

PREGNANCY, YOUNG ADULTS, METHADONE PATIENTS, AND OTHER POPULATIONS (CASES ONLY)

Goal

To prepare providers to adapt a buprenorphine practice to the needs of patient subpopulations

After completing this module (didactic + cases), participants will be able to:

- Modify buprenorphine treatment as needed for patients who are transferring from methadone treatment to buprenorphine
- Recognize, anticipate, and address complications of buprenorphine treatment in patients using multiple other substances
- Recognize the patient subpopulations having additional requirements for treatment modifications in office-based opioid treatment
- Adapt buprenorphine treatment to the needs of patient subpopulations having additional requirements

Professional Practice Gaps

TIP 40, Chapter 5, highlights the treatment of special populations¹ and is updated in later guidelines^{2,3}. Modifications to buprenorphine treatment and precautions are needed for the following special populations:

- pregnant women
- adolescents
- elderly patients
- patients with limited resources in rural areas.
- Homeless patients
- patients transferring from methadone to buprenorphine
- patients with coexisting substance use
- alcohol

- heroin
- buprenorphine
- patients with mental illness
- co-occurring medical conditions that require special management due to drug reactions, including HIV/AIDS, hepatitis C. Content is included in the module focusing on opioid medications. Providers discuss treatment with a pharmacist for any medication that might interact with buprenorphine prior to treatment and refer to treatment guidelines for each condition⁴.

Modifications for various groups may include:

- Changes in the induction protocol
- Different final dose
- More careful monitoring
- Use of adjunct medications
- Contraindication

QUIZ: QUICK CASE #1



Name: Adelina Hernandez

Age: 25 years old

Reason For Visit: Ms. Hernandez takes opioids fairly regularly, but is trying to get pregnant and wants to get off opioids altogether; she is willing to consider pharmacological treatment for her opioid use disorder.

Patient History: Ms. Hernandez has had opioid use disorder, primarily using oxycodone, for two and a half years. Her use started after a back injury 4 years ago in a motor vehicle accident. Her back no longer is painful. Ms. Hernandez is trying to get pregnant, but is scared that her use of oxycodone will harm her baby.

Ms. Hernandez has no experience with buprenorphine or methadone other than trying some buprenorphine, obtained from a friend a couple of times when she could not obtain oxycodone. This buprenorphine clinic is much more convenient for her than the methadone clinic in the closest large city, and she does not want to have to take off work to go to the methadone clinic. She does not drink alcohol, smoke, or take other drugs.

With What You Now Know, Is Ms. Hernandez A Good Candidate For Office-Based Buprenorphine Treatment At This Time? (Choose Best Answer)

1. No, because there is no safe pharmacological treatment for pregnant women with opioid use disorder.
2. No, because buprenorphine has not been proven safe to use during pregnancy.
3. Yes, a 2-month intensive buprenorphine treatment can be done, and she can be easily weaned off the drug when she gets pregnant.
4. If she starts on buprenorphine and then gets pregnant, she can be maintained on buprenorphine while pregnant, but should be switched to the monotherapy formulation.

Quick Case #1 Quiz Feedback

(1) No, Because There Is No Safe Pharmacological Treatment For Pregnant Women With Opioid Use Disorder,

(2) No, Because Buprenorphine Has Not Been Proven Safe To Use During Pregnancy:

Actually, methadone is a safe pharmacotherapy for women who are pregnant, want to become pregnant, or who are breastfeeding. And there should be no hesitation to continue a woman on buprenorphine if she conceives on buprenorphine. Women who are already on buprenorphine, (i.e., have proven adherence to buprenorphine treatment) should be supported in staying on their chosen treatment during pregnancy, with a switch to the mono-therapy buprenorphine¹¹.

(3) Yes, A 2-month Intensive Buprenorphine Treatment Can Be Done, And She Can Be Easily Weaned Off The Drug When She Gets Pregnant.

Buprenorphine works best when used for months or even years and weaning is not "easily" completed with long-term abstinence in the majority of cases. If buprenorphine is used during pregnancy and post-partum, it should be monotherapy. Actually, methadone is a safe pharmacotherapy for women who are pregnant, want to become pregnant, or who are breastfeeding. And there should be no hesitation to continue a woman on buprenorphine if she conceives on buprenorphine.

(4) If She Starts On Buprenorphine And Then Gets Pregnant, She Can Be Maintained On Buprenorphine While Pregnant But Should Be Switched To The Monotherapy Formulation.

Correct. There should be no hesitation to continue a woman on buprenorphine if she conceives on buprenorphine. Women who are already on buprenorphine, (i.e., have proven adherence to buprenorphine treatment) should be supported in staying on their chosen treatment during pregnancy, with a switch to the monotherapy buprenorphine¹¹. Methadone, also, is a safe pharmacotherapy for women who are pregnant, want to become pregnant, or who are breastfeeding.

However, because Ms. Hernandez is not currently pregnant, the safest approach, if she is willing to wait to get pregnant, to recommend that she address her opioid addiction first, get on a stable maintenance therapy, and then try to get pregnant.

QUIZ: CASE STUDY – MRS. WONG



Name: Mrs. Wong

Age: 34 years old

Reason For Visit: Regularly monthly visit for buprenorphine maintenance

Personal History: Mrs. Wong works as a hotel receptionist and is enrolled in college courses after work to earn a business degree. Mrs. Wong married her long-time boyfriend 6 months ago, and they have been discussing having a baby. During her visit, she asks whether it's ok to get pregnant on buprenorphine.

Medical History: Mrs. Wong mentioned that she just had her annual exam with her OB/GYN and talked to her about stopping birth control pills and getting pregnant. However, she did not tell her OB/GYN that she is maintained on buprenorphine, but has agreed to do so after the importance is explained.

Treatment History: Mrs. Wong is successfully maintained on 8 mg of sublingual combination buprenorphine (Suboxone) for 2 years and wonders what to do about her buprenorphine treatment if she gets pregnant.

Which Of The Following Is An Appropriate Statement For A Discussion With Mrs. Wong At This Point? (Choose All That Apply)

1. Buprenorphine can be continued during pregnancy.
2. Methadone maintenance treatment is acceptable during pregnancy.
3. You have the option of switching to a medication-free treatment program.

CASE STUDY – MRS. WONG QUIZ FEEDBACK

(1) Buprenorphine Can Be Continued During Pregnancy.

Correct. Buprenorphine is not known to be toxic or harmful during pregnancy. Since the Maternal Opioid Treatment: Human Experimental Research (MOTHER) study¹⁷, women who are stable on buprenorphine before pregnancy are often maintained on it during pregnancy (monotherapy), but all options are explored.

(2) Methadone Maintenance Treatment Is Acceptable During Pregnancy.

Possibly. Methadone maintenance treatment during pregnancy is well-researched and, before the MOTHER study⁸, which supports maintaining pregnant women on buprenorphine, had been the first line treatment of choice for pregnant women with opioid dependence.

(3) You Have The Option Of Switching To A Medication-free Treatment Program.

All options should be explored. However, consider that opioid withdrawal increases the risk of intrauterine fetal death. Maintaining her on buprenorphine (monotherapy) or switching to methadone are possible; Medication free may not be necessary.

2ND VISIT: TALKING WITH MRS. WONG

At Mrs. Wong's next visit one month later, she reports cutting her daily dose to 2 mg, but admits she has been having cravings and is thinking about using again. She asks for a pregnancy test because she thinks that her period is late. Her on-site urine toxicology screen is positive for cocaine and for hydrocodone, as well as buprenorphine. Her pregnancy test is negative. Topics to discuss with Ms. Wong at this time include the positive test results, the effect drugs can have on a potential pregnancy, the benefit of having a reliable birth control at this point in her treatment, and how to proceed with treatment.



Provider: *Your drug test came back positive for opioids. Is there something you'd like to discuss?*

Mrs. Wong: *I...I had a temporary slip and snorted some cocaine last night. It was just one hit, though. I won't do it again.*

Provider: *The pregnancy test I ran came back negative. If you were trying to get pregnant, your drug use could have negative effects on the baby, some of them permanent. It is critical that you use reliable birth control.*

Mrs. Wong: *I won't do it again, I promise. I knew it was wrong right after I did it.*

Provider: *Also, using other substances can lead to relapse to opioid use. Remember that getting back on opioids while on buprenorphine could precipitate withdrawal. If you go into acute withdrawal during pregnancy, that could be very dangerous to both you and your baby if you were to become pregnant.*

Mrs. Wong: *I don't want that.*

Provider: *I would recommend that you resume buprenorphine treatment or, if you'd rather, I could refer you to a methadone maintenance program.*

Mrs. Wong: *Oh, I don't think it's that serious. Going back on buprenorphine should help, though.*

Provider: *I also recommend you use a reliable form of birth control until you have been abstinent from drugs that could harm a baby for a long, stable period. You need to take care of yourself first. This is important.*

Mrs. Wong: *[Sighs] All right. You are right.*

Provider: *I'd also like you to come back once a week for drug testing so that we can monitor you and get you stable again.*

Mrs. Wong: *Okay, I guess I can do that.*

QUIZ: MRS. WONG – 3RD VISIT

After your discussion, Mrs. Wong agreed to increase her dose back to 8 mg per day combination buprenorphine/naloxone (Suboxone® sublingual film) and to check in to your office weekly for 4 weeks. After that, she switched to semi-monthly (twice per month) visits for one month, and then back to once-monthly visits.

After 6 months back at her stabilized dose, Mrs. Wong attends a regular office visit and reports excitedly that she is pregnant. She had a prenatal appointment the day prior and everything was fine. She tells you that she wants to keep taking buprenorphine during the pregnancy. She says that her OB/GYN thought that it should be fine, but was going to call you to discuss this.

If Mrs. Wong Insists On Continuing With Buprenorphine Maintenance Treatment And Her Obstetrician Is Not Waivered To Prescribe Buprenorphine, What Is The Best Option? (Choose One)

1. Do not change anything, but monitor her closely throughout pregnancy.
2. Switch her to buprenorphine monotherapy and monitor her closely throughout pregnancy.
3. Ask her OB/GYN to monitor her buprenorphine treatment as part of prenatal care.
4. None of the above; she cannot safely be maintained on buprenorphine while pregnant and must stop taking it during pregnancy.

MRS. WONG – 3RD VISIT QUIZ FEEDBACK

(1) Do Not Change Anything, But Monitor Her Closely Throughout Pregnancy.

This is not the best answer. The combination form of buprenorphine that most patients take is typically not used during pregnancy because it is generally best to use the least possible chemicals during pregnancy. Most physicians in the U.S. who cautiously agree to treat pregnant patients with buprenorphine are transferring these patients to the monotherapy form of buprenorphine (Subutex®). If Mrs. Wong wants to stay on buprenorphine and you think it is a sound treatment decision, you should probably transfer her to monotherapy.

(2) Switch Her To Buprenorphine Monotherapy And Monitor Her Closely Throughout Pregnancy.

Correct. This is the best answer. The combination form of buprenorphine that most patients take is typically not used during pregnancy, because it is generally best to use the least possible chemicals during pregnancy. Most physicians in the U.S. who cautiously agree to treat pregnant patients with buprenorphine are transferring these patients to the monotherapy form of buprenorphine (Subutex®). If Mrs. Wong wants to stay on buprenorphine and you think it is a sound treatment decision, you should probably transfer her to monotherapy buprenorphine. Prior to this new treatment, be sure to discuss the risks and benefits with Mrs. Wong and have her sign a consent that she understands the risks. She also would benefit from understanding that all opiates, including buprenorphine, can lead to neonatal abstinence syndrome (NAS). This means that her baby would have to be in the hospital longer than she would be. The baby would remain under observation and would possibly need treatment for physical withdrawal from opiates.

(3) Ask Her OB/GYN To Monitor Her Buprenorphine Treatment As Part Of Prenatal Care.

This is not the best answer. You should continue to provide Mrs. Wong's treatment for opioid dependence but may want to work closely with her OB/GYN during her pregnancy. The combination form of buprenorphine that most patients take is typically not used during pregnancy, because it is generally best to use the least possible chemicals during pregnancy. If Mrs. Wong wants to stay on buprenorphine and you think it is a sound treatment decision, you should probably transfer her to monotherapy.

(4) None Of The Above; She Cannot Safely Be Maintained On Buprenorphine While Pregnant And Must Stop Taking It During Pregnancy.

This is not the best answer. As discussed previously, scant research has been conducted on the use of buprenorphine during pregnancy. However, buprenorphine DOES appear to be safe. Most physicians in the U.S. who are cautiously agreeing to treat pregnant patients with buprenorphine are first transferring these patients to the monotherapy form of buprenorphine (Subutex®). If Mrs. Wong wants to stay on buprenorphine and you think it is a sound treatment decision, you should probably transfer her to monotherapy.

MRS. WONG – MAINTENANCE DURING PREGNANCY

Mrs. Wong switches to buprenorphine monotherapy during pregnancy. The transfer is uneventful. She is maintained on monotherapy during her pregnancy with no problems. However, after 4 months, she decides that she wishes to taper off of buprenorphine completely.

Patient's Request For A Taper

Although you explained the risks and benefits of using buprenorphine during pregnancy to Mrs. Wong, provided some information about methadone, and she initially chose buprenorphine monotherapy, she eventually became motivated to quit all medications and requested a taper from buprenorphine at 5 months.

Considerations For Tapering

Since she has been stable, you support her in her taper attempt, pending results of a consultation with her OB/GYN, who then approves the treatment. You consider her tapering request. You continue buprenorphine monotherapy, while she tapers. You could recommend decreasing 2 mg at a time, perhaps weekly, as tolerated. She could use scissors to cut her currently supplied film into quarters, or you could give her next prescription in the 2 mg size.

You should also offer to see her more frequently, because tapering could be destabilizing. Advise her to check in with her counselor frequently. You could enlist her husband's support in helping monitor her behavior during the taper if she consents to his involvement. Also, discuss situations when, in case of a slip or increased craving, she should call and let you know if she needs to discontinue the taper.

In this case, after two weeks of tapering, Mrs. Wong found it too stressful and asked to be returned to monotherapy. She completed the pregnancy and 6 months of nursing her baby on monotherapy and then transferred back to combination therapy.



QUIZ: ADOLESCENT QUIZ

Which Of The Following Is Part Of The Best Practice Guideline For Adolescents Entering Buprenorphine Treatment? (Choose All That Apply)

1. Should be at least 18
2. Should agree to parental involvement in treatment.
3. Should be opioid dependent for a year or more.

Adolescent Quiz Feedback

(1) Should Be At Least 18

Partially Correct. The suggested youngest age is 16 for starting buprenorphine treatment. Should have one failed attempt on methadone maintenance treatment. History of past failed treatment attempts is recommended, though not MMT specifically. An attempt at a medication-free treatment first is advisable for adolescents.

(2) Should Agree To Parental Involvement In Treatment.

Correct. Family support during treatment will increase the odds of success. Confidentiality laws protect adolescents who do not want parental involvement, however, confidentiality laws and even the definition of who is a minor vary by state. Disclosure may be a condition for payment in some cases since most adolescents are financially dependent.

(3) Should Be Opioid Dependent For A Year Or More.

Correct. Guidelines recommend that adolescents be considered for buprenorphine treatment only if they have been opioid dependent for a year or more.