THE ASAM
Treatment of Opioid Use Disorder Course

Includes waiver qualifying requirements

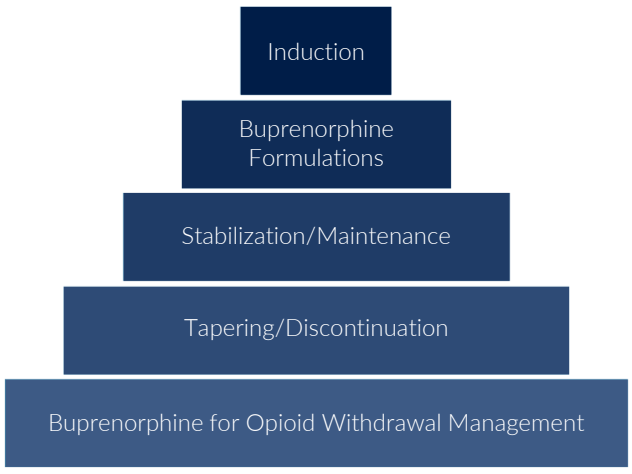
Session 3

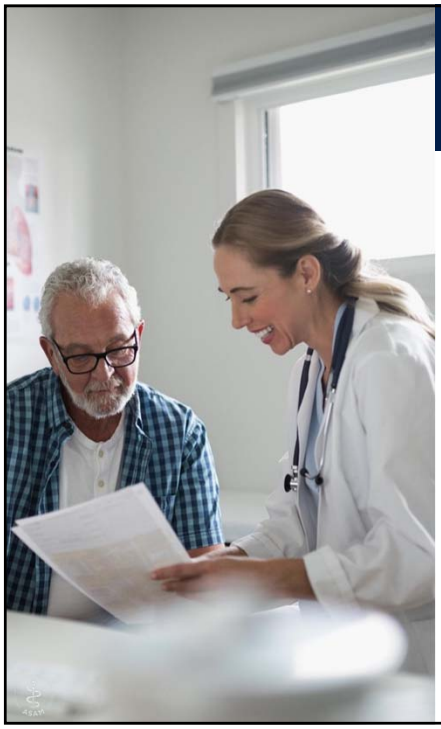
Implementing Office-Based Opioid Treatment

Session Learning Objectives

1. Monitor progress using face-to-face visits, urine drug tests, pill/film counts, and PDMP checks.
2. Discuss relapse prevention with patients.
3. Assess cause of relapse and modify treatment plan based on patient needs to progress toward treatment goals.
4. Describe procedures for setting up office systems including team-based care to support medication prescribing for opioid use disorders.
5. Implement, update, and maintain best practices for office systems to support treatment with medication for opioid use disorder.

Clinical Uses of Buprenorphine





Buprenorphine Induction: Early Stabilization

***Overall Goals:** To find the buprenorphine dose at which the patient experiences:*

- Suppression of opioid withdrawal symptoms.
- Marked reduction or discontinuation of illicit opioid use.
- Decreased opioid cravings.
- Blunted or blocked euphoria after illicit opioid use.
- Minimal/no side effects.
- Provide effective blockade preventing lethal overdose.

Buprenorphine Induction

1 Office-based (Options)

2 Home-based (Unobserved)

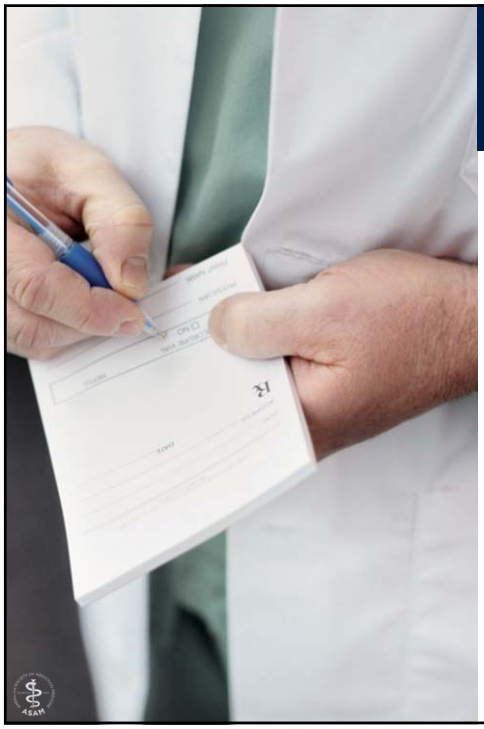
Buprenorphine Induction

Office-Based (Options):

- ***Keep medication in the office for inductions.***
  - Must keep records required by federal and state law for maintaining controlled substances for administering or dispensing.
  - Records are audited by the DEA.
- ***Have the patient:***
  - Fill a prescription for the first day's dose.

OR

  - Bring medication to the office for administration.
- ***Fax prescription to pharmacy, then have it delivered.***



Buprenorphine
The First Prescription

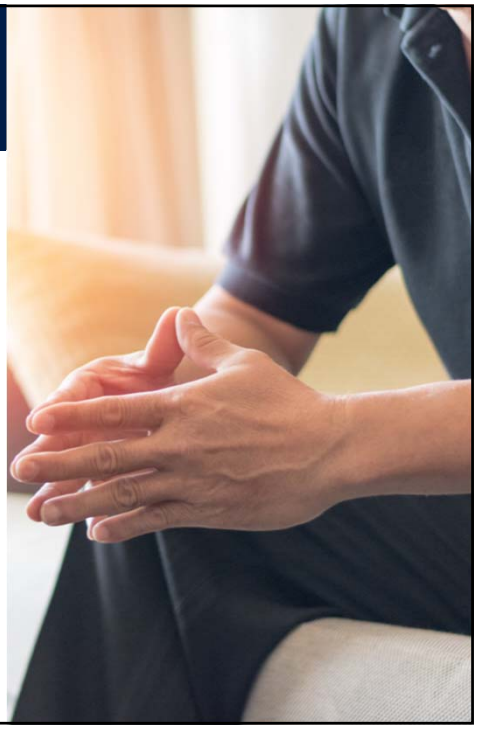
The amount of buprenorphine prescribed for induction and stabilization depends on many factors:

- Will this be an office-based or home induction?
- How adherent is the patient?
- Is there a significant other who can secure and dispense the medication? (Particularly important with younger patients.)
- How are co-pays managed? Is it reasonable to fill prescriptions every few days?
- Prior authorizations.

Buprenorphine Office-based Induction

Patient Instructions:

- Don't plan to drive home.
- Plan to be at clinic or office for up to 3 hours.
- Be ready to give urine sample.
- Bring all prescribed, OTC, and herbal medications with you.
- Bring medication bottle or have it delivered if applicable (prescribe vs. dispense).
- Be accompanied by trusted family member or friend when possible.
- Come to office in ***mild*** opioid withdrawal.



Acute Opioid Withdrawal

	Symptoms / Signs
Mild ↓	Anxiety, drug craving
	Yawning, sweating, runny nose, tearing eyes, restlessness, insomnia
	Dilated pupils, gooseflesh, muscle twitching, muscle & joint aches
	Nausea, extreme restlessness, elevated BP, heart rate > 100, fever
Severe	Vomiting, diarrhea, abdominal cramps, curled-up body position

Clinical Opiate Withdrawal Scale (COWS):
pulse, sweating, restlessness & anxiety, pupil size, aches, runny nose & tearing, GI sx, tremor, yawning, gooseflesh

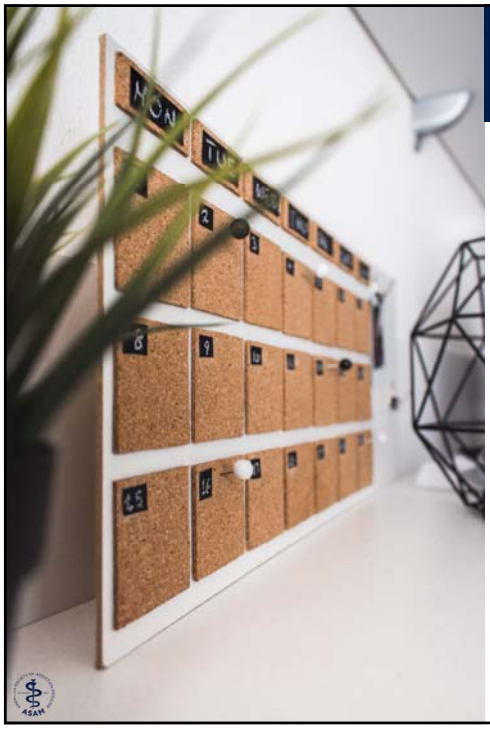
- *5-12 mild*
- *13-24 moderate*
- *25-36 moderately severe*
- *>36 severe*

Buprenorphine Induction

Unobserved "Home" Option:

- Numerous observational studies demonstrate that unobserved "home" inductions are both **effective and safe, however, there is no comparison from RCTs.**
- Should be performed in properly selected patients. Patients should be able to describe and rate opioid withdrawal and understand dosing instructions.
- Providers and patient/significant other should be able to **communicate during the induction**.
- Same protocol as in office-based induction.

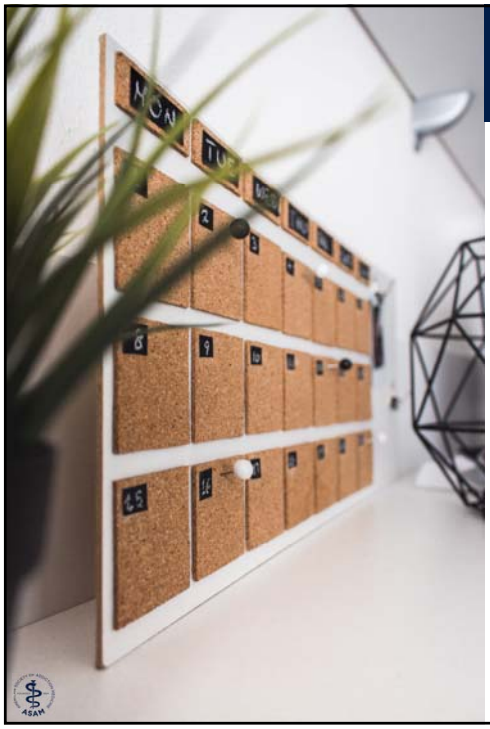
Alford DP et al. J Gen Intern Med. 2007., Lee JD et al. J Gen Intern Med. 2008., Cunningham CO et al. J Subst Abuse Treat. 2011., Sohler NL et al. J Subst Abuse Treat. 2011., Lee JD et al. J Addict Med. 2014.



Induction – Day 1

If the patient is NOT currently physically dependent on opioids:

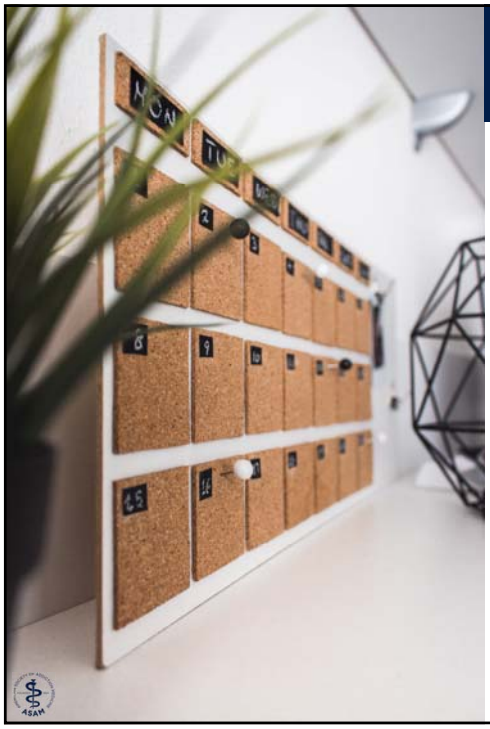
- *Post-withdrawal management, post-incarceration, post-hospitalization*
- Can still meet *DSM-5 OUD criteria*
- No precipitated withdrawal concerns
- *Start low (2 mg)* and go slow to avoid opioid side effects
- *Patients are very good at titrating* buprenorphine if given dosing schedule and parameters (e.g., maximum dose)



Induction – Day 1

If the patient is <u>physically dependent</u> on short-acting opioids:

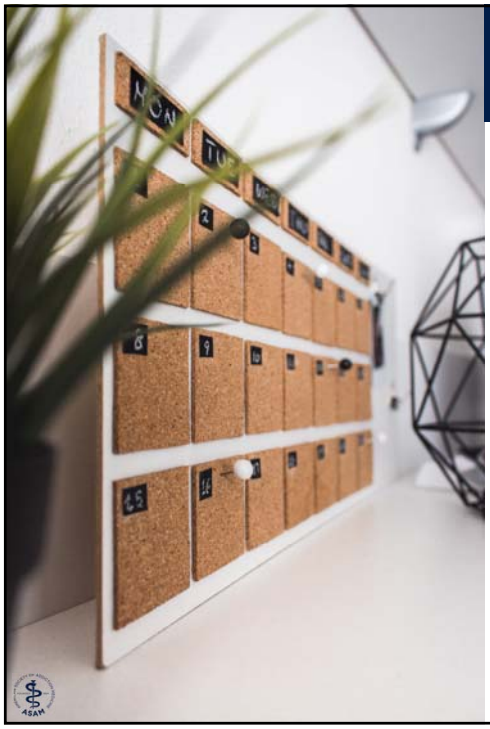
- *Instruct patients to abstain from any opioid use for 12-24 hours (so they are in mild withdrawal at time of first buprenorphine dose).*
- If the patient is not in opioid withdrawal at time of arrival in office:
- *Assess time of last use and consider:*
  - Have them return another day
  - Waiting in the office until evidence of withdrawal is seen
  - Or leaving office and returning later in day (with strict instructions to not take opioids while away from the office)



Induction – Day 1

If the patient is <u>physically dependent</u> on short-acting opioids:

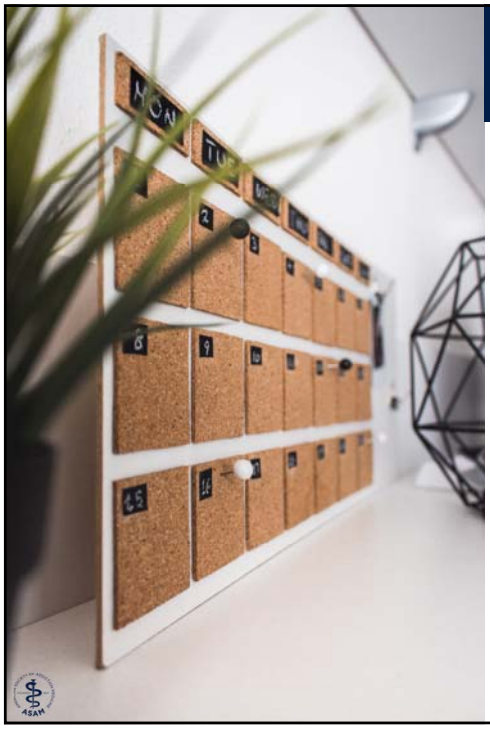
- *First dose: 2/0.5-4/1 mg SL* buprenorphine/naloxone.
- *Dose can take 3-10 minutes to dissolve fully.*
- *Monitor in office for 1-2 hours* after first dose and each subsequent dose.
- *Relief* of opioid withdrawal should begin within 30-45 minutes.
- *Period of greatest severity of buprenorphine-related precipitated withdrawal* occurs in the first few hours (1- 4 hours) after a dose.



Induction – Day 1

If the patient is <u>physically dependent</u> on short-acting opioids:

- *The length of time the patient is monitored in the office varies, depending upon:*
  - The *clinician's* familiarity with:
    - the patient
    - prescribing buprenorphine
  - The patient's level of support at home



Induction – Day 1

If the patient is <u>physically dependent</u> on short-acting opioids:

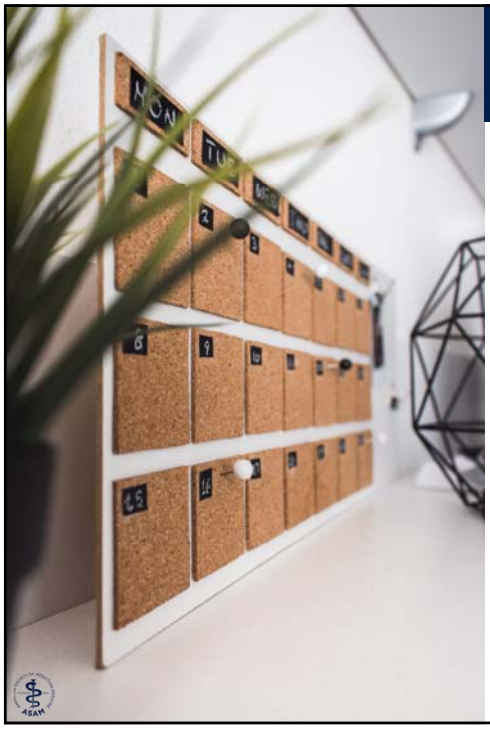
- *Can re-dose if needed* (every 1-2 hours, if opioid withdrawal subsides then reappears).
- *Maximum first day dose of buprenorphine/naloxone = 8mg -16mg.*
- Dose equivalent of other formulations (e.g., 5.7mg - 11.4mg of branded SL tablets).

Inducting Patients

The patient on Fentanyl Patch:

- According to the Fentanyl product insert, it takes >17 hours after removal for a 50% decrease in serum concentrations to be attained.
- Buprenorphine sublingual induction should follow the same general guidelines as with any other full opioid agonist.
- *Methadone should be considered if buprenorphine induction fails.* Fentanyl has a high potency and methadone may be better as a potent full agonist in comparison with buprenorphine.
- *Limited evidence available to guide this process.*

Huhn, A. S., Hobelmann, J. G., Oyler, G. A., & Strain, E. C. (2020). Protracted renal clearance of fentanyl in persons with opioid use disorder. Drug and alcohol dependence, 214, 108147.



Induction – Day 1

If the patient is <u>physically dependent</u> on long-acting opioid:

- *Recommendations vary about optimal dose of long-acting opioid for transfer* (TIP 63 states 30-40 mg/d methadone and remain on that dose for at least 1 week).
- *Begin induction at least 48-72 hours* (sometimes up to 4-5 days) after last dose of methadone, and 36 hours after last dose of sustained release oxycodone (or longer).
- *Patient should be in mild withdrawal* at time of first buprenorphine dose.
- *Use similar induction procedures to "physically dependent on short-acting opioids."*

SAMHSA TIP 63 Medications for Opioid Use Disorders. 2018

Induction – Day 1

Options for Managing Precipitated Withdrawal

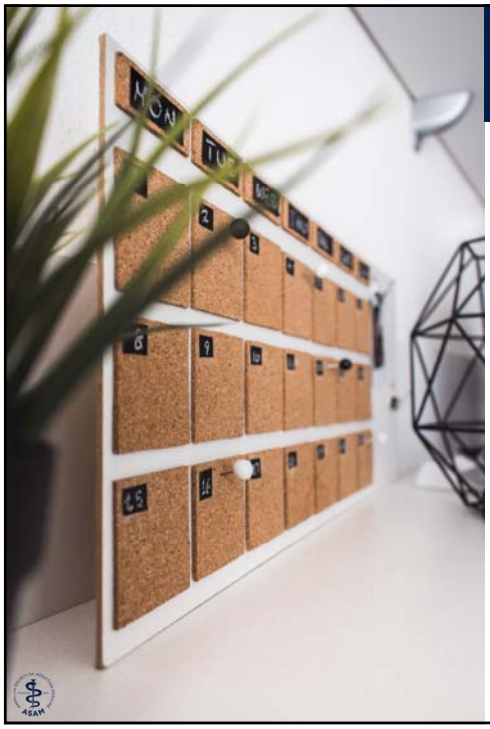
Option 1:
Give another dose of buprenorphine 2-4 mg

Attempting to provide enough agonist effect to suppress withdrawal symptoms.

VS

Option 2:
Stop induction

Treat withdrawal symptoms.
Restart induction the next day.



Induction – Day 1

Options for managing symptoms of precipitated withdrawal:

- Clonidine*, tizanidine*, lofexidine (hyperadrenergic state)
- NSAIDS (muscle cramps and pain)
- Benzodiazepines (insomnia)
- Dicyclomine (abdominal cramps)
- Bismuth subsalicylate (diarrhea)

Since stopping the induction risks loss of the patient, the first option should be considered.

**Off-label use.*

Use of Microdoses for Induction of Buprenorphine

- Even with precautions, for many patients, the induction of buprenorphine is a difficult experience due to withdrawal symptoms.
- Overlapping induction of buprenorphine maintenance treatment with full μ-opioid receptor agonist use is feasible. It may be associated with better tolerability and acceptability in some patients compared to the conventional method of induction.
- Cases illustrate that overlapping induction of buprenorphine while being on full μ-agonists is feasible, but further research is needed.

Hämmig, R., Kemter, A., Strasser, J., von Bardeleben, U., Gugger, B., Walter, M., ... & Vogel, M. (2016). Use of microdoses for induction of buprenorphine treatment with overlapping full opioid agonist use: the Bernese method. Substance abuse and

Acute Opioid Withdrawal
(Off-label for Pain)

Drug	Formulations	Maintenance Dose
Buprenorphine		
Generic	2, 8 mg SL tabs	16 mg/d
Probuphine®	74.2 mg SD implant	4 implants/6m
Sublocade®	100 mg, 300 mg SQ injection	100 mg/m
Buprenorphine/Naloxone		
Generic	2/0.5, 8/2 mg SL tabs	16/4 mg/d
Bunavail®	2.1/0.3, 4.2/0/7, 6.3/1 mg buccal film	8.4/1.4 mg/d
Suboxone®	2/0.5, 4/1, 8/2, 12/3 mg SL film	16/4 mg/d
Zubsolv®	1.4/0.36, 5.7/1.4 mg SL tab	11.4/2.8 mg/d

The Medical Letter 2018; 60(1541):35-37

Corresponding Doses of Bup/Nx

Generic SL tablets	*Suboxone® SL films*	*Zubsolv® SL tablets*	*Bunavail® Buccal films*
2 mg bup / 0.5 mg naloxone	2 mg bup / 0.5 mg naloxone	1.4 mg bup / 0.36 mg naloxone	
	4 mg bup / 1 mg naloxone	2.9 mg bup / 0.71 mg naloxone	2.1 mg bup / 0.3 mg naloxone
8 mg bup / 2 mg naloxone	8 mg bup / 2 mg naloxone	5.7 mg bup / 1.4 mg naloxone	4.2 mg bup / 0.7 mg naloxone
	12 mg bup / 3 mg naloxone	8.6 mg bup / 2.1 mg naloxone	6.3 mg bup / 1 mg naloxone
		11.4 mg bup / 2.9 mg naloxone	

Kampman, K. et al. (2015). The ASAM National Practice Guideline

Audience Response

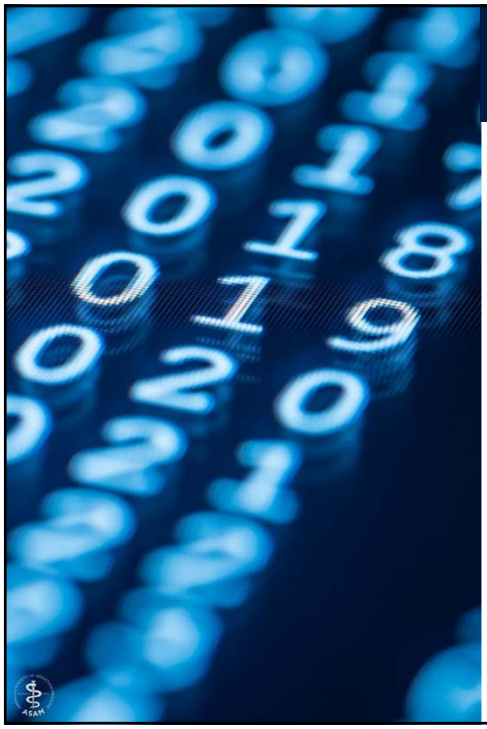
Which of the following is true of the first day of induction?

A. You should always have the patient start medication in the office.

B. Patients who start medication in the office have higher success rates than patients who start at home.

C. Starting medication at home may be preferred by patients as they can be more comfortable with withdrawal.

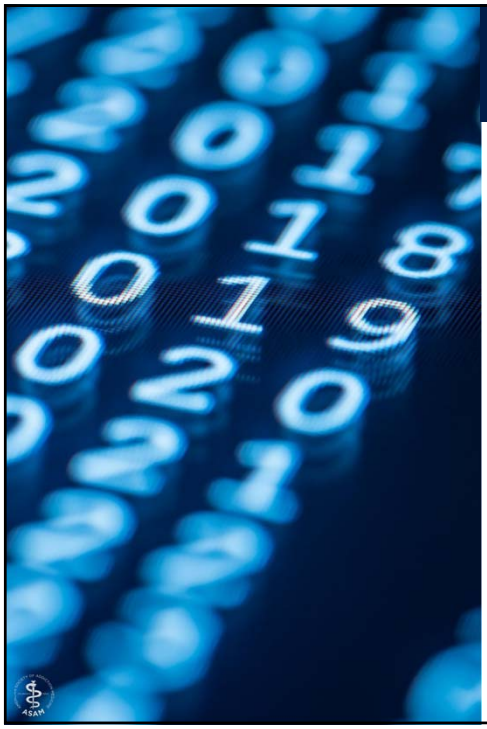
D. Starting medication at home may be preferred due to space constraints in the office for such a long appointment.



Stabilization and Maintenance

Day 2 and Beyond:

- Be in contact with patient (in office, via phone, etc.).
- Adjust dose accordingly based on patient's experiences the first day.
- Continue adjusting dose by 2/0.5-4/1 mg increments until patient is out of withdrawal—this typically occurs at dose of 8/2.
- Generally 24mg of buprenorphine is considered a maximal dose, but rarely patients may require a higher dose up to 32mg.



Stabilization and Maintenance

Day 2 and Beyond:

- After the first day of induction for patients who are physically dependent on either short-acting or long-acting opioids, the procedures are the same.
- Adjust dose according to the patient's experiences:
  - Lower dose if patient was over-medicated at end of Day 1.
  - Higher dose if there were withdrawal symptoms after leaving your office and/or if patient used opioid agonists
- Don't assume abstinence after the first day's dose.

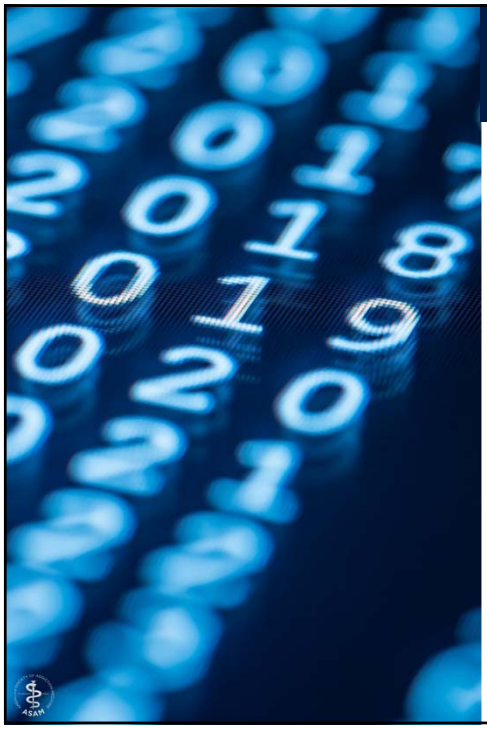
Buprenorphine Dosing

> 24 – 32 mg/day → Unusual: Full Review of Medical/Behavior Issues

> 16 – 24 mg/day → Possible

< 16 mg/day → Typical

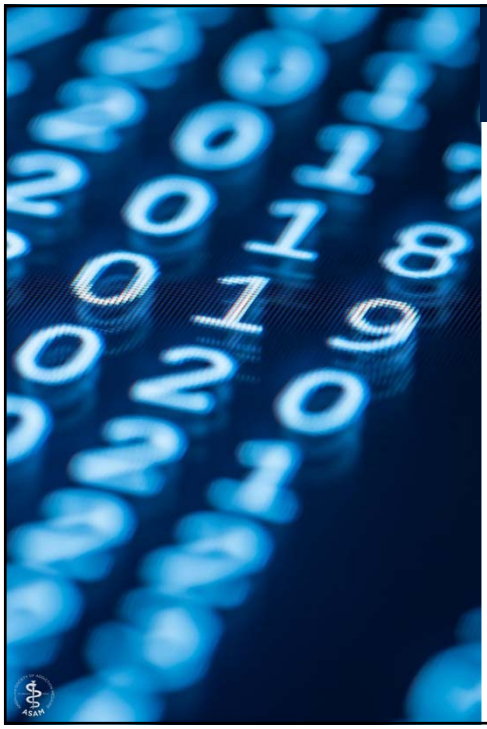
Zubieta et al., 2000; Greenwald et al. 2003; Product Information Suboxone 2005; personal communication RE Johnson, June, 2007.



Stabilization and Maintenance

The patient should receive a daily dose until stabilized:

- Patient should be dosed once daily or twice daily, but not more frequently than twice daily.
- Multiple daily doses which mimic addictive behavior is not recommended.
- Splitting the dose to Q6-8 is indicated if treating concurrent OUD and pain.



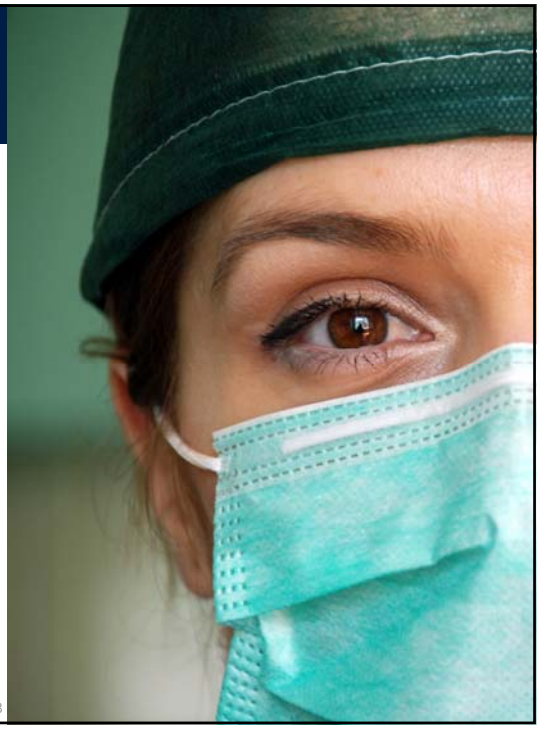
Stabilization and Maintenance

For OBOT patients, daily dosing is the norm:

- Once stabilized, the patient can be shifted to alternate day dosing (e.g., every other day, M-W-F, or every third day, M/Th).
- Non-daily dosing is most appropriate if the patient is receiving observed dosing in an OTP.
- Increase dose on dosing day by amount not received on other days (e.g., if on 8 mg/d, switch to 16/16/24 mg M-W-F).

Buprenorphine Implants *(Probuphine®)*

- FDA-approved for mod-severe OUD.
- Subdermal four implants (0.5-1 ng/ml); low continuous levels for 6 months.
- Requires certification (live training) to prescribe, insert and remove implants.
- ~30-minute procedure: follow-up in one week.
- After 1 insertion in both arms, transition to SL buprenorphine.



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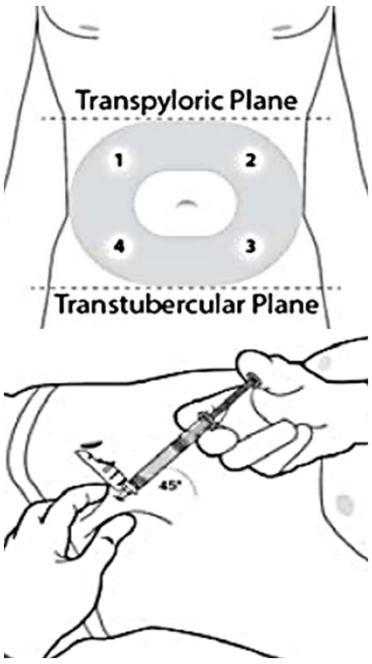
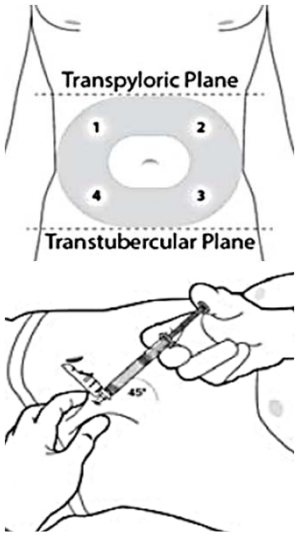
Buprenorphine Extended-Release (ER)

Subcutaneous Injection (Sublocade®)

- FDA-approved for moderate to severe OUD.
- Biodegradable delivery system.
- Releases buprenorphine at controlled rate over one month.

The Medical Letter Feb 26, 2018





Buprenorphine Extended-Release (ER)

Subcutaneous Injection (Sublocade®)

Releases buprenorphine at controlled rate over one month:

- Mean plasma concentration with monthly 100 mg is about 10% higher than 24 mg/d of SL tablets.
- Each of the 1st two monthly SQ doses should be 300 mg/1.5 ml prefilled syringe. Doses should be separated by at least 26 days
- Subsequent doses should be 100 mg/o.5 ml prefilled syringe. Some patients may need to increase maintenance dose to 300 mg monthly.

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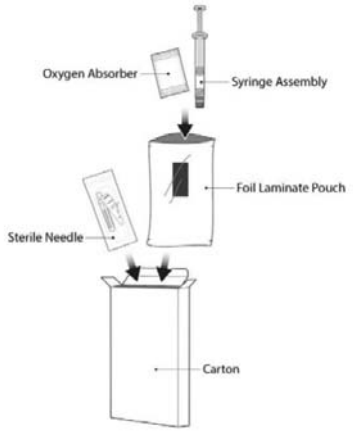


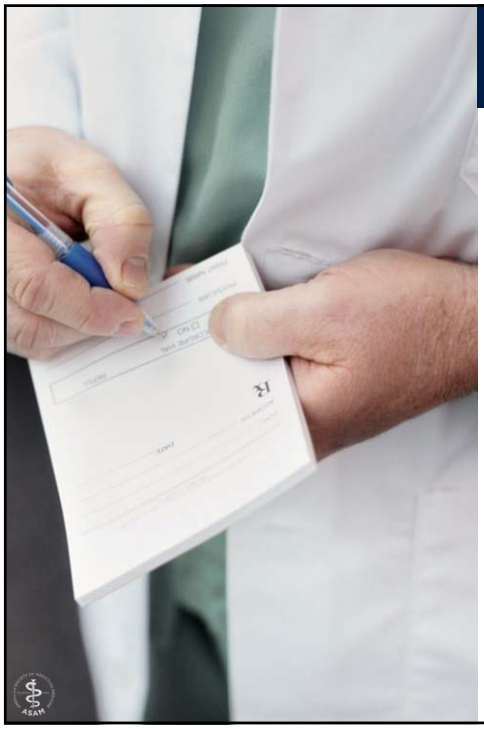
Buprenorphine ER Injection
(Sublocade®)

- Pharmacies need special certification to order and dispense.
- Before initiating, patient should be stabilized on transmucosal buprenorphine (8 mg-24 mg daily) for at least seven days.
- There is insufficient data on its use in pregnancy.
- ***Inform patient:***
  - Medication only available in specific pharmacies as IV self-administration can be fatal.
  - After abdominal injection, a lump may be present at the injection site for a few weeks. Patients should not rub or massage the lump or let belts rub against it.

Finding REMS certified pharmacies:

https://www.sublocaderems.com/Content/pdf/certified-pharmacies.pdf

SAMHSA TIP 63 Medications for Opioid Use Disorders. 2018



Buprenorphine Maintenance

How long should buprenorphine maintenance continue?

- Patients should take medication as long as they benefit from it and wish to continue.
- There is no known duration of treatment after which patients can stop medication and be certain that they will not return to illicit opioid use.
- Given the chronic nature of OUD and potentially fatal consequences of unintended opioid overdose, ***it is critical to base length of time in treatment on patients' individual needs***.

SAMHSA TIP 63 Medications for Opioid Use Disorders. 2018

Buprenorphine Discontinuation

Important Considerations: Part 1

- How has the patient responded to treatment so far?
- Why do they want to taper?
- What do they expect will be different after the taper?
- Do they understand the risk of overdose associated with return to use?
- Do they have a safety plan?

Buprenorphine Discontinuation

Important Considerations: Part 2

- **Do they understand the risks and benefits of continuing vs discontinuing treatment?**
  - Many studies show high relapse rates with tapering and withdrawal from maintenance agonist medications.
  - Some studies show normalization of brain function with maintenance.

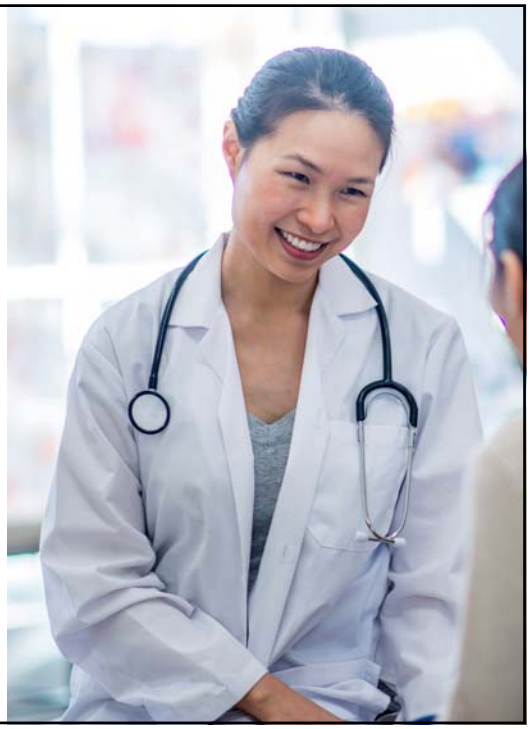
Buprenorphine Discontinuation

Important Considerations: Part 3

- **Patients should continue to be followed by provider after discontinuation.**
- Patients should be told they can resume buprenorphine treatment if cravings, lapses, or relapses occur.
- Psychosocial treatments should continue if applicable.
- Consider naltrexone.
- Associated with relapse? Do they have a safety plan?

Tapering

- ***Short-term taper ("detox") is not recommended as a stand-alone treatment.***
  - However, patients may taper from buprenorphine as part of a treatment plan.
- There is no ideal protocol but titrate slowly and carefully.
- Patient should be educated on risk of relapse after taper.
- ***ASAM does not recommend limiting length of treatment.***



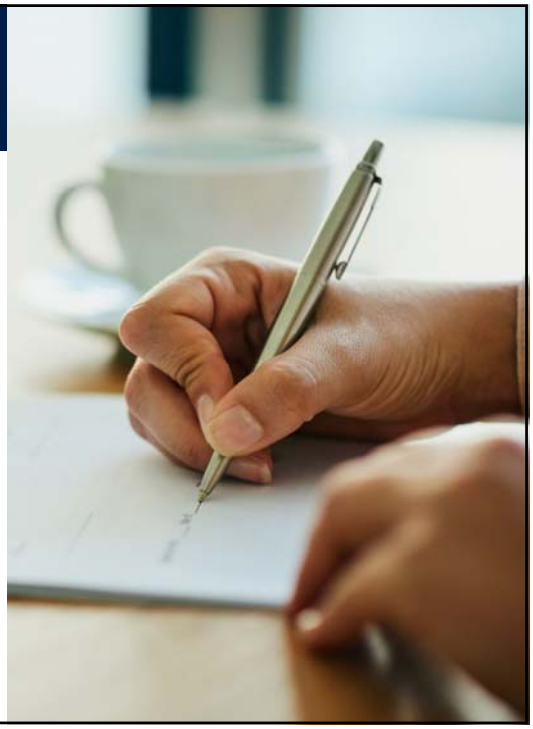
Naltrexone Formulations

Naltrexone	Formulation	Target Maintenance Dosage
Oral		
Generic	50 mg tablets	50 mg per day
Revia®		
Extended-Release IM injection (XR-NTX)		
Vivitrol®	380 mg ER suspension	380 mg IM q month

The Medical Letter 2017

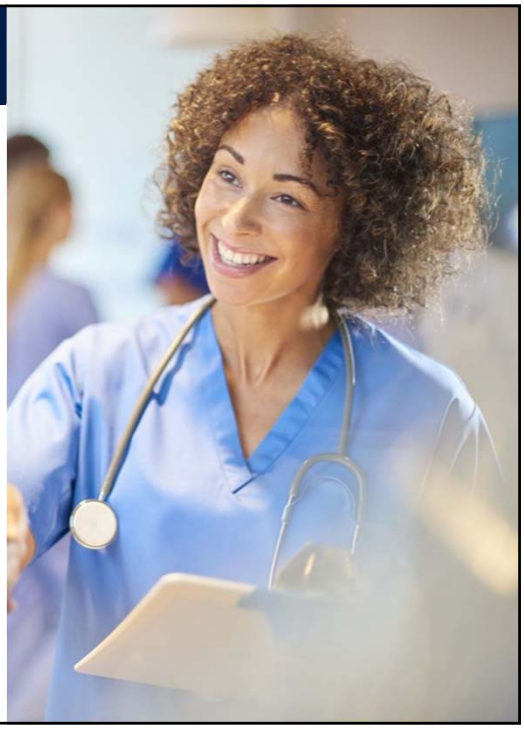
Prior to Starting Naltrexone Treatment

- **Review and sign agreement with consents and treatment plan**
  - Release information as needed to coordinate care with outside providers and supports
- **Labs reviewed and appropriate**
  - LFTs < 3-5x normal
  - Pregnancy test for women of childbearing age



Naltrexone Initiation

- **Insurance prior authorization completed if needed and medication ordered.**
  - Some private insurers require a PA.
  - Many MCOs will cover naltrexone but ordering through specialty pharmacy takes time.
- **Medical Alert identification to patient.**
- **Urine drug tests negative for all opioids prior to starting naltrexone.**
  - Patients with OUD must be fully withdrawn from all opioids, typically no use for 7-10 days.



Naltrexone Challenge Test

- ***An oral naltrexone challenge test should be performed if there is a risk of precipitating opioid withdrawal:***
  - Recommended prior to initial injection of XR-NTX and any lapse in treatment.
- In office, watch patient self-administer 25-50mg oral naltrexone.
- Observe patient for opioid withdrawal signs for minimum of 45-60 min.
- If opioid withdrawal occurs – ***DO NOT*** give XR-NTX.

Naltrexone Challenge Test

Naloxone Withdrawal

- In physically dependent individuals, naloxone will precipitate withdrawal within 5-10 min and dissipate within 30 min.
- Can be measured using standard instruments (e.g., COWS).
- Severity of withdrawal is proportional to the level of physical dependence.
- Any change from baseline, particularly objective signs = Positive Test.

Naltrexone Challenge Test

Naloxone Administration

- Naloxone is given IM 0.8-1.2 mg (2-3 cc).
- To minimize risk of significant opioid withdrawal, may administer in 2 stages, 0.4 mg followed by 0.8 mg.

Naltrexone Challenge Test

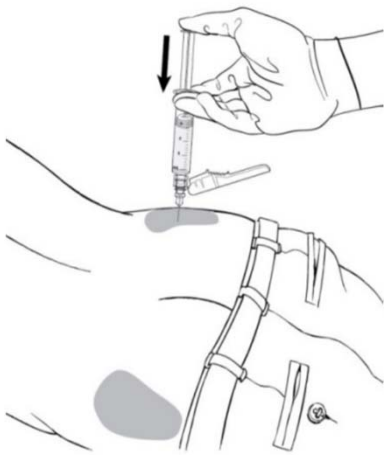
Next steps:

- With negative test → Full dose XR-NTX can be started.
- With positive test → XR-NTX should NOT be given.
  - Naloxone challenge can be repeated the next day.

XR-NTX Injection

- **Keep refrigerated**
  - Needs to come up to room temp (~45 minutes) prior to administration
- **Can stay out for a total of 7 days**
- **Reconstitute medication after patient arrives for visit**
- **Once mixed**
  - Give injection immediately so that the medication does not solidify
- **There will be 2 needle sizes 1.5" and 2"**
  - Ensure injection goes into muscle
  - Do not substitute manufacturer carton components
- **Alternate sites**

Injectable Naltrexone (XR-NTX)
Vivitrol® Package Insert



1. Using a circular motion, clean site with the alcohol swab.
2. Administer the suspension by deep IM injection into a gluteal muscle, alternating buttocks per monthly injection.
3. If blood aspirates or the needle clogs, do not inject. Change to the spare needle and administer into an adjacent site in the same gluteal region.
4. Inject the suspension in a smooth and continuous motion.
5. It must **NOT** be given **intravenously or subcutaneously.**

XR-NTX Practical Considerations

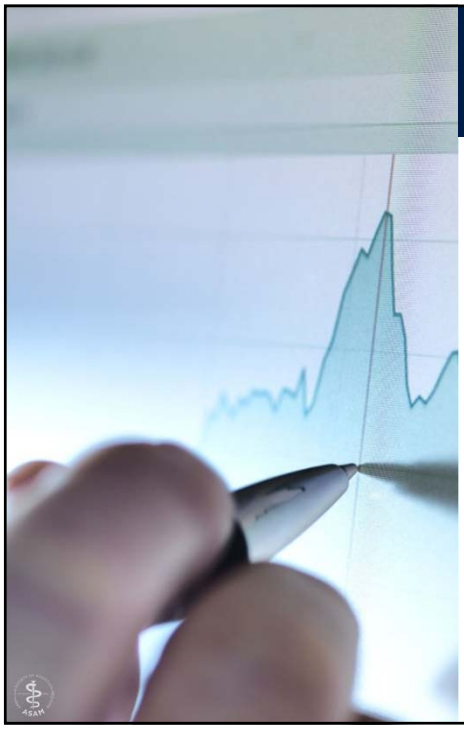
How long should I treat for?

- Unknown
- Pivotal trial 6 months of XR-NTX, then an open-label extension phase
- Reimbursement for 6-24+ months is standard

When XR-NTX stops?

- Return to non-antagonized, low tolerance
- Resume 'baseline' risk of relapse, overdose
- No evidence of otherwise higher OD risk

Lee, JD et al. Comparative effectiveness of extended-release naltrexone versus buprenorphine-naloxone for opioid relapse prevention. Lancet. 2018 Jan 27;391(10118):309-318.



Medically Supervised Withdrawal: *Outcomes*

- Low rates of retention in treatment
- High rates of relapse post-treatment
- < 50% abstinent at 6 months
- < 15% abstinent at 12 months
- Increased rates of overdose due to decreased tolerance

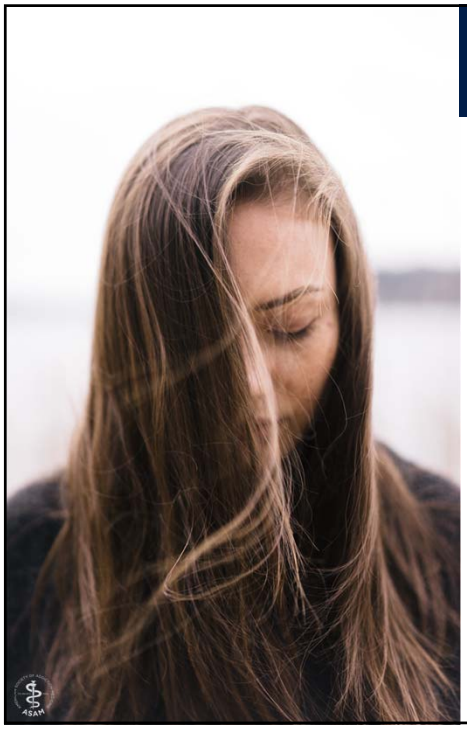
O'Connor PG. JAMA. 2005. Mattick RP, Hall WD. Lancet. 1996; Stimmel B et al. JAMA. 1977.

Audience Response

The ideal patient for injectable naltrexone is:

A. Someone who has tapered off of agonist-based therapy only.
B. Someone who does not want to be on a controlled substance.
C. Someone who is involved with the criminal-legal system.
D. Someone who does not need counseling.

PAULA'S CASE



Activity 6: Case Discussion – Paula

- **Task:** Whole Group Discussion
- **Discuss:** Let's review Paula's case.
- **Time Allocated:** 25 minutes

Paula's Case

Paula is 23-year-old graduate student in social work who is addicted to heroin. Her mother calls your office seeking treatment for her daughter. She agrees to having her mother come in with her for the consultation and evaluation. She is comfortable and not yet in opioid withdrawal during the initial consultation. You get Paula's history while her mother sits in the waiting room. She relates feeling anxious most of her life.

She started smoking marijuana and drinking alcohol on the weekends in high school. In college, she fractured her ankle playing basketball and was treated with oxycodone. She noticed that in addition to pain control, her anxiety decreased, and she reported feeling "normal" and "peaceful."

Paula's Case

She continued requesting oxycodone refills even though her pain had resolved. When the orthopedist refused to continue prescribing oxycodone she started buying them from friends, increasing to ~200mg daily.

A year ago she entered a 28-day residential program, never followed up in after care, and relapsed 6 weeks later. She has never been on medications for her opioid use disorder. Due to cost and availability she switched from oxycodone to snorting heroin, ~10 bags daily. Her last use was four hours ago. Paula agrees to have her mother present to discuss treatment options.

Paula's Case

You present the following options:

1. opioid agonist maintenance therapy (methadone, buprenorphine).
2. antagonist maintenance with naltrexone.
3. another attempt at withdrawal management and medication-free treatment.

Paula's Case

Paula and her mother have done their research; Paula has a friend doing well on buprenorphine and they decide on buprenorphine.

- They understand that you recommend some form of counseling as part of the treatment plan.
- Paula has insurance, so access is not a problem.

Paula's Case

Key Treatment Considerations:

1. Is Paula ready for buprenorphine induction currently?
2. If not, how will you decide when she is ready?
3. Is the patient a candidate for unobserved "home" induction?

You explain that since Paula is physically dependent on opioids, she must be in mild-moderate spontaneous withdrawal to avoid precipitated withdrawal. She understands. You tell her to discontinue all opioids for at least 12 hours. She has decided on doing the induction the next morning.

Paula's Case

- She returns the next day with her mother. She is visibly uncomfortable and has a COWS score of 12.
- Question:
  - ***Is she ready for the induction?***
- You instruct her that buprenorphine/naloxone is always administered sublingually or via the buccal mucosa—never swallowed whole.
- She is instructed on the proper administration procedures to maximize buprenorphine bioavailability.

Paula's Case

- You give her buprenorphine 4/1 mg.
- Questions:
  - ***How long until initial effect?***
  - ***How long until peak effect?***
- After her initial dose, you give her another 4/1 mg for continued withdrawal symptoms.
  - ***When can she leave the office?***
  - ***Can she take more buprenorphine after leaving the office?***
  - ***When should she contact you?***

Paula's Case

Key Treatment Considerations:

4. Should the stabilization dose be divided or taken once per day?
5. How often should stabilization doses be increased?
6. Once dose stabilization occurs, are maintenance dose increases due to tolerance common or are lower doses required over time?

She remained on buprenorphine/naloxone 16/4 mg per day for the next 6 months and had no relapses. She was adherent with weekly counseling and office monitoring including urine drug tests and pill counts. There were no concerning behaviors on the PDMP.

Paula's Case

Key Treatment Considerations:

7. How long should Paula be maintained on the buprenorphine?
8. How will you decide if and when she is ready to be tapered?
9. How would you taper her buprenorphine?

Patient Management: *Monitoring*

Follow-up Visits: Part 1

- Face-to-face visits to check safety and adherence.
- Initial Frequency should be every 1-2 weeks until stable, then monthly once stabilized.
- Check dosing, intervals, and sublingual technique.
- Safety issues include side effects and safe storage.

Follow-up Visits: Part 2

- Withdrawal/craving/triggers
- Tobacco, alcohol, and other drug use
- Drug tests and pill counts
- Prescription Drug Monitoring Program (PDMP)
- Confirm or reassess motivation for behavioral treatment
- Medical problems and symptoms

Follow-up Visits: Part 3

- Emotional/behavioral problems and symptoms
- Outside medications and providers
- Housing
- Reliable transportation
- Employment
- Family/relationships
- Legal Issues

Urine Drug Testing (UDT)

- ***Objective information:***
  - Evidence of therapeutic adherence
  - Evidence of use or non-use of illicit drugs
- Monitoring of treatment progress and safety
- Reinforces success with treatment, but no evidence that UDT improves outcomes
- Part of standard of care
- Identify those who may need higher level of care

ASAM's Appropriate Use of Drug Testing in Clinical Addiction Medicine Consensus Statement 2017

UDT: Frequency

- *SAMHSA TIP 63 (2018): "Periodic random testing" frequency is clinically determined.*
- At least at time of initial evaluation and initiation of medication then weekly → monthly.
- Regulation and reimbursement vary among states and insurers.
- Urine is preferred medium for testing due to:
  - Ease of obtaining sample, lowest cost
  - Ideal detection time (2-3 days)
  - Presence and persistence of metabolites
  - Availability of office-based testing tools

SAMHSA TIP 63 Medications for Opioid Use Disorders, 2018 ASAM's Consensus Statement 2017.

UDT: Implementation

- *Discuss with patient:*
  - This is for safety and this is the standard of care.
- *Know scope and limits of tests and lab:*
  - Beware false negatives and positives.
- *Consider random versus scheduled testing.*
- *Incorporate quality control procedures (temperature strip).*
- *Consider establishing consult lab linkage:*
  - GCMS/LCMS confirmatory testing.
  - Expert consultation on test interpretation.
  - Online reporting of results.

ASAM's Appropriate Use of Drug Testing in Clinical Addiction Medicine Consensus Statement 2017

UDT: Immunoassays

Pros:

- Point of care or lab-based
- Fast
- Cheap
- Specific tests available for many drugs
  - Oxycodone
  - Buprenorphine
  - Fentanyl
- Can be used as screening with option for confirmation

VS

Cons:

- Qualitative tests
  - Cutoff ng/ml
    - Opiates: 300
    - Cocaine metabolite: 300
- False positives
  - Cross-reactivity
  - Contamination
- False negatives
  - Below the cutoff

ASAM's Consensus Statement 2017

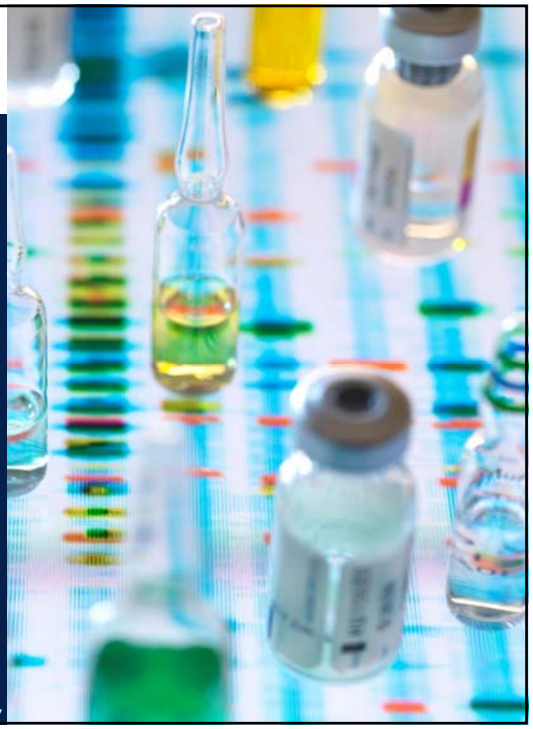
UDT: Immunoassay Detection Windows in Urine

Drug/Medication	Primary Metabolite	Ave. Detection Time (days)
Opiates (heroin, morphine)	Morphine	2-3
Semisynthetic Opioids (oxycodone, hydrocodone)	Variable Must be tested specifically	2-3
Methadone	EDDP	2-3
Buprenorphine	Nor-buprenorphine	2-3
Cocaine	benzoylecgonine	2-3
Amphetamines		2-3
Benzodiazepine	Varies by medication type	Variable with half life Unreliable immunoassays
Cannabis Occasional Cannabis Chronic	THC	1-3 Up to 30

ASAM's Consensus Statement 2017

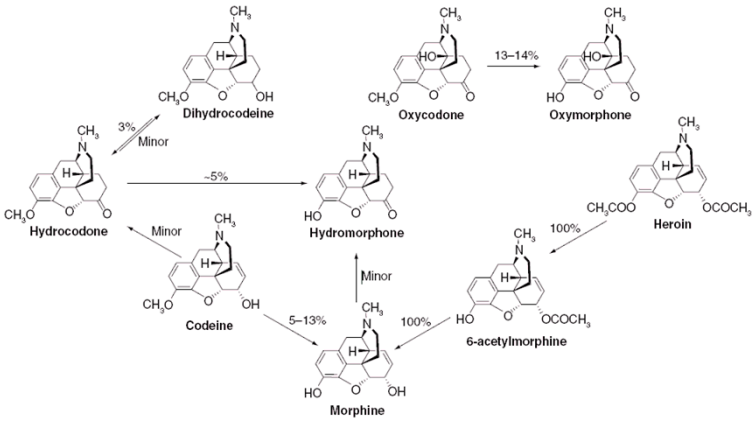
UDT: GCMS/LCMS

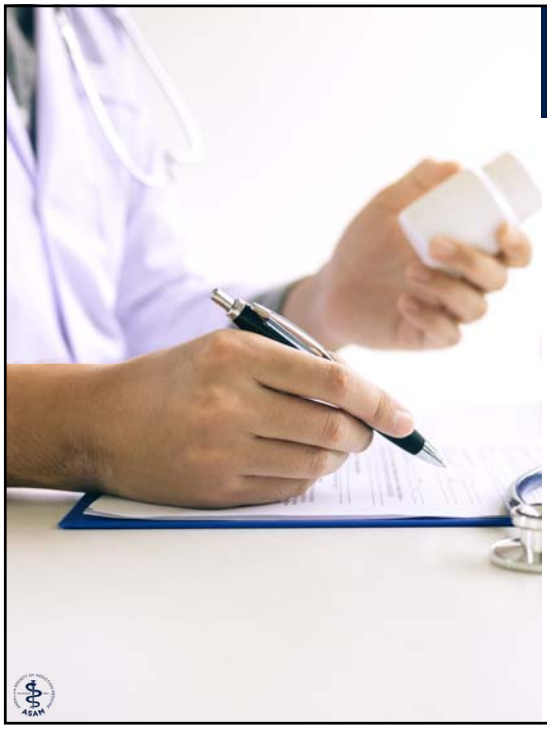
- *Gas or liquid chromatography, mass spectrometry*
- *Quantitative*
- *Limitations*
  - More costly
  - Requires specialized lab
  - Levels do not indicate amount of medication taken!
    - *Variables:*
      - time of dosing
      - metabolism
      - GFR
      - hydration



ASAM's Consensus Statement 2017

UDT: Opioid Metabolism



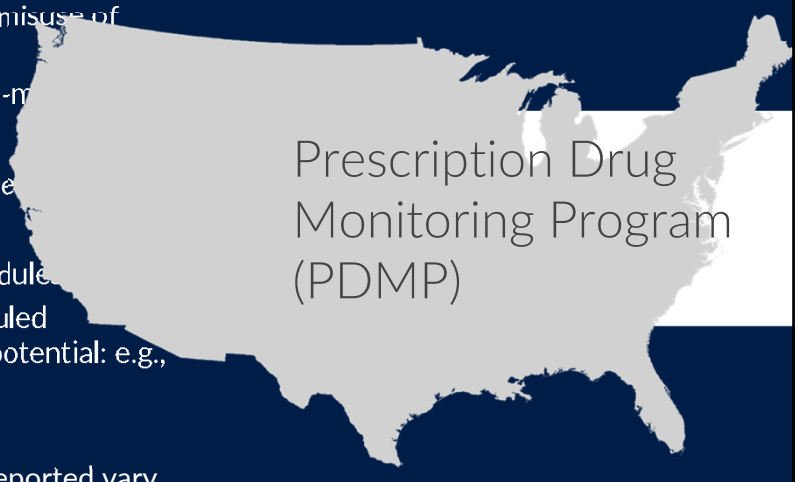


Pill Counts

- ***Objective information:***
  - Confirm medication adherence.
  - Minimize diversion.
- Frequency varies with patient progress.
- Best option when diversion suspected.
- Patient brings in medication supply.
- Confirm patient ID and fill date on bottle/box.
- Have patient count them in front of staff member.
- All tablets should be identical.
- Amount should match expected quantity.

Prescription Drug Monitoring Program (PDMP)

- ***State-wide System Tracking Prescriptions:***
  - Decreasing or preventing misuse of medications.
  - Improving clinical decision-m
- ***Pharmacies:***
  - Report information to state
- ***Information Varies:***
  - Schedule II +/- other schedule
  - Some selected non-scheduled medications with misuse potential: e.g., gabapentin, ephedrine.
- ***Data Availability:***
  - Format and medications reported vary by state.



PDMP: Limitations

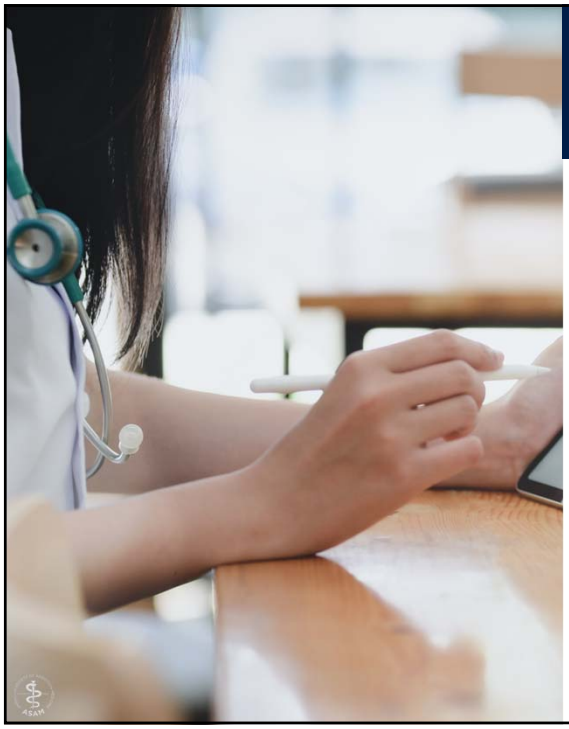
- Methadone and buprenorphine dispensed from OTPs are not listed on PDMPs.
- Not all data is readily available to providers.
- There is a lack of communication between all state programs.
- Time is needed to access reports.
- There are limitations in who can access reports.
- There is a mandatory vs. voluntary use of PDMP.

Audience Response

Which of the following is a monitoring practice that is evidence-based?

A. Checking your state's PDMP only on initiating buprenorphine.
B. UDT to make sure the patient is taking the medication and to discharge the patient if negative.
C. Random pill counts on all patients.
D. UDT to determine if the patient would benefit from additional support.

Relapse



Relapse: Prevention & Management

Relapse is a process in which return to substance use occurs in response to stressors and stimuli.

Relapse Precipitants:

- Present a negative affect (anger, fatigue, boredom, family conflict)
- Present cravings/cues (people, places and things)
- Feel social pressure/stress
- Begin using drug again

Doyle TJ, et al. Addressing Unhealthy Alcohol Use in Primary Care, 2013.

Relapse: Prevention & Management

- *Educate patients about how to anticipate/avoid/cope with these precipitants.*
- After initial use (a lapse), patients may experience guilt and shame which results in a heavy return to use.
- *Maintaining treatment is a learning process, lapses provide valuable lessons. A lapse is not a failure, but a mistake from which one can learn.*
- Returning to substance use requires prompt evaluation and review of treatment plan as well as a possible referral to additional or higher level of care.

Doyle TJ, et al. Addressing Unhealthy Alcohol Use in Primary Care, 2013.

SOPHIA'S CASE

Sophia's Case

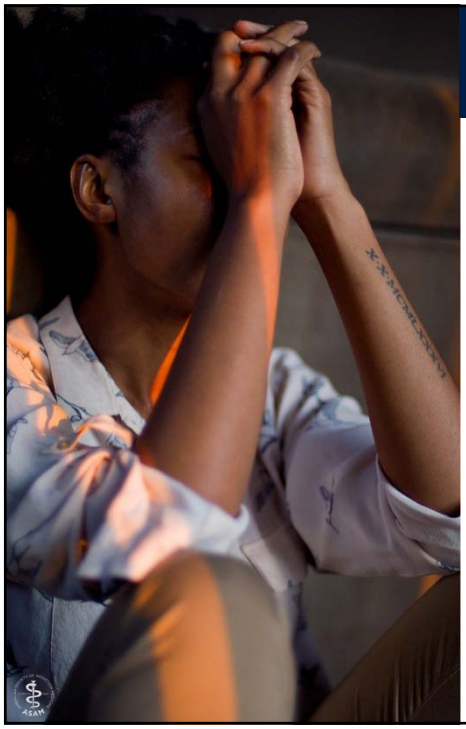
38-year-old woman followed for ongoing management of her opioid use disorder. She is presented to the buprenorphine induction clinic for induction and was quickly stabilized on bup/nx 16/4 mg SL a day. She kept all her appointments and had six weeks of urine drug tests which were negative for opioids and all other tested drugs.

Since coming into treatment with you, she has kept biweekly appointments x3, and monthly appointments x4, is reporting satisfaction with the treatment and is increasing productivity at work as a research assistant.

Sophia's Case

After her 8th visit with you, her urine drug test was positive for benzodiazepines, and confirmation reveals alprazolam and metabolites. She admits to using a friend's alprazolam (Xanax®) one night to help sleep. "With all the work stress, I just couldn't get to sleep."

She notes that she is doing much better in her life now than before when she was spending all her money on heroin and struggling to keep a job. She does not want to discontinue buprenorphine and go back to that life.



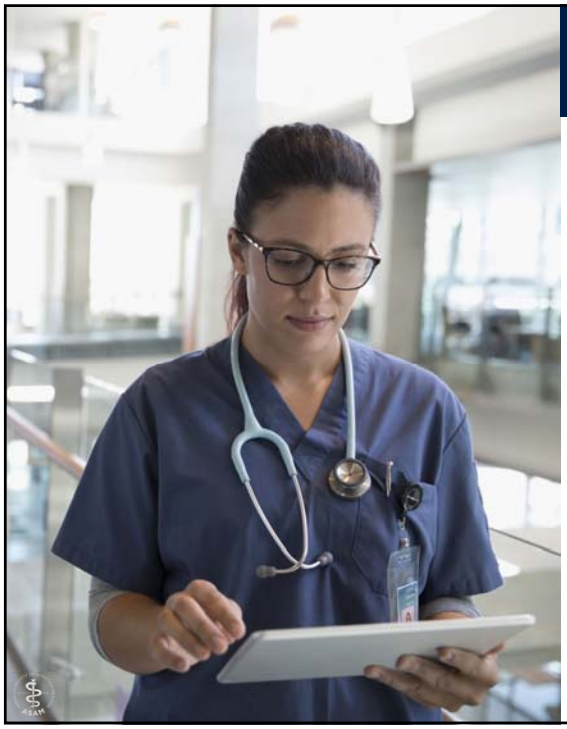
Activity 7: Case Discussion – Sophia

- **Task:** Whole Group Discussion
- **Discuss:**
  - How would you respond to these results?
  - Does the nature of the substance (benzos vs. stimulants) affect how you talk to Sophia?
  - How would you respond to these results?
- **Time Allocated:** 10 minutes

Sophia's Case

- She does not believe she has "a problem" with alprazolam.
- She denies further use.
- Repeat testing at this visit comes back positive again for benzodiazepines, with +alprazolam and metabolites.
- Question:
  - ***How would you respond to Sophia now?***

Office Management



Medication Treatment Settings

Office-Based Opioid Treatment (OBOT):

- Buprenorphine or naltrexone
- Not methadone
- Primary care (different models)
- Specialty (e.g. Infectious Disease, GI, Psychiatry, Hospitalist, Emergency Department)
- SUD treatment clinics

Implementing OBOT: Buy-in

- Do staff understand the need or gap in services?
- Do staff have accurate information about the disease of addiction and treatment options?
- Will patients be different from the ones we treat now?
- Does staff have the requisite knowledge, tools, and equipment to be successful?

https://www.niatx.net/PDF/NIATx-MAT-Toolkit.pdf

Treatment Agreement

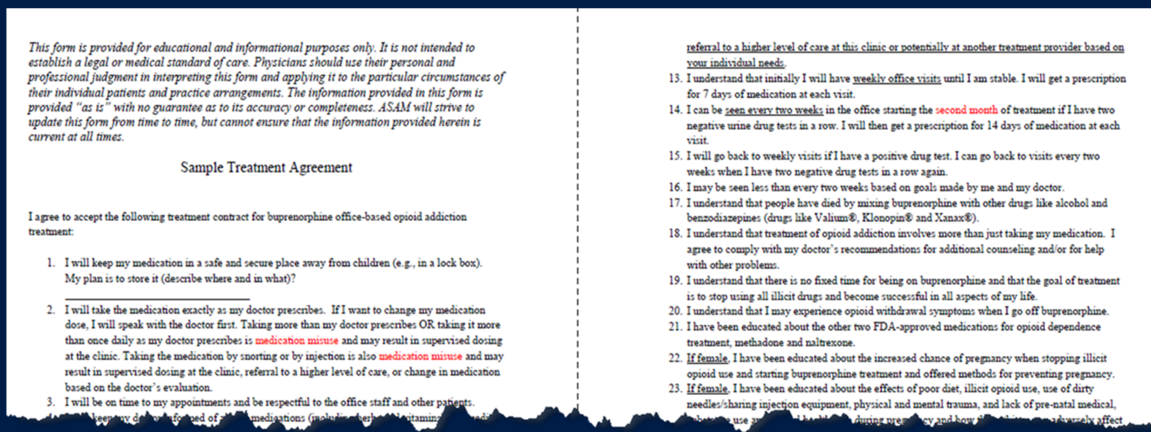
Patient Expectations:

- No medication diversion
- Adherence to treatment protocols
- Induction, maintenance
- Monitoring strategies (i.e., urine drug tests, pill counts)
- Additional treatment
- Appointments and refills
- No disruptive behavior
- Contact with other caregivers and pharmacies
- Safe storage

Provider Expectations:

- Scheduling visits
- Medication supply and refills
- Night coverage
- Response to “lost” prescriptions
- Unexpected UDT results
- Nonadherence or unexpected results
- Maintenance vs. taper

Treatment Agreement



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Sample Treatment Agreement

I agree to accept the following treatment contract for buprenorphine office-based opioid addiction treatment:

1. I will keep my medication in a safe and secure place away from children (e.g., in a lock box). My plan is to store it (describe where and in what)?
   ____
2. I will take the medication exactly as my doctor prescribes. If I want to change my medication dose, I will speak with the doctor first. Taking more than my doctor prescribes OR taking it more than once daily as my doctor prescribes is medication misuse and may result in supervised dosing at the clinic. Taking the medication by snorting or by injection is also medication misuse and may result in supervised dosing at the clinic, referral to a higher level of care, or change in medication based on the doctor's evaluation.
3. I will be on time to my appointments and be respectful to the office staff and other patients.

<u>referral to a higher level of care at this clinic or potentially at another treatment provider based on your individual needs</u>.

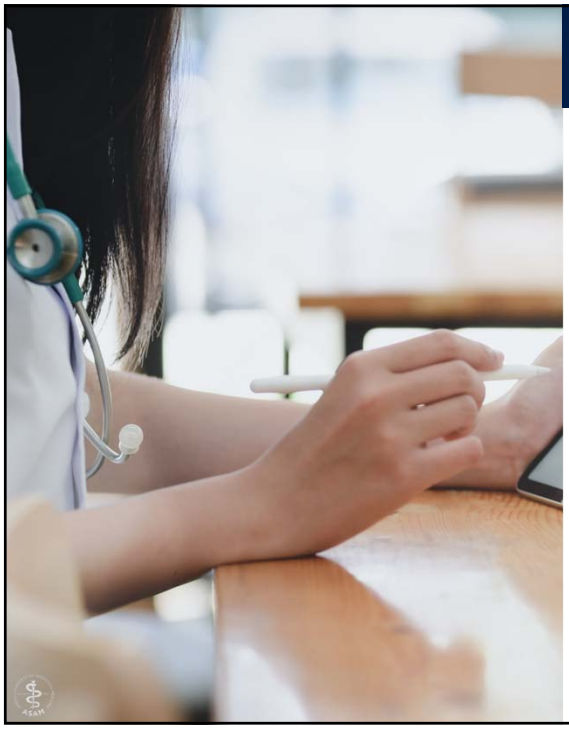
13. I understand that initially I will have <u>weekly office visits</u> until I am stable. I will get a prescription for 7 days of medication at each visit.
14. I can be <u>seen every two weeks</u> in the office starting the second month of treatment if I have two negative urine drug tests in a row. I will then get a prescription for 14 days of medication at each visit.
15. I will go back to weekly visits if I have a positive drug test. I can go back to visits every two weeks when I have two negative drug tests in a row again.
16. I may be seen less than every two weeks based on goals made by me and my doctor.
17. I understand that people have died by mixing buprenorphine with other drugs like alcohol and benzodiazepines (drugs like Valium®, Klonopin® and Xanax®).
18. I understand that treatment of opioid addiction involves more than just taking my medication. I agree to comply with my doctor's recommendations for additional counseling and/or for help with other problems.
19. I understand that there is no fixed time for being on buprenorphine and that the goal of treatment is to stop using all illicit drugs and become successful in all aspects of my life.
20. I understand that I may experience opioid withdrawal symptoms when I go off buprenorphine.
21. I have been educated about the other two FDA-approved medications for opioid dependence treatment, methadone and naltrexone.
22. <u>If female</u>, I have been educated about the increased chance of pregnancy when stopping illicit opioid use and starting buprenorphine treatment and offered methods for preventing pregnancy.
23. <u>If female</u>, I have been educated about the effects of poor diet, illicit opioid use, use of dirty needles/sharing injection equipment, physical and mental trauma, and lack of pre-natal medical,

Download from https://tinyurl.com/yanouybg

Informed Consent

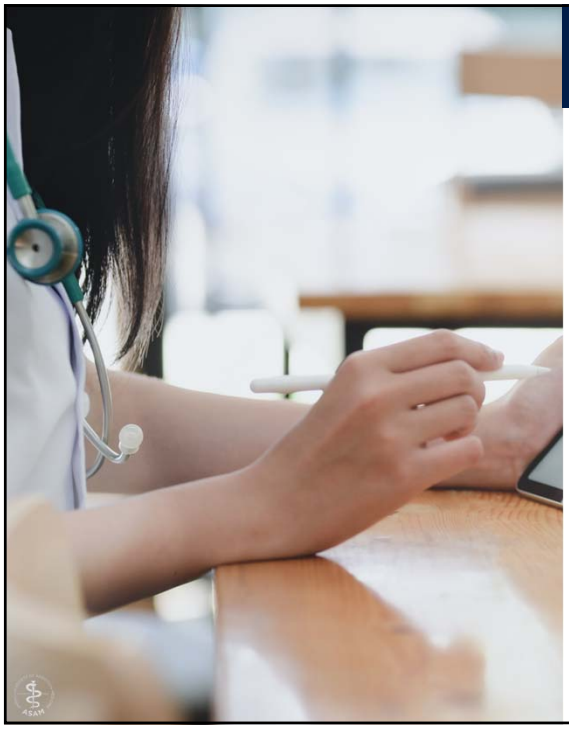
Must Address:

- Physical dependence
- Side effects:
  - Constipation
  - Sweating
  - Hypogonadism
- Risk of impairment, overdose
- Possible medication interactions
- Neonatal Abstinence Syndrome or Neonatal Opioid Withdrawal Syndrome
- Other treatments available: methadone, naltrexone, nonmedication-based treatments



Anticipate Insurance Issues

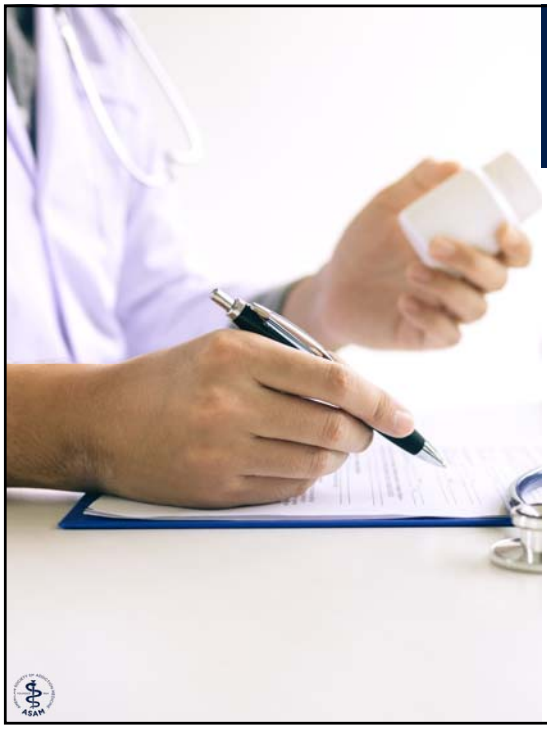
- *Is buprenorphine a covered benefit?*
  - Which formulation (tabs, film)
  - What tier?
  - What co-pays?
- Are lab services covered?
- Are there restrictions on duration of treatment?
- Is behavioral treatment covered?
- *Be aware of behavioral health carveouts*



Anticipate Insurance Issues

Anticipate prior approval procedures:

- Collect forms from each payer
- Submit forms in advance of fill
- Monitor patient's pharmacy benefits
- 340B coverage in some Community Health Centers



Office-Based Opioid Treatment (OBOT) Billing

- *OBOT is standard medical care: billing procedures are standard.*
- Physicians billing codes: (CPT) billing codes, are accepted by most payers in most states.
- *The ICD-10 Code for opioid use disorder is F11.20.*
  - The fifth (x) digit sub-classifications are: 0=unspecified, 1=continuous, 2=episodic, 3=in remission.
- *No specific addiction medicine codes.* Same codes as other ambulatory care services.

IMPLEMENTING OFFICE-BASED OPIOID TREATMENT

End of Session 3