

Guideline: Methadone in Pregnancy for Opioid Use Disorder (OUD)

The purpose of this guideline is to share best practices for pregnant people with a substance use disorder (SUD) using methadone in an Opioid Treatment Program (OTP) to maintain their recovery. Pregnancy-associated deaths involving opioids increased tenfold between 2008-2017 (1, 2). **Overdose is now the leading cause of maternal death in Illinois.** Pregnancy is a critical time to engage a patient in OUD treatment to improve short-term health outcomes related to pregnancy and, subsequently improve the parent and child's long-term social and health, and OTPs are a strategically designed to reduce overdoses amongst people living with an OUD. IDHS/SUPR endorses evidence-based approaches for the treatment of pregnant persons with an OUD.



Physicians Should Consider Meeting with Pregnant Patients Regularly

1. Adjust dosing based on the patient's:
 - Cravings
 - Withdrawal episodes
 - Safety
 - Perinatal Pharmacokinetics
2. Consider increasing the dosing throughout pregnancy and dividing the dosing (can be split up to 4 times per day) while assessing for potential over-sedation (3-6).



Consider "Take-home Doses"

1. Physicians can request an exemption for an individual patient for "take-home doses" to be taken later in the day to accommodate the metabolic state induced by pregnancy (3-6)
2. SMA 168 Exception From Requirements for Change Section
 - Select justification for number of doses
 - Temporary change of protocol
 - Check split dosing
 - Indication would be pregnancy



Wrap Around Services and Safe Care Plans Are Recommended

1. Pregnant patient benefit from wrap around services including recovery support, counseling, and mental health services.
2. Counseling attendance should NOT be a requirement for receiving medication. Per SAMHSA, "Maintaining a patient on medication, even when psychosocial treatment or other clinic services may not be yielding optimum results, is beneficial to both the individual patient and the public health."
3. Psychosocial treatment should be available to a patient but should NOT be a condition of receiving medication (3-5).
4. Develop a plan of safe care to better serve infants and their families in conjunction with the obstetrical care provider (7-8)

The purpose of this guideline is to share best practices for pregnant persons with a substance use disorder (SUD) using methadone in an OTP to maintain their recovery. This guideline does not except the physician's responsibility to promote the welfare and confidentiality of the individual patient and to protect public safety.

OUD is a life-threatening chronic medical condition and offering Medication Assisted Recovery (MAR) to pregnant persons with opioid use disorder is the clinical standard of care.

- Withdrawal management is NOT the preferred treatment for pregnant persons as it increases the risk of adverse outcomes for both the pregnant person as well as the fetus (3-5).
- Pregnancy is characterized by an ultra-rapid metabolic state that requires not only frequent dosing adjustments, but also the option of split dosing. Elevations of progesterone and estrogen during pregnancy induce the genes that code for the enzymes of the CYP450 system that metabolizes methadone. This accelerated metabolism of methadone begins in the first trimester and increases in the second and third trimesters. In fact, the half-life of methadone in the third trimester has been shown to be reduced by half. Single dose protocols will likely cause both pregnant person and fetus to experience daily episodes of withdrawals that impact the patient's stability and the health of the fetus. Managing the withdrawal by only increasing the single daily dose, will cause a high peak serum level with the possibility of oversedation, without impacting the later withdrawal (3-5).
- A positive urine test should NOT be used as a reason for denying split dosing. It makes drug use more likely if the mother goes into withdrawal in the evening and does not have a second dose (3-6).
- Split dosing due to pregnancy should not be contingent on time in treatment, that should be up to physician discretion and dosing based on safety and pharmacokinetics of methadone in pregnancy. Per leading Obstetrical and Perinatal experts, split dosing on induction is actually the safest way to start methadone, especially if the patient is a fentanyl user and one is dealing with high tolerance (3-6).

References

1. <https://ilpqc.org/wp-content/docs/ILPQC-MNO-OB-Factsheet-FINAL.pdf>
2. https://www.dhs.state.il.us/OneNetLibrary/27896/documents/By_Division/SUPR/State-of-Illinois-Overdose-Action-Plan-March-2022.pdf
3. McCarthy JJ, Jones HE, Terplan M, Rudolf VP, von Klimo MC. Changing outdated methadone regulations that harm pregnant patients. Journal of addiction medicine. 2021 Mar 1;15(2):93-
https://journals.lww.com/journaladdictionmedicine/Fulltext/2021/04000/Changing_Outdated_Methadone_Regulations_That_Harm.2.aspx
4. Cunningham CE, Fishman M, Gordon AJ. The ASAM national practice guideline for the treatment of opioid use disorder: 2020 focused update. J Addict Med. 2020;14(2S Suppl 1):1-91. https://sitefinitystorage.blob.core.windows.net/sitefinity-production-blobs/docs/default-source/guidelines/npg-jam-supplement.pdf?sfvrsn=a00a52c2_2
5. TIP 63: Medications for Opioid Use Disorder. (See Exhibit 4.2) SAMHSA May 2020 free:
<https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document/PEP20-02-01-006>.
6. <https://www.samhsa.gov/sites/default/files/split-dose-guidance-sotas-csat.pdf>
7. <https://www.childwelfare.gov/pubPDFs/safecare.pdf>
8. <https://ncsacw.acf.hhs.gov/topics/plans-of-safe-care.aspx>
9. Abuse S, Administration MH. Federal guidelines for opioid treatment programs. HHS publication no (SMA) PEP15-FEDGUIDEOTP. 2015.
10. Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence. WHO Press, World Health Organization, Geneva, Switzerland. 2009
https://www.who.int/substance_abuse/publications/Opioid_dependence_guidelines.pdf

The purpose of this guideline is to share best practices for pregnant persons with a substance use disorder (SUD) using methadone in an OTP to maintain their recovery. This guideline does not except the physician's responsibility to promote the welfare and confidentiality of the individual patient and to protect public safety.