

2021

Development of a Detox Clinical Practice Guideline for Pregnant Women Suffering from Opioid Addiction

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Walden University

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Walden University

College of Nursing

This is to certify that the doctoral study by

Becca Ward

has been found to be complete and satisfactory in all respects,
and that any and all revisions required by
the review committee have been made.

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Walden University

2021

Abstract

Development of a Detox Clinical Practice Guideline for Pregnant Women
Suffering from Opioid Addiction

by

Becca Jo Ward

MS, Indiana University, 2012

BS, Vincennes University, 2009

Project Submitted in Partial Fulfillment
of the Requirements for the Degree of
Doctor of Nursing Practice

Walden University

May 2021

Abstract

The number of women suffering from opioid use disorder during pregnancy is a national epidemic. The gap in nursing practice is the lack of detoxification and medication-assisted treatment facilities that are equipped to care for this vulnerable population. The purpose of this project was to develop a clinical practice guideline (CPG) that is safe for both the fetus and the pregnant mother. Opioid dependence during pregnancy is on the rise with the nation's current opioid epidemic. In this project, a meta-synthesis review was used to gather evidence from various sources and to develop a detox CPG that is safe for mothers and infants. An expert panel of four nurse practitioners, two psychiatrists, and two OBGYNs reviewed the CPG using the AGREE II instrument. Each area was assessed using a 7-point scale. All panelists agreed that the CPG was appropriate and required no immediate changes prior to implementation. The CPG ensures that this population is being treated with the most up-to-date treatment modalities, thus improving patient care. The potential positive social change linked to this project is reducing the number of neonatal abstinence syndrome births due to opioid use during pregnancy. A reduction has the potential to improve the mothers' and infants' health outcomes and also reduce mortality rates. The well-being of mothers and infants determines the health of the future generation and helps predict future health challenges for families, communities, and the health care system.

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Dedication

To Silas: I am forever grateful that God chose me as your Mom. Your story inspired this project. Because of you the world is a better place.

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I would like to thank my husband, Brian, and children, Sam, Jason, & Silas. You selflessly cheered me on and encouraged me on days I didn't believe in myself. I will be forever grateful for your unending love and support.

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Section 1: Nature of the Project

The number of women with opioid use disorder (OUD) at labor and delivery quadrupled between 1999 and 2014 (Gilfillan et al., 2018). Opioid use disorder or opioid addiction is a problematic pattern of opioid use that causes significant impairment or distress (Jumah, Graves & Kahan, 2015). Opioid dependence during pregnancy is on the rise with the nation's current opioid epidemic. Between 2000 and 2009, opioid use during pregnancy grew five-fold in the United States (Forsay, 2016). In 2016 alone, more than 380,000 babies were exposed to opiates (Forsay, 2016). Moreover, over 45,000 infants have been born with neonatal abstinence syndrome (NAS) since 2004 (Forsay, 2016). This public health issue is leading to infant morbidity and mortality (Walhovd et al., 2015). Despite this growing problem, there is still a lack of substance abuse treatment facilities for pregnant women (Walhovd et al., 2015). Fewer than 10% of women who abuse opiates get the help they need due to barriers, such as access to care (Forsay, 2016). Opioid dependence affects women regardless of race or socioeconomic class. This is directly related to the opioid crisis affecting the United States (Centers for Disease Control and Prevention, 2017).

Americans are routinely using a prescription or an illicit opioid. More than 109,000 women of childbearing age, 15 to 44 years, reported using heroin in 2015 (Walhovd et al., 2015). Opioids are a class of drugs used for reducing pain. They work by binding to mu, delta, and kappa receptors, blocking the intensity of pain. Their pain-blocking effects can also cause euphoria, leading to OUD (Rodriguez & Klie, 2019). The common prescription opioids include oxycodone, codeine, morphine, and

hydrocodone. Fentanyl is a synthetic opioid pain reliever that can be made illegally, while heroin is an illegal opioid (Jumah, Graves & Kahan, 2015). Pregnant women may use opioids as prescribed by their physicians; they may misuse prescription opioids; they may use illicit opioids such as heroin, or use opioids, such as opioid agonists or antagonists, as part of their medication-assisted treatment for OUD. Regardless of the type of substance used, opioid use during pregnancy can pose harm to women and their babies.

Opioid exposure during pregnancy is linked to adverse health effects for mothers and their babies (Larson et al., 2019). For example, for mothers it is associated with maternal death, while for babies, it is linked to preterm birth, poor fetal growth, specific birth defects, stillbirth, and neonatal abstinence syndrome (NAS). NAS is a group of conditions that occur when newborns withdraw from certain substances, such as opioids, to which they were introduced before birth (O'Donnell & Jackson, 2017). These newborns experience withdrawal symptoms during their first 28 days of life, and signs begin to appear within 72 hours after birth. This condition is known as the neonatal opioid withdrawal syndrome (NOWS) and its signs include: sleep problems, tremors, irritability, hyperactive reflexes, vomiting, seizures, dehydration, loose stools, increased sweating, stuffy nose, yawning, and sneezing (O'Donnell & Jackson, 2017). The effects of prenatal opioid exposure on children over time are largely unknown. However, studies show that treating OUD during pregnancy outweighs the risks (Larson et al., 2019).

Several factors have contributed to the rapid increase in the abuse of prescription drugs over the last 2 decades. In the early 1990s, concerns about undertreating pain led to

an increased emphasis on measuring and treating pain (Krans, Cochran & Bogen, 2015). This propelled the American Pain Society to introduce pain as “the fifth vital sign” and enhanced providers’ recognition of pain’s importance in patient outcomes and experiences (Krans & Patrick, 2016). However, this emphasis on pain came at a great cost, because it was coupled with the unethical marketing practices of pharmaceutical company that downplayed the addictive potential of opioid pain relievers (Krans & Patrick, 2016). This led to overprescribing and a notable shift in indications for prescription opioids to include chronic, noncancer pain. Some experts argue that Medicaid expansion has exacerbated the opioid epidemic (Krans, Cochran & Bogen, 2015). They believe that legal prescriptions have fueled the opioid epidemic by increasing access to prescription opioids. This belief is based on the rise in opioid-related deaths in Medicaid expansion states as compared to nonexpansion states (Gilfillan et al., 2018).

The opioid epidemic is a rapidly growing public health concern (Forray, 2016). Moreover, opioid use during pregnancy has also escalated (Forray, 2016). Opioid use during pregnancy affects women of all races, religions, and socioeconomic backgrounds. Improving care and knowledge of the effects of substance abuse during pregnancy is needed, now more than ever, to help combat and bring light to this national problem. Opioid use that is not treated during pregnancy has the potential to significantly affect the unborn baby. There are four benefits of detoxing women from opioids and placing them in a medication-assisted recovery program: (a) stabilizing fetal opioid levels and thus limiting withdrawals; (b) linking pregnant women to other services, such as infectious

disease services; (c) improving prenatal care, and (d) improving outcomes for both mother and child (Centers for Disease Control and Prevention, 2017; Charles, Cooper, & Jansson, 2017; Maguire et al, 2016).

This project constituted a systematic review of an effective approach to combatting OUD during pregnancy; it yielded clinical practice guidelines (CPGs) that providers can use to help pregnant women with opiate abuse. This project sought to answer the four practice-focused questions by employing a systematic and reproducible search strategy and developing guidelines from the results of the search. This approach involved identifying relevant studies, critically appraising them, and presenting an unbiased and balanced summary of findings in the form of a CPG. The potential positive social change linked to this project was reducing NAS births due to opioid use during pregnancy. This would improve the mothers' and infants' health outcomes and reduce mortality rates.

Problem Statement

Improving the well-being of mothers and infants is a crucial public health goal for the United States (Forray, 2016). Mothers' and children's well-being determines the health of the future generation and helps predict future health challenges for families, communities, and the health care system. Studies show that the number of women with OUD at labor and delivery has quadrupled over the last 15 years (Forray, 2016). Moreover, four times as many children were born with NAS over the same period. OUD during pregnancy has been linked to the following health outcomes: preterm birth, low

birth weight, breathing problems, feeding problems, and maternal mortality (Walhovd et al., 2015).

These short-term neonatal outcomes are well recognized and documented. Of the long-term health outcomes associated with opioid use during pregnancy (Rodriguez & Klie, 2019), there is a growing body of evidence to suggest that children who are exposed to opioids may have lower performance scores such as IQ scores, verbal performance, and full-scale scores. For example, they may have lower scores in the following areas: sense of well-being, psychological mindedness, responsibility, empathy, self-control, and social maturity index (Jumah, Graves & Kahan, 2015). Moreover, they score poorly in cognitive flexibility, strategic planning, decision making, short term memory, and inhibition. Furthermore, such scores are linked to behavioral problems, developmental delay, and speech/language impairments (Jumah, Graves & Kahan, 2015). Addressing OUD during pregnancy is an effective way of improving maternal and infant health. It will reduce the mortality rates and prevent future health problems for women at childbearing age and their children.

Medication-assisted treatment is the use of medications combined with behavioral therapies and counseling to treat OUD (Forray, 2016). Methadone and buprenorphine are the first-line therapy options for pregnant women with OUD. Methadone is a long-acting opioid agonist that reduces opioid craving and withdrawal and blunts or blocks the effects of opioids (Schuckit, 2016). Buprenorphine is an opioid partial agonist that produces effects such as euphoria or respiratory depression at low to moderate doses (Schuckit, 2016). However, its effects are weaker than full opioid agonists such as methadone and

heroin. Buprenorphine is safe and effective if taken as prescribed; it has unique pharmacological properties that help diminish the psychological dependency on opioids, such as cravings and withdrawal symptoms; it increases safety in cases of overdose and lowers the potential for misuse (Schuckit, 2016).

Shortly after starting opioids, a person will not be able to feel “normal” without having these drugs in their system (Terplan et al., 2018). This can even happen to individuals taking legally prescribed opioid medications. Unfortunately, the brain quickly becomes used to these drugs binding to the opioid receptors. In as little as 6 hours after last use, individuals who are dependent or addicted to opioids experience painful withdrawal symptoms (Carter et al., 2019). When a person quits using opioids, his or her body goes through a detox period, where it attempts to rid itself of the substance. The detox stage in recovery is crucial for people to reach sobriety. Unfortunately, detox is marred by withdrawal symptoms that can vary in length and intensity. For many people struggling with substance abuse, the withdrawal timeline is excruciating and daunting uphill battle (Forray, 2016).

Thus, medication such as methadone and buprenorphine are used to combat the withdrawal symptoms (Campbell, 2016). They help addicts withstand the pains of withdrawal and cravings for opioids. Consequently, they reduce the chances of relapse because the medication helps addicts complete the detox process and completely recover. Flow: Transition sentence needed to show the relationship between the following and the previous sentence. MAT is based on the harm reduction philosophy of substance abuse (Schuckit, 2016), which argues that addicts should settle for smaller and realistic goals

rather than huge goals that may end up backfiring. Studies suggest that the current obstetric practice is not to withdraw opiate-addicted women during pregnancy (France et al., 2019). This recommendation is largely a safety issue for the fetus and the pregnant mother. Research shows that stillbirth, fetal distress, and premature labor can occur in a patient who has had withdrawal symptoms shortly before delivery. Detoxification is also associated with a high rate of relapse and an increased risk of the infant developing NAS (France et al., 2019).

This project is significant for nursing. It provides more data to increase providers' understanding ways to successfully manage opiate use in pregnant women. Providers can use this information to (a) identify the causes of opioid use during pregnancy, (b) understand how opioids affect the brain, (c) identify withdrawal symptoms, (d) help patients safely overcome the withdrawal symptoms when quitting, and (e) protect the fetus.

Purpose

This project aimed to develop a detox CPG that is safe for both the fetus and the pregnant mother. This project strived to achieve this goal by answering the following practice-focused questions:

1. What is the most effective approach to avoid withdrawal symptoms during pregnancy?
2. How do gynecologists and obstetricians prevent fetal distress in pregnant women using opioids?
3. How do providers reduce the risk of infants developing NAS?

4. How do providers reduce the risk of relapse in pregnant women with OUD?

This project aimed to develop a safe detox CPG for pregnant women suffering from opioid addiction. The project began with the need to enhance the well-being of childbearing mothers and infants. It identified that opioid use during pregnancy is among the problems that lower mothers' and infants' health outcomes (Schuckit, 2016). Thus, combatting opioid use during pregnancy results in positive health outcomes for mothers and future generations. Detoxification or stopping the use of opiates is a potential solution for this problem. However, obstetric practice does not recommend detoxification in pregnant women because of safety concerns for the mother and fetus, including stillbirth, fetal distress, and premature labor, infants developing NAS, and the increased risk for a relapse. I used this information to develop a CPG that avoids the problems linked to detoxification.

Nature of the Doctoral Project

This project, an integrative review, investigated an effective approach to combat OUD in pregnant women, thus leading to the development of CPGs. It included qualitative data such as studies deriving data from focus groups, interviews, observations, and diaries. The project also included peer-reviewed articles about detoxification from opioids during pregnancy.

The sources were databases such as MEDLINE Complete, CINAHL, OVID, EBSCO, ScienceDirect, SCOPUS, PsycARTICLES, and PsycINFO. This project used meta-ethnography to organize and analyze the evidence collected from the qualitative studies. This approach involved translating concepts and metaphors across the studies and

combining them to form a summary of the findings (France et al., 2019). Of the 67 articles reviewed, 26 were found to be relevant.

This project's anticipated findings were that the use of medication in detox protects the mother and fetus from withdrawal symptoms. Detox also reduces the risk of the infant developing NAS and the risk of the mother relapsing.

Significance

This project is important to the field of nursing because OUD during pregnancy is on the rise. This is leading to an increase in health problems in infants exposed to substances in utero, as well as affecting bonding between the mother and child. Medical staff caring for the mothers during preconception, pregnancy, childbirth, and immediately after delivery can use this project's results to improve their understanding about managing opioid use in pregnant women. This project aimed to facilitate a CPG that could effectively and safely detox pregnant women from opioids in order to improve both maternal and fetal outcomes.

Summary

Pregnant women abuse opiates by misusing prescription opioids or using illicit opioids, such as heroin. Opioid abuse among pregnant women has reached epidemic proportions, and this adversely affects maternal and child health outcomes. For example, it is associated with maternal death for mothers and to preterm birth, poor fetal growth, specific birth defects, stillbirth, and NAS symptoms for babies. Improving the well-being of mothers and infants is a crucial public health goal for the United States. This is because mothers' and children's well-being determines the health of the future generation

and helps predict future health challenges for families, communities, and the health care system. Treating OUD in pregnancy is essential for reaching this goal. This project aims to develop a detox CPG for women who are abusing opiates during pregnancy. The goal of the CPG is to improve safety of both mother and fetus during pregnancy and reduce NAS symptoms after delivery. An integrative approach will be used to develop the CPG to ensure the most up-to-date recommendations are implemented.

Section 2 will discuss the theories for substance use disorders, the project's relevance to nursing practice, and the demographic characteristics of pregnant American women using opioids.

Section 2: Background and Context

Opioid use in America has reached epidemic proportions, and pregnant women are among the most affected population (Schuckit, 2016). The two primary treatments for pregnant women with OUD are opioid detoxification and opioid agonist medication assisted recovery, with medications such as buprenorphine and methadone (Carter et al., 2019). Opioid detoxification is not recommended because of its high rate of maternal relapse and the potential fetal risks associated with cycles of intoxication and withdrawal. This project developed a detox CPG that is safe for both the fetus and the pregnant mother. This section discusses the theories about substance use disorders, this project's relevance to nursing practice, and the demographic characteristics of pregnant American women using opioids.

Concepts, Models and Theories

Several theorists have developed theories to explain substance use disorders. These theories are crucial for treating patients struggling with substance abuse (Saia et al., 2016). They invite exploration and a deeper understanding of what may predispose an individual an increased likelihood of addiction. One example is the self-medication theory which posits that certain individuals abuse drugs in an attempt to self-medicate physical, psychological, or social problems (Saia et al., 2016). This theory suggests that drugs are used as a coping mechanism. This theory was first published in 1985 in the *American Journal of Psychiatry*, focusing on how individuals were drawn to and became dependent on heroin and cocaine (Awad & Voruganti, 2015). An updated version was published in 1997 in the *Harvard Review of Psychiatry*, accounting for conditions that

had been previously ignored. According to this revision, pregnant women abuse opioids to alleviate pain resulting from other illnesses or as part of their MAT for OUD (Krans, Cochran & Bogen, 2015). Pregnant women use opiates to reduce pain or manage the symptoms of opioids use disorder. The opioids' pain-blocking effects can also cause euphoria, leading to addiction (Krans, Cochran, & Bogen, 2015). The term addiction refers to the compulsive need for habit forming substances that have a negative impact on one's life (Krans & Patrick, 2016).

Another theory of substance abuse and addiction relevant to this project is the genetic predisposition theory (Krans, Cochran, & Bogen, 2015). This theory argues that drug addiction is a disease and shares many features with other chronic illnesses, one of which is heritability. This implies that drug addiction can run in the family. Thus, genes can play a role in making a person vulnerable to drug addiction or protecting against it. Studies have shown that the environment a person grows up in, the individual's behavior, along with inherited DNA, influence whether the person may become addicted to drugs (Krans & Patrick, 2016).

Scientists estimate that genetics account for close to 60% of a person's vulnerability to addiction (Krans, Cochran & Bogen, 2015). The National Institute on Drug Abuse supports research efforts to identify gene variations that make people vulnerable to drug addiction. These efforts involve studying DNA, which directs the development of every human cell. Scientists have mapped the DNA sequence in drug addicts and have managed to isolate gene sequences that indicate a greater risk of becoming addicted to drugs. These sequences contain the instructions for producing

specific proteins, PSD-95, which perform most of the body's functions (Krans & Patrick, 2016). The way these proteins function or do not function can indicate how vulnerable a person is to drug addiction.

The genetic predisposition hypothesis can be used to explain the long-term effects of opioid use during pregnancy on the infants (Schuckit, 2016). Most of the studies focus on the short-term effects of opioid exposure during pregnancy, and they link it to adverse health effects short-term effects for the babies. For example, it is associated with NAS—a group of conditions that occur when newborns withdraw from certain substances such as opioids that they were introduced to before birth (Krans & Patrick, 2016). These newborns experience withdrawal symptoms during their first 28 days of life, and these signs begin within 72 hours after birth (Schuckit, 2016). This condition is known as the neonatal opioid withdrawal syndrome (NOWS). The genetic predisposition hypothesis proposes that these infants can be vulnerable to drug addiction. These infants inherit low levels of PSD-95 protein from their parents which plays a role in addiction to drugs such as heroin, alcohol, and opioids (Krans & Patrick, 2016).

Relevance to Nursing Practice

Opioid use in the United States has reached epidemic proportions, the number of people using opioids quadrupled from 1999 to 2014 (Gilardi, Augsburg & Thomas, 2018). This crisis involves heroin and other illicit drugs in addition to prescription drugs. This dramatic change has increased opioid-involved overdose deaths. Women of childbearing age are among the population that has been particularly affected by the increase in opioid use and misuse. Between 2008 and 2012, close to 28% of women of

reproductive age with private insurance and more than 39% of those enrolled in Medicaid filled opioid prescriptions (Gilardi, Augsburger & Thomas, 2018). Opioid use in pregnancy is associated with adverse effects for the mothers and babies. Despite these known risks, the rates of opioids use in pregnant women have been increasing (Terplan et al., 2018). Opioids use in pregnancy is not only associated with health complications, but also longer hospital stay and high medical bills.

In 2017, the American College of Obstetrics and Gynecology and the American Society of Addiction Medicine collaboratively developed recommendations to guide clinicians caring for pregnant patients with OUD (Terplan et al., 2018). At the heart of these recommendations is the Universal Screening, Brief Intervention, and Refer for Treatment strategy (Gilardi, Augsburger & Thomas, 2018). SBRIT ensures that screening for substance abuse is standard practice for every woman's first prenatal visit, regardless of her ethnicity or socioeconomic status. It strives to achieve this by requiring clinicians to use a validated screening tool. However, this tool only identifies patients with OUD if they seek prenatal care and answer questions honestly (Terplan et al., 2018).

If the screening indicates that a patient may be at risk of OUD, the next step is brief intervention. This involves engaging the patient in a brief, nonjudgmental conversation, providing feedback and advice and referring the patient to the appropriate treatment services. Clinicians should understand their states' mandatory reporting before initiating patient care (Gilardi, Augsburger & Thomas, 2018). According to ACOG, patients identified with opioids use disorder should be referred to as a substance use

disorder treatment program and receive MAT. MAT combines behavioral therapy with opioid agonist pharmacotherapy.

The two primary treatments for pregnant women with OUD are opioid detoxification and opioid agonist MAT with medications such as buprenorphine and methadone (Carter et al., 2019). Opioid detoxification is not recommended because of its high rate of maternal relapse and potential fetal risks associated with cycles of intoxication and withdrawal. Pregnant patients attempting opioid detoxification should be under the supervision of a clinician experienced in peripartum addiction and have psychosocial interventions (Carter et al., 2019). Withdrawing from opioids is an extended process with numerous challenges. Thus, the patients should demonstrate commitment to treatment. The second trimester is the safest time to initiate opioid detoxification. The best results are seen in programs that gradually reduce medication based on maternal symptoms (Carter et al., 2019). Clinicians can improve outcomes by providing sensitive and supportive care to all patients regardless of their demographics or backgrounds.

Methadone is the gold standard for MAT in pregnancy, and it has been extensively studied than buprenorphine, a promising newer option (Campbell, 2016). Methadone treatment must be initiated while the women is an inpatient and or in a licensed outpatient methadone program (Campbell, 2016). It should be dispensed daily even after the maintenance dosage has been reached (Campbell, 2016). Physiological changes during pregnancy include increased intravascular volume, renal perfusion, and glomerular filtration rate to increase the renal elimination of methadone (Campbell, 2016). Most of the patients require dosage increases due to withdrawal symptoms, but

this raises concern for increased severity and incidence of NAS (Walhovd et al., 2015).

Methadone dosages are often not reduced for the first 6 weeks postpartum, but this happens based on the signs and symptoms of overmedication, including: itching, miosis, hypotension, sedation, and respiratory depression (Carter et al., 2019).

Unlike methadone, buprenorphine can be prescribed and initiated in any office setting by trained providers including nurse practitioners and physician assistants and may be dispensed either weekly or biweekly (France et al., 2019). Outpatient treatment is preferred because: it reduces the social stigma and shame linked to OUD, is convenient to the patients, reduces barriers to treatment, and increases adherence. This is a partial mu receptor agonist, it does not undergo much conformational change as full agonists such as methadone when bound to opioid receptors (Saia et al., 2016). Its activity plateaus at higher do, reducing the risk of overdose compared with full receptor agonists.

Methadone's downside is a ceiling effect: dosages greater than 32mg do not significantly increase effect (Rodriguez & Klie, 2019). Buprenorphine treatment is not recommended for all pregnant patients with OUD. Methadone treatment programs provide more structure, support, and supervision. Successful buprenorphine treatment requires the patient to express a preference for buprenorphine over methadone. The patient should provide informed consent for treatment and demonstrate that he/she is capable of sagely self-administer the medication and adhere to a schedule (Rodriguez & Klie, 2019).

Clinicians must also consider the following factors beyond the patient's condition when caring for pregnant women with OUD. First, breastfeeding is safe and recommended for mothers on the MAT (Saia et al., 2016). Studies show that infants

whose mother are on MAT have reduced the severity of NAS, and they require less pharmacotherapy to treat their NAS. Maternal transfer of methadone and buprenorphine in breast milk is minimal and considered safe. Second, women receiving MAT require high doses of analgesia to control their pain (Rodriguez & Klie, 2019). Third, pregnant women in MAT should quit smoking because of the increased risk of placental abruption, intrauterine growth restriction, preterm delivery, low birth weight, and stillbirth. Lastly, women with OUD are likely to engage in high-risk behaviors (Rodriguez & Klie, 2019). Thus, clinicians should regularly screen them for sexually transmitted diseases.

Local Background and Context

National Survey on Drug Use and Health (NSDUH) has been examining opioid use and treatment among women of childbearing age (Saia et al., 2016). This survey focuses on U.S. civilian, noninstitutionalized population aged 12 years or older. NSDUH defines opioid misuse as the use of heroin and nonmedical use of prescription pain reliever in the past month. The Treatment Episode Data Set (TEDS) also examines opioids misuse in women at childbearing age, and it focuses on those admitted with substance use treatment for opioid misuse (Saia et al., 2016). Combined data for NSDUH and TEDS reports that about 21,000 pregnant women aged 15 to 44 misuse opioids every month (Saia et al., 2016). The data indicate that OUD in pregnant women cuts across all races. It is common among white, black, Native American, Asian, and Latino pregnant women who have obtained opioid prescriptions from multiple pharmacies and those who have obtained them in combination with other scheduled medications. The younger generation is the age group with the greatest non-medical use of opioids. The data

indicate that, among pregnant women, opioid misuse is common among those aged 15 to 17 and 18 to 25 (Saia et al., 2016). The data also suggest that socioeconomic status influences the use of nonmedical opiates. It is more common among those living below the federal poverty level than those living at or above the federal poverty level (Awad & Voruganti, 2015).

Role of the DNP Student

My primary role in this project entailed collecting data to answer the practice-focused questions and developing a CPG using the collected data. I collected this data by searching for, reviewing, and selecting relevant studies that correspond to the practice-focused questions. My primary motivation was to improve maternal and infant health in America. Developing a safe detox CPG for the mother and fetus was essential in reaching this goal.

Summary

Understanding why people abuse substances is essential for developing a safe detox CPG. This project also strives to understand the long-term effects of drugs on infants exposed to illicit substances during pregnancy. This will help physicians control substance abuse during pregnancy and propel researchers to develop interventions to assist these infants.

Section 3 will discuss the design, data collection strategies, ethical considerations, and methods used to analyze the CPG.

Section 3: Collection and Analysis of Evidence

The number of women with OUD at labor and delivery has quadrupled between 1999 and 2014 (Walhovd et al., 2015). OUD during pregnancy has been linked to the following health outcomes: preterm birth, low birth weight, breathing problems, feeding problems, and maternal mortality (Walhovd et al., 2015). These short-term neonatal outcomes are well recognized and documented. There is a growing body of evidence on the long-term health outcomes associated with opioid use during pregnancy (Rodriguez & Klie, 2019). Addressing OUD at labor and delivery is an effective way of improving maternal and infant health to prevent future health problems for women at childbearing age, and their children, and reduce the mortality rate.

Practice-Focused Questions

This project aimed to develop a detox CPG that is safe for both the fetus and the pregnant mother. It achieved this goal by answering the following four questions:

1. What is the most effective approach to avoid withdrawal symptoms during pregnancy?
2. How do providers prevent fetal distress in pregnant women using opioids?
3. How do providers reduce the risk of infants developing NAS?
4. How do providers reduce the risk of relapse in pregnant women with OUD?

This project employed a qualitative approach to collect data and answer the practice-focused questions.

Sources of Evidence

Design

This project employed an integrative review of scholarly/journal articles to gain valuable insights into the project phenomenon. Under this approach, the author; searched for, selected, evaluated, summarized, and combined evidence to address the practice issue. This produced a conceptually robust account of the meaning and significance of the research issue. This integrative review used scholarly journals and peer-reviewed articles about developing a detox CPG for pregnant women with UOD.

Data Collection and Search Strategy

The sources of scientific articles considered suitable for this project were the following databases: CINAHL, MEDLINE Complete, ScienceDirect, OVID, EBSCO PubMed, PsycARTICLES, SCOPUS, and PsycINFO. Full texts were acquired using Google Scholar and ResearchGate when a PDF file was not retrievable from the database where the study was found. Free text searches were conducted in the databases to obtain knowledge of the basis in the research area. Free text searches involved searching all articles in the databases containing the keywords and displaying the results based on the question (Lachal et al., 2017). The following keywords were used: *pregnant women opioids, opioid use disorder, oud, , opioid detoxification pregnancy, detoxification opiate drugs, substance abuse, and neonatal abstinence syndrome*. The Boolean search operators AND OR were used to extend and restrict searches and to find a manageable number of relevant articles. Searches were limited to the years 2015 to 2020.

Quality Review

This project used the CASP tool to evaluate the articles critically. I preferred the CASP tool because it is useful for evaluating qualitative studies. The CASP tool contains ten questions that researchers use to examine the quality of scientific articles (Mohammed, Moles & Chen, 2016). The answer options for these 10 questions are “yes,” “can't tell,” and “no.” The first two questions require the answer “yes” for the researcher to continue reviewing the quality of an article (Mohammed, Moles & Chen, 2016). Each question carries one point meaning that the maximum points that an article can get are ten points. CASP lacks a clear delimit to the number of points required for the quality to be considered low, medium, or high (Mohammed, Moles & Chen, 2016) Therefore, the author decided the demarcation that would apply for this meta-synthesis quality review before the commencement of the evaluation. For this project, below 6 points were considered low points, 7 to 8 points were considered medium quality, and 9 to 10 points were considered to correspond to high quality. The articles were first examined under CASP individually and then jointly. Only high-quality articles were considered in the meta-synthesis.

Ethical Considerations

Meta-synthesis of qualitative studies does not involve collecting data from human subjects. However, this does not mean that the author should not engage in good ethical practices. I familiarized myself with the ethical considerations concerned with selecting and presenting the results. This meta-synthesis will adhere to all the ethical guidelines concerned with collecting second-hand data. The first moral issue associated with using

peer-reviewed journals as a source of data is respect for intellectual property (Resnik, 2015). A scholar should never plagiarize or copy the work of another person and try to pass it off as his/her own. A scholar should always acknowledge the contribution of other people to his/her study. Secondly, a scholar should maintain honesty and integrity (Doody & Noonan, 2016).

A scholar may face several challenges, such as a few case studies on the phenomena. Despite this challenge, the scholar should not make up any data or extrapolate unreasonably from some of the results. Thirdly, the scholar should avoid careless mistakes (Resnik, 2015). The work should be reviewed carefully and critically to ensure that the results are credible. Fourthly, scholars have a moral obligation to maintain and improve their professional competence and expertise (Doody & Noonan, 2016). This is attained by capitalizing on learning opportunities that arise while researching to acquire knowledge and life-long skills. Lastly, a scholar should strictly adhere to the laws and regulations governing social studies (Resnik, 2015). This will avoid tarnishing the reputation of the scholar and litigations.

Analysis and Synthesis

This project used the meta-ethnographic method to analyze the evidence collected from the articles included in the meta-synthesis. Meta-ethnography produces new interpretation, model or theory that goes beyond the findings of the individual studies synthesized and it does not simply aggregate findings (France et al., 2019). This approach has seven iterative and overlapping phases; the first phase involves deciding the focus of the synthesis. This is the intellectual interest that qualitative research will inform. The

second phase is concerned with deciding the information relevant to the metasynthesis. This involves identifying and selecting study accounts to synthesize. The third phase is reading the studies, and it involves repeated reading of the accounts to identify interpretative metaphors. This phase requires extensive attention to the details in the accounts (France et al., 2019). The fourth phase is concerned with putting together the various accounts, and it entails determining the relationship between the studies.

I created a list of the key metaphors, ideas, phrases and concepts and their relations used in each account and juxtapose them. Fifth, I translated the studies into one another. I compared the meaning of metaphors, concepts or themes and their relations across study accounts to identify the range of metaphors, concepts, and themes. In the sixth phase, I synthesized the translations to develop new interpretations that go beyond the findings of any individual study. In the last phase, I expressed the synthesis by communicating the findings to the audience in a suitable format (France et al., 2019), which in this case, was in the form of a CPG. An expert panel of four nurse practitioners, two psychiatrists and two OBGYNs reviewed the guidelines using the AGREE II instrument. The guideline was revised based on expert panel recommendations. The CPG was presented to those who will use the guidelines in practice to ensure validity.

Summary

This metasynthesis enabled the scholar to gather evidence from various sources and develop a detox CPG that is safe for mothers and infants. The guideline went beyond the findings of single studies but involve a combination of the knowledge gained from all the studies. Section 4 will discuss the project findings, limitations and strengths.

Section 4: Findings and Recommendations

Pregnant women abusing opiates constitutes a specific population that requires clear and concise treatment modalities (Walhovd et al., 2015). The stigma against substance use, specifically during pregnancy, has created barriers for these women to access the care they need (Schuckit, 2016). Lack of services or fear of obtaining services can have detrimental effects on both the mother and fetus (Walhovd et al., 2015).

The purpose of this project was to review evidence-based practice surrounding pregnant women abusing opiates and to then develop a comprehensive detox CPG for providers and medical team members to deliver patient-centered care. The CPG had to be safe for both the fetus and the pregnant mother. This project achieved this goal by answering the following questions:

1. What is the most effective approach to avoid withdrawal symptoms during pregnancy?
2. How do providers prevent fetal distress in pregnant women using opioids?
3. How do providers reduce the risk of infants developing NAS?
4. How do providers reduce the risk of relapse in pregnant women with OUD?

Findings and Implications

An expert panel of four nurse practitioners, two psychiatrists and two OBGYNs rated the CPG using the AGREE II instrument. AGREE II consists of 23 criteria across six domains. Table 1 describes each domain and how they align with the proposed CPG.

Table 1

Alignment of the AGREE II Instrument Domains

AGREE II instrument	Domain	Description
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domains alignment		
Scope and purpose	Project question and CPG aligns with evidence-based practice and patient-centered care.	
Stakeholder involvement	Eight expert panelists reviewed CPG	
Rigor and development	Best practices and current guidelines were used to develop CPG	
Clarity of presentation	CPG supported with evidence	
Applicability	CPG can be applied to specific population by various providers	
Editorial independence	Each expert panelist completed an individual review along with providing individual feedback and recommendations	

Each expert panelist rated the CPG according to the 23 criteria among the six domains along with an overall assessment score. A six-point Likert scale was used for each domain, with scores ranging from 1 (*disagree very much*) to 7 (*agree very much*). Each domain score was added up then divided by the maximum score per number of criteria in each domain. Total scores ranged from 6-7 across each domain. The AGREE II scores from the expert panel are described in their entirety in Appendix A. The final CPG is in Appendix B.

CPGs are helpful in providing evidence-based treatment recommendations thus improving patient outcomes. The expert panelists found the CPG very thorough and applicable to improving care to pregnant women suffering from opioid abuse. The

AGREE II instrument is a reliable tool to determine the quality of CPGs, and found this guideline to be a reliable, useful tool.

Recommendations

Eight expert panelists reviewed the proposed CPG using the AGREE II instrument. The overall quality score of the CPG was 6.89. The panelists all agreed the CPG was appropriate and required no immediate changes prior to implementation.

Recommendations and comments from the expert panel included the following:

- Educate staff on how to properly use screening tools.
- Ensure screening tools are available in multiple languages to serve a diverse population.
- Collaborate with the Health Department, Planned Parenthood, and Primary Care Providers to educate on utilizing screening tools in office so Clinical Practice Guideline could potentially be implemented as quickly as possible.
- Include patient education in the clinical practice guideline.

This CPG has been much needed and is long overdue. I am excited about the opportunity to implement this in my practice. It is going to improve patient care for a very high-risk population. This guideline will help more than just pregnant women; it has the potential to change the lives of many children.

Strengths and Limitations of the Project

Limited resources have inhibited pregnant women abusing opiates from obtaining the services they need. Substance abuse during pregnancy is highly stigmatized in society, leading to lack of services, available resources, and patients feeling like they

aren't able to ask for help without facing punitive measures. One strength of this project is sharing the evidence-based practice with other colleagues and communities to improve the understanding of how to best care for pregnant women abusing opiates. The CPG ensures that this population is being treated with the most up-to-date treatment modalities, thus improving patient care. Limitations include staff education, language barriers for screening tools, and financial burden it may cause on some patients. The CPG is not able to be implemented at the practice site until funding is available. It is estimated funding will be available by January 2022. Because of this, staff will need to be educated on this guideline closer to implementation. While financial strain is not problematic at the practice site where this will be implemented, it could be if other non-profit sites adopt this CPG.

Section 5: Dissemination Plan

The dissemination plan's primary goal is to raise awareness regarding the adverse implications of opioid use disorder for pregnant women and the availability of remediation measures to promote health and well-being for both mother and child. The plan identifies the primary stakeholders and audience and the channels for dissemination to optimize awareness and resulting practice. The plan will include details regarding the drug to mitigate OUD outcomes, specifications, approval, the potential benefits, and working mechanisms. Also included in the plan is the pre-initiation procedures, like clinical assessment and screening, and tests required to approve an individual for the prescription. The plan also explains dosing, monitoring, length of treatment, post-treatment care, and potential side-effects, including a summative justification for recommendations provided to enhance reliability.

The audience for the CPG is multi-faceted because it impacts several areas.

- Academia. It is ideal for peer-review and enhancing available knowledge in healthcare education for future practitioner competence development. Academia can explore research into the recommendation to establish the reliability and practicality of the solution. Including members of academia in the dissemination plan is crucial as they could influence the integration of the recommendation into learning materials as a feasible way to mitigate OUD.
- The general public is also a target audience to raise awareness regarding the adverse impacts of OUD. Such awareness would inform the importance of

proactivity in preventing opioid misuse, assistive guidance for friends or family struggling with OUD, and guidelines for home care.

- Policymakers and healthcare institutions are responsible for developing public health policies, including regulation and providing resources to develop and generate large-scale use of the solution and ways to prevent opioid misuse.
- Pregnant mothers. It would also be prudent to make information readily available to the public to ensure that pregnant mothers maintain safe opioid usage and treatment protocols for those already suffering from OUD, including the potential benefits accrued from seeking treatment.

The goal is to get as much exposure as possible, which is why social media platforms will be key to the dissemination plan. Social media has a wider coverage and will get the information to as many people from the public as possible. I will also utilize webinars, community education programs, and mobile outreach programs to reach the community and other practitioners and officials. Other electronic means to specific recipients like hospital directors and policymakers will also be prudent. These include things like email, teleconferencing, and the use of emerging virtual meeting digital technologies for presentation and illustration purposes.

Analysis of Self

I was able to grow on both a professional and personal level during this Doctoral Project. I was fortunate to work with existing colleagues along with other providers and community professionals to gain more knowledge and understanding of pregnant women with substance use disorders. I acknowledge the amount of time and effort it takes to

perform literature reviews in order to prepare a guideline with the most up-to-date evidence-based practices. This has made me both a better scholar and practitioner. I can better understand the tedious process of making and implementing CPGs. It is my goal that this guideline can serve many women and children in our community. I look forward to continuing this work with the above recommendations from the expert panelists.

Summary

The goal of this project was to find a gap in practice and implement a CPG specific to the gap in practice. This guideline can be placed in various locations, including both inpatient and ambulatory settings and has the potential to improve maternal and fetal outcomes. While this may be the end of my educational journey, I will continue to be proactive and advocate for this unique population.

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	The strengths and limitations of the body of evidence are clearly described.	7	7	7	6	6	6	7	7	6.625
	The methods for formulating the recommendations are clearly described.	7	7	7	6	7	7	7	7	6.875
	The health benefits, side effects, and risks have been considered in formulating the recommendations. There is an explicit link between the recommendations and the supporting evidence.	7	7	7	7	7	7	7	7	7
	There is an explicit link between the recommendations and the supporting evidence.	7	7	7	7	7	7	7	7	7
	The guideline has been externally reviewed by experts prior to its publication.	7	7	7	7	7	7	7	7	7
	A procedure for updating the guideline is provided.	6	6	7	7	6	6	7	7	6.5
Clarity of presentation	The recommendations are specific and unambiguous.	7	7	7	7	7	7	7	7	7
	The different opinions for management of the condition or health issue are clearly	7	7	6	6	7	7	7	7	6.75

	presented.									
	Key recommendations are easily identifiable.	7	7	7	6	6	7	7	7	6.75
Applicability	The guideline describes facilitators and barriers to its application.	6	6	7	7	7	6	6	7	6.5
	The guideline provides advice and/or tools on how the recommendations can be put into practice.	7	7	7	7	7	7	7	7	7
	The potential resource implications of applying the recommendations have been considered.	7	7	7	7	7	7	7	7	7
	The guideline presents monitoring and/or auditing criteria.	7	7	7	7	7	7	7	7	7
Editorial independence	The views of the funding body have not influenced the content of the guideline	7	7	7	7	7	7	7	7	7
	Competing interests of guideline development group members have been recorded and addressed.	7	7	7	7	7	7	7	7	7
Overall guideline assessment		7	7	7	6	7	7	7	7	6.875

Overall guideline assessment	6.92	6.88	6.92	6.25	6.88	6.83	6.92	7	6.89
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Appendix B: Final Clinical Practice Guideline

Clinical Practice Guideline to Transition Pregnant Women Abusing Opiates over to Buprenorphine

Background

The use of opioids in the United States is on the rise. Women of child-bearing age contribute greatly to the opioid use statistics (Walhovd et al., 2015). The nation is also witnessing an increase in opioid use during pregnancy. Pregnant women who use opioids do not only endanger their lives; they also harm their unborn children by exposing them to opiates (Forray, 2016). Opioid use during pregnancy increases the risk for stillbirth, poor fetal growth, specific birth defects, preterm birth and maternal death (O'Donnell & Jackson, 2017). Buprenorphine is one of the pharmacological treatments considered safe and effective in the management of opioid use disorder in pregnant women (Ecker et al., 2019). This guideline contains the utilization of buprenorphine in pregnant women. It includes the recommendations for initiation, monitoring and termination of the drug.

Buprenorphine

Buprenorphine is a drug which is recommended for the treatment of opioid use disorder. Buprenorphine works by relieving drug cravings while not producing euphoria (Velandar, 2018). Buprenorphine has a reduced risk for adverse effects as compared to full agonist opioids. The drug was approved by the Federal Drug Administration (FDA) in 2002. Buprenorphine is recommended for patients who are able to give informed consent as well as individuals with no contraindications for the drug. The treatment using the drug under analysis is guided by four goals. They are:

- Block the effects of the illicit opioids
- Relieve opioid withdrawal
- Stop and reduce the use of illicit opioid and reduce opioid craving
- Promote and enable patient engagement in treatment activities, including psychosocial intervention.

Available evidence supports the efficacy of buprenorphine in the treatment of opioid use disorder in pregnant women. The risk of overdose due to the use of buprenorphine is also lower as compared to full agonist opioids. The lower risk of overdose is due to the ceiling effects of the drug for respiratory depression at higher doses (American Society of Addiction Medicine, 2020). Buprenorphine can be in the form of a mono-product and a combination with naloxone. Buprenorphine mono-product is recommended for pregnant women in order to avoid prenatal exposure to naloxone (Rausgaard, Ibsen, Jørgensen, Lamont & Ravn, 2020). While some studies have demonstrated no adverse effect in the combined therapy, more data is needed to enable the use of the buprenorphine combined with naloxone (Committee of Obstetric Services, 2017).

Clinical Assessment

Clinical assessment should be conducted before the diagnosis of opioid abuse disorder in pregnant women and the initiation of buprenorphine. A major priority for the evaluation should be to determine any urgent or emergent medical condition that requires clinical evaluation or immediate referral (American Society of Addiction Medicine, 2020). Screening should be done on all patients during the first prenatal visit as part of the comprehensive obstetric care (Committee of Obstetric Services, 2017; Ecker et al.,

2019). Clinicians who provide care to pregnant women such as gynecologists and obstetricians should always stay alert for signs and symptoms of opioid use disorder. These signs and symptoms include intoxication or withdrawal, poor weight gain, missing appointments and seeking prenatal care late in the pregnancy (American Society of Addiction Medicine, 2020). The healthcare providers can also evaluate signs of viral hepatitis and HIV since they are higher in pregnant women who use opioids as compared to pregnant women who do not use the drugs (Krans, Cochran & Bogen, 2015). The evaluation of pregnant women should also include signs of injections such as cellulitis, abscesses and puncture marks (American Society of Addiction Medicine, 2020).

Screening needs to be universal and should not only focus on observable symptoms of OUD, such as adherence to prenatal care and adverse pregnancy outcomes. Such kind of screening is ineffective, and it also leads to stereotyping as certain populations are considered to have a higher risk of drug use as compared to others (Committee of Obstetric Services, 2017). Validated screening tools should be used to make the screening more universal. These tools include the 4Ps, NIDA Quick Screen and CRAFFT Substance Abuse Screen for Adolescents and Young Adults (Ecker et al., 2019). Screening tools are preferred for initial screening since they enable brief intervention such as patient engagement and education (Committee of Obstetric Services, 2017).

Drug tests can also be used to detect or confirm the use of opioid or other drugs. Drug testing should be done in compliance with state laws. It should also be done with the consent of the patient. State laws have different requirements for the reporting of the

results of drug tests. The laws may require the clinician to report opioid use to health authorities or child and welfare services. The American Congress College of Obstetricians and Gynecologists recommends that clinicians should work together with policymakers to change the laws that provide punitive remedies for women with addictions. Such laws discourage pregnant women from obtaining treatment or prenatal care. Clinicians should instead look for evidence-based strategies to provide care to pregnant women with opioid misuses disorder (American Society of Addiction Medicine, 2020). Urine testing is not recommended for drug use since it is not sensitive to many drugs. It also causes many false-positive and negative results (Krans, Cochran & Bogen, 2015; Bailey & Diaz-Barbosa, 2018). In case a urine testing is used, positive urine tests should be followed by a definitive drug assay (American Society of Addiction Medicine, 2020).

Laboratory tests are also recommended for the screening of OUD in pregnant women. Laboratory tests are important due to the high risk of infections caused by sharing injection syringes and reckless sexual behavior among the population group. These infections include HIV, hepatitis B and C as well as liver enzymes. Patient consent should be obtained before conducting the laboratory tests. The patient should also be counselled on the infections such as HIV before the tests. The clinicians should ensure they conduct the tests in accordance with state laws (American Society of Addiction Medicine, 2020).

Imaging assessment should also be conducted. Imaging should be done using sonography to determine a viable intrauterine pregnancy. This imaging is essential in

accepting women to opioid treatment program (OTP) designed for their needs. Imaging should also be done to confirm gestational age and assessment of fetal weight. The weight and age are essential in determining growth abnormalities (American Society of Addiction Medicine, 2020).

Psychosocial assessment should also be done. A psychosocial assessment is important since a large number of women with opioid use disorder have a history of adverse childhood experiences, domestic violence and sexual assault. Collecting information on psychological history is important while determining if the pregnant woman has opioid use disorder. The psychological needs of pregnant women receiving treatment for opioid use disorder should also be assessed. The patient should then be referred for psychosocial treatment based on their needs. Pharmacological treatment should not be delayed due to a woman's refusal to participate in psychosocial treatment. Women can be encouraged to participate in psychosocial treatments using motivational interviewing (American Society of Addiction Medicine, 2020).

Throughout the screening process, the clinicians should maintain a non-judgmental approach and inform the patients of the importance of screening (Committee of Obstetric Services, 2017).

Treatment

Once the diagnosis of OUD has been confirmed, treatment should be commenced. Treatment should be commenced early during the pregnancy (American Society of Addiction Medicine, 2020). The use of pharmacological treatment, including buprenorphine, is recommended for pregnant women with opioid use disorder instead of

psychosocial treatment or withdrawal management alone (Bruneau et al., 2018). The treatment of opioid use disorder should be managed by a clinician with experience in the treatment of opioid use disorder and obstetrical care. In case a clinician experienced in both is not available, treatment should be co-managed by a clinician experienced with obstetrical care and another one with the experience of the treatment of opioid use disorder. The clinicians should sign the release of information forms in order to ensure proper communication. The clinicians providing pharmacological treatment should discuss the treatment options with the patients. They should provide the risk and benefits of each option, including the impact of the drugs on the fetus, perinatal care, neonatal abstinence syndrome and parenting of young children. They should also document the treatment decision in their charts (American Society of Addiction Medicine, 2020).

Initiation

There is a high risk of withdrawal due to the initiation of buprenorphine therapy. The risk of withdrawal affects patients with physical dependence on opioids. To minimize the risk of withdrawal, initiation of buprenorphine should happen when the pregnant woman shows observable and objective signs of withdrawal and before the signs of severe withdrawal occur. This should take place around 6 to 12 hours after the last dose of short-acting opioid or 24 to 28 hours after the last dose of long-acting opioids. The potential of adverse events is high during the initiation of buprenorphine, especially for women in their third trimester. It is, therefore, advisable to hospitalize the patients during initiation of the drug. Initiation should commence when a Clinical Opioid

Withdrawal Scale (COWS) score is above 7 (American Society of Addiction Medicine, 2020).

Some clinicians argue that there is a need for a change in the initiation of buprenorphine in patients who use fentanyl. Fentanyl is an opioid that is increasingly being used. It is a short-acting opioid however it also has a long life of 8 to 10 hours. Its affinity for the mu-opioid receptor is also relatively higher as compared to other opioids. Other clinicians recommend that the initiation of buprenorphine should happen when the patients are at least moderate in the withdrawal at around Clinical Opioid Withdrawal Scale (COWS) score of 13 or higher. While the recommendations are based on the difference between fentanyl and other opioids, there is no evidence to support the initiation recommendations (American Society of Addiction Medicine, 2020).

Dosing

Initiation

The dosing should be 2 to 4 mg during the initiation of buprenorphine. This initial low dose is supposed to reduce the risk of withdrawal. After the initiation of treatment, the patient should be observed in order to identify any signs of precipitated withdrawal. The observation should take place from 60 to 90 minutes. With the lack of withdrawal symptoms after the observation period, the dose can be increased by 2 to 8 mg. Once established that the initial dose has been tolerated, the dose can be increased to a level that is clinically effective and provides stable effect (American Society of Addiction Medicine, 2020).

In the case of extended-release buprenorphine, one extended-release injection is indicated for initiation, stabilization and maintenance when used once weekly or once monthly. Prior to initiation, a single dose of transmucosal buprenorphine is required. Since there is little research on the extended-release buprenorphine mutations, clinicians should use the products as indicated (American Society of Addiction Medicine, 2020).

After initiation

After the initiation of the drug, the doses should be maintained at 16 mg or more per day since lower doses are not effective in suppressing illicit opioid use. The FDA recommends a limit of 24 mg per day. Higher doses beyond this are not supported by evidence and increase the risk of diversion (American Society of Addiction Medicine, 2020).

There is little need to adjust the dosing of the drug during pregnancy. However, clinicians may consider changing dosing to meet the needs of the patients. For instance, split dosing may be administered in patients who complain of craving and discomfort in the evening and afternoon. The clinical response of the patient also determines the dosing of buprenorphine. The clinician should adjust dosing based on the incidence and risk of the neonatal opioid syndrome (NOWS). Pregnant women should also be advised to stop smoking or nicotine use in order to reduce the severity of NOWS (American Society of Addiction Medicine, 2020).

Monitoring

Monitoring should be done frequently at the beginning of the treatment until the clinicians determine that the patients are stable. Stability is determined by abstinence

from illicit drugs, social functioning and participation in psychosocial treatment and other treatment activities. Once the patient has been determined stable, the monitoring can occur less frequently. Prescription drug monitoring program (PDMP) data should also be checked to determine other medications that the patient may be receiving. The state PDMP laws should be observed (American Society of Addiction Medicine, 2020).

Drug and alcohol testing is also essential, and patient self-reported information should be obtained. The testing should be done to determine if the woman is adhering to the treatment. It should also be done to determine if the woman is using controlled or illicit substances. Informed consent from the woman should be obtained to facilitate the testing. State laws on reporting drug use should be followed. The frequency of drug testing should be guided by various factors such as stability of the patient, treatment setting and the type of treatment. The testing should be conducted a minimum of eight times a year for patients in OTP. There is no recommendation on the maximum number of tests that should be conducted. The drugs that should be tested include amphetamines, opioids, benzodiazepines, cannabis, methamphetamine, cocaine, illicit opioids and buprenorphine. Buprenorphine should continue to be used even when it is discovered that the patient uses illicit substances. The change of the level of care, medication and dosage should take place instead of ending buprenorphine treatment (American Society of Addiction Medicine, 2020).

Diversion should also be reduced by the clinicians. The strategies that can be used to prevent diversion include recall visits for pill counts, observed dosing, drug testing, including testing for buprenorphine and frequent office visits. The patients should also be

counselled on how to secure their medications and prevent ingestion by children (American Society of Addiction Medicine, 2020).

Postpartum treatment

Buprenorphine therapy should be continued after delivery. While changes in the dosages during the postpartum period are not common in patients who use buprenorphine, the patients should be monitored during the pregnancy and the postpartum period in order to provide dosage adjustments when needed. The risk of relapse increases during the postpartum period; therefore, women should be routinely screened. The women should also be screened for postpartum depression and treatment and support services provided (American Society of Addiction Medicine, 2020).

Breastfeeding

Breastfeeding should continue in mothers who take buprenorphine. Breastfeeding should be taken when there are no other contraindications. A study on the use of buprenorphine while breastfeeding demonstrated a very low amount of buprenorphine metabolites secreted in breastmilk. The low amounts pose little risk to breastfeeding infants (American Society of Addiction Medicine, 2020). Breastfeeding is also recommended due to its benefits. It enhances maternal-infant bonding and reduces the impact of NOWS (American Society of Addiction Medicine, 2020; Krans, Cochran & Bogen, 2015). Breastfeeding, however, requires specialty advice for women with other physical illnesses as well as other substance use disorders. These people include women who consume cocaine, alcohol or amphetamine-type drugs. Breastfeeding

recommendations should also be changed in mothers with contraindications such as HIV (American Society of Addiction Medicine, 2020).

Length of Treatment and Termination

There is no time limit for the use of buprenorphine in treatment. Longer treatment is associated with better outcomes. Treatment that takes less than 90 days is considered to be ineffective. The termination of treatment should not be taken lightly. The process of discontinuation is slow and requires close monitoring. Tapering should be accomplished over several months. Treatment should be discontinued due to sustained opioid abstinence, lack of employment or finances, lack of housing, additional psychosocial support, involvement in a mutual-help program and other activities and persistent engagement in treatment. Patients who relapse after the termination of treatment should be returned to buprenorphine treatment (American Society of Addiction Medicine, 2020).

Patients who want to discontinue treatment should be made aware of the risks of opioid overdose, especially overdose death. They should also be informed of the risks associated with drug injection such as HIV, endocarditis, Hepatitis C and sepsis. Treatment alternatives such as naltrexone and methadone should also be discussed with people discontinuing treatment (American Society of Addiction Medicine, 2020).

Adverse Effects

The side effects include sleep disturbance, urinary hesitancy, fluid retention in lower extremities, perspiration, constipation, anxiety and headache. There is a risk of NROWS when buprenorphine is used in the treatment of opioid use disorder in pregnant women. However, the risk of the complications of untreated opioid use disorder to the fetus and

woman is higher than the risk of NOWS due to the buprenorphine treatment. There is also potential adverse interactions due to the combined use of buprenorphine and sedatives. However, the risks caused by the treatment of opioid use disorder outweigh the risk of the side effects caused by the combination of the drug with sedatives. Due to the increased risk of adverse interactions, women using buprenorphine together with a sedative, anxiolytic, hypnotic, and alcohol require intensive monitoring (American Society of Addiction Medicine, 2020).

Screening tools	Screening tools website
COWS	https://www.asam.org/docs/default-source/education-docs/cows_induction_flow_sheet.pdf?sfvrsn=b577fc2_2
CRAFFT + N interview	https://craftt.org/wp-content/uploads/2018/10/2.1-CRAFFTN_Clinician-Interview_2018-04-23.pdf
4Ps screening tool	https://dbhds.virginia.gov/library/mental%20health%20services/screener-4Ps.pdf
NIDA screening tool	https://www.drugabuse.gov/sites/default/files/pdf/nmassist.pdf

Appendix C: IRB Approval

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