School of Medicine; [2]Wikimedia Commons, 2017)

Opioids and the Reward Pathway

Opioids **activate opioid receptors**, releasing a surplus of dopamine.[1]

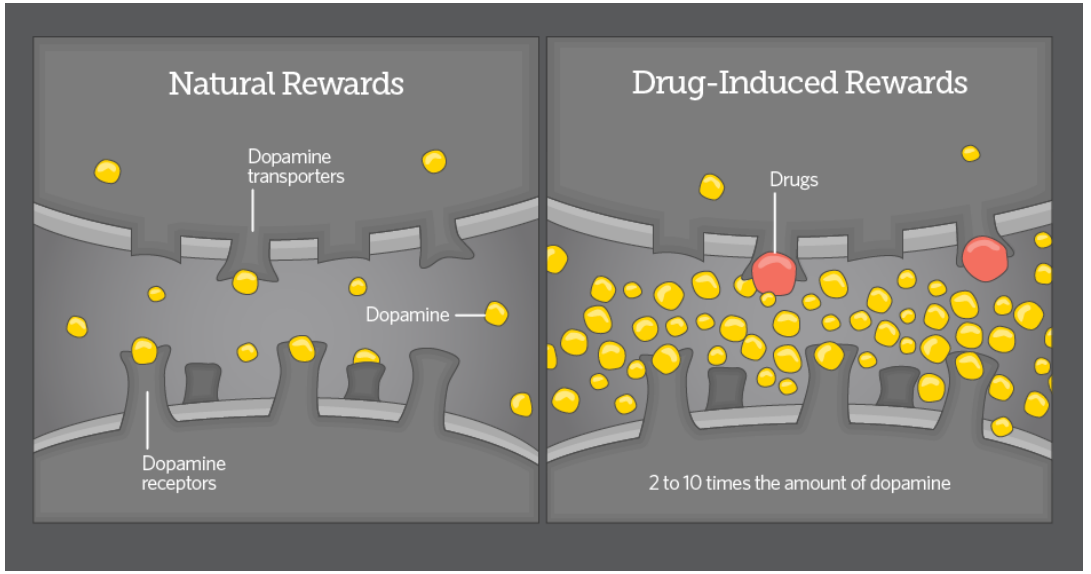


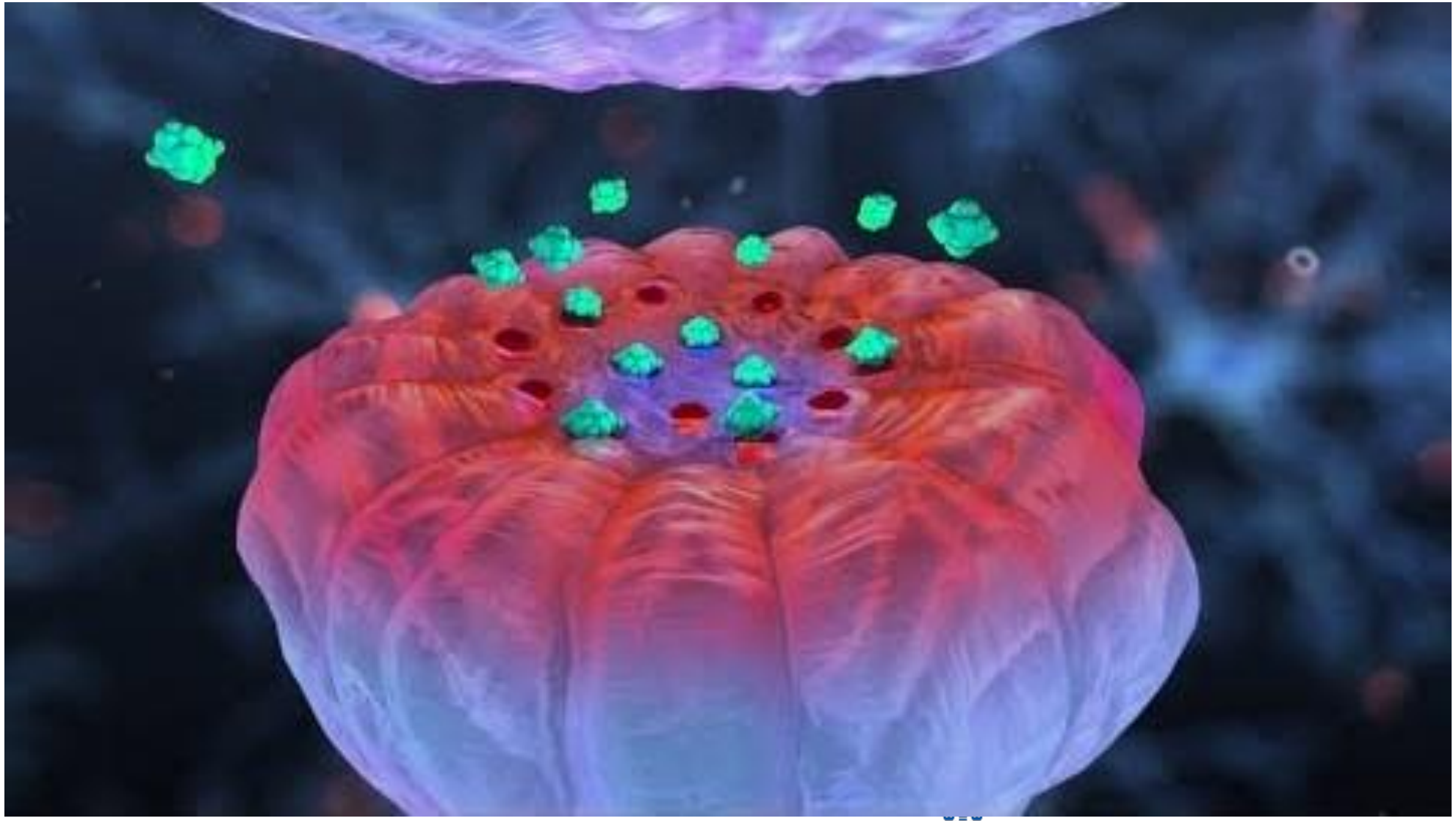
Figure 1: Dopamine Response to Natural and Drug-Induced Rewards[2]

([1]SAMHSA, 2020; [2]Bright Heart Health, n.d.)

Brain Chemistry Changes

- The brain's pleasure centers **respond to rewards**, such as eating ice cream, or petting dogs.
- Opioids **overstimulate the receptors** and create a feeling of euphoria.
- Ultimately, this change leads to the **inability to feel pleasure** from naturally rewarding activities.

(SAMHSA, 2020)



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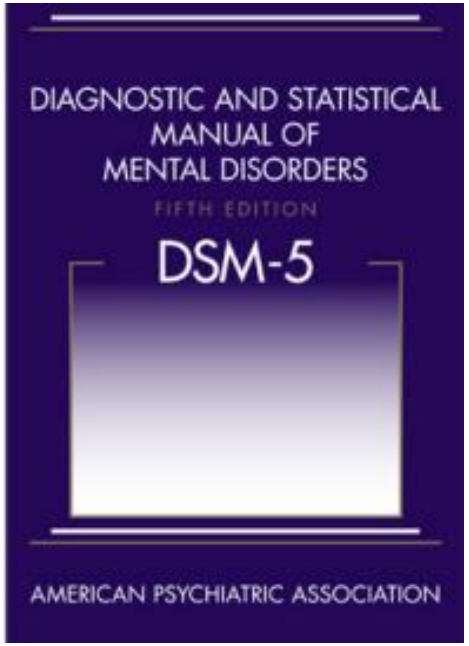
(Holt, 2018)

OUD and DSM-5 criteria

1. Opioids are used more than originally planned
2. Persistent desire or unsuccessful efforts to reduce or control opioid use
3. Spending large amounts of time seeking, using, or recovering from opioid use
4. Craving to use opioids
5. Opioid use results in failure to fulfill major role obligations at work/school/home
6. Continued use despite having persistent/recurrent social or interpersonal problems caused by or exacerbated by opioid use
7. Important social, occupation, or recreational activities are given up or reduced because of opioid use
8. Regularly using opioids in dangerous situations/environments
9. Continued opioid use despite negative physical or psychological effects
10. **Develops tolerance***
11. **Evidence of withdrawal***



**Tolerance and withdrawal alone are insufficient criteria for the diagnosis of opioid use disorder if an individual is taking prescribed opioids under medical supervision.*

(APA, 2013)

OUD Treatment

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Treatment Terminology

- **Different terminology** may be used to refer to treatments for opioid use disorder that involve medication.
- **Medication-Assisted Treatment (MAT)** refers to the use of medications in combination with behavioral therapies.[1]
- **Medications for Opioid Use Disorder (MOUD)** refers to the use of medications, with or without behavioral therapies.[2]
  - In this approach, the medication is considered the first-line treatment for OUD
  - This is in contrast to the framing of medication as “assisting” other treatment

([1]SAMHSA, 2021; [2]NASEM, 2019)

Approaches to Treatment

- There is no **one-size-fits-all** approach to treatment.
- Many patients benefit from behavioral interventions, but some patients may do well with just medication and medical management.
- Behavioral therapies can help to **engage patients with treatment**, improve problem-solving skills, and increase quality of life.
- Patient assessment can help to determine an appropriate treatment approach based on a patient's **history** and treatment **goals**.

(NASEM, 2019)

Detox Alone is Not Treatment

Detox (medically supervised withdrawal) <u>should not be the sole treatment step for OUD</u> because most patients will start using opioids again after detox.

(SAMHSA, 2020; Chang et al., 2018; Nunes et al., 2018)

Goals of MOUD

- **Stabilize** abnormal brain activity[1]
- **Reduce cravings** and **strengthen coping capacity**[2]
- Increase periods of **abstinence** and **self-efficacy**[2]
- **Improve clinical outcomes** for patients and reduce impact on family and loved ones[2]

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([1]SAMHSA, 2021; [2]CDC, 2017)

Effectiveness of MOUD

- Randomized controlled trials (RCTs) are the **highest standard** used to demonstrate effectiveness in medicine
- RCTs found methadone, buprenorphine and naltrexone (injectable) were each **more effective** at reducing opioid use than treatment not using medications
- Methadone and buprenorphine treatment are associated with **decreased risk** of overdose death

(Lee et al., 2016; Mattick et al., 2009; Mattick et al., 2014; Nielson et al., 2016)

FDA-Approved Medications for Treating OUD

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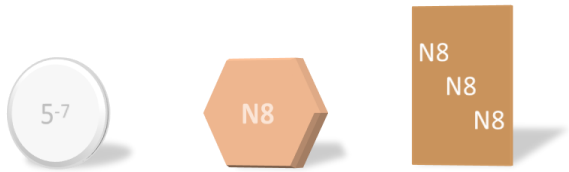
Opioid Agonists

- **Bind** to the opioid receptors in the brain
- Have an opioid effect, when used at the correct dose, they **will not** get a patient "high"
- Reduce or stop **withdrawal symptoms** and **cravings**

Methadone (full agonist)



Buprenorphine (partial agonist)

(NIDA, 2021)

Opioid Antagonists

- **Block** the effects of opioids
- Do not have **opioid** effects
- Do not stop **withdrawal** symptoms
- Can cause **withdrawal**
- Can help to **reduce the effect** of opioids and the desire to use them

Naltrexone

Naloxone

(NIDA, 2021)

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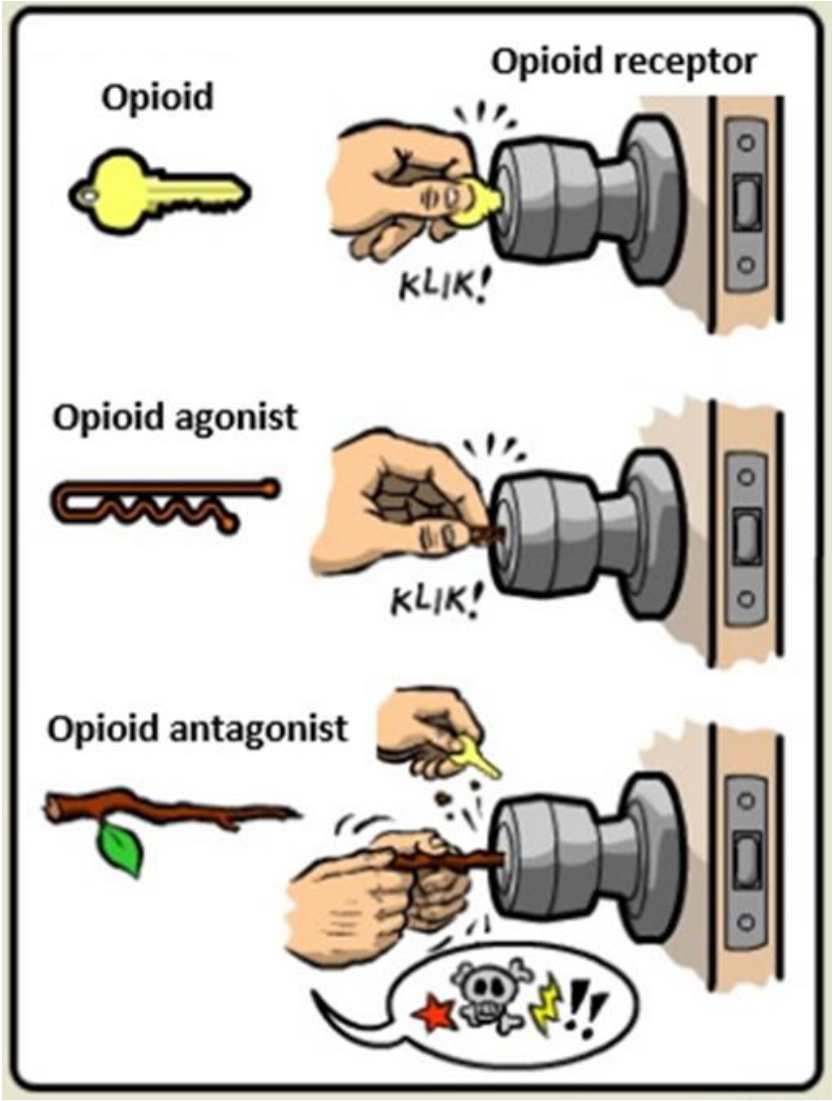
Lock & Key



(Saul, 2005)

MOUD - Medications

Methadone

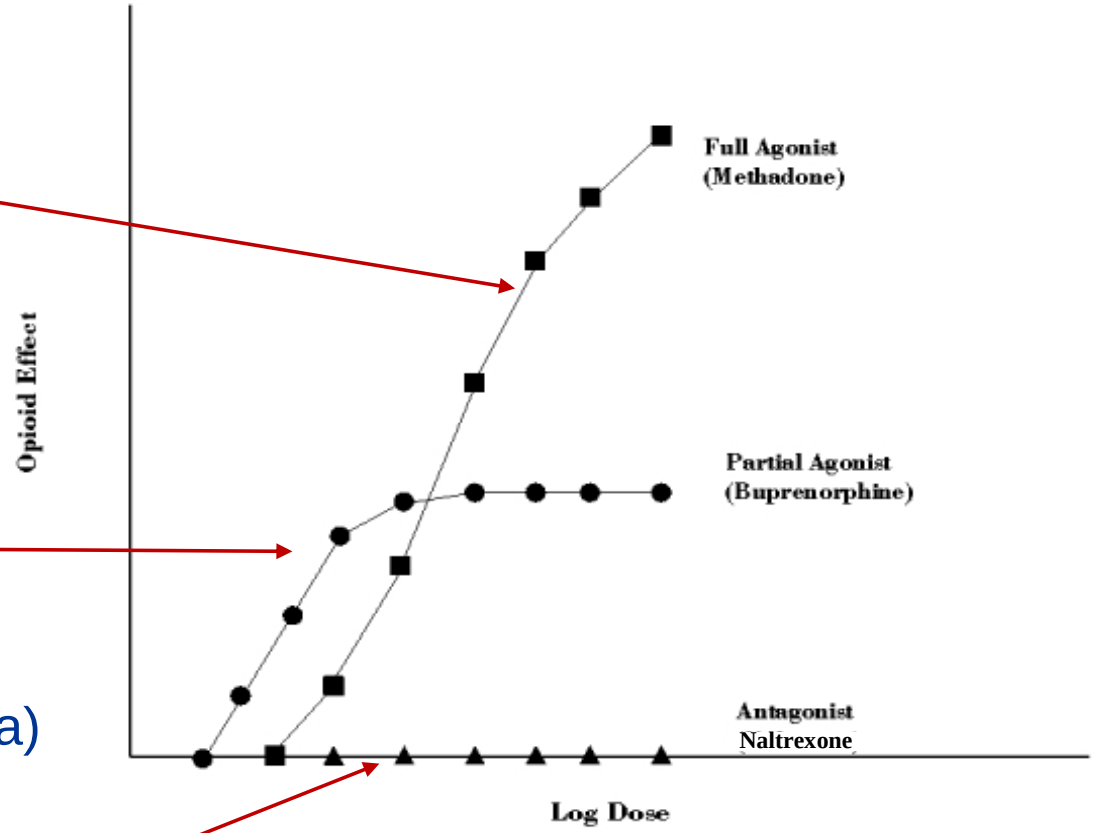
- Opioid receptor full agonist (no ceiling effect)
- Moderate receptor binding affinity
- Moderate to severe OUD

Buprenorphine

- Opioid receptor partial agonist (has ceiling effect)
- High receptor binding affinity
- Will displace full opioids agonists from the receptors (competitive antagonist)

Naltrexone

- Opioid receptor antagonist (no euphoria or analgesia)
- Very high receptor binding affinity
- Will displace partial and full opioid agonists from the receptors and blocks the effects



(SAMHSA, 2020; KCSAT, 2004; PCSS, n.d.; CSAT, 2000)

Methadone Treatment

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Methadone Treatment Criteria

Methadone can only be administered to individuals engaged in a **licensed opioid treatment program** (OTP). Individuals who meet the following criteria can be admitted to OTPs:

Those with at least a 1-year history of a moderate to severe OUD

If clinically appropriate, a program physician may waive this requirement:

- Pregnant women/adolescents;
- Previously treated patients (up to 2 years post-discharge); or
- Those released from a correctional facility within the past 6 months.

(SAMHSA, 2020)

Treatment Phases and Dosing

Induction Phase:

- Weeks 1 & 2 of treatment
- Day 1: 10-30 mg
  - Monitor 2-4 hours after

Maintenance Phase:

- 80-120 mg
- Goal: Patient able to function in day-to-day life without physical or psychological impairment due to medication

(SAMHSA, 2020)

Buprenorphine Treatment

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DATA Waiver (X-Waiver) Requirement

- Consolidated Appropriations Act of 2023 was signed **eliminating SAMSHSA's DATA-Waiver** Program.
- DATA-Waiver registration is **no longer required** to treat patients with buprenorphine for opioid use disorder
- All prescriptions for buprenorphine require **only** a standard DEA registration number.
- The **limits or patient caps** on the number of patients a prescriber may treat for opioid use disorder with buprenorphine have been **removed**.

(U.S. Department of Justice, 2023)

Buprenorphine Formulations

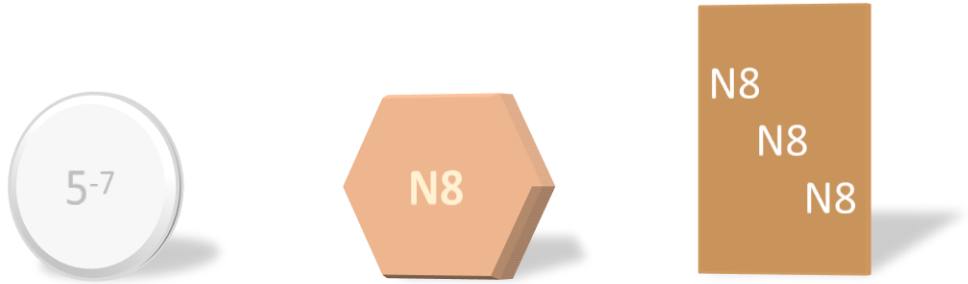
- Buprenorphine
  - Buprenorphine tabs
  - Probuphine® subdermal
  - Sublocade® injectable extended-release
- Buprenorphine/Naloxone
  - Suboxone Film®
  - Bup/nx film
  - Bup/nx tabs
  - Zubsolv®
  - Bunavail®

(SAMHSA, 2020)

Buprenorphine/Naloxone

Formulations available for transmucosal (buccal or sublingual) administration contain **both buprenorphine and naloxone**

Buprenorphine – partial mu-opioid agonist
Naloxone – opioid antagonist



- These are effective when taken as directed due to poor bioavailability of naloxone when administered orally.
- The addition of naloxone decreases risk of misuse by injection.

(SAMHSA, 2004; SAMHSA, 2020)

Buprenorphine Treatment Phases

1. **Induction** – start of treatment once patient has abstained from using opioids for at least 12 hours.

2. **Stabilization** – determining appropriate dosing where patient no longer exhibits cravings/withdrawal.

3. **Maintenance** – steady state dosing achieved and routine adjustments are no longer needed. Patient responding optimally to treatment and has stopped using opioids and other substances.

(SAMHSA, 2004; SAMHSA, 2020)

Two Types of Buprenorphine Induction

Office-based

Allows the provider to…

- **Ensure** the patient knows how to take the medication;
- **Assess withdrawal** and verify absence of precipitated withdrawal; and
- **Enhance** the therapeutic relationship.

Home

Ensure the patient is able to…

- Describe, understand, and **assess withdrawal**;
- Understand and **follow dosing instructions**; and
- **Contact their provider** about problems.

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(SAMHSA, 2004; SAMHSA, 2020)

Stabilization Includes

- Significantly **reduced** or **eliminated** illegal opioid use
- Blunted or blocked **euphoria** during illegal opioid use
- Reduced **cravings** for opioids
- Suppressed opioid **withdrawal**
- Are experiencing no or minimal **side effects**

(SAMHSA, 2004; SAMHSA, 2020)

Buprenorphine Maintenance

- Goal is to **prescribe lowest dose that can**:
  - Eliminate withdrawal;
  - Reduce or eliminate opioid cravings;
  - Reduce or eliminate euphoric effects of opioid use; and
  - Be well tolerated.

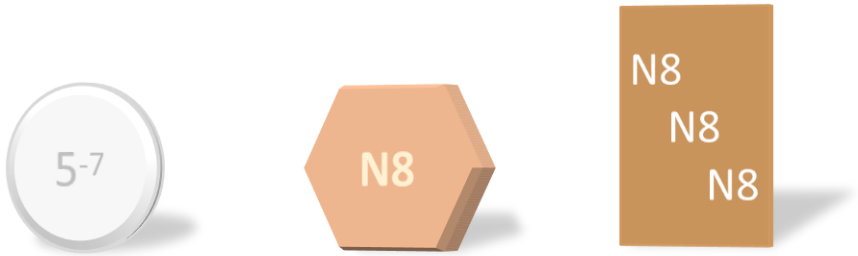
- **Typical Dose:** 4 - 24 mg taken daily

(SAMHSA, 2004; SAMHSA, 2020)

Buprenorphine Efficacy

Compared to psychosocial treatment only, **buprenorphine therapy** can lead to:

- **Higher rates** of treatment retention, completion, and attendance;
- **Reductions** in opioid use; and
- **Improved** medication/treatment compliance.



Concurrent behavioral/psychosocial treatment can further improve these outcomes.

(SAMHSA, 2020; SAMHSA. 2020; Heilig et al., 2003; Banta et al., 2007)

Naltrexone Treatment

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Naltrexone

Prior to naltrexone induction, **patients must be opioid-free** for:

- **7-10 days** (short-acting opioids); or
- **10-14 days** (long-acting opioids).

- This is due to risk of precipitated withdrawal if naltrexone is administered when there are opioids present in a person's system;

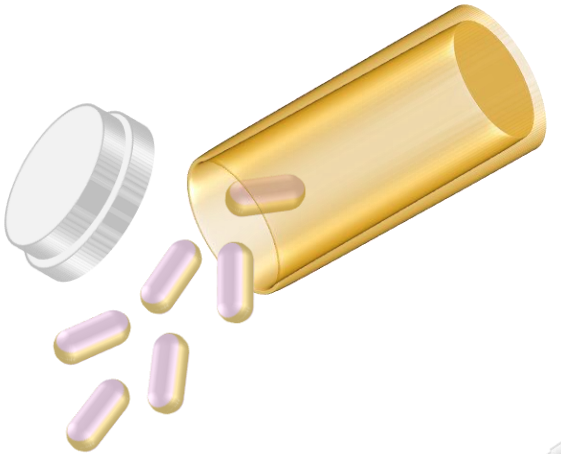
- Recall that naltrexone is an antagonist with a high binding affinity and will displace partial and full agonists from the receptors.

(SAMHSA, 2004; SAMHSA, 1998)

Naltrexone Formulations

Oral (Revia®)

- Daily 50 mg tablet



XR-Naltrexone (Vivitrol®)

- Monthly 380 mg IM injection

(SAMHSA, 2004; SAMHSA, 1998)

Naloxone or Naltrexone Challenge

Prior to receiving injectable naltrexone treatment, patients should undergo a naloxone/naltrexone challenge **to decrease risk of precipitated withdrawal**.

1. Obtain a baseline COWS score - if it is 4 or less proceed to:

   Naloxone Challenge (Intramuscular) OR **Naltrexone Challenge (Oral)**

2. If **COWS increase is less than 2**, it is safe for a patient to proceed with extended-release injectable naltrexone.

(SAMHSA, 2004; SAMHSA, 1998, Wesson et al., 2003)

Naltrexone Maintenance

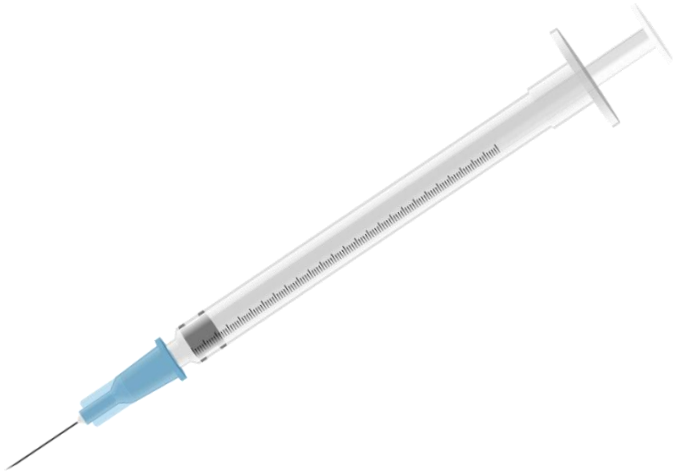
1. Monthly Intramuscular Injection
2. Periodic Laboratory Testing

(SAMHSA, 2004; SAMHSA, 1998)

Naltrexone Efficacy

Compared to psychosocial treatment only, **naltrexone therapy can lead to**:

- Patients having fever cravings;
- Decreased opioid use;
- Improved treatment retention.



(CDC, 2018; D'Onofrio, 2015, Krupitsky et al., 2011)

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Determining Patient Candidacy for MOUD

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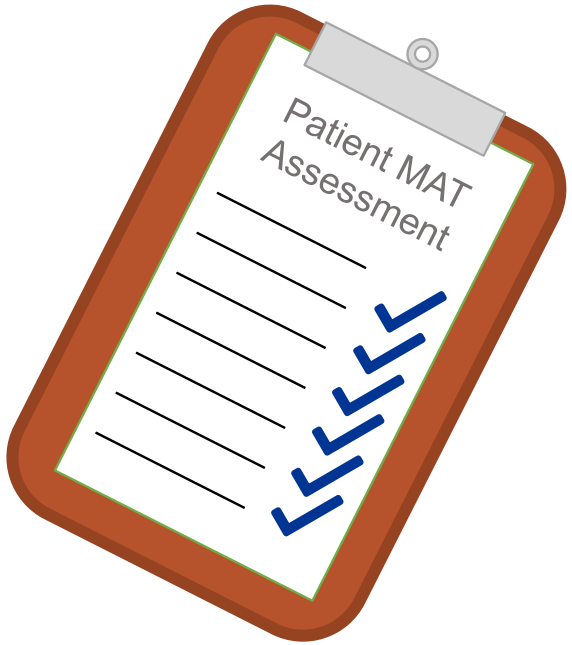
Assess Patient Candidacy: Current Status

- Complete a **level of care assessment** (required for COE clients).
- Assess for **medical and psychiatric safety.**
- Assess for **withdrawal** and need for ambulatory **detoxification.**
- Review **recent substance** use (past 90 days).
- Assess client's **treatment goals** and motivation for treatment.



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Assess Patient Candidacy: History

- **Determine severity of opioid use disorder (OUD)** via client's medical history of diagnosed substance use disorder(s) or completing a preliminary assessment of the DSM-5 OUD Criteria.
- **Complete a Prescription Drug Monitoring Program inquiry** to obtain additional history of controlled substance use and review use of contraindicated medications, if possible.
- Review substance use disorder **treatment history**.

Assess Patient Candidacy: Treatment Options

- Determine physical and psychiatric **health needs.**
- Discuss **barriers to accessing treatment**, for example, social or financial issues.
- **Review MOUD** and medications available.
- Discuss **treatment plan** and provide treatment schedule.

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Potential Candidates: Methadone

Only available from licensed Opioid Treatment Programs (OTP)

Methadone treatment may be appropriate for the following types of patients:

- Need high level of monitoring
- Dependent on several substances
- History of diversion
- No insurance or limited means
- Meets criteria for OTP admission

Methadone (full agonist)

(SAMHSA, 2004; CSAT, 2004)

Potential Candidates: Buprenorphine

Buprenorphine/naloxone oral formulations (buccal or sublingual)

Monthly injectable formulation (Sublocade™).

Buprenorphine treatment may be appropriate for the following types of patients:

- Are currently physically dependent on opioids
- History of overdose
- Limited social supports
- Have insurance and means of payment
- Experience chronic pain and require chronic opioid treatment

(SAMHSA, 2004; CSAT, 2004)

Potential Candidates: Naltrexone

Daily oral formulation (ReVia®)

Monthly injectable formulation (Vivitrol®).

Naltrexone treatment may be appropriate for the following types of patients:

- Less severe OUD
- Have been abstinent from opioids for at least one week
- Do not want to take opioid agonists or are not able to receive them
- Unsuccessful agonist treatment (or want to transition to antagonist treatment)
- Have a co-occurring alcohol use disorder

(SAMHSA, 2004; CSAT, 2004)

Misuse and Diversion

Definitions of Misuse and Diversion

Opioid Misuse:

"The use of prescription opioids in any way other than as directed by a prescriber; the use of any opioid in a manner, situation, amount, or frequency that can cause harm to self or others."

Opioid Diversion:

"Diversion is the transfer of a controlled substance from a lawful to an unlawful channel of distribution or use."

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Buprenorphine Diversion

- Vast majority using to **prevent/manage withdrawal**
- Helping patients **initiate MOUD treatment** may reduce the risk of diversion
- Case manager's role is determining the **correct level of care** and linkage to treatment

(Beveme et al, 2014)

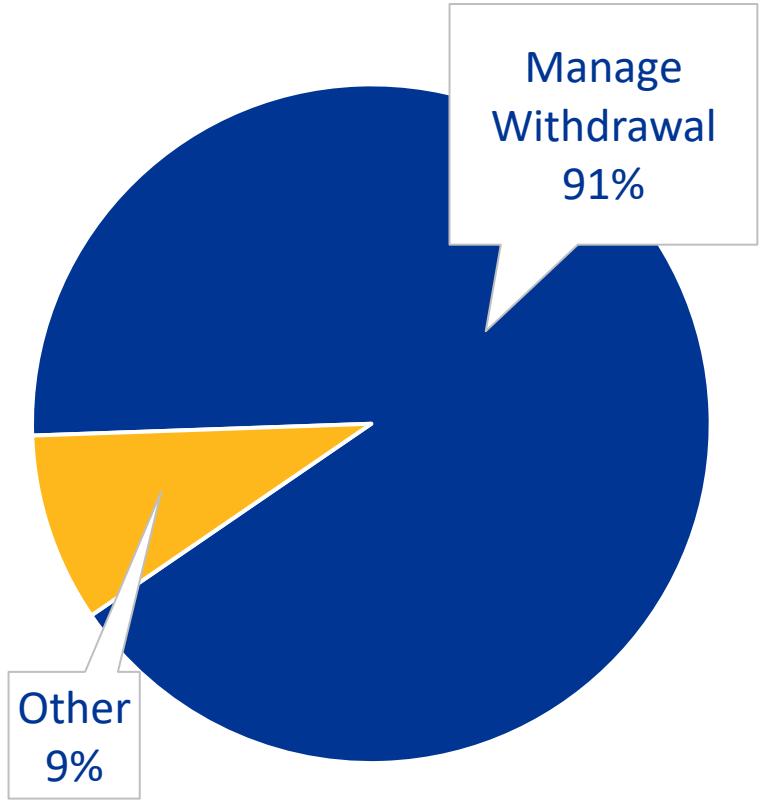
Misuse and Diversion

- A high **prevalence** rate of medication **lending** (6% – 22.9%) and **borrowing** (5% – 51.9%) exists.
- The most commonly diverted medications include:
  - Allergy medications
  - Antibiotics

(Beveme et al, 2014)

Reasons for Use of Diverted Buprenorphine

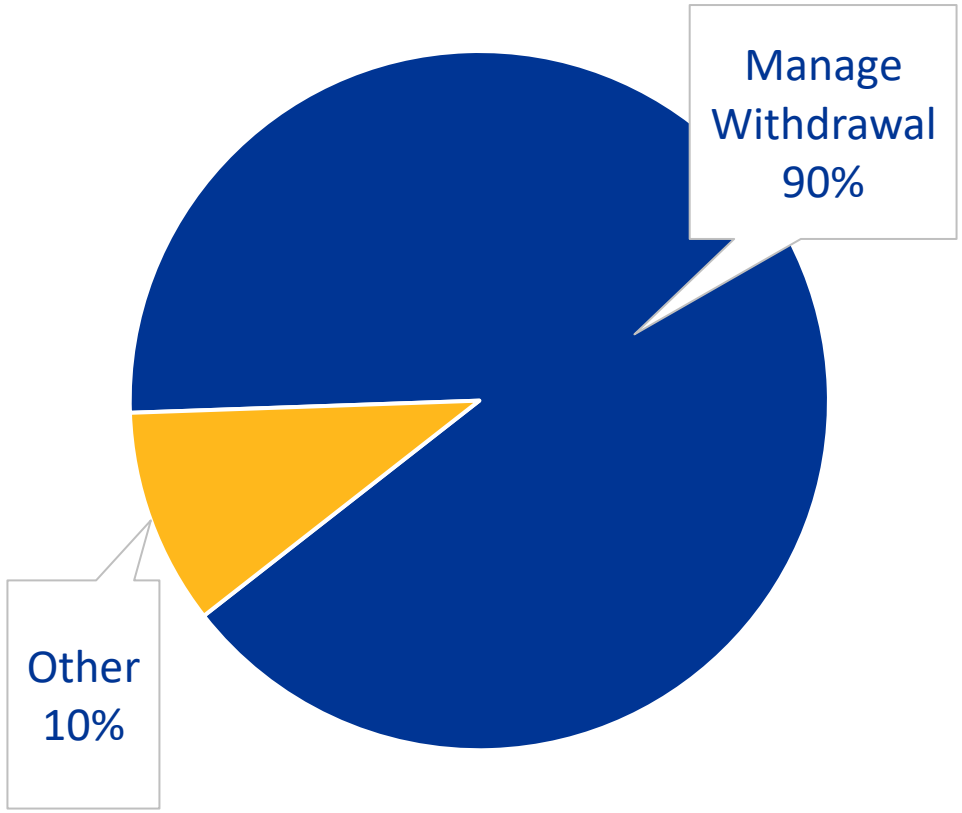
Survey on buprenorphine knowledge and use administered to 602 individuals living in Baltimore, Maryland (all current or former injection drug users).



(Genberg, Gillespie, Schuster, et al., 2013)

Reasons for Use of Diverted Buprenorphine

Survey on illicit buprenorphine use administered to 78 individuals admitted to office-based opioid treatment (OBOT) program.



(Schuman-Olivier Z, Albanese M, Nelson SE, et al 2010).

Action Items

Case managers can support patients by:

- Reviewing patient **history** for misuse and diversion risk factors
- Discussing **residential theft/diversion** by family members
- Encouraging patients **to refer friends** and family with an OUD to treatment

(Kenney et al., 2017)

Misuse and Diversion

Case managers can assist PCPs by:

- Supporting patient **treatment agreements**
- Performing **scheduled and random** urine drug screens and pill/film counts
- **Verifying treatment adherence** with the primary care physician

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Other Action Items

- Facilitate a **warm handoff** to the selected MOUD provider/facility by assisting the client in scheduling their initial assessment.
- **Develop a service plan** with the client, including the information regarding final decisions on LOC, MOUD medication, and referral agency.
- Work with the MOUD provider/facility and client to determine a **communication plan** and frequency of contact.

Questions?

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