Models of care for opioid dependent pregnant women

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ABSTRACT
As the opioid crisis continues to exist in the United States, opioid use in pregnancy is becoming a more common occurrence. Left untreated, it may result in an increased risk for adverse outcomes for both the mother and her unborn child. Unfortunately, women with opioid use disorders often face numerous barriers when trying to access prenatal care services including limited availability or treatment options, stigma, legal consequences, co-morbid psychiatric disorders, and trauma exposure. A care model that integrates prenatal care, medication assisted treatment and behavioral health services delivered in a trauma-informed environment can improve prenatal care attendance and thus have far-reaching positive implications for both the woman and her newborn child.

Introduction
Each day in the United States, more than 115 people die from an opioid overdose.1 This dramatic statistic represents a national crisis that presents serious public health, social, and economic repercussions. The current situation is grounded in the 1990s when the treatment of pain gained attention and pharmaceutical companies reassured healthcare providers that pain patients would not become dependent on opioid medications. As more prescriptions were written, so too, the rates of prescription opioid misuse dramatically increased.2 This has been particularly concerning because the overall potency of prescribed opioids, measured in morphine milligram equivalents (MME), per person in 2015 was almost three times that of those prescribed per person in 1999.4
The rates of prescription opioid misuse are closely tied to the rates of heroin use. Forty-five percent of people who report using heroin also report the use of prescription pain medication.5 Therefore, as the rates of prescription opioid misuse have increased, so has heroin use. The Centers for Disease Control and Prevention (CDC) reports that heroin use has more than doubled among young adults between the ages of 18 and 25.5 The upward trend in heroin use has held true for women who historically had lower rates of heroin use than men with rates increasing from 0.8 to 1.6 per 1000 people.
The overuse and misuse of prescription opioids and heroin have contributed to the thousands of overdose deaths. In the general population, the heroin-related overdose death rate increased 286% from 2002 to 2013.6 Between 1999 and 2015, the rate of deaths from prescription opioid overdoses increased 471% among women, compared to an increase of 218% among men. Heroin deaths among women, while overall remaining lower than that for men, increased at more than twice the rate among men.1
Given the high rates of opioid use among women in the United States as well as the high rates of unintended pregnancy, it is clear that health care providers need to be

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prepared to care for the growing population of pregnant women with opioid use disorder. Between 1999 and 2014, the United States experienced a four-fold increase in the rate of opioid use disorder at delivery hospitalization. This is consistent with the observed increased national incidence of neonatal abstinence syndrome (NAS) from 1999 through 2013.

The increase in the number of pregnant women diagnosed with opioid use disorder (OUD), has also meant that more pregnant women seek treatment services for OUD. While the overall proportion of women admitted for substance use treatment remained stable at 4% from 1992 to 2012, hospital admissions of pregnant women who reported prescription opioid use increased from 2 to 28%. Throughout the United States, pregnant women with opioid use disorders face unique barriers including inadequate insurance and underutilization of medication assisted treatment. Both of which carry the potential to negatively impact treatment outcomes.

Barriers to treatment for opioid use disorder

Only a small proportion of the population with a diagnosed substance use disorder receives treatment. The barriers that pregnant women with opioid use disorders face are numerous. There are few medical centers in the United States with the resources to support perinatal addiction treatment programs. Additionally, women with opioid use disorders often experience psychosocial challenges such as stigma, social and legal consequences, food insecurity, chronic medical conditions, psychiatric disorders, poverty, and lack of adequate housing, trauma exposure and intimate partner violence.

While there is an increasing acceptance of the chronic disease model for substance use disorders, there remains more stigmatization when compared to other health conditions. While stigma may originate in an effort to discourage unhealthy behaviors, it carries negative consequences. Women who are pregnant and have an opioid use disorder are one of the most highly stigmatized populations in the United States. The assumption is made that pregnancy should be protective and that women have personal control over their opioid use. They are, therefore, to blame for adverse perinatal outcomes.

Stigma has numerous negative effects on individuals including poor physical health, avoidance of health care services, and an increase in risky behaviors. Negative perceptions of women with substance use disorders can lead to suboptimal care and, thus unwittingly, cause women to not disclose their diagnoses to their health care providers.

In addition to being viewed as an issue of morality, substance use disorders are often criminalized. Currently, there is great variation in how states have decided to develop policies regarding the response to and reporting of opioid use during pregnancy. In 2014, Tennessee was the first state to pass legislation criminalizing illicit substance use during pregnancy. The law was later allowed to expire as it became evident that the unintended consequence was that women were not accessing prenatal care. This unintended consequence occurred within the long-established precedent that consistent prenatal care lessens the potential impact of substance use on perinatal outcomes. In spite of the Tennessee example, other states still have policies in place that mandate health care professionals to test for or report illicit substance use during pregnancy. The results of these tests may be used as evidence in child-welfare proceedings. Twenty-three states consider substance use during pregnancy to be child abuse and three consider it grounds for civil commitment.

In 2016, the Comprehensive Addiction and Recovery Act (CARA) built upon the 2010 The Child Abuse and Prevention Treatment Act (CAPTA) and required that state efforts to create safe plans of care for children affected by maternal substance use also address the treatment needs of the families and caregivers. While states were mandated to develop a monitoring system to determine if and how local entities were providing referrals, it was left to the states to define substance exposure and whether notice to child protective services (CPS) constitutes a report of child abuse or neglect.

The decision to allow each state to make independent decisions has resulted in inconsistencies in policy and differing approaches across communities to identify pregnant women who are in need of treatment. It has also resulted in different responses for the infants’ care and safety considerations. These inconsistencies combined with knowledge gaps about the relative safety of a newborn who tests positive for opioids has had tremendous implications for pregnant and parenting women with opioid use disorders. The safety of infants who test opioid positive as a result of medication assisted treatment during pregnancy may be quite different than that of an infant born to a mother using illicit opioids. The resulting decisions have major implications for family systems particularly during the critical early time of maternal-child attachment.

Existing guidelines

Several leading organizations have published recommendations for best-practices in the care of pregnant women with opioid use disorders and their infants. These organizations include the American College of Obstetricians and Gynecologists (ACOG), World Health Organization (WHO), United States Health and Human Services (US HHS), American Society of Addiction Medicine (ASAM) and the American Academy of Pediatrics (AAP). Most recently, in 2018, Substance Abuse and Mental Health Services Administration (SAMHSA) published comprehensive guidelines for the treatment of pregnant and parenting women with opioid use disorders (Table 1). DSM-V allows opioid use disorders to be classified as mild, moderate or severe. The level of care needed by women with opioid use disorders is determined by the availability of services, willingness to seek care, type of substance used, severity of use and potential implications for perinatal outcomes. For pregnant women with opioid use disorders, existing guidelines recommend treatment with maintenance therapy (either methadone or buprenorphine) as these medications may mitigate the significant risks to the mother and fetus from illicit substance use and recurring withdrawal.

There is good evidence that medication assisted treatment combined with a behavioral therapist is the most effective way to treat opioid use disorders. For pregnant women, the most dramatic improvement in perinatal outcomes is achieved when prenatal care is combined with substance
Table 1 – SAMHSA guidelines.

<table>
<thead>
<tr>
<th>Category</th>
<th>Guidelines</th>
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<tbody>
<tr>
<td>Prenatal care</td>
<td>• All pregnant women should be asked about their use of alcohol and other substances past and present</td>
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<td></td>
<td>• Screening for substance use disorders during pregnancy should be conducted in a careful and nonjudgmental way</td>
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<td></td>
<td>• Pregnant women with opioid use disorder (OUD) should receive counseling and education on the medical and social consequences of pharmacotherapy for OUD</td>
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<td></td>
<td>• Pregnant women with OUD should be offered medication assisted treatment with methadone or buprenorphine and evidence-based behavioral interventions</td>
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<tr>
<td></td>
<td>• Medically supervised withdrawal is NOT recommended</td>
</tr>
<tr>
<td></td>
<td>• There may be a need for periodic adjustments (i.e. increase in dose) of pharmacotherapy for OUD</td>
</tr>
<tr>
<td></td>
<td>• Comorbid behavioral health disorders are common and need to be addressed and treated</td>
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<td></td>
<td>• Relapse may occur and should not be seen as a setback or failure</td>
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<tr>
<td></td>
<td>• Peripartum pain relief is important and opioid agonist therapy may not provide adequate relief</td>
</tr>
<tr>
<td>Infant care</td>
<td>• Opioid-exposed infants are at risk for neonatal abstinence syndrome (NAS)</td>
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<td></td>
<td>• The use of a standardized NAS assessment and treatment protocols improves outcomes and may shorten hospital stays</td>
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<tr>
<td></td>
<td>• All infants born to women with OUD should receive nonpharmacologic care including rooming in, extended skin-to-skin contact with mother, swaddling and quiet environments</td>
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<td>• Women on opioid agonist therapy are able to breastfeed and should be educated on the risks and benefits to herself and her newborn baby</td>
</tr>
<tr>
<td>Maternal postnatal care</td>
<td>• Mothers and other caregivers need to be educated about handling NAS after discharge</td>
</tr>
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<td></td>
<td>• Maternal doses of opioid agonist therapy may need to be adjusted in the immediate postpartum period if she has complaints of drowsiness and somnolence</td>
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<tr>
<td></td>
<td>• Maternal discharge planning should include screening for co-morbid mental disorders and counseling about contraceptive options</td>
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<tr>
<td></td>
<td>• Women with OUD should be cautioned against the abrupt discontinuation of pharmacotherapy immediately postpartum</td>
</tr>
<tr>
<td></td>
<td>• If pharmacotherapy is discontinued and behavioral supports are not sufficient to prevent a return to substance use, consider the option of resuming medication assisted treatment</td>
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<tr>
<td></td>
<td>• Women should be provided with referrals to services that provide perinatal and infant care</td>
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abuse treatment including medication assisted treatment. The benefits of an integrated model of care include increased prenatal visit attendance, increased length of gestation, and decreased length of hospitalization for newborns. Women enrolled in such programs are also less likely to use illicit substances at the time of birth. Additionally, these models improve patient satisfaction and participation in care and ultimately reduce costs for the health care system.

Integrated care

Integrated care is the coordination of general and behavioral health care. The integration of mental health, substance abuse and primary care services, provides a more comprehensive approach and produces the best outcomes. Women with opioid and other substance use disorders can have complex health issues and poor retention in services. Integrated care approaches usually include a group of providers from a variety of medical backgrounds including family medicine, obstetrics, midwifery, advanced practice nursing, and nursing. In addition to the medical team, there are often psychiatrists, counselors and substance abuse treatment professionals to help address the complex needs of this population.

For integrated care models to be successful, they must adhere to the core belief that substance use disorders exist along a continuum from total abstinence to harm reduction and that each person should be counseled to make the choices that will work best for her individual life situation. For women with opioid use disorders, this open approach allows for all women, no matter the severity of their disorders, to feel supported. This, in turn, has been shown to increase prenatal care appointment attendance.

An integrated approach also improves perinatal outcomes and is cost-effective. Goler and colleagues examined the Early Start integrated program of Kaiser Permanente Northern California (KPNC) and found that women receiving concurrent prenatal care and substance abuse treatment were less likely to experience placental abruption or preterm labor and their babies were less likely to be born prematurely or be identified as low birth weight. KPNC has estimated that the Early Start program has resulted in a 30% return on investment. This is in line with ACOGs 2004 estimate that integrated treatment results in a mean net saving of $4644 in medical expenses. In addition, women receiving care in this environment report increased satisfaction with their care.

Evidenced based prenatal care

The early identification and referral of pregnant women with opioid use disorders to substance use disorder treatment is critical. There is support in the literature for an integrated care approach to providing prenatal care and substance use treatment concurrently as improved prenatal care is consistently associated with improved perinatal outcomes. There are several of these models in existence across the United States that can serve as examples for other institutions seeking to improve care for pregnant women with opioid use disorders (Table 2).

Formed in the early 1990s, the Children and Recovering Mothers (CHARM) Collaborative in Vermont had the primary
<table>
<thead>
<tr>
<th>Author/date</th>
<th>Name of model</th>
<th>Setting</th>
<th>Number of women</th>
<th>Basic program structure</th>
<th>Effect of model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meyer et al, 2012</td>
<td>CHARM</td>
<td>Rural</td>
<td>149</td>
<td>Received obstetric care in hospital-based clinic or local practice</td>
<td>Increased number of prenatal visits</td>
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<td></td>
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<td>MAT through methadone treatment program or community buprenorphine provider</td>
<td>Improved birthweight</td>
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<td></td>
<td></td>
<td>OB care coordinated with MAT</td>
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<td>Goler et al, 2008</td>
<td>Early Start</td>
<td>21 sites that are a part of Kaiser Permanente Northern California</td>
<td>49,985 screened</td>
<td>Substance abuse treatment integrated with prenatal visits</td>
<td>Number of infants treated for NAS decreased</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Increased number of infants discharged home to care of mother</td>
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<td></td>
<td></td>
<td>Women who were screened/assessed and treated had lower incidence of low birth weight and premature delivery, less likely to have placental abruption or preterm labor</td>
</tr>
<tr>
<td>Ordean et al, 2015</td>
<td>Canada</td>
<td>3 integrated care programs in Canada</td>
<td>94</td>
<td>Primary care programs based on integrated care models incorporating substance abuse treatment including methadone and obstetric care at a single-access site</td>
<td>Reductions in illicit opioid use during pregnancy</td>
</tr>
<tr>
<td>Goodman, 2015</td>
<td>Dartmouth-Hitchcock Medical Center Perinatal Addiction Program</td>
<td></td>
<td></td>
<td>Substance abuse treatment including MAT with buprenorphine integrated with prenatal visits</td>
<td>Lower incidence of preterm birth, low birth weight, and placental abruption Decreased rate of cesarean delivery Specific birth outcomes not yet reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Improved coordination of care, improved patient satisfaction and higher number of prenatal visits attended</td>
</tr>
</tbody>
</table>
goal of improving access to medication assisted treatment for pregnant women by combining these services with prenatal care.37 The data from a cohort receiving care between 2000 and 2006, reveal improvement in perinatal outcomes. Women were more likely to begin treatment at an earlier gestational age and received treatment with coordinated care.37 Neonatal outcomes also improved with improved birth weight, reduced treatment for neonatal abstinence syndrome and more women who were able to parent their newborns.37

The Kaiser Permanente Northern California (KPNC) perinatal substance abuse treatment program Early Start was initiated in 1990. The program has three key components including:1 the placement of a licensed substance abuse expert and an Early Start program specialist in the Obstetrics and Gynecology Department2, universally screening all women for drugs and alcohol by questionnaire, and educating all providers and patients about the effects of drugs, alcohol and tobacco use in pregnancy.32 Data analysis from the program has demonstrated that women identified and treated for substance use disorders were more likely to enter prenatal care earlier, have decreased rates of preterm delivery and low birth weight, and a decreased incidence of placental abruption.32 This was in spite of this same group having higher risk substance use behaviors at entry to care.37

Ordean and colleagues examined the outcomes for pregnant women entering three different integrated care programs in Canada.38 The programs represented three geographically distinct cities: Toronto, Montreal and Vancouver. Each clinic incorporated comprehensive addiction and obstetric care at a single-access site. Women in all three programs had marked reductions in heroin, prescription opioid, alcohol, cocaine and cannabis use.38 Additional analysis of this same cohort showed lower incidence of obstetrical complications such as preterm premature rupture of membranes and placental abruption. The group also had a lower incidence of birth by cesarean delivery than the Canadian national average.39 Birth data for the cohort also showed longer gestation and less pharmacologic treatment of neonatal abstinence syndrome.39

The Dartmouth–Hitchcock Medical Center Perinatal Addiction Program was started in 2013 in response to the growing number of pregnant women disclosing opioid use disorders and the limited available treatment options.41 The primary objective of the program is to address and mitigate the numerous barriers that women face to obtaining treatment for substance use disorder. The program brings together multiple services in one place at one time thus being multidisciplinary and interprofessional. Early outcomes of this program include improved coordination of care, increased satisfaction among both pregnant women and providers, improved prenatal visit attendance and increased patient satisfaction.41

Assisted opioid withdrawal

Several major professional societies including the American College of Obstetricians and Gynecologist (ACOG) and the American Society for Addiction Medicine (ASAM) have endorsed opioid agonist pharmacotherapy with either methadone or buprenorphine as the treatment of choice for pregnant women with opioid use disorders29,41,42 rather than assisted opioid withdrawal. The recommendations against opioid withdrawal during pregnancy originated from research on maternal withdrawal demonstrating an increase in catecholamine release, which may be indicative of fetal distress.43 This publication was considered in conjunction with a case report of stillbirth after opioid detoxification.44,45 The recommendation for medication assisted therapy was further supported by data that emerged from the treatment of pregnant women with methadone or buprenorphine as a part of a comprehensive prenatal and substance abuse treatment program demonstrating that women who are treated with medication assisted therapy during pregnancy have similar birth outcomes to women without a substance use disorder.46,47

Despite these recommendations, there has been a re-examination of the efficacy of detoxification during pregnancy which is predominantly in response to the escalating use of opioids during pregnancy and the number of infants needing treatment for neonatal abstinence syndrome (NAS). Yet, the role of detoxification and its efficacy as a treatment approach remains unclear.48

In a 2018 systematic review of available literature, Terplan and colleagues found that the evidence does not support detoxification as a recommended treatment option.50 Evaluation of the utility of this approach was limited by high rates of maternal relapse, low detoxification completion rates and limited data on the effects on maternal and neonatal outcomes after birth. While the evidence found in the 2018 review does not suggest that there is an increased risk of fetal demise, loss to follow up was an important limitation. Women and children need to be followed for at least one year after delivery in order to properly assess the true effects of substance use for both populations.50–52

More research is needed to determine if there is a subset of the population of pregnant women with opioid use disorders for whom detoxification would be beneficial. Such research findings would allow for the appropriate development of comprehensive guidelines that support optimal treatment without increasing morbidity and mortality risk.

How to measure success?

For women with opioid use disorders, success is most often measured by the number of prenatal visits attended, length of gestation, and overall health measures such as weight gain. For neonates, success has been defined in terms of birth weight, head circumference, Apgar scores, pharmacologic treatment for neonatal abstinence syndrome and length of stay in the hospital. While these measures are helpful, they do not represent the complete picture. Clinical care considerations and measurements of success, must focus upon the mother-infant dyad.53 Such measures are more complex and may present measurement challenges. Measures that could be considered include maternal-fetal attachment during pregnancy, rates of breastfeeding, skin to skin contact and rooming-in during the immediate postnatal time period.
There is currently a strong recommendation that in order to increase access, medication assisted treatment with buprenorphine needs to be integrated into the primary care setting. In 2000, The Drug Abuse Treatment Act (DATA) gave physicians the ability to prescribe buprenorphine for treatment of opioid use disorder. In 2016, the Comprehensive Addiction and Recovery Act (CARA) expanded the ability to prescribe to nurse practitioners and physician assistants but its use remains limited. This is particularly true in the field of obstetrics. As pregnancy is often one of the times when women consistently access health care, obstetricians, nurse practitioners and physician assistants who care for women should be encouraged to consider obtaining a waiver which would allow them to prescribe buprenorphine.

A successful model of care for women with opioid use disorders is one that can meet the complex needs of the population (Fig. 1). This requires the integration of substance abuse treatment and prenatal care services. Ideally, the services will be co-located but this may not be possible for some practices. Collaboration between medical and behavioral health care services may also occur across organizations. If multiple agencies are involved, communication and connectivity are imperative for success as they allow for fluidity and transparency.

In addition to the need for integrated or collaborative care, there are several other components of a successful program of care for women with opioid use disorders. There is a strong evidence base that when treating substance use disorders, it is important to have regular follow-up, psychosocial services, promotion of medication adherence and case management available. Multidisciplinary models of care incorporating the full spectrum of services have shown improved outcomes including increased rates of program completion, sustained recovery, increased prenatal visit attendance and improved birth outcomes. All services must take place in an environment in which all providers from physicians, nurse practitioners, midwives and nurses to clerical staff share the commitment to compassionate and non-judgmental care. It is also helpful that all staff have an understanding of opioid use in pregnancy.

Pregnant women with opioid use disorders often require more frequent visits than the standard prenatal visit schedule. Frequent visits allow for more patient contact which is critically important in a group that is often over-represented in the population who receive late, limited or no prenatal care. It has been demonstrated that similar to women with no history of a substance use disorder, regular prenatal care improves the chances of good pregnancy outcomes.

For pregnant women with opioid use disorders who are receiving co-located medication assisted treatment and prenatal care, an increased frequency of visits allows for the promotion of medication adherence and on-going education related to medication assisted treatment during pregnancy as well as broader recovery support. Additionally, more frequent contact allows clinicians more time to support women and to promote trust. This in turn may play a role in increased prenatal visit attendance and improved patient satisfaction.

Trauma-informed care is the principle that an organization should examine all aspects of programming, environment, language, and values in order to better serve clients who have experienced trauma. This approach has received increased attention among gender-specific substance use treatment programs for women because a family-centered and gender-responsive approach addresses many of the unique needs of women with opioid use disorders in a culturally responsive manner. While there is evidence that women are more successful in gender-specific programs, a 2015 database review revealed that between 2002 and 2009, there was a decline in such services across the United States. For a clinical model to be successful, service providers must recognize the signs and symptoms of trauma in clients and seek to resist any practices that may result in re-traumatization. This includes training all professionals who will have contact with women seeking care.

It is estimated that 50–80% of women with substance use disorders have experienced trauma. Pregnancy is an especially challenging time as women experience an increase in vulnerability that may further trigger previous trauma and intensify cravings to use illicit substances. In a qualitative study of pregnant and parenting women in Vancouver, Canada, Torchalla and colleagues identified six key themes related to trauma. These included adverse experiences and trauma in early childhood and adulthood, intimate partner violence, structural violence, transgenerational trauma resulting from post-traumatic stress disorder and an interest in trauma counseling.

Given the high levels of trauma reported in women seeking treatment for substance use disorders and the acceptance that pregnancy is a time when the threat of violence such as that from partners may increase, it is vital that any model of care for pregnant women with substance use disorders be prepared to address these issues. This includes the availability of mental health professionals who are trained in the assessment and treatment of trauma as well as professionals familiar with community resources for pregnant women experiencing trauma.

Trauma can also occur as a result of a woman’s interaction with the healthcare system. Pregnant women with substance
use disorders face high levels of stigmatization and judgment from both the larger society and from healthcare professionals. Despite the acceptance of the chronic disease model in the approach to substance use disorders, many health care providers continue to have negative views about caring for pregnant women with substance use disorders and may lack the training and support to effectively care for this population. It is therefore imperative that a successful model of care include the education of colleagues and staff members regarding the need for sensitivity and compassion.

**Patient-centered dyadic care**

Patient-centered care is an approach in which the health needs and desired health outcomes of the individual are the driving force behind healthcare decisions. A model for patient-centered care developed by Gereis and colleagues describes seven key domains: 1) respect for patient’s values, preferences and expressed needs, 2) coordination and integration of care, 3) information, communication, and education, 4) physical comfort, 5) emotional support and alleviation of fear and anxiety, 6) involvement of family and friends, and 7) transition and continuity. Attention to these domains allows for the provision of prenatal care to women with opioid use disorders in a safe and respectful environment.

There are several important aspects of care to be considered including the anticipation and accommodation of both late arrivals to appointments and missed clinic visits and positive reinforcement for decreased use of illicit substances. Perhaps the most critical component of care is the use of a non-judgmental approach to patient interactions and education. This approach helps to ease fear and anxiety and allows for more open provider-patient relationships and may increase patient satisfaction. Additionally, the safe environment created allows for the provision of education about neonatal abstinence syndrome (NAS) and other topics may facilitate the strengthening of maternal-fetal attachment and positively impact the long-term health of both mother and baby.

**Conclusion**

As the opioid epidemic continues to affect the United States, it is important to remember that healing and long-term recovery are possible. For pregnant women with opioid use disorders, facilitating access to integrated, trauma-informed prenatal care has the potential to create a positive impact on long-term family outcomes. While this approach requires time and collaboration, the benefits for mothers and their children are significant and may create the foundation for improved social and health outcomes for future generations.

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