Demystifying Opiate Addiction Treatment
Disclosures

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CPE Information

• Target Audience: Pharmacists
• ACPE#: 0202-0000-19-087-L03-P
• Activity Type: Knowledge-based
Learning Objectives

At the completion of this knowledge-based activity, participants will be able to:

• Describe the mechanisms underlying medication-assisted treatment (MAT) for opiate addiction.

• Discuss effective strategies in addressing dispensing challenges posed to pharmacies by buprenorphine.

• Identify MAT compliance requirements imposed by the U.S. Drug Enforcement Administration, including patient number limits, and record-keeping and inspections relating to buprenorphine.

• Discuss the unique privacy concerns of patients in addiction treatment.
Assessment Questions

1. In order to be able to dispense buprenorphine for purposes of substance abuse treatment?

   A. The pharmacist needs a special accreditation from a pharmacy board
   B. The prescription must bear a valid DEA number
   C. The prescription must bear a valid DEA number and a DEA “X” number
   D. The pharmacist must inquire of the patient the purpose of the medication
2. Which one of the following has been specifically recommended by the American Society of Addiction Medicine for treating female patients who are pregnant and suffering from opioid use disorder?

A. Pure buprenorphine and/or methadone
B. Combination buprenorphine and naloxone
C. Naltrexone
D. Marijuana
3. The maximum number of active patients for whom a practitioner may prescribe buprenorphine for substance use disorder during their first year of practice after being SAMHSA approved, and assuming they have no additional credentialing in addiction medicine or addiction psychology, and assuming they are not working in a “qualified practice setting” is:

A. 100 patients
B. 275 patients
C. 300 patients
D. 30 patients
4. The privacy of patient information relating to patients receiving Medical Assisted Treatment is governed by:

A. 21 CFR 1300
B. Board of Pharmacy Practice
C. HIPAA
D. State law, HIPAA, and 42 CFR Part 2
Demystifying Opiate Addiction Treatment
The Problem

• “National Epidemic” of opioid addiction declared “Public Health Emergency” in 2017

• 200 deaths per day (CDC), >70,000/yr.

• Up by 10% in 2017
The Problem

• Overdose deaths due to opioids exceed:
  • Motor vehicle related deaths
  • Gun related deaths

• Leading cause of death to those under 55

Currently less than 30% of those in need of treatment are receiving treatment (U.S. Surgeon General)


> 70% untreated
Is Problem Likely to Abate?

• 2018 – Hydrocodone remains most widely prescribed Drug in U.S.

• Illicit Fentanyl on rise and has eclipsed traditional opioids in overdose deaths

• Americans’ love affair with drugs to treat pain, isolation and social dysfunction and satisfy our psychosocial need for dopamine … uniquely American problem.

• 99 per cent of world’s supply of pharmaceutical opioids is consumed in United States

Overdose deaths around the world

Data from 2015 shows the United States far outpacing other countries in drug overdose deaths, according to the World Health Organization.

<table>
<thead>
<tr>
<th>Country</th>
<th>Overdoses</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>51,039</td>
</tr>
<tr>
<td>England and Wales</td>
<td>3,323</td>
</tr>
<tr>
<td>Germany</td>
<td>2,147</td>
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<td>Australia</td>
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<td>Estonia</td>
<td>95</td>
</tr>
<tr>
<td>Chile</td>
<td>81</td>
</tr>
</tbody>
</table>

Source: WHO Mortality database
Will Houp, CNN
Thinking has evolved:

• Opioid Use Disorder (OUD) is a disease state

“Opioid use disorder refers to a pattern of problematic use of opioids, whether prescription painkillers or heroin”

• See DSM 5 Criteria for OUD

https://www.cdc.gov/drugoverdose/training/oud/accessibe/index.html
Opioid Use Disorder
American Society of Addiction Medicine (ASAM) definition

• “Addiction is 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.”

• Addiction is characterized by the following:
  1. Inability to consistently abstain
  2. Impairment in behavioral control
  3. Craving
  4. Diminished recognition of significant problems with one’s behaviors and interpersonal relationships
  5. Dysfunctional emotional responses

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.

https://www.asam.org/resources/definition-of-addiction
Enter: Medical-Assisted Treatment (MAT)

- MAT = “Gold Standard” according to Surgeon General
  

- Buprenorphine (“Gold Standard within Gold Standard”)
  
MAT Medications

3 FDA APPROVED MEDICATIONS:

• Methadone
• Naltrexone
• Buprenorphine
Methadone

• Schedule II controlled Substance
  
  • For drug treatment may only be dispensed by DEA registered clinics

  • Tablet/liquid Consumed on premises

  • Serious risk of respiratory depression and cardiac events, prolonged QTc (arrhythmia) and toxicity with other drugs
Naltrexone

• Non-controlled substance

• Monthly injection

• Limitations
  • Limited effect on cravings and does not assist with withdrawal/induction
  • Annual expense: $12,000 to $14,000 vs. $4,000 to 5,000 for buprenorphine
  • Lacking evidence/data to support
Buprenorphine

• “Gold Standard” Why? Evidence-based efficacy.

• How is it taken? Dosage? How does it work? What is effect on the Patient? Frequency of prescription?

• Patient treatment regimen? Goals? Conjunctive modalities utilized?
Buprenorphine: Efficacy

• Average 80% reduction in illicit opiate use (Substance Abuse and Mental Health Services Administration - SAMHSA)

• Numerous studies

• Practice observations
Review of 24 randomized clinical trials with 4,497 patients

Conclusion buprenorphine is superior to placebo and to moderate dose methadone:
- Retaining patients in treatment
- Reducing illicit opioid use
Buprenorphine: Additional Studies


Buprenorphine: Efficacy Summary

- Less severe dependency than methadone allows for easier transitions between recovery with and without medication
- Partial agonist is safer with less overdose potential
- Lower abuse potential
- People live a normal life free from craving and withdrawal
- No evidence of damage to liver function
- Advantages of office-based treatment and “frequent visit” model and counseling support
Buprenorphine: 2 Types

• Buprenorphine with Naloxone

• Buprenorphine

• Why is combination drug preferred?
Special Population: Pregnancy Issue: Ongoing and Unresolved

- ASAM vs. SAMHSA

- Agree on methadone, but...

- Pure buprenorphine vs. Buprenorphine and Naloxone

- ASAM (2015) recommends combined product for all but pregnant women, due to concern for naloxone, so monoprodut if pregnant.


“Pre-clinical data suggest that fetal naloxone exposure leads to maternal and subsequently fetal hormonal changes”

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2858865/
Pregnancy Issue: Ongoing and Unresolved

• SAMHSA Guidance in 2018

“Experts do not agree on whether a woman on buprenorphine/naloxone for OUD who states the intention to become pregnant or is in the early stages of pregnancy should be switched from the combination buprenorphine/naloxone product to the buprenorphine-only product.

“Evidence is now building that newborn outcomes are not negatively affected by using the combination product during gestation and that pregnant women may not need to transition to the buprenorphine-only product during pregnancy to protect the fetus”.

Buprenorphine - Uses

• Buprenorphine = Schedule III controlled substance

• Pain vs. Opioid addiction treatment

• Explain dual use drug? Especially monoproduct.
Advantages: Ease of administration
Cost
Evidence-based efficacy
Buprenorphine Criticisms?

- Criticism: Replacing one drug for another?

- Criticism: Risk of diversion. How address:
  - Naloxone
  - Drug panels of patients
Buprenorphine Prescriptions

• For pain, anyone with DEA registration

• For drug treatment, must be approved SAMHSA provider
  
  • With DEA X number = same number, but first letter = X
  
  • Both numbers must appear on script
Buprenorphine: Practice Point

- Is it important for pharmacist to know the reason it is being prescribed?

  - Due diligence (21 CFR 1306.04)(“Corresponding Obligation”)

  “To be lawful, prescription must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice”.
Buprenorphine: Practice Point

- How does a pharmacist know?
  - If Only 1 number, and not an “X” number
  - But what if both numbers???
    - Use diligence skills: identity of practitioner, dosage
    - You can call prescriber, BUT 42 CFR Part 2 privacy limitations... so, it’s an issue without clear answer
Buprenorphine: Who Can Prescribe?

• Must be SAMHSA Approved – Training course

• Originally limited to physicians

• 2016 – Extended to Physician Assistants and Nurse Practitioners

• 2018 – Extended to Clinical Nurse Specialists, Certified Nurse Anesthetists, Certified Nurse Mid-Wives (Support Act, HR106, eff. 10/24/18)

• Training (8 hour/Dr.)(24 hour others)
Patient Number Limits By Regulation

- **Medical Doctor**
  
  YR. 1: 30
  
  YR. 2: 100, but if additional credentialing in addiction medicine or addiction psychology, or qualified practice setting (42 CFR 8.615), begin 100 in YR. 1 and 275 in YR. 2.

- **Other Practitioners**
  
  YR. 1: 30
  
  YR. 2: 100, but if additional credentialing in addiction medicine or addiction psychology, or qualified practice setting, begin 100 in YR. 1.
Why Limitations?

Acc. to Surgeon General: <30% currently in need are getting treatment

>70% = UNTREATED

IRONY! No limitation of how many patients MDs/PAs/NPs can treat with opiates for pain??!!
Including Buprenorphine for pain!
Practice Question

• Could a pharmacist participate in MAT treatment as a provider under a CDTA, since a pharmacist can obtain a DEA # to prescribe controlled substances?

• Answer: No, they are not “qualified practitioners” under Title 21 USC 823(g).
How are Patients Counted?

• “Patient” = any individual who is dispensed or prescribed covered medications by a practitioner.

• “If a practitioner ... provides cross-coverage for another practitioner and the covering practitioner provides a prescription for buprenorphine, the patient counts towards the cross-covering practitioner’s patient limit until the prescription or medication has expired.

• Musical Chairs/”Who’s on First?”
Who Checks?

• The DEA checks

• Regular Inspections
  • DEA routinely DOES NOT Inspect Physician Offices
  • Exception: Drug Abuse Treatment providers (21 CFR 1304.24)

▪ Records reviewed:
  • Registrations of Providers.
  • If dispensing... If by script...
  • Confirm Patient Numbers (match with physician) ...
Other Challenges for MAT Providers

- No specific SUD coding; audit challenges

- Payor Challenges (prior approvals and limitations in coverage)

- Telemedicine (requirement of state license in State and DEA registration where patient resides; but only 1 DEA “X” number; and total patients remain limited)
Privacy Challenges

- HIPAA provides general exception permitting the sharing of Protected Health Information (PHI) among medical professionals “in furtherance of treatment”... doctor to doctor/pharmacy (45 CFR § 164.506)...

- Addiction treatment providers must also comply with 42 CFR Part 2: Patient Consent or Qualified Service Organization (QSO) Agreement ... real problem... how to communicate script, talk to pharmacist...
Privacy Challenges

- Consent form: detail name, and contain statement that can’t be re-disclosed by receiving entity

- QSO: requires written agreement where pharmacy agrees to be bound by Part 2

- Does Part 2 even permit reporting to state Prescription Monitoring Programs (PMPs)?

DEBATE: Stigma and Patient Privacy vs. Need to Communicate
Role for Pharmacist in Treatment

“Unlike other maintenance medications, buprenorphine may be prescribed in very limited quantities to ensure close follow up, particularly during the induction and stabilization phase. These frequent refills provide a high level of contact at the pharmacy and the opportunity for the pharmacist to actively participate in the patient’s treatment. Concerns, progress, and missed doses should be clearly communicated with the provider. Some patients may require more intensive monitoring including provider request for supervised dosing at the pharmacy. It is recommended for the pharmacist to record in the patient’s chart a note to prevent them from receiving other opioids without direct permission from their provider. This high level of care can make a significant difference in keeping patients engaged in treatment and achieving remission from OUD.”

Tennessee Nonresidential Buprenorphine Treatment Guidelines 2018, p.47, Guidelines for Pharmacists
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