PCSS
The Half and Half Course

Buprenorphine Training
(part 1)

UNC HEALTH SCIENCES at MAHEC

Funding for this initiative was made possible (in part) by grant no. 6H79TI081968 from SAMHSA. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services; nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government.

The Half and Half Course Agenda

- Overview: Opioid Use Disorder Treatment with Buprenorphine/Naloxone
- Pharmacology
- Patient Evaluation
- Case Study #1 - The Lawyer
- Specialty Topics
- Clinical Application
- Case Study #2 - The Teacher
- Urine Drug Testing
- Case Study #3 - The Student
- Clinical Tools

Speaker Intro

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Speaker Disclosures

The contents of this activity may include discussion of off label or investigative drug uses. The faculty is aware that is their responsibility to disclose this information.

Overview

Provider Clinical Support System

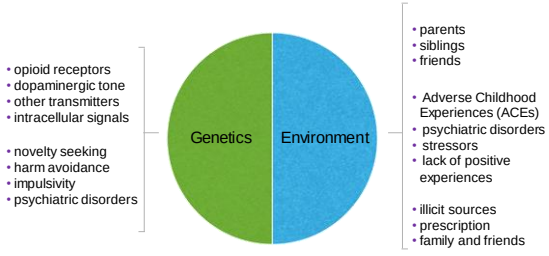
The overarching goal of PCSS is to train a diverse range of healthcare professionals in the safe and effective prescribing of opioid medications for the treatment of pain, as well as the treatment of substance use disorders, particularly opioid use disorders, with medication treatments.

Definition of Addiction

- Addiction is defined as a chronic, relapsing disorder characterized by compulsive drug seeking and use despite adverse consequences.
- It is considered a brain disorder, because it involves functional changes to brain circuits involved in reward, stress, and self-control.
- Addiction is a treatable, chronic medical disease, involving complex interactions neurobiology, genetics, the environment, and an individual's life experiences.
- Prevention efforts and treatment approaches for addiction are generally as successful as those for other chronic diseases.

NIDA, 2018
ASAM

Individual Vulnerability to SUDs



Anokhin et al., 2015
Milivojevic et al., 2012
Reed et al., 2014
Volkow et al., 2016
Goldman et.al. 2005

Substance Use Disorders (SUD) and Healthcare

- Significant financial costs
  - US Societal Costs $420 billion annually
  - Healthcare $120 billion (1,2).
- SUDs negatively affect the quality of our health, educational, and social systems.
- Effective prevention policies and practices can reduce harms and costs of these problems
- Addiction is an acquired chronic illness, like type 2 diabetes — they can be managed but not *yet* cured.

McLellan AT, 2017
Sacks JJ, 2015
National Drug Intelligence Center. 2011

Substance Use Disorders (SUD) and Healthcare

- The prevalence of substance use disorders in the general population is 8% to 10% (6% to 7% for women, 9% to 11% for men)
- Prevalence is greater in all areas of medical care:
  - 20% in typical primary care clinics,
  - 40% in general medical patients treated in hospital,
  - >70% of patients in emergency or urgent care clinics.
- Failure to screen for and address substance use is associated with:
  - misdiagnoses,
  - poor adherence to prescribed care,
  - high use of hospital and emergency services,
  - increased mortality

SAMHSA 2016, Fleming and Barry, 1992, Grodensky CA, et.al. 2012, Ford JD, 2004, Mertens JR, 2003,

SUD Treatment

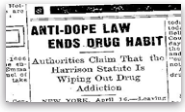
- Evidence based science has resulted in public health-oriented approach to effective, practical, and sustainable policies and practices to:
  - prevent substance "use" before it starts;
  - identify and intervene early in cases of substance "misuse";
  - effectively treat substance use disorders.
- The remission and long-term recovery is improved when care is:
  - evidence-based
  - provided for adequate periods of time
  - delivered by properly trained clinicians
  - augmented by supportive monitoring, recovery support services, and social services.
- More than 23 million previously diagnosed adults (appx. 10% of the adult population) identify themselves as in long-term recovery

Felix J, et.al., 2012

Opioids and Opioid Use Disorders (OUD)

History of Opioids

- Utilized throughout the world for various use for thousands of years
- 1800's:
  - Morphine and Heroin were marketed commercially as medications for pain, anxiety, respiratory problems
  - Invention of Hypodermic syringe allowed for rapid delivery to the brain
- The Harrison's Act of 1914 – The restriction of the sales of opioids and the onset of the illicit sales. Some site this as the beginning of the "Drug War."


ANTI-DOPE LAW ENDS DRUG HABIT

Authorities Claim That the Harrison Statute Is Wiping Out Drug Addiction

NEW YORK, April 14.—Leaving

PCSS Providers Clinical Support System 13

Pivotal Milestones in Treatment

Year	Milestone
1970	Methadone is approved by the FDA for detoxification
1973	Methadone is approved by the FDA for maintenance
1974	Opioid Treatment Programs (OTP's) able to dispense Methadone for maintenance treatment
1984	Oral Naltrexone is approved by the FDA
2000	Drug Addiction Treatment Act of 2000 (DATA 2000) allowed qualified physicians to offer Office Based Opioid Treatment (OBOT)
2002	Buprenorphine is approved by the FDA for the treatment of OUDs
2010	Extended release injectable naltrexone is approved by the FDA
2023	The discontinuation of the waiver allowing all providers with an active DEA license to prescribe approved forms of buprenorphine.

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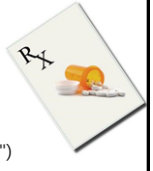
Drug Addiction Treatment Act (DATA 2000)

Federal Law allowing prescription of certain controlled substances for office based opioid treatment, (OBOT)

- Permits physicians who met certain qualifications to treat opioid use disorders with:
  - Schedule III, IV, and V narcotic medications that have specific approval by the FDA for treatment of opioid use disorders, OUD.
  - In treatment settings other than the traditional Opioid Treatment Program ("methadone clinic") settings



DATA, 2000

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Discontinuation of the Waiver

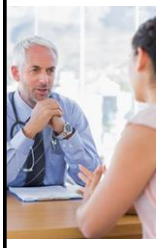
Dear DEA Registrant:

On December 29, 2022, with the signing of the Consolidated Appropriations Act of 2023 (the Act), Congress eliminated the "DATA-Waiver Program."

- A DATA-Waiver registration is no longer required to treat patients with buprenorphine for opioid use disorder.
- Going forward, all prescriptions for buprenorphine only require a standard DEA registration number. The previously used DATA-Waiver registration numbers are no longer needed for any prescription.
- There are no longer any limits or patient caps on the number of patients a prescriber may treat for opioid use disorder with buprenorphine.
- The Act does not impact existing state laws or regulations that may be applicable.

Note: The Act also introduced new training requirements for all prescribers. These requirements will not go into effect until June 21, 2023.

Opioid Treatment Programs (OTPs)



- Starting in 2013:
  - OTPs (methadone maintenance programs) were able to dispense buprenorphine in same manner as office-based practitioners.
  - The 2015 modification waives OTPs from the time *in treatment requirements* for patients receiving buprenorphine, if an OTP practitioner determines the patient is suitable for take home supplies.
- Advantages of OTPs:
  - They provide structure to patients who need closer observation than an office-based practitioner can provide
  - Offer additional services counseling, medical/mental health, case-management services.

MOUD Treatment Goals

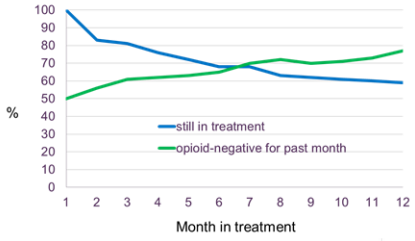
- Range of treatment goals

Minimization of harms from ongoing use ⟷ Sustained recovery with abstinence from all substances

- Treatment Options
  - Medication for Opioid Use Disorder (MOUD); FDA approved options include:
    - Buprenorphine: Partial Agonist at the mu-receptor
    - Methadone: Full Agonist at the mu-receptor
    - Naltrexone/Naloxone: Antagonists at the mu-receptor
  - Behaviorally-Oriented Treatment
- Ultimate Goal: Maintain long-term recovery while still taking medication and/or after potential discontinuation.

Treatment Retention and Decreased Illicit Opioid Use using MOUD

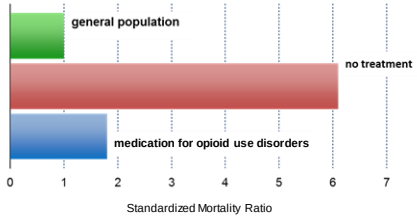
- Buprenorphine promotes retention, and those who remain in treatment become more likely over time to abstain from other opioids



Kakko et al, 2003
Soeffing et al., 2009

Benefits of Medication for Opioid Use Disorders (MOUD) Decreased Mortality

Death rates:



Dupouy et al., 2017
Evans et al., 2015
Sordo et al., 2017

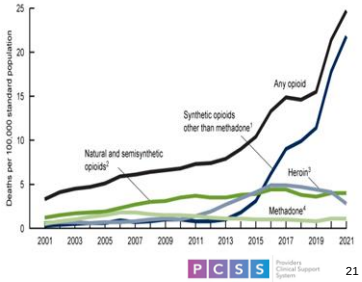
Effective medications have yet to reverse the rise in mortality.

CDC Data 2021: 106,699 drug overdose deaths occurred in 2021 and increase of 14% from 2020

In 2021,

- Drug overdose death rates increased for each race and Hispanic-origin group except non-Hispanic Asian, and highest in rates were for non-Hispanic American Indian or Alaska Native (AIAN) people.
- Rates of drug overdose deaths involving synthetic opioids other than methadone increased 22%, while rate of deaths involving heroin declined 32%.

Note: The rate of drug overdose deaths increased involving cocaine and psychostimulants with abuse potential.



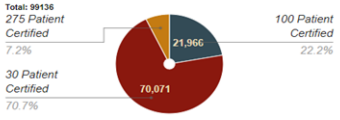
Patients receiving treatment

- Despite the scientific evidence, only 1 in 10 people with an opioid use disorder receive addiction treatment that includes these medications.
  - Methadone - 380,000 patients at 1,611 methadone treatment programs
  - Buprenorphine - 112,000 patients
  - Naltrexone (long acting injectable) - 23,000 patients
- Approximately an equal number of patients receive treatment without medication.
  - This is often due programmatic "philosophy" and/or the lack of medication availability.

SAMHSA 2021

DATA 2000 – Available Workforce Providers with Waivers

Practitioner and Program Data



- Over 99,000 practitioners have received their waiver to prescribe a buprenorphine for OUD patients.
- **40 percent of waivered practitioners do not prescribe buprenorphine and many others prescribe at far below their authorized capacity.**

Barriers to Treatment: Yet to be Overcome

- Practitioners feel a need for more training and building of confidence to treat.
- They feel starting to treat patients with OUD would be disruptive to their practice, **stigma**.

Other reasons

- preauthorization insurance requirements
- limited reimbursement when treating such patients
- DEA monitoring
- not having access to behavioral health providers
- concerns about diversion

Breaking the Barriers

- There are efforts underway to improve access to care by a variety of sources of medical education, organizations and the federal government.
  - Make medication and treatment more available
  - Reduce constraints by insurance companies and payors, reducing the time and costs of treatment.
- Professional organizations, have a variety of programs and opportunities for further education and mentoring.
- PCSS a federally granted consortium of organizations has a variety of programs and opportunities to help practitioners to feel more comfortable in providing this treatment.

*Knowledge and Skills **can** Improve Attitudes and Reduce Stigma*

Summary

- Rates of overdose deaths from opioids are at an all-time high and are continuing to increase
- Legislative initiatives have been passed to improve access to treatment for opioid use disorders
- Medication for opioid use disorder has several benefits including:
  - Decrease in the number of fatal overdoses
  - Increase patients' retention in treatment, and improved social functioning

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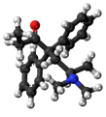
Pharmacology of Medications for Opioid Use Disorders

Methadone

- Synthetic full mu opioid agonist
- Discovered in 1937 and received FDA approval in:
  - 1947 for treating pain and coughing
  - 1970 for medically supervised withdrawal (“Detoxification”)
  - 1973 for maintenance therapy



- Metabolized in the liver and by intestinal cytochrome: CYP3A4
- Most methadone is ultimately excreted into the biliary tract, but small fractions enter the urine and are detectable in urine drug tests
  - The EDDP a metabolite of Methadone and the metabolite that is detected in the urine.
- Oral bioavailability when swallowed: 36% -100%

CSAT, 2005

Major Features of Methadone

***Full Agonist* at mu receptor**

Long acting

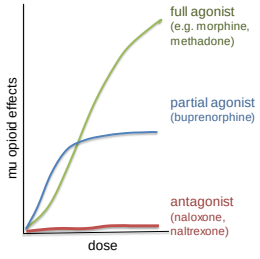
- Half-life ~ 15-60 Hours

Weak affinity for mu receptor

- *Can be displaced by partial agonists (e.g. burprenorphine) and antagonists (e.g.naloxone, naltrexone),* which can both precipitate withdrawal

Monitoring

- Significant respiratory suppression and potential respiratory arrest in overdose
- QTc prolongation



CSAT, 2005

Buprenorphine

- Semi-synthetic analogue of thebaine
- Metabolized in the liver, mainly by cytochrome P450 3A4 (CYP3A4), and has a less-active metabolite, norbuprenorphine
- Most buprenorphine is excreted into the biliary tract, but small fractions enter the urine and are detectable in urine drug tests
- Because of extensive first-pass metabolism, buprenorphine has poor oral bioavailability when swallowed (<5%),
  - all therapeutic formulations use other routes
- Sublingual administration bypasses first-pass metabolism and allows bioavailability around 30%

Mendelson et al., 1997
SAMHSA, 2016, 2016
SAMHSA, 2018

Major Features of Buprenorphine

Long acting

- half-life ~ 24-36 Hours

Partial agonist at mu receptor

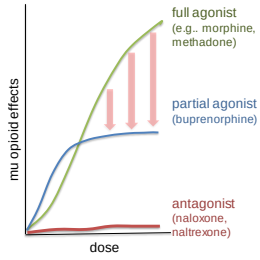
- Comparatively minimal respiratory suppression and *unlikely* to lead to fatal respiratory suppression even at high doses

High affinity for mu receptor

- *blocks* other initiated opioids
- *displaces* other current opioids
  - can precipitate withdrawal

Slow dissociation from mu receptor

- contributes to its long duration of action.



SAMHSA, 2018
Orman & Keating, 2009

How Does Buprenorphine Work for OUDs?

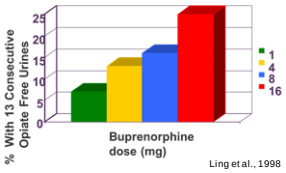
- High affinity for, and slow dissociation from the mu receptor leads to:
  - Prevention of withdrawal symptoms
  - Decreased cravings
  - Decreased effects of other opioids

- However, it is unlikely to block *all* effects from an opioid taken after initiation of buprenorphine treatment:
  - Because binding to mu receptors is a dynamic process; while effects may be less, they are not likely to be completely eliminated.

Buprenorphine Dosing: Efficacy

Findings of a 2019 systematic review:

- Withdrawal stabilization will often take place between 4 and 16mg.
- Daily doses from 8 up to 32mg may be necessary to provide adequate opioid receptor blockade, thus attenuating craving and response to other opioids.

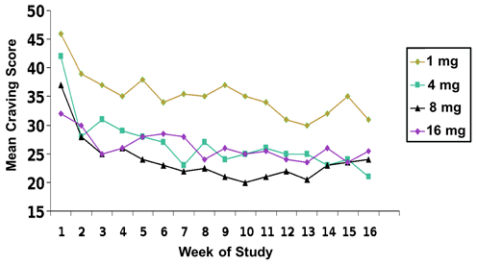


Ling et al., 1998

- There was no clear evidence regarding BUP dose on treatment retention or illicit opioid use for an individual.
- **Conclusion: BUP dose should be individualized based on a continuous benefit-risk assessment.**

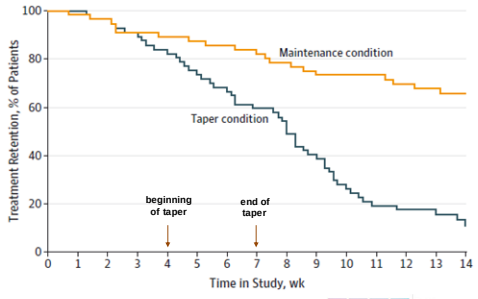
Shulman M, 2019
Greenwald MK, 2014

Mean Heroin Craving: 16 Week Completers: Reduced Craving with Therapeutic Buprenorphine Doses



Ling et al., 1998

Buprenorphine: Maintenance vs. Taper



Fiellin et al., 2014

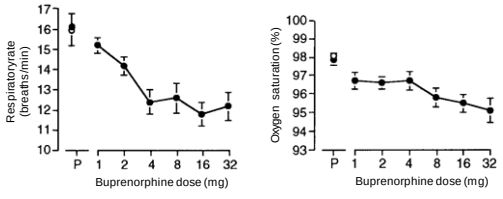
Common Adverse Effects of Buprenorphine

- Headaches
  - Management: aspirin, ibuprofen, acetaminophen (if there are no contra-indications)
- Nausea
  - Management: Consider spitting the saliva out after adequate absorption instead of swallowing.
- Constipation
  - Management: Stay well-hydrated, Consume high-fiber diet, Consider stool softeners, laxatives, naloxegol
- Xerostomia (Dry mouth) – side effect of ALL opioids
  - Complications: Gingivitis, Periodontitis
  - Management: Stay well-hydrated, Maintain good oral hygiene

SAMHSA, 2018
Wald, 2016

Buprenorphine Dosing: Safety

- Nearly all fatal poisonings involve multiple substances



- Cognitive and psychomotor effects appear to be negligible

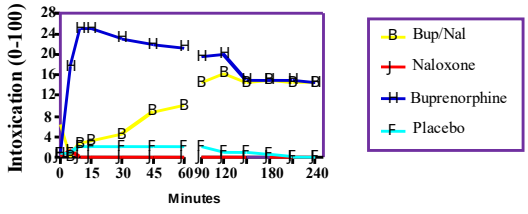
Häkkinen et al., 2012
Walsh et al., 1994
Shmygalev et al. 2011

Rationale for the Combination of Buprenorphine with Naloxone

- When used as prescribed (sublingual or buccal administration), there is minimal bioavailability of naloxone
- Compared to buprenorphine alone, the buprenorphine/naloxone combination if injected:
  - is more likely to be experienced as a "bad drug" or precipitate withdrawal in persons physically dependent on opioids. (Note: both can result in withdrawal if patient was not already in w/d)
  - will prolong the onset of buprenorphine, and a primary driver of injection drug use is the speed in which a drug gets to the brain.
  - initially will produce less euphoria (similar to placebo) in those who are physically dependent on opioids
- **Per prescription, combination product is less likely to be diverted**

Comer et al., 2010
Jones et al., 2015
Stoller et al., 2001
Mendelson et.al.,1997

Effect of IDU diversion of Buprenorphine and buprenorphine/naloxone combination



Mendelson J., et.al. J of Drug Dependence 2003

Diversion of Buprenorphine

- Has intravenous misuse potential
- Mono product tablets more likely diversion than combination formulation buprenorphine/naloxone
- In a survey of more than 4,000 patients in treatment programs in the United States, relative rates of diversion per prescribed dose were:
  - **buprenorphine/naloxone film or tablet: 1-2**(reference)
  - **buprenorphine tablet: 6.5**
- Combination product is the standard of care.

Comer et al., 2010
Jones et al., 2015
Larancea et al., 2014
Lavonas et al., 2014

Buprenorphine vs Placebo vs Methadone maintenance for OUD Treatment

- Cochrane Review of 31 trials with over 5,400 participants found:
  - Buprenorphine is an effective medication for retaining people in treatment at any dose above 2 mg, and suppressing illicit opioid use (at doses 16 mg or greater) based on placebo-controlled trials
  - No difference between medium-dose buprenorphine (7 - 15 mg) and medium-dose methadone (40 - 85 mg) in retention
  - No difference between high-dose buprenorphine (≥ 16 mg) and high-dose methadone (≥ 85 mg) in retention or suppression of self-reported heroin use

Mattick et al., 2014

Buprenorphine and Benzodiazepines

- Even used as prescribed benzodiazepines in combination with buprenorphine are associated with more accidental injuries, but not with other safety or treatment outcomes.
  - Human studies: minimal effects on respiration when both are taken at therapeutic doses.
- However:
  - Benzodiazepines are present in many fatal poisonings involving buprenorphine.
    - Animal studies: At elevated doses benzodiazepines may also suppress respirations allowing buprenorphine to produce fatal respiratory suppression in overdose.

Bardy G, et al., 2015
Jones et al., 2012
Nielsen & Taylor, 2005
Schuman-Olivier et al., 2013

Changes in FDA Recommendations

08/2016	09/2017
▪ Boxed Warning for combined use of opioid medicines with benzodiazepines or other CNS Depressants (e.g. Alcohol) ▪ Risks of slowed or difficult breathing; Sedation; Death	▪ Buprenorphine and methadone should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS). ▪ The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction can outweigh these risks. ▪ Careful medication management by health care professionals can reduce these risks.

FDA, 2016, 2017

FDA Guidance for Health Care Professionals

- Take several actions and precautions and develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants:
  - Verify the diagnosis for anxiety or insomnia and consider other treatment
  - Educate patients about the serious risks; poss. death
  - Taper the benzodiazepine or CNS depressant to discontinuation if possible.
  - Recognize that patient's medications should continue for as long as patients are benefiting.
  - Coordinate care to ensure other prescribers are aware of the patient's buprenorphine or methadone treatment.

FDA, 2017

Buprenorphine and Alcohol

- Overall recommendation is to generally avoid CNS depressants with buprenorphine
- Some evidence that treatment with buprenorphine can help decrease craving for alcohol,
- Alcohol use <u>disorder</u> is associated with higher rates of relapse to opioid use

Clark et al., 2015
Hakkinen et al., 2012
Nava et al., 2008

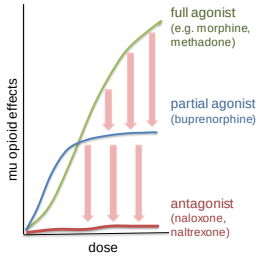
Major Features of Naltrexone

Full Antagonist at mu receptor
- Competitive binding at mu receptor

Long acting
- Half-life:
  - Oral ~ 4 Hours
  - IM ~ 5-10 days

High affinity for mu receptor
- *Blocks* other opioids
- *Displaces* other opioids
  - Can precipitate withdrawal

Formulations
- *Tablets: Revia®: FDA approved in 1984*
- *Extended-Release intramuscular injection: Vivitrol®: FDA approved in 2010*



SAMHSA, 2018

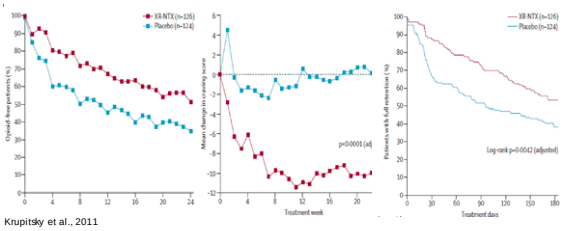
Naltrexone Treatment: Mechanism

There are two possible mechanisms of therapeutic effect:

- **Behavioral mechanism:** blockade of the reinforcing effects of heroin leads to gradual extinction of drug seeking and craving
  - Patients who use opioids while on naltrexone experience no effect of exogenous opioids and often stop using them
- **Pharmacological mechanism:** naltrexone decreases reactivity to drug-conditioned cues and decreases craving thereby minimizing pathological responses contributing to relapse

As naltrexone has a different mechanism of action than methadone or buprenorphine, it may be acceptable to or effective for, different subgroups of patients, thus helping to attract more patients into effective treatment overall.

Naltrexone: Efficacy



Krupitsky et al., 2011

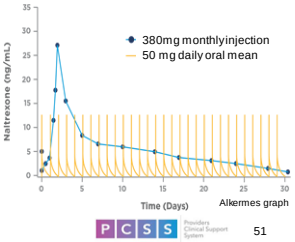
Using naltrexone there may also be a higher proportion of opioid, cocaine, benzodiazepine, cannabinoids, amphetamine - free patients.

Comer et.al.,2011

Naltrexone Treatment

- Naltrexone has an active antagonist metabolite (6-β-naltrexol).
- Plasma concentrations (>2 ng/ml) of naltrexone fully blocks all opioid effects
- A choice for patients who prefer not be on any opioids

- Naltrexone tablets
  - associated with poor adherence
- Naltrexone (extended release) depot IM
  - monthly injection, better adherence

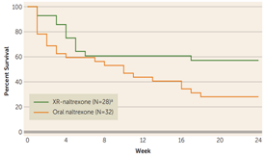


Alkermes graph

Naltrexone Considerations: Adherence

- Treatment adherence is better with injectable formulation.
- Few side effects other than soreness at injection site.
- Possible subacute withdrawal symptoms after the first injection.
  - Resolves after one or two weeks and does not recur after subsequent monthly injections
- Main safety concern is risk of relapse when injections are discontinued
- The treatment plan can include:
  - counseling,
  - anticipatory guidance,
  - motivational techniques
  - emphasis on adherence
  - Involvement of a significant other may be helpful.

Time to Dropout for Participants Receiving Oral Naltrexone or Extended-Release Injectable Suspension Naltrexone



Sullivan M, et al., Am J Psychiatry, Feb., 2019

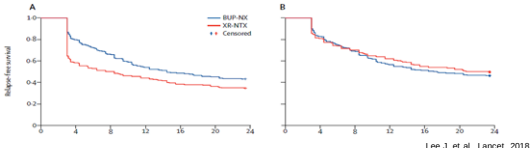
Naltrexone Considerations: Initiation

- Prescribing information recommends patients be opioid-free for 7-10 days before initiation to avoid precipitated withdrawal
  - Abstinence for 7 to 10 days is most challenging.
    - Non opioid medications for withdrawal (e.g. clonidine) can be helpful
    - Inpatient/residential treatment programs, where medically managed withdrawal can be accomplished are ideal settings for initiating.
      - There is poor access to such programs due to limited third party reimbursement
  - More rapid methods for naltrexone initiation utilizing low dose naltrexone have been reported and may shorten and protect the patient in the period prior to injection.

Williamset al., 2017
Sullivan et al., 2017

Effectiveness of Buprenorphine vs. Injection Naltrexone

- Two randomized comparative effectiveness trials in Norway and US



Lee J, et.al., Lancet, 2018

- Overall Findings:
  - Once initiated, both medications appear comparably effective, although buprenorphine doses may not have been maximized in the trials
  - Naltrexone is more difficult to initiate due to the need to get a patient through medically supervised withdrawal

Lee et al., 2018
Tanum et al., 2017

Summary

- MOUD includes:
  - Methadone: A full agonist that activates the mu-receptor
  - Buprenorphine: A partial agonist that activates the mu-receptor at lower levels
  - Naltrexone: An antagonist that occupies the mu-receptor without activating it
- Ongoing treatment with MOUD is effective at improving:
  - retention in treatment
  - decreasing use of illicit opioids.
- Short-term treatment where MOUD is tapered after a brief period of stabilization have proven ineffective.
- Pharmacodynamically, combination of methadone or buprenorphine with central nervous system depressants increases risk of sedation or respiratory depression and overdose.
  - This risk is most clearly shown with benzodiazepines, particularly with intravenous use.

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Polling #1

The *affinity* of buprenorphine results in:

a. A strong bond to the mu-opioid receptor
b. Displacement of buprenorphine by methadone
c. A prolonged bond to the mu-opioid receptor
d. An enhanced euphoric effect of buprenorphine

Patient Evaluation

Patient Evaluation
Initial vs Comprehensive

- Completion of a comprehensive assessment should not delay or preclude initiating pharmacotherapy for the patient with an opioid use disorder.
- However, if not completed before initiating treatment it should be completed soon after.
- The comprehensive assessment of your patient is important in establishing a treatment plan.

The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder
2019 Focused Update

Building a Therapeutic Alliance

- Attitude
  - Non-judgmental, curious, empathetic
- Respectful
  - Recognize adversity
  - Recognize strengths
  - Use the non-stigmatizing language
- Honesty
- Shared goals
  - Why is the patient seeking treatment?
  - Provider treatment team concerns
- Reassurance
  - Confidentiality (with qualifiers)
    - *Safety of self, well-being of others (especially children)*

Miller WR, Rollnick S, Motivational Interviewing, Guilford Press, NY NY, Third Ed., 2013, page 22.

Language and Stigma

- Addiction is one of the most stigmatized conditions
- Individuals with substance use disorders are viewed more negatively than people with physical or psychiatric disabilities
- Use of stigmatizing language (such as "substance abuser" rather than as a "person with a substance use disorder) can adversely affect quality of care and subsequent treatment outcomes

- Respectful
- Non-Judgmental
- Honest
- Clear and Understandable
- Supportive

Recovery Language	Potentially Stigmatizing Language
Substance Use Disorder	Substance Abuse
Person with a substance use disorder	Addict
Drug Free / Free from illicit and non-prescribed medications	Clean and Sober
Recurrence of substance use	Relapsed / Slipped
Medically supervised withdrawal	Detox
Positive Drug Screen	Dirty Urine
Negative Drug Screen	Clean

Botticelli and Koh, 2016
Kelly et al., 2016
ONDCP, 2016

Goals of Evaluation

Goals	Details
Therapeutic Alliance	Non-judgmental, understanding, respectful
	Use Language of recovery
	Shared goal-setting
Collateral Information	Prescription Monitoring Programs
	Significant Other
	Other Treatment Providers
* Comprehensive Assessment	Medical, Psychiatric, Review/Perform Lab Tests, Physical Exam
Signs of Withdrawal	Clinical Opioid Withdrawal Scale (COWS)
Diagnostic Clarification of Substance Use Disorder	DSM-Criteria with:
	-Descriptor: Use Disorder; Intoxication; Withdrawal
	-Specifiers: Early remission; Sustained remission; In controlled environment
	-Severity: Mild, Moderate, Severe
Risk Assessment	Active Suicidal Ideation; Homicidal Ideation; Overdose
Assessment of Appropriateness	Buprenorphine Treatment (any contraindications)
	Is OBOT appropriate for patient at this time
Plan	MAT; Therapy; Referrals; Safety Measures

*Note: A comprehensive assessment may not be attainable on the first evaluation. Understanding the limitations of your program or setting in gathering information should be balanced with maintaining safety.

ASAM, 2014
SAMHSA, 2018

First Office Visit *Considerations*

- Review Prescription Drug Monitoring Program (PDMP)
- Signed Forms:
  - Consent for treatment
  - Consider Multi-Party Release, obtaining/releasing collateral information from/to all current or prior treatment teams
  - Establish a treatment agreement
- Examples can be found at:
  - https://pcssnow.org/resources/clinical-tools/

Screening and Assessment

Overall Goals:

- Identify individuals at higher risk, examples:
  - patients with polysubstance use
    - important to assess for use, intoxication, and withdrawal from sedative-hypnotics, including alcohol
  - those with complicating physical or behavioral health illnesses
- Assess social determinants of patient's health
- Develop recommendations and plan for treatment

- May use validated SUD and MH Screening/Assessment Instruments:
  - Drugs: Drug Abuse Screening Test (DAST-10)
  - Alcohol Use Disorders Identification Test (AUDIT)
  - PHQ-9

CSAT, 2004

Medical History

- Review of current symptoms
- Review Medical History/Chronic Medical Problems
- Relationship of medical symptoms to substance use
- Treatments and response:
  - Medical/Surgical
- Obstetrics/Gynecology:
  - Clarify pregnancy status
  - Pregnancies/Menstrual Status/Birth Control
- Dental care
- Medications:
  - Present/Past
  - Response/Side Effects
- Review of Labs, ECG, etc.

Psychiatric History

- Review of symptoms
- Relationship of psychiatric symptoms to substance use – establish temporality
- Prior diagnosis
- Trauma History
- Stressors
- Treatments and response:
  - Inpatient/Residential
  - Intensive Outpatient Programs (IOPs)/ Partial Hospitalization Programs (PHPs)
  - Outpatient
- Psychotropic medications
  - Present/Past
  - Response/Side Effects

Social and Family History

- Social history:
  - Birth and early development
  - Education:
    - Completing high school on time
  - Current employment status and prior occupations
  - Marital status, children, close supports
  - Living situation
  - Legal status? (No longer part of Dx)
  - Current Stressors, e.g. Housing/finance
- Family history:
  - Substance use disorders
  - Other psychiatric conditions
  - Other medical disorders

Substance Use History

- Substance use history:
  - Ask about all substances:
    - Nicotine
    - Opioids: prescription opioids, non-prescribed opioids, heroin/fentanyl, buprenorphine
    - Alcohol,
    - Cannabis
    - Hallucinogens,
    - Sedative/hypnotics,
    - Stimulants,
    - Other?

Substance Use History: Patterns

- Substance use history:
  - Age at first use
  - Determine patterns of use over time:
    - Frequency
    - Amount
    - Route
  - Assess recent use (past several weeks)
  - Cravings and control:
    - Assess temporality and circumstances
    - Determine if patient sees loss of control over use

Substance Use History: Relapse/Treatment

- Relapse/attempts to abstain:
  - Determine if the patient has tried to abstain
    - What happened?
    - What helped?
  - Longest period of abstinence
  - Identify triggers to relapse
  - History of MOUD in the past

- Treatment episodes:
  - Response to treatment
  - Attitudes towards various treatment settings and mutual support groups (AA, NA etc.)
  - Length of abstinence

Establishing the Diagnosis: *Effects and Consequences*

- Tolerance, intoxication, withdrawal:
  - Explain what is meant by tolerance
  - Determine the patient's tolerance and withdrawal history
  - Ask about complications associated with intoxication and withdrawal
- Consequences of use:
  - Determine current vs past levels of functioning
  - Aberrant behaviors (e.g. sedation, deterioration in function)
  - Identify consequences:
    - Medical
    - Legal
    - Family
    - Psychiatric
    - Employment
    - Other

Physical Examination

System	Findings
Dermatologic	Abscesses, rashes, cellulitis, thrombosed veins, jaundice, scars, track marks, pock marks from skin popping
Ear, nose, throat, and eyes	Pupils pinpoint or dilated, yellow sclera, conjunctivitis, ruptured eardrums, otitis media, discharge from ears, rhinorrhea, rhinitis, excoriation or perforation of nasal septum, epistaxis, sinusitis, hoarseness, or laryngitis
Mouth	Poor dentition, gum disease, abscesses
Cardiovascular	Murmurs, arrhythmias
Respiratory	Asthma, dyspnea, rales, chronic cough, hematemesis
Musculoskeletal and extremities	Pitting edema, broken bones, traumatic amputations, burns on fingers
Gastrointestinal	Hepatomegaly, hernias

Looking for signs of:

- Intoxication or and withdrawal
- Injection drug use
- Acute or chronic disease secondary to injection drug use.

SAMHSA, 2018
Kampman et al., 2015

Common Signs of Opioid Intoxication and Withdrawal

Intoxication Signs	Withdrawal Signs
Drooping eyelids	Restlessness, irritability, anxiety
Constricted pupils	Insomnia
Reduced respiratory rate	Yawning
Scratching (due to histamine release)	Abdominal cramps, diarrhea, vomiting
Head nodding	Dilated pupils
	Sweating
	Piloerection

SAMHSA, 2018
Kampman et al., 2015

PCSS Providers Clinical Support System

Laboratory Testing

Baseline Labs	Recommended Labs (Case by Case and Provider Preference)
Pregnancy Test (all women of childbearing age)	CBC (with differential) and platelet count
Urine Drug Screening Including Buprenorphine and Fentanyl	Serum Electolytes
	HIV
	Hepatitis C & B
	LFTs (GGT, AST, ALT, PT, INR, albumin)
	TB
	Consider Testing for STIs

SAMHSA, 2018
Kampman et al., 2015

PCSS Providers Clinical Support System

Initial Urine Drug Screening for MOUD Patients

- Point of care testing
  - Screening for:
    - Opiates
    - Marijuana
    - Cocaine
    - Amphetamines
    - Benzodiazepine
    - Alcohol bio-markers *
- Confirmation
  - On all new patients
  - On positive POC
- Adjunctive Testing
  - Pregnancy (all women of childbearing age)
  - Fentanyl (no current CLIA waived test available)

McDonell MG, J Addict Med 2016

PCSS Providers Clinical Support System

DSM-5 Criteria

- Impaired Control
  1. Larger amounts, longer time
  2. Inability to cutback
  3. More time spent, getting, using, recovering
  4. Craving
- Social Impairment
  5. Failure to fulfill major role obligations
  6. Social or interpersonal problems related to use
  7. Important social activities given up to use.
- Risky use
  8. Physically hazardous use
  9. Continued use despite associated recurrent physical or psychological problems.
- Pharmacological
  10. Tolerance
  11. Withdrawal

- A substance use disorder is defined as having 2 or more of these symptoms in the past year
- Tolerance and withdrawal criteria are not considered when taken appropriately by Rx.
- Severity is related by the number of symptoms.

2-3 = mild
4-5 = moderate
6+ = severe

PCSS Providers Clinical Support System

Office-Based Opioid Treatment (OBOT) Level of Care

- Several factors are considered when deciding whether your OBOT is appropriate for the patient:
  - Diagnosis
  - Co-occurring disorders
  - Physiologic dependence or high risk
  - Stability/Need for additional support
  - Insurance considerations
  - Patient preference
  - Risks and benefits
  - Logistics: Can patient adhere to appointment and drug testing recommendations

- These may not preclude initiation of medication but may indicate a need for treatment in a higher level of care if available.

PCSS Providers Clinical Support System

General Principles: Prior to starting MOUD

- First meeting/assessment can also be used to give the individual information on Medication for Opioid Use Disorders (MOUD)
  - The goal is to avoid continued drug and alcohol misuse
    - Misuse of other drugs is prevalent among persons with an OUD and may interfere with overall treatment.
  - The need to inform provider if other medications are prescribed for any purpose
  - The need to store the medication safely; how will the patient do that?
  - How they must prepare to be initiated on the medication (i.e., need to be in mild-moderate withdrawal)

PCSS Providers Clinical Support System

OBOT and Concurrent SUDs and Non-prescribed Medication Use

- Medications for OUDs, are not for other drug use disorders.
  - Although reductions in other drug use may occur indirectly as a result of participating in monitored treatment.
- Other concurrent substance use disorders:
  - May need more intensive treatment such as Intensive Outpatient Programs or Residential Treatment in conjunction with initiation of MOUD.

Treatment Agreement

- Before getting started with treatment:
  - Make goals of treatment and expectations clear to patients
  - Consider Obtaining multi-disciplinary Release
- Use Treatment Agreements that outline terms of treatment:
  - What the patient can expect from you
  - What you will expect/require from the patient
  - Information for patients about buprenorphine and its safe use
  - Informed consent (see Clinical Tools at www.pcssNOW.org)
  - Know referral sources in the community if patients need more intensive care
  - Example Agreement can be found in TIP(s) - 40 and 63:
    - https://www.ncbi.nlm.nih.gov/books/NBK64245/pdf/Bookshelf_NBK64245.pdf

SAMHSA, 2018

Summary

- The initial evaluation is comprised of building a therapeutic alliance, obtaining data for treatment planning and initiation.
- Components of over an overall assessment include history of medical, psychiatric and substance use disorders.
- Comprehensive physical exam can identify current state of health and areas for further evaluation and treatment.
- Office-Based Opioid Treatment (OBOT) can be appropriate for patients able to receive the level of care that can be provided in an outpatient setting.
- Some patients may benefit from stabilization offered by higher levels of care before engaging in office-based care.
- Methadone or Naltrexone-ER are other options for MOUD and may be more suitable for patients
  - who prefer either of these options
  - OBOT is not effective or appropriate.

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Polling #2

In taking a patient history the clinician should:

a. Maintain a confrontational stance to get honest answers
b. Assure patient that the objective is concern for their health and is discussed confidentially
c. Not ask about other drug use as it will only create problems
d. Should always have a release to talk to family members or support network before starting MOUD.

Polling #3

Moderate to severe opioid use disorder is different from plain physical dependence because:

a. There is tolerance

b. There are withdrawal symptoms on discontinuation of the drug

c. There is compulsive use in the face of a variety of problems

d. Pain is the primary drive to continued use of the drug

Polling #4

When obtaining a substance use history in the evaluation of a patient for buprenorphine treatment one should remember:

a. Buprenorphine is also effective in treating alcohol and other drug use

b. Patients with opioid use disorder rarely misuse other drugs

c. Individuals using multiple substances may require more intensive treatment

d. If a patient is taking benzodiazepines, they cannot be prescribed buprenorphine

Case Study #1

The Lawyer

Case #1 Lawyer, beginning to use daily
Clinical Management

Mr. Smith is a forty–year-old man who comes to your office asking to be treated with buprenorphine. He is a criminal defense attorney in private practice, and he knows about buprenorphine because you are treating some of his clients. His goal is to use buprenorphine during the week and occasionally use heroin (by snorting) on the weekend. He has used heroin for the past 5 years.

For the past 6 months, he has used heroin primarily on the weekend, but he is concerned now because he has begun to use small amounts of heroin daily. If he doesn't use heroin, he gets loose stools, is irritable, and has difficulty getting and staying asleep. He has no desire to completely stop heroin use, but he doesn't want to use it during the week.

His passion is playing jazz and he has organized a band. He says that heroin use is common in the club where his band plays. All the members of the band use heroin and many of his friends who come to the club also snort or inject heroin. He rarely buys heroin, as his friends usually give it to him.

Case #1 Lawyer, beginning to use daily cont.

His only other drug use is marijuana and alcohol (3-6 drinks/night on the weekend), again primarily used on the weekend. He has never been arrested or had significant medical consequences from his heroin use. He is not married. He has a 14-year-old son who he has supported and sees often.

Case #1 Lawyer, beginning to use daily cont.

Polling Question

What is the diagnosis?

- ***Would you prescribe buprenorphine?***

Discussion points:

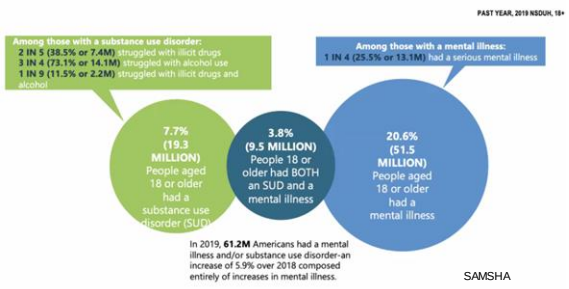
- **How would you approach this with him?**
- **What aspects of his presentation might you use to point out his assets and liabilities?**
- **What is your treatment plan for him?**

Module 5: Specialty Topics

Objectives

1. Diagnose and discuss appropriate treatment of co-occurring substance use and other psychiatric disorders
2. Discuss strategies for treating acute, perioperative, and chronic pain for patients taking buprenorphine
3. Describe appropriate treatment of opioid use disorder during pregnancy
4. Discuss appropriate treatment of opioid use disorder in adolescents
5. Addressing treatment of patients with HIV and an OUD.

Mental Illness and Substance Use Disorders in the United States



Depressive and Anxiety Symptoms

- Mood instability and anxiety symptoms are common at treatment entry
- Symptoms may resolve within few days to a few weeks of stable SUD treatment
- Symptoms that persist beyond acute intoxication and withdrawal can be worthwhile targets for treatment:
  - For example, with Selective Serotonin Reuptake Inhibitors
- Patients treated with MOUD respond to medications for depression and anxiety at rates similar to those without opioid use disorders

Trauma and Substance Use D/O

- Trauma is highly associated with substance use disorders both before and after the onset.
  - Lifetime trauma is reported in up to 66% of treatment seeking patients.
- Post Traumatic Stress Disorder, PTSD, is known to often precede the onset of SUDs
  - Prevalence of lifetime PTSD in patients with an SUD ranges from 26% to 52%
    - Women 27.9% - Men 51.9%
    - SUD seen 4.46 x more often in women **with** PTSD **than without**.
    - Men 3 times more often
- Comorbid illness is more difficult to treat than either individual disorder.
  - Treatment of the SUD often results in improvement of PTSD symptoms but not visa versa.
  - Overtime the SUD becomes a more difficult and persistent illness.
- Treatment should include both concurrently.
  - Combination of psychotherapeutic and pharmacologic management is most effective.

Wav e 2 of the National Epidemiologic Survey on Alcohol and Related Condition 2010
Sartor et al., 2011
McCauley, et al, Clin Psychol (New York). 2012 Sep 1; 19(3):

Treatment of Co-Occurring Psychiatric Disorders

- With consent, attempt to gain collateral information from other providers, family, and/or friends.
- Repeatedly review the Prescription Drug Monitoring Program.
- As previously outlined: **Avoid use of benzodiazepines**
  - Risk of misuse (taken other than prescribed), is an indicator of polysubstance use and associated with more erratic behavior
  - Increase risk of respiratory depression and overdose.
  - The first-line treatments for anxiety and depression are:
    - Selective serotonin reuptake inhibitors alone or with norepinephrine reuptake inhibitors
    - Psychotherapy (e.g.: cognitive behavioral therapy)
- Stimulants
  - If there is concern for Attention Deficit Hyperactivity Disorder (ADHD), consider Adult ADHD Self-Report Scale (ASRS) or refer patient for a psychiatric assessment
  - Continue stimulants if the diagnosis has been definitively established.

Chang et al., 2005
Kampman et al., 2015

Treatment of Co-Occurring Psychiatric Disorders

- Attempt to facilitate treatment in an integrated care setting.
- Treat the co-occurring illnesses as equally important to manage.
- Reduction in use and for many abstinence:
  - will be important in establishing improvement of symptoms (neurobiologic stabilization)
  - will often also improve adherence to psychotherapeutic and medication treatment recommendations.

Patients currently on *Buprenorphine* Acute Pain Management

- Different Approaches:
  - Initially non-opioid analgesics (ketorolac or NSAIDs)
  - Continue same buprenorphine dose but in a split regimen
    - Buprenorphine analgesic duration is only a few hours
    - May add or continue non-opioid analgesics
  - Increase buprenorphine dose while continuing split dose
  - Add full opioid to buprenorphine regimen
    - Typically, only done in a controlled setting
  - Stop buprenorphine and initiate full agonist therapy dosed to effect. Then return to buprenorphine following stabilization.
    - (Note: this approach may destabilize the patient and lead to worsening outcomes)

Lembke A, et al, Pain Med. 2019
Buresh M, et al, J Gen Intern Med. 2020

Patients currently on *Buprenorphine* Perioperative Management

- Problem to overcome:
  - Patients fear mistreatment
  - Providers fear deception
  - Lack of consensus in the field – often based on preference of surgical/anesthesia teams
- Pre-Op:
  - Confirm Multi-Party Consent
  - Coordination of care with providers
  - If patient is already on Partial Agonist:
    - There should be strong consideration for continuing buprenorphine on consultation with surgeon.
      - Continue and use full agonists as needed during and after procedure.
    - Alternatively discontinue buprenorphine 24 hrs prior to procedure.
    - Remember: Higher dosing of short-acting opioids may be required post surgical due to tolerance

Merrill et al., 2002
Wenzel et al., 2016

Patients currently on *Buprenorphine* Post Op Options

Options	Considerations
Continue partial agonist at optimized dosing, with full agonist as indicated for breakthrough pain as indicated. Return to maintenance partial agonist dose as tolerated post-op.	More frequent partial agonist dosing Consider an increase in total dose Review the plan with the patient and surgeon/anesthesiologist. Establish signs and symptoms indicating appropriate time to return to baseline dose.
Discontinue partial agonist, will have to provide additional full agonist opioid to treat both pain and to satisfy opioid debt in dependent patients. Reinduction onto partial agonist post-op as pain subsides.	Open communication with surgeon Short acting full agonists for breakthrough pain Discuss risk of relapse with the patient Review security and safety of agonist medication

Merrill et al., 2002
Wenzel et al., 2016
TIP 63 – SAMHSA 2019

PCSS Providers Clinical Support System

Patients currently on *Naltrexone* Acute Pain Management

Clinical Scenario	Management Options
Mild Pain	Non-opioid options, e.g., Full dose of NSAIDS (e.g., ketorolac injection)
Elective Surgery	Schedule surgery in accordance with patient's treatment. · Oral naltrexone: Schedule surgery at least 72 hours after d/c naltrexone · Extended-release naltrexone: Schedule surgery at least 4 weeks after injection. May need to use oral product for a few days.
Major Pain or Emergency	· Regional anesthesia · Conscious sedation · General anesthesia (Note: high potency fentanyl analogues may be needed to override blockade)

Alford et al., 2006
CSAT, 2004
Kampman et al., 2015
WHO, 2009

PCSS Providers Clinical Support System

Patients Currently on *Methadone* Acute Pain Management

- May split the dose to 3 or 4 times a day for greater analgesia.
- May require higher dosing of methadone and higher doses of additional full agonists, due to increased opioid tolerance.
- Consult a pain specialist or addiction medicine specialist

PCSS Providers Clinical Support System

Individuals Treated with MOUD CoMorbid for a Chronic Pain Disorder

- Continue buprenorphine
  - Consider splitting the dose and/or increase as indicated.
- Try non-opioid and adjuvant analgesics
- Consider non-pharmacologic therapies
- Consider Multidisciplinary Team Approach
- Consider consulting a pain medicine specialist

Opioid Use Disorder and Pregnancy

- Epidemiology:
  - 15% of pregnant women had used illicit substances in the past year
  - 7% of women report using prescription opioid pain relievers during pregnancy.
  - Of those, 1 in 5 report misuse of opioids
  - ACOG recommends screening for substance use
    - All patients
    - Important at first prenatal visit.

- Recommend using and screening tools:
  - All patients Screening Brief Intervention and Referral to Treatment (SBIRT) – validated in primary care
  - 5P's (Parents, Peers, Partner, Past, Present);
  - NIDA Quick Screen
  - CRAFFT (for women 26 years or younger)

Vital Signs: Prescription Opioid Pain Reliever Use During Pregnancy — 34 U.S. Jurisdictions, 2019
ACOG/ASAM 2017

Methadone Treatment in Pregnancy

- Commonly used for pregnant women with OUD
  - Though methadone and buprenorphine are both considered first line treatments
- Methadone adjustment during pregnancy:
  - Second and third trimester:
    - With advancing gestational age: Plasma levels of methadone progressively decrease, and clearance increases
      - The half-life of methadone falls from an average of 22–24 hours in non-pregnant women to 8.1 hours in pregnant women
    - Assess for increased craving or discomfort
      - Consider possible increased dose for stabilization,
      - Split dosing is often required for adequate avoidance of opioid withdrawal symptoms and/or craving

ASAM Guidelines., 2015
J Addict Med. 2018

Use of Buprenorphine With or Without Naloxone in the Pregnant Patient

- Buprenorphine mono-product has been the most well studied.
  - Initial concerns:
    - naloxone fetal effect.
    - if injected it will not cause precipitated withdrawal.
- Buprenorphine/Naloxone – growing literature and recommendations
  - FDA designates **sublingual** naloxone:
    - No known teratogenic effects in animals
    - Controlled studies have not been conducted in humans
  - Evidence points to buprenorphine-naloxone safety in pregnancy, and it is frequently used.
    - Minimal naloxone absorption
    - Reducing injection drug use diversion.

Wiegand SL, et al., *Obstet Gynecol.* 2015, Debelak K, et al. *Am J Addict.* 2013
ASAM Updated OBOT Guidelines 2019, Lund et al., 2013

Buprenorphine Treatment in Pregnancy

- Initiation should begin when a woman shows objective, observable signs of withdrawal, but before severe withdrawal symptoms are evidenced.
  - >23 weeks gestation should have in-clinic observation during initiation of treatment with buprenorphine. Hospitalization may be advisable.
- Buprenorphine dosing is the same as in nonpregnant women.
  - Dosage is not linked to increased incidence of NOWS
- During pregnancy: No significant dose increases needed though may require split dosing in 3rd trimester
- Postpartum: Continue current dose of buprenorphine.
  - Return to the combination product if patient was converted to the mono product during pregnancy. No dosage changes.

Jones H, et.al, 2013; Jones et al., 2014; Lund et al., 2013).

Neonatal Opioid Withdrawal Symptoms (NOWS)

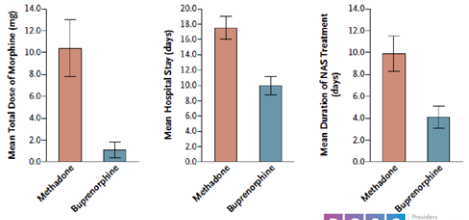
- Epidemiology:
  - Increasing incidence of NOWS
  - Incidence of NOWS in newborns born to women with OUD is between 70 and 95% and ~50% of infants will need treatment

- Symptoms:
  - Irritability, fever, diarrhea, hyperreflexia, seizure
  - Begins 24-72 hours of birth, with peak symptoms at 3-4 days, and continues for up to one week
- Complications:
  - Associated with untreated maternal OUD
    - Increased risk of placental abruption, preterm labor, maternal obstetric complications, and fetal death

Kakko et al., 2008
Patrick at al., 2015
Smith et al., 2017

Maternal Opioid Treatment:
Human Experimental Research (MOTHER) Study

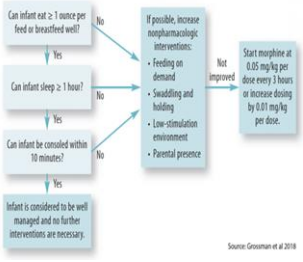
- Buprenorphine vs Methadone effect on NOWS
  - One tenth the amount of morphine needed to control symptoms
  - Nearly one half the time spent in the hospital
  - More than a third reduction in duration of treatment



Jones et al., 2010

Treatment of NOWS

- Non-Pharmacologic Novel Approaches:
  - "Eat, Sleep, Console"
  - Rooming in results in a reduction in NOWS length of stay and cost
- Medications:
  - Opioid therapy is preferred first-line intervention
    - PRN Morphine/Methadone
  - Clonidine



Holmes et al., 2016
Hudak et al., 2012
Slowiczek L, 2018

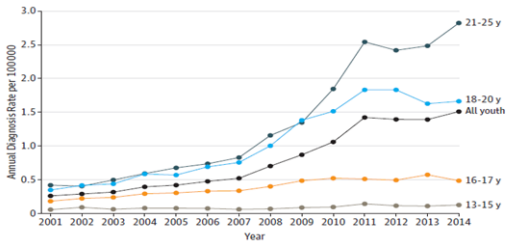
https://www.myamericannurse.com/caring-for-infants-and-families-affected-by-neonatal-abstinence-syndrome/

Breast Feeding

- Breastfeeding not contraindicated while taking MOUD
  - Improved maternal and infant bonding
  - Favorable effects on NOWS
- Transferred amounts of methadone or buprenorphine are insufficient to prevent symptoms of NOWS
- Levels in human milk are low with calculated infant exposures of the maternal weight-adjusted dose being:
  - <3% for methadone
  - 2.4% for buprenorphine

Sachs et al., 2013

New Diagnoses of Opioid Use Disorder in Youth



Hadland et al., 2017

Adolescents

- ***American Academy of Pediatrics***:
  - Recommends that pediatricians consider offering MOUD to their adolescent.
- ***FDA Approved Medication Options:***
  - Buprenorphine (approved for patients>16yo)
    - Often considered to be the first choice
    - Much better treatment retention in comparison to no MOUD
    - Decreased injection drug use
  - Methadone
    - A person under 18 years of age is required to have had two documented unsuccessful attempts at short-term detoxification or non-medication treatment.
    - Parental of guardian consent.
  - Naltrexone ER (approved for patients>18yo)
- ***Psychosocial Treatment Options:***
  - Family Intervention Approaches
  - Educational and/or Vocational support
  - Behavioral interventions; CBT and Contingency Management

AAP, 2016; Fishman et al., 2010; ASAM Guidelines., 2015; Woody et al., 2008

Patients with HIV Infection

- CYP 3A4 is the primary hepatic enzyme involved in metabolism of both methadone and buprenorphine
  - There are no clinically relevant buprenorphine-ART interactions.
  - This was most frequently an issue with older ART and methadone
  - There is little or no interactions with naltrexone
- Providers should consider:
  - referral to specialized HIV treatment programs and services – if available
  - coinfection with HIV and HCV is common (62%–80%) among injection-drug users who have HIV.
    - People with HIV/AIDS should be vaccinated against hepatitis A and B and tested for hepatitis B and hepatitis C.
    - Consider screening for STIs and TB

CSAT, 2004
McCance-Katz et al., 2010
Moatti et al., 2000
Montoya et al., 1995
Centers for Disease Control and Prevention;

Patients with Renal Failure

- Suitable to use MOUD medications in patients with renal failure
- No significant difference in kinetics of buprenorphine in patients with renal failure versus healthy controls
- No significant side effects in patients with renal failure
- Buprenorphine and methadone can be prescribed to patients undergoing hemodialysis
- Naltrexone is safe in dialysis, but blood should be continually monitored.

Patients with Compromised Hepatic Function

- Buprenorphine undergoes hepatic metabolism, primarily by the CYP450 3A4 system
- Patients with compromised hepatic function,
  - LFTs 3-5 times normal, could have reduced metabolism of buprenorphine, with resultant higher blood levels of the medication.
  - Patients should be monitored closely though not shown to be clinically relevant.
  - Acute fulminant hepatitis should be appropriately evaluated and treated.
    - Consider the risks of delaying treatment.
- No specific hepatotoxicity has been demonstrated for either methadone or buprenorphine

Photo by: CDC/Dr. Thomas F. Sellers/Emory University
Bruce RD, Am J Drug Alcohol Abuse, 2007

Summary

- Approximately 60% of adults with SUD had a co-occurring psychiatric disorder. Diagnosis and treatment of mental illness can potentially have a positive impact on OUD.
- Peri-operative pain management practices for patients with OUD are variable and require close coordination with surgical team.
- Patients taking methadone or buprenorphine for OUD, should be continued on these medications and pain treated with additional modalities.
- Methadone has historically been considered first-line treatment of OUD in pregnant women. However, increasing evidence demonstrates that buprenorphine/naloxone is well-tolerated and efficacious with potential benefits for the newborn.

Summary

- Although buprenorphine is approved for individuals over 16 years of age and methadone is approved for individuals over 18 years of age providers can consider naltrexone ER in combination with psychosocial treatment options for adolescents with OUD.
- There is no significant MOUD interactions with ART for HIV, encourage linking care.
- Buprenorphine is suitable to use in patients with renal failure.
- Unless the patient has acute hepatitis, pharmacotherapy with methadone or buprenorphine is not contraindicated on the basis of mildly elevated liver enzymes and in most cases should not be delayed.

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Polling #5

Substance-induced psychiatric symptoms vs. a primary psychiatric conditions are identified:

a. Easily on the first meeting with the patient
b. Only after a full month of abstinence
c. Without regard for family history
d. There is no specific period of time used to differentiate these disorders

Medication Treatment Clinical Application

Clinical Uses of Buprenorphine

- Initiation
- Stabilization and Maintenance
- Withdrawal

Buprenorphine Initiation
Rationale

- Overall goal:
  - Assist patients in switching from full opioid agonists, whether legally prescribed or obtained from other sources, to prescribed buprenorphine.
- Specific goals of buprenorphine initiation:
  - Identify dose of buprenorphine at which the patient:
    - Significantly decreased or absent withdrawal symptoms
    - Has minimal/no side effects
    - Experiences decreased cravings
    - Discontinues or markedly reduces use of other opioids

SAMHSA, 2004

Buprenorphine Formulations

- Choice of formulations is based on:
  - Insurance/Third party payer considerations
  - Patient preferences
  - Safety
  - Diversion potential
- Formulations:
  - Sublingual films, tablets
  - Depot injection
  - Subdermal implants (taken off the market in the US in 2020)
- All the approved forms have demonstrated similar efficacy for treating opioid use disorder

NOTE: Buprenorphine formulations by transdermal (via patch), intravenous (via injection), and buccal delivery are available for analgesic use only. These specific products are not approved for treating OUDs

SAMHSA, 2016, 2016

Buprenorphine Formulations for Opioid Use Disorder

Content	Route	Product	Available Doses	Equivalent Dose
Combo product (with Naloxone)	Sublingual	Film - Generic, Suboxone	2 mg Bup/0.5mg Nx	
			4 mg Bup/1mg Nx	
			8 mg Bup/2mg Nx	8mg
			12mg Bup/3mg Nx	
	Sublingual	Tablet-Generic	2 mg Bup/0.5mg Nx	
			8 mg Bup/2mg Nx	8mg
	Sublingual	Tablet-Zubsolv	1.4mg Bup/0.36mg Nx	
			2.9mg Bup/0.7mg Nx	
			5.7mg Bup/1.4mg Nx	5.7mg
			8.6mg Bup/2.6mg Nx	
			11.4mg Bup/4mg Nx	
	Sublingual	Film - Cassipa	16mg Bup/4mg Nx	2 x 8mg
Mono Product	Sublingual	Tablet-Generic	2mg Bup	
			8mg Bup	8 mg
	Subcutaneous	Sublocade	100mg	approx 12 mg
			300mg	approx 24 mg
Pending Mono Product	Injectable	"Brixadi"	Weekly and Monthly	

Dong R, Drugs RD 2019

Buprenorphine Initiation
First Prescription

- Factors/Considerations for treatment
  - Review that patient meets initiation criteria
  - How is patient to pay for treatment/medication
    - Insurance vs Self Pay
  - Confirm the pharmacy they will be using.
  - Review urine drug testing protocols/expectations

- Location of Initiation
  - Office Initiation:
    - Patient fills prescription and brings medication to the office where it will be administered
  - Home Initiation:
    - Patient goes home with instructions, follow-up appointment, and a prescription for medicine
    - May be considered as an option for all patients
    - Most often done with patients having prior experience of taking buprenorphine

Office Buprenorphine Initiation
Day #1

- Timing
  - Some offices prefer inductions earlier in the week – Consider Monday, Tuesday and avoid Fridays
  - Consider scheduling office initiation earlier in the day

- Decrease likelihood of precipitated withdrawal at initiation by:
  - Ensuring mild to moderate withdrawal at the time of initiation
    - Document using Clinical Opiate Withdrawal Scale (COWS)
  - Start with low dose: 2-4mg equivalents

Office Buprenorphine Initiation
Day #1

- Instruct the patient to abstain from any opioid use for a minimum of:
  - 12-16 hours for short-acting opioids
  - 24 hours for sustained-release opioid medications
  - 36 hours for methadone
- Observe and document Mild vs. Moderate withdrawal:
  - **NOTE:** Be aware of **Fentanyl;** do not induce unless moderate withdrawal (COWS 13 to 15) is observed.

Clinical Opiate Withdrawal Scale

For each item, circle the number that best describes the patient's signs or symptom. Rate on just the apparent relationship to opiate withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increase pulse rate would not add to the score.

Patient's Name:_____ Date and Time _____/_____/_____:_____

Reason for this assessment:_____

Resting Pulse Rate: _____beats/minute *Measured after patient is sitting or lying for one minute* 0 pulse rate 80 or below 1 pulse rate 81-100 2 pulse rate 101-120 4 pulse rate greater than 120	**GI Upset:** *over last ½ hour* 0 no GI symptoms 1 stomach cramps 2 nausea or loose stool 3 vomiting or diarrhea 5 Multiple episodes of diarrhea or vomiting
Sweating: *over past ½ hour not accounted for by room temperature or patient activity.* 0 no report of chills or flushing 1 subjective report of chills or flushing 2 flushed or observable moistness on face 3 beads of sweat on brow or face 4 sweat streaming off face	**Tremor** *observation of outstretched hands* 0 No tremor 1 tremor can be felt, but not observed 2 slight tremor observable 4 gross tremor or muscle twitching
Restlessness *Observation during assessment* 0 able to sit still 1 reports difficulty sitting still, but is able to do so 3 frequent shifting or extraneous movements of legs/arms 5 Unable to sit still for more than a few seconds	**Yawning** *Observation during assessment* 0 no yawning 1 yawning once or twice during assessment 2 yawning three or more times during assessment 4 yawning several times/minute
Pupil size 0 pupils pinned or normal size for room light 1 pupils possibly larger than normal for room light 2 pupils moderately dilated 5 pupils so dilated that only the rim of the iris is visible	**Anxiety or Irritability** 0 none 1 patient reports increasing irritability or anxiousness 2 patient obviously irritable anxious 4 patient so irritable or anxious that participation in the assessment is difficult
Bone or Joint aches *If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored* 0 not present 1 mild diffuse discomfort 2 patient reports severe diffuse aching of joints/ muscles 4 patient is rubbing joints or muscles and is unable to sit still because of discomfort	**Gooseflesh skin** 0 skin is smooth 3 piloerrection of skin can be felt or hairs standing up on arms 5 prominent piloerrection
Runny nose or tearing *Not accounted for by cold symptoms or allergies* 0 not present 1 nasal stuffiness or unusually moist eyes 2 nose running or tearing 4 nose constantly running or tears streaming down cheeks	Total Score _____ The total score is the sum of all 11 items Initials of person completing Assessment: _____

Score: 5-12 = mild 13-24 = moderate 25-36 = Moderate >36 = severe withdrawal

Office Buprenorphine Initiation
Patient Education

- Sublingual tablets and films must be held under the tongue several minutes to dissolve

- **Instruct to:**
  - Start with a moist mouth, avoid acidic drinks (coffee or fruit juice)
  - Avoid using nicotine products as this interferes with absorption
  - Avoid speaking with the sublingual medication
  - Keep dissolving medicine under tongue
  - After medication is completely dissolved, leave in mouth an additional 5 min before swallowing or spitting remaining sputum

Buprenorphine Initiation
Day #1

If patient is not in opioid withdrawal on arrival in office:

- Assess and confirm time of last opioid use
- Have patient wait in the office until you see evidence of withdrawal

  OR

- Consider home initiation

Photo by: Wouterhagens

Office Buprenorphine Initiation

- Patient dependent on short-acting opioids (e.g. heroin/oxycodone/ hydrocodone):
  - Instruct patient to abstain from any opioid use for 12 to 24 hours prior to initiation
    - Waiting at least 36 hours for methadone
  - Arrive in mild-moderate withdrawal at initiation visit
    - Use opioid withdrawal scale (COWS > 8):
      - Document and assess severity of withdrawal

Office Buprenorphine Initiation

- Start buprenorphine when patient manifests signs of opioid withdrawal (COWS> 8)
  - Starting at lower doses of buprenorphine/naloxone less likely to precipitate withdrawal.
- Example:
  - opioid withdrawal verified,
  - initial dose of 2 mg/0.5 mg can be given.
  - patients continues opioid withdrawal
    - administer another 2 mg/0.5 mg dose and continue approximately every 2 hours as needed (holding for sedation)
- Initiation should be conducted slowly;
  - Be alert to any increase in withdrawal symptoms, this may suggest precipitated withdrawal.
  - Consider treating unrelieved withdrawal symptoms with continued small incremental dosing and/or nonopioid therapies as needed

TIP 63

Buprenorphine Initiation
Review

- First dose: 2-4 mg SL buprenorphine/naloxone
- Monitor in office for 2+ hours after first dose
  - Relief of opioid withdrawal symptoms should begin within 30-45 minutes after the first dose
- Re-dose every 2-4 hours, if opioid withdrawal subsides then reappears
- Stabilize at dose that eliminates craving; typical dose range from 8 mg to 16 mg
- Gradually increase dose after establishment of a steady state (approx. 5 days) as needed for continued craving.

Note: This can be increased more rapidly if the patient has a significant craving.

Precipitated Withdrawal Management

- If opioid withdrawal worsens shortly after the first dose buprenorphine may have precipitated a withdrawal syndrome
- If a patient has precipitated withdrawal, consider:
  - Giving another 2mg dose of buprenorphine, attempting to provide enough agonist effect from buprenorphine to suppress the withdrawal

OR

  - Stopping the initiation, provide symptomatic treatments for the withdrawal symptoms, and have patient return the next day

Since the latter risks losing the patient, the first option is preferred.

Home Initiation
Multiple Approaches but Subtle Clinical Variance

- Similar outcomes noted for observed and home initiation in terms of safety and efficacy
- Process:
  - Teach patient about how bup/nx works and how it is absorbed
  - Review typical withdrawal symptoms with patient
    - Start assessing withdrawal symptoms 12 hours after short-acting opioids and 24 - 36 hours long-acting opioids
    - Self administer 2 to 4 mg bup/nx when experiencing mild to moderate withdrawal symptoms.
    - Self assess again in 1-3 hours. If still withdrawing, self administer another 2 to 4mg dose
  - May repeat until a maximum total dose of 8-16mg the first day

Home Initiation Instructions
Day #2

- Day #2: Continue dose established on Day #1
  - Encourage patient to preferably take Day #1 dose on the morning of Day #2
  - Contact patient on Day #2 to assess dose response
  - Response to contact with patient:
    - If patient feels well, instruct patient to continue Day #1 dosing
    - If patient is experiencing cravings or discomfort consider increasing dose by 2-4 mg

OR

    - discuss relapse prevention and assure patient that discomfort will stabilize as the medication reaches a steady state.
  - Avoid rapid dose adjustments

Buprenorphine Initiation
Day #2 and Beyond

- Stabilization will occur for most patients between 8 to 16mg per day:
  - Most individuals do not need more than 16mg per day but occasionally higher doses may be needed for persistent cravings and/or ongoing opioid use
    - Most insurance companies limit daily doses to 24 mg
    - Though there is approval for a maximum dose of 32mg, doses above 24mg may increase risk of diversion
  - Note – If there are concerns for diversion:
    - Consider more intensive monitoring [E.g. more frequent urine testing, shorter prescription durations, supervised dosing]

Initiation to Buprenorphine in the Patient Using Fentanyl

- Fentanyl – often sold as heroin in the street drug supply is:
  - a synthetic opioid
  - with strong affinity to the opioid mu receptor
  - highly lipophilic
- Initiation to buprenorphine may be problematic due to:
  - fentanyl competitive binding to the opioid receptor
  - persistent slow release of fentanyl after repetitive use from adipose cells resulting in difficult stabilization with buprenorphine.
- Some patients having tried buprenorphine on the street and experiencing withdrawal symptoms will present choosing to initiate methadone.
- If in the hospital setting one can use full opioid agonists or buprenorphine products not approved for use in the outpatient setting to assist in transitioning patients to maintenance buprenorphine.

Using Alternative Methods in Transitioning Patients from Fentanyl to Buprenorphine
"High Dose Initiation"

- There is literature primarily out of emergency medicine using "high dose" buprenorphine in the transition.
  - Patients presenting in withdrawal, COWS > 13, known to have been using fentanyl, can be given 8 to 16mg on first dose. If withdrawal continues you may increase this 8mg at a time up to 32mg as needed.
    - If given 24 to 32 mg, this may have the additional benefit of holding off withdrawal for greater than 24 hours to get to follow-up care.

Herring AA, *JAMA Network Open*. 2021;4(7):

Using Alternative Methods in Transitioning Patients from Fentanyl to Buprenorphine
"Micro or Low Dose" Initiation

- This protocol has been established in a variety of ways.
- Start with a very low dose and titrates up to a standard maintenance dose.
  - The most available method conducive to use in the outpatient setting involves instructing the patient to split a 2mg BPN/NTX film or tablet in quarters initially.
  - Example:
    - Day 1: 0.5 mg once a day
    - Day 2: 0.5 mg twice a day
    - Day 3: 1 mg twice a day
    - Day 4: 2 mg twice a day
    - Day 5: 3 mg twice a day
    - Day 6: 4 mg twice a day
    - Day 7: 12 mg (stop other opioids in patients with co-occurring pain)

Note: It is prudent to use alpha 2 agonist medications, clonidine or lofexidine, and other comfort medications to assist in reducing any discomfort patient may experience during the transition.

Randhawa PA, 2020

PCSS Providers Clinical Support System

Stabilization and Maintenance

- Continue to reassess patient technique in medication administration:
  - Usual administration of buprenorphine/naloxone dosing is daily however preferably no more than twice-daily dosing
  - For proper absorption, no more than two film strips or two tablets should be taken at once

- Adjust daily dose by increments of 2-4 mg as needed:
  - Increase primarily for persistent cravings

PCSS Providers Clinical Support System

How Long Should Buprenorphine Maintenance Be?

- Evidence is of maintaining treatment;
  - Studies of up to 16 weeks show high relapse rates on medication withdrawal
  - There is improved retention rates with extended buprenorphine maintenance treatment.
- Continue maintenance as long as the patient is benefitting from treatment; (decreased substance use, meeting employment, educational, relationships goals):

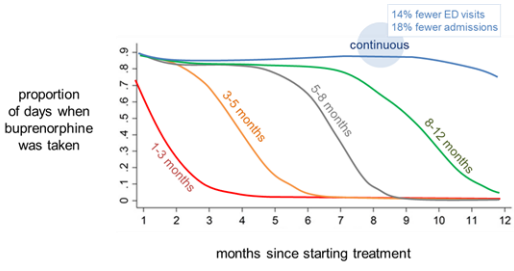
Key Point : Providers may have discussions regarding reduction in dose with improving stability or patient preference however:

- Caution patients about discontinuing medication too early in treatment

Kakko et al., 2003
Weiss et al., 2011

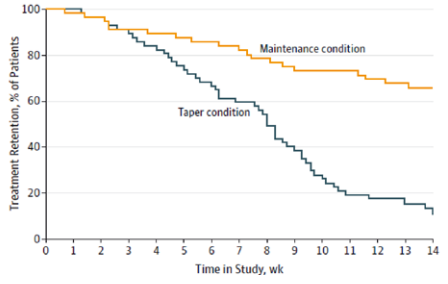
PCSS Providers Clinical Support System

Optimal Duration of MOUD



Lo-Ciganic et al., 2016

Treatment Retention and Buprenorphine Dosage



Fiellin et al., 2014

XR-NTX Practical Considerations

- Logistics
  - Adequate insurance or program coverage
    - Out of pocket XR-NTX is ~ $1100/dose
  - Ordered from specialty pharmacy, shipped to physician
  - Keep refrigerated until dosing visit
- Check Opioid free status of patient by self-report and verified by urine drug screen
- Consider administering Naloxone challenge before first dose

  OR
- Preload oral Naltrexone

Naltrexone
Initiation

- Naltrexone is an opioid receptor antagonist and can only be started in individuals who are completely free of opioids
- Official prescribing information for injection naltrexone recommends 7-10 days "washout" period between the two phases: last dose of opioid and first dose of NTX
- When naltrexone is given to patients who are physically dependent, or have opioids in their system, naltrexone will displace opioids off the receptor and withdrawal symptoms will rapidly emerge
  - Precipitated withdrawal as opposed to a slow onset of a spontaneous withdrawal can look atypical and can involve delirium

XR-NTX Considerations

- XR-NTX injection
  - Side Effects
    - Opioid blockade may interfere if acute pain management is needed
    - Headaches, nausea, flu-like: common with 1st injection, but not subsequent injections
    - Injection site pain: common

Medically Supervised Acute Withdrawal

Approach	Details
Symptomatic-only treatment	A variety of adjunctive medications are used to decrease specific symptoms of withdrawal
Rapid medically supervised withdrawal using antagonist	Naltrexone is added few (3•4, days after the last dose of opioid starting with very low doses (3-6 mg} Emerging withdrawal symptoms are treated with adjunctive medications to minimize discomfort

Acute Withdrawal Using Buprenorphine

Withdrawal can be acute treatment or termination of period of maintenance therapy

- Many regimens can be used based on clinical practice and patient needs

- **Acute Treatment**
  - Example: Withdrawal over 3 days:
    - First day: 8/2-12/3 mg s.l.
    - Third (last) day: 6/1.5 mg s.l.
  - Can extend taper by 2-3 days if patient has trouble tolerating the procedure; offer reassurance and treat emerging insomnia, anxiety, and/or myalgias

NOTE: Studies of withdrawal alone have shown this is unlikely to result in long-term abstinence

- **Termination from Maintenance**
  - Slow taper over weeks to months.
  - Lower symptom severity than full agonists but symptoms may be prolonged.
  - May add symptomatic treatments.

Adjunctive Medication Options
During Medically Supervised Withdrawal

Withdrawal Symptoms	Adjunctive Medications
Anxiety/restlessness	▪ $a\text{-}_2$ Adrenergic agonists (e.g. clonidine)
Insomnia	▪ Sedating antidepressants (e.g. trazodone)
Musculoskeletal pain	▪ Acetaminophen, Ibuprofen
GI Distress (nausea, vomiting, diarrhea)	▪ Oral hydration ▪ Antiemetics (e.g. ondansetron) ▪ Anti-diarrheals (e.g. loperamide)

Initiating IM Naltrexone (XR-NTX)
Summary

- Effective suppression of withdrawal symptoms, accomplished with a range of adjunctive medications, is essential to the success
- Effective method will balance the degree of discomfort and the duration of treatment
- Ability of the team to expect and respond to emerging complications, to maintain enthusiasm as confidence in the method can influence outcome
- Anticipatory guidance and motivational techniques should accompany the initiation of treatment with XR-NTX to improve long-term adherence as many patients will experience internal barriers to continuation

Sigmon et al., 2012

Case Study #2

The Teacher

Case #2 Robert, a 35-year old teacher
Considering Treatment Options

The patient is a 35-year-old school teacher. He has been injecting heroin on and off since he was 16. He has never been arrested. He has been through many episodes of heroin detoxification, mostly outpatient methadone detoxification but has also been in three inpatient drug treatment programs. The last inpatient program was a 28-day, drug-free recovery program, and he remained both heroin and alcohol free for about 6 months following treatment. He teaches math at a junior high school and is in some difficulty because of "calling in sick too much." His wife is in recovery, and insisted that he return to treatment after she discovered he was taking large quantities of codeine pills from several doctors for a back injury following an automobile accident. She is unaware that he is also injecting heroin at least once daily. He has been alcohol abstinent for the past two years. His only current medical problem is that he is hepatitis C positive and he has been so for at least 10 years.

He states "Doc, I know I'm an addict. My wife cleaned up when she was pregnant with our daughter, and she just got her 12-year chip. She moved on with her life, but I'm stuck. My back injury threw me into a tailspin. At first, I really needed the codeine, but now I'm just using them to stave off heroin withdrawal. I really need your help. If my wife finds out I'm back on the needle, she'll leave me this time."

Case #2 Robert, a 35-year old teacher

Polling Questions

- ***What is the diagnosis?***
- ***What do you think is the best treatment option?***

Urine Drug Testing

General Goals of Drug Testing in Office-Based Treatment

- Important and routine component of treatment
- Urine testing can be viewed as a means for helping the provider to help the patient
- Testing is not meant to "catch" the patient, and a positive test result should not simply lead to discharge from treatment, but an opportunity for reviewing the patient's Recovery Management

Drug Testing in Office-Based Treatment Specifics

- Laboratory testing for evidence of substance use has several roles in office-based treatment for opioid use disorder, including:
  - Initial assessment
  - Treatment planning
  - Screening to identify non-prescribed substances/medications
  - Monitoring adherence to pharmacotherapy
  - Evaluating efficacy of treatment and assist in treatment planning

- Ideally laboratory testing should be:
  - Random
  - Observed (Some states prohibit this due to confidentiality violations
  - Convenient for the patient
  - High quality
  - Able to offer timely result

CSAT, 2004
SAMHSA, 2012

Screening and Confirmatory Tests

- A common clinical approach:
  - Test for a panel of commonly-used substances using screening tests
  - Then to perform confirmatory tests for:
    - Positive results whose accuracy is important for treatment planning
    - Periodic general screening assessing commonly used substances that are not evident on POCT
    - Identification of prescribed medications or metabolites
- Confirmatory testing is not necessary at every visit

DuPont et al., 2013
Moeller et al., 2017
SAMHSA, 2012

Common Tests

- Some commonly-used screening tests include:
  - Benzodiazepines
  - Cannabinoids
  - Amphetamines
  - Cocaine metabolite (benzoylecgonine)
  - Opiates (detects morphine, codeine, and metabolites)
- Less commonly-used screening tests include:
  - Alcohol metabolite (ethyl glucuronide or ethyl sulfite)
  - Buprenorphine
  - Fentanyl
  - Oxycodone
  - Methadone

these and other synthetic opioids require specific tests—they are not detected by the test for opiates

Moeller et al., 2017

Testing for Buprenorphine

- Testing for buprenorphine during treatment can be useful to monitor adherence and detect possible diversion
- Confirmatory testing will distinguish buprenorphine and its metabolite, norbuprenorphine, which is usually present in greater concentrations
- Individuals vary in the ratio of buprenorphine to norbuprenorphine due to individual metabolism and co-administered inducers or inhibitors of CYP3A4
- Buprenorphine with little or no metabolite (i.e. a ratio of norbuprenorphine:buprenorphine: < 0.02) suggests that buprenorphine was added to the urine

Sethi & Petrakis, 2013
Hull et al., 2008

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Polling #6

The *goals* of buprenorphine maintenance treatment include:

a. Discontinued or markedly reduced use of other opioids
b. Persistent cravings
c. Persistent withdrawal symptoms
d. The expectation of some continued sedation

Polling #7

Medically managed withdrawal (formerly known as "detox") without MOUD in the treatment of opioid use disorders:

a. Results in long-term opioid abstinence
b. Is unlikely to result in long term abstinence
c. Results in fewer ED visits and hospital admissions
d. Always results in decreased overdose risk

Polling #8

During buprenorphine stabilization and maintenance, the patient should be:

a. Taking a fixed dose of buprenorphine daily to suppress withdrawal and reduce risk of relapse
b. Prescribed a total daily dose of 24/6 mg to 32/8 mg daily
c. Informed they will be tapered off buprenorphine within a six-month period
d. Taking buprenorphine throughout the day whenever they have physical or emotional discomfort

Case Study #3

The Student

19-year-old university student
Clinical Management - Part I

A 19-year-old woman university student comes to you asking for treatment of her heroin use. She has been using heroin intranasally for the last 15 months, daily for the last 3 months. She is now using about 1 gram daily. Some of her friends are now switching to intravenous use because it takes less heroin to keep from getting sick. She says she doesn't want to do that but may be "forced" to because she cannot keep paying the "extra cost" of nasal use. She has used all the money her parents gave her for school expenses to buy heroin, her credit cards are maxed out, and she has borrowed money from her friends. Until last semester, she had an overall B average, but this semester she is in academic difficulty. When she doesn't use heroin, she has muscle aches, diarrhea, insomnia, and anxiety. She recognizes the symptoms as heroin withdrawal and was surprised because thought she could not develop an addiction with nasal use. She has no prior history of drug treatment.

19-year-old university student
Clinical Management - Part I

Polling Questions

- ***What is the diagnosis?***
- ***What do you think is the best treatment option?***

Discussion points:

- ***What are the treatment goals?***
- ***What is the initial treatment plan?***

19-year-old university student
Clinical Management - Part II

The clinic physician gives her a prescription for 6 day supply of buprenorphine/naloxone film strips at 4 mg/day, and she is told to participate in the clinic's relapse prevention workshop six days a week and call back to schedule individual counseling at the clinic once a week.

She returns 3 days later having taken 8 mg/day over the past 3 days. She has not attended the relapse prevention workshop nor scheduled an individual counseling session. The counselor is not available to see her when she comes.

19-year-old university student
Clinical Management - Part I

Polling Question

What might you have done differently?

1. Prescribed 2mg/0.5mg strips 6/day, enough until the next clinic appointment. Call her the next day and discuss dose adjustment.
2. I would not have done anything differently.
3. Prescribe 8mg/2mg strips to take once a day.
4. I would not do anything different except to have the office call her the next day to see how she is doing and discuss dose adjustment.

19-year-old university student
Clinical Management - Part III

Part III

She returns the following day at a time when neither the group nor the counselor is available. She is told she has to attend the relapse prevention workshop in order to get medication. She does not return to the clinic for 4 weeks. When she does, she is smoking more heroin than before, but having no difficulty with finances because she has dropped out of school and is working in a high-risk environment with greater access to opioids.

- ***What are you thinking would be a good plan at this point?***

Clinical Tools

https://pcssnow.org/

Buprenorphine Clinical Tools

Home » Education » Buprenorphine Clinical Tools

Patient/Family Information

- Sample Buprenorphine patient information
- Sample Buprenorphine information for family members
- Resources for more information about Buprenorphine

Intake

- Sample intake questionnaire
- Sample consent for release of information
- Sample initial patient contact about Buprenorphine
- Sample medical history and PE form
- DSM-IV criteria for Opioid dependence

Treatment Agreements

- Sample 1 Treatment Agreement
- Sample 2 Treatment Agreement
- Sample 3 Treatment Agreement
- Sample 4 Treatment Agreement

Induction

- Clinical opiate withdrawal scale
- Modified COWS form

Drug Accountability Forms (if dosing in office)

- Buprenorphine stock drug accountability record
- Drug accountability — patient doses

Ongoing Treatment

- Progress note example
- Protocol for follow up appointments
- Follow up appointments
- Billing information

https://pcssnow.org/resources/clinical-tools/

www.pcssnow.org

- For More Information and FREE training and educational resources on MOUD visit www.pcssnow.org.
- PCSS is a collaborative effort led by the American Academy of Addiction Psychiatry (AAAP) in partnership with the: Addiction Technology Transfer Center (ATTC); American Academy of Family Physicians (AAFP); American Academy of Neurology (AAN); American Academy of Pain Medicine (AAPM); American Academy of Pediatrics (AAP); American College of Emergency Physicians (ACEP); American College of Physicians (ACP); American Dental Association (ADA); American Medical Association (AMA); American Osteopathic Academy of Addiction Medicine (AOAAM); American Psychiatric Association (APA); American Psychiatric Nurses Association (APNA); American Society of Addiction Medicine (ASAM); American Society for Pain Management Nursing (ASPMN); Association for Medical Education and Research in Substance Abuse (AMERSA); International Nurses Society on Addictions (IntNSA); National Association of Community Health Centers (NACHC); National Association of Drug Court Professionals (NADCP), and the Southeast Consortium for Substance Abuse Training (SECSAT).
- PCSS-MAT's mission is to provide free, evidence-based resources to train clinicians and the public about the effectiveness of medications used for treating opioid addiction, including buprenorphine, naltrexone and methadone, in order to more effectively address this public health crisis.

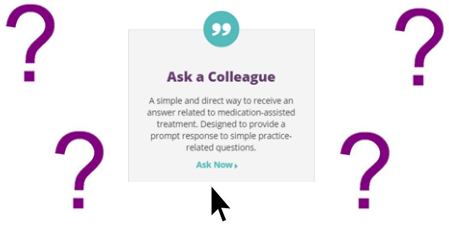
PCSS Mentoring Program

- PCSS Mentor Program is designed to offer general information to clinicians about evidence-based clinical practices in prescribing medications for opioid addiction
- PCSS Mentors are a national network of providers with expertise in **addictions, pain, evidence-based treatment including medication- treatment**
- 3-tiered approach allows every mentor/mentee relationship to be unique and catered to the specific needs of the mentee
- No cost

For more information visit:
pcssNOW.org/clinical-coaching

PCSS Discussion Forum

Have a clinical question?



http://pcss.invisionzone.com/register

PCSS Providers Clinical Support System

PCSS is a collaborative effort led by the American Academy of Addiction Psychiatry (AAAP) in partnership with:

American Academy of Family Physicians	American Psychiatric Association
American Academy of Neurology	American Society of Addiction Medicine
Addiction Technology Transfer Center	American Society of Pain Management Nursing
American Academy of Pain Medicine	Association for Medical Education and Research in Substance Abuse
American Academy of Pediatrics	International Nurses Society on Addictions
American College of Emergency Physicians	American Psychiatric Nurses Association
American College of Physicians	National Association of Community Health Centers
American Dental Association	National Association of Drug Court Professionals
American Medical Association	Southeastern Consortium for Substance Abuse Training
American Osteopathic Academy of Addiction Medicine	