A Collaborative Approach to the Treatment of Pregnant Women With Opioid Use Disorders

Practice and Policy Considerations for Child Welfare, Collaborating Medical, and Service Providers

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Center for Substance Abuse Treatment
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Introduction

This guidance publication is intended to support the efforts of states, tribes, and local communities in addressing the needs of pregnant women with opioid use disorders and their infants and families.[1] National data show that from 2000 to 2009 the use of opioids during pregnancy increased from 1.19 to 5.63 per 1,000 hospital births (Patrick, Schumacher, Benneyworth, Krans, McAllister, & Davis, 2012). Because of the high rate of opioid use and misuse among all women, including pregnant women, medical, social service, and judicial agencies are having to confront this concern more often and, in some communities, at alarming rates.

Opioids are drugs that reduce the intensity of pain signals. The term "opiates" refers only to natural opium derivatives, and the term "opioids" refers to drugs that activate opioid receptors, including opiates, heroin, and synthetic opioids (e.g., certain prescription painkillers, such as oxycodone) (CSAT, 2004).

Data from SAMHSA's National Survey on Drug Use and Health show that between 2007 and 2014, the numbers of past-year heroin initiates, heroin users, and people with heroin dependence increased significantly (SAMHSA, 2015). The pattern of initiating heroin use has changed over the past decade. Approximately three-quarters of persons who use heroin report prior non-medical use of prescription opioids, as well as current abuse or dependence on additional substances such as stimulants, alcohol, and marijuana. Conversely a small percentage, approximately four percent, of persons with non-medical use of prescription drugs initiate heroin use. However given the 10.3 million persons who reported non-medical use of prescription drugs in 2014, this small percentage of conversion to heroin generates several hundred thousand new heroin users (Compton, Jones & Baldwin, 2016).

When pregnant women use opioids, their infants may be affected. Neonatal abstinence syndrome (NAS) is the common term used to represent the pattern of clinical findings typically associated with opioid withdrawal in newborns (Hudak & Tan, 2012). However, the U.S. Food and Drug Administration (FDA) now uses the term "neonatal opioid withdrawal syndrome" on warning labels when referring to the maternal use of opioids during pregnancy.[2] Most newborns of mothers who used opioids during pregnancy develop symptoms of NAS, a postnatal drug withdrawal syndrome, primarily caused by maternal opioid use (Patrick et al., 2012). The range and severity of the symptoms experienced by the infant depends on a variety of factors, including the type of opioid the infant was exposed to and whether the infant was exposed to multiple substances. Treatment of NAS includes non-pharmacological and pharmacological methods.

Abrupt discontinuation of opioid use during pregnancy can result in premature labor, fetal distress, and miscarriage. Medical withdrawal from opioids should be conducted under the supervision of physicians experienced in perinatal addiction (Kaltenbach, Berghella, & Finnegan, 1998). However, pregnant women who stop using opioids and subsequently relapse are at greater risk of overdose death. There is also an increased risk of harm to the fetus. Because NAS is treatable, medication-assisted treatment (MAT) is typically recommended instead of withdrawal or abstinence (Jones, O'Grady, Malfi, & Tuten, 2008).

[1] According to the U.S. National Library of Medicine, the term "infant" is used to describe a child from newborn to 1 year (http://www.nlm.nih.gov/medlineplus/ency/article/002004.htm), and the term "newborn" (neonate) is used to describe an infant who is 4 weeks old or younger (http://www.nlm.nih.gov/medlineplus/ency/article/002271.htm). For the purpose of this document, these definitions are applied.

[2] "What is the Federal Government Doing to Combat the Opioid Abuse Epidemic?" Statement of Douglas C. Throckmorton, M.D., Deputy Director for Regulatory Programs, Center for Drug Evaluation and Research, Food and Drug Administration, Department of Health and Human Services before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives on May 1, 2015. http://www.fda.gov/newsevents/testimony/ucm446076.htm

The use of MAT during pregnancy is a recommended best practice for the care of pregnant women with opioid use disorders[3] (American College of Obstetricians and Gynecologists Committee on Health Care for Underserved Women, & American Society of Addiction Medicine, 2012). MAT is the use of medications in combination with counseling and behavioral therapies to provide a whole-patient approach to the treatment of substance use disorders (SAMHSA, 2014a). Research shows that a combination of medication and behavioral therapies is most successful for substance use disorder treatment. MAT is clinically driven and focuses on individualized patient care.

Medications used to treat opioid use disorders include methadone and buprenorphine. Both of these medications stop and prevent opioid withdrawal and reduce opioid cravings, allowing the person to focus on other aspects of recovery.

Like any medication given during pregnancy, the use of MAT in pregnant women has both risks and benefits to the mother and fetus. Therefore, MAT needs careful consideration by the pregnant women themselves as well as coordination by the providers and agencies that have influence and authority over this population of pregnant women and their infants.

To inform this guidance document, the National Center on Substance Abuse and Child Welfare (NCSACW), the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Administration on Children and Families (ACF) formed a national panel of experts (listed in *Appendix 6: Additional Acknowledgments*). This panel identified the practice and policy considerations that each partner agency or organization needs to consider when working with, and on behalf of, pregnant women with opioid use disorders and their children. These experts met several times over six months in 2014.

Panel members agreed that building knowledge, skills, and expertise within the healthcare (including obstetrics, pediatrics, substance abuse treatment, and mental health), child welfare, and judicial systems and tribal communities will enable these entities to better deliver coordinated services to this population of pregnant women and their families. This guidance document is designed to assist these systems in improving their collaborative practice and to provide information about additional resources that will strengthen their capacity to provide coordinated, best-practice care and services.

The overarching message of this guide is that a coordinated, multi-system approach best serves the needs of pregnant women with opioid use disorders and their infants. Collaborative planning and implementation of services that reflect best practices for treating opioid use disorders during pregnancy are yielding promising results in communities across the country. Advance planning for the treatment of pregnant women with opioid use disorders that addresses safe care for mothers and their newborns can help prevent unexpected crises at the time of delivery. This guidance document provides background information on the treatment of pregnant women with opioid use disorders, summarizes key aspects of guidelines that have been adopted by professional organizations across many of the disciplines, presents a comprehensive framework to organize these efforts in communities, and provides a collaborative practice guide for community planning to improve outcomes for these families. A set of appendices provides details on implementing the recommendations in the guide as well as a summary of lessons from one community's experience over the past decade.

[3] The fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders* ([DSM-5] American Psychiatric Association, 2013) uses the term "opioid use disorder" to include abuse of or dependence on opioids. Previous editions of the DSM differentiated between the two categories. The DSM-5 combines abuse and dependence into a single disorder, measured on a continuum from mild to severe.

Background

Opioid medications used to relieve pain are beneficial to many people but are often overprescribed.[4] The overuse and misuse of these medications in the United States over the past decade has contributed to thousands of overdose deaths. According to the Centers for Disease Control and Prevention (CDC), from 1999 to 2010, yearly prescription opioid overdose deaths among women increased from 1,287 to 6,631 (CDC, 2013). These numbers represent a 400 percent increase over 10 years (see *Scope of the Problem* on page 5 for additional information). The use of heroin has also increased greatly over the last decade. Between 2007 and 2014, the numbers of past-year heroin initiates, heroin users, and people with heroin dependence has increased significantly (SAMHSA, 2015).

The use of MAT, in combination with counseling and behavioral therapies, and access to a range of supportive services, such as housing and employment services, assists the mother in achieving a more stable life (Newman & Kagen, 1973; Finnegan, 1991; CSAT, 2005). In turn, it also stabilizes the intrauterine environment and avoids subjecting the fetus to repeated episodes of withdrawal, which places the fetus at higher risk for morbidity and mortality (Kaltenbach & Finnegan, 1998; Jones et al., 2005; CSAT, 2005). According to the National Institute on Drug Abuse (NIDA):

"Methadone maintenance therapy (MMT) enhances an opioid-dependent woman's chances for a trouble-free pregnancy and a healthy baby. Compared with continued opioid [use], MMT lowers her risk of developing infectious diseases, including hepatitis and HIV; of experiencing pregnancy complications, including spontaneous abortion and miscarriages; and of having a child with challenges including low birth weight and neurobehavioral problems.

Along with these benefits, MMT may also produce a serious adverse effect. Like most drugs, methadone enters fetal circulation via the placenta. The fetus becomes dependent on the medication during gestation and typically experiences withdrawal when it separates from the placental circulation at birth. The symptoms of withdrawal, known as neonatal abstinence syndrome (NAS) include hypersensitivity and hyperirritability, tremors, vomiting, respiratory difficulties, poor sleep, and low-grade fevers. Newborns with NAS often require hospitalization and treatment, during which they receive medication (often morphine) in tapering doses to relieve their symptoms while their bodies adapt to becoming opioid-free." (Whitten, 2012).

Methadone has been accepted as a treatment for opioid use disorders during pregnancy since the late 1970s (Kaltenbach & Finnegan, 1998; Kandall et al., 1999; CSAT, 2005). In 1998, a National Institutes of Health consensus panel recommended methadone maintenance as the standard of care for pregnant women with opioid use disorders (National Consensus Development Panel on Effective Medical Treatment of Opiate Addiction, 1998). However, the use of buprenorphine for the management of opioid use disorders is becoming more widely used, with the emergence of data from randomized clinical

[4] The Office of Disease Prevention and Health Promotion has developed Pathways to Safer Opioid Use, a training resource that uses the principles of health literacy and a multimodal, team-based approach to promote the appropriate, safe, and effective use of opioids to manage chronic pain. http://www.health.gov/hcq/training.asp#pathways

trials that demonstrate its safety and efficacy (Jones et al., 2005; Fischer et al., 2006; Jones et al., 2010). Between 2005 and 2008, A National Institute on Drug Abuse (NIDA)-supported clinical trial, the Maternal Opioid Treatment: Human Experimental Research (MOTHER) study, examined the use of both methadone and buprenorphine maintenance therapy during pregnancy. Both medications are widely used to help individuals with opioid use disorders achieve stability and decrease illicit opioid use. The study also found that infants exposed to buprenorphine required shorter treatment duration and less medication to treat the symptoms of NAS and experienced shorter hospital stays when compared to infants exposed to methadone. No significant difference was found with respect to any serious maternal or neonatal adverse events (e.g., abnormal fetal health, neurological symptoms; Jones et al., 2010).

Methadone and buprenorphine are classified as Pregnancy Category C[5] drugs by the FDA, meaning that adequate, well-controlled studies of how these drugs affect pregnant women are lacking. However, prescribing methadone or buprenorphine during pregnancy is not considered "off-label." Choosing to proceed with methadone or buprenorphine treatment during pregnancy is an individual decision that women should make with their health care providers.

Another medication used to treat opioid use disorders is naltrexone. Naltrexone functions as a pure opioid blocker; however, withdrawal can be induced if naltrexone is administered to an individual who is engaged in current opioid use. Thus, induction to naltrexone requires detoxification and an opioid-free period, which may lead to relapse vulnerability, re-establishment of physical dependence, increased risk behaviors, treatment dropout, and possible opioid overdose and death. There is insufficient research to support the use of naltrexone during pregnancy. When considering naltrexone use during pregnancy, the potential risk to the fetus should be given due consideration. Before research is conducted to determine the safety of naltrexone use during pregnancy, the benefits and risks must be carefully weighed (Jones, Chisolm, Jansson, & Terplan, 2013). Additional information on the use of methadone, buprenorphine, and naltrexone appears in *Appendix 4: Key Features of Medications Approved for Treating Opioid Use Disorders*. As more women using MAT during pregnancy give birth to newborns, the field is gaining knowledge about the typical withdrawal course that newborns experience, based on the types and doses of medications mothers are given to treat opioid use disorders as well as other aspects of their prenatal obstetrical care.

Some distinctions among women who use opioids during pregnancy are paramount to understand because of care coordination for both mothers and infants. Although women who use opioids during pregnancy test positive for opioid use at the birth of their newborn, the supports and system responses should differ depending on whether or not the mother's opioid use is medically managed. Generally, women who use opioids during pregnancy and/or at delivery can be categorized within one of the following groups:

- Are receiving pain management with medications under the care of a physician.
- Are under the care of a physician and undergoing treatment for an opioid use disorder with medications, such as methadone or buprenorphine.
- Are misusing or abusing opioid pain medications with or without a prescription (e.g., obtaining pills illegally for a non-medical use, "doctor shopping," obtaining a prescription illegally).
- Are using or abusing illicit opioids, particularly heroin.

[5] In December 2014, the FDA published the Requirements for Pregnancy and Lactation Labeling Rule. The nomenclature is not used in the final rule, which requires the removal of the Pregnancy Categories A, B, C, D, and X from all human prescription drug and biological product labeling. Labeling is based on descriptive subsections for pregnancy exposure and risk, lactation, and effects to reproductive potential for females and males. Retrieved from http://www.gpo.gov/fdsys/pkg/FR-2014-12-04/pdf/2014-28241.pdf (accessed August 19, 2015).

Women with opioid use disorders often face a host of complex and entwined issues. Although they may come from all socioeconomic backgrounds, their lives are complicated by psychosocial and environmental factors. Often, there is a history of sexual abuse and/or interpersonal violence, inadequate social supports, unpredictable parenting models, poor nutrition, unstable housing, and co-occurring psychiatric conditions. Pregnant women with opioid use disorders are likely to use multiple substances during pregnancy, including tobacco and alcohol. Fetal Alcohol Spectrum Disorders (FASD) is a term used to describe the range of conditions, including physical, mental, and behavioral conditions as well as learning disabilities, that can be experienced by an individual prenatally exposed to alcohol.[6] Infants prenatally exposed to multiple substances are at risk for developing a wide spectrum of physical, emotional, and developmental problems. Exposure to multiple substances can affect an infant's withdrawal symptoms. Other factors that can affect the infant's withdrawal symptoms include the type of opioid that the mother used, whether the mother's opioid use disorder was medically managed, and whether she received routine prenatal care. The hospital environment itself, such as the methodology used to treat the infant's withdrawal symptoms is also an important factor that can reduce or exacerbate the infant's withdrawal (see the section on *Neonatal Abstinence Syndrome* for additional information).

Growing concerns about the substantial increase in the number of pregnant women and newborns who test positive for opiates, coupled with the overwhelmingly inaccurate and alarmist reporting by the popular media regarding this issue, prompted more than 50 leading national and international researchers and experts to release an open letter to the media and policy makers in March 2013. In an effort to counter misinformation about pregnant women and prescription opioid use, these experts noted the following:

Newborn babies are NOT born "addicted" and referring to newborns with NAS as "addicted" is inaccurate, incorrect, and highly stigmatizing.

Portraying NAS babies as "victims" results in the vilification of their mothers, who are then viewed as perpetrators, and further perpetuates the criminalization of addiction.

Using pejorative labels such as "oxy babies," "oxy tots," "victims," "tiny addict," or "born addicted" places these children at substantial risk of stigma and discrimination and can lead to inappropriate child welfare interventions.

NAS is treatable and has not been associated with long-term adverse consequences.

Mischaracterizing MAT as harmful and unethical contradicts the efficacy of MAT and discourages the appropriate and federally recommended treatment for opioid use disorder.

— International Drug Policy Consortium, 2013

Scope of the Problem

Opioid Use Trends

Rates of prescription opioid pain medication use vary across regions of the country and among subpopulations. From 2000 through 2013, the rate of overdose deaths related to heroin increased across all regions—11-fold in

[6] Resources for FASD include (1) the CDC website (http://www.cdc.gov/ncbddd/fasd/facts.html) and (2) the FASD Center for Excellence (http://fasdcenter.samhsa.gov).

the Midwest, more than 4-fold in the Northeast, more than 3-fold in the South, and doubled in the West (Hedegaard, Chen, & Warner, 2015). As the opioid crises emerged, by 2008 the states with the highest rates of opioid-related morbidity and mortality were concentrated in the Appalachian region (e.g., Kentucky, West Virginia, and Ohio) (Behavioral Health Coordinating Committee [BHCC], 2013). States vary a great deal in rates of: (1) non-medical use of opioid pain medications, (2) prescriptions for opioid pain medications, and (3) drug overdose deaths (Centers for Disease Control and Prevention, 2013). States with lower rates of non-medical use of and prescriptions for opioid pain medications also had lower rates of drug overdose deaths (Centers for Disease Control and Prevention, 2011).

Opioid use and related consequences also vary by several key demographics. For example, the Medicaid patient population is more likely to receive prescriptions for opioid pain medications and to have opioids prescribed at higher doses and for longer periods of time than the non-Medicaid patient population. Opioid medication overdose deaths are also more common among Medicaid-eligible populations (BHCC, 2013).

The overall rate of first time heroin use increased among all women, from 0.06 percent in 2002–2004 to 0.10 percent in 2009–2011, estimated to be an increase from 43,000 women to 77,000 women (SAMHSA, 2013). Among women, the number of overdose deaths due to the use of prescription opioid pain medications has increased significantly since 2007, surpassing deaths from motor vehicle-related injuries. Overdose deaths due to opioid medication increased among women more than 5-fold between 1999 and 2010, totaling 47,935 during that period (CDC, 2013).

From 1992 to 2012, treatment admissions for pregnant women among all female admissions remained stable at four percent. However, the proportion of pregnant women entering treatment who reported any prescription opioid misuse increased substantially from two percent in 1992 to 28 percent in 2012, an increase from 351 to 6,087 women. The proportion of pregnant women who entered treatment and reported prescription opioids as their primary substance increased from one percent in 1992 to 19 percent in 2012, an increase from 124 to 4,268 women (Martin, Longinaker, & Terplan, 2014).

Neonatal Abstinence Syndrome

Among infants, the incidence of NAS increased from 1.20 per 1,000 hospital births in 2000 to 3.39 in 2009 (Patrick et al., 2012) and 5.80 in 2012 (Patrick, Davis, Lehmann & Cooper, 2015). In a study of 299 neonatal intensive care units (NICU) across the country, the rate of NICU admissions for infants with NAS increased from 7 cases per 1,000 admissions in 2004 to 27 cases per 1,000 admissions in 2013 (Tolia, Patrick, Bennett, Murthy, Sousa, Smith, Clark & Spitzer, 2015). The study by Patrick et al. (2012) did not distinguish between NAS that resulted from illicit opioids, prescription opioid pain medications, or MAT. Between 2006 and 2012, the rate of infant and maternal hospitalizations related to substance use increased substantially, from 5.1 to 8.7 per 1,000 infant hospitalizations and from 13.4 to 17.9 per 1,000 maternal hospitalizations, resulting in a total cost of $944 million in 2012 (Fingar, Stocks, Weiss & Owens, 2015). In 2012, among the neonatal stays with a substance-related condition, approximately 60% were related to neonatal drug withdrawal or NAS. Among maternal stays related to substance abuse, almost one-fourth involved opioids (Finger et al., 2015).

As previously discussed, NAS is the term used to represent the pattern of effects that are associated with opioid withdrawal in newborns (Hudak & Tan, 2012). NAS symptoms are affected by a variety of factors, including the type of opioid the infant was exposed to, the point in gestation when the mother used the opioid, genetic factors, and exposure to multiple substances (Wachman, Hayes, Brown, Paul, Harvey-Wilkes, Terrin, Huggins, Aranda, & Davis, 2013). To assess the severity of the infant's symptoms, a scoring system,

such as the Finnegan Neonatal Abstinence Scoring System or the Lipsitz Neonatal Drug-Withdrawal Scoring System is used. The results of the scoring system are used in conjunction with an assessment of other factors, including the infant's gestational age, overall health, medical history, exposure to other substances, and tolerance or response to medications, to determine the course of treatment (Jansson, Velez, & Harrow, 2009).

Non-pharmacological treatment is the standard of care for the infant with NAS and should start at birth and continue throughout the infant's hospitalization and beyond (Velez & Jansson, 2008). Non-pharmacological treatment seeks to soothe the infant's symptoms, while also encouraging the mother–infant bond. Some of the symptoms associated with NAS can be challenging and disruptive to the attachment between the mother and infant, particularly for women who have substance use disorders and may have difficulty responding to an infants' cues. Non-pharmacological methods include rooming together post-delivery and modification of the environment to support attachment and provide a soothing environment for the infant. Environmental modifications include swaddling the infant and reducing his or her exposure to light and excessive noise.

Pharmacological treatment is primarily intended to relieve NAS symptoms and its associated complications, such as fever, weight loss, and seizures. Pharmacological treatment typically entails using a neonatal morphine solution or methadone (Hudak & Tan, 2012). Supports are necessary to address the challenges and risk factors that mothers and infants may face following discharge from the hospital. As previously described, women with opioid use disorders often face complex psychosocial, environmental, and cultural factors that can impact treatment, recovery, and parenting. Post-discharge supportive services can include identifying family or others for social support and participating in ongoing support groups, counseling, housing services, and follow-up services for the infant. See *Appendix 5: Children and Recovery Mothers (CHARM) Collaborative in Burlington, Vermont: A Case Study*, for information on post-discharge supportive services.

Treatment considerations for newborns with prenatal substance exposure are available in a 2012 clinical report from the American Academy of Pediatrics. The Academy recommends that staff with training in identifying signs of withdrawal monitor these infants and initiate therapy when indicated.

"Each nursery that cares for infants with neonatal withdrawal should develop a protocol that defines indications and procedures for screening for maternal substance abuse. In addition, each nursery should develop and adhere to a standardized plan for the evaluation and comprehensive treatment of infants at risk for or showing signs of withdrawal."

—Hudak & Tan, 2012

The advent of new medications used in treating opioid use disorders during pregnancy calls for additional studies on the long-term impact of prenatal exposure to opioids to better understand the best course of treatment for affected children (Wahlsten & Sarman, 2013; Hamilton, McGlone, MacKinnon, Russell, Bradnam, & Mactier, 2010; Farid, Dunlop, Tait, & Hulse, 2008).

Guidelines for Supporting Collaborative Policy and Practice

This guidance is intended to support the development of collaborative, interagency policies and practices that can assist communities to develop approaches that support the health, safety, well-being, and recovery of pregnant women with opioid use disorders and their infants. These approaches begin with prevention strategies designed to help all women of childbearing age, as well as their health care providers, to understand both the implications of opioid use during pregnancy and the interventions in the prenatal period that extend through—and ideally beyond—the postpartum time frame. This guidance highlights key decision points and recommended strategies based on the research literature as well as evidence from innovative strategies being implemented around the country.

Any response to the many barriers facing the families of pregnant women with opioid use disorders must be grounded in solutions within the community that reflect best practices (e.g., evidence-based practices) as well as perspectives, resources, and policies that address the needs of the community. A number of communities across the United States have developed collaborative initiatives to make systems and processes work more effectively for women with opioid use disorders and their infants. Although these approaches vary, they share a focus on coordinating the goals and efforts of an array of partners. In particular, efforts focus on effective screening and linkages to treatment in the prenatal period, as well as efficient communication between hospitals and community partners. One of these well-developed initiatives is described in the case study in *Appendix 5: Children and Recovery Mothers (CHARM) Collaborative in Burlington, Vermont: A Case Study*.

Existing Guidelines

Research shows that a combination of medication and behavioral therapies is the most successful way to treat opioid use disorders and increases the likelihood of cessation of opioid abuse (CSAT, 2005). Similarly, the literature summarizing the most current research offers best-practice guidance for developing efficacious practices and policies for women with opioid use disorders and their infants.

Recommendations have been published in the last several years by national and international organizations, such as the American College of Obstetricians and Gynecologists (ACOG), World Health Organization (WHO), US HHS, SAMHSA, American Society of Addiction Medicine (ASAM), Legal Action Center, and American Academy of Pediatrics. Although this publication is not intended to provide an exhaustive literature review, some of the key recommendations from these organizations are cited throughout, and select highlights are presented in the section that follows. Links to these publications are provided in *Appendix 3: Training Needs and Resources* .

American College of Obstetricians and Gynecologists and American Society of Addiction Medicine

The following excerpt from the 2012 ACOG and ASAM Committee Opinion on Opioid Abuse, Dependence, and Addiction in Pregnancy summarizes the current knowledge of the risks and benefits of MAT for opioid use during the prenatal and postpartum period.

Opioid use in pregnancy is not uncommon, and the use of illicit opioids during pregnancy is associated with an increased risk of adverse outcomes. The current standard of care for pregnant women with opioid use disorders is referral for opioid-assisted therapy with methadone, but. . .evidence suggests that buprenorphine also should be considered. Medically supervised tapered doses of opioids during pregnancy often result in relapse to former use.[7] Abrupt discontinuation of opioids in an opioid-dependent pregnant woman can result in preterm labor, fetal distress, or fetal demise. During the intrapartum and postpartum period, special considerations are needed for women who are opioid dependent to ensure appropriate pain management, to prevent postpartum relapse and a risk of overdose, and to ensure adequate contraception to prevent unintended pregnancies. Patient stabilization with opioid-assisted therapy is compatible with breastfeeding. Neonatal abstinence syndrome is an expected and treatable condition that follows prenatal exposure to opioid agonists. All infants born to women who use opioids during pregnancy should be monitored for neonatal abstinence syndrome and be treated if indicated.

World Health Organization

The WHO's *Guidelines for the identification and management of substance use and substance use disorders in pregnancy* (2014) provide technical guidance primarily for health care professionals who work with women and their infants from conception to birth as well as during the postnatal period. The publication also offers guidelines on identifying and managing alcohol and other substance use in pregnant women, with the goal of ensuring healthy outcomes for both pregnant women and their infants. While developing the recommendations, WHO established the following overarching principles to provide guidance in planning, implementing, and evaluating the most relevant recommendations, based on regional contexts and available resources.

PRIORITIZING PREVENTION. Preventing, reducing and ceasing the use of alcohol, tobacco and illicit drugs before and during pregnancy and in the postpartum period for breastfeeding mothers are essential for optimizing the health and well-being of women and their children. Ensure that women who are receiving opioid treatment for a medical condition understand the risks of prenatal exposure and have access to highly effective birth control methods.

ENSURING ACCESS TO PREVENTION AND TREATMENT SERVICES. All pregnant women and their families affected by substance use disorders should have access to affordable prevention and treatment services and interventions delivered with special attention to confidentiality, legal and human rights; women should not be excluded from accessing health care because of their substance use. Treatment, especially residential programs, for postpartum women should incorporate consideration for the infant and siblings.

RESPECTING PATIENT AUTONOMY. The autonomy of pregnant and breastfeeding women should always be respected; each woman with a substance use disorder needs to be fully informed

[7] The optimal methadone dosage for pregnant women generally increases throughout pregnancy, and this increase does not necessarily increase fetal exposure to methadone. See John Drozdick, III, et al., *Methadone Trough Levels in Pregnancy*, 187 American Journal of Obstetrics and Gynecology, 1184 (2002); John J. McCarthy, *Addiction Treatment Forum, Methadone Dosing During Pregnancy: Does Anyone Have a Clue?* (Oct. 2012).

about the risks and benefits, for herself and for her fetus or infant, of available treatment options, when making decisions about her health care and the care of her infant.

PROVIDING COMPREHENSIVE CARE. Services for pregnant and breastfeeding women with substance use disorders should have a level of comprehensiveness that matches the complexity and multifaceted nature of substance use disorders and their antecedents in this population.

SAFEGUARDING AGAINST DISCRIMINATION AND STIGMATIZATION. Interventions should be provided to pregnant and breastfeeding women in ways that prevent stigmatization, discrimination, criminalization, and marginalization of women seeking treatment to benefit themselves and their infants. Prevention and treatment should promote and facilitate family, community and social support as well as social inclusion by fostering strong links with available childcare, economic supports, education, housing, and relevant services.

In addition to these principles, WHO makes specific practice recommendations. One recommendation suggests that pregnant women should be advised to continue or begin opioid maintenance therapy with methadone or buprenorphine.

American Society of Addiction Medicine

ASAM's *National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use* (2015) provides information on evidence-based treatment of opioid use disorder, including guidelines for the treatment of pregnant women. The publication discusses recommendations on assessment and diagnosis, treatment, and the use of psychosocial treatment in conjunction with medications. ASAM's recommendations for the treatment of opioid use disorders in pregnant women include:

ASSESSMENT OF OPIOID USE DISORDER IN PREGNANT WOMEN. A comprehensive assessment, including medical examination and psychosocial assessment is recommended in evaluating opioid use disorder in pregnant women. The clinician should ask questions in a direct and nonjudgmental manner to elicit a detailed and accurate history.

OPIOID AGONIST TREATMENT IN PREGNANCY. Decisions to use opioid agonist medications in pregnant women with opioid use disorder revolve around balancing the risks and benefits to maternal and infant health. Opioid agonist treatment is thought to have minimal long-term impacts on children relative to harms resulting from maternal use of heroin and prescription opioids. Therefore, women with opioid use disorder who are not in treatment should be encouraged to start opioid agonist treatment with methadone or buprenorphine monotherapy (without naloxone) as early in the pregnancy as possible. Pregnancy in women with opioid use disorder should be co-managed by an obstetrician and an addiction specialist physician.

OPIOID AGONISTS VERSUS WITHDRAWAL MANAGEMENT. Pregnant women who are physically dependent on opioids should receive treatment using agonist medications rather than withdrawal management or abstinence as these approaches may pose a risk to the fetus. Furthermore, withdrawal management has been found to be inferior in effectiveness over pharmacotherapy with opioid agonists and increases the risk of relapse without fetal or maternal benefit.

INDUCTION AND DOSING OF OPIOID AGONISTS. Treatment with methadone should be initiated as early as possible during pregnancy.

BREASTFEEDING. Mothers receiving methadone and buprenorphine monoproduct for the treatment of opioid use disorders should be encouraged to breastfeed.

In addition to these aforementioned organizations, state and local jurisdictions have developed guidelines for hospitals, child welfare agencies, treatment providers, and other care providers regarding MAT, NAS treatment, and responses to pregnant women with opioid dependency. These guidelines may help ensure a more consistent approach among communities within a given state or region. Addressing disparities in treatment related to resource shortages and geographic and financial barriers to accessing health care and other services is another vital consideration in meeting the needs of pregnant women with opioid use disorders.

One example of a regional approach that incorporates best practice guidelines is the CHARM Collaborative in Burlington, Vermont—a multidisciplinary group of agencies serving women with opioid use disorders and their families during pregnancy and through infancy. The CHARM Collaborative focuses on meeting the needs of pregnant and postpartum women who have a history of opioid use and their infants. This group emerged in the late 1990s in response to the increasing need for MAT resources for pregnant women with opioid use disorders. Today, the CHARM Collaborative includes 11 organizations that collectively provide this population of women with coordinated comprehensive care from child welfare, medical (including obstetrics and pediatrics) and substance abuse treatment professionals across Vermont. Their efforts have ensured that the vast majority of pregnant women are identified and provided treatment during the prenatal period. They jointly develop plans for the infant and family's safety and well-being prior to the baby's birth. Additional information on the approach and practices of the CHARM Collaborative is provided in *Appendix 5: Children and Recovery Mothers (CHARM) Collaborative in Burlington, Vermont: A Case Study*.

Need for Collaboration Among Multiple Agencies

Professionals in the child welfare, judicial, medical (including obstetrics, pediatrics, substance abuse treatment, and mental health), and addiction treatment systems generally share significant concerns about pregnant women who misuse opioids and newborns with NAS and other problems related to in utero drug or alcohol exposure. However, this is often where the consensus ends. At times, the responses of various systems to the needs of these families diverge, resulting in apparent conflicts among treatment practices, medical recommendations, and the policies and oversight provided by courts and child welfare services.

The types of agencies and professionals that provide treatment and other services to pregnant women with opioid use disorders and their infants can vary widely from one community to another. A considerable range and mix of approaches, settings, programs, and professionals can be involved, and health and social service systems typically operate and intersect in ways that are unique to each community. This mixture of participating systems and relationships among them affects service coordination. For example, several different professionals and specialty providers within the medical care system (i.e., an obstetrician, neonatologist, pediatrician, and addiction specialist) might provide care to a woman and her infant during the prenatal and postpartum periods. Within the substance abuse treatment system, treatment is delivered in a variety of settings (e.g., residential facilities, outpatient clinics, and offices of physicians who provide MAT), using a combination of therapeutic approaches (e.g., medications, individual and group counseling, and self-help groups). In the child welfare system, services are delivered along a continuum, based on risk

and safety factors that range from supports to children remaining in the custody of their parents (often referred to as in-home services) to out-of-home care (e.g., foster or kinship care).

Different systems and provider communities also have different policies, priorities, and perspectives. For example, hospitals—even those in the same state or county—often have inconsistent protocols for screening infants for prenatal substance exposure and sometimes have seemingly inconsistent practices for contacting child welfare agencies if substance use is detected or NAS is diagnosed. Even when hospitals have clear policies in place, adherence to these policies depends largely on the relationships between hospital staff and child welfare workers. Adherence to policies also varies by medical team members' perceptions of whether a positive toxicology screen for the newborn is likely to trigger legal consequences for the mother, which may be perceived to not be in the best interest of the mother and infant (National Abandoned Infants Assistance Resource Center, 2012).

"Medication-Assisted Treatment (MAT) is an evidence-based practice that combines pharmacological interventions with substance abuse counseling and social support. Although not for everyone, it is an essential part of the comprehensive array of services available to people struggling with addiction to alcohol or other drugs.

A paradox in our field is that although we recognize addiction as a chronic, relapsing disease, some substance abuse counselors and administrators have been reluctant to embrace new technologies for its treatment. At the same time, most physicians and other health care professionals receive little or no training in the treatment of addiction. As a result, adoption of MAT has been slow in some areas."

— Mark G. Stringer, Director
Missouri Department of Health,
Division of Behavioral Health

The fact that many non-medical professionals can potentially affect treatment decisions for pregnant women with opioid use disorders further exacerbates the care of women and their infants. These professionals may include judges (if the woman is involved in the criminal justice system) or residential substance abuse treatment providers that do not offer MAT. If a woman is already involved in the child welfare system as a result of a case related to her older children, child welfare social workers and judicial representatives related to this separate case also influence decisions regarding her care, and these decisions might not be consistent with her treatment plan or best practice recommendations. If a woman is receiving MAT in an opioid treatment program (OTP) or buprenorphine from her doctor, she is likely to experience conflict if she also participates in a substance abuse treatment program or a mutual aid support group that does not embrace the use of MAT. It is essential to recognize that each mutual aid support group is autonomous and self-directed; and group members may have their own views on the use of MAT. Despite this potential conflict, each professional and the organizations or systems that they represent are responding to the directives issued from their respective fields of practice. If no such directives exist, they must rely on their best professional judgment when making critical decisions that affect women and their infants and that have the potential to impact entire families.

Every professional involved needs to understand the different contexts of opioid use by a pregnant woman to accurately assess her distinct needs and those of her family members in order to implement the most appropriate and comprehensive plan of care. In addition to being familiar with effective and evidence-based addiction treatment, treatment counselors, social workers, health care

providers, and legal system professionals need to be aware of the primary risk and protective factors that promote or inhibit resiliency in women and their children. These factors have a direct impact on the types and intensities of support and supervision that a woman requires throughout pregnancy as well as during the critical first year of parenting a newborn.

For example, child welfare agencies have the complicated dual role of supporting families while monitoring them to prevent child maltreatment. These agencies have risk and safety assessment policies and practices that are intended to identify immediate safety concerns for children, while evaluating the risk and protective factors of each family. When making decisions about whether to intervene and how to do so in the most supportive manner, staff must take into account the distinctions related to a woman's history, motivation, and pattern of opioid use (and other drug use).

The Child Abuse and Prevention Treatment Act (CAPTA) Reauthorization Act of 2010 require states to have policies and procedures for hospitals to notify child protective services (CPS) of all children born who are affected by illegal substance use or withdrawal symptoms resulting from prenatal drug exposure or

The privacy provisions in the U.S. Code of Federal Regulations (C.F.R.), Title 42, Part 2, describe the limited circumstances in which information about a patient's treatment for a substance use disorder may be disclosed with and without the patient's consent. The regulations are available at http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&sid=b7e8d29be4a2b815c404988e29c06a3e&rgn=div5&view=text&node=42:1.0.1.1.2&idno=42

42 C.F.R. 2 applies to all clinicians who use a controlled substance (i.e., methadone and buprenorphine) for detoxification or maintenance treatment of a substance use disorder. Such physicians must register with the federal Drug Enforcement Agency (DEA), and their DEA license, along with representations concerning their status as opioid treatment providers, makes them subject to the regulations.

With limited exceptions, 42 C.F.R. 2 requires patient consent for disclosures of protected health information, even for the purposes of treatment, payment, or health care operations. Consent for disclosure must be in writing.

42 C.F.R. 2 does not apply to information on substance use treatment maintained in connection with the Veterans' Administration or the Armed Forces (42 CFR § 2.12 (c)).

Most substance-abuse treatment programs are also subject to the Health Insurance Portability and Accountability Act of 1996 Privacy Rule. In 2004, SAMHSA issued a guidance document that summarizes the differences between the two rules and implementation solutions, which is available at http://www.samhsa.gov/sites/default/files/part2-hipaa-comparison2004.pdf

Frequently asked questions (FAQs) about substance abuse confidentiality regulations are available on the SAMHSA website. The FAQs include information on exceptions to 42 C.F.R. 2 (e.g. medical emergencies) and guidance on which entities or individuals are subject to the regulations. http://www.samhsa.gov/about-us/who-we-are/laws/confidentiality-regulations-faqs

indications of FASD (CAPTA, 2010). CAPTA requires CPS agencies to develop a plan of safe care for every such infant referred to their agency and address the health and substance use disorder treatment needs of the infant. The 2016 Title V, *Section 503, "Infant Plan of Safe Care"* of S. 524, "Comprehensive Addiction and Recovery Act of 2016" requires the plan of safe care to also address the treatment needs of affected family or caregivers and requires states to develop a monitoring system to determine whether and how the local entities are providing referrals to and delivery of appropriate services for the infant and affected family or caregiver. The Comprehensive Addiction and Recovery Act of 2016 was signed into law on July 22, 2016. CAPTA also requires that all children who are younger than three years who are substantiated victims of child maltreatment are referred to early intervention agencies that provide developmental disabilities services (Office on Child Abuse and Neglect, 2003). However, state, tribal, and local agency policies determine how newborns with prenatal substance exposure are identified, whether notice to CPS constitutes a report alleging child abuse or neglect, and the level and type of proof needed to warrant further investigation (Young et al., 2009). For these reasons, CPS agencies handle referrals of infants with prenatal substance exposure in ways that vary greatly by state and community. A February 2015 analysis by the Guttmacher Institute showed that four states require health care professionals to test newborns for prenatal drug exposure when drug use is suspected, while 15 states require providers to report women to CPS for suspected drug use during pregnancy (Guttmacher Institute, 2015). Different CPS agencies also make very different decisions regarding whether an infant remains in the custody of the mother. These decisions determine how infants are evaluated for early intervention service needs and whether they receive these services when needed. These inconsistencies in policy and practice result in differing approaches across communities to identify pregnant women in need of treatment and different responses for the infant's care and safety considerations.

In addition to these practice and policy concerns, there are often knowledge gaps about the risk and safety of a newborn who tests positive for opioids. For example, professionals need to understand distinctions in risk and safety between infants exposed to opioids as a result of the mother's opioid use or misuse versus infants exposed to opioids as a result of the mother's treatment for opioid dependency with medications under a doctor's care. In addition, in the well-meaning effort to maintain child safety, child welfare agencies may establish uninformed requirements on minimal dosing of MAT medications or withdrawal from MAT for women as a condition for keeping custody of their newborns[8] and may use a positive toxicology result for methadone or buprenorphine at birth as a presumptive cause for child removal.

These decisions often have negative and sometimes irrevocable consequences for families, including interference with the critical mother–infant attachment process. In addition, many Family Treatment Drug Courts (FTDCs) around the country treat a woman's use of MAT as a criterion for excluding her from participating in or graduating from the program until she is no longer taking medications. The National Association of Drug Court Professionals (NADCP) resolved that drug courts should not impose blanket prohibitions against the use of MAT for their participants and further suggests that drug courts attain reliable expert consultation on the appropriate use of MAT for their participants, including partnering with substance abuse treatment programs (NADCP, 2013). In addition, recognizing that MAT may be an essential part of a comprehensive treatment plan, SAMHSA Treatment Drug Court grantees were encouraged, beginning in 2015, to use a percentage of the annual grant award to pay for FDA-approved medications.

State laws vary regarding legislation on the use of substances during pregnancy. The variance includes whether there is criminal prosecution or if substance use is considered maltreatment and grounds for termination of parental rights under civil statutes. The 2013 National Drug Control Strategy states that criminal justice professionals should include the use of MAT

[8] Minimal dosing may in fact *increase* the likelihood of relapse as well as *increase* risks to both the mother and infant. Important health issues are associated with proper dosing. (Kaltenbach et al., 1998)

as appropriate treatment for an opioid use disorder for those individuals involved in the judicial system (Office of National Drug Control Policy, 2013). The previously described analysis by the Guttmacher Institute showed that one state allows assault charges to be filed against pregnant women who use certain substances and that 18 states consider evidence of substance use during pregnancy (often only evidence of use and not a diagnosis of dependency or addiction or findings of harm) to indicate child abuse and provide grounds for termination of parental rights (Guttmacher Institute, 2015). On the other hand, some states have begun to implement Safe Harbor legislation to facilitate access to treatment for pregnant women. Safe Harbor laws provide a provision in a law or agreement that protects against liability or penalty as long as set conditions have been met. Two states have implemented or introduced Safe Harbor laws in which pregnant women who seek treatment for opioid and other substance use disorders, in the absence of other risk or safety factors, will not have to fear risking loss of custody of their infant or termination of parental rights.

As amended in 2010, the Child Abuse Prevention and Treatment Act (CAPTA) requires states to include the following in their state plans.

An assurance in the form of a certification by the Governor of the State that the State has in effect and is enforcing a State law, or has in effect and is operating a statewide program relating to child abuse and neglect that includes:

A) policies and procedures (including appropriate referrals to child protection service systems and for other appropriate services) to address the needs of infants born with and identified as being affected by illegal substance abuse or withdrawal symptoms resulting from prenatal drug exposure, or a Fetal Alcohol Spectrum Disorder, including a requirement that health care providers involved in the delivery or care of such infants notify the child protective services system of the occurrence of such condition in such infants, except that such notification shall not be construed to: (I) establish a definition under Federal law of what constitutes child abuse or neglect; or (II) require prosecution for any illegal action;

B) the development of a plan of safe care for the infant born and identified as being affected by illegal substance abuse or withdrawal symptoms, or a Fetal Alcohol Spectrum Disorder.

The CAPTA Reauthorization Act of 2010 is available at: http://www.gpo.gov/fdsys/pkg/BILLS-111s3817enr/pdf/BILLS-111s3817enr.pdf

— Section 106(b)(2)(B)(ii-iii) of the Child Abuse Prevention and Treatment Act [42 U.S.C. 5106a(b)(2)(B)(ii-iii)]

Title V, Section 503, "Infant Plan of Safe Care," of S. 524, "Comprehensive Addiction and Recovery Act of 2016" was signed into law on July 22, 2016. The bill amends CAPTA to address the health and substance use disorder treatment needs of the infant and affected family or caregiver; and to ensure the development and implementation by the State of monitoring systems regarding the implementation of plans to determine whether and in what manner local entities are providing, in accordance with State requirements, referrals to and delivery of appropriate services for the infant and affected family or caregiver.

The 2016 changes also provide monitoring and oversight changes for HHS.

The Comprehensive Addiction and Recovery Act of 2016 is available at: https://www.congress.gov/bill/114th-congress/senate-bill/524

The various configurations and approaches in each discipline can exacerbate the challenges in coordinating services among providers, agencies, and organizations. The many differences that exist need to be reconciled to facilitate a coordinated cross-disciplinary approach. The purpose of this document is to assist communities in assessing their current practice and to develop practice and policy improvements to better meet the needs of these families.

Comprehensive Framework for Intervention

As discussed in the previous section, many professionals may be involved in decisions related to the treatment, care, and supervision of pregnant women with opioid use disorders. These decision makers might include health care providers, substance abuse treatment providers, child welfare workers, and judicial system representatives (e.g., judges, parents' lawyers, and children's lawyers or advocates). Each of these professionals and the systems they represent are responding to directives that stem from a combination of federal regulations, state legislation, ethics, and system-specific guidelines.

Ideally, these directives are aligned to ensure the best possible outcomes for both mothers and infants. Unfortunately, however, this is not usually the case, particularly when state laws or agency policies are silent on or conflict with best practices, or are driven by misinformation. When directives are unclear, conflicting, or missing, workers must rely on their professional judgment to determine the best approach and course of action.

Without proper training and knowledge about best practices, professionals might not serve the best interests of mothers, children, and families. To surmount this risk, professionals must establish mechanisms for working together across systems, agencies, and providers to develop a coordinated and cohesive approach. Such an approach has the highest likelihood of achieving successful outcomes related to maternal and child health, newborn care, mother–infant attachment, positive parenting practices, child safety, and family well-being.

Strategies to help are typically most effective when designed to address needs beyond substance abuse treatment, such as for co-occurring mental health issues, trauma, housing, child care, employment, parenting, and a range of other personal supports. A family-centered and gender-responsive approach addresses many of these needs in a culturally responsive[9] manner (Werner, Young, Dennis, & Amatetti, 2007; King, Duan, & Amaro, 2014). When states, tribes, and communities recognize the positive and often cost-effective impact of a collaborative approach, public agencies and private providers have a powerful incentive to work together in alternative and innovative ways.

Overview of Substance-Exposed Infants (SEI) Framework

This guidance leverages and is informed by the five-point intervention framework developed by the NCSACW and funded by SAMHSA and the Administration on Children, Youth, and Families. This framework, which was the organizing foundation for the SAMHSA report *Substance-Exposed Infants: State Responses to the Problem*, serves as a comprehensive model that identifies five major time frames when intervention in the life of an infant can help reduce the potential harm of prenatal substance exposure (Young et al., 2009).

[9] For more information on cultural competence, see SAMHSA's Treatment Improvement Protocol (TIP) 59 – *Improving Cultural Competence* (http://store.samhsa.gov/shin/content//SMA14-4849/SMA14-4849.pdf).

The five points of intervention are:

1. Pre-pregnancy: During this time, interventions can include promoting awareness among women of child-bearing age and their family members of the effects that prenatal substance use can have on infants.
2. Prenatal: During this time, health care providers have the opportunity to screen pregnant women for substance use as part of routine prenatal care and to make referrals that facilitate access to treatment and related services for the women who need these services.
3. Birth: Interventions during this time include health care providers testing newborns for prenatal substance exposure at the time of delivery.
4. Neonatal: During this time, health care providers can conduct a developmental assessment of the newborn and ensure access to services for the newborn as well as the family.
5. Throughout childhood and adolescence: During this time, interventions include the ongoing provision of coordinated services for both child and family.

The framework also illustrates the following key issues:

- The birth event is only one of several opportunities to affect outcomes. Therefore, it is important to understand the extent of those opportunities and which interventions are most needed and most likely to be effective at each point in time.
- Cross-system linkages are necessary to ensure services are coordinated across the spectrum of prevention, intervention, and treatment.

The NCSACW's five-point framework emerged from a multi-year review and analysis of existing policies and practices in 10 states regarding prenatal exposure to alcohol and other drugs. This effort was designed to help state, tribal, and local governments to identify opportunities for strengthening interagency efforts that address prevention, intervention, identification, and treatment of complications related to prenatal substance exposure. The framework focuses on immediate and ongoing services for infants, mothers, and families. The NCSACW reviewed states' policies regarding:

ACOG's 2015 legislative priorities include promoting public health efforts to reduce maternal opioid dependence and NAS as well as opposing punitive legislation against women with opioid dependence whose babies are born with NAS (ACOG, 2015).

- Pre-pregnancy efforts to engage women with substance use disorders in treatment to prevent prenatal substance exposure in the women's future infants.
- Screening and assessment during pregnancy to ensure that women have access to treatment and needed supports.
- Health care, supportive services at birth, and notification of CPS when infants are identified as having been prenatally affected by illegal substances, as consistent with CAPTA.
- Services to infants with prenatal substance exposure or infants who require care (along with their parents and siblings) during the neonatal period.
- Ongoing coordinated services for this population of children and their families throughout childhood and adolescence (Young et al., 2009).

This review showed a wide variation in state policies and practices related to meeting the needs of infants with prenatal substance exposure, thus highlighting the need for guidance based on best practices and current literature in the field. This guidance also needs to provide recommendations that can be adapted and customized to benefit women and children within the context of each community's unique mix of resources, challenges, and perspectives.

Compared to efforts by individual agencies and systems, collaboration across multiple agencies and systems, coupled with strong leadership and consistent communication, offers a more effective approach, a more efficient way of doing business, and ultimately leads to better outcomes.

This five-point intervention framework highlights opportunities for cross-system collaboration and policy development at each critical point in time, from pre-pregnancy throughout an infant's early years. The framework also integrates recommendations for best practices related to outreach, engagement, treatment, and support for mothers and their infants along the five-point continuum. The framework shows that no single system has the necessary resources, information, or influence needed to adequately serve this vulnerable mother–infant dyad and other involved family members who are likely to need services. All those who have a role in improving outcomes for such families need to collaborate in order to put the necessary policies and practices in place. These collaborations can set the stage for maternal recovery from substance use disorders, child safety, and the well-being of all those involved.

A Guide for Collaborative Planning

The opportunity for practice and policy improvement exists largely because so many different agencies, organizations, and providers have a legal or professional responsibility to act or address the needs of pregnant women with opioid use disorders and their infants. Without a comprehensive coordinated response that includes child welfare and healthcare, including obstetrics, pediatrics, substance abuse treatment, and mental health professionals, families are not well served. Cross-system initiatives lead to better results by facilitating better communication, clearly defining the roles of the various professionals who serve these families, and maximizing the resources of multiple stakeholders who have a vested interest in accomplishing shared goals.

Efforts that specify the roles and responsibilities of each partner help ensure that efforts from multiple systems to support individuals, families, and communities have a stronger cumulative impact and are sustained over time to address the full range of practice and policy considerations (Young, Nakashian, Yeh, & Amatetti, 2006). However, collaborative practice can be difficult to establish and implement for a number of reasons, including competing priorities, rules in agencies or organizations that conflict with the approaches of others, lack of leadership, confusion about roles, unmet training needs, use of different terminologies, limits on time and resources, information gaps, and mistrust. Communities are often unprepared to provide services to the large number of pregnant women who misuse prescription medications and heroin, and these agencies have not yet organized a coordinated response. In other communities, all of the involved parties might not know the rules, regulations, and practice standards that operate in the various systems. In fact, partner agencies often need to understand what services are available and who the providers are in each system.

To understand the array of local services and overcome the barriers to coordinating services to meet the needs of this population of pregnant woman and their infants, prospective collaborative partners from each of the primary systems of health care, substance abuse treatment, mental health, child welfare, and dependency and Family Drug Courts need to know what questions to ask when they begin their joint planning. These questions must be identified regardless of whether the potential partners' intent is to initiate, expand, or truly integrate their services and systems.

Building the Collaborative Team[10]

To build and foster cross-system collaboration, building an effective coordinating team is of paramount importance. This section presents a description of a collaborative team. Ideally, collaborative teams include a steering committee, a core team, and work groups.

The Collaborative Team

Preferably, the state, tribe, or local government creates the collaborative team and endows it with the capacity and resources needed to support and sustain its major initiatives. A well-designed collaborative team can support the plans set in motion and ensure goals are met, especially if the team convenes on a regular and predictable basis and keeps its focus on systems change, improved outcomes, and sustainability.

One way to organize the team is as follows:

- **Steering Committee**—This committee oversees and designates the members of the core team (defined below); facilitates necessary cabinet, council, commission, and legislative policy changes;[11] and works to remove system barriers. The committee consists of multidisciplinary top executives, directors, and leaders across each of the collaborating entities. Participation and presence of key decision makers will increase the efficiency and effectiveness of the meetings.

  TIP: *Keep steering committee leaders engaged by informing members of the collaborative team's progress so that they are prepared to pave the way for necessary change.*

- **Facilitator**—Guides the team in decision making. The facilitator role can be fulfilled by bringing in an outside facilitator, appointing representatives from the different systems to conjointly fulfill the role, or appointing representatives from the different systems to rotate in the facilitator role. These strategies can help the systems share responsibility, while also avoiding the perception that the initiative is being "run" by one agency. Having system representatives fulfill the facilitator role requires the representative to be aware and understand his or her multiple and potentially conflicting roles. In the facilitator role, system representatives must diligently maintain the distinction between their role as the facilitator and as the system representative. When the boundaries of these roles are delineated and respected, others will be more inclined to trust and respect the boundaries as well. Ideally, the facilitator role, or the various configurations that can fulfill the facilitator role, requires familiarity with the subject matter and how the systems operate (Pennsylvania State University, 2015).

  TIP: *Facilitate decision making among multiple systems by appointing a formal facilitator. Facilitating a multidisciplinary team requires skills that differ from those required to direct single-agency work groups; stakeholders from different disciplines do not have jurisdiction over each other, and decision making by decree or majority rule will not work in these situations.*

- **Core Team**—Responsible for implementing policy changes at each organization. The core team is multidisciplinary and consists of mid-management representatives from each

[10] For more information on developing a collaborative team and structure, see Screening and Assessment for Family Engagement, Retention, and Recovery (SAFERR) https://www.ncsacw.samhsa.gov/resources/SAFERR.aspx

[11] If using federal funding, these actions must be taken in compliance with Section 503(b) of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2016 (S. 1695). Section 503(b) provides that no federal funds from the HHS annual appropriations act may be used to pay the "salary or expenses of any grant or contract recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature." https://www.congress.gov/bill/114th-congress/senate-bill/1695

collaborating entity in addition to consumers, advocates, and representatives of other organizations, as appropriate.

TIP: *Include no more than six to eight individuals in the core team. Core Team members should have sufficient authority and flexibility to approve agency-level practice and policy changes to sustain the collaborative team's momentum by achieving "quick wins."*

- **Work Groups**—Created by the steering committee to address priorities of the collaborative initiative. Work groups include members of the core team and additional key stakeholders, such as providers and practitioners, consumers and advocates.

TIP: *Give your work groups specific challenges they can address by using first-hand knowledge from key stakeholders regarding effective tools and strategies, such as devising a communication protocol.*

This type of structure can be used at the state, tribal, and local levels. At the local level, for example, the health department might convene the collaborative team. Ideally, all of these entities work closely together to accomplish jointly identified goals and shared priorities for improving practice and policy.

This structure helps ensure:

- Sustainability of the initiative through the authority and endorsement of the steering committee;
- Communication through accountability in the hierarchical and peer-to-peer relationships of the core team;
- Regional broad-level buy-in through the participation and investment of the diverse stakeholders who make up the work groups; and
- Internally supported change through the investment and commitment of multiple systems to achieve collaboratively defined outcomes.

Cross-system teams must consider several steps as they prepare to engage in collaborative planning. These steps, (1) setting the stage for collaboration, (2) engage key stakeholders and establish work groups, (3) define shared goals, and (4) identify strategies and jointly monitor outcomes, are discussed below. Questions are posed to guide the purpose and outcome of each step. *Appendix 1: Facilitators Guide* includes a facilitator's guide and a set of tools to help the development of a work plan, based on prioritization of identified goals. The tools include a Cross-System Guide, to develop a baseline understanding of areas of strength and opportunities for improvement, and five System-Specific Guides, to understand the context of the initiative from multiple points of view. For instance, each system's perspective of the "primary" client (e.g., mother, infant, or family) differs. The identified "primary" client often drives the system's response and goal. For example, the MAT provider may consider the mother as the primary client, with interventions targeted solely at her. In comparison, the infant's neonatologist or pediatrician may identify the infant as the primary client. Although each service provider must provide services within their scope of practice, understanding the impact of opioid use disorders on the mother and infant as well as what services and supports are needed for optimal outcomes requires a mutual understanding of the involved systems. The guides can provide the necessary background for teams before making decisions about—and committing valuable resources to—statewide practice and policy changes.

STEP 1: Setting the Stage for Collaboration

Once the core team has been formed, some general fact gathering and sharing by all team members is necessary so that each member understands:

- What practices and policies are in place in each team member's service system and in the other service systems;
- Partner mandates and priorities that are likely to affect, and possibly limit, their level of involvement;

- The terminology that each team member's organization uses most frequently and how the organizations define these terms (e.g., "treatment");
- The baseline resources, resource gaps, and barriers in each system; and
- What needs to be addressed and improved, particularly from the perspective of mothers, children, and family members, to provide the necessary care.

STEP 2: Engage Key Stakeholders and Establish Work Groups

To determine which partners should be involved in the initiative, an assessment of the current level of collaboration is helpful. Questions to answer include: Who is currently working on the issue being tackled? What does each of these individuals or organizations contribute? And, significantly, which key stakeholders are missing from the conversation?

Core team members on the collaborative team should, at a minimum, include child welfare professionals, key dependency court and family drug court professionals, mental health providers, Medicaid officials, and healthcare providers. Healthcare providers include office- and hospital-based obstetricians, pediatricians, neonatologists, primary care providers, hospitalists, medical social workers, and opioid treatment and other substance abuse treatment providers (including residential, intensive outpatient, and outpatient treatment providers).[12, 13] Other stakeholders, including lead staff from agencies such as Temporary Assistance for Needy Families, maternal and child health agencies, and housing authorities, may also play key roles in the collaborative team.

Other potential participants include organizations that are unique to the community and provide services for this population of families, such as women's or children's health resource centers; early child intervention organizations; and clinical, financial, or legal resource centers as well as representation from tribes in communities with American Indian populations and/or tribal leadership. Finally, it is critical to ensure that pregnant women or mothers representing the target population have a voice in the process and are active participants in planning, informing, communicating, and collaborating.

Key stakeholder participation in the collaborative team is likely to be determined by existing partnerships and whether the overall effort is intended to provide new services, expand existing services, or increase levels of service integration across systems.

STEP 3: Define Shared Goals

Every state, tribe, and community is supported and challenged by its own systems, issues, beliefs, and ideals. On occasion, the existing protocols, culture, and financial constraints may affect the collaborative team's ability to be successful in coordinating their approach and share accountability for the outcomes. Therefore, each team member needs to evaluate how their system-specific and individual principles and values will lead practice and policy change and understand the perspectives that are influencing the positions and decisions of the other partners.

To create principles for their work together, the team should collectively examine and discuss fundamental questions, such as:

- What is each represented agency's role in achieving shared priorities and outcomes (e.g., How does child welfare services support parent recovery? How do treatment providers for parents support child safety and permanency and family well-being?)

[12] Dependency courts refer to courts that handle dependency cases involving children and youth under 18, including child maltreatment (see https://www.childwelfare.gov/pubPDFs/cwandcourts.pdf).

[13] Family Drug Courts (also referred to as Family Dependency Treatment Courts, Family Treatment Courts, Dependency Drug Courts, and Family Treatment Drug Courts) use a multidisciplinary approach, recognizing that their clients (i.e., parents, children, and families who enter the Family Drug Court) often face a range of challenges in addition to a substance use disorder (see http://www.cffutures.org/files/publications/FDC-Guidelines.pdf).

- What does each team member believe about the nature of substance use and substance use disorders?
- Do team members agree on the markers of effective practice and service delivery? What are those markers?
- How is "best interest" defined for infants? For mothers? For families? Do mothers have sufficient input in determining this?
- What do team members or policy leaders believe about the use of MAT for women who are pregnant or breastfeeding?
- What do team members believe constitutes recovery?

STEP 4: Identify Strategies and Jointly Monitor Outcomes

A crucial component of developing a coordinated response is the ongoing transfer of knowledge across professionals, agencies, and organizations. This knowledge transfer enables the team to establish and maintain a shared understanding of evidence-based practices for pregnant women with opioid use disorders and their infants from a multi-system perspective. To facilitate this knowledge transfer, the team needs to:

- Review the desired outcomes for each system by, for example, determining how success is defined and measured, identifying baseline levels for clients, and finding out whether better (or additional) indicators are available to demonstrate progress. For example, hospitals may be focused on positive birth outcomes, child welfare focused on child safety, and substance use disorder treatment agencies may be focused on measures of recovery.
- Determine the metrics (e.g., number of pregnant women treated with MAT) that need to be developed and tracked to effectively measure success over time. This can include assessing what technology is available to track outcomes. Recent developments, such as electronic health records and Health Information Exchanges, can help facilitate communication across systems and, ultimately, be an avenue to measure outcomes.
- Create a method for communicating progress related to key indicators (e.g., a report card or dashboard) to ensure transparency and promote accountability for results.
- Review the plan for sustaining change and determine, for example, how the team will document, maintain, and build on the collaboration's institutional knowledge.

To facilitate the development of a work plan that addresses the needs of pregnant women with opioid use disorders and their infants, see *Appendix 1: Facilitator's Guide* for the tools.

Concluding Thoughts

This report provides practical, evidence-informed guidance to help collaborative, cross-disciplinary teams support effective, healthy outcomes for pregnant women with opioid use disorders and their infants. This guide underscores the potential impact of opioid use during pregnancy and the importance of a systems-level approach that is driven and endorsed by state and tribe leadership to mobilize resources and facilitate cross-system practice and policy changes. It also provides a framework for communities to take stock of their current policies and identify areas for improvement. It is the view of the national panel of experts that informed this guide that top-down approaches that do not include the views of local practitioners, other professionals, and families will likely lead to resistance and uneven implementation. For collaborative practices to be successful, all parties involved must witness and experience the benefits.

It is beyond the scope of this guidance to adequately address the entire range of topics related to pregnant women with opioid use disorders and their families; however, it is important to highlight some additional focus areas that states, tribes, and communities might want to factor into their planning and policy development.

Value of Prevention. For the vast majority of women, drug use or misuse begins long before they become pregnant. Therefore, key drivers

for achieving healthier pregnancies and births and better child safety outcomes is ensuring women of childbearing age have better access to effective birth control methods[14] and engaging women of childbearing age who have substance use disorders to seek treatment before they become pregnant. Broad community approaches to preventing opioid use disorders are underway in many states and should be expanded to target opioid use during pregnancy. Current community approaches include SAMHSA's Strategic Prevention Framework Partnerships for Success, which seeks to target the use and misuse of prescription medications and heroin among persons ages 12–25 (SAMHSA, 2014b).

Improved Data Collection, Management, and Reporting. Improved data collection is urgently needed to better illuminate the challenges these families face and to be able to measure the success and effectiveness of different interventions and approaches. The prevalence of substance use during pregnancy is often underreported, mostly because pregnant women feel shame and guilt, aggravated by the societal stigma which is so pervasive in most communities. Most health care systems do not use universal screening for substance use during pregnancy or delivery, contributing to the lack of data. Community responses to infant prenatal exposure, child welfare referrals, and case dispositions are also unevenly tracked. Identifying crucial indicators, such as referrals to child welfare agencies, as part of the CAPTA requirements and developing ways to collect information would strengthen responses to families and the use of community resources.

As we seek to learn more about how to respond successfully to the unique needs of pregnant women with opioid use disorders, we can draw from and build on lessons from the past. In this guidance document, we have focused on the unique needs of pregnant women with opioid use disorders. However, much of the guidance and principles provided are applicable to all women with substance use disorders and their infants. We hope that strengthening collaborative relationships to respond to this need will ensure that those relationships endure and offer a ready resource for addressing other challenges in the future.

[14] Visit the ACOG website for information on contraception, including guidance on which forms of birth control are most appropriate, based on each woman's needs: http://www.acog.org/Womens-Health/Birth-Control-Contraception.