

**MAT TRAINING**

**PROVIDERS' CLINICAL SUPPORT SYSTEM**  
For Medication Assisted Treatment

# The ASAM National Practice Guideline For the Use of Medications in the Treatment of Addiction Involving Opioid Use

Kyle M. Kampman, MD  
Professor of Psychiatry, Perelman School of Medicine at the  
University of Pennsylvania

# Kyle M. Kampman, MD, Disclosures

- Grant support
  - Alkermes
  - Braeburn
  - Indivior

*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.*

# ASAM Lead Contributors, CME Committee and Reviewers Disclosure List

Name	Nature of Relevant Financial Relationship		
	Commercial Interest	What was received?	For what role?
Yngvild Olsen, MD, MPH, FASAM	None		
Adam J. Gordon, MD, MPH, FACP, DFASAM, CMRO, Chair, Activity Reviewer	None		
Edwin A. Salsitz, MD, DFASAM, Acting Vice Chair	Reckitt-Benckiser	Honorarium	Speaker
James L. Ferguson, DO, DFASAM	First Lab	Salary	Medical Director
Dawn Howell, ASAM Staff	None		

# ASAM Lead Contributors, CME Committee and Reviewers Disclosure List, Continued

Name	Nature of Relevant Financial Relationship		
	Commercial Interest	What was received?	For what role?
Noel Ilogu, MD, MRCP, FASAM	None		
Hebert L. Malinoff, MD, FACP, DFASAM, Activity Reviewer	Orexo Pharmaceuticals	Honorarium	Speaker
Mark P. Schwartz, MD, DFASAM, FAAFP	None		
John C. Tanner, DO, DFASAM	Reckitt-Benckiser	Honorarium	Speaker and consultant
Jeanette Tetrault, MD, FACP, FASAM	None		

# Accreditation Statement

- The American Society of Addiction Medicine (ASAM) is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

# Designation Statement

- The American Society of Addiction Medicine (ASAM) designates this enduring material for a maximum of one (1) *AMA PRA Category 1 Credit™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.
  - Date of Release: April 4, 2016
  - Date of Expiration: July 31, 2016

# System Requirements

- In order to complete this online module you will need Adobe Reader. To install for free click the link below:
  - <http://get.adobe.com/reader/>

# Target Audience

- The overarching goal of PCSS-MAT is to make available the most effective medication-assisted treatments to serve patients in a variety of settings, including primary care, psychiatric care, and pain management settings.



# Educational Objectives

- At the conclusion of this activity participants should be able to:
  - Understand the need for a guideline for the use of medications in the treatment of addiction involving opioid use
  - Describe the process of developing the guideline
  - Describe the steps involved in a complete evaluation of an opioid addicted individual
  - State the main medications used for the treatment of opioid addiction and better understand how they are used
  - Describe the use of medications for the treatment of opioid addiction among special populations including pregnant women, adolescents, pain patients and patients with co-occurring psychiatric illness

# Outline

- Why do we need a guideline?
- How was the guideline developed?
- Assessment guidelines
- Opioid withdrawal management guidelines
- Methadone maintenance guidelines
- Buprenorphine guidelines
- Naltrexone guidelines
- Psychosocial treatment with medication guidelines
- Special populations guidelines
- Naloxone for opioid overdose guidelines

# Case of an Individual with Addiction Involving Opioid Use

- A 28-year-old woman presents for treatment of opioid problem. She was involved in a car accident several years ago and was treated with oxycodone for pain associated with her injuries. She recovered from her acute injuries but continued to use the oxycodone because it gave her a “burst of energy.” She still has chronic pain but is no longer prescribed narcotics. She buys oxycodone off the street and sometimes uses heroin if she can’t get oxycodone. She was recently arrested and has a pending court case. She could face jail time. She wants treatment because she is tired of being sick all the time.

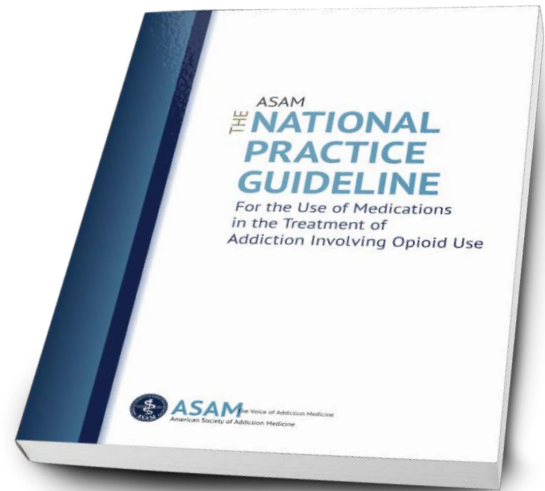
# Case Questions

## Questions for consideration

1. What should her initial evaluation include?
2. What treatment is least likely to be successful?
3. What if she were pregnant?
4. What steps might be taken to help manage her pain?
5. How should be she treated should she go to jail?

Lets look to the guideline for answers...

# The ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use



**ASAM** American Society of  
Addiction Medicine

# What is The ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use ?

- ASAM developed this National Practice Guideline to provide information on evidence--based treatment of opioid use disorder (OUD).
- **This is the first guideline publication to include all FDA-approved medications in a single document.**
  - Other existing guidelines typically do not include information on special populations (e.g. pregnant women, adolescents, pain patients, patients involved in the criminal justice system)
- This presentation is an introduction to the National Practice Guideline, which identifies current practices and recommendations regarding the safe and effective use of medications for the treatment of opioid use disorder.
- Overall, the Practice Guideline contains recommendations for the evaluation and treatment of opioid use disorder, opioid withdrawal management, psychosocial treatment, special populations, and opioid overdose.
  - The medications covered in the Guideline are mainly, but not exclusively, those that have been FDA-approved for the treatment of opioid addiction. **They are Methadone, Buprenorphine, Naltrexone (in oral and extended-- release injectable formulations), and Naloxone.**
  - The National Practice Guideline is intended primarily for clinicians involved in evaluating patients and providing authorization for pharmacological treatments at any level (physicians, prescribing healthcare providers, medical educators, and clinical care managers)

# Why is this guideline so important?

- 1.9 million people in the U.S. with Opioid Use Disorder (OUD)<sup>1</sup>
- 517,000 with heroin use disorder<sup>2</sup>
- Overdose deaths > deaths due to motor vehicle crashes<sup>3</sup>
- Societal costs of opioid misuse ~ \$55 billion<sup>4</sup>
- Opioid use is associated with increased mortality. The leading causes of death in people using opioids for nonmedical purposes are overdose and trauma.<sup>5</sup>
- The number of unintentional overdose deaths from prescription opioids has **more than quadrupled** since 1999.<sup>6</sup>
- Heroin use increases the risk of exposure to HIV, viral hepatitis, and other infectious agents through contact with infected blood or body fluids (e.g., semen) that results from sharing syringes and injection paraphernalia, or through unprotected sexual contact.<sup>7</sup>

# Most opioid addicted individuals do not receive medications

- FDA-approved medications to treat OUD are clinical and cost-effective interventions
  - Saves lives, saves money
  - One component, along with psychosocial treatment
- 30% of treatment programs offer medications<sup>8</sup>
- Less than half of eligible treatment program patients receive medications<sup>9</sup>
- Missed opportunity to utilize most effective treatments



# How was this Guideline Developed?

- This *Practice Guideline* was developed using the RAND/UCLA Appropriateness Method (RAM), a process that combines scientific evidence and clinical knowledge to determine the appropriateness of a set of clinical procedures.
- The RAM is a deliberate approach encompassing review of existing guidelines, literature reviews, appropriateness ratings, necessity reviews, and document development.
- For this project, ASAM selected an independent committee to oversee guideline development, participate in review of treatment scenarios, and to assist in writing.
- ASAM's Quality Improvement Council, chaired by Margaret Jarvis, MD, oversaw the selection process for the independent development committee, referred to as the Guideline Committee.

# The Guideline Committee and Quality Improvement Council

## Guideline Committee

- Sandra Comer, PhD
- Chinazo Cunningham, MD, MS
- Marc J. Fishman, MD, DFASAM
- Adam Gordon, MD, MPH, DFASAM
- Kyle Kampman, MD, Chair
- Daniel Langleben, MD
- Ben Nordstrom, MD, PhD
- David Oslin, MD
- George Woody, MD
- Tricia Wright, MD, MS, FACOG, FASAM
- Stephen Wyatt, DO, FASAM

## Quality Improvement Council

- John Femino, MD, DFASAM
- Margaret Jarvis, MD, DFASAM, Chair
- Margaret Kotz, DO, DFASAM
- Sandrine Pirard, MD, MPH, PhD, FASAM
- Robert J. Roose, MD, MPH, FASAM
- Alexis Geier-Horan, ASAM Staff
- Beth Haynes, ASAM Staff
- Penny S. Mills, MBA, ASAM, Executive VP

## External Reviewer

- Michael M. Miller, MD, FAPA, DFASAM

The Guideline Committee was comprised of ten experts and researchers from multiple disciplines, medical specialties, and subspecialties including academic research, internal medicine, family medicine, addiction medicine, addiction psychiatry, general psychiatry, obstetrics/gynecology, pharmacology, and clinical neurobiology.

# Opioid Use Disorder (OUD) and Addiction Involving the Use of Opioids

- Opioid Use Disorder (OUD) is a chronic, relapsing disease.
  - Many readers of may recognize the term “opioid use disorder” as it is used in the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) developed by the American Psychiatric Association; others may be more familiar with the term “opioid dependence,” as used in previous editions of the DSM.<sup>10</sup>
- ASAM released its definition of addiction in 2011. **It defines addiction as a primary, chronic disease of brain reward, motivation, memory and related circuitry.** Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors.<sup>11</sup>
- Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one’s behaviors and interpersonal relationships, and a dysfunctional emotional response.
  - Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death.
- ASAM encourages the use of the term addiction. However, given the widespread use of the DSM’s categorization of disorders, the Practice Guideline, for the sake of brevity and convention, uses the term “opioid use disorder” (OUD).

# Guideline for Assessment of a Patient with Opioid Use Disorder

- Identify and refer urgent medical or psychiatric problems
- Screen for concomitant medical conditions including infectious diseases (hepatitis, HIV, and TB), acute trauma, and pregnancy.
- Physical exam (comprehensive assessment)
- Laboratory testing
  - Initial laboratory testing should include a complete blood count, liver function tests, and tests for hepatitis C and HIV. Testing for TB and sexually transmitted infections should also be considered. Hepatitis B vaccination should be offered, if appropriate.
- Pregnancy testing and contraception query
- Mental health and psychiatric assessment
- Evaluation of past and current substance use
  - An evaluation of past and current substance use as well as a determination of the totality of substances that surround the addiction should be conducted.
  - The use of marijuana, stimulants, or other addictive drugs should not be a reason to suspend opioid use disorder treatment.
  - **However, evidence demonstrates that patients who are actively using substances during opioid use disorder treatment have a poorer prognosis.**<sup>12,13,14</sup>
  - The use of benzodiazepines and other sedative hypnotics may be a reason to suspend agonist treatment because of safety concerns related to respiratory depression.

# Guideline for Assessment of a Patient with Opioid Use Disorder

- Tobacco use query & cessation counseling
  - A tobacco use query and counseling on cessation of tobacco products should be completed routinely for all patients, including those who present for evaluation and treatment of opioid use disorder.
- Social & environmental factors assessment
  - An assessment of social and environmental factors should be conducted (as outlined in the ASAM Standards of Care<sup>15</sup>) to identify facilitators and barriers to addiction treatment, and specifically to pharmacotherapy.
  - Before a decision is made to initiate a course of pharmacotherapy for the patient with opioid use disorder, the patient should receive a multidimensional assessment in fidelity with the *ASAM Criteria: Treatment Criteria for Addictive, Substance-Related, and Co-occurring Conditions*<sup>16</sup> (the “ASAM Criteria”).
    - Addiction should be considered a bio-psycho-social-spiritual illness, for which the use of medication(s) is but only one component of overall treatment.

# Guideline for Diagnosis of a Patient with Opioid Use Disorder

- Provider confirms OUD diagnosis
  - Other clinicians may diagnose opioid use disorder, but **confirmation of the diagnosis by the provider with prescribing authority and who recommends medication use must be obtained before pharmacotherapy for opioid use disorder commences.**
- History and physical exam
  - Opioid use disorder is primarily diagnosed on the basis of the history provided by the patient and a comprehensive assessment that includes a physical examination.
- Scales measure OUD withdrawal symptoms
  - Validated clinical scales that measure withdrawal symptoms, e.g., the OOWS, SOWS, and the COWS may be used to assist in the evaluation of patients with opioid use disorder.
- Frequency of urine drug testing determined
  - Urine drug testing during the comprehensive assessment process, and frequently during treatment, is recommended.
  - Frequency of drug testing is determined by a number of factors including: the stability of the patient, the type of treatment, and the treatment setting.

# DSM-5 Criteria for Opioid Use Disorder<sup>17</sup>

- The diagnosis of opioid use disorder is based on criteria outlined in the DSM--5. The criteria describe a problematic pattern of opioid use leading to clinically significant impairment or distress.
- There are a total of 11 symptoms and severity is specified as mild (2--3 symptoms), moderate (4--5 symptoms) or severe (6 or more symptoms) within a 12-month period.
- Opioid use disorder requires that **at least two** of the following 11 criteria be met within a twelve-month period:
  - (1) taking opioids in larger amounts or over a longer period of time than intended;
  - (2) having a persistent desire or unsuccessful attempts to reduce or control opioid use;
  - (3) spending excess time obtaining, using or recovering from opioids;
  - (4) craving for opioids;
  - (5) continuing opioid use causing inability to fulfill work, home, or school responsibilities;
  - (6) continuing opioid use despite having persistent social or interpersonal problems;
  - (7) lack of involvement in social, occupational or recreational activities;
  - (8) using opioids in physically hazardous situations;
  - (9) continuing opioid use in spite of awareness of persistent physical or psychological problems;
  - (10) tolerance, including need for increased amounts of opioids or diminished effect with continued use at the same amount – as long as the patient is not taking opioids under medical supervision; and
  - (11) withdrawal manifested by characteristic opioid withdrawal syndrome or taking opioids to relieve or avoid withdrawal symptoms – as long as the patient is not taking opioids under medical supervision



# Guideline for Treatment Setting

- Clinician and patient share treatment option decisions
  - Consider patient preferences, treatment history and setting to determine medication
- Clinicians should consider the patient's preferences, past treatment history, and treatment setting when deciding between the use of methadone, buprenorphine, and naltrexone in the treatment of addiction involving opioid use.
  - Level 1 treatment setting in the ASAM Criteria may be a general outpatient location such as a clinician's practice site.
  - Level 2 treatment setting in the ASAM Criteria may be an intensive outpatient treatment or partial hospitalization program housed in a specialty addiction treatment facility, a community mental health center, or another setting.
  - The ASAM Criteria describes Level 3 or Level 4 treatment respectively as a residential addiction treatment facility or hospital.
- Venue as important as medication selected
  - The venue in which treatment is provided is as important as the specific medication selected.
  - Opioid Treatment Programs (OTPs) offer daily supervised dosing of methadone, and increasingly of buprenorphine.
  - In accordance with federal law (21 CFR §1306.07), OBOT, which provides medication on a prescribed weekly or monthly basis, is limited to buprenorphine.
    - Naltrexone can be prescribed in any setting by any clinician with the authority to prescribe any medication.
  - Clinicians should consider a patient's psychosocial situation, co-occurring disorders, and risk of diversion when determining whether OTP or OBOT is most appropriate.



# Guideline for Treatment Setting

- Office treatment may not be suitable for patients with selected drug addiction issues
  - OBOT may not be suitable for patients with active alcohol use disorder or sedative, hypnotic, or anxiolytic use disorder (or who are in the treatment of addiction involving the use of alcohol or other sedative drugs, including benzodiazepines or benzodiazepine receptor agonists).
  - It may also be unsuitable for persons who are regularly using alcohol or other sedatives but do not have addiction or a specific substance use disorder related to that class of drugs.
- **The prescribing of benzodiazepines or other sedative--hypnotics should be used with extreme caution in patients who are prescribed methadone or buprenorphine for the treatment of an opioid use disorder.**
- OTPs offer daily dosing and supervision
  - Methadone is recommended for patients who may benefit from daily dosing and supervision in an OTP, or for patients for whom buprenorphine for the treatment of opioid use disorder has been used unsuccessfully in an OTP or OBOT setting.

# Guideline for Withdrawal Management

- Medications for withdrawal preferred to abrupt cessation
  - Abrupt cessation of opioids may lead to strong cravings, often leading to continued use.
- Advise patients medications alone for opioid withdrawal not a complete treatment method
  - Patients should be advised about risk of relapse and other safety concerns from using opioid withdrawal management as standalone treatment for opioid use disorder.
- Medical history and physical exam focus on withdrawal signs and symptoms
  - Opioid withdrawal management on its own is not a treatment method.
- Methadone withdrawal symptom management in OTP or inpatient setting
  - Opioid withdrawal management in cases in which methadone is used must be done in an inpatient setting or in an OTP.
  - For short acting opioids, tapering schedules that decrease in daily doses of prescribed methadone should begin with doses between 20 mg to 30 mg per day and should be completed in 6 to 10 days.
- Buprenorphine can be used to manage withdrawal symptoms
  - Opioid withdrawal management in cases in which buprenorphine is used should not be initiated until 12 to 18 hours after the last dose of a short-acting agonist such as heroin or oxycodone, and 24 to 48 hours after the last dose of a long-acting agonist such as methadone.
  - A dose of buprenorphine sufficient to suppress withdrawal symptoms is given (this can be 4 mg to 16 mg per day) and then the dose is tapered. The duration of the tapering schedule can be as brief as 3 to 5 days or as long as 30 days or more.

# Guideline for Withdrawal Management

- Combination buprenorphine and low dose oral naltrexone to manage withdrawal and facilitate ER injectable naltrexone shows promise
  - More research is needed before this can be accepted as standard practice.
- Clonidine to support opioid withdrawal
  - The Guideline Committee recommends, based on consensus opinion, the inclusion of clonidine as a recommended practice to support opioid withdrawal.
  - Clonidine is not FDA-approved for the treatment of opioid withdrawal but it has been extensively used off-label for this purpose.
  - Clonidine may be used orally or trans-dermally at doses of 0.1 to 0.3 mg every 6 to 8 hours with a maximum dose of 1.2 mg daily to assist in the management of opioid withdrawal symptoms.
    - Its hypotensive effects often limit the amount that can be used.
    - Clonidine can be combined with other nonnarcotic medications targeting specific opioid withdrawal symptoms such as benzodiazepines for anxiety, loperamide for diarrhea, acetaminophen or NSAIDs for pain, and ondansetron or other agents for nausea.
- Anesthesia ultra-rapid opioid detoxification (UROD) is NOT recommended—too high risk
- Increased risk of overdose or death with stopping agonist therapy and resuming opioid use

# Guideline for Methadone Maintenance Treatment

- Methadone is a treatment option recommended for patients who are physiologically dependent on opioids, able to give informed consent, and who have no specific contraindications for agonist treatment
- **It should be dispensed in the context of an appropriate plan that includes psychosocial intervention**
- Methadone in monitored program setting
  - The initial administration of methadone should be monitored because unsupervised administration can lead to misuse and diversion.
  - OTP regulations require monitored medication administration until the patient's clinical response and behavior demonstrates that the provision of non-monitored doses is appropriate.
- Recommended initial dose 10 to 30 mg; usual daily dosage from 60 to 120 mg
  - The recommended initial dose ranges for methadone are from 10 mg to 30 mg with reassessment in 3 to 4 hours and a second dose not to exceed 10 mg on the first day if withdrawal symptoms are persisting.
  - Federal law mandates that the initial dose cannot exceed 30 mg and not exceed 40 mg in one day.
    - The usual daily dosage of methadone ranges from 60 mg to 120mg.
  - Some patients may respond to lower doses and some patients may need higher doses.
- Methadone for relapse or at risk for relapse
  - Methadone should be reinstated immediately if relapse occurs, or when an assessment determines that the risk of relapse is high for patients who previously received methadone in the treatment of opioid use disorder but who are no longer prescribed such treatment.
- Relapse prevention strategies part of comprehensive treatment

# Guideline for Methadone Maintenance Treatment

- May switch from methadone to other medication if side effects or other issues
- Low doses of methadone first if switching to buprenorphine
  - Patients on low doses of methadone (30 to 40mg per day or less) generally tolerate the transition to buprenorphine with minimal discomfort; whereas patients on higher doses of methadone may find that switching causes significant discomfort.
  - Patients should be closely monitored during such a switch since there is a risk that stable methadone patients may become unstable when switching to buprenorphine.
- Complete withdrawal from methadone before switching to oral or ER naltrexone
  - **Patients switching from methadone to naltrexone need to be completely withdrawn from methadone and other opioids.**
    - This can take up to 14 days but can be typically achieved in 7 days.
    - A naloxone challenge may be useful.
- No recommended/optimal treatment duration (depends on patient response)

# Guideline for Buprenorphine Treatment

- The guideline acknowledges the multiple formulations of buprenorphine currently available and that these multiple formulations have different bioavailability and different buprenorphine/naloxone dose strengths.
  - The guideline document includes bioequivalence charts.
  - Because of the possibility of slight differences in bioavailability between different buprenorphine formulations, patients switching from one form to another should be monitored for adverse effects.
- For this guideline, recommendations using the term “buprenorphine” refers generally to both the buprenorphine alone and the combination buprenorphine/naloxone formulations. When recommendations differ by product, the term buprenorphine monoprodut is used and the combination product is called “combination buprenorphine/naloxone.”
- Patients should be experiencing mild to moderate opioid withdrawal symptoms before starting buprenorphine
  - Generally, buprenorphine initiation should occur at least 6 to 12 hours after the last use of heroin or other short-acting opioids, or 24 to 72 hours after their last use of long-acting opioids such as methadone.
- Start with 2 to 4 mg; increase dosage in 2 to 4 mg increments
- Observe patients in office during induction, home inductions if experienced physician or patient
- After induction  $\geq 8$  mg a day; 4 to 8 mg increases w/continued opioid use (daily dose 12 to 16 mg or higher)
- Regarding dosing – the FDA approves dosing to a limit of 24 mg per day, and there is limited evidence regarding the relative efficacy of higher doses.
  - The use of higher doses may increase the risk of diversion.

# Guideline for Buprenorphine Treatment

- Clinicians should take steps to reduce buprenorphine diversion
  - Strategies to reduce the potential of diversion include:
    - frequent office visits
    - urine drug testing including testing for buprenorphine and metabolites
    - observed dosing
    - recall visits for pill counts.
  - Patients receiving treatment with buprenorphine should be counseled to have adequate means to secure their medications to prevent theft. Unused medication should be disposed of safely.
- Frequent urine drug tests are recommended (including buprenorphine)
- Frequent visits until stable
- If/when buprenorphine is tapered, the taper should be slow and monitored
- Clinicians should wait 7 to 14 days between the last buprenorphine dose and the first dose of naltrexone when switching to naltrexone
- In switching from buprenorphine to methadone, no time delay is necessary
- There is no recommended time limit for treatment



# Guideline for Naltrexone Treatment

- **Naltrexone is intended to prevent relapse in patients not physically dependent on opioids.**
  - Patients need to be off all opioids prior to starting naltrexone.
  - Naltrexone is available as an oral medication or as a once monthly injectable medication
- Oral naltrexone taken daily in 50 mg doses or 3x weekly in two 100 mg doses, followed by one 150 mg dose.
  - Oral formula naltrexone may be considered for patients where adherence can be supervised or enforced. Extended-release injectable naltrexone may be more suitable for patients who have issues with adherence.
- Naltrexone ER administered every 4 weeks at set dosage of 380 mg/injection
- No recommended length of treatment
- Plan and monitor naltrexone to agonist switches
  - Switching from naltrexone to methadone or buprenorphine should be planned, considered, and monitored.
  - Switching from an antagonist such as naltrexone to a full agonist (methadone) or a partial agonist (buprenorphine) is generally less complicated than switching from a full or partial agonist to an antagonist because there is no physical dependence associated with antagonist treatment and thus no possibility of precipitated withdrawal.
  - Patients being switched from naltrexone to buprenorphine or methadone will not have physical dependence on opioids and thus the initial doses of methadone or buprenorphine used should be low.
  - Patients should not be switched until a significant amount of the naltrexone is no longer in their system, about 1 day for oral naltrexone or 30 days for extended-release injectable naltrexone.



# Guideline for Psychosocial Treatment Plus Medications

- Recommended with any pharmacological treatment—at a minimum—should include:
  1. Psychosocial needs assessment
  2. Supportive counseling
  3. Links to existing family support
  4. Referrals to community services
- Extensive literature reviews were conducted on psychosocial treatment with medications.
  - Most recommendations for psychosocial treatments are not correlated with any specific pharmacological approach.
- Collaboration with behavioral provider
  - Psychosocial treatment generally recommended for patients receiving opioid agonist treatment
- Offered with oral and extended-release injectable naltrexone
  - Extended release naltrexone has not been shown to be effective in the absence of psychosocial treatment<sup>18</sup>
- While not considered by ASAM to be a psychosocial treatment on its own, mutual help (e.g., NA, SMART, AA, etc.) compliments professional treatment **but is not a substitute for professional treatment.**
  - Many providers recommend mutual help programs but there is anecdotal information to suggest that some of these programs may be less accepting of patients receiving medications for OUD.

# Guideline for Medications for OUD in Pregnant Women

- First, identify and refer urgent medical conditions
- A complete medical and psychosocial examination should be done
- OB/Gynecologists be alert to signs of OUD
  - Pregnant women with opioid use disorder are more likely to seek prenatal care late in pregnancy, miss appointments, experience poor weight gain, or exhibit signs of withdrawal or intoxication.<sup>19</sup>
- Psychosocial treatment is recommended
- HIV and Hepatitis (B and C) testing and counseling should be provided
- With patient consent, urine testing for opioids and other drugs should be done.
  - State laws differ on reporting substance use during pregnancy.
  - Laws that penalize women for use and for obtaining treatment serve to prevent women from obtaining prenatal care and worsen outcomes.
- Treat OUD women with methadone or buprenorphine rather than no medication
  - Hospitalization during initiation of methadone and treatment with buprenorphine may be advisable due to the potential for adverse events, especially in the third trimester.
  - In an inpatient setting, methadone should be initiated at a dose range of 20 mg to 30 mg. Incremental doses of 5 mg to 10 mg are given every 3 to 6 hours, as needed, to treat withdrawal symptoms.
  - After induction, clinicians should increase the methadone dose in 5 mg to 10 mg increments per week.
    - The goal is to maintain the lowest dose that controls withdrawal symptoms and minimizes the desire to use additional opioids.

# Guideline for Medications for OUD in Pregnant Women

- Pregnant women with OUD should be co-managed with OB/GYN and addiction specialist
- Pregnancy affects pharmacokinetics
  - Pharmacokinetics of methadone are affected by pregnancy.
  - With advancing gestational age, plasma levels of methadone progressively decrease and clearance increases.
  - Increased or split doses may be needed as pregnancy progresses.
  - After childbirth, doses may need to be adjusted downwards.
- Buprenorphine monotherapy is an alternative to methadone
  - While there is evidence of safety, there is insufficient evidence to recommend the combination buprenorphine/naloxone formulation.
- If a woman becomes pregnant while she is receiving naltrexone, it is appropriate to discontinue the medication if the patient and doctor agree that the risk of relapse is low.
  - If the patient is highly concerned about relapse and wishes to continue naltrexone, she should be informed about the risks of staying on naltrexone and provide her consent for ongoing treatment.
  - If the patient wishes to discontinue naltrexone but then reports relapse to opioid use, it may be appropriate to consider treatment with methadone or treatment with buprenorphine.
- No naloxone unless overdose
- Breastfeeding encouraged with methadone and buprenorphine

# Guideline for the Treatment of Pain and OUD

- The first goal should be to obtain a correct diagnosis and identify targets for treatment
- If pharmacological treatment is considered for individuals with pain, non-opioid medications such as acetaminophen and NSAIDs should be tried first.
- Consider methadone or buprenorphine for patients with active OUD who are not in treatment
- Pharmacotherapy should be accompanied by psychosocial counseling
- Because of the tolerance associated with daily methadone dosing, the usual dose of methadone may be inadequate for pain control.
  - Patients in treatment with methadone will require doses of opioids in addition to their regular daily dose of methadone to manage acute pain.
  - However, in some cases, the tolerance associated with daily methadone dosing may result in the need for higher doses of opioid analgesics.
  - Methadone patients who have chronic pain should optimally be treated in consultation with a pain specialist.
  - For patients being treated with buprenorphine, increasing buprenorphine may be helpful for treating mild acute pain

# Guideline for the Treatment of Pain and OUD

- For severe acute pain, discontinuing buprenorphine and commencing on a high potency opioid (such as fentanyl) is advisable.
  - Patients should be monitored closely and additional interventions such as regional anesthesia should also be considered.
- The decision to discontinue buprenorphine prior to an elective surgery should be made in consultation with the attending surgeon and anesthesiologist.
  - If it is decided that buprenorphine should be discontinued prior to surgery, this should occur 24 to 36 hours in advance of surgery and restarted post-operatively when the need for full opioid agonist analgesia has passed.
- Treat naltrexone patients with mild pain NSAIDs and with ketorolac for severe pain
- Discontinue naltrexone 72 hours and ER naltrexone 30 days prior to surgery

# Guideline for the Treatment of OUD in Adolescents

- Clinicians should consider treating adolescents who have opioid use disorder using the full range of treatment options, including pharmacotherapy.
- Opioid agonists (methadone and buprenorphine) and antagonists (naltrexone) may be considered for treatment of opioid use disorder in adolescents.
  - Age is a consideration in treatment, and federal laws and FDA approvals need to be considered for patients under age 18.
    - Buprenorphine is FDA-approved for patients 16 and older
    - There are no controlled trials evaluating methadone for the treatment of OUD in adolescents under the age of 18. However, the federal code on opioid treatment, offers an exception for patients aged 16 and 17 who have a documented history of at least two prior unsuccessful withdrawal management attempts, and have parental consent.
  - Naltrexone may be considered for young adults aged 18 and older with OUD.
- Confidentiality is of particular importance in treatment adolescents.
  - Adolescents have reported that they are less likely to seek treatment if services are not confidential. There are many clinical and legal responsibilities when young person requests confidentiality.<sup>20</sup>
  - More than half the states in the US, by law, permit adolescents less than 18 to consent to addiction treatment without parental consent.
- Psychosocial treatment is recommended
- Adolescents may benefit from treatment in specialized facilities with multidimensional services

# Guideline for the Treatment of Co-Occurring Psychiatric Disorders

- A comprehensive assessment including determination of mental health status should evaluate whether the patient is stable.
  - Patients with suicidal or homicidal ideation should be referred immediately for treatment and possibly hospitalization.
  - Reduce, manage, and monitor suicide risk
- Management of patients at risk for suicide should include:
  - a) reducing immediate risk;
  - b) managing underlying factors associated with suicidal intent; and
  - c) monitoring and follow-up.
- Assessment for psychiatric disorder should occur at the onset of agonist or antagonist treatment.
  - Reassessment using a detailed mental status examination should occur after stabilization with methadone, buprenorphine or naltrexone.
- Pharmacotherapy in conjunction with psychosocial treatment should be considered for patients with opioid use disorder and a co-occurring psychiatric disorder.



# Guideline for the Treatment of OUD in the Criminal Justice Population

- All adjudicated individuals, regardless of type of offense and disposition, should be screened for opioid use disorder and considered for initiation or continuation of medication for the treatment of opioid use disorder regardless of the length of sentence.
  - For incarcerated individuals, it should be initiated a minimum of 30 days prior to release, and aftercare should be arranged in advance.
- The combination of pharmacotherapy and psychosocial treatment is recommended
- Opioid agonists (methadone and buprenorphine) and antagonists (naltrexone) may be considered for treatment.
  - There is insufficient evidence to recommend any one treatment as superior to another for prisoners or parolees.



# Guideline for the Use of Naloxone for the Treatment of Opioid Overdose

- Naloxone should be given in case of opioid overdose.
- There are few studies comparing the superiority of naloxone by route of administration including: intranasal, intramuscular, or intravenous.
- Naloxone can and should be administered to pregnant women in cases of overdose in order to save the mother's life.
- Patients who are being treated for opioid use disorder and their family members/significant others should be given prescriptions for naloxone.
  - Patients and family members/significant others should be trained in the use of naloxone in overdose.
- First responders, e.g., emergency medical services personnel, police officers, and firefighters should be trained in and authorized to administer naloxone.

# References

1. Substance Abuse and Mental Health Services Administration. (2014). Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings. NSDUH Series H-48, HHS Publication No. (SMA) 14-4863.
2. Substance Abuse and Mental Health Services Administration. (2014). Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings. NSDUH Series H-48, HHS Publication No. (SMA) 14-4863.
3. Centers for Disease Control and Prevention. (2014). Web-based Injury Statistics Query and Reporting System (WISQARS) [online]. <http://www.cdc.gov/injury/wisqars/fatal.html>.
4. Birnbaum HG, White AG, Schiller M, Waldman T, Cleveland JM, Roland CL. (2011). Societal costs of prescription opioid abuse, dependence, and misuse in the United States. *Pain Medicine*, 12: 657-667.
5. Degenhardt L, Randall D, Hall W. (2009). Mortality among clients of a state-wide opioid pharmacotherapy program over 20 years: risk factors and lives saved. *Drug Alcohol Depend*, 105: 9-15.
6. Centers for Disease Control and Prevention. (2015). National Vital Statistics System mortality data. <http://www.cdc.gov/nchs/deaths.htm>.
7. National Institute on Drug Abuse. (2014). Why does heroin use create special risk for contracting HIV/AIDS and hepatitis B and C? <https://www.drugabuse.gov/publications/research-reports/heroin/why-are-heroin-users-special-risk-contracting-hiv-aids-hepatitis-b-c>
8. Knudsen HK, Abraham AJ, Roman PM. (2011). Adoption and implementation of medications in addiction treatment programs. *Journal of Addiction Medicine*, 5: 21–27. Table 3.
9. Knudsen HK, Abraham AJ, Roman PM. (2011). Adoption and implementation of medications in addiction treatment programs. *Journal of Addiction Medicine*, 5: 21–27. Table 3.
10. American Psychiatric Association. (2013). Diagnostic and statistical manual of mental disorders: DSM-5.
11. American Society of Addiction Medicine. (2011). <http://www.asam.org/for-the-public/definition-of-addiction>
12. Ghitza UE, Epstein DH, Preston KL. (2007). Nonreporting of cannabis use: predictors and relationship to treatment outcome in methadone maintained patients. *Addict Behav*, 32: 938–949.
13. Lions C, Carrieri MP, Michel L. (2014). Predictors of non-prescribed opioid use after one year of methadone treatment: an attributable-risk approach (ANRS-Methaville trial). *Drug Alcohol Depend*, 135: 1–8.
14. Preston KL, Silverman K, Higgins ST. (1998). Cocaine use early in treatment predicts outcome in a behavioral treatment program. *J Consult Clin Psychol*, 66: 691–696.
15. American Society of Addiction Medicine. (2014). The ASAM Standards of Care for the Addiction Specialist Physician. Page 8.
16. American Society of Addiction Medicine. (2013). The ASAM Criteria: Treatment Criteria for Addictive, Substance-Related, and Co-occurring Conditions.
17. American Psychiatric Association. (2013). Diagnostic and statistical manual of mental disorders: DSM-5.
18. Krupitsky E. (2011). Injectable extended-release naltrexone for opioid dependence: a double-blind, placebo-controlled, multicentre randomised trial. *Lancet*, 377(9776): 1506-1513.
19. Edelin KC, Gurganious L, Golar K, Oellerich D, Kyei-Aboagye K, Adel Hamid M. (1988). Methadone maintenance in pregnancy: consequences to care and outcome. *Obstet Gynecol*, 71(3 Pt 1): 399-404.
20. Ford CA, Millstein SG, Halpern-Felsher BL. (1997). Influence of physician confidentiality assurances on adolescents' willingness to disclose information and seek future health care. A randomized controlled trial. *J Am Med Assoc*, 278: 1029-1034.

# PCSS-MAT Mentoring Program

- PCSS-MAT Mentor Program is designed to offer general information to clinicians about evidence-based clinical practices in prescribing medications for opioid addiction.
- PCSS-MAT Mentors comprise a national network of trained providers with expertise in **medication-assisted treatment, addictions and clinical education.**
- Our 3-tiered mentoring approach allows every mentor/mentee relationship to be unique and catered to the specific needs of both parties.
- The mentoring program is available, at no cost to providers.

**For more information on requesting or becoming a mentor visit:**

**[pcssmat.org/mentoring](https://pcssmat.org/mentoring)**

# PCSS-MAT Listserv

Have a clinical question? Please click the box below!



## Ask a Colleague

A simple and direct way to receive an answer related to medication-assisted treatment. Designed to provide a prompt response to simple practice-related questions.

[Ask Now ▶](#)



P

C

MAT

TRAINING

S

S

PROVIDERS' CLINICAL SUPPORT SYSTEM

For Medication Assisted Treatment

**PCSSMAT** is a collaborative effort led by American Academy of Addiction Psychiatry (AAAP) in partnership with: American Osteopathic Academy of Addiction Medicine (AOAAM), American Psychiatric Association (APA), American Society of Addiction Medicine (ASAM) and Association for Medical Education and Research in Substance Abuse (AMERSA).

For More Information: [www.pcssmat.org](http://www.pcssmat.org)



Twitter: [@PCSSProjects](https://twitter.com/PCSSProjects)

*Funding for this initiative was made possible (in part) by Providers' Clinical Support System for Medication Assisted Treatment (5U79TI024697) 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.*

# Please Click the Link Below to Access the Post Test for this Online Module

[Click here to take the Module Post Test](#)

## Upon completion of the Post Test:

- If you pass the Post Test with a grade of 80% or higher, you will be instructed to click a link which will bring you to the Online Module Evaluation Survey. Upon completion of the Online Module Evaluation Survey, you will receive a CME Credit Certificate or Certificate of Completion via email.
- If you received a grade of 79% or lower on the Post Test, you will be instructed to review the Online Module once more and retake the Post Test. You will then be instructed to click a link which will bring you to the Online Module Evaluation Survey. Upon completion of the Online Module Evaluation Survey, you will receive a CME Credit Certificate or Certificate of Completion via email.
- After successfully passing, you will receive an email detailing correct answers, explanations and references for each question of the Post Test.