

Opioid Dependence and Buprenorphine Management

Kevin Kapila, MD

Fenway Health

Medical Director of Behavioral Health

Instructor in Medicine Harvard Medical School

Learning Objectives

- Understand the rationale and evidence for office-based buprenorphine treatment as an effective public health strategy to contain the epidemic of opioid dependence.
- Evaluate patients to determine if they are appropriate candidates for buprenorphine treatment, including assessment of co-morbid psychiatric and medical disorders.
- Describe the basic clinical use of buprenorphine, including mechanism of action and strategies for induction, stabilization, and withdrawal.
- Become familiar with models for use of buprenorphine in primary care, including individual treatment, shared medical appointments, and nurse-led programs.
- Address common clinical issues encountered managing patients on buprenorphine including perioperative management and management of acute pain.
- Access resources for buprenorphine training and tools useful in setting up an office-based practice.
- Identification and counseling of those patients at high risk for the misuse of buprenorphine

Learning Objectives

- The course is meant to be a overview of Buprenorphine treatment in the primary care setting using clinical scenarios. It is not a training course that will qualify participants to obtain the DEA waiver to prescribe Buprenorphine

Why do we need Buprenorphine?

- Heroin use **more than doubled** among young adults ages 18–25 in the past decade.
- More than **9 in 10** people who used heroin also used at least one other drug.
- **45%** of people who used heroin were also addicted to prescription opioid painkillers.

• CDC. MMWR July 10, 2015 / 64(26);719-725:

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6426a3.htm?s_cid=mm6426a3_w

Why do we need Buprenorphine?

- In the United States over 2.1 million people are suffering from substance use disorders related to prescription opioid pain relievers.
- The number of unintentional overdose deaths from prescription pain relievers has soared in the United States, more than quadrupling since 1999.

What is Buprenorphine?

- Buprenorphine is a partial agonist for the mu opioid receptor. Doses beyond ceiling effect do not produce greater effect.
- So in contrast to full mu agonist, there is lower potential for abuse, less physical dependence, less discomfort with withdrawal, and is safer in overdose.
- Buprenorphine has high affinity for the mu receptors so is not displaced by full agonists and displaces full agonists.
- Buprenorphine has high receptor affinity with low intrinsic activity.

What is Buprenorphine?

- Buprenorphine has poor oral bioavailability so must be taken sublingually.
- Since there is still abuse potential, especially if it is injected, buprenorphine has been co-formulated with Naloxone, which forms Suboxone.
- When taken sublingually, buprenorphine predominates if dissolved, and if injected the Naloxone predominates and precipitates withdrawal.

Buprenorphine Formulations

- Suboxone: Buprenorphine and Naloxone
- Subutex: Buprenorphine only
- For the purpose of this presentation, we will use the term Suboxone. This is how clients and most clinician refer to Buprenorphine/Naloxone treatment.
- Formulations: Tablet (generic) and a film
- There should be extreme caution with using Suboxone with benzodiazepines.

Case 1

- Pat, a 36 year old male, presents for a primary care follow up visit. They disclose they have been abusing Oxycontin. They have tried to stop “cold turkey” but can not. The methadone program would not allow them to maintain employment. They have attempted to find a provider who prescribes Suboxone. They ask if you or someone in your practice would prescribe. You have considered getting your Suboxone training and waiver but there has been reluctance among some providers in the practice. They do not want the problems that “come with treating opiate addicts.”

Why should I prescribe Suboxone in
my practice?

Why should I prescribe Suboxone in my practice

- Opiate dependence is a major public health problem.
- Office based treatment can help reduce the stigma around treatment.
- Methadone program requirements can make it difficult for someone to maintain employment.

Why are primary care providers reluctant to prescribe Suboxone?

- What are some feelings we have as providers about people struggling with opiate addiction?
- Why are providers worried about prescribing Suboxone?

Why are primary care providers reluctant to prescribe Suboxone?

- Our feelings about opiate addiction
- Worries about safety in clinic
- Worries about diversion
- Worries about monitoring by DEA
- Suboxone providers always seem to be getting in trouble.
- Worries about increased work load
- Would I be replacing one addiction with another?

Case 2

- Sandy, a 23 year old woman, presents wanting treatment for her opiate dependence which started two years prior. She has Hepatitis C with normal liver function, is sexually active with her boyfriend and not using any form of contraception. She would keep the baby if she became pregnant. Sandy had one episode of severe depression at age 19 which required brief hospitalization and responded well to treatment. What are some of the issues that would make you uncomfortable with prescribing Suboxone for this client?

Co-Morbid Medical Conditions

- Patients with opiate dependence are at increased risk of having of HIV, Hepatitis C, endocarditis, Hypertension, cellulitis as well as others. Appropriate screening is needed.
- Suboxone has fewer drug interactions with HIV medications than methadone. No current absolute contraindications.
- With hepatitis C there needs to have closer monitoring of liver function with suboxone treatment. Consultation with liver specialist when starting treatment for hepatitis C. Avoid treatment with suboxone if transaminase levels are over 3 times the upper limits of normal without consultation with Hepatologist.
- When starting any new medication interactions should be checked and client should be assessed for signs of being overmedicated or having detox symptoms.

Co-Morbid Psychiatric Conditions

- Psychiatric comorbidities are common with opiate dependence.
- The provider should assess if the psychiatric symptoms are a result of the substance or a primary psychiatric disorder. Primary disorders may improve but will not resolve with the treatment of the addiction.
- Guidelines recommending treatment with suboxone when psychiatric condition is “stable” are often not helpful. How stable is does the client have to be? Would anyone struggling with addiction and severe depression every really look stable? How would you assess for stability?

How would I know if someone was psychiatrically stable enough to start Suboxone?

- Assess if the client is so unstable they need inpatient psychiatric treatment.
- Assess if the symptoms so impair their judgement they would not be able to follow through with treatment in a primary care setting.
- Assess if their history of self harm and impulsivity is so severe they would be at high risk of overdose.
- Evaluate if you have the supports available to you to treat the client. This would include support from mental health professionals as well as nursing and case management support.

Buprenorphine and Pregnancy

- Methadone has been the traditional treatment of choice for opiate dependency in pregnancy.
- Subutex (Buprenorphine) – Buprenorphine monotherapy with Naloxone is not FDA approved and category C. This is evolving.
- The American Society for Addiction Medicine concluded that based on the data available, Buprenorphine monotherapy for the treatment of pregnant women with opioid use disorder is safe (Kraus et al. 2011).
- Buprenorphine monotherapy is an acceptable choice for pregnant women where Methadone is not available or if they are not willing or able to enter a Methadone program.

Kraus ML, Alford DP, Kotz MM, et al. Statement of the American Society of Addiction Medicine Consensus Panel on the Use of Buprenorphine in Office-Based Treatment of Opioid Addiction. *Journal of Addiction Medicine* . 2011; 5(4): 254-263

Case 2

- You evaluate Sandy and decide she would benefit from treatment with Suboxone in the outpatient setting. The liver function tests are only mildly elevated and the Liver Clinic clears her for treatment with Suboxone and would rather she have her addiction better controlled before starting treatment for Hep C. You counsel her on risk of pregnancy with Suboxone as well as Hep C and she agrees to start birth control. She has no acute or recent suicidal ideation, and will be seeing a therapist as well as attending group therapy during her treatment.

Case 3

- Duncan, a 42 year old male patient of yours, presents to the clinic to start treatment with Suboxone. He has been unable to stop on his own. He has been using Oxycodone when available but if not will use heroin. He has had to escalate his use, has physical cravings, and experiences withdrawal if he does not use. He is motivated to stop using opiates and has a lot of shame around the impact on his career and family. He had a physical six months ago with you and has no active medical issues.

Would Duncan be a good candidate for outpatient treatment with Suboxone in a primary care setting?

What factors make this client a good candidate for outpatient treatment?

Would Duncan be a good candidate for outpatient treatment with Suboxone in a primary care setting?

- The client is motivated to seek treatment. We have to be careful as providers to not be more motivated than the client.
- Client meets addiction criteria: Escalation of use, tolerance, craving, inability to stop despite negative consequences.
- For a provider who is new to prescribing, it may be more comfortable starting with a relatively stable client, such as Duncan, with whom they already have a treatment relationship.

Case 3

You and Duncan discuss Suboxone treatment. His CBC, LFTs, Chem 7, HIV, RPR, Hep A, B and C, and PPD are all negative. The urine tox is positive for opiates. You vaccinate for Hep A and B. You plan to start induction with Suboxone with the client. He knows he will have to stop use the day prior to induction and will experience some of the early signs of withdrawal. What are some of the early signs of withdrawal?

What would the early signs of withdrawal look like?

- Anxiety/Restlessness
- Nausea, abdominal cramps, vomiting
- Mydriasis (pupil dilation)
- Hot and cold flashes, sweating
- Muscle aches
- Yawning
- Tremors

Induction

- The goal of this phase is to find the minimum use of Suboxone to alleviate symptoms.
- If the client is not in early withdrawal, the Suboxone will precipitate withdrawal.
- Often clients have used Suboxone they have bought off the streets and are familiar with effects.
- You confirm withdrawal and can start with first dose in office, patient may stay in office or return in two hours for evaluation and dose adjustment.
- The induction phase ends when the client is on a dose where the withdrawal symptoms are alleviated or to a level where the client finds them manageable.

Case 3

- Duncan presents for follow up on Suboxone film 12/3 mg on a twice a day schedule. He feels better and like he finally has more control over his addiction. He wants to know how often he needs to see you and how long he will need to be on this medication.

Stabilization/Maintenance

- There should be frequent clinic contact, weekly visits and when stable monthly visits with prescriber.
- Regular urine toxicology. This should be for drugs of abuse. There should also be periodic checks for Buprenorphine in the urine to make sure there is not diversion.
- There should be some type of substance abuse counseling in place. 12 step supports are also encouraged.
- Discourage use of benzodiazepines. You will see clients in the community on benzodiazepines and Suboxone - it is not recommended.

Case 3

- One year later Duncan has been stable on treatment. He feels he has benefitted from the group treatment and is involved in Narcotics Anonymous. He wants to keep 12 step supports in place, but wants to stop treatment with Suboxone.

Discontinuation

- Patients with longer periods of stability on Suboxone have lower risk of relapse.
- Assess why they want to go off the treatment.
- The taper should be done slowly with education about signs of withdrawal.
- Education about risk of relapse should be provided and create environment where client feels safe returning to treatment if needed.

Case 4

- 44 year old male who has moved to the area is presenting for routine follow up for management of his Suboxone treatment. He likes working with you but feels like he needs more support and there is not enough time in the visit to discuss his opiate treatment, weight gain, high blood pressure, and high cholesterol. Previously, he was in a nurse led Suboxone treatment program.

Models of Care

- Psychiatric practice: prescribing psychiatrist who also may provide therapy or provide group treatment support. These are often in a private practice model.
- Opiate treatment program where there is case management, group treatment, individual treatment. These often have long wait lists.
- Intensive outpatient program: This may be where a client starts treatment, daily groups, and regular visits with psychiatric provider/addiction specialist.
- Primary care practice based treatment, where there are many different models.

Primary Care Practice

- Nursing Case Management: The nursing team will run the program in coordination with the prescriber. They do pill counts, schedule urine toxicology, check in with client. Some nurses are trained to run group treatment.
- The physician in this case may see the client less frequently and have team meetings with the nurse.

Primary Care Practice

- Nurse/Prescriber group-based program: The prescriber would stay for first part of group for check in and questions and then select people with whom they need to meet.
- Prescriber/Nurse/Master's level therapist: This would add a therapist who may run or co-lead group, meet with clients, and be part of team meetings.
- What would you see as the benefits of the above models of care?

What are the elements of success in any model of care?

- There is more support than just medication.
- There is at least group therapy and ideally individual therapy as well.
- There is accountability, pill counts, toxicology screening, and an expectation that client shows up for treatment.
- There should be support in place for relapses. Relapses are part of substance abuse treatment.

Case 5

- Adam, a 46 year old male, stabilized on Suboxone has slipped on the ice and fractured his shoulder. He notifies the treatment team he will need surgery and pain management. The client has been compliant with treatment and follows the protocol set up by the clinic. The surgeon calls the office and is unwilling to manage the pain medication. The client is having severe pain. What are some options for this client?

Pain Management on Suboxone

- Maximize non-opiate pain medications
- Split dose of the Suboxone to 3-4 times a day to see if there is better pain control. The analgesic effects last 6-8 hours.
- If there's an anticipated procedure, discontinue Suboxone 3 days prior to procedure, use Methadone or long-acting opiate.
- If there's an unanticipated event, stop the Suboxone and use high receptor affinity and potency drugs, like Fentanyl or Hydrocodone. Remember if you do this, it may take up to 72 hours for total effect of Suboxone to go away, so watch for toxicity.

Case 5

- Adam has his pain controlled with slight increase in Suboxone dose and change to 8 hour dosing along with addition of NSAIDS. Six months later you see the client for follow up. He saw the orthopedist and will need a shoulder replacement.
- What would you do?

Case 5

- You work with the client and the pain specialist to set up a plan for the client to stop his Suboxone and start a long acting opiate. He does well with the procedure. He requires high doses of narcotics for pain control which makes his inpatient treatment team uncomfortable, and they reduce his pain medication without contacting you. The patient become verbally abusive to the staff who further reduce his pain medication. He leaves AMA, and sees you two weeks later for follow up and admits to using heroine.
- What would you do?

Case 5

- There are different options for this client:
 - Take him back and start induction process
 - Have him stabilize in a partial hospital or intensive outpatient program.
 - Take him back and start induction process but increase supports and services offered.
 - You can refer for inpatient treatment, but often difficult to get the client in and focus is often detoxification.

Case 6

- Bonnie is a 53 year old female with opiate dependence and poorly controlled diabetes complicated by severe neuropathy. She has had her longest periods of sobriety on Suboxone treatment, but has been tapered off due to diverting medication to buy Valium, “losing her medications,” and having tox screens positive for cocaine and cannabis. She comes back to see you and wants to start back on Suboxone because she has been using large amounts of Oxycodone. She is willing to engage in substance abuse treatment. She is clear she does not think she can give up cannabis.
- What would you do?

How do we manage a client at high risk for misusing Suboxone?

- Patients who struggle with addiction will relapse, lie, divert, and abuse drugs. This behavior is to be expected and is part of the disease process.
- How much a provider will tolerate will depend on if they are taking a harm reduction approach vs. an abstinence based approach. There are benefits to both approaches.
- Harm reduction should not be mistaken for enabling the client.
- It is very important to work with a team model when working with clients who are at high risk.

Case 7

- 46 year old primary care provider presents for follow up visit with panic attacks. They are struggling with keeping up with documentation, prior authorizations, and have to sit for their 10 year board recertification exam. Their “heartless medical director” is now mandating they take on prescribing Suboxone.

How do I get certified to prescribe Suboxone?

- PCSS Course – Half the training is online and the other half is in person.
<http://pcssmat.org/education-training/waiver-eligibility-training/>
- Online Trainings
 - American Academy of Addiction Psychiatry
<http://www.aaap.org/education-training/buprenorphine/>
 - American Osteopathic Academy of Addiction Medicine
<http://www.aoaam.org/>
 - American Psychiatric Association
<http://www.apaeducation.org/ihtml/application/student/interface.apa/index.htm>
 - American Society of Addiction Medicine
<http://www.buppractice.com/>

Supports

- SAMHSA Website

<http://buprenorphine.samhsa.gov/index.html>

- Guidelines protocol: **This book/PDF is the main reference for this talk. The trainings for obtaining a waiver are all based of this resource.**

<http://buprenorphine.samhsa.gov/index.html>

- The American Society of Addiction Medicine also provides useful links in addition to training.
- Developing a peer group with other prescribers or a consultative relationship with an addiction specialist is also helpful.

Summary

- Be aware of your own feelings and beliefs about clients who have issues with addiction.
- Suboxone treatment on its own is usually not sufficient. Clients should be engaged with other supports including group therapy, individual therapy, and 12 step support groups.
- The prescriber should also have supports in place which can include a Suboxone team, peer support with other prescribers, and a consultation relationship with an addiction specialist.
- As providers we would expect a client with severe arthritis to have flare ups of their joint pain; clients with addiction are not any different and will often relapse, lie, divert, and manipulate - it is part of the disease process.