Initial Management of Incarcerated Pregnant Women With Opioid Use Disorder

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Abstract

The epidemic of opioid and other drug use and related arrests are a growing public health crisis in the United States. The national prevalence of pregnant women with opioid use disorder (OUD) has increased dramatically from 1.5 per 1,000 delivery hospitalizations in 1999 to 6.5 in 2014. The combination of these factors has led to an increased frequency of pregnant women with OUDs in the correctional health care system. This protocol provides evidence-based treatment recommendations including the initiation of methadone and buprenorphine in the inpatient or jail setting. It also explores many of the nuances around caring for this vulnerable patient population and discusses ways in which the medical and correctional health care teams can efficiently collaborate to improve patient outcomes.

Keywords

opioid use disorder, medication-assisted treatment, incarceration, buprenorphine, methadone

Introduction

The epidemic of opioid and other drug use is a growing crisis in the United States. With more than 64,000 drug overdose deaths in 2016, it is now the leading cause of death among Americans under 50 (Centers for Disease Control and Prevention [CDC], 2017; National Institute on Drug Abuse, 2017). The opioid crisis has impacted women of childbearing age as well. Recent data from the CDC (2018) indicate that the national prevalence of women with opioid use disorder (OUD) increased from 1.5 per 1,000 delivery hospitalizations in 1999 to 6.5 in 2014. The vast majority of pregnancies in women with OUD are unintended (86%; Heil et al., 2011). The use of illegal drugs can also lead to incarceration, and there were more than 2 million arrests of women of childbearing age during 2014 (Snyder et al., 2018).

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The combination of these factors and the increasing frequency of arrests of pregnant women with OUD led to the creation of a multidisciplinary work group at a rural hospital in Maine. The work group included medical and nursing staff, social work, hospital administrators, and law enforcement. While this protocol was developed at an institution in Maine, the goal is to assist medical, nursing, and other staff at facilities in other states in the initial management of incarcerated women with OUD who may be pregnant. Clinicians are encouraged to confirm that the protocol is consistent with their own state laws prior to implementation.

It should be noted that the availability and experience of medical providers in initiating treatment with either methadone or buprenorphine varies widely in the correctional health care system. In some circumstances, it may be appropriate to initiate pregnant women on medication-assisted treatment (MAT) within the jail setting. Similarly, if the medical staff at the jail is able to quickly obtain prenatal and MAT records and has access to the appropriate medication, inpatient care may not be necessary. This protocol does not capture all of the issues that need to be addressed during the women's pregnancy and should not replace clinical judgment or consultation with addiction medicine and obstetric specialists as needed.

Flow Sheet for Incarcerated Pregnant Women

Incarcerated pregnant patients often first present to the emergency department (ED) in the custody of a law enforcement officer. The following treatment algorithm (see Figure 1) has been developed to assist with patient evaluation and management. Variations in this flow sheet may be appropriate depending upon the jail setting and available resources. Screening/confirmation of the pregnancy may be done at the jail, in the ED, or in an inpatient unit. Each facility should define the appropriate unit to evaluate obstetric patients based upon criteria that include gestational age, medical condition, and/or available medical staff (American College of Obstetricians and Gynecologists, 2016). Dating of the pregnancy may be determined by first day of last menstrual period and/or dating ultrasound. Verification of ongoing treatment for OUD should include checking the prescription drug monitoring program (PDMP) and obtaining a release of information. Methadone dispensed at an addiction treatment facility will not be listed in the PDMP.

Initial Medical Management

Beyond the dating ultrasound, appropriate initial testing includes:

1. Prenatal panel
2. Comprehensive metabolic panel
3. Hepatitis C screening (even if a history of intravenous drug use is denied)
4. HIV screening
5. Urine drug screen and urine alcohol screen (if not part of the standard screen)

If staff is able to access prior prenatal records, duplicative testing can be avoided as appropriate. A thorough physical exam includes an assessment for cellulitis/abscesses related to intravenous drug use. The risk of sepsis should also be considered, and the presence of a murmur would raise concern for possible endocarditis.

What are Her Plans for the Pregnancy?

After confirming pregnancy, counseling should be initiated to determine whether the patient plans to continue with the pregnancy. For women wishing to terminate the pregnancy, appropriate referrals should be made. For women who choose to continue the pregnancy with the intent of either

Figure 1. Treatment algorithm. If staff is able to access prenatal records, some of the recommended labs may not be necessary. Verification of treatment should include prescription drug monitoring program and/or medical release. Each facility should have written guidelines defining the appropriate unit to evaluate obstetric patients based upon gestational age and/or medical condition. If night/weekend or jail cannot obtain medication, the patient will return to L&D (if > 18 weeks) or ED (if < 18 weeks) for daily dosing. Only 3 days of buprenorphine can be administered without an X waiver. Consideration should be made for once daily MAT dosing. On repeat visits, perform NST (if > 28 weeks) or FHTs (if < 28 weeks). OUD = opioid use disorder; FHT = fetal heart tones; NST = nonstress test; MAT = medication-assisted treatment.

continuing to care for the infant or referring the child to an adoption agency, a referral to social work (at the clinic that will care for the pregnancy and the care manager on the obstetric floor) should be made as early as possible. This will also help facilitate the mandated report of the drug-affected infant at birth if required by state law.

How Long is the Patient Likely to be Incarcerated?

When a patient presents to the ED in the custody of a police officer or correctional officer, the law enforcement official is often helpful in determining how long the patient is likely to be incarcerated. From a patient management perspective, it may be helpful to understand whether the incarceration is likely to be a few days or weeks or whether the patient is expected to be incarcerated for the remainder of her pregnancy. It is also critical for the medical provider to understand the status of the patient while in the hospital setting regarding what restrictions, if any, are being placed on the patient (e.g., visitors, access to phone). This information should be contained in the furlough document that the officer present should be able to provide to the medical team. Hospitals do not have the same security safeguards as a jail, and in general, patients are free to leave against medical advice. However, the hospital can help assist in limiting access to visitors/belongings and can quickly contact law enforcement should the patient depart the facility.

Does the Patient Have an OUD?

The next, and arguably most important, step in evaluating a pregnant woman for OUD is determining whether she has an OUD. This is primarily achieved by taking a thorough history to establish whether the patient meets Diagnostic and Statistical Manual of Mental Health Disorders, 5th Edition criteria for an OUD (American Psychiatric Association, 2013). Supporting physical exam findings, such as signs of intoxication or withdrawal, and lab findings, such as a positive urine toxicology screen or confirmation for opioids, are helpful but cannot alone solidify the diagnosis. The provider should also obtain a thorough history around the use of other substances including, but not limited to, alcohol, nicotine, marijuana, amphetamines, and benzodiazepines.

Does the Patient Want Treatment for OUD?

Like all patients, incarcerated pregnant women with OUD have autonomy and are able to make decisions regarding their own medical treatment. It is imperative that the medical providers involved in her care discuss which options might be available to her and which options might be most appropriate, given her medical history. It should be noted that available resources are sometimes limited. However, pregnant women should expect priority admission to treatment. Motivational interviewing can be helpful for women who are ambivalent about entering treatment.

Treatment Options for OUD

MAT, whether with methadone or buprenorphine, is considered the standard of care for OUD during pregnancy (World Health Organization, 2014.) While methadone has been used much longer in the treatment of OUD during pregnancy, buprenorphine appears to be linked with a shorter duration and less severe neonatal abstinence syndrome (NAS; Jones et al., 2010). When compared to women maintained on methadone during pregnancy, women on buprenorphine have significantly longer gestations, fewer instances of preterm birth, and, on average, have infants with greater birth weight and head circumference (Meyer et al., 2015). MAT with methadone has been associated with a reduced risk of relapse and other high-risk behaviors as well as enhanced compliance with prenatal care (Kaltenbach et al., 1998). The PDMP should be checked prior to beginning an induction with

MAT, although it is important to note that methadone dispensed at an addiction treatment facility will not be listed in the PDMP.

Which MAT Option is Most Appropriate?

Methadone and/or buprenorphine may be appropriate depending upon a patient's individual needs and situation. Methadone is generally considered a higher level of care and may be more appropriate in situations where significant polysubstance use and/or social instability exist (Maine Department of Health and Human Services, 2018). The patient should be appropriately consented to the benefits and risks of the use of MAT during pregnancy, including the risk of NAS and the related extended hospital stay for the monitoring for NAS as well as state laws on drug-affected infant reporting (as applicable). This discussion should be documented in the medical record.

Scoring Opioid Withdrawal Symptoms

Prior to initiating induction with either methadone or buprenorphine, the patient should be scored using the Clinical Opioid Withdrawal Scale (COWS; Wesson & Ling, 2003). While the patient can be inducted onto methadone if she is not in opioid withdrawal, buprenorphine induction should be initiated only if the patient is in opioid withdrawal (or it will precipitate acute opioid withdrawal).

Methadone

Methadone clinics are federally licensed facilities that provide MAT with daily dosing of liquid methadone. These clinics typically also provide substance abuse counseling. Methadone is one of the highest levels of care because it is daily treatment. Methadone is a complete mu opioid receptor agonist. Its pharmacokinetics are such that the full effect of a dose may not be seen until 5 to 7 days after initiating treatment with that dose. When patients are inducted onto methadone in the inpatient setting, the goal is to determine an initial stabilization dose within the first 72 hours. This will make the patient considerably more comfortable and will allow the medical team to observe for side effects and coordinate the patient's care with the local methadone clinic (which will assume treatment of the OUD at discharge). Methadone clinics often limit intake appointments to certain days, so coordinating with the local methadone clinic is critical. During the inpatient induction in the hospital, it is necessary to use methadone tablets rather than liquid/wafers, but all patients will be placed on liquid/wafers in the outpatient setting. There are a myriad of initial dosing regimens for methadone induction. It is important to recognize that this is not an opioid rotation, and attempting to calculate morphine milligram equivalents will likely serve as a distraction. Unlike buprenorphine, the patient does not need to be actively withdrawing from opioids but should not be intoxicated when being inducted.

Methadone induction: Day 1. Current consensus recommends initiating induction with 10 to 30 mg of methadone daily (Baxter et al., 2013; Sevarino, 2018). A typical initial methadone dose is 20 mg, though a 10 mg initial dose could be considered if the patient presents with a history of lower daily opioid use (e.g., one to two bags of heroin daily; Sevarino, 2018). A lower induction dose may also be considered in situations in which the patient has recently used benzodiazepines or sedative hypnotics and/or is on sedating antidepressants and/or has concurrent alcohol use disorder. Providers should proceed with extreme caution if the patient has known cardiac risk factors such as a prolonged QT interval or cardiac arrhythmias.

After the initial dose, the patient should be reassessed with the COWS in 2 to 4 hours, which correlates with the peak serum methadone concentration. At that time, an additional 5 mg dose could

be administered if the COWS score is 6 to 12 or a 10 mg dose if the COWS score is greater than 12. Dosing during the first 24 hours should not exceed 40 mg (Baxter et al., 2013).

Methadone induction: Day 2 and beyond. The minimum daily dose on Day 2 is 30 mg. The provider should give either the total daily dose from Day 1 in one morning dose or 30 mg once in the morning, whichever dose is larger. If the patient continues to have withdrawal symptoms at this dose, an additional 2.5 to 5 mg of methadone can be administered every 4 to 6 hours as needed for withdrawal symptoms up to a total daily dose of 50 mg. The patient's methadone treatment is often transferred to a federally licensed addiction facility after the first 72-hour period. Following the initial induction, methadone doses are often increased 5 to 10 mg per week to an average pregnancy dose of approximately 120 mg per day (Seligman et al., 2018).

Split daily dosing. Split daily dosing, or the option of giving the total daily dose in two divided doses separated by at least 8 hours, is often pursued during the third trimester of pregnancy when the metabolism of methadone and clearance rates increase (Jones et al., 2008). It is rarely required during the initial stabilization and may increase the risk of error.

Measuring methadone trough levels. Measuring trough levels likely will not be necessary for patients in the inpatient setting. Trough levels should be measured when the patient is sedated without using any other substances and in women who remain symptomatic despite increasing methadone doses. Trough levels > 0.24 mg/L are suggestive of adequate dosing (Drozdick et al., 2002). Note that the goal is symptom management, not a specific serum level. Asymptomatic women with lower trough levels do not require a dose increase.

Fetal monitoring. During the inpatient stay, daily fetal heart tones (FHTs, prior to methadone dosing) are recommended if the patient is less than 28 weeks gestation. If the patient is greater than 28 weeks gestation, daily fetal nonstress tests (NSTs) are recommended.

Discharging patient to jail following inpatient induction onto methadone. If the patient is discharged at night or on the weekend and the jail is unable to obtain the medication, the patient will return to labor and delivery (if greater than 18 weeks gestation) or the ED (if less than 18 weeks gestation) for daily dosing of methadone. Treatment location may vary by facility. Once daily methadone dosing is preferable. On repeat visits, perform FHTs (if less than 28 weeks) and fetal NST (if greater than 28 weeks).

Legality of administering methadone inpatient for OUD. One of the most common questions raised is the legality of corrections medical staff and/or hospital medical staff administering methadone to incarcerated pregnant patients with OUD without the typical separate registration as a narcotic treatment program. Federal law allows that methadone may be administered in such circumstances when the following conditions are met:

A practitioner, or authorized hospital staff, may administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction. Pregnancy is recognized as a medical condition by both DEA and FDA, and, therefore, this would be considered medical treatment of a condition other than addiction. Such medical treatment is allowed "in a hospital" or institutional setting. However, the Department of Corrections must be licensed by both the state and DEA as a clinic, a hospital, or a hospital/clinic. (FDA Administering or dispensing of narcotic drugs, 2005)

Buprenorphine

Once considered second-line treatment because of limited data around its safety during pregnancy, it is now considered first-line treatment for pregnant women with OUD. Buprenorphine is a partial mu opioid receptor agonist. It has high affinity for the mu opioid receptor and minimizes withdrawal symptoms and inhibits the effects of other opioid receptor agonists. The pharmacokinetics of buprenorphine limits the euphoric activity of opioids (either prescribed or used illicitly). A typical therapeutic dose for buprenorphine is 8 to 16 mg daily. Buprenorphine monotherapy is still considered the standard of care during pregnancy, though this is rapidly evolving as evidence supports the efficacy and safety of the combination buprenorphine/naloxone product. The combination product also mitigates the risks of misuse/diversion. Because the naloxone is not orally activated, withdrawal symptoms do not occur when the combination product is dissolved sublingually as directed. In the inpatient setting, any provider able to prescribe schedule III–controlled substances can also prescribe buprenorphine. In the outpatient setting, a special license (“X waiver”) is required to prescribe the medication.

Buprenorphine induction: Day 1. Prior to commencing buprenorphine induction, the provider should confirm the presence of opioid withdrawal using the COWS as the administration of buprenorphine will precipitate opioid withdrawal if not already present. Again, there are a variety of induction protocols and the following recommendations are adapted from O'Connor and Alto (2013) and Strain (2018).

If the patient is moderately to severely symptomatic (COWS score of 13 or more), the patient should be prescribed a loading dose of 4 mg, followed by 2 mg every 4 to 6 hours as needed to treat withdrawal symptoms. If the patient presents mild to moderately symptomatic (COWS score 5 to 12), the patient should be prescribed a loading dose of 2 mg, followed by 2 mg every 4 to 6 hours as needed. A total daily dose of buprenorphine of 4 to 8 mg on the first day of therapy is often adequate and no more than 12 mg should be administered on Day 1. Mild symptoms (COWS score less than 5) may be managed adequately with supportive care and clonidine 0.1 mg orally every 4 to 6 hours instead of incremental doses of buprenorphine.

Buprenorphine induction: Day 2. The total daily dose on Day 1 should be administered as a single morning dose on Day 2. An additional 2 to 4 mg of buprenorphine may be administered every 4 to 6 hours as needed for withdrawal symptoms up to 16 mg daily.

Buprenorphine induction: Day 3 and beyond. The patient should be continued on the Day 2 daily dose (administered as one dose in the morning). Incremental daily adjustments to buprenorphine dosing can be made until withdrawal symptoms are minimal or eliminated, and this is considered the stabilization dose. The maximum daily dose typically should not exceed 16 mg.

Fetal monitoring. During the inpatient stay, daily FHTs are recommended if the patient is less than 28 weeks gestation. If the patient is greater than 28 weeks gestation, daily fetal NSTs are recommended.

Discharging patient to jail following inpatient induction onto buprenorphine. If the patient is discharged at night or on the weekend and the jail is unable to obtain the medication, the patient will return to labor and delivery (if greater than 18 weeks gestation) or the ED (if less than 18 weeks gestation) for daily dosing of buprenorphine. Treatment location may vary by facility. Once daily buprenorphine dosing is preferable. Only 3 days of buprenorphine can be administered without an X waiver. On repeat visits, perform FHTs (if less than 28 weeks) and fetal NST (if greater than 28 weeks).

Detoxification Followed by Naltrexone

If the patient is not willing to consider methadone or buprenorphine, she may be willing to consider detoxification under medical supervision followed by outpatient treatment with naltrexone, a mu receptor antagonist. Data on its safety in pregnancy are limited. However, if the risk of relapse is high and the patient is not willing to consider methadone or buprenorphine, naltrexone may be a viable option. Detoxification can be done in the hospital, either by gradually prescribing lower doses of opioids or by treating the patient symptomatically with loperamide, methocarbamol, or clonidine. There are limited safety data on all of these medications in pregnancy. Naltrexone is dosed at 50 mg daily (or as a monthlong injectable suspension, Vivitrol), and the patient must have abstained from the use of any opioids for at least 5 days prior to administration or it may precipitate acute opioid withdrawal.

The patient should be counseled that this is not the standard of care and that withdrawal places the fetus at high risk of complications, including death. Many providers become anxious about the idea of a pregnant woman withdrawing from opioids due to the potential risk to the fetus. It is important to remember that the patient has likely experienced recurrent rounds of highs, lows, and withdrawals throughout the course of the pregnancy.

Detoxification Followed by Abstinence

Alternatively, if the patient is unwilling to consider MAT, medically supervised detoxification followed by abstinence could be recommended. This option comes with a high risk of relapse and should be reserved only for women unwilling to consider other options or those that will be under strict supervision, such as jail or prison, for the remainder of their pregnancy. Detoxification could be considered as above but, again, is not the standard of care and places the pregnancy at risk.

Behavioral Health Treatment

The pregnant patient with an OUD has significant behavioral health needs. She will benefit from a rapid evaluation of any and all co-occurring mental health disorders and the related initiation of substance use and mental health counseling. Ideally, this can be initiated in the inpatient setting or jail. If not, the appropriate level of care can be determined at the time of discharge depending upon the expected duration of incarceration.

Naloxone

Naloxone is a short-acting opioid antagonist that can rapidly reduce opioid overdose. Although it precipitates acute withdrawal, it should be administered (and prescribed) to pregnant women in the case of maternal overdose in order to save the woman's life.

Resources to Assist With Ongoing Management of Pregnant Women With OUD

- American College of Obstetricians and Gynecologists (2017)
- Maine Department of Health and Human Services (2018)
- O'Connor and Alto (2013)

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