Medication Assisted Treatment For Opioid Dependent Women

BrookStone Medical Center

“Access to medication-assisted treatment can mean the difference between life or death”

- Michael Botticelli, October 23, 2014 Director, White House Office of National Drug Control Policy
Clinical Definition of Opioid Dependence

- Addiction is defined as a chronic, relapsing brain disease
- It is considered a brain disease because drug use changes the brain structure and how it works
- Characterized by compulsive drug seeking and use, despite harmful consequences.
Medication Assisted Treatment (MAT)

- Medications combined with behavioral counseling for a “WHOLE PATIENT”
- This combination has been shown to provide the best long term outcome for individuals 18 years and older with Opioid Dependence

“Not informing patients about the effectiveness of treating addiction with medication is like a doctor not telling a cancer patient about chemotherapy... Scientifically, this is a settled matter”

- Dr. Mark Willenbring, National Institute for Alcohol Abuse and Alcoholism (former director)
Medication-Assisted Treatment (MAT) is the use of medication, combined with counseling and behavioral therapies, to provide a whole patient approach to the treatment of substance use disorders. (http://www.dpt.samhsa.gov)

2001 SAMHSA begins governing use of MAT treatments (formerly overseen by FDA)

Ensures all treatment centers are accredited (CARF, Joint Commission etc.), to ensure highest patient care practices.

MAT centers are monitored and accredited by:
- Substance Abuse and Mental Health Administration (SAMHSA)
- Approved Accrediting Body
- DEA
- Utah Pharmacy Board
- State of Utah Office of Licensing
What Daily Treatment Looks Like

MAT Services:

- History and Physical (on intake and yearly)
- STD Screening
- Pregnancy Testing (on intake, yearly, and when tapering)
- Naloxone Kit Training
- Daily clinic visits to receive medication
- Crisis Support
- Suicide - Homicide Screening (ongoing)
- Random UA, (results reviewed with client)
MAT SERVICES Continued...

- Individualized Treatment Plans
- Relapse Prevention Training
- Counseling sessions: Individual, Couple, Group
- Emotional Recovery
- Anxiety & Stress
- Grief & Loss
- Improving Social Skills
- Improving Family Relationships
- Recovery Group Support
- Life Skills Classes
- WRAP
- Resume and Interviewing Skills Class
- Budgeting Class
- Medical Education classes
- Medication Interactions

Under DSM-5 diagnostic criteria for opioid use disorder—
“A person receiving MAT as directed is no longer diagnosed in active ‘addiction.’”
Take Home Medications May Be Offered...

- Once “clean” UA’s and program time have been established
- Medications allowed to be kept at home MUST be locked in a safe place away from children.
- Clients are instructed to keep medication in safe place, locked and out of the reach of children, pets and other people.
- Children who take medications may overdose and die
CLIENT AND COMMUNITY SAFETY DRIVE ALL TAKE HOME DECISIONS

- Take home privileges are monitored based on community safety, medication safety and possible medication diversion.

- All take home medications are subject to random call backs

- Take Home medication is considered a client privilege NOT a client right

- All medication is dispensed and labeled by licensed Pharmacist

- Any take home request outside of the recommended schedule must be reviewed by the state and federal government prior to approval
Coordinating Care

- Opioid Treatment Programs in Utah have access to DOPL (we know what you are prescribing)
- Opioid Treatment Programs NOT REPORT TO DOPL (you do not know what we are prescribing)
- Each OTP in UTAH is in communication to verify that clients are NOT dosing in multiple clinics
- Clients are informed missed doses are NOT available in the ER
Care Coordination is STRONGLY encouraged

- Allows better communication among medical personal
- Allows better understanding of “whole picture” of client
- Allows better coordination of medication prescribing and monitoring
Reasons clients refuse to allow coordination of care

Clients Fear:
- Loss of services
- Medication being discontinued
- Being discharged
- Family being informed
- Employer being informed
- Fear of being labeled
- Fear of loosing new born/children
Optimal Response from Opioid agonist in Maintenance Treatment

- Prevention of onset of withdrawal syndrome for 24 hours or more
- Reduction or elimination of drug hunger or craving
- Blockade of euphoric effects of illicit self-administered opioids
- Allows clients to focus on behavioral therapies and begin to repair situations damaged by prior substance use.
Pregnancy, Postpartum & Breastfeeding

“If you’re pregnant and using drugs such as heroin or abusing opioid prescription pain killers, its important that you get help for yourself and your unborn baby. Methadone maintenance treatment can help you stop using those drugs. It is safe for the baby, keeps you free of withdrawal, and gives you a chance to take care of yourself.”

- SAMHSA
Pregnant women better manage their addiction while avoiding health risks to both mother and baby such as:

- Reduced STD by decreasing risky sexual behaviors and sexual exploitation
- Decrease in spread of HIV and HEP C from needle sharing
- Reduction in violence, abuse and rape
- Prevents symptoms of opioid withdrawal which causes the uterus to contract and may bring on miscarriage or premature birth
Methadone is the only drug used in MAT approved for women who are pregnant or breastfeeding.

Infant withdrawal usually begins a few days after birth but may begin two to four weeks after birth.

Research has shown that the benefits of breastfeeding outweigh the effect of the small amount of methadone that enters the breast milk.

New guidelines advocate for treatment to continue at a minimum of pregnancy through 1 year postpartum.
Advancing the Care of Pregnant and Parenting Women With Opioid Use Disorder and Their Infants: A Foundation for Clinical Guidance

Electronic Access  This publication, Docket No. SAMHSA-2016-0002, may be downloaded from http:// www.regulations.gov. The Federal Register Notice serves as the executive summary for this report.
The Report

- SAMHSA, with oversight by a steering committee of 13 other federal agencies and offices, has undertaken to develop a critically needed document: a clinical guide (hereafter referred to as the guide) that will inform health providers’ decisions regarding the evaluation, care, and treatment of pregnant and parenting women with opioid use disorder and their opioid-exposed infants.

Assistant Secretary for Planning and Evaluation (ASPE)
Bureau of Prisons (BOP)
Centers for Disease Control and Prevention (CDC)
Centers for Medicare & Medicaid Services (CMS)
Department of Defense (DOD)
Department of Veterans Affairs (VA)
Food and Drug Administration (FDA)
Health Resources and Services Administration (HRSA)

Agencies and Offices Participating in the Federal Steering Committee
Indian Health Service (IHS)
National Institute on Drug Abuse (NIDA)
Office of the Assistant Secretary for Health (OASH)
Office of National Drug Control Policy-the White House (ONDCP)
Office of Women’s Health,
U.S. Department of Health and Human Services (OWH)
Substance Abuse and Mental Health Services (SAMHSA)
BACKGROUND

The current Diagnostic and Statistical Manual of Mental Disorders (DSM-5) definition of opioid use disorder (American Psychiatric Association, 2013) is in use throughout this document.

- Opioid use disorder is a chronic disease with potential serious negative consequences for the individual, the family, and society as a whole.
- Prenatal maternal opioid use increased from 2000 to 2009 from 1.19 to 5.63 per 1,000 hospital births per year (Patrick et al., 2012).
- From 2009 to 2012 the incidence of neonatal abstinence syndrome (NAS), a withdrawal syndrome found frequently in newborns following prenatal exposure to opioids, significantly increased from 3.4 to 5.8 per 1,000 hospital births per year, a nearly twofold increase (Patrick, Davis, Lehmann, & Cooper, 2015).
- The need to treat individuals with opioid use disorder has exceeded treatment capacity each year. The number of people needing treatment has increased from 634.1 per 100,000 in 2003 to 891.8 per 100,000 in 2012 (Jones et al., 2015).
Opioid use disorder is associated with higher rates of HIV and hepatitis C infection, overdose, and trauma.

Opioid use disorder with medication assisted treatment (MAT) can reduce the risk behaviors associated with these problems (Degenhardt et al., 2009; Gowing, Hickman, & Degenhardt, 2013; Lepere et al., 2001; Marsch, L. 1998; Soyka et al., 2012; Tsui et al., 2014).

Without treatment, women with opioid use disorder who become pregnant face increased risks of preterm delivery and low birth weight (Binder and Vavrinková, 2008).

Mothers who inject drugs are at risk of transmitting HIV and hepatitis C to infants (Fiore et al., 2004; Resti et al., 2002).

Parenting women with opioid use disorder must meet the needs of an infant with opioid exposure and possibly NAS often while coping with unstable housing, limited income, and few social supports (Fraser, Barnes, Biggs, & Kain, 2007), and other children in the household may be impacted.
• In homes where alcohol and substance use is ongoing, there is a higher risk of domestic violence and other crime that, in some cases, increases the risk of injury or death to a child (Huxley and Foulger, 2008).

• Despite the longstanding scientific consensus that opioid use disorder is a chronic brain disease, legal and policy barriers based on criminalization of drug use are often barriers to treatment and prenatal care for both women and healthcare providers.

• The consequences of untreated opioid use disorder in pregnant and parenting women underscore the urgent need to provide clinicians with clear, practical, and concrete guidance on the optimal strategies to identify and intervene for both mother and child.

• Such guidance must include the management of NAS, a treatable medical condition, based on existing research evidence as well as clinical experiences deemed appropriate and applicable for a variety of settings.
The ultimate goal has been to produce a patient-focused clinical guide that considers the maternal–fetal and maternal–infant dyad as a unit and is comprehensive enough to be useful in daily clinical practice.

This process and the findings made maximum use of existing guidelines to avoid replicating work already completed and, as expected, are consistent with the few established recommendations that exist for professionals caring for pregnant and parenting women with opioid use disorder and their children.

One of the principal challenges to developing guidance for the management of pregnant and parenting women with opioid use disorder and their infants is the absence of placebo-controlled trials in this population.

Moreover, both opioid use disorder and its treatment are subject to misunderstanding and bias on the part of both professionals and the public. Add to this the enormous social and legal complexities associated with opioid use in general, and more specifically in pregnancy, and it is no longer surprising that comprehensive national guidance has not yet been produced.
Pregnancy Counseling

- A pregnant woman with opioid use disorder should be screened for other substance use at presentation for care (1) by interview, (2) by self-completed formal screening instrument, (3) by urine toxicology, and (4) by review of state prescription drug monitoring database.

- A pregnant woman with opioid use disorder should be screened for other substance use at the time of delivery (1) by interview and (2) by urine toxicology.

- A pregnant woman with opioid use disorder should receive Screening, Brief Intervention, and Referral to Treatment (SBIRT) for possible other substance use.

- A pregnant woman with opioid use disorder should be screened for comorbid mental health conditions at presentation of care.
Pregnancy Counseling cont.

- The prescription drug monitoring program information of a pregnant woman with opioid use disorder should be checked and monitored as part of her routine management.

- When information about substance use is gathered from a pregnant woman with opioid use disorder, she should receive education and counseling about possible (1) social consequences and (2) medical consequences for herself and her infant of MAT and illicit substance use.
Pregnancy Counseling cont.

- A pregnant woman with opioid use disorder who requires (1) benzodiazepines, (2) selective serotonin reuptake inhibitors (SSRIs), (3) amphetamines, and (4) other pharmacotherapy for comorbid mental health conditions should be educated about the impact of this intervention on her baby’s risk for NAS and on her lactation options and should be educated about the risks and benefits of using or not using this pharmacotherapy to treat her condition.

- A pregnant woman with opioid use disorder who uses other substances should be informed of the impact (1) illicit substances, (2) misuse of licit substances, (3) tobacco, (4) alcohol, (5) benzodiazepines, (6) amphetamines, and (7) SSRIs has/have on the severity of NAS and other effects on the infant.

- A pregnant woman with opioid use disorder and untreated comorbid mental health conditions should be informed about the possible impact of her condition on NAS.

- A pregnant woman with opioid use disorder and comorbid (1) depression and (2) anxiety treated with an SSRI should be informed that this pharmacotherapy is independently associated with NAS and may worsen her baby’s NAS.
A pregnant woman with opioid use disorder should be started on (1) methadone or (2) buprenorphine.

A woman on buprenorphine (or buprenorphine/naloxone) or methadone for opioid use disorder who states the intention to become pregnant should be advised of the likelihood of her newborn’s experiencing NAS if the woman conceives and gives birth while taking buprenorphine or methadone.

A woman on buprenorphine (or buprenorphine/naloxone) or methadone for opioid use disorder who states the intention to become pregnant should be advised that there are no known increased risks of birth defects associated with buprenorphine or methadone at this time.

A pregnant woman with opioid use disorder should be encouraged to stop smoking.

(These indications were rated and supporting literature was provided based on data available at the time of the RAM meeting. The research papers used for the RAM process were selected according to a methodology outlined in Chapter II. Other federal agencies and offices apply different methodologies to the evidence or research used to support their decision-making. The clinical guide to be developed based on recommendations in this report will have greater latitude to include additional relevant source material.)
Dose Adjustment or Change of Medications During Pregnancy

- A pregnant woman previously stable on buprenorphine (or buprenorphine/naloxone) or methadone for opioid use disorder should be assessed for a dose increase if she complains of (1) withdrawal symptoms or (2) cravings and (3) should receive additional behavioral interventions.

- A pregnant woman stable on buprenorphine (or buprenorphine/naloxone) or methadone for opioid use disorder who wants to decrease her dose so her baby will have less withdrawal at birth should be advised that the mother’s dose of buprenorphine or methadone is not associated with the intensity of NAS and should be told about other evidence-based strategies for minimizing NAS.
A pregnant woman stable on buprenorphine (or buprenorphine/naloxone) or methadone for opioid use disorder who wants to decrease her dose so her baby has less withdrawal should be advised (1) that smoking cessation may reduce opioid withdrawal her baby may experience, (2) that cessation of other substance use may reduce opioid withdrawal her baby may experience, (3) that breast-feeding may reduce opioid withdrawal her baby may experience, and (4) that nonpharmacologic interventions for the infant may reduce opioid withdrawal her baby may experience.

A pregnant woman stable on methadone who wants to switch to buprenorphine so her baby will have milder or shorter neonatal opioid withdrawal should not be switched to buprenorphine.
Medically Supervised Withdrawal

- A pregnant woman with opioid use disorder should be advised that detoxification (defined as medically supervised withdrawal) is associated with high rates of relapse and is not the recommended course of treatment.

- A pregnant woman stable on buprenorphine (or buprenorphine/naloxone) or methadone for opioid use disorder who wishes to be withdrawn from medication should be advised that medically supervised withdrawal from medication-assisted treatment is not advisable during pregnancy due to the stress on the fetus and risk of relapse.

- A pregnant woman with opioid use disorder who refuses medication-assisted treatment may undergo detoxification (medically supervised withdrawal) during the second trimester if the benefits outweigh the risk.
Treatment for Pregnant Women Who Relapse to Substance Use

- A pregnant woman, previously stable on buprenorphine (or buprenorphine/naloxone) or methadone for opioid use disorder, who relapses to opioid use (1) should have her dose assessed for effectiveness, (2) should receive additional behavioral interventions, and (3) should be referred for a higher level of care.

- A pregnant woman on buprenorphine (or buprenorphine/naloxone) or methadone for opioid use disorder who has concurrent ongoing other substance use (e.g., alcohol, tobacco, illicit substances) (1) should receive behavioral interventions for these substance use disorders, (2) should receive pharmacologic interventions for these substance use disorders, and (3) should be referred for a higher level of care.

- A woman who discontinues naltrexone after becoming pregnant and relapses to opioid use should begin use of buprenorphine or methadone.
Pain Relief

- A woman who is stable on buprenorphine or methadone for opioid use disorder should receive education about intra-and postpartum pain relief before delivery.

- If a pregnant woman with opioid use disorder and not currently maintained on either buprenorphine or methadone is in labor, she should be offered an epidural and a short acting opioid analgesic to manage her pain.

- A woman who is stable on buprenorphine (or buprenorphine/naloxone) or methadone for opioid use disorder and requests pain relief during labor (1) can receive epidural or spinal anesthesia, (2) should not receive butorphanol, nalbuphine, or pentazocine, and (3) may require higher doses of opioid analgesics to experience pain relief, whether she is having a vaginal delivery or a C-section.
A woman who is stable on buprenorphine (or buprenorphine/naloxone) or methadone for opioid use disorder and requests pain relief for postpartum days 1 to 3 or after a C-section may require higher doses of opioid analgesics to experience pain relief.
Treatment for Infants Exhibiting NAS

- An infant born to a mother who misused opioids (analgesic or heroin) throughout her pregnancy should be managed with a formal protocol for NAS.

- The management of an infant exhibiting NAS should be informed by an interview with the mother about other substance and pharmacotherapy use during pregnancy and the clinical status of the infant.

- The management of an infant exhibiting NAS should be informed by toxicology screening of the mother to assess for other substance use.

- Infants at risk for NAS could have toxicology testing on (1) meconium, (2) urine, and/or (3) umbilical cord tissue.

- An infant who exhibits mild signs of NAS should be managed with nonpharmacologic interventions and monitored for development of more severe symptoms in a formal protocol for NAS.

- An infant who exhibits moderate to severe signs of NAS should be managed with nonpharmacologic interventions in a formal protocol for NAS and, when needed, (1) pharmacotherapy with liquid oral morphine or (2) pharmacotherapy with liquid oral methadone.
An infant who exhibits moderate to severe signs of NAS should be managed with nonpharmacologic interventions in a formal protocol for NAS and, when needed, (1) adjuvant therapy with clonidine or (2) adjuvant therapy with phenobarbital.

An infant with NAS that cannot maintain adequate hydration or loses weight despite optimal management should have a medical examination to rule out other potential medical conditions along with consideration given to a possible transfer to a neonatal intensive care unit.

On discharge, an infant treated for NAS should have (1) home visitation and early intervention services, (2) a home nursing consult, and (3) a social work consult.
On discharge, the mother of an infant treated for NAS should be (1) educated about signs of withdrawal, and (2) the mother should receive an early referral to a pediatrician who is knowledgeable about NAS and accessible from the time of infant hospital discharge.

An infant who required pharmacotherapy for NAS will benefit from a stable and enriched home environment.

A mother who reports her baby, who completed a taper of opioids for NAS, is fussy and having loose stools should have the baby evaluated by a medical provider.
Counseling for Potential Neurodevelopment Issues

- A mother who is worried about the effects of intrauterine exposure to the buprenorphine or methadone used to treat her opioid use disorder should be given information on (1) how NAS is diagnosed and treated, (2) the absence of known long-term consequences, and (3) the importance of maternal drug treatment such that the benefits to her baby outweigh the risks of not receiving treatment.

- A mother who requests a developmental assessment for her child who had NAS (1) should be interviewed about her concerns, (2) should receive ongoing developmental screening for her child, (3) should have her child screened for early intervention purposes, and (4) should be informed that enriching the child’s home environment may bring about improvement.
Counseling for Potential Neurodevelopment Issues cont.

- A mother whose child has developmental delays (1) should be interviewed about her concerns, (2) should receive ongoing developmental screening for her child, (3) should have her child screened for early intervention purposes, and (4) should be informed that enriching her child's home environment may bring about improvement.

- A mother who is worried that her history of opioid use disorder will make her baby more likely to have a substance use disorder should be counseled that there are genetic and social factors that increase the risk of addiction in children of people with substance use disorders and that a stable, healthy home environment can reduce that risk.
A mother who is worried that NAS will make her baby more likely to have a substance use disorder in adulthood should be counseled that there are genetic and social factors that increase the risk of addiction in children of people with substance use disorder and that a stable, healthy home environment can reduce that risk.

Addiction Risk

A mother who is worried that NAS will make her baby more likely to have a substance use disorder in adulthood should be told that future addiction is not a known consequence of NAS.
Dose Adjustment or Change of Medications After Delivery and Issues Relating to Breastfeeding

- A woman on buprenorphine or methadone who has no contraindications should be encouraged to breastfeed her baby.
- A woman on buprenorphine or methadone who has recently given birth and is now experiencing drowsiness and falling asleep holding her baby should be assessed for (1) medical illness, (2) relapse to substance use, and (3) dose adjustment.
- A new mother who is stable on buprenorphine or methadone and complains of cravings should (1) be assessed for dose adjustment and (2) receive additional behavioral intervention.
- A new mother who is stable on buprenorphine or methadone but being instructed/required by her family/supportive housing/corrections officer to discontinue buprenorphine or methadone should continue to take buprenorphine or methadone.
- These indications are meant to capture clinical decision points. The possible legal and social consequences to the patient and how to address them will be discussed in the clinical guide.
- A new mother who is bottle feeding her infant and is stable on buprenorphine or methadone who chooses to discontinue her buprenorphine or methadone and begin extended-release injectable naltrexone (1) may attempt to withdraw from buprenorphine or methadone under close supervision and with increased behavioral supports and (2) should be counseled continue bottle feeding her infant.
Treatment for New Mothers Who Relapse to Substance Use

- A new mother who was previously stable on buprenorphine or methadone but has relapsed to opioid use (1) should be assessed for dose adjustment, (2) should receive additional behavioral intervention, and (3) counseled on lactation options.

- A new mother who is breastfeeding her infant and who was previously stable on buprenorphine, methadone, or naltrexone but has relapsed to benzodiazepine/cocaine/methamphetamine use should be (1) assessed for both additional behavioral intervention and dose adjustment and (2) advised to discontinue breastfeeding.
The ultimate goal of MAT is full recovery, including:

- Improve patient survival
- Increase retention in treatment
- Decrease illicit opiate use
- Decrease criminal activity among people with substance use disorders (Ball & Ross)
- Increase patients ability to gain and maintain employment
- Improve birth outcomes among women who have substance abuse disorders and are pregnant
- Lowering persons risk of contracting HIV (Bourne, ’88, Novick ‘90, Metzger ‘93)
- Reduce potential for relapse (Ball & Ross ‘91)
- Reduction death rates (Grondblah, ’90)
- Reduction of IV drug use (Ball & Ross ’91)
“Opioid dependence and addiction are most appropriately understood as a chronic medical disorder, like hypertension, schizophrenia, and diabetes. As with those other diseases, a cure for drug addiction is unlikely, and frequent recurrences can be expected; but long-term treatment can limit the disease’s adverse effects and improve the patient’s day-to-day functioning.”

- Thomas R Kosten, MD and Tony P George MD 2002
Sources cont.


Sources

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- The Neurobiology of Opioid Dependence Thomas R Kosten, MD and Tony P George MD 2002.