Administrative, Medico-Legal, and Regulatory Aspects of Opioid Use Disorder Medication-Assisted Treatment

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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:

• Describe the regulatory oversight for opioid agonist replacement treatment

• State the guidelines for documentation and informed consent procedures when providing opioid use disorder (OUD) medication-assisted treatment (MAT)

• Identify how to determine the adequate level of psychosocial treatment and frequency of pharmacotherapy visits when providing MAT

• Implement documentation and administrative practices into care of patients receiving OUD MAT
Outline

- Regulatory governance of medication-assisted treatment (MAT) for opioid use disorder (OUD)
- Guidelines for documentation and informed consent procedures for providing MAT for OUD
- Determining optimal schedule for office visits and urine toxicology testing, and appropriate psychosocial treatment
- Medico-legal and regulatory challenges associated with providing MAT for OUD
Role of MAT in OUD

- OUD is a medical condition with substantial morbidity and mortality
  - Fatal overdose risk is epidemic in US
  - OUD is major cause of HIV and Hepatitis C infections
- MAT offers substantial clinical benefit for OUD reducing both morbidity and mortality
- Psychosocial treatment alone compares unfavorably to MAT with respect to clinical outcomes
- Period after detoxification is the most dangerous phase of OUD, with a significant risk of overdose and death
  - Lower opioid tolerance after treatment for withdrawal is mechanism of increased risk
MAT for OUD

- Three main medications available in US
- Opioid agonist (replacement) treatments
  - Methadone
  - Buprenorphine
- Opioid antagonist (blocker) treatment
  - Naltrexone
    - Available in oral and long-acting injection formulations
Regulatory Oversight of MAT for OUD

- FDA-approved medications for OUD
  - Methadone
  - Buprenorphine (monotherapy and combination with nalaxone)
  - Naltrexone (oral and long-acting injection)
- Methadone and buprenorphine are controlled substances regulated by the Drug Enforcement Agency (DEA), Substance Abuse and Mental Hygiene Services Administration (SAMHSA) and individual state opioid treatment authorities
- Naltrexone is an FDA-approved treatment for OUD, not a controlled substance and is not subject to special regulatory oversight
History of Opioid Agonist Treatment Regulation

- Until 1914, there were no illegal drugs in America
  - Opioids commonly prescribed by physicians for non-medical purposes
- In 1914, the Harrison Narcotics Tax Act was passed into law
  - Physicians and pharmacists allowed to prescribe "in the course of his professional practice only."
    - Eventually interpreted to exclude treatment of addiction, as it was not considered a medical condition
- Current federal legislation
    - Buprenorphine treatment of OUD first permitted in US
  - In 2001, change in federal regulation moving oversight from FDA to SAMHSA's Center for Substance Abuse Treatment (CSAT)
    - More flexibility in dosing, visits, and urine toxicology testing
Methadone—Regulatory

- Highly effective medication treatment for OUD in use for more than 40 years
- FDA-approved for OUD MAT
- Maintenance of opioid addiction treatment with methadone is approved “in conjunction with appropriate social and medical services”
- Full opioid agonist
  - DEA Schedule II controlled substance
  - Therapeutic doses potentially fatal for non-tolerant individuals
  - Potential for diversion in the community
Methadone Treatment Availability Limitations

- Methadone can be dispensed only at an outpatient opioid treatment program certified by SAMHSA and registered with the DEA, or to a hospitalized patient in an emergency.
- Only legal outpatient treatment using methadone for OUD is in clinics licensed by state and federal governments.
  - Some county and municipal governments have additional regulations.
- Methadone is not available for “office-based treatment”.
  - While methadone is available by prescription as a pain medication, prescribing methadone for OUD treatment is not permitted outside of specially licensed clinics for outpatient maintenance treatment.
- Commonly used for brief inpatient medical supervised withdrawal in hospital settings.
- Methadone treatment availability varies widely throughout the US.
**Buprenorphine—Regulatory**

- FDA-approved for the treatment of OUD
  - DEA Schedule III (refills permitted)
- Authorized by Drug Abuse Treatment Act of 2000
  - Qualifying physicians to receive a *waiver* from the special registration requirements in the Controlled Substances Act for the provision of medication-assisted opioid therapy
- Initial waiver for 30 patients
- After 1 year, can submit 2\textsuperscript{nd} notification for approval to 100 patients
Buprenorphine “Qualifying Physicians”

- One of following criteria:
  - Certification in addiction from American Board of Medical Specialties (Addiction Psychiatry), American Society of Addiction Medicine, or American Osteopathic Association
  - Eight hours of training in treatment and management of opioid-addicted patients
  - The physician has such other training or experience as the State medical licensing board (of the State in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opioid-addicted patients
  - Participation as an investigator in one or more clinical trials leading to the approval of a Schedule III, IV, or V narcotic drug for maintenance or detoxification treatment
Regulatory Differences: Methadone and Buprenorphine

- Urine drug testing
  - Methadone—at least 8 tests per year
  - Buprenorphine—as clinically appropriate
    - Initial evaluation; more frequent at onset of treatment or when clinically indicated; less frequent in long-term stable maintenance

- Clinical visit frequency
  - Methadone—Ruling by CSAT depending on length in treatment and clinical status
  - Buprenorphine—as clinically appropriate

- Days’ supply of medication
  - Methadone—Progressive increases over first 2 years of treatment, with maximum of one month supply
  - Buprenorphine—as clinically appropriate, schedule III permits refills up to 6 months
Buprenorphine—Wide Availability

• Fewer restrictions than methadone because:
  ▪ Pharmacology—partial opioid agonist associated with lower overdose risk
  ▪ One of main goals of DATA 2000: increase availability of MAT for OUD
    – DATA 2000 specifies MAT that are schedule III, IV, or V
      – Intention was to permit refills when appropriate
      – Less explicit regulation of treatment parameters
        – Intention was to increase access to care and allow more clinician flexibility

• However, clinicians must exercise good judgment when determining treatment plans
  ▪ Absence of explicit regulations with regard to office visit frequency, urine drug testing, and medication supply does not obviate the need to consider patient safety risks and potential for diversion of medication
Office-Based MAT with Buprenorphine

- Considerations for best practices
  - Selection of appropriate patients
  - Frequency of clinical visit schedule
  - Frequency of urine drug testing
  - Determination of appropriate psychosocial treatment
  - Documentation of informed consent
Selection of MAT for OUD

- Many patients with OUD would benefit from multiple or all MAT modalities (methadone, buprenorphine or naltrexone)
- However, patient characteristics may influence choice of MAT
  - Definitive evidence for treatment matching is lacking except for specific examples (e.g., pregnancy)
  - In the absence of evidence, good clinical judgment must be exercised in determining treatment plan
- When making recommendation for MAT, informed consent must be obtained
  - Patients should be advised of risks, benefits and alternatives of the available MATs for OUD
  - Risk-benefit discussion should be documented in the medical record
  - Specific consent form is not required, but some physicians or treatment programs may use this approach to optimize documentation and communication with patient, and to manage expectations
Clinical Visit Frequency

- Clinical visit frequency for buprenorphine or naltrexone should be individualized for the patient.
- More frequent visits are required at the initiation of treatment or at times when clinical status is less stable (e.g., relapse, active psychiatric symptoms).
- Rationale for frequency of clinical visits should be documented in the medical record.
- Frequency of visits should be adjusted as clinical status either improves or worsens.
- Clinical visit schedule is very often linked to medication supply:
  - Patient plans to return to clinic when needing new prescription.
Buprenorphine Medication Supply

- When prescribing buprenorphine, need to balance clinical safety and risk of diversion vs. concerns of overburdening patient unnecessarily.
- Initial prescriptions for induction or early maintenance period should be for relatively small amounts; cover patient until next clinical visit.
- In established patients who are clinically stable, prescriptions that cover incrementally increasing period of time are appropriate.
- As the interval between prescriptions increases, the risk of diversion or undetected clinical decompensation increases.
- The rationale for prescribing interval for buprenorphine should be documented in the medical record.
- If interval between prescriptions is unnecessarily restrictive, patient burden increases and risk of noncompliance or discontinuation of effective treatment increases.
Buprenorphine Formulation Selection

- Buprenorphine for OUD MAT available in mono-product (only buprenorphine) and in combination with naloxone
- Combination product (includes naloxone) is preferred product for prescribing as naloxone moderates buprenorphine subjected effects when injected
- Buprenorphine mono-product is preferred for pregnant women, and in patients who are allergic to naloxone or have tolerance difficulties with the naloxone containing product
- Rationale to prescribe mono-product should be indicated in the medical record
- While the buprenorphine mono-product is currently the cheapest formulation available, cost alone is probably insufficient justification for prescribing
Buprenorphine Diversion

- Buprenorphine has high street value (~$20/dose)
- Patients may divert all or some of their medication supply for money or other drugs
- Dose of buprenorphine should be optimized to reduce craving and opioid use
- However, as the dose of buprenorphine increases, risk of diversion increases
  - Patients can lower maintenance dose below that of prescribed dose and divert “extra”
- Rationale for dosing decisions should be documented in the medical record
Detecting Misuse and Diversion

- Buprenorphine is a controlled substance with a risk of misuse and diversion
- Signs of misuse or diversion include:
  - Repeated lost prescriptions
  - Discordant pill count
  - Excessive preoccupation with securing medication supply
  - Multiple prescribers
- Caveat: Beware of misinterpreting pseudoaddiction
  - Patients receiving buprenorphine treatment often are fearful of disruptions in medication supply and resultant opioid withdrawal
Buprenorphine Diversion/Misuse Risk Reduction Strategies

- Limit and keep track of medication supply provided
- Check state prescribing/insurance databases
- Obtain urine toxicology screens
  - Absence of buprenorphine in urine testing indicates noncompliance
- Appropriate frequency of clinical visits
- Involve family if appropriate to monitor or control medication supply
- Emphasize to patient to take medications regularly, not on “as needed” basis
- Discuss with patient safe storage and not advertising/sharing medications with others
- Limit-setting: compassionate, yet boundaries observed
Psychosocial Treatment

• OUD MAT is FDA-approved to be provided in the context of appropriate psychosocial treatment

• Appropriate psychosocial treatment is clinically determined and individualized to patient

• Depending on training and expertise of physician prescribing OUD MAT
  - Prescribing physician may provide psychosocial treatment
  - Or may refer to other providers

• Rationale for decisions regarding psychosocial treatment should be documented in the medical record
Individualizing Psychosocial Treatment

- Psychosocial treatment should be targeted at areas of clinical concern
  - All patients receiving OUD MAT are at risk for relapse to opioid use and require interventions for reduction in relapse risk
  - Risk of relapse decreases with:
    - Length of time abstinent from opioids
    - Abstinence from other substance use
    - Level of psychosocial functioning (e.g., employment, absence of criminal activity)
  - As risk of relapse reduces, intensity and type of psychosocial treatment may lessen
  - Other psychiatric co-occurring conditions require clinical attention
  - Job training and education referrals should be considered
Urine Drug Testing

- Urine drug testing (UDT) is an important source of information when providing MAT for OUD
  - UDT is important when conducting initial comprehensive evaluation
  - Compliance with prescribed MAT (methadone or buprenorphine) can be monitored
  - Use of other opioids and other substances can be detected and treatment plan adjusted accordingly
- Results of urine drug testing and rationale for frequency of testing should be documented in the medical record
- Patient self-report is often insufficient to determine status of substance use
- Other clinical characteristics, e.g., social and occupational functioning, external contingencies, should be considered when determining urine drug testing frequency
Limits of urine drug testing

• Urine drug testing (UDT) results may be falsely reassuring
  ▪ Even observed tests are subject to manipulation
  ▪ Opioid and other substance use may go undetected despite frequent testing
  ▪ Only extreme non-compliance (e.g., not taking medication for multiple days) can be detected
• Inappropriately burdensome testing may damage therapeutic alliance and discourage continuation of effective MAT
  ▪ Patients may interpret excessive demands for testing as not being trusted or believed
  ▪ Depending on methodology used, false positive results may be possible; resultant changes to treatment plan may damage therapeutic alliance
• UDT must be interpreted in context of overall clinical presentation and is not a replacement for clinical judgment
Naltrexone

• Opioid Antagonist
• Not a controlled substance or opioid agonist
  ▪ No risk of diversion or misuse
• However, other administrative and medico-legal concerns for patients with OUD apply
  ▪ Documentation of risk of overdose if attempting to override opioid blockade or if non-compliant with naltrexone dosing schedule
  ▪ Monitoring of response to treatment with urine drug testing
  ▪ Consideration of appropriate level of psychosocial treatment
Case Presentation: History

- 34-year-old man with opioid use disorder (OUD), using 4 bags of heroin IN daily
- 10 year history of OUD
- Prior treatment with methadone for 2 years starting age 28; remained abstinent during treatment, but reports “can’t stand going to the clinic and waiting in line every day”
- Refuses any treatment involving inpatient treatment; “I can’t miss work or I will lose my job”
- Employed full time as sanitation worker
- No recent criminal justice issues
Evaluation Summary

- No current medical problems
- Has 5-year history of low mood, low energy, anhedonia, and decreased interest in sex
- No prior treatment for mood disorder
- Reports no substance use other than heroin; urine drug testing confirms self-report
- Has health insurance provided by job
MAT for OUD Options

- Patient has ruled out methadone
- Refusal to participate in any inpatient treatment makes long-acting injectable naltrexone likely infeasible
- Good clinical response to prior treatment with agonist (methadone), suggests buprenorphine would be potential valuable option
Regulatory and Administrative Concerns

- Patient should be informed of your rationale for recommending buprenorphine
- The risks, benefits, and alternatives should be discussed and summarized in the medical record
- Recommendation for appropriate psychosocial treatment should be made
- Psychiatric referral for management of mood symptoms
Concerns with this patient

- Was dissatisfaction with methadone treatment structure reasonable?
- Or will this patient have difficulty complying with treatment recommendations that accompany buprenorphine prescribing?
Management Approach

• Straightforward discussion with patient that while buprenorphine treatment is potentially more flexible than methadone treatment, there are still requirements for clinical visit attendance, urine drug testing, and participation in indicated psychosocial treatment

• Consider written informed consent
Resources


- Substance Abuse and Mental Health Services Administration (SAMHSA). Buprenorphine. Access available online: [http://buprenorphine.samhsa.gov/about.html](http://buprenorphine.samhsa.gov/about.html); Last Access November 2014

- Substance Abuse and Mental Health Services Administration (SAMHSA). Methadone. Access available online: [http://buprenorphine.samhsa.gov/about.html](http://buprenorphine.samhsa.gov/about.html); Last Access November 2014


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
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