

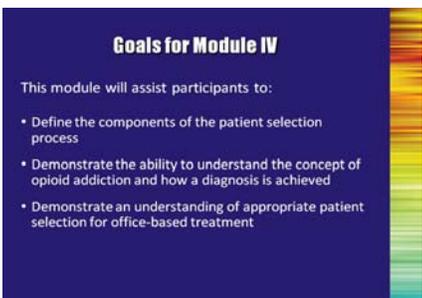
Module IV

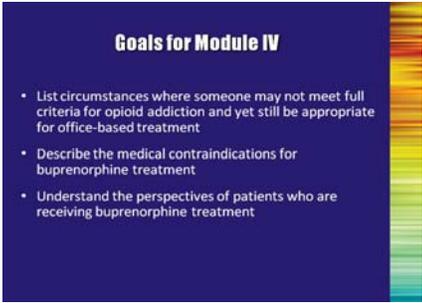
Identification of Patients for Buprenorphine Treatment



Module IV: Identification of Patients for Buprenorphine Treatment

Overall Notes: Be sure to keep people on task – this is the one module where attendees may feel compelled to go beyond the scope of their training/experience, or may start to ask a lot of questions related to the medical aspects of buprenorphine treatment. Remind them of the objectives of this course and proceed with the content of Module IV.

 <p>BUPRENORPHINE TREATMENT: A Training For Multidisciplinary Addiction Professionals</p> <p>Module IV: Identification of Patients for Buprenorphine Treatment</p>	<p>Slide 1: Title Slide</p> <p>Conducting assessments of patients for their suitability for this medication and for the most suitable location for treatment (office-based vs. opioid treatment program, or OTP-based) is a critical process. Multidisciplinary addiction professionals should have a good understanding of the essential components of this process. This module will explore the issue of selecting appropriate patients for buprenorphine treatment.</p> <p>Although the physician will most likely be the individual to determine suitability for buprenorphine treatment, multidisciplinary addiction professionals should be knowledgeable about patient selection and suitability issues for the following reasons:</p> <ul style="list-style-type: none"> • The patient’s appropriateness for treatment may change during the course of buprenorphine treatment; • Potential patients or other treatment providers may ask the counselor about appropriateness for treatment; and • Useful and informed communication with the physician is enhanced by a complete knowledge of the entire treatment process. 	<p>Slide 1</p>
 <p>Goals for Module IV</p> <p>This module will assist participants to:</p> <ul style="list-style-type: none"> • Define the components of the patient selection process • Demonstrate the ability to understand the concept of opioid addiction and how a diagnosis is achieved • Demonstrate an understanding of appropriate patient selection for office-based treatment 	<p>Slide 2: Goals for Module IV</p> <p><i>This module will assist participants to:</i></p> <ul style="list-style-type: none"> • Define the components of the patient selection process. • Demonstrate the ability to understand the concept of opioid addiction and how a diagnosis is achieved. • Demonstrate an understanding of appropriate patient selection for office-based treatment. 	<p>Slide 2</p>

 <p>Goals for Module IV</p> <ul style="list-style-type: none"> • List circumstances where someone may not meet full criteria for opioid addiction and yet still be appropriate for office-based treatment • Describe the medical contraindications for buprenorphine treatment • Understand the perspectives of patients who are receiving buprenorphine treatment 	<p>Slide 3: Goals for Module IV</p> <ul style="list-style-type: none"> • List circumstances where someone may not meet full criteria for opioid addiction and yet still be appropriate for office-based treatment. • Describe the medical contraindications for buprenorphine treatment. • Discuss the case studies presented in the CD-ROM entitled, "Put Your Smack Down! A Video About Buprenorphine." 	<p>Slide 3</p>
 <p>Who is Appropriate for Buprenorphine Treatment?</p>	<p>Slide 4: Who is Appropriate for Buprenorphine Treatment?</p> <p>The following set of slides will review assessment questions, situations in which multidisciplinary addiction professionals should consult with the treating physician, and additional issues relating to patient selection.</p>	<p>Slide 4</p>

Patient Selection: Assessment Questions

- Is the patient addicted to opioids?
- Is the patient aware of other available treatment options?
- Does the patient understand the risks, benefits, and limitations of buprenorphine treatment?
- Is the patient expected to be reasonably compliant?
- Is the patient expected to follow safety procedures?

Slide 5: Patient Selection: Assessment Questions

The patient selection process includes determining if the patient is addicted to opioids, if buprenorphine is the optimal medication for the patient, and if an office or a clinic is the optimal site for treatment. Once a thorough assessment is conducted, the physician can determine if addiction to opioids is present using the DSM-IV-TR criteria mentioned earlier. Treatment success is enhanced by good patient assessment and selection. Ten simple criteria can help to guide patient assessments of appropriateness of office-based buprenorphine treatment.

Read criteria aloud and discuss as follows:

Bullet #1: Is the patient addicted to opioids? Treatment with buprenorphine will generally be conducted with individuals who meet criteria for opioid addiction. However, a physician may consider buprenorphine treatment for a patient with problematic opioid use that has not progressed to addiction. An example of this might be if, in the physician's clinical judgment, the patient has a high risk of progression to addiction or is injecting opioids. Additional candidates include patients with a history of good response to buprenorphine who have had their medication discontinued (perhaps due to incarceration) and are now at risk of relapse (released from prison).

Bullet #2: Is the patient aware of other available treatment options? Even if a patient is addicted to opioids and a suitable candidate for buprenorphine treatment, he/she may not be best treated in an office setting. Patients should be made aware of all of the options available to them and be assisted in making a decision regarding their treatment. Their willingness to participate is critical to compliance with any treatment regimen.

Co-occurring disorders (other substance use disorders, psychiatric disorders, or medical conditions) may lead to the decision to not treat the individual in an office-based setting, since that office cannot provide the other needed services. For example, a physician's office may not be able to provide psychotherapy needed by a patient with a severe personality disorder or the monitoring needed for a patient with AIDS.

Slide 5



	<p>Slide 5: Patient Selection: Assessment Questions, Continued</p> <p>Bullet #3: Does the patient understand the risks, benefits, and the limitations of buprenorphine treatment? The patient needs to be conscious/aware of what buprenorphine WILL and WILL NOT do. Are there indications to suggest that the patient is reliable (i.e., steady employment, showing up on time for appointments, taking other medications as prescribed)? Have cost issues been explained and compared with other treatment options?</p> <p>Bullet #4: Is the patient expected to be reasonably compliant? Is the patient in a situation where he/she can be expected to attend sessions as required, manage the medication appropriately, and take it as prescribed? If the answer is “no,” the treatment team should explore the possibility of conducting the treatment in a highly structured environment (e.g., residential, partial hospitalization)</p> <p>Bullet #5: Is the patient expected to follow safety procedures? Can the patient manage his/her medication appropriately (e.g., keep it away from children in the home), and take it as prescribed?</p>	Slide 5
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Patient Selection: Assessment Questions

- Is the patient psychiatrically stable?
- Is the patient taking other medications that may interact with buprenorphine?
- Are the psychosocial circumstances of the patient stable and supportive?
- Is the patient interested in office-based buprenorphine treatment?
- Are there resources available in the office to provide appropriate treatment?

Slide 6: Patient Selection: Assessment Questions

Read the remaining criteria aloud.

Bullet #1: Is the patient psychiatrically stable? Do they need to be stabilized first? Do they need treatment for co-occurring disorders?

Additional Information for the Trainer(s): According to the Buprenorphine Treatment Guidelines (TIP 40), the presence and severity of co-morbid psychiatric conditions must be assessed prior to initiating buprenorphine treatment, and a determination made whether referral to specialized behavioral health services is necessary. The psychiatric disorders most commonly encountered in patients addicted to opioids are other substance abuse disorders, depressive disorders, posttraumatic stress disorder, substance-induced psychiatric disorders, and antisocial and borderline personality disorder.

Reference:

Center for Substance Abuse Treatment. *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*. Treatment Improvement Protocol (TIP) Series 40. DHHS Publication No. (SMA) 04-3939. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2004.

Bullet #2: Is the patient taking other medications that may interact with buprenorphine? Other medications may include naltrexone, benzodiazepines, or other sedative hypnotics. Another way of asking this question is, "Is this an appropriate medication for the person to be taking?" Additional medications and health conditions should be brought to the attention of the physician, so that the physician is fully informed in making the decision to prescribe buprenorphine or any other medication.

Bullet #3: Are the psychosocial circumstances of the patient stable and supportive? What stressors, relationships, supports, living situation, etc. does the patient have that can contribute to or undermine the success of the recovery plan?

Slide 6



Slide 6: Patient Selection: Assessment Questions, Continued

Read the remaining criteria aloud.

Bullet #4: Is the patient interested in office-based buprenorphine treatment? Even if a patient is a suitable candidate for buprenorphine treatment, he/she may not be best treated in an office setting. Stability and structure of the patient's living situation will help the treatment team determine the most appropriate setting.

Bullet #5: Are there resources available in the office to provide appropriate treatment? Has a comprehensive recovery plan been developed and coordinated between the psychosocial treatment team and the physician? What additional resources need to be added in order to facilitate coordinated care?

If resources are not available in the physician's office, attempts should be made to work in cooperation with a local substance abuse treatment program.

Slide 6



Patient Selection
Issues Involving Consultation with the Physician

Several factors may indicate a patient is less likely to be an appropriate candidate, including:

- Patients taking high doses of benzodiazepines, alcohol or other central nervous system depressants
- Significant psychiatric co-morbidity
- Multiple previous opioid addiction treatment episodes with frequent relapse during those episodes (may also indicate a perfect candidate)
- Non-response or poor response to buprenorphine treatment in the past

Slide 7: Patient Selection: Issues Involving Consultation with the Physician

The multidisciplinary addiction professional should be aware of the following factors and inform the physician of any changes or arising information.

Read factors aloud.

Bullet #1: Patients taking high doses of benzodiazepines, alcohol or other central nervous system (CNS) depressants. The use of benzodiazepines in combination with buprenorphine (especially if injected in an overdose attempt) may result in death. Since alcohol is a sedative-hypnotic, patients should be cautioned to avoid alcohol while taking buprenorphine.

Bullet #2: Significant psychiatric co-morbidity. This may or may not be an issue (case-specific), but should be evaluated to determine appropriate course of treatment for drug addiction and other psychiatric conditions.

Bullet #3: Multiple previous opioid addiction treatment episodes with frequent relapse during those episodes (may also indicate a perfect candidate). Again not exclusionary, but understanding what led to previous treatment failures may help to shape the current recovery plan. Changing to a new treatment, rather than continuing an unsuccessful one, may work well for them.

Bullet #4: Non-response or poor response to buprenorphine treatment in the past.

Slide 7



Patient Selection
Issues Involving Consultation with the Physician

Several factors may indicate a patient is less likely to be an appropriate candidate, including:

- Active or chronic suicidal or homicidal ideation or attempts
- Patient needs that cannot be addressed with existing office-based resources or through appropriate referrals
- High risk for relapse to opioid use
- Poor social support system

Slide 8: Patient Selection: Issues Involving Consultation with the Physician

Read factors aloud.

Bullet #1: Active or chronic suicidal or homicidal ideation or attempts.

Bullet #2: Patient needs that cannot be addressed with existing office-based resources or through appropriate referrals.

Bullet #3: High risk for relapse to opioid use. For example, living in a place where others are consuming heroin or other opioids. This may be an issue of timing; the patient may need a more structured environment (e.g., residential care), or they may be saying that they are not ready to enter treatment.

Bullet #4: Poor social support system. A poor social support system is not ideal for any recovery process. The treatment team should work with the patient to develop a plan to help the person strengthen and engage effective support.

Slide 8



Pregnancy-Related Considerations



- Methadone maintenance is the treatment of choice for pregnant opioid-addicted women.
- Opioid withdrawal should be avoided during pregnancy.
- Buprenorphine may eventually be useful in pregnancy, but is currently not approved.

(Jones et al., 2005)

Slide 9: Patient Selection: Pregnancy-Related Considerations

Slide 9

Bullet #1: Methadone maintenance is the treatment of choice for pregnant opioid-addicted women.

Bullet #2: Pregnancy itself is traumatic to the body (especially if the woman is experiencing “morning sickness”). Generally, it is not recommended for a woman who is already in a vulnerable condition to go through any additional trauma/discomfort of withdrawing from an opioid. If withdrawal is indicated in the treatment plan, most physicians will urge the patient to wait until after delivery. Methadone plus behavioral treatment would then be considered for the immediate treatment plan.

Bullet #3: Buprenorphine may eventually be useful in pregnancy, but is currently not FDA approved.

Reference:

Jones, H. E., Johnson, R. E., Jasinski, D. R., O’Grady, K. E., Chisholm, C. A., Choo, R. E., ... Milio, L. (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.



The Use of Buprenorphine During Pregnancy

- Currently buprenorphine is a Category C medication. This means it is not approved for use during pregnancy.
- Studies conducted to date suggest that buprenorphine *may be* an excellent option for pregnant women.
- Randomized trials are underway to determine the safety and effectiveness of using buprenorphine during pregnancy.



Slide 10: Patient Selection: The Use of Buprenorphine During Pregnancy

Slide 10

There is no evidence of any harmful effects of buprenorphine relative to pregnancy, but in the absence of controlled clinical trials, risk cannot be ruled out.

Bullet #1: Currently buprenorphine is a Category C medication. This means it is not approved for use during pregnancy.

Bullet #2: Studies conducted to date suggest that buprenorphine *may be* an excellent option for pregnant women.

Bullet #3: Randomized trials are underway to determine the safety and effectiveness of using buprenorphine during pregnancy.

Specific Research on Buprenorphine and Pregnancy

- Case series in France: safe and effective, possibly reducing NAS
- One preliminary study in US: examining the use of buprenorphine versus methadone in the treatment of pregnant opioid-dependent patients: effects on the neonatal abstinence syndrome (Jones et al., 2005)

Slide 11: Specific Research on Buprenorphine and Pregnancy

Research on the use of buprenorphine is limited. In a case series conducted in France, buprenorphine was found to be safe and effective and to possibly reduce neonatal abstinence syndrome (NAS).

There has been one preliminary study conducted in the United States by Jones and colleagues (2005). This study examined the use of buprenorphine versus methadone in the treatment of pregnant opioid-dependent patients and effects on NAS.

Reference:

Jones, H. E., Johnson, R. E., Jasinski, D. R., O’Grady, K. E., Chisholm, C. A., Choo, R. E., ... Milio, L. (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.

Slide 11



Specific Research on Buprenorphine and Pregnancy

- Head to head randomized blinded comparison between methadone and buprenorphine in pregnant women
- Women admitted during second trimester
- One statistically significant finding: shorter stay for buprenorphine
- Other trends for buprenorphine: fewer infants treated for NAS, less NAS medication used.
- Multi-site trial in progress now.

Slide 12: Specific Research on Buprenorphine and Pregnancy

This research was conducted as a head to head randomized, blinded comparison between methadone and buprenorphine in pregnant women. Women were admitted during their second trimester.

One statistically significant finding was that the length of hospitalization was shorter for buprenorphine-exposed neonates than for methadone-exposed neonates.

Other trends showed that fewer buprenorphine-exposed infants were treated for neonatal abstinence syndrome; of those treated for NAS, less medication was administered.

Results suggest that buprenorphine is not inferior to methadone on outcome measures assessing NAS and maternal and neonatal safety when administered starting in the second trimester of pregnancy.

A multi-site trial is now in progress.

Reference:

Jones, H. E., Johnson, R. E., Jasinski, D. R., O’Grady, K. E., Chisholm, C. A., Choo, R. E., ... Milio, L.. (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.

Slide 12



**Summary:
Opioid Addiction and Pregnancy**

- Methadone maintenance is still the treatment of choice and standard of care in the US.
- Buprenorphine treatment is possible, evidence still lacking.
- Detoxification is relatively contraindicated unless conducted in hospital setting where the patient can be closely monitored.

Slide 13: Summary: Opioid Addiction and Pregnancy

Bullet #1: Methadone maintenance is still the treatment of choice and standard of care in the United States.

Bullet #2: Buprenorphine treatment is possible, evidence still lacking.

More research is needed before buprenorphine is approved for this indication. In the meantime, it can be used off-label if methadone is not available or appropriate AND the benefits of treatment outweigh the risk of using this medication.

Note to the Trainer(s): *In cases where it is determined that the benefits of buprenorphine treatment during pregnancy outweigh the risks, it is important to utilize the mono-product to minimize the chance of precipitated withdrawal.*

Bullet #3: Detoxification is generally contraindicated unless conducted in a hospital setting where the patient can be closely monitored.

In general, complete withdrawal from opioids is contraindicated. If indicated:

- It should be done in a hospital with careful monitoring.
- Risk of relapse is high and detrimental; ongoing care with monitoring is essential.

Slide 13



**Patient Selection:
Issues Involving Consultation with the Physician**

Patients with these conditions must be evaluated by a physician for appropriateness prior to buprenorphine treatment:

- Seizures
- HIV and STDs
- Hepatitis and impaired hepatic function (Carrier et al., 2000)
- Use of alcohol, sedative-hypnotics, and stimulants (Reynaud, Petit, Potard, & Courty, 1998; Reynaud et al., 1998)
- Other drugs

Slide 14: Patient Selection: Issues Involving Consultation with the Physician

Slide 14

In all cases, consult with the physician who will make medical decisions as to how to treat these individuals.

Bullet #1: Seizures: Seizures can occur with some opioids. While not seen with buprenorphine, careful evaluation should be made.

Bullet # 2 and #3: Human immunodeficiency virus (HIV), hepatitis C virus (HCV), and sexually transmitted diseases (STDs): Of particular concern for opioid-addicted patients are issues regarding HIV/AIDS and HCV. Multidisciplinary addiction professionals should ask patients about their HIV and HCV status, and when they were last tested. If patients have not been tested recently, they should be referred to a physician or given information on how to locate a testing site. If patients are positive for HIV or HCV, they should be asked about the medications they are taking and encouraged to comply with their medication regimen. The treatment team should communicate any new information to the physician regarding the patient's medications in order to monitor potential medication interactions with buprenorphine.

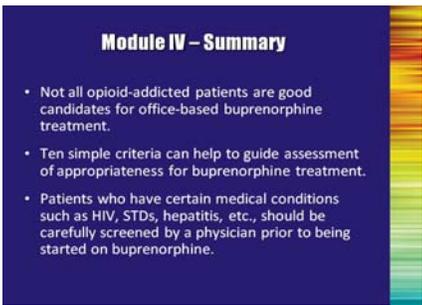
Additional Information for the Trainer(s): Buprenorphine should be used cautiously in combination with HIV antiretroviral medications that may inhibit, induce, or be metabolized by the same liver enzyme system involved with the buprenorphine (cytochrome P450 3A4) enzyme system. Protease inhibitors inhibit cytochrome P450 3A4. Metabolism of buprenorphine and/or the antiretroviral medications may be altered when they are combined. Therefore, therapeutic blood levels may need to be monitored. **Note** that this is a precaution, not a contraindication; successful treatment of addiction with buprenorphine in HIV-infected patients has been well demonstrated (Carrieri et al., 2000).

Bullet #4: Use of alcohol, sedative-hypnotics, and stimulants: As was previously mentioned, the combination of other drugs should be carefully evaluated, especially given the fact that reported overdoses have been related to a combination of CNS depressants and buprenorphine (Reynaud, Petit, Potard, & Courty, 1998; Reynaud, Tracqui, Petit, Potard, & Courty, 1998).



	<p>Slide 14: Patient Selection: Issues Involving Consultation with the Physician, continued</p> <p><u>Bullet #5:</u> Other drugs: Buprenorphine is a treatment for opioid addiction, not other substance use disorders. Addiction to other drugs (e.g., stimulants or sedatives) is common among opioid-addicted patients and may interfere with overall treatment adherence. Patients should be encouraged to abstain from the use of all non-prescribed drugs while receiving buprenorphine treatment. However, although a predictor of poor adherence, use of other drugs IS NOT an absolute contraindication to buprenorphine treatment. They may need to be referred for more intensive treatment.</p> <p><u>References:</u></p> <p>Carrieri, M.P., Vlahov, D., Dellamonica, P., Gallais, H., Lepeu, G., Spire, B., & Obadia, Y. (2000). Use of buprenorphine in HIV-infected injection drug users: Negligible impact on virologic response to HAART. The Manif-2000 Study Group. <i>Drug and Alcohol Dependence</i>, 60(1), 51–54.</p> <p>Reynaud, M., Petit, G., Potard, D., & Courty, P. (1998). Six deaths linked to concomitant use of buprenorphine and benzodiazepines. <i>Addiction</i>, 93(9), 1385–1392.</p> <p>Reynaud, M., Tracqui, A., Petit, G., Potard, D. & Courty, P. (1998). Six deaths linked to misuse of buprenorphine-benzodiazepine combinations. <i>American Journal of Psychiatry</i>, 155(3), 448–449.</p>	<p>Slide 14</p> 
 <p>Patient Selection</p> <ul style="list-style-type: none"> • Patients who do not meet criteria for opioid addiction may still be appropriate for treatment with buprenorphine <ul style="list-style-type: none"> – Patients who are risk of progression to addiction or who are injecting – Patients who have had their medication discontinued and who are now at high risk for relapse 	<p>Slide 15: Patient Selection</p> <p>There are instances in which patients who do not meet criteria for current opioid addiction may still be candidates for buprenorphine treatment.</p> <p>Read the two examples aloud.</p> <ul style="list-style-type: none"> • Patients who are at risk of progression to addiction or who are injecting; • Patients who have had their medication discontinued and who are now at high risk for relapse. 	<p>Slide 15</p> 

<p>Patient Selection: Additional Details</p> <ul style="list-style-type: none"> • Suitability determined by a physician • What is the relevance to counselors? <ul style="list-style-type: none"> – Patient’s appropriateness may change during treatment – Potential patients or other providers may inquire about treatment – More useful and informed communication with physician 	<p>Slide 16: Patient Selection: Additional Details</p> <p>The multidisciplinary addiction professional can have a lot of impact on or influence over the physician’s decision regarding patient suitability – even though the addiction professional is not personally responsible for determining suitability.</p>	<p>Slide 16</p>
<p>Case Studies: “Put Your Smack Down!” <small>A video from the O.A.S.I.S. Clinic, Oakland, CA</small></p>	<p>Slide 17: Optional</p> <p>Case Studies: “Put Your Smack Down!” A Video from the O.A.S.I.S. Clinic, Oakland, CA</p> <p><i>Preface the video with the following statement:</i></p> <p>We are now going to watch a video that was developed by the O.A.S.I.S. Clinic in Oakland, CA. The video shows people talking about their experience with taking buprenorphine.</p> <p>The purpose of showing this video is to add the patient experience into the conversations. However, it is important to remember that this is only their opinion. Some of the statements come across as if buprenorphine should replace methadone. As we have discussed, buprenorphine is one option for treatment, not a replacement for any existing treatment. Also, there is a lot of talk about how long someone needs to be abstinent from heroin prior to induction with buprenorphine. Physicians use a variety of induction strategies; the 24-hour wait is one way of handling it.</p> <p><i>Play the video now. Make sure that the computer speakers are turned up.</i></p>	<p>Slide 17</p> 

 <p>Group Discussion "Put Your Smack Down! A Video about Buprenorphine"</p>	<p>Slide 18: Optional</p> <p>Group Discussion of Case Studies Presented in "Put Your Smack Down! A Video About Buprenorphine"</p> <p><i>Upon completion of the video, spend a few minutes discussing the buprenorphine patients' experiences and other possible case studies, if people have specific examples.</i></p> <p>What reactions, comments or questions do you have about the information in the video?</p> <p>Does anyone have any other case examples that they would like to share?</p>	<p>Slide 18</p> 
 <p>Module IV – Summary</p> <ul style="list-style-type: none"> • Not all opioid-addicted patients are good candidates for office-based buprenorphine treatment. • Ten simple criteria can help to guide assessment of appropriateness for buprenorphine treatment. • Patients who have certain medical conditions such as HIV, STDs, hepatitis, etc., should be carefully screened by a physician prior to being started on buprenorphine. 	<p>Slide 19: Module IV – Summary</p> <ul style="list-style-type: none"> • Not all opioid-addicted patients are good candidates for office-based buprenorphine treatment. • Ten simple criteria can help guide assessment of appropriateness for buprenorphine treatment. • Patients with certain medical conditions, including HIV, STDs, and HCV, should be evaluated by a physician prior to beginning buprenorphine treatment. 	<p>Slide 19</p>