



## **PREGNANCY AND OPIOID EXPOSURE: GUIDANCE FOR NORTH CAROLINA**

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# I. INTRODUCTION AND PURPOSE

A multidisciplinary working group of stakeholders from across North Carolina met in fall 2012 to discuss opioid use in pregnancy. In recent years, the rates of opioid-exposed pregnancies have risen sharply across the state, and stakeholders from medical, behavioral health, child welfare, and justice have shared the multiple challenges they have faced with this increasing prevalence. This guidance document presents the result of the stakeholders identifying a need for quality, comprehensive information on the topic of pregnancy and opioid exposure that is suitable for the wide variety of professionals who serve women and their families.

A variety of life experiences can lead to opioid-exposed pregnancies. Some of the more common pathways include women with active addictions to opioids, and who may or may not be receiving

opioids through medical means; women in recovery enrolled in a medication-assisted treatment program and who are taking methadone or buprenorphine as prescribed; and women who experience chronic pain and are taking opioids as prescribed. Each path calls for differing opportunities for intervention. Each of these groups encounters professionals who are struggling to address opioids, pregnancy, and best practices for addressing the convergence of both. Professionals who are equipped to provide women and their families with fact-based information are well positioned to help decrease preventable opioid exposed pregnancies, increase engagement in substance use disorder treatment, and support families with the occurrence of neonatal abstinence syndrome (NAS), including decreasing length of hospital stays. Effective engagement of women requires that the professional use a trauma informed approach<sup>1</sup> and utilize non-stigmatizing language, such as 'person first' language.

The purpose of this document is to support the use of best practices by professionals in North Carolina. State, national, and international organizations working with women and their substance-exposed infants have concluded that the most effective public health approaches are those that support healthy outcomes for the mother and baby.<sup>2, 3, 4</sup>

Opportunities exist for both prevention and



1 SAMHSA's *Concept of Trauma and Guidance for a Trauma-Informed Approach*. HHS Publication No.(SMA) 14-4884. Rockville, MD: Substance Abuse and Mental Health Service Administration, 2014.

2 Association of State and Territorial Health Officials. *Neonatal Abstinence Syndrome, How States Can Help Advance Knowledge Base for Primary Prevention and Best Practices of Care*. Arlington, VA. 2014

3 World Health Organization. *Guidelines for the identification and management of substance use and substance use disorders in pregnancy*. WHO Press. Geneva.2014

4 American College of Obstetricians and Gynecologists: *Opioid abuse, dependence, and addiction in pregnancy*. Committee Opinion No.524. Obstetrics & Gynecology 2012; 119: 1070-6

intervention. The National Center on Substance Abuse and Child Welfare (NCSACW) served as the organizing foundation for the Substance Abuse and Mental Health Services Administration (SAMHSA) report, *Substance-Exposed Infants: State Responses to the Problem*.<sup>5</sup> The SAMHSA report used a 5-point intervention framework (*Appendix 1*) to organize the comprehensive activities of states. Under that framework, the report highlighted the following issues as critically important:

“The birth event is only one of several opportunities to affect outcomes, so it is important to understand the range 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 for services to be coordinated across the spectrum of prevention,

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5 Young, N. K., Gardner, S., Otero, C., Dennis, K., Chang, R., Earle, K., & Amatetti, S. *Substance-Exposed Infants: State Responses to the Problem*. HHS Pub. No. (SMA) 09-4369. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2009.

intervention, and treatment.”<sup>6</sup>

Based on the information used to prepare this guide to best practices, we anticipate North Carolina will experience<sup>4,7,8</sup>

improved outcomes of opioid exposed pregnancies;

increased numbers of women of childbearing age with opioid-use disorders who are engaged in treatment and recovery; and

expansion of the current level of collaboration among professionals who work with pregnant women who are taking opioids.

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6 SAMHSA and NCSACW, Medication-Assisted Treatment for pregnant women with opioid dependence. Practice and Policy Considerations for Health care, addiction treatment providers, child welfare and courts. IN PRESS2014

7 Ashley, O.S. Marsden, M. E., & Brady, T. M. (2003). Effectiveness of substance abuse treatment programming for women: A review. *American Journal of Drug and Alcohol Abuse*, 29(1), 19-53. <http://dx.doi.org/10.1081/ADA-120018838>

8 Jones, HE; Heil, SH; Baewert, A. et al. Buprenorphine treatment of opioid-dependent pregnant women; a comprehensive review. *Addiction*, , 11/2012, Volume 107, Issue 1, pp. 5 – 27 doi:10.1111/j.13600443.2012.04035.x



## APPENDIX 1

### SAMHSA'S FIVE-POINT INTERVENTION FRAMEWORK (REPRINTED)

Since many substance exposed infants are not identified prenatally or at birth, an approach that addresses all stages of development for the affected child is critical. Most previous work related to substance exposed infants has focused on pregnancy and the birth event. However, a more comprehensive view is needed that takes multiple intervention opportunities into account, beginning with pre-pregnancy and continuing throughout a child's developmental milestones.

The framework around which this report is organized asserts that there are five major time frames when intervention in the life of the substance exposed infants can reduce the potential harm of prenatal substance exposure:

#### 1. PRE-PREGNANCY

This timeframe offers the opportunity to promote awareness of the effects of prenatal substance use among women of child-bearing age and their family members;

#### 2. PRENATAL

This intervention point encourages health care providers to screen pregnant women for substance use as part of routine prenatal care and make referrals that facilitate access to treatment and related services for women who need those services;

#### 3. BIRTH

Interventions during this timeframe incorporate testing newborns for substance exposure at the time of delivery;

#### 4. NEONATAL

Developmental assessment and the corresponding provision of services for the newborn as well as the family at this intervention point, immediately after the birth event, are the emphasis; and

#### 5. THROUGHOUT CHILDHOOD AND ADOLESCENCE

This timeframe calls for ongoing provision of coordinated services for both child and family.

This framework formed the basis for a review of State practices with substance exposed infants. Within this context, States' policies and practices in developing system linkages within and among State agencies were reviewed. States need interagency collaboration to address the substance exposed infants problem. This need makes the issue of developing system linkages as important as the issue of handling each of the five intervention points, since the linkages pull the interventions in the five areas together.

To access Substance Exposed Infants: States Responses to the Problem

<http://store.samhsa.gov/product/Substance-Exposed-Infants-State-Responses-to-the-Problem/SMA09-4369>



## II. SCOPE OF THE ISSUE

**N**ationally, the misuse and abuse of opioids has been called an epidemic.<sup>1</sup> Privately and publicly insured women of childbearing age have been prescribed opioids at high rates, with an average of 27.7% and 39.4% respectively over a four year period.<sup>2</sup> North Carolina has not been immune to the increased availability of prescription opioids, subsequent diversion, and increased opioid use disorders. Statewide in North Carolina, from 1997 to 2010, the federal Drug Enforcement Administration (DEA) recorded an 839% increase



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1 Hayes, M J; Brown, M S. Epidemic of prescription opiate abuse and neonatal abstinence. *Journal of the American Medical Association*. 2012;307:18 1974-1975

2 Ailes, E C, Dawson, A L, Lind, J N. et al. MMWR Morb Mortal Wkly Rep 2015;64:38-41

in sales of the opioid oxycodone.<sup>3</sup> From 2010 to 2012, an estimated 4% of the North Carolina population older than 12 years reported non-medical use of prescription pain relievers.<sup>4</sup> Across the state, rates of emergency department visits due to drug overdoses have also surged with opioids and benzodiazepines leading the list of ingested substances. For Women of childbearing age, including teens, the rates of overdoses treated in emergency departments are surpassing the rates of men (see fig.1).

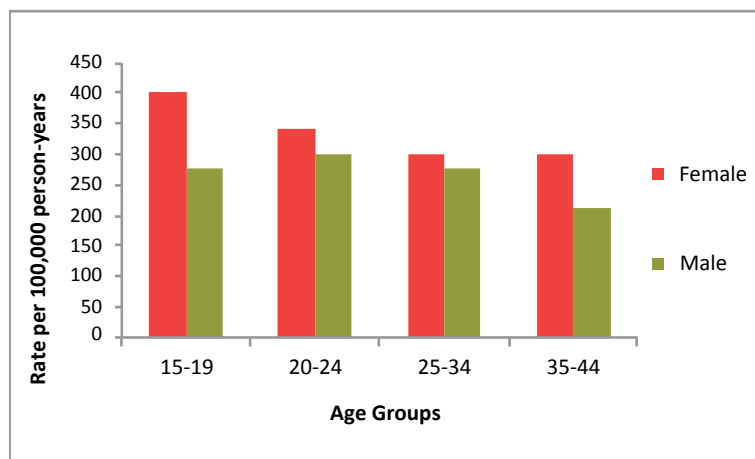


Figure 1. NC Emergency Department Visits for Medication/Drug Overdoses, Childbearing Years, 2012  
Adapted from NC DETECT (2012)<sup>5</sup>

chronic non-medical drug use, emergency department visits, substance abuse treatment admissions, and deaths are increasing in parallel.<sup>1,2</sup> We would add that this parallel upward trajectory includes opioid-exposed pregnancies. The increased availability of opioids has negatively affected pregnancy outcomes of women who have become opioid dependent and their infants who had been exposed to opioids in utero. Data from the National Survey on Drug Use and Health indicate the rate of heroin use by pregnant women has increased somewhat over time whereas, in just the past decade,

The combination of increased availability of opioids and increasing prevalence of substance misuse has unleashed a cascade of negative effects as noted in a recent report on drug and alcohol dependence in North Carolina: "...it is now clear that opioid sales,

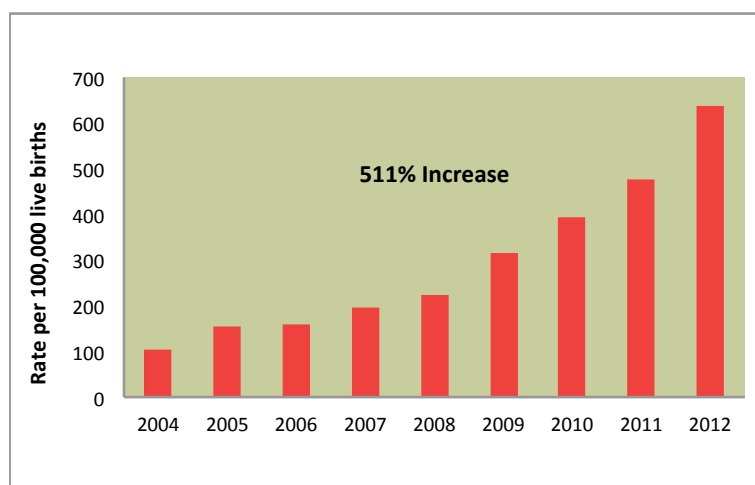


Figure 2. Rates of Infants Identified with Drug Withdrawal Syndrome by NC hospitals, per 100,000 Live Births. Adapted from North Carolina State Center for Health Statistics, Injury Epidemiology and Surveillance Unit (2014).<sup>7</sup>

this population has experienced a 33% increase in non-medical use of prescription pain relievers.<sup>6</sup> To obtain an estimate of the increase in opioid exposed pregnancies in North Carolina, we can look to the North Carolina State Center for Health Statistics, Injury Epidemiology and Surveillance Unit

analysis of data from 2004 to 2012 that reported a 511% increase in infants diagnosed with drug withdrawal

3 Modarai F, Mack K, Hicks P, Benoit S, Park S., Jones C, Proescholdbell S, Ising A, Paulozzi L. Relationship of opioid prescription sales and overdoses, North Carolina. Drug and Alcohol Dependence

4 Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. (January 8, 2013). *The NSDUH Report: State Estimates of Nonmedical Use of Prescription Pain Relievers*. Rockville, MD.

5 NC DETECT North Carolina Injury and Violence Prevention. Annual Injury Report, North Carolina Emergency Department Visits For Injuries Due to Medication or Drug Overdoses.2012.

6 Substance Abuse and Mental health Services Administration (SAMHSA) National Survey on Drug Use and Health, 2003, 2004, 2005, 2006: Table 7.51B. 2006.



syndrome.<sup>7</sup> Of the 4,037 women of childbearing age with opioid-use disorders who entered treatment through the North Carolina public system in 2013, approximately 4% or 162 women were pregnant.<sup>8</sup>

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7 North Carolina State Center for Health Statistics, Injury Epidemiology and Surveillance Unit. 'Medication & Drug Overdoses North Carolina' presentation. Overdose Summit July 2014.

8 N.C. Department of Health and Human Services, Division of MH/DD/SAS, correspondence 10/3/14

Although the withdrawal symptoms can be treated, in some cases opioid use and, ultimately withdrawal in infants might be prevented with better information prior to conception, and ideally, best managed through family centered collaboration of well-informed care providers.



# III. OVERVIEW OF PREGNANCY AND OPIOID EXPOSURE

**W**e know that a variety of life experiences can lead to opioid-exposed pregnancies. Some of the more common pathways include women with active addictions to opioids, and who may or may not be receiving opioids through medical means; women in recovery enrolled in a medication-assisted treatment program and who are taking methadone or buprenorphine as prescribed; and women who experience chronic pain and are taking opioids as prescribed.

## CHRONIC PAIN, OPIOIDS AND PREGNANCY

Studies have found that women are more likely to experience chronic pain than men. Conditions that women are commonly diagnosed with that cause chronic pain include fibromyalgia, irritable bowel syndrome, and migraine headaches. Women are more likely to be prescribed prescription opioids and to be given higher doses than men.

*Chronic pain, by the way, isn't just acute pain that doesn't go away after a few months; it's a transformation of the nervous system that can literally shrink the brain.<sup>1, 2</sup>*

Women of child-bearing age who experience chronic pain may be prescribed opioids as a medical treatment to manage the pain and achieve a functional quality of life. They may, at some point, decide to have children. However, becoming pregnant and starting a family will not cure the cause of the chronic pain, and changing physical stress and hormone

levels might exacerbate some conditions. Chronic pain is a physical stressor and — if left untreated and unmanaged — contributes to lower functioning, poor nutrition and depression, which are significant risks for poor birth outcomes. A woman with chronic pain who chooses to become pregnant will need to consult with her health providers to determine her best plan for pain management. At times, the best plan might be to continue opioid medication. Women who are prescribed opioids for a pain condition and who do not have a concurrent substance use disorder, are not candidates for opioid treatment programs (OTP's) as the result of pregnancy alone. Substance use treatment providers cannot accept patients for pain management alone, even if that management has led to a physical dependence.

Notably, people, including women who are pregnant, can experience physical dependence of opioids *without* having an opioid use disorder. Women may become physically dependent on prescription opioids more quickly than men.<sup>6</sup>

*Physical dependence occurs because of normal adaptations to chronic exposure to a drug. Those who are physically drug dependent usually experience withdrawal symptoms when the drug is abruptly discontinued. They often develop a tolerance to the drug and require higher doses for the same effect.<sup>6</sup>*

Women with chronic pain may or may not share some of the same struggles of the women who have an opioid use disorder such as a history of physical and/or sexual trauma, co-occurring mental health diagnosis, use of other substances such as alcohol or tobacco. Women who have experienced intimate interpersonal violence in their lifetimes are more likely to experience

1 Foreman J. Why women are living in the discomfort zone. *Wall Street Journal*. Jan.31, 2014.

2 Apkarian, A.V., Sosa,Y, Sonty,S et al. Chronic back pain is associated with decreased prefrontal and thalamic gray matter density. *Journal of Neuroscience*. 24(46).2004. DOI:10.1523/JNEUROSCI.2541-04.2004

chronic pain.<sup>3</sup> The landmark Adverse Childhood Experiences (ACE) study revealed the correlation between childhood stress and trauma and later health difficulties including, for women, unintended pregnancies, sexually transmitted infections and fetal death.<sup>4</sup> Histories of trauma and violence should be taken into consideration when considering how best to support a woman and her pregnancy.<sup>5</sup>

## OPIOID USE DISORDERS

Many women in treatment for opioid use disorders describe a common pathway that began with opioids prescribed for an injury or chronic pain and ended with an opioid use disorder. In the beginning, the women took the medication as prescribed, but over time, most found they needed to increase the number of pills or frequency of their dose to achieve the same effect. Taking opioids over even over a short of time can create physical dependence, which can result in withdrawal if they are stopped. If not consulting with the prescriber, this can lead to 'misuse' Other factors often contribute to misuse of prescription opioids, including a woman's history of trauma, co-occurring mental health issues, a history of addiction, or genetic vulnerability – all of which can affect the same woman. As with other substance use disorders, if left unaddressed and untreated, misuse of prescription drugs may progress to become a chronic disease. As the disease progresses, women may see multiple doctors for real or perceived pain complaints to obtain prescriptions for opioids. When prescribed medications cannot be obtained, they may turn to seeking illicit opioids. Cost of opioids dispensed through pharmacies typically ranges

from \$1–\$3 a pill, whereas the street value of opioids can exceed \$60 a pill. The high street cost of prescription medications may lead a woman to a cheaper alternative, which is often heroin.

Addiction involving opioids is classified as “opioid use disorder” based on the criteria of the 2013 *Diagnostic and Statistical Manual of Mental Disorders (DSM-5)*<sup>6</sup>. This disorder can range from mild to severe. The primary characteristics of a substance use disorder are described by the American Society of Addiction Medicine as

*...a chronic disease of the brain reward, motivation, memory and related circuitry. It can be complicated by comorbid physical and psychological conditions and influenced by genetic and environmental elements.*<sup>7</sup>

Similar to all substance use disorders, an opioid use disorder is a chronic disease that can affect any person, regardless of income level, race/ethnicity, education, or beliefs.

The prescription opioids include hydrocodone, fentanyl, oxycodone, and the controlled-release form of oxycodone (OxyContin®). The use of heroin, a semi-synthetic opioid with a rapid onset of effect, is increasing throughout North Carolina.<sup>8</sup> Although heroin is typically injected, an increasing number of people are inhaling or smoking heroin. Individuals with opioid use disorders often report using other substances as well, including, marijuana, alcohol and tobacco.

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3 Coker, AL, Smith, PH, Fadden MK. Intimate partner violence and disabilities among women attending family practice clinics. *J Womens Health (Larchmt)*. 2005 Nov;14(9):829-38.

4 Anda, R.F, Butchart, A, Felitti, V.J. Building a framework for global surveillance for the public health implications of adverse childhood experiences. *American Journal of Preventive Medicine*. 2010;39(1).

5 Substance Abuse and Mental Health Services Administration. *SAMHSA's Concept of Trauma and Guidance for a Trauma-Informed Approach*. HHS Publication No. (SMA) 14-4884 Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014.

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6 American Psychiatric Association. *Diagnostic and statistical manual of mental disorders* (5th ed.). Washington, DC. 2013

7 Public policy statement on pharmacological therapies for opioid use disorder. American Society of Addiction Medicine. Adopted by the ASAM Board of Directors April 24, 2013.

8 North Carolina Injury & Violence Prevention Branch. Medication & drug overdoses- North Carolina. Presented at Overdose Summit, July 2014.

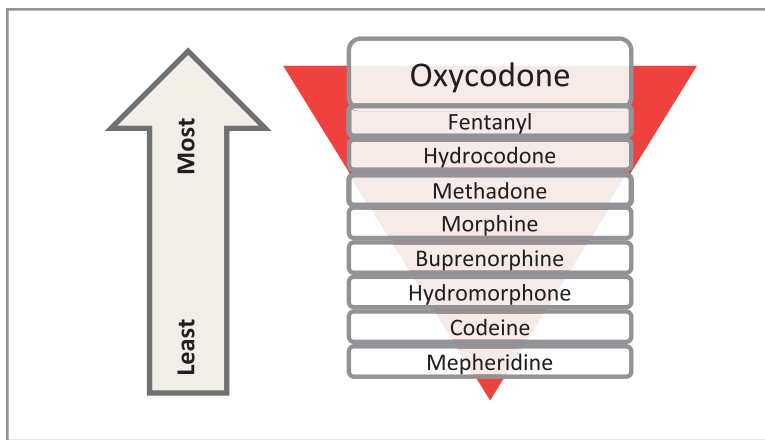


Figure 1. Most Frequently Prescribed Opioids in NC, 2010. Adapted from Modarai, et al (2013)<sup>4</sup>

Whether naturally occurring or lab-created, all opioids work by directly affecting the central nervous system. Opioids stimulate the opiate receptors in the brain, producing effects that range from euphoria and pain relief to respiratory depression and nausea. Chronic use of opioids is associated with drug tolerance, meaning higher doses of the drug are required to obtain the same effect. Tolerance leads to physical dependence. The chronic use of opioids changes the neuro-chemical balance in the central nervous system, and the sudden absence of the drug triggers a withdrawal syndrome. Opioid withdrawal is characterized by a variety of symptoms including agitation, nasal congestion, yawning, muscle cramps, diarrhea, nausea, vomiting, and depression. The extreme physical discomfort of the withdrawal experience can prompt resumption of use.

The standard of care for individuals with an opioid use disorder is medication-assisted treatment (MAT) with opioid-agonists in conjunction with counseling and supportive services. Methadone and buprenorphine are the most commonly prescribed medications for opioid use disorders. Long-term research has demonstrated the efficacy of MAT for opioid use disorders. Evidence has shown that treatment including medication results in longer sustained recovery from addiction and improved quality

of life. The efficacy of MAT also holds true for women who are pregnant.<sup>9</sup>

## OPIOID USE AND PREGNANCY

When a pregnant woman with opioid dependence, which can include an opioid use disorder, experiences a cycle of opioid use and withdrawal, the physical effects are particularly problematic to the developing fetus. Minimal disruption in the level of opioids during is ideal, so as not to cause withdrawal in the fetus.

Repetitive patterns of use and withdrawal reduces the blood flow to the placenta, lowering the supply of oxygen available to the fetus and negatively affecting development. The consequences to the fetus include increased risk of prematurity, low birth weight, and fetal death. Thus, engaging pregnant women with opioid use disorders in comprehensive services, including prenatal care, is essential for positive birth outcomes.

Since the 1970s, the standard of care for pregnant women with an opioid use disorder has been medication-assisted treatment (MAT) with methadone. The efficacy of methadone as one element of comprehensive treatment services has been widely acknowledged and endorsed as a highly effective tool in recovery.<sup>10,11,12</sup> Comprehensive treatment services include case-

9 Center for Substance Abuse Treatment. Medication-assisted treatment for opioid addiction in opioid treatment programs. Treatment Improvement Protocol (TIP) Series 43. DHHS Publication No. (SMA) 05-4048. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2005.

10 Association of State and Territorial Health Officials. Neonatal Abstinence Syndrome: how states can advance the knowledge base for primary prevention and best practices of care. 2014. <http://www.astho.org/Prevention/NAS-Neonatal-Abstinence-Report/>

11 Clausen,T, Waal,H.Thoresen,M. et al. Mortality among opiate users:opioid maintenance therapy,age and causes of death. *Addiction*. 2009. (104)1356-1362 doi:10.1111/j.1360-0443.2009.02570.x

12 Zhang, Z. Freidmann,P.D. Gerstein,D.R. Does retention matter? Treatment duration and improvement in drug use. *Addiction*.2002 (98)673-684. DOI: 10.1046/j.1360-0443.2003.00354.x

management, life skills and childcare.<sup>13</sup> At appropriate dosages, methadone, a synthetic opioid, eliminates withdrawal symptoms, reduces cravings for the substance of choice, and blocks the euphoric effects of any other opioids ingested. Another benefit of methadone is the drug's stability and its long half-life, that is, the amount of time it takes for half of the medication to be eliminated from the blood stream. The long half-life of methadone and the predictable dosing used in MAT prevents fluctuating opioid levels in the fetus, which contributes to a longer term pregnancy and improved fetal growth.

As a woman's pregnancy progresses, her body will metabolize methadone more rapidly and higher doses are typically required to continue MAT effectiveness. Although some early reports suggested the dosage amount of methadone correlated with both the occurrence and the severity of neonatal withdrawal, this relationship has not been found in more recent evidence.<sup>14</sup> It is well understood that lowering the dose of methadone during pregnancy can trigger physical withdrawal symptoms and might lead to increased use of illicit drugs, exposing both mother and fetus to greater levels of health risk and harm.

Buprenorphine, a partial opioid-agonist, has been approved by the U.S. Food and Drug Administration (FDA) for the treatment of opioid addiction in an outpatient office setting. The FDA has established five categories indicating the potential of a drug to cause birth defects when used during pregnancy (Categories A, B, C, D, X). Buprenorphine is a Pregnancy Category C medication in pregnancy, meaning there is limited data, but the potential benefits

may warrant use of the drug. Physicians are encouraged to do a risk-benefit analysis in considering the use of buprenorphine in the treatment of an opioid use disorder with a woman who is pregnant.<sup>15</sup> Preliminary research of buprenorphine use during pregnancy is promising.<sup>16</sup>

In addition to the health concerns related to opioid withdrawal, women with opioid use disorders are also at elevated risk for hepatitis B, hepatitis C, and HIV transmission through needle sharing and unsafe sexual practices. Screening for these infections should be done by the woman's medical provider, and in the case of HIV infection, treatment should be initiated.

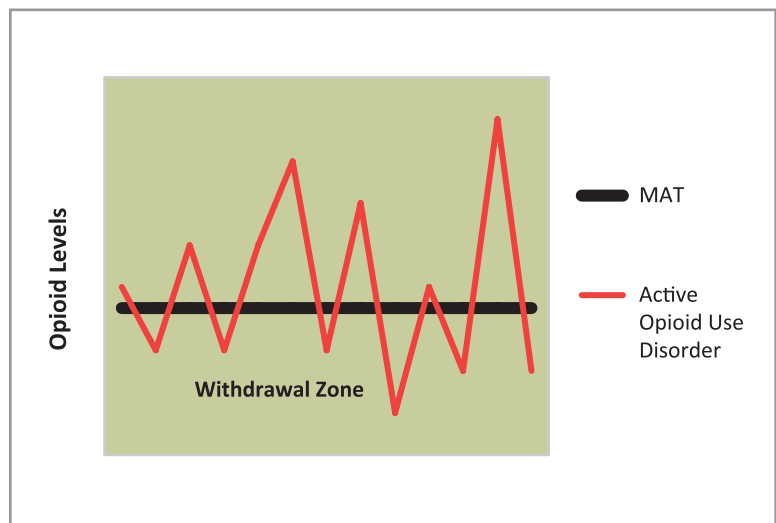


Figure 2. Opioid levels with active use versus medication assisted treatment

Over the years we have learned from the women entering treatment for substance use disorders in North Carolina, that their needs are complex. The analysis of 10 years of data from the North Carolina Perinatal and Maternal Substance Abuse Initiative has produced the following picture of this population:

13 Substance Abuse and Mental Health Services Administration. Substance abuse treatment: addressing the specific needs of women. Treatment Improvement Protocol (TIP) Series, No. 51. HHS Publication No. (SMA) 13-4426. Rockville, MD: 2009.

14 Cleary B, Donnelly J, Strawbridge J, *et al.* Methadone dose and neonatal abstinence syndrome—a systematic review and meta-analysis. *Addiction*. 2010 Dec;105(12):2071-84. doi: 10.1111/j.1360-0443.2010.03120.x.

15 Martin J, Sullivan, MA. Pregnancy and buprenorphine treatment. MAT training providers' clinical support system for medication assisted treatment. <http://www.buppractice.com/howto/assess/pregnant.2014>

16 Jones HE, Finnegan LP, Kaltenbach K. Methadone and buprenorphine for the management of opioid dependence in pregnancy. *Drugs*. 2012 Apr 16;72(6):747-57. doi: 10.2165/11632820-000000000-00000.



- 60% of women in treatment report a history of intimate partner violence;
- 53% have experienced sexual abuse;
- 70% of women have a family history of substance abuse;
- 36% are involved with the child welfare system, with most seeking to regain custody of one or more children; and
- 70% need assistance with transportation for medical appointments for mother and/or children, social services appointments, behavioral health services, housing assistance, or vocational aspects of their treatment plan.<sup>17</sup>

As this statistical picture illustrates, women and their families are involved in multiple systems, which further compounds their challenges given the lack of uniform, comprehensive services. The challenges of dealing with multiple systems can be overwhelming.

*Services may be fragmented, requiring a woman to negotiate a maze of service agencies to obtain assistance for housing, transportation, child care, substance abuse treatment, vocational training, education, and medical care. In addition, many agencies have requirements that conflict with each other or endorse repetitive intake processes, including different forms that gather the same information. Overall, these simultaneous demands can discourage a woman, particularly when seeking treatment or during early recovery.<sup>11</sup>*

<sup>17</sup> Correspondence with Dr. Sherri Green, UNC SHEPS Center for Health Services Research.

This guidance document seeks to promote collaborative approaches that support women's access to treatment and recovery from opioid use disorder, and in ways that enable the focus to be on the health and well-being of infant and mother.

## OPIOID OVERDOSE RISK

Any woman taking opioids is at risk of fatal overdose. The rate of fatal overdoses among women has risen dramatically.<sup>18</sup> Opioids depress the central nervous system, and when mixed with other substances including alcohol or other prescribed medication such as anti-anxiety medication (e.g., benzodiazepines) result in an increased risk of overdose. Women should be

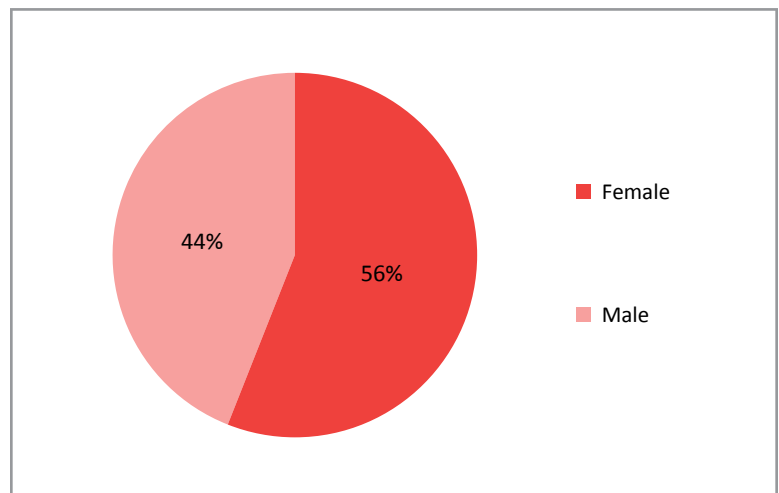


Figure 3. NC Medication/Drug Overdose, Emergency Department Visits by Gender, 2012. Adapted from NC DETECT (2012)<sup>15</sup>

made aware of their risks for overdose, how to prevent an overdose, and safety steps to be prepared in case of an overdose.

The initial effects of an opioid overdose can be reversed with the prescription medication naloxone. Having prescribed naloxone on hand — and making sure a friend or family member knows the location, can

<sup>18</sup> <sup>16</sup> Center for Disease Control and Prevention. Vital Signs: Painkiller Overdoses, a growing epidemic among women. July 2013.



quickly access the medication, and knows the dose to administer — can be an important piece of preventing a fatal overdose. Being prepared by having access to naloxone is considered one part of a continuum of substance use disorder and health services.<sup>19</sup> Naloxone has no psychoactive effects and does not have any potential for abuse.<sup>20</sup>

*Naloxone can safely be used to manage opioid overdose in pregnant women. The lowest dose to maintain spontaneous respiratory drive should be used to avoid triggering acute opioid withdrawal, which may cause fetal distress.<sup>17</sup>*

Access to prescribed naloxone has expanded in North Carolina. In 2013, North Carolina enacted the Good Samaritan/Naloxone Access Law, protecting individuals involved in seeking medical care for a potential overdose victim from prosecution of drug related offenses. This legislation also limits civil liabilities of prescribers of naloxone, while acting in good faith, providing the prescription to persons at risk

of experiencing an opioid overdose, a friend, family member or other person in a position to help.<sup>21</sup>

Community Care of North Carolina's Project Lazarus, The North Carolina Harm Reduction Coalition, and other partners have worked to make naloxone available through as many avenues as possible including, but not limited to, community pharmacies, health departments, law enforcement officials, opioid treatment programs, and directly to patients via standing order.

**[For more information on preventing opioid overdoses see the SAMHSA Overdoses Kit: <http://store.samhsa.gov/product/opioid-overdose-prevention-toolkit/all-new-products/sma13-4742>, CCNC's Chronic Pain Toolkit <https://www.communitycarenc.org/population-management/chronic-pain-project/>, and The North Carolina Harm Reduction Coalition: <http://www.nchrc.org/>]**

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19 National Association of State Alcohol and Drug Abuse Directors. Policy statement on efforts to prevent fatal opioid overdose. September 2014.

20 Substance Abuse and Mental Health Services Administration. SAMHSA opioid overdose prevention toolkit. HHS Publication No. (SMA) 14-4742. Rockville, MD: 2014.

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21 General Assembly of North Carolina. Session 2013. Session Law 2013-23. Senate Bill 20.

## IV. TREATMENT MATTERS

**M**any strong reasons exist for helping women who are struggling with substance use disorders to connect with treatment. Consider the following reasons to connect women to treatment:

1. Treatment can prevent a substance-exposed pregnancy

The earlier in the pregnancy a woman can be connected to treatment, the less impact her substance use will have on the development of the baby.<sup>1</sup>



2. Treatment can improve birth outcomes<sup>2</sup>

Overwhelming evidence shows that women who engaged in substance-use disorder treatment had better birth outcomes, defined by higher birth weight, full-term births, and lower infant mortality.

3. Treatment makes a difference.<sup>3</sup>

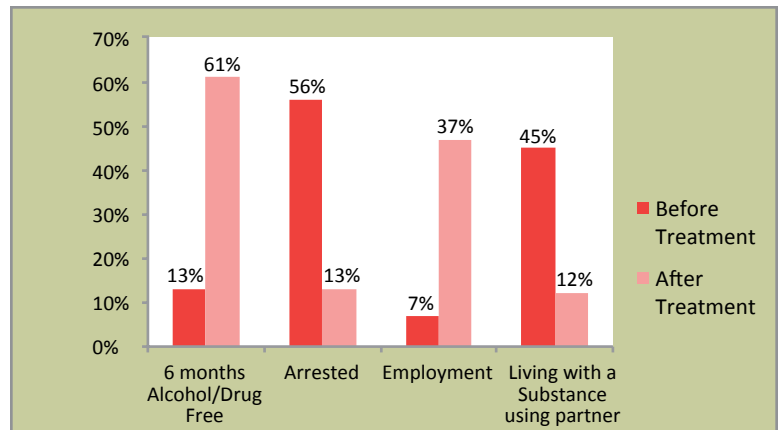


Figure 1. Outcomes of Participants in Pregnant and Post-partum Women's and Residential Treatment Programs Nationwide.

Adapted from Caliber Associates(2003)<sup>3</sup>

4. Treatment can improve the quality of life for women and their families.

In cases of out-of-home placement of children, the mother's treatment for substance-use disorders is linked to increases in mother-child reunification.<sup>4</sup>

5. Treatment can lead to recovery: People *do* recover from substance-use disorders.

Recovery is "...a process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential."<sup>5</sup>

1 American College of Obstetricians and Gynecologists. (2008). At risk drinking and illicit drug use: Ethical issues in obstetric and gynecologic practice. *ACOG Committee Opinion No.422*. Obstetrics & Gynecology. Retrieved from <http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Ethics/At-Risk-Drinking-and-Illicit-Drug-Use-Ethical-Issues-in-Obstetric-and-Gynecologic-Practice>

2 Ashley, O.S. Marsden, M. E., & Brady, T. M. (2003). Effectiveness of substance abuse treatment programming for women: A review. *American Journal of Drug and Alcohol Abuse*, 29(1), 19-53. <http://dx.doi.org/10.1081/ADA-120018838>

3 Caliber Associates (2003). RWC/PPW Cross-Site Evaluation, RWC/PPW Program and Cross-Site Fact Sheets. Retrieved from <http://www.samhsa.gov/sites/default/files/women-children-families-rwc-ppw-cross-site-fact-sheets.pdf>

4 Grella, C, Needell, B., Shi,Y, Hser, Y. Do drug treatment services predict reunification outcomes of mothers and their children in child welfare? *Journal of Substance Abuse Treatment* 36, 2009, 278-293. doi:10.1016/j.jsat.2008.06.010

5 Substance Abuse and Mental Health Services Administration. (2012). *SAMHSA's working definition of recovery: 10 guiding principles of recovery*. Retrieved from <https://store.samhsa.gov/shin/content/PEP12-RECDEF/PEP12-RECDEF.pdf>

6. Treatment is cost-effective; researchers have determined that **treatment saves \$7 for every \$1 spent**.<sup>6</sup>
7. Treatment for substance-use disorders has been shown to have efficacy similar to that of treatment regimens for other chronic illnesses. Rates of returning to pre-treatment status are the same as other chronic illnesses such as type I diabetes, hypertension, and asthma.<sup>7</sup>

## WHAT IS SUBSTANCE-USE DISORDER TREATMENT?

There are a variety of definitions of treatment. The American Society of Addiction Medicine (ASAM; [www.asam.org](http://www.asam.org)) defines treatment for substance-use disorders as follows:

*The use of any planned, intentional intervention in the health, behavior, personal, and/or family life of an individual suffering from alcohol use disorder or from another drug addiction, and which is designed to facilitate the affected individual to achieve and maintain sobriety, physical, spiritual, and mental health, and a maximum functional ability.*

In addition to this helpful definition of treatment, the ASAM has established a set of treatment criteria that are widely used to determine which level of care will best meet the needs of an individual, given his or her unique treatment needs. Matching the individual to the appropriate level of care can greatly enhance treatment outcomes for substance-use disorders. Treatment

referrals should be based on a multidimensional assessment that considers the following ASAM Criteria dimensions:

## SIX DIMENSIONS

- Dimension 1: Acute intoxication and/or withdrawal potential
- Dimension 2: Biomedical conditions and complications
- Dimension 3: Emotional, behavioral, or cognitive conditions and complications
- Dimension 4: Readiness to change
- Dimension 5: Relapse, continued use, or continued problem potential
- Dimension 6: Recovery environment<sup>8</sup>



6 Ettner, S. L., D. Huang, Evans, E., Ash, D. R., Hardy, M., Jourabchi, M., & Hser, Y.-I. (2006). Benefit-cost in the California treatment outcome project: Does substance abuse treatment “pay for itself”? *Health Services Research*, 41(1), 192-213. <http://dx.doi.org/10.1111/j.1475-6773.2005.00466.x>

7 McLellan, T. Lewis, D., et al. (2000). Drug dependence, a chronic medical illness: Implications for treatment, insurance, and outcomes evaluation. *Journal of the American Medical Association*, 284, 1689-1695. <http://dx.doi.org/10.1001/jama.284.13.1689>

8 Mee-Lee D, Shulman GD, Fishman MJ, and Gastfriend DR, Miller MM eds. (2013). *The ASAM Criteria: Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions*. Third Edition. Carson City, NV: The Change Companies.



<b>ASAM CRITERIA LEVEL OF CARE</b>		
<b>Level of Care</b>	<b>Adult Title</b>	<b>Description</b>
0.5	Early Intervention	Assessment and education for at-risk individuals who do not meet diagnostic criteria for substance use disorder
1	Outpatient Services	Less than 9 hours of service/week (adults); less than 6 hours/week (adolescents) for recovery or motivational enhancement therapies/strategies
2.1	Intensive Outpatient	9 or more hours of service/week (adults); 6 or more hours/week (adolescents) to treat multidimensional instability
2.5	Partial Hospitalization	20 or more hours of service/week for multidimensional instability not requiring 24-hour care
3.1	Clinically Managed Low-Intensity Residential	24-hour structure with available trained personnel; at least 5 hours of clinical service/week
3.3	Clinically Managed Population-Specific High-Intensity Residential	24-hour care with trained counselors to stabilize multidimensional imminent danger. Less intense milieu and group treatment for those with cognitive or other impairments unable to use full active milieu or therapeutic community
3.5	Clinically Managed High-Intensity Residential	24-hour care with trained counselors to stabilize multidimensional imminent danger and prepare for outpatient treatment. Able to tolerate and use full active milieu or therapeutic community
3.7	Medically Monitored Intensive Inpatient	24-hour nursing care with physician availability for significant problems in Dimensions 1, 2 or 3. Sixteen hour/day counselor ability
4	Intensive Inpatient	24-hour nursing care and daily physician care for severe, unstable problems in Dimensions 1, 2 or 3. Counseling available to engage patient in treatment.
OTP (level 1)	Opioid Treatment Program (Level 1)	Daily or several times weekly opioid agonist medication and counseling available to maintain multidimensional stability for those with severe opioid use disorder
Adapted from Mee-Lee, D. et al (2013)8 with permission. See the ASAM Criteria: Treatment Criteria for Addictive, Substance Related-, and Co-Occurring Conditions, for a full description and guidance for the use of criteria.		

Within the different levels of care listed by ASAM, there are numerous approaches to treatment that may be employed. Several of the treatment approaches most relevant to women struggling with opioid or other substance-use disorders are described in the following sections that are reprinted with permission, from the

### a. Gender-Specific Treatment for Women

Traditionally, substance abuse treatment programming has been geared toward males without regard for the specific needs of women. Yet, increased research on gender differences in substance use disorders highlights the importance of gender-specific programs.<sup>9</sup> A recent survey showed that substance abuse treatment facilities with special programs for women generally offer individual, group, and family counseling; discharge planning; social services assistance; child care; domestic violence services; and accommodation for children.<sup>10</sup> Many substance using women are in relationships with drug-abusing, and often violent, partners or spouses and they are more likely than men to consider this relationship to be the cause of their drug abuse.<sup>9</sup>

Research suggests that the benefits from group therapy are better maintained when women participate in women-only groups compared to mixed-gender groups, perhaps because there are particular issues (e.g., physical or sexual abuse) that many clients feel more comfortable sharing only with other women.<sup>11</sup> Pregnancy-specific treatment programs have also been developed to address concerns specific to this

population (e.g., health and nutrition during pregnancy) and provide pregnancy support that more traditional women’s programs might not offer. Research indicates that women in pregnancy-specific programs are more likely to complete treatment compared to those in traditional treatment groups.<sup>12</sup>

Providers who work with substance using women consistently point to stable, nurturing relationships with peer workers, professional case managers, or others as key to supporting women. Building upon this, the recovery coach model is emerging as a promising approach to serving substance using pregnant women.<sup>13</sup> A recovery coach is a paraprofessional who assists parents in obtaining needed benefits, coordinates child welfare and substance abuse treatment staff, and connects the family with treatment providers. Coaches often participate in joint home visits with child welfare workers or substance abuse treatment staff, but are independent from these agencies, ensuring that their focus remains on the family. Evaluations have found that the use of recovery coaches significantly decreases the risk of substance exposure at birth.<sup>11</sup>

**[For more information see:** *Substance Abuse Treatment: Addressing the Specific Needs of Women. A Treatment Improvement Protocol (TIP) Series. No. 51. HHS Publication No.(SMA)13-4426. Rockville, MD: Substance Abuse and Mental Health Service Administration, 2009. Or go to: <http://www.samhsa.gov/women-children-families>]*

9 Greenfield, S. F., Brooks, A. J., Gordon, S. M., Green, C. A., Kropp, F., McHugh, R. K.,...Miele, G. M. (2007). Substance abuse treatment entry, retention, and outcome in women: A review of the literature. *Drug and Alcohol Dependence* 86(5), 1-21. <http://dx.doi.org/10.1016/j.drugalcdep.2006.05.012>

10 Substance Abuse and Mental Health Services Administration. (2006). *Results from the 2005 National Survey on Drug Use and Health: National findings.*, (NSDUH Series H-30, DHHS Publication No. SMA 06-4194). Rockville, MD: . <http://doi.org/10.3886/ICPSR04596.v4>

11 Brady, T. M., & Ashley, O. S. (2005). *Women in substance abuse treatment: Results from the Alcohol and Drug Services Study (ADSS)*. Rockville, MD: SAMHSA, Office of Applied Statistics. Retrieved from <http://oas.samhsa.gov/WomenTX/WomenTX.htm>

Bride, B. (2001). Single-gender treatment of substance abuse: Effect on treatment retention and completion. *Social Work Research*, 25(4), 223-232.

12 Weisdorf, T., Parran, T., Graham, A., & Snyder, C. (1999). Comparison of pregnancy-specific interventions to a traditional treatment program for cocaine-addicted pregnant women. *Journal of Substance Abuse Treatment*, 16(1), 39-45. [http://dx.doi.org/10.1016/S0740-5472\(98\)00006-3](http://dx.doi.org/10.1016/S0740-5472(98)00006-3)

13 Ryan, J. P., Choi, S., Hong, J. S., Hernandez, P., & Larrison, C. R. (2008). Recovery coaches and substance exposed births: An experiment in child welfare. *Child Abuse & Neglect*, 32(11), 1072-1079. <http://dx.doi.org/10.1016/j.chiabu.2007.12.011>

## **b. Residential Substance Abuse Treatment**

Residential treatment for women and their children is one method of concurrently addressing the needs of both substance using mothers and their children. These programs have higher retention rates compared to outpatient clinics and long-term positive effects, particularly if they are gender specific and family-focused.<sup>14</sup> Participants in women-specific residential treatment have also been shown to be more likely to participate in continuing care following discharge.<sup>15</sup> Such programs are often geared toward women-specific issues, promoting the parent-child relationship,

and addressing the many other problems associated with chemical dependency (e.g., housing, social, psychological, and employment issues). For example, they can involve teaching hands-on parenting skills to substance users which may bring stability into the lives of their at-risk children, including both the newborn and older children.<sup>16</sup> Furthermore, residential treatment programs for pregnant women have been shown to lead to better birth outcomes in terms of infant mortality, premature delivery and low birth weight, as well as improved economic well-being and personal relationships.<sup>17</sup>

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14 Clark, H. (2001). Residential substance abuse treatment for pregnant and postpartum women and their children: Treatment and policy implications. *Child Welfare*, 80(2), 179-198.

15 Claus, R. E., Orwin, R. G., Kissin, W., Krupski, A., Campbell, K., & Stark, K. (2007). Does gender-specific substance abuse treatment for women promote continuity of care? *Journal of Substance Abuse Treatment*, 32(1), 27-39. <http://dx.doi.org/10.1016/j.jsat.2006.06.013>

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16 Porowski, A. W., Burgdorf, K., & Herrell, J. M. (2004). Effectiveness and sustainability of residential substance abuse treatment programs for pregnant and parenting women. *American Journal of Drug and Alcohol Abuse*, 30(3), 537-550. <http://dx.doi.org/10.1081/ADA-200032290>

17 Substance Abuse and Mental Health Services Administration. (2001). *Benefits of residential substance abuse treatment for pregnant and parenting women*. Rockville, MD: U.S. Department of Health and Human Services.

### c. Trauma-informed Treatment

Because many pregnant substance users also have a history of trauma, treatment is most effective if it is also trauma-informed.<sup>18</sup> Current delivery systems are not yet consistently screening for and addressing trauma in treatment. Further, they tend to be poorly integrated and focus on the client's immediate safety rather than long-term recovery from the trauma and co-occurring disorders. Recognizing the inadequacy of treatment for women with co-occurring disorders and histories of trauma, **SAMHSA identified four core principles to inform best practices with this population** [emphasis added]:

1. Organizations and services must be integrated.
2. Settings and services must be trauma-informed.
3. Consumers, survivors or recovering persons must be integrated into the design and provision of services.
4. A comprehensive array of services must be made available.<sup>19</sup>

Implementing these elements may take time, additional staff training and support, and the collaboration of various organizations, but the result will be a service delivery system better equipped to serve women with co-occurring disorders and trauma histories.

18 Cocozza, J. J., Jackson, E. W., Hennigan, K., Morrissey, J. P., Reed, B. G., Fallot, R., & Banks, S. (2005). Outcomes for women with co-occurring disorders and trauma: Program level effects. *Journal of Substance Abuse Treatment*, 28(2), 109-119. <http://dx.doi.org/10.1016/j.jsat.2004.08.010>

19 Huntington, N., Moses, J. D., & Veysey, B. M. (2005). Developing and implementing a comprehensive approach to serving women with co-occurring disorders and histories of trauma. *Journal of Community Psychology*, 33(4), 395-410. <http://dx.doi.org/10.1002/jcop.20059>

[For more information see: SAMHSA's *Concept of Trauma and Guidance for a Trauma-Informed Approach*. HHS Publication No.(SMA) 14-4884. Rockville, MD: Substance Abuse and Mental Health Service Administration, 2014. Or go to: <http://www.samhsa.gov/nctic>]

### d. Treatment for Co-occurring Disorders

The fact that mental illness so often co-occurs with substance use disorders in women also necessitates the development of effective programs that treat both disorders. Several models currently exist to address the treatment of co-occurring disorders in pregnant and parenting women.<sup>20</sup> In the *serial model*, substance abuse is addressed first after which the client moves on to traditional psychotherapy.<sup>21, 22</sup> However, this model might be ineffective given the high substance abuse relapse rate among addicts and those with severe psychiatric disorders. In the *parallel model*, treatment for psychological problems and addiction are delivered at the same time but in different milieus. This method allows for close collaboration between agencies, but may still not be coordinated enough for clients with acute mental disorders. The third, *integrated model*, is recommended for clients with severe or pervasive psychological illness. This treatment model brings together addiction treatment and psychological therapy for an intensely integrated treatment plan.

[For more information go to: <http://www.samhsa.gov/co-occurring>]

20 Price, A., & Simmel, C. (2002). *Partners' influence on women's addiction and recovery: The connection between substance abuse, trauma and intimate relationships*. Berkeley, CA: National Abandoned Infants Assistance Resource Center. Retrieved from <http://aia.berkeley.edu/media/pdf/partners.pdf>

21 Drake, R. E., Mueser, K. T., Brunette, M. F., & McHugo, G. J. (2004). A review of treatments for people with severe mental illnesses and co-occurring substance use disorders. *Psychiatric Rehabilitation Journal*, 27, 360-374. <http://dx.doi.org/10.2975/27.2004.360.374>

22 Horsfall, J., Clearly, M., Hunt, G.E., & Walter, G. (2009). Psychosocial treatments for people with co-occurring severe mental illness and substance use disorders (dual diagnosis): A review of the empirical evidence. *Harvard Review of Psychiatry*, 17(1), 24-34. <http://dx.doi.org/10.1080/10673220902724599>



### e. Family Treatment Drug Court

Families affected by substance use disorders may also benefit from family treatment drug courts (FTDCs) which, unlike standard courts, are tailored to the needs of substance abusing parents.<sup>23</sup> Like adult drug courts, FTDCs include regular court hearings, judicial monitoring, drug testing and treatment, and regular monitoring of performance with predictable rewards and sanctions.<sup>24, 25</sup> However, the primary focus of FTDCs is family reunification, rather than avoidance of jail time, as is the case in adult drug courts.

FTDCs offer services addressing the needs of the entire family, which may include older children, multiple parents, grandparents, and other relatives. Services generally are in the form of case management, drug and alcohol assessment and treatment, education, parenting support, and domestic violence services.<sup>23, 24</sup> FTDCs also form partnerships with medical and social service providers in the community to help connect families to the other services they need. A four-year study of FTDCs found that they are more effective in helping substance abusing women complete treatment and reunify with their children than traditional child welfare case processing; FTDC children also spend less time in out-of-home care than children in traditional courts.<sup>23</sup>

**[For more information on Family Treatment Drug Courts, see:**

<https://www.ncsacw.samhsa.gov/resources/resources-drug-courts.aspx>]

23 Jaeger, N. (2010, June). *Problem solving courts: Collaboration*. Presentation at the National AIA Resource Center Substance Exposed Newborns Conference, Alexandria, VA.: Yew, E. *The family wellness court for infants and toddlers* [PowerPoint slides]. Retrieved from [www.cwda.org/downloads/tools/americanpoverty/JudgeYew.ppt](http://www.cwda.org/downloads/tools/americanpoverty/JudgeYew.ppt)

24 NPC Research. (2007, March). *Family Treatment Drug Court final report*. Retrieved from [http://www.npcresearch.com/Files/FTDC\\_Evaluation\\_Final\\_Report.pdf](http://www.npcresearch.com/Files/FTDC_Evaluation_Final_Report.pdf)

25 Yew, E. (2010, June). *The family wellness court for infants and toddlers* [PowerPoint slides]. Retrieved from [www.cwda.org/downloads/tools/americanpoverty/JudgeYew.ppt](http://www.cwda.org/downloads/tools/americanpoverty/JudgeYew.ppt)

### f. North Carolina Perinatal, Maternal and CASAWORKS for Families Initiative

Introduction to Initiative by Jude Johnson Hostler, LCAS (Click on the image below to view the video.)



The North Carolina Perinatal and Maternal Substance Abuse and CASAWORKS for Families Initiatives (Initiatives) represent a nationally recognized state-wide approach to the many social and health challenges associated with family addiction. It is comprised of 28 programs using evidence-based treatment models located in 13 counties across the state. The Initiatives include a robust effort for cross-service area referral so that no pregnant woman or woman with children seeking treatment and who is willing to engage in her own community, or move to another site in the state should her community not have services, need go without treatment. Women with substance use and associated co-morbidities are supported to engage with family-centered, gender-responsive treatment with their children.

Over 20 years of research show that women are motivated to engage with treatment and recovery by concern for their children or pregnancy but that they are often unwilling to seek treatment if it means leaving their children. The NC Initiatives address this by providing family-responsive care. All of the programs in the Initiatives are considered cross-service area, which helps to meet the need of pregnant and parenting women who do not have gender- or family-responsive

treatment in their home communities. Through a capacity management system, health care providers, department of social services social workers, and treatment providers can refer women and their children to the services they need anywhere in the state. Women in need of services and their families can also access this system to identify appropriate treatment resources statewide.

Programs provide gender-responsive and family-centered services that include, but are not limited to:

- Evidence-based behavioral health treatment services for pregnant and parenting women
- Referral for and coordination with medical care for women
- Arrangements for treatment and prevention services for children
- Pediatric and developmental care for children
- Job readiness and job coaching are key provisions in our 8 CASAWORK for Families sites which have a primary goal of self-sufficiency
- Parenting education and support
- Case management
- Transportation services

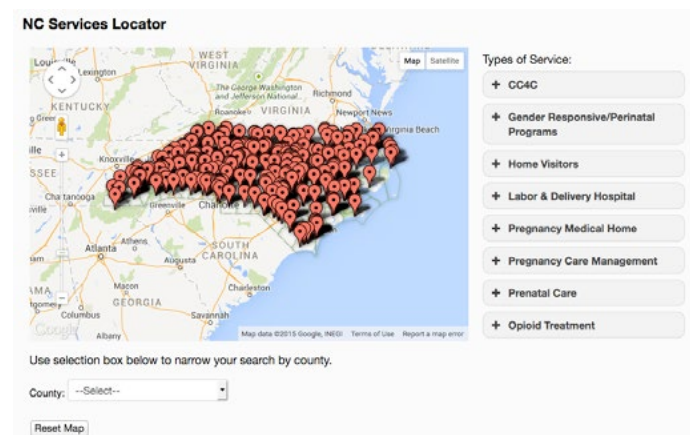
**For more information, see:** <http://alcoholdrughelp.org/getting-help/womens-services>

## g. Connecting Women to Treatment in North Carolina

The NC Perinatal Substance Use Specialist at the Alcohol Drug Council of North Carolina, provides information and referral to alcohol and drug treatment for pregnant and parenting women. She can be contacted at 1-800-688-4232.

**Local Management Entities-Managed Care Organizations (LME-MCO)** provide telephone-based screening, triage, and referral to treatment for residents of their catchment areas. To determine which LMC-MCO to call for a county of residence, consult the listing available at: <http://www.ncdhhs.gov/mhddsas/lmeonblue.htm>

Treatment resources can also be accessed here: <http://ncpoep.org/services>



# V. NORTH CAROLINA GUIDELINES: MEDICATION ASSISTED TREATMENT (MAT) IN PREGNANCY

## PURPOSE & DISCLAIMER

The North Carolina Guidelines for Medication-Assisted Treatment (MAT) in Pregnancy were created to provide North Carolina prescribers and practitioners with a consolidated set of recommendations for the management of opioid-use disorders during pregnancy. These guidelines are intended to complement standard medical care as well as the resources available through the American College of Obstetrics and Gynecology, the Substance Abuse and Mental Health Services Administration (SAMHSA; [www.samhsa.gov](http://www.samhsa.gov)), and SAMHSA's Center for Substance Abuse Treatment ([www.csat.samhsa.gov](http://www.csat.samhsa.gov)). These guidelines are not intended as requirements for practitioners, and should not be considered as medical advice.

## ACKNOWLEDGEMENTS

The guidelines that follow have been adapted with permission from the Treatment of Opioid Dependence in Pregnancy: Vermont Guidelines. The North Carolina Guidelines for Medication-Assisted Treatment (MAT) in Pregnancy have been edited by Jana Burson, MD, Eric Morse, MD, Melissa Godwin, LCSW, and Katie Clark, CSAC.

## MEDICATION-ASSISTED TREATMENT (MAT) IN PREGNANCY — OVERVIEW

### OPIOID MAINTENANCE DURING PREGNANCY

Opioid-use disorder is a chronic disease with high rates of relapse. Acute opioid withdrawal is physiologically stressful, characterized by profound activation of the sympathetic nervous system with hypertension, tachycardia, and gastrointestinal symptoms. In the 1970s, a series of case reports of women who presented in late pregnancy with acute opioid withdrawal reported frequent occurrences of stillbirth and meconium aspiration (i.e., when a neonate inhales a mixture of the first feces and amniotic fluid).<sup>1</sup> Coincident with these reports, randomized trials in the general population of



<sup>1</sup> Medications Development for the Treatment of Pregnant Addicts and Their Infants. National Institute on Drug Abuse Research Monograph Series, No.149. 1995.

those with opioid dependence demonstrated that as compared with acute withdrawal, methadone

maintenance decreased opioid craving and enabled rehabilitation more effectively. As methadone became accepted as appropriate medical therapy for the treatment of opioid-use disorders, the use of methadone during pregnancy to prevent maternal (and fetal) withdrawal was examined. Prescribed methadone during pregnancy improved prenatal care, reduced illicit drug use, and minimized the risk of fetal *in utero* withdrawal.<sup>2</sup> The demonstrated benefits of methadone maintenance led to the current recommendation for opioid agonist treatment for women who have an opioid-use disorder during pregnancy.

## MEDICATION AND TREATMENT SETTING OPTIONS

Treatment with an opioid agonist, such as methadone or buprenorphine, improves pregnancy outcomes for women with opioid-use disorders.<sup>3,4</sup> The best outcomes are achieved when women are enrolled in a comprehensive treatment program. The overarching goals of therapy for opioid-use disorders during pregnancy is to provide medical support to prevent withdrawal during pregnancy, minimize fetal exposure to illicit substances, and engage the mother as a leader in her recovery. Such engagement provides the mother with the opportunity to receive both medical and support services, which will enable her to successfully parent her child. Recognizing that engagement into a comprehensive treatment program can be a gradual process, medication providers are likely to face the difficult task of distinguishing between women who

need a bit more time to become fully engaged in their treatment plan and women who are not ready for treatment. Making this distinction might require assessment of treatment progression over some weeks.

Office-based therapy with buprenorphine during pregnancy favors the woman who is highly motivated to her recovery and parenting. Women for whom office-based buprenorphine is a better fit, typically agree to participate in substance-use disorder counseling and pregnancy home visitation programs to assist in their recovery. Women who are unable to readily engage in these services may benefit from the structure of an opioid treatment program that offers methadone and/or buprenorphine along with comprehensive treatment services, which could include residential treatment. However, including substance-use disorder counseling and comprehensive, wrap-around services should be strongly encouraged for all women with opioid-use disorders because medication alone is not sufficient for optimal recovery or pregnancy and parenting outcomes.<sup>5</sup>

The decision regarding the most appropriate medication should be made jointly with the opioid-agonist provider, the obstetrician, and the woman. Women who are pregnant and are not a candidate for office-based buprenorphine therapy should be referred to an opioid-treatment program. In conjunction with the medication management, pregnant women should be connected to the appropriate level of treatment, ranging from outpatient treatment to residential treatment programs. An essential step in supporting an optimal recovery process is to ensure recommendations of appropriate level of treatment are matched to the patient's individual needs and are based on a comprehensive substance-use disorder assessment using the [American Society of Addiction Medicine \(ASAM\) criteria](#).

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2 Opioid abuse, dependence and addiction in pregnancy. Committee Opinion No. 524. American College of Obstetrics and Gynecologists. *Obstet Gynecol* 2012;119:1070-6

3 Center for Substance Abuse Treatment. Medication-assisted treatment for opioid addiction in opioid treatment programs. Treatment Improvement Protocol (TIP) Series 43. DHHS Publication No. (SMA) 05-4048. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2005.

4 Jones HE, Heil SH, Baewert A, et al. Buprenorphine treatment of opioid-dependent pregnant women: a comprehensive review.

*Addiction* 2012;107(suppl 1):5-27.

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5 World Health Organization. Guidelines for the identification and management of substance use and substance use disorders in pregnancy. WHO Press. 2014



## METHADONE: OPIOID TREATMENT PROGRAM (OTP)

Methadone is classified as a pure mu opioid-agonist with a long half-life (24-36 hours), which allows for once-daily dosing. Methadone is the medication of choice for opioid-use disorder treatment during pregnancy, owing to the simple fact that more data are available on neonatal outcomes following *in utero* exposure to methadone. The Food and Drug Administration (FDA) has established five categories of pregnancy drugs based on the potential of a drug to cause birth defects when used during pregnancy; methadone is a Pregnancy Category C drug. Methadone has not been approved by the FDA specifically for treatment of opioid dependence during pregnancy despite widespread recommendations of methadone as the medication of choice in pregnancy. Initiating treatment to methadone should be offered to all women who are pregnant and have an opioid-use disorder.<sup>3</sup>

Methadone for the treatment of an opioid-use

disorder is available only through opioid-treatment programs. These programs provide medical screening and substance-use disorder counseling, including a full social assessment. Provision of these ancillary services has been shown to improve retention in treatment and treatment outcomes.

Pregnant women are a high priority for treatment with methadone and will automatically be enrolled in a treatment program even though there may be wait lists for other patients.<sup>6</sup> In North Carolina, the major barriers to methadone treatment are the restricted times at treatment centers for daily dosing, cost, and the travel that is often required to access treatment. These issues are particularly difficult for women who are in school, working, have young children at home, and those who live a long distance from a treatment center. Access to medication and the ability to realistically comply with a treatment program should be considered in the overall decision regarding medication choice.

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6 US Department of Health and Human Services. Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction; Final Rule. Federal Register / Vol. 66, No. 11 / Wednesday, January 17, 2001 / Rules and Regulations.

## BUPRENORPHINE:

### OFFICE-BASED MEDICATION-ASSISTED TREATMENT OR OTP

Buprenorphine is a partial mu opioid-agonist approved for the treatment of opioid-use disorders. Unlike methadone, buprenorphine can be prescribed both in medical offices and in opioid-treatment programs. SAMHSA's *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*<sup>7</sup>

outline the background of office-based medication-assisted therapies and provides guidance to prescribers on the management of opioid-dependent persons. Buprenorphine is available under several brand names that contain a combination of buprenorphine and naloxone, including Suboxone, Zubsolv, and Bunavail, as well as Subutex, which is buprenorphine alone.

Studies have found buprenorphine to be safe and effective in the treatment of opioid-use disorders during pregnancy.<sup>8</sup> However, because it is a relatively

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7 Center for Substance Abuse Treatment. Clinical guidelines for the use of buprenorphine in the treatment of opioid addiction. Treatment Improvement Protocol (TIP) Series 40.(Publication No. SMA 04-3939). Rockville, MD: Substance Abuse and Mental Health Services Administration, 2004.

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8 Jones HE; Heil, SH; Baewert, A. et al. Buprenorphine treatment of opioid-dependent pregnant women: a comprehensive review. *Addiction*. 2012 Nov;107 Suppl 1:5-27. doi: 10.1111/j.1360-0443.2012.04035.x.

newer medication, there is a lack of data on the long-term outcomes of neonates exposed to buprenorphine *in utero*, and women seeking treatment should be informed of this gap. Nonetheless, the relative risk/benefit may favor buprenorphine even if the woman is pregnant but otherwise a candidate for buprenorphine therapy. The available data suggest that as compared with no treatment, treatment with buprenorphine provides better outcomes for mother and newborn.<sup>9</sup>

Candidates for buprenorphine are women who were stable on buprenorphine before pregnancy or those who are unable to attend an opioid treatment program that uses methadone. Pregnancy **does not** automatically make women candidates for office-based therapy with buprenorphine, even if buprenorphine is the only medication available in the community. Moreover, the woman's engagement in counseling and other services during pregnancy is vital for successful postpartum transition and recovery.

## Medication Selection

Please see the *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*<sup>1</sup> for detailed information regarding the choice of medication and how to determine whether a person—regardless of pregnancy status—is a candidate for buprenorphine treatment.

Choosing the best medication for treatment during pregnancy is a discussion ultimately best suited to the medication provider and the woman. Recognizing that many women will look to their obstetric care provider before initiating medication, it might be helpful for the medication provider and obstetric provider to

discuss the treatment plan before presenting the final recommendation to the woman.

Methadone is the medication of choice due to the substantial data on long-term neonatal outcomes. Buprenorphine is a reasonable alternative for select patients. The discussion and decision for medication should be reviewed with the woman and documented in her chart. Please see *Appendix 2* for a sample Patient Treatment Information sheet regarding medication during pregnancy, which can be reviewed with the woman.

When methadone is not available and a woman is not an optimal candidate for buprenorphine treatment, providers may want to consider a stepwise approach of initiation with buprenorphine, with very close and frequent follow-up, used in conjunction with substance-use disorder counseling. A different level of treatment, including residential or an opioid treatment program that offers buprenorphine, could be considered for women who have difficulty in adhering to office-based buprenorphine treatment.

When you are uncertain about the optimal medication for a woman who is pregnant, these guidelines recommend consultation with an experienced provider to assist you in this decision-making process.

Examples of when a provider and a woman might choose one treatment over another are as follows:

### Methadone if:

- Unstable living situation
- Abused buprenorphine (snorting, intravenous use)
- Declines/non-compliant with counseling

<sup>9</sup> Jones HE; Finnegan LP, Kaltenbach K. Methadone and buprenorphine for the management of opioid dependence in pregnancy. *Drugs*. 2012 Apr 16;72(6):747-57.doi: 10.2165/11632820-000000000-00000.

- Inability to coordinate ancillary services
- In a mandatory recovery program (e.g., parole)
- Non-compliant with obstetric or pediatric care
- If a woman has ongoing use of multiple substances, including alcohol or benzodiazepines, buprenorphine in an opioid-treatment program is considered the safer choice than methadone in an opioid-treatment program.

#### **Office-based buprenorphine if:**

- Informed consent regarding new medication for pregnancy/ lack of data on long-term outcomes
- Opioids are the only substances of abuse
- Stable living situation
- Accepts counseling
- Can coordinate ancillary services or is engaged in a community-based program that will do so
- Compliant with obstetric and pediatric care
- No alternative is available and the patient understands treatment may be initiated on a trial basis

For consultation regarding residential and outpatient treatment resources, the Perinatal Substance Use Specialist at 1800-FOR BABY can be contacted to assist in triaging a specific woman's situation.

#### **Medication Management**

This section provides additional information for medication initiation during pregnancy. For detailed

information about initiation of medication, patient selection, or other issues related to the initiation of buprenorphine, see the *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*<sup>1</sup>

Medication should not be initiated until both opioid dependence **and** a viable intrauterine pregnancy (ultrasound with heartbeat) are confirmed. Pregnancy is an indication for priority treatment but is *not* an emergency.

For initiation of medication during pregnancy, there must be a diagnosis/confirmation of pregnancy. Home pregnancy tests (i.e., urine tests) are not sufficient for initiation of treatment. A viable intrauterine pregnancy should be confirmed by an obstetric providers or community health clinic.

For a diagnosis/confirmation of physical opioid dependence, a urine test for opioids can be run as either an office-based point-of-care test or a laboratory test. Physical opioid dependence should be documented by the presence of opioid withdrawal symptoms, using a tool such as Clinical Opiate Withdrawal Scale (COWS) found in *Appendix 8*. In addition, query of the North Carolina Controlled Substances Reporting System (CSRS) to assess prescription opioid use is recommended. Occasional use of opioids may not cause physical dependence, and therefore, might not require agonist therapy; however monitoring is imperative.

While a woman may have previously been physically opioid dependent, any period of abstinence, including involuntary abstinence due to jail or other institutionalization, needs to be determined through careful assessment, including laboratory tests and establishing opioid withdrawal symptoms.

#### **Methadone or Buprenorphine Initiation**

The provider, in consultation with the woman, should decide on the medication of choice. Induction of

medication will follow the same procedure used in your practice for patients who are not pregnant; pregnant women should be considered a priority induction, with a goal of initiation of medication within one week of the medication decision.

Mild or even moderate symptoms of opioid withdrawal (CINA 10-12 range, See *Appendix 7*) are not dangerous to pregnancy. For the purposes of medication induction, it is reasonable to ask the woman to abstain from opioid use (and have withdrawal symptoms). Buprenorphine mono-therapy (Subutex) is recommended during pregnancy.<sup>2</sup>

### **Continuation of Medication during Pregnancy**

(After induction or in a person who was previously stable on medication):

If buprenorphine is being used, change to buprenorphine monotherapy at the same dose.

- Assess for withdrawal symptoms weekly (see Medication Provider Visit Flow Sheet, *Appendix 9*) and adjust dose of buprenorphine as indicated; one refill (total of 2 weeks of medications) may be considered for the stable woman in counseling.
- To minimize diversion/theft/loss of medication, provide only one week of buprenorphine medication at a time

### ***Pregnancy-specific dosing notes:***

- 70% of patients stable prior to pregnancy will need a modest dose increase of buprenorphine (3-5 mg) during pregnancy<sup>10</sup>, which should be prescribed gradually throughout gestation. This is due to the increase in blood volume through the pregnancy.

- The average buprenorphine dose at the end of pregnancy is 16 mg<sup>1</sup> for women who began buprenorphine treatment during pregnancy.
- Large increases in buprenorphine requirements have not been noted during pregnancy; if such increases are needed, consider alternative diagnoses.
- If the woman is in office-based buprenorphine treatment and has difficulty in engaging in ancillary services and counseling, consider switching her to an opioid-treatment program.
- If methadone is being used, very high doses of methadone might need to be split, due to increased excretion.<sup>2</sup>

### **Pregnancy Management for the Medication Provider:**

As the provider of methadone or buprenorphine, you will have the longest history with the woman and the best visit compliance. Referrals for ancillary services during pregnancy are best made through your medication visits. Due to the confidentiality protections in place of information related to substance use disorder treatment, your role inherently means you have access to more information than other medical providers involved with the woman. It is very important, with HIPAA-compliant and 42 CFR Part 2-compliant consents, that contact and case coordination is initiated with her other health care providers.

### **At Initiation of Pregnancy Care:**

If a pregnant woman is insured with Medicaid, you should refer the woman to your region's Community Care of North Carolina (CCNC) Pregnancy Care Manager (PCM). See the "[Services for Women with Opioid Exposed](#)

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<sup>10</sup> Fletcher Allen Hospital Burlington, Vermont data

[Pregnancies in North Carolina](#)” for the agency in your region that houses the CCNC PCM (typically the county health department). After the referral, continue to see the patient in weekly visits and for urine drug screens.

The stress of pregnancy and having a newborn warrant closer follow-up, even if the woman has not needed substance-use disorder counseling in the past. Weekly monitoring with urine toxicology screens is recommended. Obtain HIPAA-compliant and 42 CFR Part 2-compliant consents to permit communication with the woman’s obstetric provider, counselor, and planned pediatric provider. Communication is essential between the caregivers for the woman, in order to provide the best care possible. Ideally this consent will be obtained at the onset of treatment. (See *Appendix 1* for samples).

Contact the obstetric provider and pediatric provider directly to document medication (methadone or buprenorphine) use in pregnancy. You should also consider which hospital in the region is best able to manage delivery and potential neonatal needs. Refer to the [“Services for Women with Opioid Exposed Pregnancies in North Carolina”](#). Document the woman’s estimated due date (patient self-report is sufficient).

#### **Recommendations for Weekly Buprenorphine Office Visits** (assessments can be done by a nurse):

- Assessment of withdrawal symptoms or evidence of functional impairment
- Confirmation of woman’s adherence with counseling recommendations
- Confirmation of woman’s adherence with community-based nursing (parenting) plans
- Confirmation of woman’s adherence to obstetric care (monthly visits until 28 weeks; visits every 2 weeks from 28-36 weeks; weekly visits from 36

weeks to due date at 40 weeks)

- For office-based treatment: Assessment and planning for difficulty with adherence to the treatment plan (i.e., prenatal care, counseling, connection with ancillary services) should be made with each weekly prescription.
- For patients with repeated lack of treatment adherence: Reassess whether the woman should remain in an office-based buprenorphine treatment program
- Urine drug screen
- Provide prescription

#### **Between 24-32 Weeks**

*Establish referrals by directly referring the patient OR by making a specific request to the obstetric provider that he/she make the referral.*

- Pediatric provider consultation for evaluation and treatment of neonatal abstinence syndrome (NAS), specifically emphasizing the ability to receive all care at the hospital planned for delivery.
- Anesthesia consultation for pain management plan (reasonable for all women; most important for those planning cesarean delivery).

#### **36-40 Weeks: Delivery and Postpartum Planning**

- As the delivery date nears, update the obstetric provider with the appropriate dose of medication
- Remind the obstetric provider that **NALBUPHINE (Nubain) and BUTORPHANOL (formally Stadol), and PENTAZCINE (Talwin) are CONTRAINDICATED because** they can precipitate acute withdrawal



- Care Coordination for Children (CC4C) referral for ancillary social services
- Encourage breastfeeding
- Refer to home visiting program for mothers for parenting skills and support
- Refer woman's partner to substance-use disorder treatment, if warranted
- Neuraxial analgesia (spinal, epidural) is effective for pain control during labor or for cesarean delivery for women who are opioid dependent.
- Intravenous short-acting **NALBUPHINE (Nubain)** and **BUTORPHANOL** (formally Stadol) and **PENTAZCINE (Talwin)** are **CONTRAINDICATED** because as they can precipitate withdrawal.

- ◊ If any of these drugs is administered mistakenly, and the patient has withdrawal symptoms, an opioid-agonist should be administered to alleviate withdrawal symptoms, and the patient should be closely monitored for respiratory depression.

## Labor, Delivery, and Postpartum

- During labor and delivery, as well as the postpartum process, reassure the woman that providing her with adequate pain control is important; discuss your pain control plan with the woman to reassure her and reduce anxiety.
- Your conversations with obstetric and anesthesia providers should reflect that when a stable patient is requesting pain medication in an appropriate clinical setting, there is no reason to suspect such requests are drug-seeking behaviors.
- Hospital pediatrics should be notified that an opioid exposed neonate will be delivered soon.
- A referral can be made to hospital-based social work to evaluate any needs of the patient postpartum.
- Continue scheduled methadone or buprenorphine during labor and delivery hospitalization. The obstetric provider can order these medications in the hospital even if he or she is not a buprenorphine prescriber, but will not be able to prescribe this medication after the woman's hospital discharge.
- An anesthesia consult should be made when the patient arrives in labor, as indicated.

After the delivery, continue medication-assisted therapy, as indicated, and request the hospital-based social worker assess the patient's needs.

The methadone or buprenorphine for treatment of the opioid-use disorder **will not** treat acute pain associated with childbirth.

- For pain control for **mild and moderate** pain, acetaminophen and non-steroidal anti-inflammatory (NSAID) agents should be used with short-acting opioid analgesics as needed. In a vaginal birth, short-acting opioids can be made available on a PRN basis, just as for non-opioid dependent women.
- For a routine delivery, opioids for pain control should not be needed following hospital discharge.
- In the case of a cesarean delivery, continuous short-acting analgesics for 48 hours patient controlled analgesia with intravenous morphine or hydromorphone can be used the first 24 hours.

Oral opioids can also be used.

Adequate pain control in women with opioid-use disorders may require up to a 70% increase in short-acting opioid analgesics. Often, a more potent oral agent (i.e., hydromorphone) is required for pain control following a cesarean delivery. If available, consider using individual controlled epidural analgesia, as this approach is effective for severe pain. Expect that short-acting opioids will be needed in decreasing amounts for 5-7 days following cesarean delivery.

## BREASTFEEDING

*Breastfeeding is encouraged **for all** patients except those with HIV or other contraindications.*

- If breastfeeding is **declined**, switch the woman back to co-formulated buprenorphine/naloxone immediately after delivery or continue methadone.
- If breastfeeding is **accepted**, consult with the pediatric provider to confirm that he/she is aware of the mother's medication-assisted treatment and all other medications being taken. Referral to a lactation consultant is warranted to support successful initiation of breastfeeding.
- If newborn **is not** receiving methadone, morphine, or other opioid for treatment of neonatal abstinence syndrome (NAS), switch mother back to co-formulated buprenorphine/naloxone.
- If the newborn **is** being treated with methadone, morphine or other opioid for neonatal abstinence syndrome, continue buprenorphine monotherapy until neonate is off medication or weaned from breast milk. There may be some women in whom combination buprenorphine/naloxone is recommended; given evidence of minimal bioavailability in breast milk,

breastfeeding should be encouraged. For more information on breastfeeding see the Breastfeeding Section in this document.

### Postpartum Plan for Opioid-Agonist Medication:

- Current evidence **does not** indicate that immediate dose decreases of methadone or buprenorphine are needed postpartum. Importantly, rapid dose reduction should be avoided due to the risk of relapse. Special attention for drowsiness is warranted.
- Pay special attention to the potential for women to relapse and return to illicit drug use, especially following breastfeeding cessation and at 3-6 months postpartum. Anecdotal



evidence suggests that 3-6 months postpartum is a particularly vulnerable time for a woman in recovery, and a period of high risk for return to use. Encourage mothers at this stage to continue participating in home-visiting programs to receive parenting support and other recovery support services (or make a referral to a home-visiting if the woman has not been referred previously or declined an initial referral).

- Ensure each woman has a follow-up appointment with BOTH her medication provider and substance-use disorder counselor.

## CONTRACEPTION AND FERTILITY

As the patient's substance use disorder recovery proceeds and her physical health is restored, her fertility may also increase. Women should not assume that infertility problems experienced in the past will continue after opioid-use disorder treatment is initiated. If a woman is planning a pregnancy, beginning a regimen of prenatal vitamins (including 800 mg folic acid) prior to conception is recommended to reduce birth defects. If a woman is sexually active and not using contraception, prenatal vitamins should be recommended given the high risk of pregnancy. A referral for contraceptive counseling should be made for women who are not planning a pregnancy and those who do not want to become pregnant.

Contraceptive counseling and treatment are covered under Medicaid. If a woman does not qualify for Medicaid, she may qualify for the 'Be Smart' program. Contraception is available with no charge under the "Be Smart" program from local health departments, rural health clinics, federally qualified health centers, private medical providers and Planned Parenthood clinics that accept Medicaid. Please see *Appendix 12* for information on the "Be Smart" program. County Health Department Family Planning clinics also provide contraceptive

counseling and treatment using a sliding scale fee.

No evidence indicates a medication interaction between oral contraceptives and methadone or buprenorphine. Long-acting reversible contraception (LARC) should be considered for women in medication-assisted treatment who are sexually active and not planning a pregnancy. To afford the woman the best chance for a successful recovery, address her partner/family substance abuse treatment and plan, as indicated.

### Common Clinical Challenges:

Women with a history of substance-use disorders often have chaotic lives, experience intimate partner violence, and have unstable housing. The structure imposed by treatment programs can be a difficult adjustment. Relapses (or return to use) are common, especially in the early stages of treatment. A comprehensive treatment plan developed by the woman in conjunction with both her obstetrician and her medication provider to appropriately balance maternal and fetal risk is imperative.

### Treatment Non-Adherence

Treatment non-adherence can take many forms, including a woman's inability to remain abstinent, non-engagement or non-compliance with counseling, or demonstration of other high-risk behaviors. Options include:

- Use ASAM criteria to evaluate patient's need for more intensive services and more structured program (e.g., intensive outpatient program, residential treatment, methadone or buprenorphine at an opioid-treatment program (OTP).
- If patient declines other options, discharge her from office-based buprenorphine therapy, refer to an OTP with buprenorphine or methadone treatment. Promptly communicate these actions to the woman's obstetrician, pediatrician, and



social work team at the delivery hospital.

- Useful cross discipline strategies for treatment non-adherence include linking the woman's ability to receive a buprenorphine prescription or methadone dose to her receipt of prenatal care by requiring she first visit her obstetric provider. Consider linking the ability to pick-up a buprenorphine prescription or methadone dose to counseling and referral to residential treatment. However, consistent medication is so important to the health of the mother and fetus, you do not want to impose linking rules that would abruptly stop medication without first making sure another level of care is in place.
- ***For recurrent positive drug screens showing benzodiazepine use:*** Particular care must be taken in management of patients dependent upon

benzodiazepines and opioids due to synergistic respiratory depression. Provision for coordination of care must be made and consideration given to admission for benzodiazepine detoxification.

- Education should be given about the potential synergy between methadone, buprenorphine, and benzodiazepines, including warnings about driving or operating machinery. This intervention should be documented in the medical record.
- Other strategies for addressing benzodiazepine dependence (even if the benzodiazepines are prescribed) include increased frequency in counseling and consideration of alternative medication for anxiety (i.e., sertraline).



\* ***Patient may not be a candidate for office-based therapy if using benzodiazepines and might be better served at an OTP.***

- ***For recurrent positive drug screens with cocaine:***

Discuss the specific dangers of cocaine use in pregnancy, including fetal loss, bleeding, preterm labor, and fetal stroke. Education should be provided and documented regarding potential levamisole contamination of cocaine and the additional dangers posed by this adulterant.

\* ***Patient may not be a candidate for office-based buprenorphine therapy if using cocaine, and should be referred to an OTP center for a more structured program and reassessed for appropriate ASAM level of treatment.***

- ***For recurrent positive drug screens with cannabis:*** Use of any illicit substance should be discouraged. Given the relatively scant data showing harmful effects in pregnancy caused by the primary psychoactive agent in marijuana (tetrahydrocannabinol, THC) is harmful in pregnancy combined with the clear benefit of opioid maintenance therapy, consider continuation with close follow-up and reassessed for appropriate ASAM level of treatment.

- ***Non-adherence for other reasons:*** Non-adherence with medication visits due to transportation problems or other social barriers present complex problems to successful recovery. This situation can be addressed by contacting and engaging with the CCNC Pregnancy Care Manager and other community-based nursing/social work resources to develop a transportation plan (i.e., Medicaid-sponsored transportation) and address other barriers.

## CLINICAL RISK MANAGEMENT STRATEGIES

Documentation is crucial and the following elements must be covered: referral for treatment; treatment refusal; and planned use of medications not approved by the FDA, including use of methadone versus buprenorphine. Ancillary services provided should also be documented.

### Clinical Management: Frequently Asked Questions

The following scenarios may help prenatal care providers and medication providers understand the treatment decisions regarding a woman with opioid-use disorder. As for any other medical illness, frequent and close communication between providers will enable coordinated care and an optimal medical approach.

#### **Do I have to offer office-based buprenorphine to a pregnant patient because she refuses methadone?**

- The patient should receive optimal care during pregnancy
- If she is not a candidate for office-based buprenorphine, then she should receive a referral to an OTP that offers buprenorphine, and/or referral to a residential treatment program.
- If an OTP that offers buprenorphine is not logistically possible, consider offering the patient referral to a residential treatment program, with transfer to office-based buprenorphine treatment after she successfully completes the residential program.

#### **Do I have to start buprenorphine immediately because the patient is pregnant?**

- *Pregnancy is not an emergency* — it's simply a priority.



- Confirm opioid dependence
- Confirm viable pregnancy

**May I stop prescribing buprenorphine to a pregnant patient who is non-compliant with treatment?**

- The patient's continued engagement in risky behaviors is unsafe for the woman and her fetus.
- Medication can be discontinued for any medical reason when there is lack of benefit; alternative treatment plans should be offered (e.g., residential treatment programs, or OTP center that offer buprenorphine)
- Continued high-risk behaviors demonstrated by patients receiving office-based treatment suggest the need for residential and OTP care as well as re-evaluation of patient needs.
- Document instances of non-compliance and all offers of alternative treatments and/or more structured programs.

**How do I know when to decline further office-based care with buprenorphine?**

- When there is evidence of concurrent use of benzodiazepines
- When there is evidence of concurrent use of cocaine
- When the patient has difficulty engaging in counseling
- This decision is often dependent on the local availability of an OTP that offers buprenorphine. If an OTP is available, you can offer to refer the patient to the OTP so she can be stabilized on buprenorphine. Once she is stabilized, allow her

to return to office-based care.

- This decision can depend on the ease of switching to methadone. If no treatment is the only option, then the medical provider must carefully assess the overall maternal/fetal risk/benefit of continuing office-based care with buprenorphine; the medication provider has some latitude if the risk/benefit favors office-based care.

**What should I do when I decide I cannot prescribe office-based buprenorphine to a pregnant patient?**

- Document the rationale for your decision in the medical record.
- Offer the patient a referral to an OTP that offers buprenorphine and/or methadone treatment, even if the patient will have to travel some distance to access the program.
- If the option is office-based buprenorphine treatment versus no treatment:
  - Consider residential treatment. NC has residential programs for women who are pregnant and/or parenting.
  - Consider referral to a gender-specific outpatient treatment program, with communication regularly between office-based prescriber and treatment program.
- Inform the patient of your decision, and document the conversation.

**Suggested “scripted” approaches for the MAT provider discussing medication treatment options**

*Initial visit script:*

- I'm glad you decided to seek help.
- First, we need to confirm that you are pregnant, and then clarify the level of your opioid use and dependence.
- We routinely check the North Carolina Controlled Substance Reporting System for all patients seeking treatment at our clinic.
- The FDA considers both buprenorphine and methadone to be Pregnancy Category C drugs, meaning we have limited data and the potential benefits need to be weighed against the risks in pregnancy.<sup>11</sup> We have more years of data on the safety and side effects of methadone than buprenorphine, although we do have relatively large studies showing that buprenorphine is an acceptable alternative to methadone.
- Key factors in making a successful recovery from addiction and successfully parenting a child seem to be fully participating in substance-use disorder counseling and actively engaging with community-based services to get the help needed for recovery and parenting.
- Will you agree to attend counseling and agree to receive help from community-based services such as a home-visiting program for pregnant women and new mothers?

#### *Follow-up sessions:*

- Based on your toxicology screen, I see that you have continued to use cocaine. How shall we address this together?

- Let's review our plan for management of your pregnancy while you are receiving treatment using buprenorphine/methadone.
- Have you been able to keep your appointments with substance-abuse counseling? Your prenatal care visits? Appointments with other medical providers?
- What problems have you faced in trying to keep your appointments? What do you need to overcome those issues?

## PROVIDER INFORMATION AND SUPPORTS

- **Physician Clinical Support System (PCSS-O)**, is a national training and mentoring project, which is funded in part by SAMHSA. PCSS-O makes no-cost educational programs available to health care professionals interested in learning about the safe and effective use of opioids for treatment of chronic pain and opioid-use disorder. **[For more information, see the PCSS-O website <http://pcss-o.org/> or call 855-227-2776.]**

### SAMHSA websites

- The SAMHSA websites at [www.samhsa.gov](http://www.samhsa.gov) and [www.buprenorphine.samhsa.gov](http://www.buprenorphine.samhsa.gov) provide information on the *DATA 2000* physician waiver qualifications, how to request a waiver form, buprenorphine trainings, and other information on treatment options for opioid-use disorders and other substance use problems.
- **Center for Substance Abuse Treatment (CSAT):** <http://www.samhsa.gov/about-us/who-we-are/offices-centers/csat>. Phone: 866-BUP-CSAT or 240-276-166

<sup>11</sup> Martin J, Sullivan, MA. Pregnancy and buprenorphine treatment. MAT training providers' clinical support system for medication assisted treatment. [Internet]. 2014. Available at: <http://www.buppractice.com/howto/assess/pregnant>.

- **National Clearinghouse for Alcohol and Drug Information** (NCADI; a service of SAMHSA):
- Website: <http://www.health.org/> E-mail: [info@health.org](mailto:info@health.org) Phone 800- 729-6686 or 301-468-2600; Spanish line: 877-767-8432

## RISK MANAGEMENT REFERENCES:

ACOG Committee on Ethics. ACOG Committee Opinion #321: maternal decision making, ethics, and the law Obstet Gynecol. 2005 Nov;106(5 Pt 1):1127-37.

ACOG Committee. ACOG Committee Opinion No. 363: patient testing: ethical issues in selection and counseling. Obstet Gynecol. 2007 Apr;109(4):1021-3.Reaffirmed 2012.

American College of Obstetrics and Gynecology. ACOG Committee Opinion No. 390, December 2007. Ethical decision making in obstetrics and gynecology. Obstet Gynecol. 2007 Dec;110(6):1479-87.Reaffirmed 2013.

American College of Obstetrics and Gynecology. ACOG Committee Opinion No. 422: at-risk drinking and illicit drug use: ethical issues in obstetric and gynecologic practice. Obstet Gynecol. 2008 Dec;112(6):1449-60. doi:10.1097/AOG.0b013e318192499b.

## RESOURCES FOR OFFICE-BASED TREATMENT FOR OPIOID DEPENDENCE WITH BUPRENORPHINE.

Substance Abuse and Mental Health Services Administration. *TIP 40: clinical guidelines for the use of buprenorphine in the treatment of opioid addiction* (Publication No. SMA07-3939). Rockville, MD. 2004. Available at: <http://store.samhsa.gov/product/TIP-40-Clinical-Guidelines-for-the-Use-of-Buprenorphine-in-the-Treatment-of-Opioid-Addiction/SMA07-3939>

Vermont Department of Health, Division of Alcohol and Drug Abuse Programs; Department of Vermont Health Access. *Vermont buprenorphine practice guidelines*. Available at: <http://dvha.vermont.gov/.../buprenorphine-practice-guidelines-dec-2012.pdf>

## APPENDIX 1

### CONSENT FOR RELEASE OF CONFIDENTIAL INFORMATION

\_\_\_\_\_  
PATIENT NAME

\_\_\_\_\_  
PATIENT DATE OF BIRTH

I, \_\_\_\_\_ authorize

\_\_\_\_\_ to disclose to

(Behavior Health Services Provider)

\_\_\_\_\_  
(Name of provider or agency)

\_\_\_\_\_  
The following information: (Client needs to initial each category that applies.)

\_\_\_\_\_ My name and other personal identifying information

\_\_\_\_\_ Assessment

\_\_\_\_\_ Dates of services

\_\_\_\_\_ Recommendations for treatment

\_\_\_\_\_ Progress and compliance with treatment

\_\_\_\_\_ Attendance

\_\_\_\_\_ Date of discharge and discharge status

\_\_\_\_\_ Discharge plan

The purpose of these disclosures is to: Provide permission to the above named Behavior Health Services provider to disclose information as initialed to the above named provider or agency for the coordination of care.

**For Clients with Substance Use Disorders:** I understand that my records are protected under the federal regulations governing Confidentiality of Alcohol and Drug Abuse Records, 42 CFR Part 2, and cannot be disclosed without my written consent unless otherwise provided for in the regulations. I also understand that, except for action already taken, I may rescind this consent at any time.

**Protected Health Information:**

I understand that my alcohol and/or substance use disorder treatment records are protected under the Federal regulations governing Confidentiality and Drug Abuse Patient Records, 42 C.F.R. Part 2, and the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), 45 C.F.R. pts 160&164, and cannot be disclosed without my written consent unless otherwise provided for by the regulations. I also understand that I may revoke this consent in writing at any time except to the extent that action has been taken in reliance on the consent. I understand that generally \_\_\_\_\_

(name of substance use disorder treatment program)

may not condition my treatment on whether I sign a consent form, but that in certain limited circumstances I may be denied treatment if I do not sign a consent form.

If I do not rescind this consent, it expires automatically as one year from the date this consent is signed.

\_\_\_\_\_

Date signed

Client's signature

\_\_\_\_\_

Date signed

Witness Signature

\_\_\_\_\_ Client has received a copy of this consent form for his/her records.

☐ Client signed consent

☐ Client did not sign consent. Reason \_\_\_\_\_



## APPENDIX 2

### TREATMENT INFORMATION SHEET

Healthy moms are certainly more likely to have a healthy baby. It is common for women to decide to take action to treat medical problems for the health of their growing baby. A decision to receive medical treatment for opioid dependence during pregnancy is an important step in your life and that of your baby. Medical treatment can reduce other drugs in your system and increase the chances of a full recovery.

Both methadone and buprenorphine are used for the treatment of opioid dependence. Below are some facts to consider as you and your physician decide which medication is best for you:

- We have the most data about the long-term health of you and your baby when treated with methadone.
- Buprenorphine is a new drug, and while it appears to be safe when we examine newborns, long-term effects on the baby are unknown.
- The ability to receive medication close to home may be a consideration in deciding what medication to use. Neonatal abstinence syndrome can occur following treatment with either methadone or buprenorphine.
- It is important that you are willing and able to be compliant with whichever treatment you and your medical provider select.
- Counseling is an essential part of treatment, regardless of medication.
- Not all people are candidates for office-based treatment with buprenorphine; in those cases, treatment with methadone or buprenorphine through an opioid-treatment program is strongly advised.
- If buprenorphine treatment does not seem to be effective for you, treatment with methadone may be recommended even if following the daily dosing regimen would be difficult.
- Some women that strongly desire buprenorphine may do best to start treatment in a residential treatment setting.

## APPENDIX 3A

### TEN FACTOR OFFICE-BASED CRITERIA CHECK LIST

In general, 10 factors help determine whether a patient is appropriate for office-based buprenorphine treatment. This checklist may be useful during the screening process.

Check “yes” or “no” next to each factor.

#### Factor

- |   |                              |                             |
|---|------------------------------|-----------------------------|
| 1. Does the patient have a diagnosis of opioid dependence?  | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 2. Is the patient interested in office-based buprenorphine treatment?   | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 3. Is the patient aware of the other treatment options?   | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 4. Does the patient understand the risks and benefits of buprenorphine treatment and that it will address some aspects of the substance abuse, but not all aspects?   | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 5. Is the patient expected to be reasonably compliant?  | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 6. Is the patient expected to follow safety procedures?   | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 7. Is the patient psychiatrically stable?   | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 8. Are the psychosocial circumstances of the patient stable and supportive?   | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 9. Are resources available in the office to provide appropriate treatment?<br>Are there other physicians in the group practice?<br>Are treatment programs available that will accept referral for more intensive levels of service? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 10. Is the patient taking other medications that may interact with buprenorphine, such as naltrexone, benzodiazepines, or other sedative-hypnotics?   | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

Source: Based on the CSAT-funded curriculum “Use of Buprenorphine in the Pharmacologic Management of Opioid Dependence.” *American Academy of Addiction Psychiatry*, on-line training. Eric Strain, MD and Jeff Novey, MPH. Course revised by Elinore F. McCance-Katz, MD, Ph.D., 2004.

## APPENDIX 3B

### GUIDELINES FOR ASSESSING APPROPRIATENESS FOR OFFICE-BASED THERAPY

The following guidelines will help in deciding whether to treat with buprenorphine in the office. They assume the person is opioid dependent.

#### SCORING KEY

- 0-5: Excellent candidate for office-based treatment.
- 6-10: Good candidate for office-based treatment.
- 11-15: Good candidate, but only with tightly structured program providing supervised dosing and on site counseling.
- 16-20: Candidate for office-based treatment by board certified addiction physician in a tightly structured program or hub induction with follow-up by office-based provider or methadone clinic referral.
- 21-25: Candidate for methadone program only.

**For each answer check YES or NO and add points for YES and NO below.**

Questions	Points:	Yes	No	Possible
Is the person employed?		<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Is the family intact?		<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Does the person have a partner who uses drugs or alcohol?		<input type="checkbox"/> 1	<input type="checkbox"/>	<input type="checkbox"/> 1
Is the person's housing stable?		<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Does the person have legal issues?		<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Does the person have any convictions for drug dealing?		<input type="checkbox"/> 2	<input type="checkbox"/>	<input type="checkbox"/> 2
Is the person on probation?		<input type="checkbox"/> 1	<input type="checkbox"/>	<input type="checkbox"/> 1
Does the person have psychiatric problems, e.g., major depression, bipolar, severe anxiety, PTSD, schizophrenia, personality subtype of antisocial, borderline, or sociopathy?		<input type="checkbox"/> 2	<input type="checkbox"/>	<input type="checkbox"/> 2
Does the person have a chronic pain syndrome that needs treatment?		<input type="checkbox"/> 2	<input type="checkbox"/>	<input type="checkbox"/> 2
Does the person have reliable transportation?		<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Does the person have a reliable phone number?		<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Has the person been on medicated assisted treatment before?		<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Was the medicated assisted treatment successful?		<input type="checkbox"/>	<input type="checkbox"/> 2	<input type="checkbox"/> 2
Does the person have a problem with alcohol?		<input type="checkbox"/> 2	<input type="checkbox"/>	<input type="checkbox"/> 2
Does the person have a problem with cocaine?		<input type="checkbox"/> 1	<input type="checkbox"/>	<input type="checkbox"/> 1
Does the person have a problem with benzodiazepines?		<input type="checkbox"/> 2	<input type="checkbox"/>	<input type="checkbox"/> 2
Is the person motivated for treatment in the office?		<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Is the person currently going to counseling, AA, or NA?		<input type="checkbox"/>	<input type="checkbox"/> 2	<input type="checkbox"/> 2
Total points possible: 25	Total each column:			
	Total both columns:			

Provided to Treatment of Opioid Dependence in Pregnancy: Vermont Guidelines by John Brooklyn, MD, May 21, 2009

## APPENDIX 4

### BUPRENORPHINE TREATMENT AGREEMENT/CONTRACT

As a participant in the buprenorphine protocol for treatment of opioid abuse and dependence, I freely and voluntarily agree to accept this treatment agreement/contract, as follows:

- I agree to keep, and be on time to, all my scheduled appointments with the doctor and his/her assistant.
- I agree to attend substance abuse counseling at least weekly; more often at the initiation of treatment.
- I understand that urine collections will be performed to send for drug screens.
- I agree to conduct myself in a courteous manner in the physician's office.
- I agree not to arrive at the office intoxicated or under the influence of drugs. If I do, the doctor will not see me, and I will not be given any medication until my next scheduled appointment.
- I agree not to sell, share, or give any of my medication to another individual. I understand that such mishandling of my medication is a serious violation of this agreement and would result in my treatment being terminated without recourse for appeal.
- I agree not to deal, steal, or conduct any other illegal or disruptive activities in the doctor's office.
- I agree that my medication (or prescriptions) can be given to me only at my regular office visits. Any missed office visits will result in my not being able to get medication until the next scheduled visit.
- I agree that the medication I receive is my responsibility and that I will keep it in a safe, secure place. I agree that lost medication will not be replaced regardless of the reasons for such loss.
- I agree not to obtain medications from any physicians, pharmacies, or other sources without informing my treating physician. I understand that mixing buprenorphine with other medications, especially benzodiazepines such as valium and other drugs of abuse, can be dangerous. I also understand that a number of deaths have been reported among individuals mixing buprenorphine with benzodiazepines.
- I agree to take my medication as the doctor has instructed and not to alter the way I take my medication without first consulting the doctor.
- I understand that medication alone is not sufficient treatment for my disease, and I agree to participate in the patient education and relapse prevention programs, as provided, to assist me in my treatment.
- I understand that I may be transitioned to Suboxone (buprenorphine/naloxone) following delivery (exception: breastfeeding and baby in treatment).

---

PATIENT SIGNATURE

---

PRINTED NAME

## APPENDIX 5

### TREATMENT OF OPIOID DEPENDENCE DURING PREGNANCY DEMOGRAPHIC SHEET

NAME	DATE OF BIRTH
MEDICATION	
OBSTETRIC PROVIDER	FAX NO.
PEDIATRIC PROVIDER	FAX NO.
MEDICATION PROVIDER	FAX NO.
SUBSTANCE TREATMENT COUNSELOR	FAX NO.
HOME HEALTH NURSE	FAX NO.
HOSPITAL FOR DELIVERY	



## APPENDIX 6

### OPIOID-AGONIST THERAPY DURING PREGNANCY MEDICATION PROVIDER CHECKLIST

---

PATIENT NAME

DATE OF BIRTH

---

☐ **Discuss risk benefits/Patient given risk benefit fact sheet**

- ☐ Methadone
- ☐ Buprenorphine
- ☐ **No medication**/wean

☐ **Substance Treatment counselor**

- ☐ Name: \_\_\_\_\_
- ☐ Refer to counseling if not already in treatment (counseling is strongly recommended)

☐ **Obstetrician**

- ☐ Name: \_\_\_\_\_
- ☐ Hospital of Delivery: \_\_\_\_\_
- ☐ Anesthesia consult at 24-32 weeks \_\_\_\_\_

☐ **Pediatrician**

- ☐ Name: \_\_\_\_\_

*Refer at 24-32 weeks*

☐ **Home Visiting Nurse**

- ☐ Name: \_\_\_\_\_

☐ **Urine Drug Screens**

- ☐ Obstetrician
- ☐ Medication Provider

## APPENDIX 7

### CLINICAL INSTITUTE NARCOTIC ASSESSMENT (CINA) SCALE FOR WITHDRAWAL SYMPTOMS

The Clinical Institute Narcotic Assessment (CINA) Scale measures 11 signs and symptoms commonly seen in patients during narcotic withdrawal. This can help to gauge the severity of the symptoms and to monitor changes in the clinical status over time.

Parameters Based on Questions and Observation	Findings	Points
1 Abdominal changes: Do you have any pains in your abdomen? Crampy abdominal pain, diarrhea, active bowel sounds.	No abdominal complaints, normal bowel sound. Reports waves of crampy abdominal pain.	0 1 2
2 Changes in temperature: Do you feel hot or cold? clammy to touch. Uncontrolled shivering.	None reported. Reports feeling cold, hands cold and	0 1 2
3 Nausea and vomiting: Do you feel sick in your stomach? Have you vomited?	No nausea or vomiting. Mild nausea; no retching or vomiting. Intermittent nausea with dry heaves. Constant nausea; frequent dry heaves and/or vomiting.	0 2 4 6
4 Muscle aches: Do you have any muscle cramps?	No muscle aching reported, arm and neck muscles soft at rest. Mild muscle pains. Reports severe muscle pains, muscles in legs, arms or neck in constant state of contraction.	0 1 3
Parameters based on Observation Alone	Findings	Points
5 Goose flesh	None visible. Occasional goose flesh but not elicited by touch; not permanent. Prominent goose flesh in waves and elicited by touch. Constant goose flesh over face and arms.	0 1 2 3
6 Nasal congestion	No nasal congestion or sniffing. Frequent sniffing. Constant sniffing, watery discharge.	0 1 2
7 Restlessness	Normal activity. Somewhat more than normal activity; moves legs up and down; shifts position occasionally. Moderately fidgety and restless; shifting position frequently. Gross movement most of the time or constantly thrashes about.	0 1 2 3
8 Tremor	None. Not visible but can be felt fingertip to fingertip. Moderate with patient's arm extended. Severe even if arms not extended.	0 1 2 3
9 Lacrimation	None. Eyes watering; tears at corners of eyes. Profuse tearing from eyes over face.	0 1 2
10 Sweating	No sweat visible. Barely perceptible sweating; palms moist. Beads of sweat obvious on forehead. Drenching sweats over face and chest.	0 1 2 3
11 Yawning	None. Frequent yawning. Constant uncontrolled yawning.	0 1 2
TOTAL SCORE	Sum of points for all 11 parameters	

Minimum score = 0, Maximum score = 31. The higher the score, the more severe the withdrawal syndrome.

Percent of maximal withdrawal symptoms = total score/31 x 100%.

Source: Adapted from Peachey JE, Lei H. Assessment of opioid dependence with naloxone. Br J Addict. 1988 Feb;83(2):193-201.

## APPENDIX 8

### CLINICAL OPIATE WITHDRAWAL SCALE (COWS)

For Suboxone (buprenorphine/naloxone) induction: Enter scores at time zero, 1-2 hours after first dose, and at additional times Suboxone is given over the induction period.

	Date/Time	Date/Time	Date/Time
<b>Resting Pulse Rate:</b> (record beats per minute) <i>Measured after patient is sitting/lying for one minute.</i> <b>0</b> pulse rate 80 or below <b>1</b> pulse rate 81-100 <b>2</b> pulse rate 101-120 <b>4</b> pulse rate greater than 120			
<b>Sweating:</b> <i>Over past ½ hour not accounted for by room temperature or patient activity.</i> <b>0</b> no report of chills or flushing <b>1</b> one subjective report of chills or flushing <b>2</b> flushed or observable moistness on face <b>3</b> beads of sweat on brow or face <b>4</b> sweat streaming off face			
<b>Restlessness:</b> <i>Observation during assessment.</i> <b>0</b> able to sit still <b>1</b> reports difficulty sitting still, but is able to do so <b>3</b> frequent shifting or extraneous movements of legs/arms <b>2</b> unable to sit still for more than a few seconds			
<b>Pupil Size:</b> <b>0</b> pupils pinned or normal size for room light <b>1</b> pupils possibly larger than normal for room light <b>2</b> pupils moderately dilated <b>2</b> pupils so dilated that only rim of the iris is visible			
<b>Bone or Joint Aches:</b> <i>If patient was having pains previously, only the additional component attributed to opiate withdrawal is scored.</i> <b>0</b> not present <b>1</b> mild diffuse discomfort <b>2</b> patient reports severe diffuse aching of joints/muscles <b>4</b> patient is rubbing joints or muscles and is unable to sit still because of discomfort			
<b>Runny Nose or Tearing:</b> <i>Not accounted for by cold symptoms or allergies.</i> <b>0</b> not present <b>1</b> nasal stuffiness or unusually moist eyes <b>2</b> nose running or tearing <b>4</b> nose constantly running or tears streaming down cheeks			
<b>GI Upset:</b> <i>Over last ½ hour.</i> <b>0</b> no GI symptoms <b>1</b> stomach cramps <b>2</b> nausea or loose stools <b>3</b> vomiting or diarrhea <b>5</b> multiple episodes of diarrhea or vomiting			
<b>Tremor:</b> <i>Observation of outstretched hands.</i> <b>0</b> no tremor <b>1</b> tremor can be felt, but not observed <b>2</b> slight tremor observable <b>4</b> gross tremor or muscle twitching			
<b>Yawning:</b> <i>Observation during assessment.</i> <b>0</b> no yawning <b>1</b> yawning once or twice during assessment <b>2</b> yawning three or more times during assessment <b>4</b> yawning several times/minute			
<b>Anxiety or Irritability</b> <b>0</b> none <b>1</b> patient reports increasing irritability or anxiousness <b>2</b> patient obviously irritable, anxious <b>4</b> patient so irritable or anxious that participation in the assessment is difficult			
<b>Gooseflesh Skin</b> <b>0</b> skin is smooth <b>3</b> piloerection of skin can be felt or hairs standing up on arms <b>5</b> prominent piloerection			
<b>Total Score</b>			
<b>Observer's Initials</b>			
<b>Blood Pressure/Pulse</b>			
<b>Dose of Suboxone Given</b>			

**SCORE**    Mild: 5-12    Moderate: 13-24    Moderately Severe: 25-36    Severe Withdrawal: More than 36

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## APPENDIX 9

### MEDICATION PROVIDER VISIT FLOW SHEET

Due date: \_\_\_\_\_

Medication/dose: \_\_\_\_\_

Symptoms of withdrawal (check all withdrawal symptoms/physical findings that apply):

- ☐ Craving
- ☐ Sweating
- ☐ Lacrimation
- ☐ Runny nose
- ☐ Gooseflesh
- ☐ Yawning
- ☐ Abdominal pain
- ☐ Diarrhea

Have you seen a substance abuse counselor in the last week? \_\_\_\_\_

When is the next appointment with your obstetric care provider? \_\_\_\_\_

Have you seen community-based nursing recently? \_\_\_\_\_

## APPENDIX 10

### COMMUNITY-BASED NURSING/SOCIAL SERVICES CHECKLIST

---

PATIENT NAME

DATE OF BIRTH

---

☐ OB Provider:

☐ Medication Provider:

☐ Substance Use Disorder Tx

---

☐ Primary Care Provider:

☐ Pediatrician:

☐ WIC

☐ CCNC Pregnancy Care Manager

☐ Social Services

☐ Economic services

☐ Housing

☐ Employment

☐ Child care



**APPENDIX 11**

**COMMUNICATION TOOL FAX FORM**

To:		From:	
Fax:		Pages:	
Phone:		Date:	

Name: \_\_\_\_\_

Date of birth: \_\_\_\_\_

Due date: \_\_\_\_\_

Medication/dose: \_\_\_\_\_

Visit type:

☐ Counseling

☐ OB visit

☐ Community nurse

☐ Pediatric visit

Date of visit: \_\_\_\_\_

## APPENDIX 12

### MEDICAID FAMILY PLANNING “BE SMART” PROGRAM

#### **Be Smart. Be Ready.**

#### **Free Reproductive Health Services in North Carolina**

#### **Facts about the Medicaid Family Planning “BE SMART” Program**

##### **What is the Medicaid Family Planning BE SMART program?**

The Medicaid Family Planning Program — or BE SMART program— is designed to reduce unintended pregnancies and improve the well-being of children and families in North Carolina. Family planning/reproductive health services are provided to eligible men and women whose income is at or below 195% of the federal poverty level.

Who can enroll with Medicaid to provide Family Planning Services under the “BE SMART” program?

- Ambulatory surgery centers
- Birthing centers
- Certified Registered Nurse Anesthetists
- Federally Qualified Health Centers
- Laboratories
- Local health departments
- Nurse practitioners
- Nurse midwives
- Outpatient hospitals
- Physicians
- Rural health clinics

For information on enrolling as a North Carolina Medicaid provider, refer to the Division of Medical Assistance (DMA) website at <http://www.ncdhhs.gov/dma/provenroll/>

##### **What services are covered under the BE SMART program?**

The following services are covered through the “Be Smart” when provided as part of a family planning visit:

- Annual and periodic office visits (including counseling, patient education, and treatment)
- Specific laboratory procedures (i.e., Pap tests, pregnancy tests)
- FDA-approved and Medicaid-covered birth control methods, procedures, pharmaceutical supplies, and devices
- Screening for HIV (Human Immunodeficiency Virus)
- Screening and treatment for specific sexually transmitted infections (STIs)
- Voluntary sterilization (in accordance with federal sterilization guidelines)

**Note:** There is no co-payment for beneficiaries for services received through the BE SMART program.

When services are not covered under the BE SMART program and the provider does not offer affordable or free care, patients should be referred to their local department of social services (DSS) for a list of primary care “safety net” providers.

**Who can sign up for the BE SMART program?**

Eligible individuals whose income is at or below 195% of the federal poverty level and who are:

- U.S. citizens, documented immigrants, or qualified aliens;
- Residents of North Carolina;
- Not incarcerated;
- Not pregnant; and
- Not permanently sterilized.

**How can I sign my patients up for the BE SMART program?**

Individuals interested in applying may get an application from their local DSS, health department or on-line at <http://www.ncdhhs.gov/dma/medicaid/applications.htm>

The completed application must be returned to their local DSS.

**Who do I contact if I have questions about the BE SMART program?**

**[For more information about this special Medicaid program, please visit North Carolina’s Medicaid website at <http://www.ncdhhs.gov/dma/medicaid/familyplanning.htm>]**

*Services for the BE SMART program are covered under the State Eligibility Option for Family Planning Services (State Plan Amendment), with no lapse in services previously provided under the Family Planning Waiver.*

N.C. Department of Health and Human Services Division of Medical Assistance and Division of Public Health DMA-3153

## VI. MEDICAID COVERAGE AND STATE-FUNDED SERVICES

**P**rivate health insurance covers the cost of substance-use disorder treatment and services to varying degrees. Each insurer has its own policy, and insured individuals will need to refer to the policy of their respective insurance companies to determine the extent of services that are covered. Many women needing treatment, including pregnant women, may have once had private insurance but have lost that insurance. This section presents information for women who are uninsured, women who may qualify for Medicaid insurance, and women who are currently insured with Medicaid.

### MEDICAID SERVICES FOR WOMEN AND CHILDREN

- **Medicaid for Infants and Children**

Medicaid for Infants and Children (MIC) provides medical coverage for children younger than 19 years old. The income limits are determined by the family size and the age of the child or children applying for benefits. There is no limit on resources.

- **Medicaid for Families with Dependent Children**

Medicaid for Families with Dependent Children provides medical coverage for parent(s) or other caretaker/relative with a child 18 years or younger in the household and for children under age 21. A pregnant woman may also qualify.

The family cannot have more than \$3,000 in assets such as savings in the bank.

If the family income is above the cut-off and the child and/or family has high medical bills, the family might still qualify for Medicaid (with a Medicaid

deductible).

- **Medicaid for Pregnant Women**

Medicaid for Pregnant Women covers only services related to pregnancy:

- Prenatal care, delivery, and 60 days postpartum care (after the 60-day postpartum period, the woman can apply for Medicaid for Families with Dependent Children, if applicable)
- Services to treat medical conditions that might complicate the pregnancy (some services require prior approval)
- Behavioral health services including mental health and substance-use disorder services
- Childbirth classes
- Family planning services

A pregnant woman may apply for this program before or after she delivers. A woman who has experienced a recent pregnancy loss might also be eligible for this program.

To be eligible for this Medicaid coverage, the pregnant woman's monthly family income cannot exceed 196% of the federal poverty level, but the program does not put a limit on resources held by the family. If a pregnant woman is covered by Medicaid on the date she delivers, her newborn child may be eligible for Medicaid up to age 1 without a separate application.

**[For more information regarding any of the Medicaid benefits listed above, visit: <http://www.ncdhhs.gov/dma/medicaid/families.htm>]**

## NC HEALTH CHOICE FOR CHILDREN

The North Carolina Health Choice (NCHC) Health Insurance Program for Children is a comprehensive health coverage program for low-income children. The goal of the NCHC Program is to reduce the number of uninsured children in the State. If the family makes too much money to qualify for Medicaid, but too little to afford private or employer-sponsored health insurance, the child or children may qualify for NCHC.

[For more information about NC Health Choice, visit: <http://www.ncdhhs.gov/dma/healthchoice/who.htm>]

## STATE-FUNDED SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES

Each Local Management Entity-Managed Care Organization (LME-MCO) in NC receives state and federal funds to provide mental health, developmental disabilities, and substance-use disorder services to individuals who are not Medicaid eligible or do not have a third-party payer (e.g. private insurance, Tricare). To be eligible for state-funded services, individuals must meet the eligibility requirements for one or more of the State Benefit Plans.

One of the State Benefit Plans for substance abuse treatment specifically includes pregnant women, and considers pregnant women a priority population.

## BENEFIT PLAN FOR ADULT SUBSTANCE ABUSE SERVICES – WOMEN (ASWOM):

Persons eligible for this program will meet the following criteria: Adult women 18 years and older with a primary substance-use disorder covered in the Benefit Plan Diagnosis Array\* **AND** who would benefit from assessment, initiation, engagement, treatment, continuity of treatment services, and/or supports for relapse prevention and recovery stability, **AND** who are:

- Currently pregnant,

**OR**

- Has one or more dependent child younger than 18 years old,

**OR**

- Is seeking custody of a child younger than 18 years old.

[For more information about state-funded benefit plans and services, please contact the Local Management Entity-Managed Care Organization based on the individual's county of residence who is in need of services. Please go to <http://www.ncdhhs.gov/mhddsas/lmeonblue.htm> for a list of LME-MCOs by county.]

\*The Benefit Plan Diagnosis Array may be found at: <http://www.ncdhhs.gov/mhddsas/providers/nctracks/index.htm>.



# VII. NEONATAL ABSTINENCE SYNDROME

## PURPOSE & DISCLAIMER

**T**his content is intended to be used for informational purposes only, and should not be considered as medical advice. For medical guidance, practitioners should consult the resources available through the American Academy of Pediatrics [www.aap.org](http://www.aap.org). This information is not intended as requirements for practitioners.

## ACKNOWLEDGEMENTS

What follows has been adapted with permission from the *Treatment of Opioid Dependence in Pregnancy: Vermont Guidelines*. Neonatal Abstinence Syndrome has been edited by Melissa Godwin, LCSW and Mary Ellen Wright, PhD, APRN, CPNP

## NEONATAL ABSTINENCE SYNDROME OVERVIEW

Neonatal abstinence syndrome (NAS) refers to a constellation of signs in the newborn due to substance or medication withdrawal. In most cases, exposure to the substances occurs during pregnancy, but NAS also describes a syndrome that occurs secondary to withdrawal of opioids and sedatives given to neonates with serious medical conditions. Opioids (naturally occurring, synthetic and semi-synthetic) are the most common substances that create the signs and symptoms typically associated with NAS. NAS due to opioid exposure during pregnancy can occur as a result of a prescription for the ongoing treatment of pain, through medication-assisted therapy (either methadone or buprenorphine) for the management of an opioid use disorder, or due to an active opioid use disorder involving heroin or prescription opioids.

## OPIOID ADDICTION

Opioid use and use disorders during pregnancy continue to be a significant public health problem. Heroin, a semi-synthetic opioid with a rapid onset of action and a short half-life, is one of the most frequently used opioids during pregnancy. Although heroin is typically injected, an increasing number of users are inhaling or smoking heroin. The use of other opioids during pregnancy has also escalated in recent years, including increased use of oxycodone; hydrocodone; and the controlled-release form of oxycodone, OxyContin®. Data from the National Survey on Drug Use and Health indicate a recent increase has occurred in the non-medical use of prescription opioids and heroin by pregnant women.

Use of heroin and other opioids stimulate the opiate receptors in the brain, bringing physical responses that range from euphoria, to pain relief, to respiratory depression, and nausea. Repeated ongoing use of opioids is associated with increasing tolerance levels, that is, repeated use leads to the need for higher doses of the substance to obtain the same effect. Tolerance leads to physical dependence, resulting in a change to the neuro-chemical balance in the central nervous system, and, in the absence of the opioid, a withdrawal syndrome. Opioid withdrawal is characterized by a range of symptoms including agitation, nasal congestion, yawning, perspiration, muscle cramps, diarrhea, nausea, vomiting, and depression.

Several mechanisms have been proposed to explain the phenomena of tolerance, dependence, and withdrawal in the occurrence of chronic opioid exposure. These include

- increased metabolic breakdown of opioid compounds;
- decreased neurotransmitter release that results in an increased number and sensitivity of post-synaptic receptors; and
- down-regulation of opioid receptors, resulting in decreased production of endogenous endorphins.

Given these physiological processes and changes, some with opioid use disorders will need medication-assisted treatment for prolonged periods, possibly for the rest of their life.

The standard of care for people with an opioid use disorder is medication-assisted treatment with opioid-agonists in conjunction with counseling and supportive services.<sup>1</sup> Methadone and buprenorphine are the most commonly prescribed medications used as part of the treatment of opioid-use disorders.

## OPIOIDS AND PREGNANCY

The cycle of opioid use and withdrawal is particularly problematic for the developing fetus. A repeated pattern of use and withdrawal compromises the blood flow to the fetus, leading to insufficient oxygen levels. These problems are primary contributors to increased risk of prematurity, low birth weight, and fetal death. Comprehensive prenatal care is essential to improve outcomes for mother and child.

For several decades, the standard of care for pregnant women with opioid use disorders has been medication-assisted treatment. At appropriate dosages and with proper monitoring, the synthetic opioid methadone can be safely used in pregnant women

to eliminate symptoms of withdrawal, reduce drug cravings, and block euphoric effects if other opioids are used. The long half-life of methadone and a predictable schedule of dosing prevents drastic fluctuations in the opioid levels in the fetus; the stabilized exposure level is associated with a longer duration of the pregnancy and improved fetal growth. As the pregnancy progresses, methadone is metabolized more rapidly in the mother's body and higher doses are required. Although some early reports suggested the dose of methadone was correlated with the incidence and severity of neonatal withdrawal signs, recent evidence has not demonstrated that relationship.<sup>2,3</sup> It is now well understood that lowering the dose during pregnancy may lead to increased illicit opioid use, exposing the mother and fetus to more harm.



1 Substance Abuse and Mental Health Services Administration. (2008). *Medication-assisted treatment for opioid addiction in opioid treatment programs: TIP 43*. (Treatment Improvement Protocol Series). Rockville, MD: U.S. Dept. of Health and Human Services. Retrieved from <http://www.ncbi.nlm.nih.gov/books/NBK64164/pdf/TOC.pdf>

2 Cleary et al. (2010). Methadone dose and neonatal abstinence syndrome—Systematic review and meta-analysis. *Addiction* 105, 2071–2084 doi:10.1111/j.1360-0443.2010.03120.x

3 McCarthy, J.J., et al., (2005). High-dose methadone maintenance in pregnancy: Maternal and neonatal outcomes. *American Journal of Obstetrics and Gynecology*, 193,606–610. doi: <http://dx.doi.org/10.1016/j.ajog.2005.03.072>

Buprenorphine, a partial opioid-agonist, is approved by the United States Food and Drug Administration for the treatment of opioid addiction in an outpatient office setting. Although not yet approved for use in pregnancy, increasing evidence on the impact of the mother and baby is informing the promise of buprenorphine's role as part of the continuum of care of treating opioid use disorders during pregnancy.<sup>4,5</sup>

In addition to the concern regarding withdrawal, the prevalence of hepatitis B, hepatitis C, and human immuno-deficiency virus (HIV) is elevated in women who are pregnant and have an opioid use disorder, primarily due to needle sharing and unsafe sex practices.<sup>6,7</sup> Women should be screened for these infections, and in the case of HIV infection, treatment should be initiated.

The management of an opioid use disorder in pregnancy is highly complex and attention must be focused on medication and the complicated psychological and social needs of these women. A high number of women with substance use disorders have histories of intimate partner violence, and other traumas (including childhood abuse), have a low level of education, are financially limited, and have difficult relationships with partners who may also have substance use disorders. The families that many of the women grew up in experienced multiple challenges, including a high prevalence of substance use disorders. Many of these women may also have co-occurring mental health

struggles, most commonly depression and bipolar disorder, and suffer from low self-esteem.<sup>8</sup>

Regardless of the source of the opioid exposure during pregnancy, women need to be informed of the possibility of NAS for the infant and provided information on how it will be managed and treated at the hospital of delivery. An unexpected admission to a Neonatal Intensive Care Unit (NICU) can cause crisis, stress, and guilt. Providing the mother and her support system, with an opportunity to prepare for NAS, can assist in preventing a crisis and can help her engagement in the caretaking of her infant.

## NEONATAL ABSTINENCE SYNDROME

There are many variables that impact if, how, and when an infant will experience withdrawal symptoms. These include:

- timing of the mother's most recent intake of opioid
- maternal metabolism
- placental metabolism
- infant metabolism and excretion
- maternal taking of other substances, including cigarettes, cocaine, hypnotics sedatives, and/or barbiturates<sup>9</sup>

Opioid withdrawal in a newborn causes central nervous system excitability or hyperirritability, such as tremors, stiff or rigid muscle tone, and vasomotor signs, as well as gastrointestinal signs, including vomiting

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4 Association of State and Territorial Health Officials (ASTHO). (2014). *Neonatal Abstinence Syndrome: How states can help advance the knowledge base for primary prevention and best practices of care*. Arlington, VA: Author. Retrieved from <http://www.astho.org/Prevention/NAS-Neonatal-Abstinence-Report/>

5 Jones H.E., et al.(2005). Buprenorphine versus methadone in the treatment of pregnant opioid-dependent patients: Effects on the neonatal abstinence syndrome. *Drug and Alcohol Dependence*, 79, 1-10. doi: <http://dx.doi.org/10.1016/j.drugalcdep.2004.11.013>

6 Yeung, K. R. (2001). Mother to infant transmission of hepatitis C virus. *Hepatology*, 34 (2), 223-229. doi: 10.1053/jhep.2001.25885

7 American Academy of Pediatrics. (2009). Hepatitis C. In L. K. Pickering, C.J. Baker, D.W. Kimberlin, & S.S. Long (Eds.), *Red book: 2009 Report of the Committee on Infectious Diseases* (28th ed. pp. 357-360). Elk Grove Village, IL: Author.

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8 Kaltenbach K. B. V., et al. (1998). Opioid dependence during pregnancy. Effects and management. *Obstetrics and Gynecology Clinics of North America*, 25,139-151. doi:10.1016/S0889-8545(05)70362-4

9 Hudak, M. L., Tan, R. C., Committee on Drugs, & Committee on Fetus and Newborn. (2012). Neonatal drug withdrawal. *Pediatrics*, 129, e540-e560. doi:10.1542/peds.2011-3212

and loose stools. The onset of the symptoms varies; however, infants exposed to heroin or other short-acting opioids will typically show symptoms within the first 48–72 hours after birth. Those exposed to methadone or buprenorphine, which are longer acting opioids, will often present symptoms later than 72 hours, but usually within the first 4 days. The severity and duration of the withdrawal symptoms can be influenced by exposure to other substances, including tobacco and barbiturates.<sup>4</sup> Poly-substance use may be more the rule for women with an opioid-use disorder, with two notable exceptions: (a) women who are in long-term recovery and receiving medication-assisted treatment (who become pregnant after beginning treatment), and (b) women whose opioid use was limited to prescribed opioids taken under medical supervision for pain management.

To assess the signs and severity of withdrawal in an infant, practitioners use a standardized scoring system such as the system first developed by Finnegan<sup>10</sup> and later modified by Jansson<sup>11</sup> and others. When this type of standardized scoring tool is used by well-trained healthcare professionals, the instrument enables the practitioner to make an assessment, identify the withdrawal symptoms, document the infant's withdrawal, and initiate the appropriate treatment regimen, when needed.<sup>12</sup> Increasingly, practitioners are teaching the mothers how to use the scoring tool, allowing the mother to actively participate in her infant's monitoring. Elevated scores indicate a clinically significant withdrawal, and the infant might be a candidate for pharmacologic

treatment.

At times, substance exposure is identified using toxicology screening of the newborn's urine and meconium (i.e., first stool), especially in cases in which the mother has not been in a substance-use disorder treatment program and has not been forthcoming with the medical team. Urine testing (i.e., urinalysis) generally reflects substance exposure within the past several days, depending upon the substance. Results of these tests are rapidly available; however, urinalysis produces a high rate of false-negative results due to the rapid clearance of most drugs from the newborn's system and the difficulty in obtaining the volume of urine need for testing from an infant in the first day of life. Meconium toxicology screens can reveal substance exposure during the previous several months of pregnancy. However, obtaining the meconium test results may take several days, by which time the mother and infant are likely to have been discharged. Umbilical cord tissue is another diagnostic for infant toxicology. One advantage of umbilical cord tissue sampling is that the cord is always available, where meconium can be missed due to excretion in utero. The results are available faster, which allows for better informed treatment and going home decisions. The test requires six inches of umbilical cord tissue and provides a longer histology of prenatal drug exposure, but may also detect medications used in labor and delivery.

Opioid withdrawal symptoms can mirror symptoms of other conditions in a newborn, such as infections, very low blood sugar, very low blood calcium, low thyroid hormone, and problems with the brain (e.g., cerebral palsy).<sup>6</sup>

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10 Finnegan, L.P., & Kaltenbach, K. (1992). Finnegan Neonatal Abstinence Scoring—Neonatal abstinence syndrome. In R. A. Hoekelman S.B. Friedman, N. M. Nelson, et al. (Eds.), *Primary pediatric care* (2nd ed.; pp. 1367-1378). St. Louis, MO: Mosby.

11 Jansson, L. M., Velez, M., & Harrow, C. (2009). The opioid exposed newborn: Assessment and pharmacologic management. *Journal of Opioid Management*, 5(1), 47-55. Retrieved from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2729086>

12 Sarkar, S., & Donn, S. (2006). Management of neonatal abstinence syndrome in neonatal intensive care units: A national survey. *Journal of Perinatology*, 26, 15–17. doi:10.1038/sj.jp.7211427



# NEONATAL ABSTINENCE SYNDROME (NAS) SCORING AND MANAGEMENT

The Finnegan Neonatal Abstinence Scoring System is the most commonly used scoring tool, although the original tool has been modified frequently.<sup>13</sup> Below is a modified Finnegan NAS Scoring form developed by Jansson, Velez, and Harrow<sup>11</sup> and further modified by the Fletcher Allan Hospital of Vermont. See Appendix A for an explanation of the scoring.

MRN	NAME	DOB
<b>SIGNS</b> Observations from past 3–4 hours. <b>Start new scoring sheet each calendar day.</b>		Birth Weight: _____ grams (x 90% = _____ grams) Daily Weight: _____ grams
<b>DATE:</b>	<b>SCORE</b>	<b>TIME</b>
High pitched cry: inconsolable >15 sec. OR intermittently for <5 min.	2	
High pitched cry: inconsolable >15 sec. AND intermittently for ≥5 min.	3	
Sleeps <1 hour after feeding	3	
Sleeps <2 hours after feeding	2	
Sleeps <3 hours after feeding	1	
Hyperactive Moro	1	
Markedly hyperactive Moro	2	
Mild tremors: disturbed	1	
Moderate–severe tremors: disturbed	2	
Mild tremors: undisturbed	1	
Moderate–severe tremors: undisturbed	2	
Increased muscle tone	1–2	
Excoriation (indicate specific area): _____	1–2	
Generalized seizure	8	
Fever ≥37.2°C (99°F)	1	
Frequent yawning (≥4 in an interval)	1	
Sweating	1	
Nasal stuffiness	1	
Sneezing (≥4 in an interval)	1	
Tachypnea (rate >60/min.)	2	
Poor feeding	2	
Vomiting (or regurgitation)	2	
Loose stools	2	
≤90% of birth weight	2	
Excessive irritability	1–3	
Total score		
Initials of scorer		

Printed Name	Signature/Title	Initials	Printed Name	Signature/Title	Initials

13 Sarkar, S., & Donn, S. (2006). Management of neonatal abstinence syndrome in neonatal intensive care units: A national survey. *Journal of Perinatology*, 26, 15–17. doi:10.1038/sj.jp.7211427



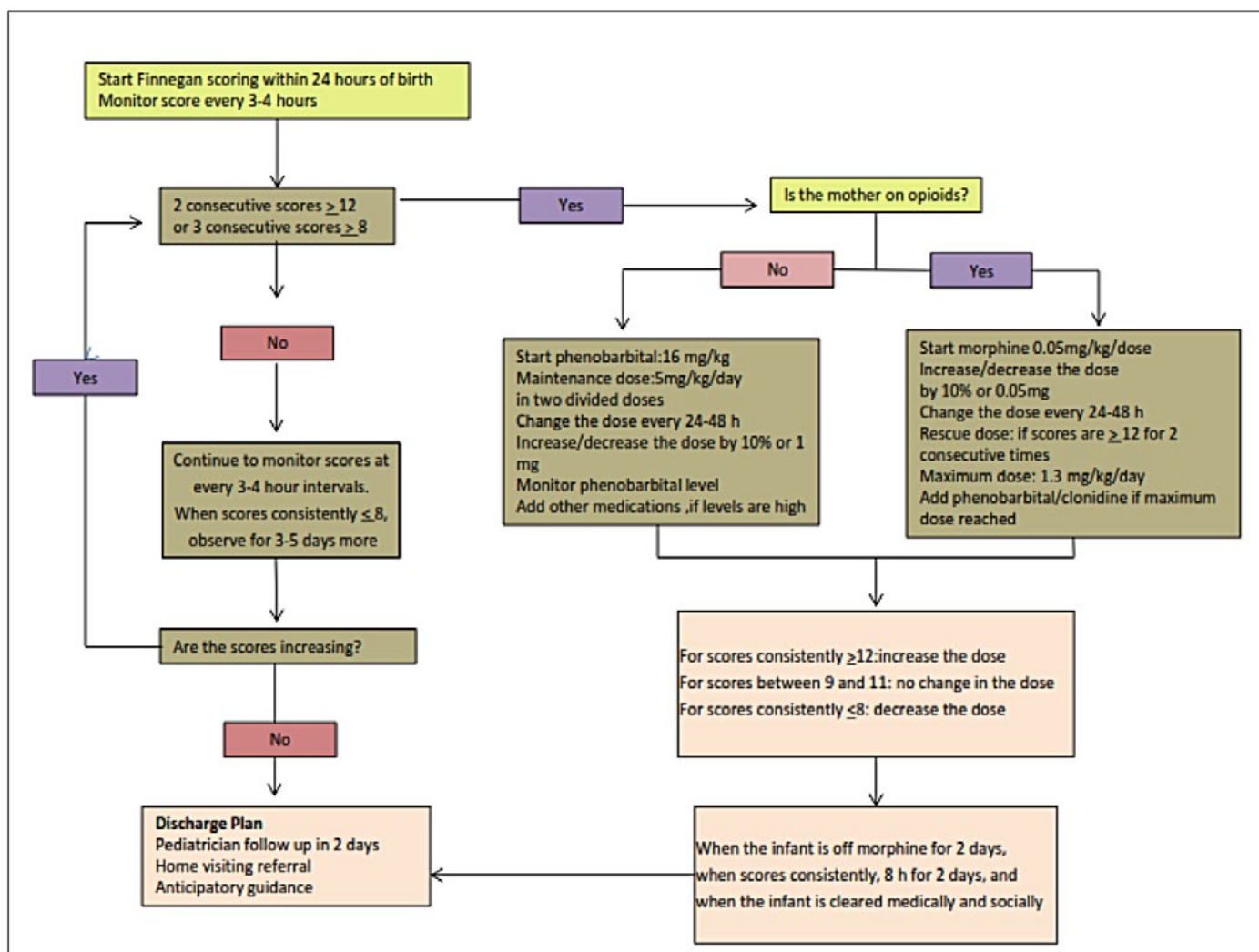


Figure 1. A sample hospital management plan for neonates with NAS. Adapted from Kocherlakota (2014)<sup>14</sup>

14 Jansson, LM, Velez, M, Harrow, C., (2009). The opioid exposed newborn: assessment and pharmacologic management. Journal of Opioid Management, 5 (1), 47-55.

## TREATMENT OF NAS

Approximately 50% –75% of infants exposed to opioids before birth will require pharmacologic treatment for opioid withdrawal. At the delivery of a known opioid-dependent woman, naloxone should be avoided in resuscitation of the infant because the drug can precipitate seizures.

Initial treatment of infants showing signs of withdrawal is focused on supportive care. It is important that this treatment approach is standardized within care settings. Supportive care can include creating a low-stimulation environment that is dark and quiet, swaddling the infant to inhibit self-stimulation, and providing frequent/on-demand feedings to reduce infant stress.<sup>6</sup> Other beneficial strategies include encouraging skin-to-skin contact for comfort and promotion of the infant's attachment to the mother/caregiver, as well as other comforting techniques such as rocking or swaying the infant.<sup>15</sup> Providing frequent feedings helps to address the infant's hydration level, although many infants will require intravenous fluids to maintain adequate hydration. Frequent feedings also address the high energy expenditures associated with withdrawal (thus a need for increased calorie intake) and a symptom of withdrawal where infants engage in excessive sucking but with poor feeding.<sup>16</sup> Teaching these techniques to families and caregivers, including careful, detailed demonstrations, is an important factor in the success of the supportive care approach.

Breastfeeding is encouraged in cases when the mother is receiving medication-assisted treatment and has no contraindications, such as positive HIV status. However, the infant's weight must be carefully

monitored to ensure that the infant continues to gain weight. Breastfeeding has been associated with specific benefits for opioid-exposed infants, including less severe NAS and reduced need for pharmacologic intervention.<sup>17,18,19</sup>

Pharmacologic therapy is indicated for infants who have greater severity of symptoms of exposure and in cases in which the infant has severe vomiting, diarrhea, or excessive weight loss. Infants may be treated with a variety of medications including short-acting opioids (e.g., morphine sulfate) or long-acting opioids (e.g., methadone).<sup>6</sup> The majority of physicians in the United States use morphine or methadone in the treatment of NAS:<sup>11</sup>

*...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.<sup>6</sup>*

The Perinatal Quality Collaborative of North Carolina (PQCNC) began a quality improvement project in 2014 for NAS. Across the state, 29 hospitals have enrolled in the quality improvement effort. The project's primary aim is to help hospitals provide a standardized, multidisciplinary approach to the identification, evaluation, treatment, and discharge of infants who have experienced NAS. This protocol includes the infants' families. Each hospital team has engaged in an intensive process of *Plan, Do, Study, Act*,

15 Kocherlakota, P. Neonatal Abstinence Syndrome. *Pediatrics* 2014;134:e547–e56. doi:10.1542/peds.2013-3524

16 Sublett, J. (2013). Neonatal Abstinence Syndrome therapeutic interventions. *American Journal of Maternal/Child Nursing*, 38(2), 102-107. doi:10.1097/NMC.0b013e31826e978e

17 Abdel-Latif, M. E., Pinner, J., Clews, S., Cooke, F., Lui, K., & Oei, J. (2006). Effects of breast milk on the severity and outcome of neonatal abstinence syndrome among infants of drug dependent mothers. *Pediatrics*, 117, e1163–e1169. doi: 10.1542/peds.2005-1561

18 Isemann, B., Meinen-Derr, J., & Akinbi, H. (2011). Maternal and neonatal factors impacting response to methadone therapy in infants treated for neonatal abstinence syndrome. *Journal of Perinatology*, 31(1), 25–29. doi:10.1038/jp.2010.66

19 O'Connor, A.B., Collett, A., Alto, W. A., & O'Brien, L. M. (2013). Breastfeeding rates and the relationship between breastfeeding and neonatal abstinence syndrome in women maintained on buprenorphine during pregnancy. *Journal of Midwifery Women's Health*, 58(4), 383-388. doi:10.1111/jmwh.12009

to determine the most effective standardized practices for their respective setting. The early, important outcomes of the PQCNC effort to standardize NAS protocols have included reducing the length of stay in the hospital for the infant and family. For more information: <http://www.pqcnc.org/node/13348>

## LOCATION OF CARE IS SPECIFIC TO THE HOSPITAL

The majority of hospitals that monitor infants for signs and symptoms of withdrawal conduct such assessment on the following units:

- Mother/Baby
- Newborn Nursery
- Neonatal Intensive Care Unit (NICU)
- Special Care Nursery or Level II nursery
- Pediatric ward

If a delivery hospital does not have a NICU or is otherwise not equipped to provide pharmacologic treatment to the infant, the infant should be transferred to a hospital that is able to provide appropriate treatment for the infant.

## DISCHARGE CONSIDERATIONS

A new mother undergoes significant stress during the post-partum period, and this stress may be heightened for a woman who has an opioid-use disorder or is in recovery from an opioid-use disorder. Therefore, it is essential for the well-being of the mother and infant that a comprehensive discharge plan is developed to address critical factors, including maternal substance-use disorder treatment, a safe living environment, and parenting and community support. In addition, if not already involved, the mother should

receive referrals to Care Coordination for Children (CC4C) and the local home-visiting program. See “[Services for Women with Opioid Exposed Pregnancies in North Carolina](#)” referral agencies.

## ANTICIPATORY GUIDANCE

Caregivers of infants and children exposed to substances (e.g., opioids, alcohol) during their fetal development, will need to be aware of developmental milestones and track which milestones the child has achieved and those that may be lagging behind. Making the child’s pediatrician aware of all exposures will assist him or her in tracking the child’s development, including behavioral development. Referrals to specialists, including developmental-behavioral pediatricians, can help identify and assess other areas in which the child may need support. Areas of focus for the pediatrician with the infant will include:

- motor deficits and cognitive delays;
- hyperactivity, impulsivity, and attention-deficit in preschool-aged children, and in addition to school absence, school failure, and other behavioral problems in school-aged children; and
- growth and nutritional benchmarks to identify failure to thrive and short stature.<sup>15</sup>

Caregivers of infants should give special attention to safe sleep practices (e.g., placing infant on back, removing toys, blankets, and pillows from cribs) and the elevated risk of Sudden Infant Death Syndrome (SIDS) for a substance exposed infant, should be



emphasized.<sup>20,21,22</sup>

Environmental factors also have an impact on child development. Thus, an important area of focus is identifying the available supports and linking caregivers with those supports to promote a stable, violence free, nurturing home environment. The earlier a need is identified and supports are offered, the better the long-

term outcomes for the child.<sup>23</sup>

*The complexity and challenging nature of the home atmosphere should never be underestimated in these situations. The importance of an optimal home environment for the global development of these children should be emphasized to all parents.<sup>15</sup>*

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20 U.S. Department of Health and Human Services. (2006). *The health consequences of involuntary exposure to tobacco smoke: A report of the Surgeon General*. Atlanta, GA. Retrieved from <http://www.surgeongeneral.gov/library/reports>

21 U.S. Department of Health and Human Services. (2014). *The health consequences of smoking—50 years of progress: A report of the Surgeon General*. Atlanta, GA. Retrieved from <http://www.surgeongeneral.gov/library/reports>

22 OLeary, C., Jacoby, P., et al. (2012). Maternal alcohol use and sudden infant death syndrome and infant mortality excluding SIDS. *Pediatrics*.131, e770-e778. doi:10.1542/peds.2012-1907

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23 Hebbeler, K., Spiker, D., et al. (2007). *Early intervention for infants and toddlers with disabilities and their families: Participants, services and outcomes. Final report of the National Early Intervention Longitudinal Study*. U.S. Department of Education, Office of Special Education Programs.

## APPENDIX A

### Neonatal Abstinence Syndrome (NAS) Scoring Explanation

*Reprinted with permission from Treatment of Opioid Dependence in Pregnancy: Vermont Guidelines.*

#### Assessment & Documentation

- The infant is scored at 2 hours of age and every 3-4 hours prior to a feeding
- The NAS score will be recorded for the 3-4 hour period immediately before the scoring activity  
Signs and symptoms are documented on the NAS form and totaled for a score

- The infant should be quieted if irritability or crying is present. This will insure that the jitteriness, if present, is due to withdrawal rather than agitation.

Hyperactive Moro: arms stay up 3-4 sec with or without tremors (Score = 1)

Markedly Hyperactive Moro: arms stay up > 4 sec with or without tremors (Score = 2)

#### Sleeping

For every sign except sleeping, a score of 0 = not present

Use the longest single continuous time sleeping since last feeding

Sleeps 3 or more hours continuously  
(Score = 0)

Sleeps 2-3 hours after feeding (Score = 1)

Sleeps 1-2 hours after feeding (Score = 2)

Sleeps less than 1 hour after feeding  
(Score = 3)

When repeating a score within 1 hour after a feeding: Use the same sleep score obtained before the feeding.

#### Moro Reflex

Cup infant's head in your hand and raise his/her head about 2-3 inches above the mattress, then drop your hand while holding the infant.

#### Tremors

- Tremors = jitteriness

Involuntary movements that are rhythmical

If the infant is asleep, it is normal to have a few jerking movements of the extremities

Mild tremors: hands or feet only, last up to 3 seconds (Score = 1)

Moderate-severe tremors: arms or legs, last more than 3 seconds

(Score = 2)

Undisturbed: Tremors that occur in the absence of stimulation

#### Increased Muscle Tone

While the infant is lying supine, extend and release the infant's arms and legs to observe for recoil

Infant supine, grasp arms by wrists and gently lift infant, looking for head lag



Difficult to straighten arms but is possible; head lag is present (Score =1)

No head lag noted or arms or legs won't straighten (Score = 2)

### **Excoriation**

Red or broken skin from excessive rubbing (eg: extremities or chin against linens)

Skin red but intact or is healing and no longer broken (Score = 1)

Skin breakdown present (Score = 2)

### **Sweating**

Wetness felt on the infant's forehead, upper lip (Score = 1)

Sweating on the back of the neck may be from overheating such as swaddling

### **Nasal Stuffiness**

Any nasal noise when breathing (Score =1 )

Runny nose may or may not be present

### **Sneezing**

Infant sneezes 4 or more times in the scoring interval of 3-4 hours (Score =1)

### **Tachypnea**

- The infant must be quieted if crying first; count respirations for full minute

Respiratory rate > 60/min (Score = 2)

### **Nasal Flaring**

Outward spreading of the nostrils during breathing (Score = 1)

### **Poor Feeding**

Poor feeding is defined as any 1 of the following (Score = 2)

Infant demonstrates excessive sucking prior to a feeding yet sucks

infrequently while feeding and takes a small amount of formula/

breast milk.

Demonstrates an uncoordinated sucking reflex (difficulty sucking and swallowing)

Infant continuously gulps while eating and stops frequently to breathe.

Inability to close mouth around bottle/breast

Feeding takes more than 20 minutes

### **Regurgitation/Vomiting**

Frequent regurgitation (vomits whole feeding or vomits 2 or more times during feed) not associated with burping (Score = 2)

### **Loose Stools**

Infant has a stool that is at least half liquid (Score = 2)

When repeating a score within 1 hour after a feeding: Use the same stool score obtained before the feeding.



### **Current Weight < 90% of Birth Weight**

Infant is weighed once a day and then that score is carried through the rest of the day

- Weight is < 90% of birth weight (Score = 2)

Continue to score until infant gains weight and is > 90% of birth weight Use workspace at top of form

Infant becomes fussy or irritable with light, touch, or handling, despite attempt to console

Consoling calms infant in 5 minutes or less (Score = 1)

Consoling calms infant in 6-15 minutes (Score = 2)

Consoling takes more than 15 minutes or no amount of consoling calms infant (Score = 3)

### **Excessive Irritability**

Distinct from, but may occur in conjunction with crying

Marked by frequent grimacing, excessive sensitivity to sound and light.