



MICHIGAN MEDICINE
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Opioid Use Disorders in Pregnancy

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Disclosure

- I have no actual or potential conflict of interest in relation to this presentation

References

- **Substance Abuse and Mental Health Services Administration (SAMHSA)** Clinical Guidance for Treating Pregnant and Parenting Women With Opioid Use Disorder and Their Infants (2018). <https://store.samhsa.gov/system/files/sma18-5054.pdf>
- Obstet Gynecol. 2012 May;119(5):1070-6. ACOG Committee Opinion No. 524: Opioid abuse, dependence, and addiction in pregnancy

Treatment Guidelines and Resources

- The Substance Abuse and Mental Health Services Administration (SAMHSA) has published clinical guidance for the care of women with OUD and substance exposed infants. <https://store.samhsa.gov/system/files/sma18-5054.pdf>
- The *ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use* devotes a chapter to special pharmacotherapy concerns for pregnant and parenting women (ASAM, 2015).

Presentation Outline

- Case
- Epidemiology of OUD in pregnancy
- Diagnosis of addiction
- Assessing the pregnant patient for OUD/SUD
- Treatment and management strategies
- Questions

Case

- A 20 year-old pregnant female at 20 weeks presents to your family practice clinic with a report of heroin use over last 3 years.
- She uses heroin intravenously, and reports using 12-18 hours prior to presentation.
- She appears comfortable, but pupils are pinpoint, and her appearance is deshelled.
- Physical exam is otherwise unremarkable, and vital signs are within normal limits.

Case (continued)

- Psychiatric history is significant for bipolar disorder and PTSD.
- Past medical history is unremarkable.
- Current medications include Paxil, Klonopin, Abilify, and trazodone.
- A urine drug screen is conducted in your office, and is positive for opiates, cannabinoids, and benzodiazepines.
- A urine GC/MS confirms the following: morphine, codeine, nordiazepam, mono-acetyl morphine, THC, and dextromethorphan

Case – Question

- What would be the most appropriate clinical intervention, at this time?
 - **A.** Refer patient to an inpatient program for medical detoxification, and engagement in a drug-free treatment program.
 - **B.** Begin buprenorphine (Suboxone), and schedule an induction in your office the following day.
 - **C.** Urgently refer the patient to methadone maintenance program.
 - **D.** Begin out-patient counseling with weekly OB visits and frequent UDS monitoring.

Epidemiology

- In 2015, more than 27 million people in the US reported current use of an illicit drug or misuse of Rx drugs in the past 30 days (*Center for Behavioral Health Statistics and Quality [CBHSQ], 2016*)
- CDC estimates that one-third of reproductive-age women enrolled in Medicaid and more than one-quarter of those with private insurance filled a prescription for an opioid each year between 2008 and 2012 (*Ailes et al., 2015*).
- The prevalence of OUD during pregnancy more than doubled between 1998 and 2011 to 4 per 1,000 deliveries (*Maeda, Bateman, Clancy, Creanga, & Leffert, 2014*).

Consequences of OUD

- Women with OUD are at higher risk for HIV/AIDS and viral hepatitis infection than women who do not use substances.
- The majority of women entering treatment for OUD have a history of sexual assault, trauma, or domestic violence and/or come from homes where their caregivers used drugs
- Increased risks of:
 - Preterm delivery
 - Low infant birth weight
 - Transmitting HIV to their infants (Binder & Vavrinková, 2008).
 - Overdose and death during pregnancy

Consequences of OUD

- Risky Behaviors:
 - Prostitution
 - Theft
 - Violence

Such activities expose women to sexually transmitted infections, becoming victims of violence, and legal consequences, including loss of child custody, criminal proceedings, or incarceration.

American College of Obstetrics and Gynecology, Committee Opinion: Opioid Abuse, Dependence, and Addiction in Pregnancy

Addiction – Definition

- 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 – Definition

- Addiction is characterized by:
 - Inability to consistently abstain from substance use
 - Impairment in behavioral control
 - Craving
 - Diminished recognition of significant problems with one's behaviors and interpersonal relationships.
 - 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.

Addiction – Definition

- **Addiction is much more than compulsive drug use**
- Addiction is a **BEHAVIORAL SYNDROME**, which involves, personality changes, functional decline, and lapses in judgement, insight, and decision making.
- Addiction can be **VERY DIFFICULT** to diagnose, in some cases.
- Patients can be very well versed in concealing the problem from healthcare providers.

Substance Use Disorder – DSM-5 Criteria

- A maladaptive pattern of substance use leading to clinically significant impairment or distress, as manifested by 2 (or more) of the following, occurring within a 12-month period:
 - 1. Recurrent substance use resulting in a failure to fulfill major role obligations at work, school, or home.
 - 2. Recurrent substance use in situations in which it is physically hazardous.
 - 3. Continued substance use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of the substance.

Substance Use Disorder – DSM-5 Criteria

- 4. Tolerance (**excluded if the drug is prescribed under medical supervision**)
- 5. Withdrawal (**excluded if the drug is prescribed under medical supervision**)
- 6. The substance is often taken in larger amounts or over a longer period than was intended.
- 7. There is a persistent desire or unsuccessful efforts to cut down or control substance use.
- 8. A great deal of time is spent in activities necessary to obtain the substance, use the substance, or recover from its effects.

Substance Use Disorder – DSM-5 Criteria

- 9. Important social, occupational, or recreational activities are given up or reduced because of substance use.
- 10. The substance use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.
- 11. Craving or a strong desire or urge to use a specific substance.

Substance Use Disorder – DSM-5 Criteria

- Severity specifiers:
 - Mild: 2-3 positive criteria
 - Moderate: 4-5 positive criteria
 - Severe: 6 or more positive criteria

Specify if:

- With Physiological Dependence: evidence of tolerance or withdrawal (i.e., either Item 4 or 5 is present)
- Without Physiological Dependence: no evidence of tolerance or withdrawal (i.e., neither Item 4 nor 5 are present)

Assessment

- The World Health Organization's (WHO's) Guidelines for the Identification and Management of Substance Use and Substance Use Disorders in Pregnancy recommends that healthcare professionals ask **ALL** pregnant women about their use of alcohol and other substances (i.e., past, present, prescribed, licit, and illicit use) as early as possible in the pregnancy and at every follow-up visit (WHO, 2014).

Assessment

- Signs and Symptoms of Addiction During Pregnancy
 - Seeking prenatal care late in pregnancy
 - Poor adherence to appointments
 - Experience poor weight gain
 - Symptoms of sedation, intoxication, withdrawal, or erratic behavior.
 - Track marks from intravenous injection
 - Lesions from inter-dermal injections or “skin popping,” abscesses, or cellulitis.
 - Positive results of serologic tests for HIV, hepatitis B, or hepatitis C

Assessment

- Comprehensive social, psychiatric and substance use history.
- Physical exam
- Prescription Drug Monitoring Program (PDMP)
- Screens:
 - EPDS (for depression)
 - CRAFFT
 - 4 P's
 - SBIRT
- Urine drug screen

Assessment

- Most effective approach is to conduct an empathetic, non-judgmental, and open-ended interview.
 - Establish rapport
 - Make patient feel comfortable
 - Light conversation to begin with, and appear at ease.
 - Emphasize your role as a clinician, who's intent is to be helpful.
 - “I'm here to be helpful, and make sure that you have a uneventful pregnancy.”
 - Normalize the situation, and make an admission of use less intimidating
 - “I see heroin use quite frequently, and the moms who seek treatment do very well.”

Assessment – Social/Demographic History

- City of residence
- Who are you living with?
- Employment, if unemployed, source of income.
- Current relationship status
- Assess for interpersonal violence
 - If FOB is in exam room, politely ask him to leave
 - *Do you feel safe at home?*
 - *Is anyone saying things to you that cause you to feel bad about yourself?*
- Current legal concerns
- Assess for trauma (sexual, physical, emotional abuse)
 - *What was it like growing up for you?*
 - *Are there some things you'd like to forget, but you can't?*

Assessment – Urine Drug Screen

- MUST obtain consent (verbal is sufficient in most clinical settings).
 - *I'd like to get a drug screen today, is that okay?*
- Understand the limitations of the drug screen
 - Immunoassays are presumptive positives, and false positives are common.
- Review results with patients at f/u visit.
 - Positive results should be conveyed in an open ended, and unbiased manner.
- Drug screens are meant to help guide treatment, and to verify the patient's self-report.
- Drug screens should NEVER be used in a punitive manner.

Treatment – Fundamental Concepts

- **Majority of the current evidence supports the use of Medication Assisted Treatment (MAT) with either buprenorphine or methadone for pregnant women with OUD.**
- Evidence-based behavioral interventions should accompany MAT, when available.
- For mothers already on MAT prior to pregnancy, discontinuation of this treatment **is NOT recommended.**

Treatment – Fundamental Concepts

- Detoxification off opioids alone, even under medically supervised settings, **is NOT recommended.**
 - The authors of a Norwegian study (Ravndal & Amundsen, 2010) assessing the mortality risk after inpatient medically supervised withdrawal in a non-pregnant population concluded that: **“The elevated risk of dying from overdose within the first 4 weeks of leaving medication-free inpatient treatment is so dramatic that preventive measures should be taken.”**

Medication Assisted Therapy (MAT)

- MAT refers to the use of buprenorphine, methadone, or naltrexone, for the treatment of opioid use disorders (OUD).
- There is insufficient information about the safety of extended-release injectable naltrexone during pregnancy and the effects of intrauterine exposure to this medication.

Opioid Maintenance Therapy (OMT)

- OMT is a form of MAT which refers to the use of buprenorphine or methadone for the treatment of OUD.
- Both buprenorphine and methadone are long-acting opioids, which help diminish drug craving and addictive behaviors, in patients struggling with OUD.
- OMT is an evidence-based approach which has shown to be quite effective in the management of OUD, and has been shown to produce benefits both at the individual and societal level.
 - Reduction in death rates
 - Reduction in IVDU
 - Reduction in crime days
 - Reduction in rate of HIV seroconversion
 - Reduction in relapse to IVDU
 - Improved employment, health, & social function

OMT during Pregnancy

- By blocking cyclic withdrawal symptoms associated with the misuse of short-acting opioids, methadone or buprenorphine can provide a more stabilized intrauterine environment.
- By controlling the symptoms of OUD (e.g., withdrawal, cravings), the pregnant woman can regain control, reengage in important obligations and activities in her life, and rebuild a stable social environment for herself and her family.

OMT during Pregnancy

- Research has not shown that buprenorphine and methadone can cause an increase in birth defects.
- A woman receiving either buprenorphine or methadone should be informed that the **benefits of pharmacotherapy for OUD during pregnancy outweigh the risks of untreated OUD.**

Reference: SAMHSA *Clinical Guidance for Treating Pregnant and Parenting Women With Opioid Use Disorder and Their Infants* (2018)

Treatment – Initial Consultation

- The woman's fully informed consent should be obtained after review of the risks and benefits of the course of treatment selected.
- Healthcare professionals should educate women about potential legal, social, and medical consequences of each treatment option, specifically the risks of NAS (neonatal abstinence syndrome).
 - **Avoidance of NAS should not be the deciding factor in the initiation or dose of pharmacotherapy for OUD during pregnancy.**
 - **The risk and severity of NAS is independent of the dose of methadone or buprenorphine**

Treatment - Buprenorphine

- Buprenorphine can only be prescribed to treat OUD by provider who has obtained **a practitioner waiver to prescribe or dispense buprenorphine under the Drug Addiction Treatment Act of 2000 (DATA 2000)**.
 - Physicians are required to complete an eight-hour training to qualify for a waiver to prescribe and dispense buprenorphine
 - NPs, PAs, CNSs, CRNAs, and CNMs must obtain no fewer than 24 hours of initial training.
 - This can include the eight-hour DATA-waiver course and the additional 16-hour course offered for free by SAMHSA.

Treatment – Buprenorphine

- Is a partial agonist on the mu opioid receptor
- May be prescribed in an in-office setting, as opposed to methadone.
- Some studies show treatment dropout is higher than that for methadone.
- Typically dose: 16 mg daily
- Lower risk of overdose compared with full opioid agonists; overdose is possible when combined with other CNS depressants.
- **Generally safe in breastfeeding**, if mother is stable.
- NAS may be milder with buprenorphine compared with full mu opioid agonists such as most opioid analgesics and methadone.
 - Most studies show shorter NAS duration compared with methadone

Treatment – Buprenorphine

- Buprenorphine is available under many brands, including: Suboxone, Zubsolv, and Bunavail, which contain both buprenorphine and naloxone.
 - Naloxone is not pharmacologically active when the drug is taken sublingually, as directed.
- Buprenorphine alone (Subutex) was initially recommended over the combination product (with naloxone) during pregnancy.
 - To date, 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.

Treatment – Buprenorphine

- Why was the use of the combination product initially not recommended during pregnancy?
 - Protect the fetus from exposure to naloxone.
 - If the combination product was injected intravenously, an acute withdrawal syndrome would result, given the bioavailability of naloxone when injected intravenously.

Treatment – Methadone

- Is a full mu opioid agonist
- Requires daily visits to a federally certified opioid treatment program; take-home medication is provided for patients meeting specific requirements.
- Some studies show treatment retention is higher than that for buprenorphine.
- Typical dose: 80–120 mg daily. The optimal dose will be determined by regular assessment of the individual and her response to treatment.
- Generally safe in breast feeding, if mother is stable.
- Most studies show longer NAS duration compared with buprenorphine.

Case

- **Question:** What would be the most appropriate clinical intervention, at this time?
 - **A.** Refer patient to an inpatient program for medical detoxification, and engagement in a drug-free treatment program.
 - **B.** Begin buprenorphine (Suboxone), and schedule an induction in your office the following day.
 - **C.** Urgently refer the patient to methadone maintenance program.
 - **D.** Begin out-patient counseling with weekly OB/Gyn visits and frequent UDS monitoring.

Conclusion

- Questions?
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