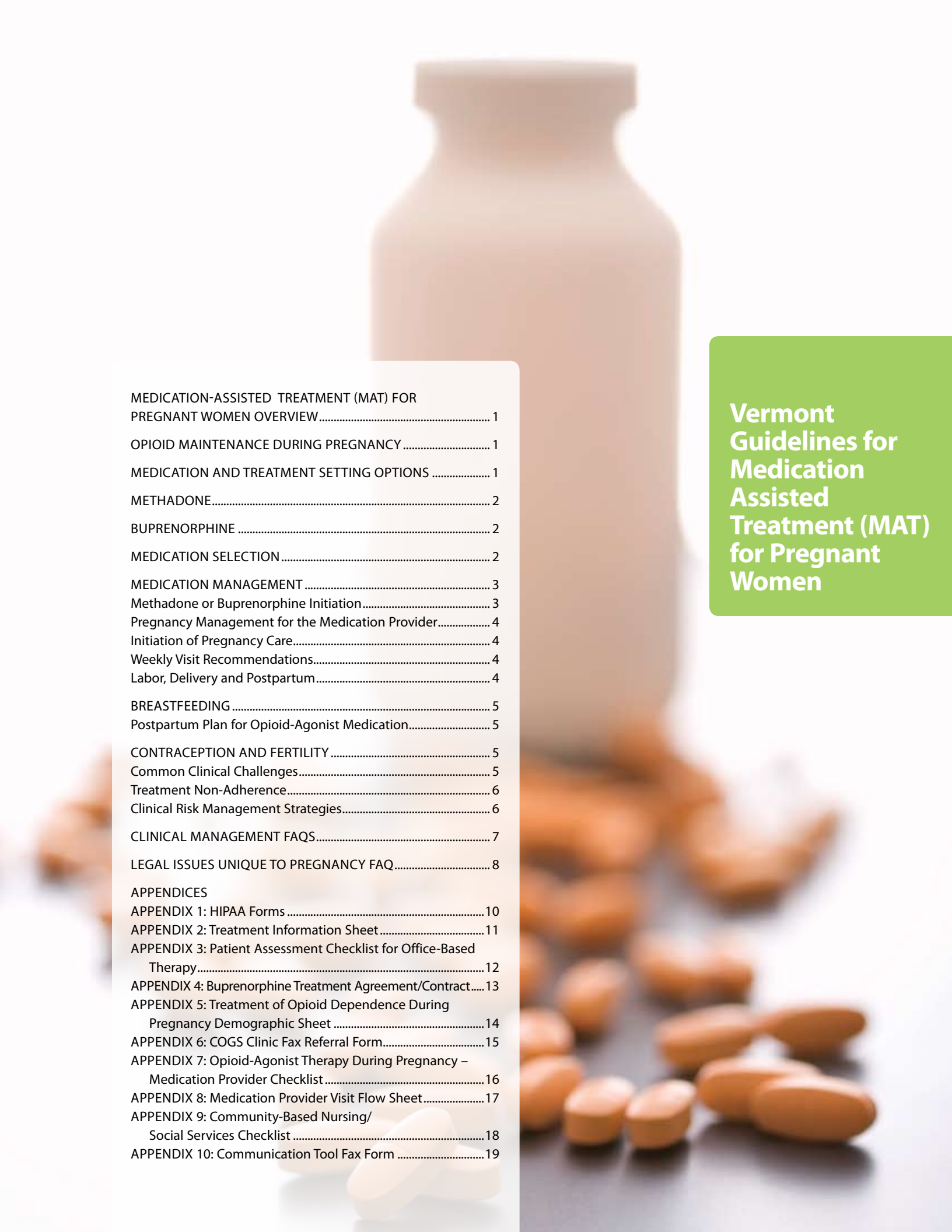
A blurred white pill bottle stands in the center background. In the foreground, numerous orange, oval-shaped pills are scattered across a dark, reflective surface. The lighting is soft, creating a shallow depth of field that keeps the pills in the foreground sharp while the bottle is out of focus.

**Vermont
Guidelines for
Medication
Assisted
Treatment (MAT)
for Pregnant
Women**



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PURPOSE/DISCLAIMER

The Vermont Guidelines for Medication-Assisted Treatment (MAT) for Pregnant Women were created to provide Vermont practitioners with a consolidated set of recommendations for the management of opioid dependence during pregnancy. The content of these guidelines is intended to complement standard medical care, the *Vermont Buprenorphine Practice Guidelines*, and other resources available through the American College of Obstetrics and Gynecology and Substance Abuse and Mental Health Services Administration (www.samhsa.gov) and Community-based Substance Abuse Treatment (www.csat.samhsa.gov).

These guidelines are not intended as requirements for practitioners. They should not be considered as medical advice.

ACKNOWLEDGEMENTS

The Vermont Guidelines for the Treatment of Opioid Dependence in Pregnancy are a collaborative effort of the Vermont Department of Health, Division of Alcohol and Substance Abuse Programs (VDH/ADAP) and the Department of Vermont Health Access (DVHA), with the guidance of local treatment providers. Many people contributed to developing these guidelines. Special thanks go to the following individuals:

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Barbara Cimaglio
Peter Lee
Todd W. Mandell, MD
Wendy Davis, MD
Vicki Loner
Jerilyn Metayer, RN
Anne Johnston, MD
Miriam Sheehey, RN
Nancy Lefebvre, RN
Marjorie Meyer, MD
Eleanor Capeless, MD

Medication-Assisted Treatment (MAT) for Pregnant Women Overview

OPIOID MAINTENANCE DURING PREGNANCY

Opioid addiction is a chronic, relapsing disease. 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 and animal studies reported stillbirth and meconium aspiration when patients presented late in gestation in acute opioid withdrawal. Coincident with these reports, randomized trials in the general opioid dependent population demonstrated that methadone maintenance decreased opioid craving and allowed rehabilitation more effectively than acute withdrawal. As methadone maintenance for the treatment of opioid dependence became accepted as appropriate medical therapy, the use of methadone during pregnancy to prevent maternal (and fetal) withdrawal was examined. Methadone maintenance during pregnancy improved prenatal care, reduced illicit drug use, and minimized the risk of fetal *in utero* withdrawal. These demonstrated benefits led to the current recommendation for opioid agonist maintenance for opioid dependent women during pregnancy.

MEDICATION AND TREATMENT SETTING OPTIONS

Treatment with an opioid-agonist improves pregnancy outcomes for opioid-dependent women. The best outcomes are observed when women are enrolled in a comprehensive treatment program. The overarching goals of therapy for opioid dependence 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 her the opportunity to receive both medical and ancillary services which will allow her to successfully parent her child. Recognizing that engagement into a comprehensive treatment program can be a gradual process, medication providers may face the difficult task of distinguishing the patient that needs a bit more time to become engaged in a treatment plan from the patient that is not ready for treatment. Assessment of treatment progression over some

weeks may be needed.

Office-based therapy during pregnancy favors the patient that is highly motivated to recovery and parenting. Such women usually agree to substance abuse counseling and the assistance of community-based nursing to assist in recovery. Patients unwilling to engage these services may not be optimal candidates for office-based therapy and may benefit from the structure of a methadone program or residential treatment before proceeding to office-based therapy. Inclusion of substance abuse counseling and wrap around services should be strongly encouraged for all patients, as medication alone is not sufficient for optimal pregnancy and parenting outcome.

The decision regarding the most appropriate medication should be made jointly with the opioid-agonist provider, the obstetrician, and the patient. Women that are pregnant but are not a candidate for office-based therapy should

GREATEST BENEFIT

Comprehensive treatment program opioid-agonist therapy (methadone or buprenorphine)

OPTIMAL TREATMENT

Buprenorphine without counseling; no illicit use

GREATEST RISK

Methadone or buprenorphine with continued other illicit substance use

Continued illicit drug use with no treatment

be referred to a methadone treatment center (Chittenden Center or BAART); an alternative is a residential program with reassessment for office-based therapy following successful completion of the residential treatment program.

METHADONE: OPIATE PROGRAM CENTER-BASED TREATMENT

Methadone is a pure mu opioid-agonist with a long half life (24 hours) which allows for daily dosing. Methadone is the medication of choice for treatment during pregnancy, owing to the simple fact that there are more data regarding neonatal outcomes following *in utero* exposure. It is a pregnancy category C drug and is not specifically approved for treatment of opioid dependence during pregnancy by the FDA, despite widespread recommendations as the medication of choice in pregnancy. Initiating or switching treatment to methadone should be offered to all opiate dependent pregnant patients.

Methadone for the treatment of opioid dependence is available only through opioid treatment centers. In Vermont, these centers provide medical screening and substance abuse counseling, including a full social assessment. Provision of these ancillary services has been demonstrated 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, despite long waiting lists for other patients. In Vermont, the major barriers to methadone treatment are the restricted daily dosing times and the travel time that is often needed. These issues are particularly difficult for women in school, working, with small children at home, and those that live a distance from a treatment center. Access to medication and ability to realistically comply with a treatment program can be considered in the overall decision regarding medication choice.

BUPRENORPHINE: OFFICE-BASED MEDICATION-ASSISTED TREATMENT

Buprenorphine is a partial mu opioid-agonist approved for the treatment of opioid dependence. Unlike methadone, buprenorphine is prescribed in medical offices rather than at licensed clinics. The *Vermont Buprenorphine Practice Guidelines* outline the background of office-based medication-assisted therapies and guidance for prescribers on the management of opioid dependent patients. Brand names for buprenorphine include Suboxone, which is a buprenorphine/naloxone combination and Subutex, which is buprenorphine alone.

Small cohort studies have found buprenorphine to be safe and effective in the treatment of opioid dependence during pregnancy. However, because it is a relatively new medication, long term outcome data of neonates exposed to buprenorphine *in utero* are lacking and patients seeking treatment should be informed of this. Nonetheless, risk/benefit may favor buprenorphine if the patient is otherwise

a candidate for office-based therapy and there are barriers that preclude her attending a methadone program. The data suggest that treatment with buprenorphine provides better outcomes for mother and newborn compared to no treatment.

Candidates for buprenorphine are women that are stable on buprenorphine prior to pregnancy or those unable to attend a methadone treatment center AND are otherwise candidates for office-based therapy. Pregnancy does NOT make women automatically candidates for office-based therapy with buprenorphine, even if that is the only medication available in the community. Engagement in counseling and other services is vital during pregnancy and recovery for successful postpartum transition. Some women may benefit from residential treatment with office-based therapy following stabilization.

MEDICATION SELECTION

Please see the *Vermont Buprenorphine Practice Guidelines* for detailed information regarding the choice of medication and how to determine whether a patient, irrespective of pregnancy issues, is a candidate for office-based treatment.

Choosing the best medication for pregnancy is a discussion ultimately best suited to the medication provider and the patient. Recognizing many pregnant patients will look to their obstetric care provider before initiating medication, it may be helpful for the medication provider and obstetric provider to discuss the plan before presenting the final decision to the patient.

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

For patients that are not optimal candidates for buprenorphine when methadone is not available, a step wise approach of initiation with buprenorphine with close follow-up could be considered. In these instances, buprenorphine with very close and frequent follow-up could be considered with initiation of medication and counseling. Residential treatment or methadone could be considered for difficulty in buprenorphine treatment adherence.

If you are uncertain about the optimal medication for a pregnant patient, Fletcher Allen Health Care Comprehensive Obstetrics and Gynecology Clinic or Neonatology Service can assist in this decision making process and provide care to any opioid dependent patient.

The Fletcher Allen Comprehensive Obstetrics and Gynecology Clinic is available to treat any opioid dependent women during pregnancy. (See *Appendix 6* for referral forms).

Methadone or start with residential treatment if:

- Polysubstance abuse, including alcohol or benzodiazepines
- Unstable living situation
- Abused buprenorphine (snorting)
- Declines/noncompliant with counseling
- Inability to coordinate ancillary services
- In a mandatory recovery program (parole)
- Noncompliant with obstetric or pediatric care

Office-based buprenorphine if:

- Informed consent re: new medication for pregnancy
- Opioids are the only substance of abuse
- Stable living situation
- Accepts counseling
- Can coordinate ancillary services or there is a community-based program that will do so
- Compliant with obstetric and pediatric care
- There is no alternative and the patient understands treatment may be initiated on a trial basis



MEDICATION MANAGEMENT

The information in this document is additional information for medication initiation during pregnancy. For more detailed information about initiation of medication, patient selection, or other issues surrounding initiation of buprenorphine, see the *Vermont Buprenorphine Practice Guidelines* in this booklet.

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. Urine home pregnancy tests are not sufficient for initiation of treatment. Obstetric providers, community health clinic or Planned Parenthood clinics can assist with diagnosis of or confirmation of a viable intrauterine pregnancy.

For a diagnosis/confirmation of opioid dependence, a positive urine test for opioids run as either an office-based point of care test or a laboratory test can be run. Opioid dependence should be documented by the presence of opioid withdrawal symptoms, such as COWS. (see *Vermont Buprenorphine Practice Guidelines, Appendix 5, page 13*)

Query of the Vermont Prescription Monitoring System to assess prescription opioid use is recommended.

Occasional use of opioids may not cause physical dependence and therefore may not require agonist therapy; substance abuse counseling and monitoring is imperative.

Methadone or Buprenorphine Initiation

The provider should decide on medication of choice (refer to the *Vermont Buprenorphine Practice Guidelines*).

Induction of medication will be the same procedure used for non-pregnant patients in your practice (see *Vermont Buprenorphine Practice Guidelines*); 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 (CINA 10-12 range) symptoms of opioid withdrawal are not dangerous to pregnancy. It is reasonable to ask the patient to abstain from opioid use (and have withdrawal symptoms) for the purposes of induction. Patients may be referred to an induction center for buprenorphine if that is your usual approach. Buprenorphine mono-therapy is recommended during pregnancy.

Continuation of Medication During Pregnancy

(after induction or in a previously stable patient):

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 8*) and adjust dose as indicated; one refill (total of two weeks of medications) may be considered for the stable patient in counseling if not well.

Provide only one week of medication at a time to minimize diversion/theft/loss of medication.

- Pregnancy specific dosing notes:
 - 70% of patients stable prior to pregnancy will need a modest dose increase (3-5 mg) during pregnancy (Fletcher Allen data); prescribed gradually throughout gestation
 - The average dose at the end of pregnancy in women started during pregnancy is 16 mg (Fletcher Allen data)
 - Large increases in buprenorphine requirements have not been noted during pregnancy; if such increases are needed, consider alternative diagnoses
- If the patient has difficulty in engaging in ancillary services and counseling, consider switch to residential program or a methadone treatment program
If methadone is being used, methadone dose may need to be split if very high doses are needed due to increased excretion.

Pregnancy Management for the Medication Provider:

As the provider of methadone or buprenorphine, you will have the longest history with the patient and the best visit compliance. Referrals for ancillary services during pregnancy are best made through your medication visits.

At Initiation of Pregnancy Care:

Referral to your district Children's Integrated Services Coordinator (CIS) should occur. See the resource section in this booklet for the agency in your district that houses the CIS intake coordinator. See the patient in weekly visits and for urine drug screens.

The stresses of pregnancy and having a newborn warrant closer follow-up even if substance abuse counseling has not been needed in the past. Obtain HIPAA consents to permit communication with obstetric provider, counselor, and planned pediatric provider. This consent should be a condition of office-based treatment. (See *Appendix 1* for samples).

Contact the obstetric provider and pediatric provider directly to document medication (methadone or buprenorphine) use in pregnancy (they will know whether delivery in your local/regional hospital is appropriate). Refer to the Services for Opioid-Dependent Pregnant Women in Vermont at the beginning of this document.

There should be documentation of estimated due date (patient report is sufficient).

Weekly Visit Recommendations (can be done by a nurse):

- Urine drug screen
- Assessment of withdrawal symptoms or evidence of functional impairment.
- Confirmation of adherence with counseling recommendations
- Confirmation of adherence with community-based nursing (parenting) plans

- Confirmation of adherence to obstetric care (monthly visits until 28 weeks; every 2 week visits 28-36 weeks; weekly visits 36 weeks to due date at 40 weeks)
- Assessment and plan for difficulty with adherence to the treatment plan (i.e.: prenatal care, counseling, connection with ancillary services) should be made with each weekly prescription
- Reassess whether the patient should remain in an office-based treatment program for repeated lack of adherence
- Provide prescription

Between 24-32 weeks establish these referrals (either send the patient directly OR specifically request the obstetric provider):

- Pediatric provider consultation for evaluation and treatment of neonatal abstinence syndrome (with specific emphasis on ability to receive all care at the hospital of planned delivery)
- Anesthesia consultation for pain management plan (reasonable for all patients; most important for those planning cesarean delivery)

36-40 weeks: Delivery and Postpartum planning

- Update the obstetric provider with the appropriate dose of medication near delivery
- Remind the obstetric provider that **NALBUPHINE and BUTORPHANOL are CONTRAINDICATED** as they can precipitate withdrawal
- Children and Infant Services referral for ancillary social services
- Encourage Breastfeeding
- Community-based nursing for parenting skills
- Partner treatment if not already done

Labor, Delivery and Postpartum:

During labor and delivery, as well as the postpartum process, reassure the patient that providing her adequate pain control is important. Conversations with obstetric and anesthesia providers should reflect that in a stable patient, there is no reason to suspect drug seeking if requesting pain medication in the appropriate clinical setting. 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. During labor and delivery, continue scheduled methadone or buprenorphine during hospitalization. The obstetric provider can order these medications in the hospital even if not a buprenorphine prescriber, but will not be able to prescribe this medication after hospital discharge. An anesthesia consult should be made when the patient arrives in labor as indicated.

Neuraxial analgesia (spinal, epidural) is effective for pain control during labor or for cesarean delivery in opioid dependent women.

Intravenous short-acting **NALBUPHINE and BUTORPHANOL** are **CONTRAINDICATED** as they may precipitate withdrawal. If inadvertent administration occurs and the patient has withdrawal symptoms, an opioid-agonist should be administered to alleviate withdrawal symptoms; monitor for respiratory depression.

After the delivery, continue medication-assisted therapy as indicated and have hospital based social work see the patient.

For pain control, acetaminophen and non-steroidal anti-inflammatory agents should be used for mild and moderate pain with short-acting opioid analgesics used as needed. In a vaginal birth, short-acting opioids can be made available on a PRN basis, just as for non-opioid dependent patients.

Opioids for pain control should not be needed following discharge for a routine delivery. 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.

You may expect a 70% increase in short-acting opioid analgesic requirement; often a more potent oral agent (hydromorphone) is required. Patient controlled epidural analgesia is effective for severe pain if available. 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).

If Breastfeeding is declined, switch the patient back to combination buprenorphine/naloxone immediately after delivery or continue methadone.

If breastfeeding *is* accepted, consult with pediatric provider to confirm that they are aware of patient's medication-assisted treatment use.

If newborn *is not* receiving methadone or morphine for neonatal abstinence syndrome, switch mother back to buprenorphine/naloxone. If the newborn is being treated with methadone or morphine for neonatal abstinence syndrome, continue buprenorphine monotherapy until neonate is off medication or weaned from breastmilk. There may be some patients in whom combination buprenorphine/naloxone is recommended; given evidence of minimal bioavailability in breastmilk, breastfeeding should be encouraged.

Postpartum Plan for Opioid-Agonist Medication:

There is currently no evidence that dose changes of methadone or buprenorphine are needed postpartum. Special attention for somnolence is warranted. Pay special attention to relapse, especially 3-6 months postpartum. There is anecdotal evidence to suggest that this is a particularly vulnerable time for a woman in recovery. Encourage continuation of community nursing for parenting support (or start initial referral at discharge if not done previously).

Ensure each patient has a follow-up appointment with BOTH her medication provider and substance abuse counselor.

CONTRACEPTION AND FERTILITY

As with many underlying diseases, as the patient's recovery proceeds, her fertility may also increase. Patients should not assume that because they have had infertility problems in the past that it will continue after treatment is initiated. If a patient is planning a pregnancy (or sexually active without contraception), prenatal vitamins (800 mcg folic acid) are recommended prior to conception to reduce birth defects. If a patient is sexually active and not using contraception, prenatal vitamins should be recommended given high risk of pregnancy.

Contraceptive counseling and treatment are available at low cost (or free) from community health clinics and Planned Parenthood. There is no evidence of medication interaction between oral contraceptives and methadone or buprenorphine. To afford the patient 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 abuse often have chaotic lives, experience domestic violence, and have tenuous housing. The structure imposed by treatment programs can be a difficult adjustment. Relapses are

common, especially early in treatment. A combined treatment plan developed by the patient with the obstetrician and medication provider that appropriately balances maternal and fetal risk is imperative.

Treatment Non-Adherence

The inability to remain abstinent, non adherence with counseling, or demonstration of other high-risk behavior constitutes treatment non-adherence.

Options include:

- Evaluate for more intensive services to more structured program (intensive outpatient program, residential treatment, methadone) using ASAM criteria.
- Discharge the patient from office-based therapy if she declines other options. Communication with the obstetrician, pediatrician, social work team at the hospital of planned delivery and the Department of Children and Families (DCF) should occur promptly.
- Useful cross discipline strategies for treatment non-adherence include linking the ability to pick up a buprenorphine prescription or methadone dose with prenatal care by requiring a visit to the obstetric provider office first. Consider linking the ability to pick up a buprenorphine prescription or methadone dose to counseling and referral to residential treatment or consider switch to methadone if adherence to office-based care is not possible
- For recurrent positive drug screens with benzodiazepines, particular care must be taken in management of patients dependent upon benzodiazepines and opioids, due to synergistic respiratory depression, even if the benzodiazepines are prescribed. 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 which includes warnings about driving or machine operation. This intervention should be documented in the medical record.
- Other strategies include an increase 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 opioid treatment center or residential treatment center.***
- 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. The patient may not be a candidate for office-based therapy if using cocaine and should be referred to an opioid treatment center or residential treatment for a more structured program. Education should be provided and documented regarding potential Levamisole contamination of cocaine.
- For recurrent positive drug screens with cannabis, use

of any illicit substance should be discouraged. Given the relatively little data that THC is harmful in pregnancy combined with the clear benefit of opioid maintenance therapy, consider continuation with close follow-up or residential treatment.

- Non-adherence due to transportation and other social barriers present complex problems to successful recovery. Referral to community-based nursing/social work to develop a transportation plan (i.e.; Medicaid sponsored transportation) should be made.
- Offer residential treatment for intensive counseling which can allow for less frequent (once a week) counseling after discharge. Inadequate housing, partner use of illicit substances, and domestic violence are common issues to be addressed with counseling and community-based nursing.

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 vs. buprenorphine. Document when Department of Children and Families notification of drug use is made. Ancillary services provided should be documented.



Clinical Management FAQs

The following scenarios may help the obstetricians and medication providers understand treatment decisions. Close communication between providers will enable the optimal medical approach (as for any other medical illness):

Do I have to offer buprenorphine to a pregnant patient because she refuses methadone?

- The patient should receive the optimal care during pregnancy
- If she is not a candidate for buprenorphine, then she should receive methadone or referral to residential treatment
- Consider offering residential treatment and transfer to buprenorphine after successful completion of the residential program

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

- Pregnancy is not an emergency*; simply a priority
- Confirm opioid dependence
- Confirm viable pregnancy

May I stop prescribing buprenorphine to the non-compliant patient during pregnancy?

- It is unsafe for the mother and fetus to continue to engage in risky behavior
- Medication can be discontinued for any medical reason when there is lack of benefit; alternatives should be offered (residential treatment; methadone treatment center)
- Continued high-risk behaviors in the office-based setting suggest the need for residential or center-based care.
- Document non-compliance and offers of alternative, more structured care

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

- Concurrent use of benzodiazepines
- Concurrent use of cocaine
- Difficulty engaging in counseling
- Can depend on ease of switching to methadone: assessment of overall maternal/fetal risk/benefit of continued treatment if no treatment is the option; the medication provider has some latitude if it is decided that risk/benefit favors office-based care

What should I do when I decide I cannot prescribe to a patient during pregnancy?

- Document rationale in medical record
- Offer methadone even if the patient needs to travel
- If option is buprenorphine versus no treatment:
 - Consider residential treatment
 - Consider supervised pregnancy residence
- Contact local child protection services when you discontinue medication; they can often follow-up in the hospital at delivery
- Tell the patient you must do this and document the conversation

Suggested “scripted” approaches to discussing treatment options

Initial visit script:

- Good for you in seeking help with addiction
- We need to confirm that you are pregnant and clarify the level and nature of your opioid abuse
- We routinely check the Vermont Prescription Monitoring System in all patients seeking treatment at our clinic
- Methadone is the medication of choice for the treatment of opioid dependence during pregnancy because we have years of experience with neonatal exposure
- I understand you would like to be treated with buprenorphine
- Buprenorphine is not approved for use in pregnancy and we do not have many years of experience; the oldest children are only 5 or 6
- Substance abuse counseling and engagement in community-based services to help with parenting is necessary for recovery and parenting
- Will you agree to attend counseling and receive help from community-based nursing?

Follow up sessions:

- I see that you have continued to use cocaine based on your toxicology screen. How shall we address this together?
- Let us review our plan for management of your pregnancy using buprenorphine/methadone
- Have you been able to keep your appointments with counseling and other medical providers?

Legal Issues Unique to Pregnancy FAQ

Misperceptions about legal issues are an important reason that opioid-dependent and pregnant women avoid treatment. Common misconceptions regarding treatment of the pregnant patient are addressed below.

Example: A 19 year-old with heroin addiction learns she is pregnant at a community health clinic.

Misconception: She should stop heroin immediately or she will go to jail

Fact: The American College of Obstetrics and Gynecology has a series of Committee Opinions that address ethical issues in Obstetrics and Gynecology, with the use of alcohol and illicit substances specifically considered.

- Pregnant women should be allowed to make decisions on their own behalf
- Most women will choose to proceed with treatment for the health of the fetus/newborn
- Incarceration, where there are few services, results in worse outcomes (mother: less prenatal care, less treatment, higher relapse; newborn: worse outcome in foster care than with a recovering mother)

Misconception: She should not use opioid-agonist therapy because her baby will be an addict

Fact: Randomized trials have demonstrated the long-term (3 year) benefit of methadone treatment versus taper. Studies show less relapse and neonatal outcomes similar to controls (after demographic adjustment).

Misconception: She must receive opioid-agonist therapy although she requests a taper

Fact:

- Opioid-agonist therapy is clearly the treatment of choice as it improves prenatal care, reduces relapse, and reduces exposure to other illicit drugs.
- There are no data to suggest medication-assisted withdrawal early in pregnancy (before 24 weeks) is harmful
- Abrupt withdrawal from heroin late in gestation is associated with *in utero* withdrawal, increased meconium aspiration, and may be associated with fetal death
- Once informed, if the patient would like to taper, a gradual taper of 10% per week is reasonable. Many patients will become uncomfortable and stop a taper even after requesting it.



Misconception: If she has any relapses, she will lose custody of her child

Fact: Reporting laws vary by state, but most have some mandatory reporting of any maternal behavior that can impair the wellbeing of a child. However:

- Most states will work closely with a patient in recovery to allow her to maintain custody
- Many cannot intervene until after delivery (Vermont: case can be opened 30 days prior to expected delivery)
- Reinforce to the patient that treatment during pregnancy, even if has a few slips, will improve the chances of custody retention
- Reporting during pregnancy allows social work time to understand all aspects of patient care
- Reinforce to patient that the goal of all is to help her maintain custody and receive appropriate treatment for her to parent her child. The opioid-agonist treatment provider can play an important patient advocacy role here.

RISK MANAGEMENT REFERENCES:

(2005). "ACOG Committee Opinion #321: Maternal decision making, ethics, and the law." *Obstet Gynecol* 106(5 Pt 1): 1127-37.

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

(2007). "ACOG Committee Opinion No. 390, December 2007. Ethical decision making in obstetrics and gynecology." *Obstet Gynecol* 110(6): 1479-87.

(2008). "ACOG Committee Opinion No. 422: at-risk drinking and illicit drug use: ethical issues in obstetric and gynecologic practice." *Obstet Gynecol* 112(6): 1449-60.

SAMHSA Tip 40 Guidelines for the use of buprenorphine and the *Vermont Buprenorphine Practice Guidelines* are excellent resources for the office-based treatment for opioid dependence. These guidelines below contain ancillary information for those providers that choose to prescribe opioid-agonist medication for women during pregnancy.

Providers that do not choose to prescribe during pregnancy can contact Marjorie Meyer MD or Eleanor Capeless MD at Fletcher Allen Health Care for questions (firstname.lastname@vtmednet.org) or arrange for transfer of the patient through the Comprehensive Obstetrics and Gynecology Service at Fletcher Allen Health Care at 802-847-1400.

Appendix 1: HIPAA Form

MRN

PATIENT NAME

PATIENT DATE OF BIRTH

NOTICE OF PRIVACY PRACTICES

I have received the Notice of Privacy Practices at Fletcher Allen Health Care informing me of how Fletcher Allen Health Care will use my personal health information.

My understanding of this Notice will help me ensure the accuracy of my health information, better understand who, what, where and why others may access my health information.

I acknowledge receipt of the Notice and understand any questions pertaining to Fletcher Allen Health Care's privacy policies may be answered by contacting the Fletcher Allen Health Care Patient Relations Department at (802) 847-3500.

PATIENT / GUARDIAN

DATE OF RECEIPT

RELATIONSHIP TO GUARDIAN

Patient unable to sign Patient refused to sign

Reason: _____

WITNESS

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

Appendix 3: Patient Assessment Checklist 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 by John R. 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 will be transitioned to Suboxone (buprenorphine/naloxone) following delivery (exception: breastfeeding and baby in treatment).

PATIENT SIGNATURE

DATE

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 ABUSE COUNSELOR _____ FAX NO. _____

HOME HEALTH NURSE _____ FAX NO. _____

HOSPITAL FOR DELIVERY _____

Appendix 6: COGS Clinic Fax Referral Form

Patient name: _____

Referring provider (with contact and fax number): _____

Reason for referral: _____

LMP (or gest age): _____ US done: YES NO (attach record)

Prior prenatal care: YES NO Provider: _____

Medications (dose and prescribing physician; note if you will continue prescribing medication or request transfer of prescribing responsibility and last day of medication): _____

Substance abuse counselor after discharge (note if we need to set this up): _____

Appointment: _____

Date and time: _____

Place: _____

Provider: _____

Social worker appointment: _____

Fax to COGS clinic: 802-847-8433

Phone: 802-847-1400

Email: (provider to provider only): marjorie.meyer@uvm.edu

Note: please do not use patient identifiable information in the email

Appendix 7: Opioid-Agonist Therapy During Pregnancy – Medication Provider Checklist

PATIENT NAME _____ DATE OF BIRTH _____

MRN _____ DATE _____

Discuss risk benefits/Patient given risk benefit fact sheet

- Methadone
- Buprenorphine
- No Treatment/wean

Substance abuse counselor

Name: _____

Refer to counseling if not already in treatment (counseling is strongly recommended in pregnancy)

Obstetrician

Name: _____

Hospital of Delivery: _____

Anesthesia consult 24-32 weeks

Pediatrician

Name: _____

Refer at 24-32 weeks

Home Visiting Nurse

Name: _____

Urine Drug Screens

- OB
- or
- Medication Provider

Appendix 8: 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
- Adbominal 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 9: Community-Based Nursing/Social Services Checklist

PATIENT NAME	DATE OF BIRTH
MRN	DATE

OB Provider: _____

Medication Provider: _____

Substance Abuse Provider: _____

Primary Care Provider: _____

Pediatrician: _____

WIC

Social Services

Economic services

Housing

Employment

Child care

Appendix 10: 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: _____