

ZOOM FEATURES

- You will join the meeting muted, however, this is an interactive meeting and lines will be unmuted during discussions
- We encourage you to have your video on – Start Video
- The preferred audio is using “Phone Call” and enter your participant ID so that your name is associated with your phone number
- Use the “Chat” feature to type in a question or make a comment
- Q&A will start after all three counties have presented
- Use the “Raise Your Hand” feature by going to Manage Participants. You will see your name and can raise your hand
- Polling questions will be used



Sublocade™ (Injectable Extended Release) Buprenorphine



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| TODAY'S PRESENTERS



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Disclosures:

Dr. Robinson discloses that she is an employee of Health Management Associates, a national research and consulting firm providing technical assistance to a diverse group of healthcare clients.

LEARNING OBJECTIVES

At the end of presentation participants will be able to discuss:

- buprenorphine formulations
- initiating long acting formulations of buprenorphine
- monitoring someone on long acting formulations of buprenorphine
- discontinuing long acting formulations of buprenorphine

The End Game:

- MAT is provided throughout incarceration as clinically indicated
 - Which medication, dosage and duration are determined by patient and provider

AGENDA



- Introduction
- Review buprenorphine formulations
- Initiating long acting formulations of buprenorphine
- Monitoring long acting formulations of buprenorphine
- Discontinuing long acting formulations of buprenorphine
- Experience from the field
 - Community Experience: San Luis Obispo County
 - Correctional Experience: Santa Clara County
- Questions

CASE

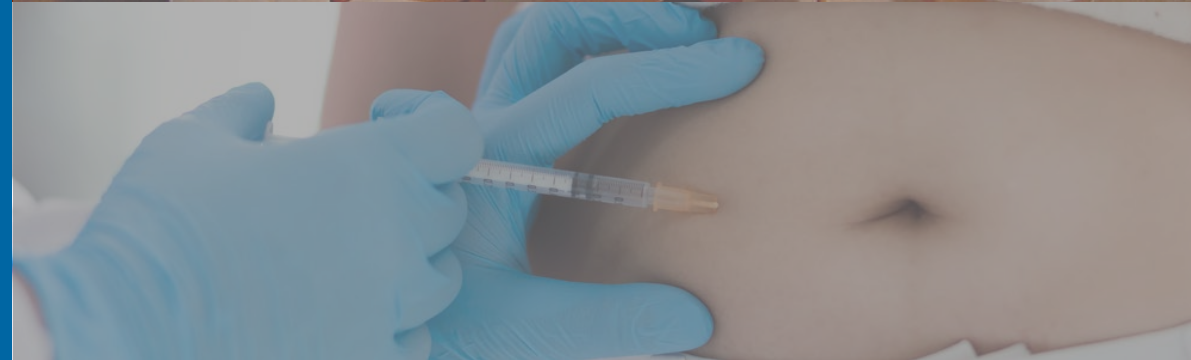
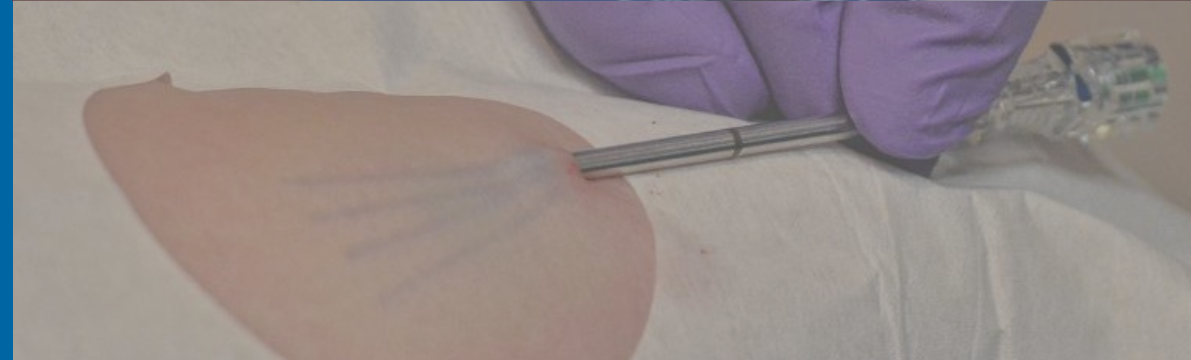
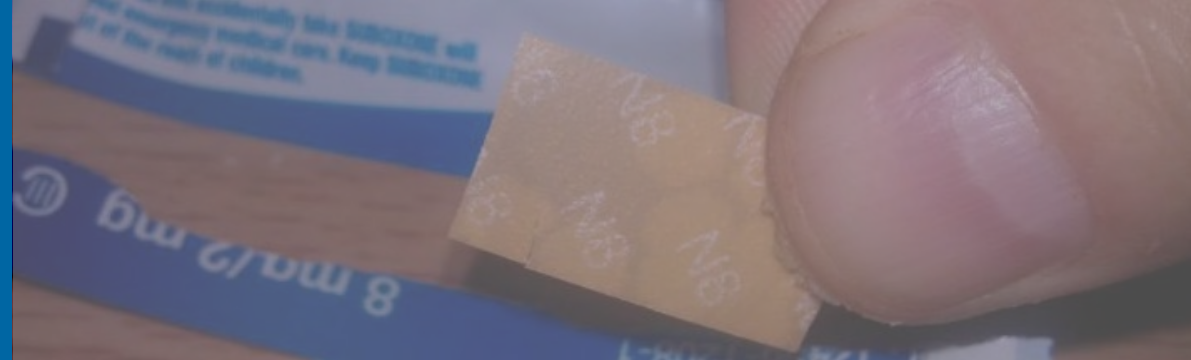


I CASE

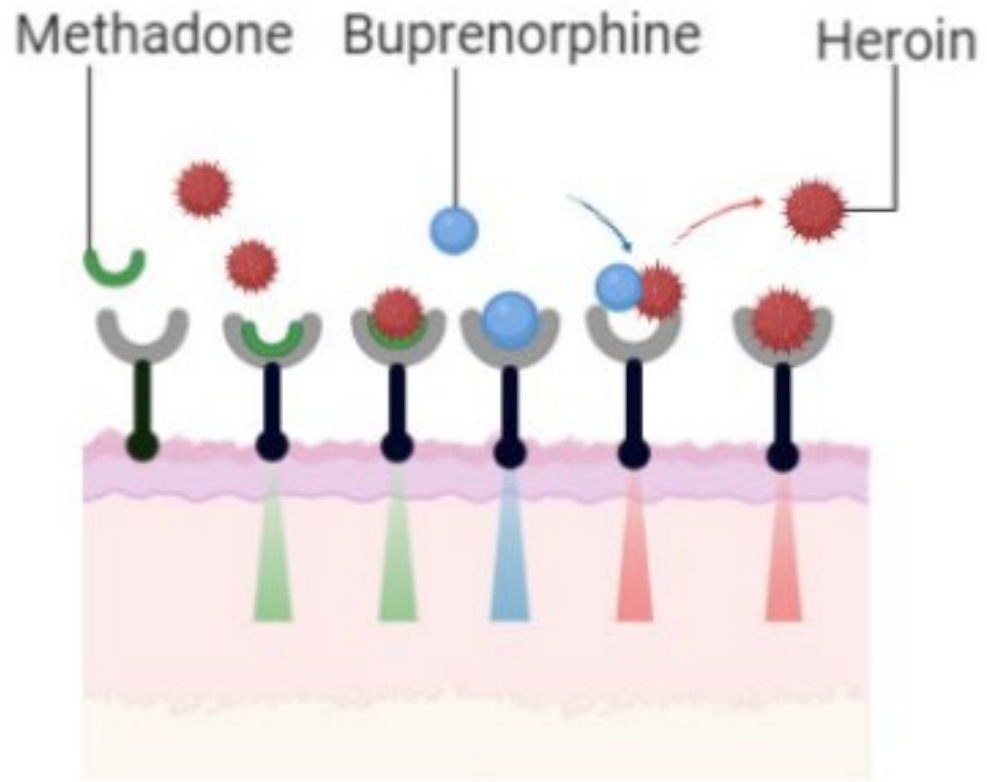
Sue Barnes presents to your jail clinic with a history of OUD treated with 16mg/ 4mg per day buprenorphine/ naloxone in the community (confirmed by the PDMP); she reports to you she only wants 8mg per day in jail as she was selling the other 8mg. What do you prescribe her?

- A. Keep her on 16mg/ 4mg per day buprenorphine/ naloxone, because you don't want to be accused of destabilizing the patient.
- B. Stop her buprenorphine, because she was diverting it.
- C. Decrease her buprenorphine/naloxone to 8mg/ 2mg per day; document your rationale; obtain consent and speak with outside provider.
- D. Switch her to long acting injectable buprenorphine, because it is harder to divert.

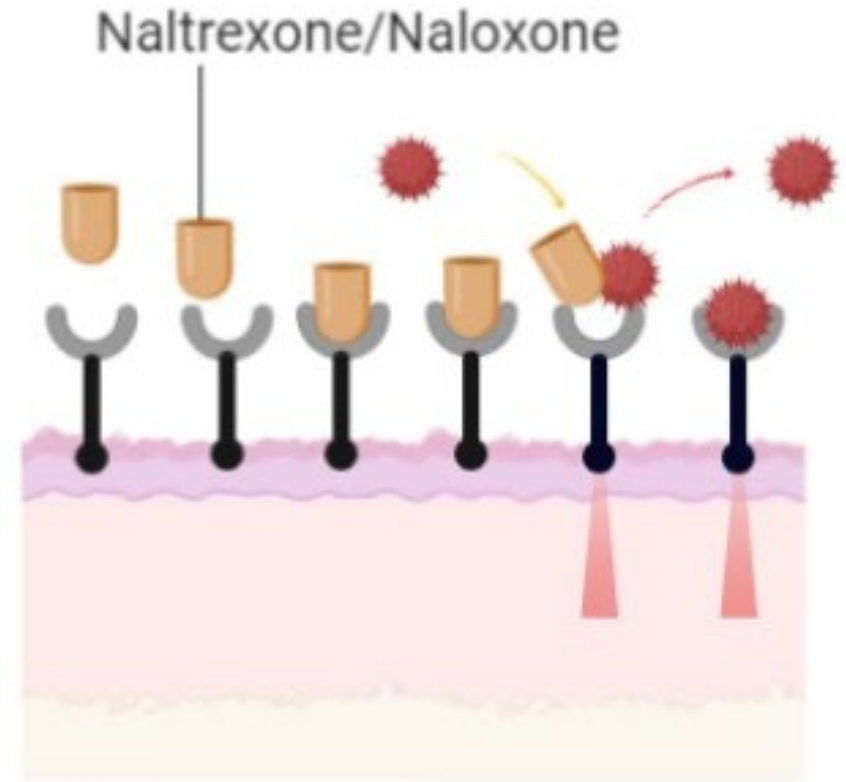
BUPRENORPHINE



MU OPIOID RECEPTOR BINDING



Agonist Treatment



Antagonist Treatment

I BUPRENORPHINE OVERVIEW

Starting buprenorphine when opioid receptors are saturated causes precipitated withdrawal

Start buprenorphine when patient is in moderate withdrawal, then buprenorphine binds receptors & relieves withdrawal

Partial mu opioid agonist with ceiling effect

- Increasing dose does not result in “getting high” for some with physiologic dependence on opioids
- Increased side effects and duration of effect
- Much harder to overdose on than methadone

Only “opioid naïve” people get a high from it

I BUPRENORPHINE PROPERTIES

- Typical dose 16 q day
- Dosing <8 mg is NOT evidence based & rarely effective
 - Does not provide sufficient relief from cravings
- Ceiling effect
 - Doses above 24-32 mg are no more effective for treatment of OUD
 - Doses above ~32 mg do not cause more euphoria
- Binds strongly to receptors & can't be “kicked off”
 - Other opioids are not as effective when buprenorphine is present
 - Buprenorphine is a deterrent to other opioid use, more than methadone

I BUPRENORPHINE FORMULATIONS⁷

With/without Naloxone

- Naloxone added to prevent diversion
- When taken under the tongue the naloxone is not absorbed
- When injected naloxone is absorbed & binds the receptor, precipitating withdrawal

Sublingual/ Buccal:

- Not effective if swallowed or regurgitated
- Sublingual tablet (SL): slow dissolving, but has been crushed to speed up dissolving (not FDA approved for crushing)
- Sublingual film or Buccal film

Implantable/ Injectable:

- Implant (6 m) & Injection (28 d); 12.20 more injectable options
- Cons: Need to start on sublingual; Upfront cost; Gradual withdrawal if discontinued
- Pros: Low diversion potential; Client does not have to “choose” treatment daily

Implant:

- Pharmacokinetically equivalent to <8mg/day SL buprenorphine
- 18% required augmentation with oral buprenorphine
- Requires training to insert and remove; risks associated with procedure
- Procedure takes <30minutes; 1-week wound check
- Can only be inserted one time each arm, i.e. 12months

Injectable:

- Subcutaneous injection of 300mg for 2 months, then 100mg thereafter; may increase to 300 mg monthly.
- Pharmacokinetically equivalent to 26mg/ day SL buprenorphine

I BUPRENORPHINE ER INJECTION

Risk Evaluation & Mitigation Strategy

- Pharmacy needs certification to order and dispense
- Medication is not dispensed to the patient; must go to the healthcare provider
- IV administration can be fatal
- Pt must be stable on 8-24mg per day for at least 7 days
- Insufficient use in pregnancy
- Lump present at injection site for a few weeks; do not rub or let belt... rub it

Finding REMS certified pharmacies:

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

■ BUPRENORPHINE FORMULATIONS EFFECTIVENESS AND COSTS

Effectiveness

- Implant & Injection some data to support increased efficacy
- Implant may require augmentation with SL dosing

Cost effectiveness

- Costs of drug, newly acquired HCV, ED, hospital, rehab, criminality and lost wages
- Implant- lower total cost & more quality of life in 1 of 2 studies***
- Injection- no data as of 9-18-20

Upfront cost of implant and injection must be weighted by lower healthcare costs, less staff time to administer, etc. In a jail the lower healthcare costs may not occur during a short sentence.

Decreased diversion.

? Cost effective if you remove silos of funding from your equation.

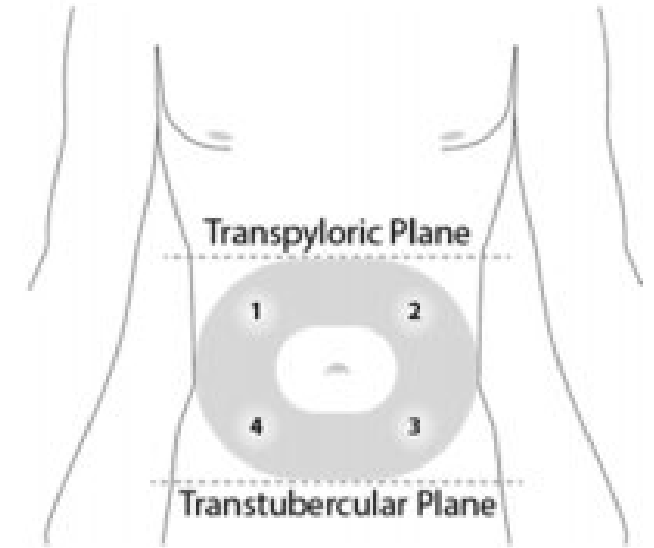
I BUPRENORPHINE FORMULATIONS FOR OUD⁹

	Formulations	Maintenance Dose	Cost/6 Mo
Buprenorphine			
Generic	2, 8 mg SL tabs	16 mg/d	\$1,083
Subutex	Discontinued due to generic		
Belbuca [®]	Not approved for OUD		
Probuphine [®]	74.2 mg SD implant 100 mg	4 implants/6m	\$4,950
Sublocade [®]	300 mg SQ injection	100 mg/m	\$9,480
Brixadi [®]	8, 16, 24, 32 mg/ wk & 64, 96, 128/ mo		Not released
Buprenorphine/Naloxone			
Generic	2/0.5, 8/2 mg SL tabs	16/4 mg/d	\$2,339
Bunavail [®]	2.1/0.3, 4.2/0/71 6.3/1 mg buccal film	8.4/1.4mg/d	\$2,793
Suboxone [®]	2/0.5, 4/11 8/2, 12/3 mg SL film	16/4 mg/d	\$2,933
Zubsolv [®]	1.4/0.36, 5.7/1.4 mg SL tab	11.4/2.8 mg/d	\$2,989

ER BUPRENORPHINE INITIATION

- Stabilize on oral for 7 days before giving injection
- Subcutaneous injection in abdomen 300mg for 2 n
- Then 100mg q 28 days thereafter
- May increase to 300 mg monthly

- Buprenorphine peak <24 hours; slowly lowers to p
- Reaches steady state at 4-6 months



- Adverse reactions:

Dose after initial 2 injections	Injection Site Reaction
300mg monthly	19%
100mg monthly	14%
placebo	9%

- Can be surgically removed, if needed, within 14 days of injection

I BUPRENORPHINE MONITORING

- Monitor for
 - Effectiveness via self report, visible symptoms and behavior
 - Toxicology Testing
 - LFTs- no frequency guidelines, twice yearly acceptable

WHY SWITCH FORMULATIONS OF BUPRENORPHINE

Pt has witnessed diversion:

- Reasons for diversion
 - Patient threatened by others for buprenorphine
 - Patient giving some to someone in need
 - Patient saving some for later

Toxicology is inconsistent with expectations:

- No norbuprenorphine detected?
- No buprenorphine detected?
- Ongoing opioid use?
 - Is dose of MAT adequate?
 - Are there drug interactions: 3A4 and 2C8?

Witnessed diversion and toxicology inconsistent

Cost effective or other nonpatient specific reason(s)

■ DIVERSION

- Buprenorphine diversion is almost always used for their intended use: opioid withdrawal/OD
- Be proactive
 - Informed consent discussing appropriate use of medication (SL)
 - Always follow nurse and custody directions
 - Diversion will result in altering your treatment
- Report to MAT team same day
- MAT team to discuss with patient ASAP- in a confidential setting
- Treatment likely altered, but many options
 - Switch from oral buprenorphine to injectable or implant
 - Switch from buprenorphine to methadone
 - Switch from buprenorphine to naltrexone
 - Remember abstinence-based treatment DOES NOT work
- Diversion of ER Buprenorphine- thus far its an urban legend



ER BUPRENORPHINE DISCONTINUATION

- Half life ranges from 43 to 60 days
- Slowly dissipates
 - 75-92% mu opioid receptor blockade for 28 d following last injection
 - Subjective effects of hydromorphone are blocked for 8 weeks
- No withdrawal symptoms over the month following discontinuation
- Transmucosal could be given if withdrawal symptoms occurred

REENTRY PLANNING BEGINS UPON INITIATION OF TREATMENT

- Release from incarceration has always been unpredictable; COVID 19 has increased this
- Reentry planning should begin upon admission
- If the person is on MOUD at the time of entry to jail
 - Obtain consent to communicate with prescriber
 - Communicate release to the provider as quickly as possible
- If the person is initiated (or continued) on MOUD while incarcerated
 - First dose: **provide documentation** to the patient, along with how to obtain post release
 - Provide additional documentation to the patient with all dose changes
- DC paperwork
 - To patient
 - To receiving provider

**COMMUNITY
EXPERIENCE WITH
ER BUPRENORPHINE:
SLO COUNTY AS MAT
PROVIDER AFTER CUSTODY**

HEALTH MANAGEMENT ASSOCIATES

I KATIE DOLEZAL NP

- San Luis Obispo County Drug and Alcohol Service-Medi-Cal provider
 - MAT program started in 2007
 - Sublocade covered by Medi-Cal December 2018
 - First injection April 2019
 - Approximately 140 doses
- Talking points to clients
 - Convenience
 - No risk of theft/loss/ “forgetting”
 - No “horrible taste”
 - Stable dosing –no “ups and downs”
- Detractors to this therapy
 - Painful injection
 - Beads remain for months
 - Fear of needles/injection

WHY CLIENTS START; WHY CLIENTS STOP

- SLO County very difficult time with recovery residence accepting SL buprenorphine
 - Hopeful be more accepting
- Client view of benefits
 - “I can’t manipulate my suboxone!”,
 - History of skipping days and using opiates, then re-induct self
 - “Consistent feeling...not the ups and downs”
 - Don’t have to worry about losing or forgetting it
 - “So happy to not have to take medication every day”
 - “I hate the taste of suboxone!”
- Why clients stopped
 - Not enough coverage for cravings
 - Side effects-next slide
 - Went to jail/lost to continued treatment
 - Was forced to start as part of RR requirements-resentment
 - Stigma – ‘old school’ community support

REMS: RISK EVALUATION AND MITIGATION STRATEGY

- Goals:
 - Mitigate the risks of accidental overdose, misuse, and abuse
 - Inform prescribers, pharmacists, and patients of the serious risks associated with buprenorphine-containing products.

“Prescribers who prescribe or dispense buprenorphine products for opioid dependence must:

Before treatment initiation (first dose)

1. Assess the patient’s condition to verify the patient meets the diagnostic criteria for opioid dependence.
2. Counsel the patient on the risks described in the Prescribing Information and Medication Guide.
3. Counsel the patient on safe storage of the medication.

During treatment; at the first visit following induction

4. Prescribe a limited amount of medication.

During treatment; at visits scheduled at intervals commensurate with patient stability

5. Assess the patient’s compliance with the prescribed medication, appropriateness of the dosage prescribed, whether patient is receiving the necessary psychosocial support, and whether patient is making adequate progress towards treatment goals.
6. Counsel the patient about compliance with their medication

This checklist is a useful reminder of the safe use conditions and monitoring requirements for prescribing buprenorphine-containing transmucosal products for opioid dependence.

Requirements to address during each patient's appointment include:

- understanding and reinforcement of safe use conditions
- the importance of psychosocial counseling
- screening and monitoring patients to determine progress towards treatment goals

If a patient continues to abuse various drugs or is unresponsive to treatment, including psychosocial intervention, it is important that you assess the need to refer the patient to a specialist and/or a more intensive behavioral treatment environment.

Additional resource: Providers Clinical Support System for Medication Assisted Treatment: <http://pcssmat.org/>

The following checklist may be used during the induction period and filed in the patient's medical record to document safe use conditions. After the induction period, use the maintenance checklist on the next page.

INDUCTION CHECKLIST		
ASSESSMENT TO ENSURE APPROPRIATE USE		NOTES
Date:		
CHECK	INDUCTION	
<input type="checkbox"/> Appropriate Diagnostic Criteria	Verified patient meets appropriate diagnostic criteria for opioid dependence	
<input type="checkbox"/> Prescription Drug Monitoring	Checked patient's prescription profile in the Prescription Drug Monitoring Program (PDMP) , as appropriate	
<input type="checkbox"/> Opioids/CNS Depressants	<ul style="list-style-type: none"> • Reviewed all medications (e.g., benzodiazepines, other opioids, CNS depressants) and illicit substances to assess for appropriateness of co-prescribing 	
<input type="checkbox"/> Risks and Side Effects	<p>Discussed the risks and side effects described in professional labeling and Medication Guide with patient including</p> <ul style="list-style-type: none"> • potential for abuse and misuse • potential for fatal additive effects with benzodiazepines and other CNS depressants, including alcohol 	
<input type="checkbox"/> Conditions of Safe Storage	<p>Explained or reviewed conditions of safe storage of medication</p> <ul style="list-style-type: none"> • Reinforced importance of secure storage and keeping the medication out of the sight and reach of all others, especially children 	
<input type="checkbox"/> Induction Doses	Provided induction doses under appropriate medical supervision	
<input type="checkbox"/> Limited Amount of Medication	Prescribed limited amount of medication at first visit <ul style="list-style-type: none"> • enough to last until next visit 	
<input type="checkbox"/> Professional Counseling	Provided or referred to professional counseling and support services	
<input type="checkbox"/> Scheduled Next Visit	<p>Scheduled next visit at interval commensurate with patient stability</p> <ul style="list-style-type: none"> • Weekly, or more frequent, visits are recommended for the first month 	

MAINTENANCE CHECKLIST		
ASSESSMENT TO ENSURE APPROPRIATE USE		NOTES
Date:		
CHECK	INDUCTION	
<input type="checkbox"/> Take Medication As Prescribed	Assessed and encouraged patient to take medication as prescribed	
<input type="checkbox"/> Pill/Film Count/Dose Reconciliation	<ul style="list-style-type: none"> • Consider pill/film count/dose reconciliation 	
<input type="checkbox"/> Appropriateness of Dosage	<p>Assessed appropriateness of dosage</p> <ul style="list-style-type: none"> • Buprenorphine combined with naloxone is recommended for maintenance: <ul style="list-style-type: none"> • Buprenorphine/Naloxone SL tablet and film (generic equivalents of Suboxone®): doses ranging from 12 mg to 16 mg of buprenorphine are recommended for maintenance • Buprenorphine and naloxone sublingual film (Cassipa®): a target dose of 16 mg of buprenorphine is recommended for maintenance • Buprenorphine/Naloxone SL tablet (Zubsolv®): a target dose of 11.4 mg buprenorphine is recommended for maintenance • Buprenorphine/Naloxone Buccal Film (Bunavail®): a target dose of 8.4 mg of buprenorphine is recommended for maintenance • Doses higher than this should be an exception • The need for higher doses should be carefully evaluated 	
<input type="checkbox"/> Urine Drug Screens	Conducted urine drug screens as appropriate to monitor compliance with prescribed buprenorphine treatment plan or ascertain use of illicit substances	
<input type="checkbox"/> Prescription Drug Monitoring Program	Checked patient's prescription profile in the Prescription Drug Monitoring Program (PDMP) , as appropriate	
<input type="checkbox"/> Professional Counseling	Assessed participation in professional counseling and support services	
<input type="checkbox"/> Benefits vs. Risks	Assessed whether benefits of treatment with buprenorphine-containing products outweigh risks associated with buprenorphine-containing products	
<input type="checkbox"/> Progress Toward Treatment Goals	<p>Assessed whether patient is making adequate progress toward treatment goals</p> <ul style="list-style-type: none"> • Considered results of urine drug screens as part of the evidence of the patient complying with the treatment program • Considered referral to more intensive forms of treatment for patients not making progress 	
<input type="checkbox"/> Scheduled Next Visit	<p>Scheduled next visit at interval commensurate with patient stability</p> <ul style="list-style-type: none"> • Weekly, or more frequent, visits are recommended for the first month 	

REMS: IN CLINICAL PRACTICE

ADMISSION CRITERIA MET PER Risk Evaluation and Mitigation Strategy (REMS)

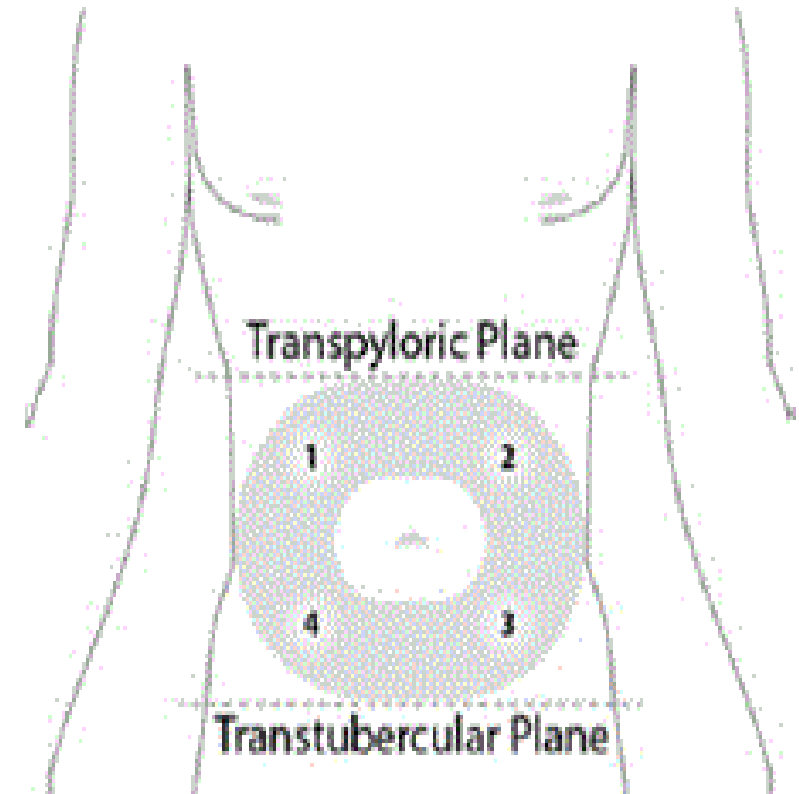
- Verified patient meets appropriate dx criteria for opioid dependence
 - Discussed risks described in professional labeling and Medication Guide with patient
 - Explained or reviewed conditions of safe storage of medication, including safe storage of medication, including keeping it out of sight and reach of children
 - Provided induction doses under appropriate supervision: already taking buprenorphine
 - Using heroin/withdrawal-provided education on precipitated withdrawal risk; self-inducting
 - Prescribed limited amount of medication at first visit
 - Scheduled next visit at interval commensurate with patient
- Narcan: Needs Already Has

REMS IN CLINICAL PRACTICE:

- **BUPRENORPHINE/SUBOXONE TREATMENT AGREEMENT**

- Please read the following agreement regarding buprenorphine/Suboxone as related to your therapy. This information is very important for your safety, well-being, and successful management of your recovery. I understand that buprenorphine/Suboxone is a partial-opioid agonist and as such may have side effects even when taken as prescribed; additionally, daily therapy may result in opiate withdrawal symptoms if abruptly stopped.
- Please initial on each line that you have read and agree with the terms of the agreement
- **_____ I agree that the medication I am prescribed is my responsibility and I agree to keep it in a safe, secure place. I agree that lost medication will not be replaced regardless of why it was lost.**
- **_____ I agree not to sell, share, or give any of my medication to another person.**
- **_____ I agree that my medication/prescription can only be given to me at my regular office visits. A missed visit will result in my not being prescribed until the next scheduled visit.**
- **_____ I understand that mixing buprenorphine with other medications or alcohol, especially benzodiazepines (for example, Valium, Klonopin, or Xanax), can be dangerous.**
- **_____ I agree to take my buprenorphine as prescribed -strips per day/mg per day -as I risk opiate/buprenorphine withdrawal symptoms from lack of continued therapy**
- **_____ I agree to provide random urine samples at every appointment and understand a prescription will not be provided without a urine sample**
- **_____ I agree that I will provide a urine screen at NP Dolezal's office if called to do so. I agreed to provide this sample no later than 24 hours after being called unless discussed with NP**
- **_____ I agree to notify NP Dolezal of any change in health status, including pregnancy**

GIVING THE INJECTIONS



■ SIDE EFFECTS

- 3 Main side effects –Reviewed at every visit
 - Sexual dysfunction
 - Male clients manipulate when taking dosing-no control with ER
 - NP refers to men’s clinic for testosterone work-up
 - Excellent success “I feel like a teenager again”
 - Constipation- of course
 - Written and verbal instructions
 - Meds as needed
 - Urinary hesitancy
 - Challenging side effects-only relieved with dose reduction
 - Verify not severe before ER
- Sweating
 - Uncomfortable but not life threatening
- Injection itself
 - Client with history of muscling and frequent abscesses forced to stop due to continued irritation at injection site

ONGOING TREATMENT AND DISCONTINUATION

- 300 mg to 100 mg
 - Downplay move from 300 to 100: fears of withdrawal “not enough”
 - First 300 dose a few clients need supplement with SL -4 mg and only to withdrawal symptom
 - If have very high tolerance, 300 mg might not be enough
 - Need 24 mg
- Poly substance use
 - If **continue** with therapy, dedicated to their recovery
 - “Last ditch effort”
 - More likely if forced to take ER- such as recovery residence
- Discontinuing:
 - Notes from the field: may or may not be as in literature
 - Some clients have little to no withdrawal symptoms for months
 - Some clients feel effects right away-?
 - Use COWS to judge efficacy of supplementation
 - Urine drug toxicology

CORRECTIONAL EXPERIENCE WITH ER BUPRENORPHINE

HEALTH MANAGEMENT ASSOCIATES

EMILEE WILHELM-LEEN, MD

- Experience with ER Buprenorphine in jails
- Informed consent specific to injection
- Local wound reactions
- How long does it really last
- 300mg vs 100mg maintenance
- All long acting injectables in EHR
- Discontinuing ER Buprenorphine

XR BUPRENORPHINE IN THE SANTA CLARA COUNTY JAILS

- We chose the XR formulation for agonist maintenance therapy in our jails because:
 - We were concerned about diversion of SL formulations,
 - Nursing time for directly observed therapy is at a premium in our institution, and
 - We had a grant to cover the initial cost of the medication
- After a year and about 70 buprenorphine inductions, we're going strong!

XR BUPRENORPHINE IN JAIL - OUR PROTOCOL

- Report of opioid use at booking:
 - OTC medications
 - COWS monitoring for buprenorphine taper
 - Referral for overdose prevention training/Narcan at release
 - Referral to the MAT MSW for prescreening for MAT
- MAT MSW visit generally in the first month of incarceration:
 - Prescreening for OUD and AUD
 - Consent for participation in our MAT program
 - Referral for MD evaluation
 - Release planning begins
- MD visit generally 2-4 weeks following prescreening:
 - Medical assessment for eligibility
 - Detailed discussion of available medications and logistics of induction
 - Monthly MD visits
 - Wound checks 1 day and 1 week following each dose

I XR BUPRENORPHINE IN JAIL - THE GOOD

- In general, patients like this formulation
 - Feel well
 - Appreciate the steady drug level; no “ups and downs”
 - Almost daily receive peer referrals for other patients
- Convenience of monthly dosing
 - Limited time spent in pill call
- No evidence in our setting that patients are attempting to divert XR buprenorphine
- Many people report they plan to continue XR buprenorphine after release

I XR BUPRENORPHINE IN JAIL - THE BAD

- Minor injection site issues are common (~5-10%)
 - Erythema
 - Itching
 - Palpable granuloma that persist > 1 month
- For some patients the medication does seem to wear off a few days early
 - Possible manual manipulation of the depot
 - Consider checking a serum buprenorphine level
 - Consider switching to 300 mg monthly dose
- Some patients seem to do better on 300 mg monthly dose
 - Higher use prior to induction
 - History of IV use
- The challenge of delayed induction
 - Consider slower ramp up of SL buprenorphine before XR injection

I XR BUPRENORPHINE IN JAIL - THE UGLY

- One case of a necrotic ulcer following injection
- Otherwise young and healthy patient with appropriate SQ tissue for injection
- Had previously received XR buprenorphine without complication
- Injection was not thought to be complicated at the time
- 2-10 days following injection, developed wound
- Now doing well with regular wound care, nearly healed

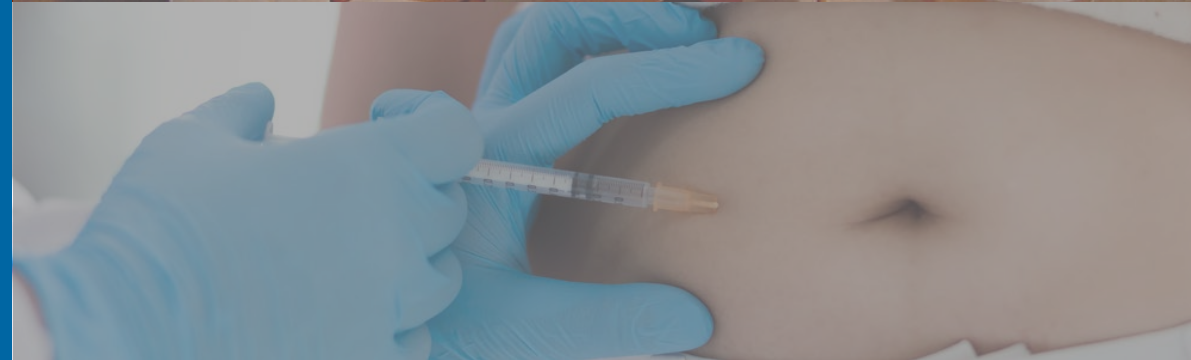
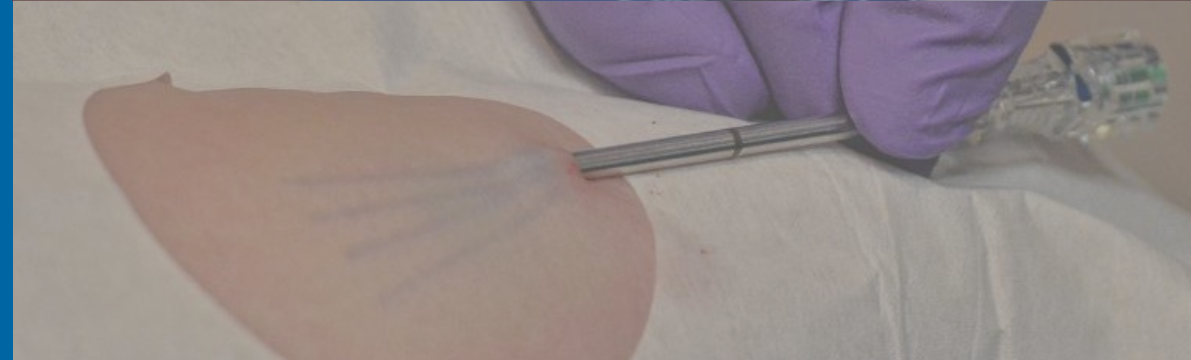
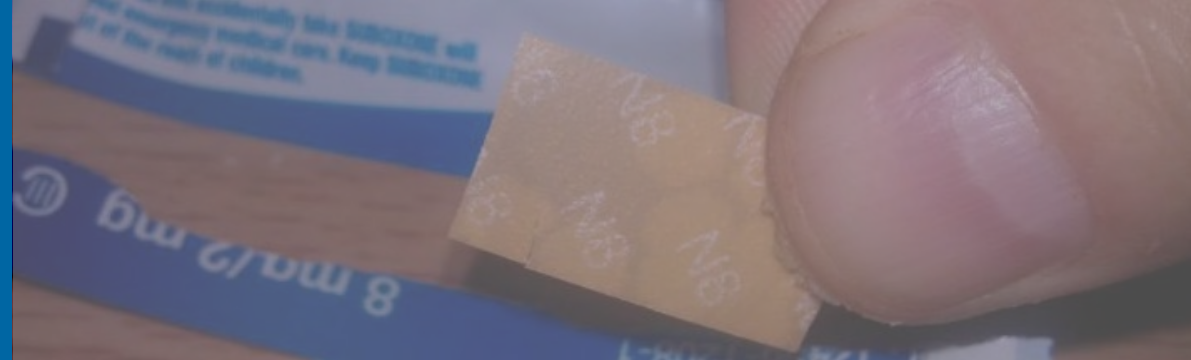


I CASE

- Male with a history of myasthenia gravis and blood clot in his leg with opioid use disorder.
- Started on extended release injectable buprenorphine 8 months ago while incarcerated.
- Returns to jail.
- Seen by RN in booking and note says,

“I DON’T USE HEROIN ANYMORE. I’M TAKING ALL OF MY MEDICATIONS.”

QUESTIONS



■ EVALUATION

- Overall, today's webinar was:
 - A. Very useful
 - B. Somewhat useful
 - C. Not very useful
 - D. Not useful at all

- The material presented today was:
 - A. At the right level
 - B. Too basic
 - C. Too detailed

REFERENCES/RESOURCES

- Sheriff's Association & National Commission on Correctional Health Care. (2018) Jail-Based Medication Assisted Treatment: Promising Practice Guidelines and Resources For the Field.
- American Society of Addiction Medicine www.asam.org Treatment of Opioid Use Disorder Course
- The 2020 Focus Update, ASAM National Practice Guideline Treatment of Opioid Use Disorder; https://www.asam.org/docs/default-source/quality-science/npg-jam-supplement.pdf?sfvrsn=a00a52c2_2
- SAMHSA Tip 63: <https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document/PEP20-02-01-006>
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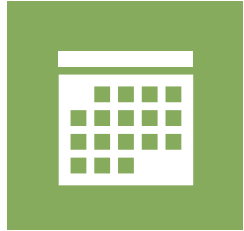
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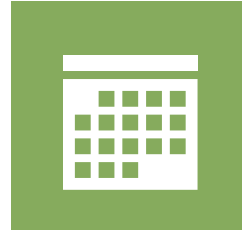
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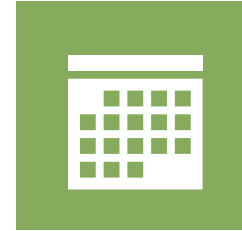
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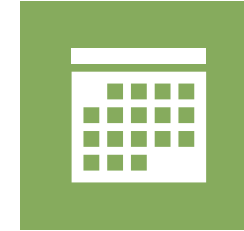
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