Integrating Buprenorphine Treatment for Opioid Use Disorder in HIV Primary Care

Dissemination of Evidence Informed Interventions
Boston University School of Public Health
AIDS United
Health Resources and Services Administration (HRSA) Special Programs of National Significance
Background

The intersection of opioid use, particularly via injection, and HIV is well documented. In the United States, contracting HIV through injection drug use, either directly or via sexual contact with a person who injects drugs, accounts for more than one-third of estimated AIDS cases since the beginning of the AIDS epidemic, and 9% of estimated new infections. Untreated opioid use disorder is problematic, particularly as injecting behavior is associated with increased risk of HIV transmission, as it interferes with antiretroviral treatment adherence and impedes HIV viral suppression. The devastating outbreak of more than 180 HIV infections diagnosed in 2015 among persons injecting oxymorphone in rural southeastern Indiana is an example of the way in which injection drug use can be the primary driver of localized epidemics.

In recent years, dramatic increases in opioid-related fatal overdoses and acute hepatitis C infections underscore the urgent need to identify and treat opioid use disorder in both persons living with HIV (PLWH) and people at risk of HIV infection. In January 2016, the CDC reported that since 2000, there’s been a 200% increase in the rate of overdose deaths involving opioids.

Opioid use disorder is treatable with FDA-approved pharmacotherapies. Buprenorphine is one such treatment option, which can be delivered in the primary care office setting. For PLWH, office-based buprenorphine treatment delivered in HIV clinics is associated with decreased opioid use, increased ART use, higher quality of HIV care, and improved quality of life.

Buprenorphine Treatment Overview

Buprenorphine, a partial opioid agonist, was approved by the FDA in 2002 for the treatment of opioid dependence. As per the Drug Addiction Treatment Act of 2000, buprenorphine may be prescribed outside the Narcotic Treatment Program (NTP) setting by physicians who have completed a necessary 8-hour training and received a special waiver.

Currently, buprenorphine is available in two sublingual preparations. One is composed of buprenorphine hydrochloride. The other is a combination tablet or film composed of buprenorphine hydrochloride and naloxone hydrochloride. Naloxone is not absorbed sublingually and use of the combination tablet decreases the risk of diversion, injection, and fatal overdose. The only indications to use the buprenorphine mono-product is with pregnancy and allergy to naloxone.

Since buprenorphine acts as a partial agonist at mu opioid receptors, it may precipitate opioid withdrawal in a patient who has recently used opioids. Patients should not be induced on buprenorphine if they have opioids in their system. The duration of time in which opioids may stay in patients’ system depends on the specific pharmacologic properties of the opioid and patients’ liver function (because opioids are metabolized through the liver). Typically, if patients have used a short-acting opioid such as heroin, it will remain in their system for up to 6-8 hours, or, if they used a long-acting opioid such as methadone, it can remain in their system for up to 24 hours to several days. Patients should only be initiated on buprenorphine if they are showing objective signs of opioid withdrawal (unless they have been opioid-free for at least several days).

Prior to taking a history and conducting a physical exam, one should confirm that the patient is appropriate for buprenorphine treatment, including having a diagnosis of an opioid use disorder. An initiation phase beginning with a low dose of buprenorphine, followed by increasing doses over several days is recommended to minimize the likelihood of precipitating opioid withdrawal. After initiation, buprenorphine may be taken once or twice daily. Once a stable dose of buprenorphine is established, a therapeutic dose can be maintained over a stable period of time.
How to use this guide

There are three main resources that will facilitate a successful implementation of this intervention. The Implementation and Technical Assistance Center (ITAC) at AIDS United, the Dissemination and Evaluation Center (DEC) at Boston University, and the Health Resources and Services Administration (HRSA) have collaborated to create the following:
1. Training Manual
2. Implementation Manual
3. Evaluation Protocol

This Implementation Manual is the road map for the implementation process. It follows the intervention’s logic model (Appendix A) and 3 year work plan (Appendix C). This manual complements the training provided by the ITAC, and is not meant to serve as a substitution for any training components provided by the ITAC. If your site feels as though it needs additional training on any of the content or activities addressed in this manual, contact the ITAC:

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All evaluation activities, protocols, and tools are included in the evaluation protocol. For all evaluation related questions or technical assistance needs, contact the DEC:

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Pre-implementation activities

The following are programmatic requirements that need to be addressed prior to the start of implementation:

**Assess internal and external clinic systems:**
1. Clinic administrators will assess clinic space and identify and secure space for intervention activities.
2. Clinic administrators will work with the intervention team to obtain any necessary technology for the intervention (tablet, laptop, etc.) and secure internet capabilities at all locations where data could be entered.
3. Intervention team members will establish (or strengthen existing) relationships with mental health and substance use treatment providers (on site or in the community).
   a. Create a Memorandum of Agreement (MOU) for referrals of patients who need more intensive services for addiction medicine with an agreed upon process and timeline for referral appointments.
   b. Establish community referral networks with organizations providing the following services: counseling, mutual support groups, withdrawal management, vocational training, methadone treatment, intensive outpatient treatment, and residential treatment.

4. Clinic administration will determine and document fees, payment plans, and policies, including the types of insurance that will be accepted and whether or not to apply to patient assistance programs. Clinic administration will identify the staff person at the clinic who will be the point person for addressing issues related to insurance authorization.

5. Intervention team members will secure sustainable patient access to buprenorphine medication. In order to do so, the intervention team will establish working relationship with onsite or community pharmacy that will dispense medication and working with benefits counselors to obtain coverage for opioid treatment pharmacotherapies. The intervention team will work with the pharmacy to insure that the pharmacy is able to stock the various sublingual formulations of buprenorphine (unless the patient also is pregnant, most patients will receive co-formulated buprenorphine and naloxone tablets or film).

Hire or identify intervention team members:
1. Clinic administration will hire or identify intervention team members including 2 prescribing providers, 1 clinical coordinator, and a data manager (utilizing the job descriptions and staffing plan in Appendix B).
2. Buprenorphine prescribers will identify and have access to a clinical mentor, defined as another health professional with expert knowledge and practical experience in buprenorphine treatment. Ideally, this mentor will maintain a buprenorphine practice in the same health network or geographic locale and meet for case conferences month. Clinic prescribers also will be encouraged to participate in the Physician Clinical Support System for Medication Assisted Treatment (PCSS-MAT), a national training and mentoring project.
   a. To find a mentor or learn more about mentorship, visit www.pcssb.org or http://ceitraining.org/bupren/ . To chat with other DATA-waiver approved physicians, join the free SAMHSA buprenorphine clinical discussion web board at http://bup-webboard.samhsa.gov/login.asp?target=default.asp.
3. Intervention team members will participate in all trainings provided by the ITAC regarding the intervention, implementation, and contextual factors related to the patient population.
4. Intervention team members will participate in all trainings provided by the DEC regarding data collection methods, tools, and protocols.
5. Providers will participate in all necessary trainings to receive buprenorphine prescription waivers.
6. In year 2 of the intervention, the providers will apply to the DEA to treat additional patients.
7. The clinical coordinator will complete an online, non-specific buprenorphine training (identified by the ITAC).

Develop, review, and implement necessary protocols and materials:
1. Intervention team members will review the following clinical guidelines provided the implementation phase of this manual that correspond to 1) patient stability and experience and 2) provider skills and confidence, and make any additions necessary:
   a. Initial patient selection and assessment
   b. Preparing patients for treatment
   c. Treatment initiation and stabilization
   d. Maintenance treatment and monitoring
e. Patient-centered treatment intensification (i.e. more frequent visits, more counseling, referral to other outpatient drug treatment programs)
f. Treatment failure and/or transfer of care
g. Re-initiation of treatment after drop out

2. Intervention team members will create procedures to follow federal mandates for record keeping practices. Intervention team members will create procedures to follow federal mandates for record-keeping practices. This includes keeping and maintaining a patient log for each prescriber, ensuring secure medical record storage, and maintaining records for Drug Enforcement Administration (DEA) visits.

3. Intervention team members will create protocols for provider on-call and back-up systems that answers questions related to managing care outside of normal clinic hours. For example, do all clinic patients currently have access to an HIV provider during clinic hours and through an answering service at nights and on weekends? Does that provider know how to manage patients on buprenorphine for the treatment of opioid use disorder? If not, does that provider know how to contact the buprenorphine provider on call?

4. The intervention team will develop a protocol for referral in the local health care community, so that the intervention team can refer patients who need supplemental or higher levels of care and/or the treatment of comorbid substance use and mental health disorders. Examples of types of care include counseling, mutual support groups, withdrawal management, methadone treatment, intensive outpatient treatment, crisis management interventions, and residential treatment.

5. The intervention team will implement policies that address safety and boundary issues to protect both the intervention team and the clinic staff.

6. The intervention team will develop a protocol for accepting referrals (internal and external) to receive buprenorphine treatment. The protocols will be based on the following criteria:

   **Inclusion criteria (patients must meet ALL requirements to be eligible)**
   - HIV-positive
   - Eligible for primary care at the intervention site
   - Diagnosed with an opioid use disorder as determined by DSM-5 criteria and desiring pharmacotherapy for this disorder
   - Currently receiving primary care (or willing to start primary care) at the intervention site
   - Age ≥ 18 years or emancipated minor able to consent for medical and substance use treatment
   - It is recommended that female patients receiving buprenorphine use adequate birth control methods (pill, IUD, condom with spermicide, abstinence, etc.)
   - Able to comply with buprenorphine treatment program policies.

   **Exclusion criteria (patients meeting ANY of these criteria are ineligible)**
   - Severe hepatic dysfunction, i.e. AST and/or ALT ≥ 5x upper limit of normal
   - DSM-5 criteria for benzodiazepine use disorder
   - DSM-5 criteria for alcohol use disorder
   - Active suicidal ideation
   - Psychiatric impairment that impedes ability to provide informed consent to make decision regarding their own care(dementia, delusional, actively psychotic)
   - Methadone or opioid analgesic doses exceed levels allowing for safe transition to buprenorphine (methadone >30-60 mg)
   - Patients with acute or chronic pain syndrome requiring chronic use of opioid analgesics
   - Patient has serious/uncontrolled/untreated medical problems (hypertension, hepatic failure, asthma, diabetes, etc.) or psychiatric disorders.
Patient requires a higher level of care than can be offered in the HIV clinic (i.e., methadone maintenance or mental illness chemical addiction [MICA] program)

- Patient has a known allergy/hypersensitivity to buprenorphine or naloxone

Eligible patients may be identified by their primary care or other providers at the clinic and may be referred for evaluation and treatment at the clinic. Patients also may be self-referred or be referred by any provider in the community. Using the referral protocol developed by your clinic in the pre-implementation phase, a member of the clinical team (previously identified in the referral protocol) will make contact with the patient, and will make an appointment for the patient to meet with prescribing provider for a patient assessment.

7. The intervention team will review existing patient education materials referenced in this implementation manual, and will make any necessary clinic specific additions.

Prepare for evaluation

1. The intervention team will obtain Institutional Review Board (IRB) approval to participate in the multisite evaluation study. All intervention team members will need to complete the human subjects training.

Establish intervention team communication

Throughout the implementation of the Integrating Buprenorphine Treatment for Opioid Use Disorder in HIV Primary Care intervention:

1. The intervention team (the prescribing providers, clinical coordinator, and data manager) will meet weekly for case conferencing.
2. The clinical coordinator will receive weekly supervision from the prescribing provider.
3. The prescribing physicians will meet with their clinical mentors on a monthly basis.
4. The intervention team will have consistent meetings with the ITAC and the DEC.

Selecting and assessing patients for treatment

The objectives of the assessment process are to determine the patient’s clinical eligibility for buprenorphine treatment, provide the basis for a treatment plan, and establish a baseline measure to evaluate a patient’s response to treatment. The intervention team will utilize the protocol established in the pre-implementation phase to establish whether the patient meets clinical eligibility. The team will determine with the patient whether the potential benefits of buprenorphine treatment (improved health outcomes, reduced transmission risks) outweigh any potential risks (overdose, diversion) to the patient or to the community.

Components of the patient assessment conducted by the treatment team will include an initial clinical encounter to:

1. Establish the diagnosis of opioid use disorder, including the duration and severity of opioid use.
2. Discuss current opioid use and patterns, including level of tolerance, prior quit attempts, prior experiences with opioid agonist treatment, nature and severity of opioid withdrawal symptoms, time of last use, history of overdose, and current withdrawal status (Appendix D).
   b. Observe possible substance intoxication, including, but not limited to, alcohol odor, nystagmus, positive Romberg test, patient disinhibition, or other altered mental status.
   c. Document drug or needle use sequelae, including presence of track marks, abscesses, and cellulitis.
3. Document the patient’s use of other substances, including tobacco, alcohol, benzodiazepines, and other drugs.
   a. Current opioid habit, including type of opioid, method of administration, frequency of use, last use
b. Review alcohol, sedative, and other substance use. Chaotic alcohol and sedative (e.g. benzodiazepines) use in conjunction with the injection of pulverized buprenorphine tablets has been associated with opioid overdose. The combined buprenorphine/naloxone formulation is recommended to deter this practice.

c. Review past treatment experiences, including patient response to treatment, side effects, and perceived effectiveness.

d. Note: DSM-5 Diagnostic Codes Related to Substance Use Disorders can be found here: http://www.buppractice.com/printpdf/2633

4. Identify patients who need medically supervised withdrawal management from alcohol, benzodiazepines, or other sedatives prior to initiating buprenorphine treatment.

5. Identify comorbid medical conditions and psychiatric disorders and determine how, when, and where they will be addressed.
   a. **Liver disease:** Patients with decompensated cirrhosis may require closer monitoring. See below regarding AST/ALT.
   b. **Pain syndromes:** Buprenorphine has analgesic properties, but it cannot be used in patients with acute or chronic pain syndromes requiring high doses of full opioid agonist therapy (e.g. morphine, methadone, oxycodone, fentanyl, hydromorphone).
   c. **Medications** metabolized by cytochrome P450 3A4 system, e.g. many HIV antiretroviral and psychiatric medications; 3A4 inhibitors may increase drug levels of buprenorphine causing symptoms of opioid excess. For example, patients on ritonavir-boosted regimens, notably ritonavir-boosted atazanavir may require a downward dose adjustment of buprenorphine, though this is not so common.
   d. **ALT, AST**—results over 5 times the normal upper limit may increase the risk of buprenorphine-induced hepatitis; buprenorphine treatment should be delayed until transaminitis has resolved;
   a. **Urine drug testing:** Expect opiate-positive urine toxicology screens. These can help inform the team of other substance use.
   b. **Pregnancy test** (serum or urine HCG) within 72 hours for female patients of childbearing age. Assess and document an effective **birth control method** for female patients of childbearing age (if the patient is using one).

6. Screen for communicable diseases (e.g. viral hepatitis, TB, syphilis) and manage them as clinically indicated.

7. Assess patients’ access to social supports, family, friends, employment, housing, finances, and legal assistance.

8. Determine patients’ readiness to participate in treatment and their goals for engaging in treatment.

9. Identify how the buprenorphine treatment will be covered (on an individual basis)

10. Provide patient education on naloxone (materials available at prescribetoprevent.org)

11. After completing the initial screen, the clinical coordinator will explain the intervention (including the role of the physician and the clinical coordinator).

12. The clinical coordinator will explain the multi-site evaluation and ask the patient if they want to participate in the multi-site evaluation. This should be facilitated as quickly as possible to avoid delay of treatment.
   a. If the patient wants to participate in the multi-site evaluation, the clinical coordinator will make an appointment for the patient to meet with the data manager who will enroll them into the multi-site evaluation. The meeting with the data manager should ideally occur on that day. If this is not possible, the meeting between the data manager and the patient must occur within seven days from the initial meeting between the clinical coordinator and the patient.
     i. If the patient does want to participate in the multi-site evaluation, the data manager will consent the patient into the evaluation and administer the baseline survey (the data manager should refer to the evaluation protocol for specific instructions on administering the baseline survey).
     ii. The data manager will explain the process for withdrawing from the intervention and/or the evaluation:
1. If the patient chooses to withdraw from multi-site evaluation: The patient must tell a staff member. That staff member will inform the data manager and the clinical coordinator. The patient can still be enrolled in the intervention after discontinuing engagement in the multi-site evaluation.

2. If the patient chooses to withdraw from the intervention: The patient must tell a staff member and the staff member must then inform the clinical coordinator. The patient can still be enrolled in the multi-site evaluation even after discontinuing engagement in the intervention.

iii. If the patient decides that he/she does not want to participate in the multi-site evaluation, the clinical coordinator will explain his/her options for care (receiving the buprenorphine treatment, the standard of care, or another program offered at the clinic). The clinical coordinator will complete the form documenting the patient’s reason(s) for declining participation and patient what care the patient ultimately receive. Raw, individual patient level data from patients who decline to be a part of the multi-site evaluation will not be submitted to the DEC (only aggregate data will be reviewed).

Once the patient has been consented into the study and completed the baseline survey, the clinical coordinator will prepare the patient for treatment.

Preparation of patients for treatment

The steps to prepare a patient for treatment are performed by the prescribing provider or the clinical coordinator (the treatment team), and include the following:

1. Educate the patient about buprenorphine treatment, including how to properly administer, safeguard, and discard the medication, what they can expect to experience at each stage of treatment, and alternatives to buprenorphine treatment.

   - The treatment team will provide the following resources to patients:
     - The Facts About Buprenorphine for Treatment of Opioid Addiction (U.S. Department of Health and Human Services) [http://store.samhsa.gov/shin/content/SMA09-4442/SMA09-4442.pdf](http://store.samhsa.gov/shin/content/SMA09-4442/SMA09-4442.pdf)
     - Medication-Assisted Treatment for Opioid Addiction: Fast Facts for Family and Friends (U.S. Department of Health and Human Services) [https://store.samhsa.gov/shin/content/SMA09-4443/SMA09-4443.pdf](https://store.samhsa.gov/shin/content/SMA09-4443/SMA09-4443.pdf)
     - Useful information for patients about what buprenorphine treatment is like and how to prepare for treatment initiation can be found at the website of The National Alliance of Advocates for Buprenorphine Treatment: [http://www.naabt.org/education/what_bt_like.cfm](http://www.naabt.org/education/what_bt_like.cfm)
     - Patient Handouts listed in Appendix I.

2. The treatment team will work with the patient to complete a treatment agreement describing the goals of treatment, the risks and benefits of treatment, and the relationship between the patient and the treatment team (Appendix F).

3. The treatment team will communicate with other providers in patient’s circle of care about the treatment plan, especially with other substance use treatment or mental health providers. This will require signed releases of information to exchange health information protected by federal 42 CFR Part 2 confidentiality regulations.

4. The treatment team will refer patients who need medically supervised withdrawal management from alcohol, benzodiazepines, or other sedatives prior to initiating buprenorphine treatment (using the MOU developed in the pre-implementation phase).
5. The treatment team will prepare patients who have not completed withdrawal to achieve a mild-moderate state of opioid withdrawal on the day of buprenorphine initiation. The patient should exhibit signs of at least mild withdrawal prior to receiving their first dose of buprenorphine.

- Heroin withdrawal typically begins 12 to 24 hours after last use, peaks at 2 to 3 days, and lasts 5 to 7 days. Heroin use should be stopped at least 12 hours prior to buprenorphine initiation.
- Methadone withdrawal typically begins 1 to 3 days after last use, peaks at 5 to 7 days, and lasts 14 to 21 days. For patients on methadone, a taper down to dose of 30mg/day is recommended prior to buprenorphine initiation to reduce the risk of precipitated opioid withdrawal. Methadone administration should be stopped at least 24-48 hours prior to buprenorphine initiation.

6. In preparation for initiating treatment and to ease discomfort, the treatment team may wish to dispense small quantities of medications to provide symptomatic relief of opioid withdrawal symptoms beforehand. In addition to anticipatory guidance, the program may wish to dispense or prescribe “kick-packs” or “comfort packs” (i.e. small quantities of medications to provide symptomatic relief of opioid withdrawal symptoms).

- Clonidine 0.1 to 0.3mg PO q4 to 6 hours PRN lacrimation, diaphoresis, rhinorrhea, piloerection;
- Loperamide (Imodium) 4mg PO x 1 PRN diarrhea, then 2mg PO PRN each loose stool or diarrhea thereafter, NTE 16mg/24h;
- OTC acetaminophen 500-1000 mg q 4-6 hrs, ibuprofen 600 mg q 8 hrs, or naproxen 500 mg q 12 hrs PRN myalgias or arthralgias

**Initializing, stabilizing, and maintaining patients**

The goal of initiation and stabilization is to find the lowest dose of buprenorphine at which the patient discontinues or markedly reduces the use of other opioids without experiencing withdrawal symptoms, significant side effects, or cravings. When a stable buprenorphine dose is achieved, patients enter into a maintenance phase of treatment.

- Clinically appropriate patients will have been prepared for treatment (described above) and present for treatment initiation in an opioid-free state to reduce the risk of precipitated withdrawal. On the day of initiation, the patient should exhibit signs of at least mild withdrawal (COWS > 5) prior to receiving their first dose of buprenorphine.

- The treatment team should determine if it will offer home and/or office based treatment initiation to patients and review protocols for each (and make any clinic specific additions). Factors to consider when deciding between home and office-based induction include:
  a. Provider’s and patient’s experience with initiating buprenorphine treatment: Patients who have prior experience with buprenorphine tend to have better outcomes than those who do not have experience with buprenorphine, and may be well-suited for home-based inductions.
  b. Patients who have previously taken buprenorphine and are familiar with its pharmacodynamics, know their withdrawal/craving symptoms, and have demonstrated both comfort and skill at starting the medicine without clinical observation, are good candidates for home-based inductions. It is ideal for such patients to have telephone access to providers for advice and/or coaching through the induction, if needed.
  c. Patient’s ability to tolerate opioid withdrawal symptoms: Patients who are very concerned or anxious about experiencing opioid withdrawal may want to experience withdrawal and undergo induction within a clinical setting where they can be observed. Often patients with underlying anxiety may have difficulty differentiating their symptoms due to anxiety versus opioid withdrawal. In this case, home-based inductions may be challenging.
  d. Patients transferring from methadone to buprenorphine: These patients may have difficulties with the induction for two reasons:
i. They may have not experienced opioid withdrawal symptoms in years (because of having received methadone treatment for years) and be quite fearful or anxious of experiencing withdrawal.

ii. Because methadone is so long-acting, they are at higher risk of precipitated withdrawal than patients who use opioids other than methadone. These patients are likely best suited for office-based inductions.

e. Patient’s circumstances: Some patients may have a difficult time taking several days off of work when buprenorphine treatment is initiated. They would likely benefit from a home induction that can occur over a weekend.

f. Patients without telephones, are homeless, or are unstably housed may do better with an office-based induction.

**Home-based induction**

For patients who undergo home-based inductions, the treatment team should review the home induction kit and create a clear plan with the patient for induction, stabilization, and maintenance (Appendix G).

1. The medications that will typically be provided include:
   a. Buprenorphine 8/2mg – Typically provide enough buprenorphine such that patients can achieve a dose of 16mg per day until the next scheduled visit within 3-7 days.
   b. Ancillary medications to treat symptoms of withdrawal, including clonidine, loperamide, and an NSAID (see section X of this document).

2. The treatment team will review symptoms that patients will experience during opioid withdrawal. Patients are expected to experience at least 5 of the 13 symptoms listed in the Subjective Opioid Withdrawal Scale (SOWS) (available here: http://www.buppractice.com/node/5775).

3. The treatment team will review things that patients should not do. These include NOT taking buprenorphine when they have opiates in their system (including opioid analgesic or methadone), are drinking alcohol, or are taking benzodiazepines. In addition, the patient should NOT swallow buprenorphine (they should take it sublingually) or lose their medication.

4. The treatment team will review how to take buprenorphine sublingually and not orally. Refer to the picture in the home induction kit.

5. The treatment team will develop a clear plan on dosing and timing of medication. Review when patients should stop taking their current opioid and when they should start taking buprenorphine. Write out approximate times and doses. Include the length of time that patients should wait to reassess their withdrawal symptoms. Provide contact information for patients if they have questions or problems.

6. The treatment team will review with patients how to track the amount of medication they take. Review with them how they should start day 2 with the total amount of medication they took during day 1. And to start day 3 with the total amount they took during day 2. Review with them that they should typically take up to a maximum of 16mg daily until they are further assessed by a provider.

   g. Resource to distribute to patients: “What is Buprenorphine Treatment Like?” From The National Alliance of Advocates for Buprenorphine Treatment (https://www.naabt.org/education/what bt like.cfm)

**Office-based induction**

The following treatment initiation protocol details the office-based procedures for assessing for physical dependence (symptoms of withdrawal) and starting and maintaining patients on buprenorphine. Patients already will have been assessed for treatment appropriateness, including confirmation of diagnosis of moderate-to-severe opioid use disorder and other clinical criteria (as described above).

One of the most important aspects of the initial visit for office-based induction is to assess the level of opioid withdrawal that patients are experiencing.
1. Using the COWS, first document the patient’s opioid withdrawal symptoms: cravings, cravings, anxiety, discomfort, pain, nausea, hot or cold flushes.

2. Next, based on physical exam, document the patient’s signs of withdrawal, including autonomic excitation (elevated BP, increased HR), mydriasis, tremors, agitation/restlessness. Also note the presence or absence of yawning, rhinorrhea, piloerection, hot and cold flushes, diaphoresis, lacrimation, vomiting, and muscle fasciculations. Use the COWS to score the patient’s opioid withdrawal as mild, moderate or severe.
   a. Patients should exhibit signs of at least mild withdrawal (COWS > 5) prior to receiving their first dose of buprenorphine. If patients appear intoxicated or exhibits no signs of withdrawal, then they should not be started on buprenorphine at this visit. Patients should be rescheduled for a later date or time and counseled regarding the need to present when they are experiencing at least mild opioid withdrawal. An exception may be made for patients who have gone through medical detoxification (e.g. inpatient detoxification program) or non-medical detoxification (e.g. jail) and now present opioid free and with drug craving.

3. In addition to assessing opioid withdrawal, also assess for possible substance intoxication, including but not limited to EtOH odor, nystagmus, positive Romberg test, patient disinhibition, or other altered mental status.

4. Review lab results: Urine will be collected on the first day of initiation and sent to the lab for routine toxicology, or tested in the clinic using a point-of-care test kit. This test can be done more frequently if needed, e.g. weekly during stabilization period.

Initial buprenorphine doses for office-based induction
Patients who are determined to be in at least mild opioid withdrawal (COWS >5) and who do not have signs of intoxication of other substances should receive their initial doses of buprenorphine as described below.

1. For patients exhibiting mild withdrawal, give buprenorphine 2 mg SL. For patients exhibiting moderate to severe withdrawal, give buprenorphine 4 mg SL. The sublingual tablet or film must dissolve completely under a moist tongue, which may take 5-10 minutes. Most patients experience relief of withdrawal symptoms or reduction in cravings within the first 15-20 minutes after taking the tablet or film.
   a. Note: Depending on the specific formulation prescribed, the initial doses of buprenorphine may be portions of a tablet or film, or the entire tablet or film. Because of possible authorization issues required by many insurance companies, prescribing the 8 mg tab or film may be the most feasible. In this case, patients may need to take ¼ or ½ of the tablet or film as the initial dose.

2. Re-evaluate patient after 20-30 minutes.
   a. If there is no change in symptoms (no worsening), or symptoms are somewhat improved, an additional dose of buprenorphine 2 to 4 mg SL may be given. Reassess the patient again in 20-30 minutes for symptom relief. This process of providing an additional dose and reassessment may occur again, or the patient may be provided with two additional -4mg take-home doses should withdrawal or marked craving recur in the evening. The total amount of buprenorphine that is typically provided on the first day of dosing is 8-12mg.
   b. A sudden exacerbation of opioid withdrawal symptoms after administering buprenorphine usually indicates the continued presence of other (full agonist) opioids and the phenomenon known as “precipitated withdrawal.” Discuss with patient and review time of last opioid use. Give other medications at the clinic for symptom management and instructed to return the following day for re-evaluation.
      i. Clonidine 0.1 PO q 6 hours PRN lacrimation, diaphoresis, rhinorrhea, piloerection;
      ii. Loperamide (Immodium) 4mg PO x 1 PRN diarrhea, then 2mg PO PRN each loose stool or diarrhea thereafter, not to exceed 16mg/24hrs;
      iii. ibuprofen 600 mg q 8 hrs, or naproxen 500 mg q 12 hrs PRN myalgias or arthralgias
2. Patients should return to clinic in the next 1-2 days for re-evaluation and upward dose titration. Some patients who are well-engaged in care or have prior experience with this medication can be given a week’s worth of medication on the day of induction and are able to be re-evaluated over the telephone during week 1 of induction.
   a. Note: Initial doses that are too high may acutely exacerbate withdrawal symptoms, while titrating up too slowly may needlessly prolong withdrawal—either of these situations may result in patient relapse or other treatment non-compliance.

Typical doses during the induction are as follows: for
- first 24 hours: typically 8 and 12 mg total; should not exceed 16mg.
- day 2-3: if symptoms of opioid withdrawal continue, increase daily dose by 2-4mg depending on severity of opioid withdrawal (e.g. add 2 mg for mild withdrawal or 4 mg for mod-severe withdrawal). Typical dose is between 8-16mg, not to exceed 24 mg.

Stabilization Visits
After buprenorphine initiation, the treatment team will monitor patients either daily (for unstable patients) or once or twice weekly (stable patients). Stabilization occurs over 2 visits typically (around day 3-7 and again around day 10-14). The prescribing provider will increase the buprenorphine dose daily until the patient no longer has signs and symptoms of withdrawal or craving and has not developed signs or symptoms of opioid excess.

First stabilization visit
1. The treatment team will assess opioid withdrawal using COWS worksheet (Appendix H) and review use of any adjunct medications for symptom management.
2. The treatment team will order a urine sample for toxicology.
3. The treatment team will give total daily dose administered on the previous day. Add an additional 2 to 4mg as needed (up to 16mgs) based on severity of withdrawal symptoms (e.g., add 2 mg for mild withdrawal or 4 mg for mod-severe withdrawal). A typical dose at the first stabilization visit is 16mg, with a typical range between 8-24mg.

Second stabilization visit
1. The treatment team will have patient return for continued monitoring and stabilization – either daily (for unstable patients) or twice-three times per week with phone monitoring (very stable patients).
2. The treatment team review symptoms of opioid withdrawal (using COWS at each visit) and craving. Most likely at the second stabilization visit, patients will no longer be experiencing signs or symptoms of opioid withdrawal. However, they may continue to experience cravings.
3. Continue to increase buprenorphine dose daily by 2 to 4 mg until patients no longer experiences opioid withdrawal or cravings.
   a. Criteria for dose increases:
      ▪ Significant opioid craving (especially towards end of dosing cycle)
      ▪ Significant opioid withdrawal symptoms (especially towards end of dosing cycle)
      ▪ Urine toxicology persistently positive for opioids
4. Target Dose is the dose that results in the optimal relief of objective and subjective opioid withdrawal symptoms and cravings. The median expected dose is 16mg daily, though lower doses such as 8mg per day may be sufficient and higher doses such as 24mg may be required. Maximum daily dose is 24mg.
   a. Most patients reach their target dose within the first two weeks of treatment. Review with patients that diversion or misuse of buprenorphine may result in treatment discontinuation. Make sure that patients have an adequate supply of medication until their next visit.
Maintenance Visits
Most patients reach their target dose within the first two weeks of treatment and progress to the maintenance stage of treatment. Monitoring visits, which may include counseling and functional assessments and urine drug testing, can be scheduled between weekly and monthly, depending on patient’s clinical stability.

There are two primary kinds of maintenance visits:
1. Medication visits: Medication visits can be scheduled between weekly and monthly, depending on patient’s clinical stability. At a minimum, stable patients should see the prescribing provider at least every 3 months. If patients relapse or destabilize, they should return to more frequent monitoring or to a higher level of care. (See schedule below)

   Medication visit frequency for home based induction:
   - Visit Pre-induction
   - Visit 3-7 days post initiation of treatment
   - Visit 2-3 weeks post initiation of treatment
   - Visit 4-7 weeks post initiation of treatment
   - Monthly visits until 6-12 months
   - If doing very well, visits every 2 months starting at month 7-13.

   Medication visit frequency for office-based induction
   - Visit Pre-induction
   - Visits on day 1, 2, 3 when initiate treatment
   - Visit 1-2 weeks post initiation of treatment
   - Visit 3-6 weeks post initiation of treatment
   - Monthly visits until 6-12 months
   - If doing very well, visits every 2 months starting at month 7-13.

2. Urine drug testing (UDT): UDT in clinical practice is a consensual diagnostic test that:
   a. Provides objective documentation of compliance with the mutually agreed-upon treatment plan;
   b. Aids in the treatment and management of addiction or drug misuse;
   c. Advocates for the patient in family and social issues.

   UDT provides an opportunity for patients to discuss substance use issues with their provider. UDT provides information about whether the prescribed buprenorphine is present and whether other substances (opioids, cocaine, benzodiazepines, etc.) are present. Results demonstrating ongoing opioid use or other substance use (e.g. cocaine) should be managed in a non-punitive manner. Opioid negative urine tests should receive positive reinforcement. Unexpected results of urine tests are opportunities for counseling and brief intervention. Remember that opioid agonist therapy is not an effective treatment for substance use disorders other than opioid use disorder.

   UDT frequency:
   - Week 1-4: Once weekly during initiation and stabilization
   - Month 2-12: Weekly to monthly depending upon clinical stability

   It is important for providers to become familiar with the urine drug tests available in their health care systems. It is ideal to include buprenorphine in the UDT, along with opiates, oxycodone, and methadone. Other substances included in the UDT (cannabinoids, methamphetamines, benzodiazepines, cocaine, etc.) often depend on particular labs and regional epidemiology of substance use.
**Counseling**

Legislation mandates that all providers have the ability to refer buprenorphine-treated patients to counseling, however, recommending counseling to patients should be done on a case-by-case basis. All patients should receive an assessment of whether counseling is indicated, which should then affect treatment decisions and care plans.

**Transitioning patients to the standard of care**

Transitioning patients to the standard of care will look different for every patient. Patients can stay on buprenorphine treatment indefinitely, but could be transitioned to working with their primary care provider instead of the intervention team. Alternatively, patients could be tapered off of buprenorphine. Transitioning patients to the standard of care is done on a case-by-case basis, following the protocols developed by the intervention team during pre-implementation.

**Tapering off buprenorphine:** The ideal candidate for tapering off buprenorphine is socially stable, has developed supportive relationships with persons not using drugs, has discovered alternative ways of dealing with the precipitants to drug use, and is confident and motivated to taper off opioid agonist therapy. Buprenorphine-maintained patients who were clinically stable and want to discontinue treatment should be tapered slowly (e.g. decrease their buprenorphine dose by 10-25% each month). Slow tapers have been shown to be more successful than rapid tapers. The pace of a voluntary taper should be determined by the patient and should be halted or reversed at the patient’s request. The pace of the taper should be decided on and monitored and adjusted by the patient and provider as a team. A situation in which a patient’s dose might be discontinued abruptly is if a patient is diverting the medication and not taking it at all (supported by bup-neg UDT). As a general rule, a provider can’t force a patient to take more medication than s/he wants, but a provider can prescribe less or none based on risk-benefit.

**Diversion, theft, threatening behavior, violence:** Procedures should be developed to manage incidents when buprenorphine diversion is suspected. Witnessed diversion activity usually results in involuntary detoxification and discharge. Other reasons for termination from may include an act or threat of violence against a patient or clinic staff; possession of weapons; violation of the program rules and regulations; harassment of other patients or staff on the basis of gender, ethnicity, or sexual orientation; stealing or other illegal acts on the clinic grounds; duplicate registrations in this and other opioid agonist treatment programs (methadone or buprenorphine); and tampering with urine toxicology samples.

**No significant improvement or worsening clinical course:** When a patient shows no significant improvement or a worsening clinical course, it may be due to progression of the illness, additional physical or psychological stressors, inadequate or inappropriate treatment, or noncompliance with treatment. The treatment team should work closely with patients during these times to help identify contributing factors and strategies to overcome them. The frequency of monitoring and counseling should be increased. When the current level of care cannot meet the needs of the patient, outside providers or programs such as intensive case management, day treatment, supportive housing, or residential treatment should be considered and offered. Transfer from office-based buprenorphine to more structured methadone treatment may be another option.

**Integrating the intervention into the clinic**

The following activities will take place to solidify integration of the intervention throughout the clinic setting:

1. The intervention team will create an internal communication plan that outlines the ways in which information is diffused throughout the clinic setting. This plan will address:
   a. How is information about new programs or interventions typically disseminated at a clinic?
b. How is information about new programs or interventions typically shared with community partners?

c. What are the best ways for the intervention team to communicate with each other?

2. The intervention team and the clinic staff will continue to work together to assess patients which patients could benefit from the buprenorphine intervention.
   a. In order to accomplish this goal, the intervention team and staff will:
      i. Provide ongoing training to clinic staff on addiction treatment (e.g., overview of addiction and addiction treatment, urine toxicology, confidentiality issues, motivational interviewing), polysubstance abuse, and buprenorphine-specific subjects (e.g., patient selection, induction, stabilization, documentation, forms, regulations, and case studies).
      ii. Participate in at least 2 annual meetings with all clinic staff and intervention team members to review the status of the intervention and how all staff roles intersect with the intervention (or ways that staff roles could better intersect with the intervention in the future).

3. The clinical team will hold ongoing meetings that discuss the buprenorphine treatment process, eligible patients, patient outcomes, case conferences.

4. The intervention team will determine if any changes need to be made in their clinic electronic medical record (EMR) to better support documentation of patient level data in this intervention.

5. The clinic administration will meet with the intervention team at least 2 times per year to discuss the status of the intervention, any ongoing programmatic needs or concerns, and potential methods for spreading information about the intervention throughout the clinic (or clinic system if the site is part of a larger clinical network).

6. Recruit and train additional prescribing providers at the clinic site.

7. Each clinic will participate in supporting, sponsoring, or hosting buprenorphine prescription waiver training in order to grow a network of prescribing providers. The determination to either support, sponsor, or hosting a training will be clinic specific, and dependent on clinic resources, community (or regional) training needs. Each clinic will document their decision to either support, sponsor, or host a training.

8. The intervention team will participate in 2 annual meetings with community partners to discuss intervention activities, the opioid problem in the local community, and systems coordination.
### Appendix A: Logic Model

<table>
<thead>
<tr>
<th>Resources</th>
<th>Activities</th>
<th>Outputs</th>
<th>Short Term Outcomes</th>
<th>Intermediate Outcomes</th>
<th>Long Term Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Staff</strong></td>
<td><strong>Staff will participate in:</strong></td>
<td><strong># prescribing physicians</strong></td>
<td><strong>Increase in number of buprenorphine prescribers at clinic</strong></td>
<td><strong>Increase in patient retention in buprenorphine treatment</strong></td>
<td><strong>Reduction in patient opioid and substance use</strong></td>
</tr>
<tr>
<td>• Prescribing Physicians</td>
<td>• Education and training sessions</td>
<td>• # staff members attending training</td>
<td>• Increased clinic provider awareness of treatment options</td>
<td>• Increase in patient retention in HIV care</td>
<td><strong>Improvement in the following patient outcomes:</strong></td>
</tr>
<tr>
<td>• Buprenorphine Coordinator</td>
<td>• Mentorship</td>
<td>• referral wait time</td>
<td>• Increased patient awareness of treatment outcomes</td>
<td></td>
<td>• HIV viral load</td>
</tr>
<tr>
<td>• Clinical Mentors</td>
<td>• Care coordination meetings</td>
<td>• # eligible patients</td>
<td>• Increased community health provider awareness of treatment options</td>
<td></td>
<td>• Quality of life</td>
</tr>
<tr>
<td>• Program evaluator/data manager</td>
<td>• Make referrals</td>
<td>• # patients induced</td>
<td>• Increased provider confidence in maintaining, sustaining, and supporting a patient while on buprenorphine</td>
<td></td>
<td>• Engagement in behavioral health treatment as needed (substance use disorder; mental health)</td>
</tr>
<tr>
<td>• Pharmacy</td>
<td>• Staff will work with patients through:</td>
<td>• # patients maintained</td>
<td>• Increased provider confidence in maintaining, sustaining, and supporting a patient while on buprenorphine</td>
<td></td>
<td>• Increase in patient satisfaction with care</td>
</tr>
<tr>
<td>• Community Health Centers</td>
<td>• Intake</td>
<td>• # prescriptions filled</td>
<td>• Increase in patient linkage to care</td>
<td></td>
<td><strong>Integration of buprenorphine treatment for opioid use disorder in HIV primary care in the clinic setting</strong></td>
</tr>
<tr>
<td>• Community Partners (including substance abuse and mental health resources)</td>
<td>• Screening</td>
<td>• # patients referred to community health centers and community partners</td>
<td>• Reduction in patient opioid and substance use</td>
<td></td>
<td>• Hosting, sponsoring, or supporting an opioid prescription waiver program</td>
</tr>
<tr>
<td></td>
<td>• Assessment of eligibility</td>
<td>• # patient acute care visits</td>
<td></td>
<td></td>
<td><strong>Reduction in fatal and nonfatal opioid overdose</strong></td>
</tr>
<tr>
<td></td>
<td>• Substance abuse diagnosis</td>
<td>• # patient overdose events</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Appendix B: Staffing Plan and Job Descriptions

<table>
<thead>
<tr>
<th>Physicians (at least 2 MD or DO)</th>
<th>The lead physician is responsible for all aspects of patient treatment including:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Conducting or reviewing patient assessments;</td>
</tr>
<tr>
<td></td>
<td>• Prescribing buprenorphine in accordance with Schedule III requirements;</td>
</tr>
<tr>
<td></td>
<td>• Managing initiation, stabilization, and maintenance of buprenorphine treatment (with the support from the Clinical Coordinator);</td>
</tr>
<tr>
<td></td>
<td>• Record keeping that may be referenced for a DEA inspection;</td>
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<tr>
<td></td>
<td>• Providing clinical guidance and direct supervision to the Clinical Coordinator.</td>
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<tr>
<td></td>
<td>A second physician or prescriber is required to provide backup coverage in the event that the lead physician is on vacation, ill, or unavailable for any other reason.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinical Coordinator</th>
<th>The Clinical Coordinator is responsible for:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Availability to see patients in the clinic daily, participating in patient assessment and preparation, including day-to-day program concerns, education, and counseling;</td>
</tr>
<tr>
<td></td>
<td>• Supporting the patient and prescriber in buprenorphine initiation, stabilization, and maintenance treatment procedures under the supervision of the prescribing physician;</td>
</tr>
<tr>
<td></td>
<td>• Assisting the prescribing physician in making referrals to community providers for counseling or higher levels of care when needed;</td>
</tr>
<tr>
<td></td>
<td>• Maintaining therapeutic relationships with both the patient and the medical provider;</td>
</tr>
<tr>
<td></td>
<td>• Overseeing the following patient care components:</td>
</tr>
<tr>
<td></td>
<td>• Case management;</td>
</tr>
<tr>
<td></td>
<td>• Medication management and treatment monitoring;</td>
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<tr>
<td></td>
<td>• Insurance authorization and troubleshooting;</td>
</tr>
<tr>
<td></td>
<td>• Relationship building and patient linkage to additional support (drug treatment services and mental health care);</td>
</tr>
<tr>
<td></td>
<td>• Relationship building and facilitation of ancillary services (including patient transportation).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Data Manager</th>
<th>The Data Manager is responsible for:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Consenting patients into the study;</td>
</tr>
<tr>
<td></td>
<td>• Collecting and submitting data required for multi-site evaluation;</td>
</tr>
<tr>
<td></td>
<td>• Coordinating the collection of patient surveys, encounter forms, basic chart data abstraction, and implementation measures, and reporting them to the Dissemination and Evaluation Center (DEC); and</td>
</tr>
<tr>
<td></td>
<td>• Providing quality assurance reports and updates to intervention team about study referrals, enrollment retention, etc.</td>
</tr>
</tbody>
</table>
Description of the Integrating Buprenorphine Treatment for Opioid Use Disorder in HIV Primary Care Intervention
This HIV primary care model intervention aligns with the medical home model as it allows patients to readily access comprehensive HIV and addiction services under one roof. The Integrating Buprenorphine Treatment for Opioid Use Disorder in HIV Primary Care model follows principles of harm reduction, including reducing the harms of addiction. This enables providers to treat addiction along with other chronic medical conditions experienced by their patients. The approach secures additional patient buy-in by investing in the existing trust and communication they develop with their primary care providers.

Purpose of Position
The prescribing physician is responsible for all aspects of patient treatment and the supervision of the clinical coordinator.

Key Responsibilities
The prescribing physician has overall responsibilities for all aspects of patient treatment including:
1. Conducting patient assessments;
2. Reviewing patient assessments;
3. Prescribing buprenorphine in accordance with Schedule III requirements;
4. Managing initiation, stabilization, and maintenance of buprenorphine treatment (with the support from the Clinical Coordinator);
5. Oversee record keeping that may be referenced for a DEA inspection; and
6. Participating in professional development and supervision meetings with a clinical mentor.

The prescribing physician has overall clinical responsibilities including:
1. Providing clinical guidance and direct supervision to the Clinical Coordinator;
2. Completing 8 hours of approved training; and
3. Obtaining a waiver from SAMSHA’s Center for Substancse Abuse Treatment (and receiving an accompanying ID number and Drug Enforcement Agency [DEA] registration number). After the first year of prescribing buprenorphine, submitting a second notification to be able to treat up to 100 patients.

Qualifications/Requirements
- Licensed MD or DO.
- Prior clinical experience working with patients with substance use disorders, and mental health diagnoses.
- Knowledge of harm reduction philosophy, patient centered, counseling, and motivation interviewing techniques.
- Demonstrated ability to work collaboratively in a team environment.
- Demonstrated computer literacy in Microsoft and web-based applications.
- Excellent verbal and written communication skills.
- Excellent interpersonal and organizational skills.
• Knowledge of community resources; demonstrated ability to network and build strong relationships with community organizations serving priority populations as identified by the agency and/or funder.
• Demonstrated ability to working with patients of diverse backgrounds, underserved communities, and co-morbidities.
• Demonstrated knowledge of working with patients with HIV/AIDS.

Preferred Skills
• American Academy of HIV Medicine (AAHIVM) credentials.
• HIV Medicine Association (HIVMA) credentials.
• 2 years of experience managing HIV primary care.
Clinical Coordinator

Job Description

Description of the Integrating Buprenorphine Treatment for Opioid Use Disorder in HIV Primary Care Intervention

This HIV primary care model intervention aligns with the medical home model as it allows patients to readily access comprehensive HIV and addiction services under one roof. The Integrating Buprenorphine Treatment for Opioid Use Disorder in HIV Primary Care model follows principles of harm reduction, including reducing the harms of addiction. This enables providers to treat addiction along with other chronic medical conditions experienced by their patients. The approach secures additional patient buy-in by investing in the existing trust and communication they develop with their primary care providers.

Purpose of Position

The clinical coordinator is a key member of the buprenorphine treatment team and serves an essential role in the implementation process. This person must possess not only the clinical knowledge and skills to participate in individual patient treatment, but also the organizational and communication skills to execute systems level activities. The clinical coordinator is the point person that will have the most contact with the patients, and will be in constant contact with the physicians in order to communicate patient’s needs and shape patients’ care.

Key Responsibilities

The Clinical Coordinator is responsible for:

1. Seeing patients in the clinic daily, participating in patient assessment and preparation, including day-to-day program concerns, education, and counseling;
2. Enrolling patients, including informed consent procedures and initial assessment;
3. Supporting the patient and prescriber in buprenorphine initiation, stabilization, and maintenance treatment procedures under the supervision of the prescribing physician;
4. Assisting members of the health care team in the formulation and implementation of the plan of care;
5. Assisting the prescribing physician in making referrals to community providers for counseling or higher levels of care when needed;
6. Maintaining therapeutic relationships with both the patient and the medical provider;
7. Overseeing the following patient care components:
   a. care coordination including medication management and treatment monitoring;
   b. insurance authorization and troubleshooting;
   c. relationship building and patient linkage to additional support (drug treatment services and mental health care);
   d. relationship building and facilitation of ancillary services (including patient transportation);
8. Sharing information with other members of the health care team and evaluation team through chart documentation, interdisciplinary team meetings and email; and
9. Record keeping that may be referenced for a DEA inspection.

Qualifications/Requirements

- Licensed RN, PA, or NP.
- Knowledge of harm reduction philosophy, patient centered, counseling, and motivation interviewing techniques.
- Prior experience conducting individual patient education and counselling sessions.
- Demonstrated ability to work collaboratively in a team environment.
- Demonstrated computer literacy in Microsoft and web-based applications.
- Excellent verbal and written communication skills.
- Excellent interpersonal and organizational skills, including problem solving with a team.
- Knowledge of community resources; demonstrated ability to network and build strong relationships with community organizations serving priority populations as identified by the agency and/or funder.
- Demonstrated ability to working with patients of diverse backgrounds, underserved communities, and co-morbidities.
- Demonstrated knowledge of working with patients with HIV/AIDS.

Preferred Skills
- Prior clinical experience working with patients with substance use disorders and mental health diagnoses.
- Completion of the Addiction Technology Transfer Center Network Buprenorphine Training for Multidisciplinary Addiction Professionals.
Description of the Integrating Buprenorphine Treatment for Opioid Use Disorder in HIV Primary Care Intervention

This HIV primary care model intervention aligns with the medical home model as it allows patients to readily access comprehensive HIV and addiction services under one roof. The Integrating Buprenorphine Treatment for Opioid Use Disorder in HIV Primary Care model follows principles of harm reduction, including reducing the harms of addiction. This enables providers to treat addiction along with other chronic medical conditions experienced by their patients. The approach secures additional patient buy-in by investing in the existing trust and communication they develop with their primary care providers.

Purpose of the Position

The Data Manager is responsible for the overall coordination of the data collection and management for the Integrating Buprenorphine Treatment for Opioid Use Disorder in HIV Primary Care intervention at the site level. The Data Manager will work with the Dissemination and Evaluation Center (DEC) at the Boston University School of Public Health to insure that data collection and management is consistent with the multi-site evaluation protocol.

Key Responsibilities

1. Consent patients into the study and track and manage follow up interviews.
2. Implement data collection procedures developed by the DEC.
3. Coordinate the collection of:
   a. Patient surveys
   b. Encounter forms
   c. Basic chart data abstraction
   d. Implementation measures
   e. Monthly eligible patient list
4. Review and monitor quality of the incoming data collection forms to ensure data are complete and consistent.
5. Ensure that all data collection and management activities are performed with the utmost attention to participant confidentiality, as well as HIPAA and IRB requirements.
6. Serve as a liaison between the DEC and clinic for all data collection and reporting.
7. Communicate problems with data collection and management to the DEC.
8. Participate in technical assistance and training sessions conducted by the DEC.

Qualifications/Requirements

- Knowledge of fundamental concepts of collecting and processing research data.
- Ability to communicate clearly and concisely, both verbally and in writing.
- Understanding of HIPAA and IRB requirements for health care research.
- Ability to manage competing priorities; willing and able to work flexible hours.
- Ability to work in a team as well as independently and to establish and maintain cooperative, supportive relationships with project staff.
- Experience with MS Office software (e.g. Access, Excel) is strongly preferred.
- Familiarity with basic computer programming and statistical software packages (SAS, Stata, SPSS) is preferred.
- Bachelor’s degree required.
## Appendix C: Integrating Buprenorphine Treatment for Opioid Use Disorder in HIV Primary Care 3 Year Work Plan

<table>
<thead>
<tr>
<th>Goal</th>
<th>Action Steps</th>
<th>Project Staff Responsible</th>
<th>Post-notice of award</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stage: Pre-implementation</strong></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Assess internal clinic and external systems</td>
<td>Assess clinic space and secure space for intervention activities</td>
<td>Clinic administration intervention team</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Obtain necessary technology (tablet, laptop, etc.) and secure internet connection at all locations where data could be entered.</td>
<td>Clinic administration intervention team</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Establish/strengthen relationships with external medical and social service providers.</td>
<td>Clinic administration intervention team</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Determine and document the types of insurance that will be accepted</td>
<td>Clinic administration intervention team</td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Secure sustainable access to buprenorphine medication</td>
<td>Clinic administration intervention team</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hire or identify intervention team members</td>
<td>Hire or identify intervention team members (providers, clinical coordinator, data manager)</td>
<td>Clinic administration</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Identify a clinical mentor for the prescribing provider</td>
<td>Prescribing provider, ITAC</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Participate in trainings provided by ITAC</td>
<td>Intervention team, ITAC</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Participate in trainings provided by DEC</td>
<td>Intervention team, DEC</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Complete waiver training</td>
<td>Prescribing provider</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Goal</td>
<td>Action Steps</td>
<td>Project Staff Responsible</td>
<td>Post-notice of award</td>
<td>Year 1</td>
<td>Year 2</td>
<td>Year 3</td>
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<td>-------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Complete non-prescriber online training</td>
<td></td>
<td>Clinical coordinator</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Develop, review, implement protocols and materials</td>
<td>Create procedures to follow federal mandates for record keeping practices</td>
<td>Intervention team</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Create on-call and back-up protocols</td>
<td>Intervention team</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Review guidelines in implementation manuals</td>
<td>Intervention team</td>
<td>X</td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Develop protocol for referral to local medical and social service providers</td>
<td>Intervention team</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Develop protocol for referral from local health care providers</td>
<td>Intervention team</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Develop protocol for referral from internal providers</td>
<td>Intervention team</td>
<td>X</td>
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<td></td>
<td>Develop protocol for creating an eligible patient list</td>
<td>Intervention team</td>
<td>X</td>
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<tr>
<td></td>
<td>Implement policies that address safety and boundary issues</td>
<td>Intervention team</td>
<td>X</td>
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<tr>
<td></td>
<td>Review existing patient education materials referenced in the implementation manual, make any clinic specific additions</td>
<td>Intervention team</td>
<td>X</td>
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<tr>
<td>Prepare for evaluation</td>
<td>Participate in human subjects training</td>
<td>Intervention team</td>
<td>X</td>
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<td></td>
<td>Obtain IRB approval</td>
<td>Intervention team</td>
<td>X</td>
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<tr>
<td>Establish communication timing and methods</td>
<td>Weekly meetings for case conferencing</td>
<td>Intervention team</td>
<td>X</td>
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<td></td>
<td>Clinical supervision</td>
<td>Clinical coordinator, prescribing provider</td>
<td>X</td>
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<td></td>
<td>Clinical mentorship</td>
<td>Prescribing provider, clinical mentor</td>
<td>X</td>
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<td></td>
<td>Meetings with the ITAC</td>
<td>Intervention team, ITAC</td>
<td>X</td>
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<td>Goal</td>
<td>Action Steps</td>
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<td><strong>Stage: Implementation and Maintenance</strong></td>
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<tr>
<td>Assess patients for treatment</td>
<td>Document that patient receives HIV primary care at the clinic</td>
<td>Treatment team</td>
<td>X</td>
<td>X</td>
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<tr>
<td></td>
<td>Establish the diagnosis of opioid use disorder, including the duration and severity of use.</td>
<td>Treatment team</td>
<td>X</td>
<td>X</td>
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<tr>
<td></td>
<td>Discuss current opioid use and patterns, including level of tolerance, prior quit attempts, prior experiences with opioid agonist treatment, nature and severity of opioid withdrawal symptoms, time of last use and current withdrawal status; leverage strengths and successes from treatment</td>
<td>Treatment team</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td></td>
<td>Document patient's use of other substances and treatment experience with other substances</td>
<td>Treatment team</td>
<td>X</td>
<td>X</td>
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<tr>
<td></td>
<td>Educate the patient about alternatives to buprenorphine treatment</td>
<td>Treatment team</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td></td>
<td>Identify patients who need medically supervised withdrawal management from opioid, alcohol, benzodiazepines, or other sedatives prior to initiating buprenorphine treatment</td>
<td>Treatment team</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td></td>
<td>Identify comorbid medical conditions and psychiatric disorders and determine how, when, and where they will be addressed</td>
<td>Treatment team</td>
<td>X</td>
<td>X</td>
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<td></td>
<td>Complete baseline screening lab work and screen patients for communicable diseases (viral hepatitis, TB, syphilis, and other STDs) and address them as needed</td>
<td>Data manager</td>
<td>X</td>
<td>X</td>
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<td></td>
<td>Assess patient's access to social supports, family, friends, employment, housing, finance, and legal assistance</td>
<td>Treatment team</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td></td>
<td>Discuss proper and secure storage of buprenorphine in the patient's home</td>
<td>Treatment team</td>
<td>X</td>
<td>X</td>
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<td>Goal</td>
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<tr>
<td>Enroll patient into study through informed consent process</td>
<td>Treatment team</td>
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<tr>
<td>Determine patient's readiness to participate in treatment and their goals for engaging in treatment</td>
<td>Treatment team</td>
<td></td>
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<tr>
<td>Prepare patients for treatment</td>
<td>Educate the patient about buprenorphine treatment and how to properly administer, safeguard, and discard the medication</td>
<td>Treatment team</td>
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<tr>
<td>Prepare patients for treatment</td>
<td>Educate the patient about what they can expect at each stage of treatment</td>
<td>Treatment team</td>
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<tr>
<td>Prepare patients for treatment</td>
<td>Refer patients who need medically supervised withdrawal management from opioid, alcohol, benzodiazepines, or other sedatives before initiating treatment</td>
<td>Treatment team</td>
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<tr>
<td>Prepare patients for treatment</td>
<td>Complete a treatment agreement describing the goals of treatment, the risks and benefits of treatment, and the relationship between the patient and the treatment team</td>
<td>Treatment team</td>
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<tr>
<td>Prepare patients for treatment</td>
<td>Obtain patient consent to communicate with other providers in the patient's circle of care about the treatment plan</td>
<td>Treatment team</td>
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<tr>
<td>Prepare patients for treatment</td>
<td>Communicate with other providers in the patient's circle of care about the treatment plan</td>
<td>Treatment team</td>
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<tr>
<td>Prepare patients to initiate treatment</td>
<td>Determine whether to offer an at home or in office based treatment initiation</td>
<td>Treatment team</td>
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<tr>
<td>Prepare patients to initiate treatment</td>
<td>Prepare patients to achieve a mild-moderate state of opioid withdrawal on the day of buprenorphine initiation</td>
<td>Treatment team</td>
<td></td>
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<tr>
<td>Prepare patients to initiate treatment</td>
<td>Dispense &quot;kick packs&quot; or &quot;comfort packs&quot; as necessary</td>
<td>Treatment team</td>
<td></td>
<td></td>
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<tr>
<td>Initiate treatment</td>
<td>Follow home or office based initiation protocol</td>
<td>Treatment team</td>
<td></td>
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<tr>
<td>Stabilize patients</td>
<td>Determine when a patient reaches their target dose</td>
<td>Treatment team</td>
<td></td>
<td></td>
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<tr>
<td>Stabilize patients</td>
<td>Monitor patients either daily or 1-2 times per week with phone monitoring</td>
<td>Treatment team</td>
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<tr>
<td>Goal</td>
<td>Action Steps</td>
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<tr>
<td>Provide ongoing support</td>
<td>Monitoring visits, which may include counseling and functional assessments and urine drug testing, can be scheduled between weekly and monthly, depending on patient’s clinical stability. At a minimum, patients should be seen by the prescribing provider every 3 months.</td>
<td>Treatment team</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td></td>
<td>Include the following in patient monitoring during follow-up: patient use of alcohol or illicit drugs, non-medical use of prescription drugs, degree of compliance with the treatment regimen, changes with social functioning and relationships, avoidance of high-risk individuals/situations, extent to engagement in counseling or other therapies, presence or absence of medication side effects, presence or absence of medical sequelae of substance use and its remission.</td>
<td>Treatment team</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td></td>
<td>Address relapse through the following: identify environmental cues and stressors that act as relapse triggers, help patients develop skills to cope with or manage negative emotional states, help patients work towards a more balanced lifestyle, help patients understand and manage cravings, identify and interrupt lapses and relapses, develop a recovery support system.</td>
<td>Treatment team</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td></td>
<td>Return patients to more frequent care monitoring, treatment re-initiation, or refer to a higher level of care if patients relapse or destabilize</td>
<td>Treatment team</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td></td>
<td>Provide insurance authorization and troubleshooting</td>
<td>Treatment team</td>
<td>X</td>
<td>X</td>
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<tr>
<td><strong>Stage:</strong> Implementation, Maintenance, Integration</td>
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<tr>
<td>Integrate intervention into the clinic setting</td>
<td>Create internal communicational plan for clinic setting</td>
<td>Intervention team</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td></td>
<td>Continue to assess patients that could benefit from buprenorphine</td>
<td>Intervention team</td>
<td>X</td>
<td>X</td>
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<td>Goal</td>
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<tr>
<td>Hold clinic staff trainings and all clinic meetings</td>
<td>Hold clinic staff trainings and all clinic meetings</td>
<td>Intervention team, clinical team, clinic staff</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Determine if any changes need to be made to the EMR to support the intervention</td>
<td>Determine if any changes need to be made to the EMR to support the intervention</td>
<td>Intervention team</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Semi-annual meeting between clinic administration and intervention team</td>
<td>Semi-annual meeting between clinic administration and intervention team</td>
<td>Intervention team, clinic administration</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Recruit and train additional prescribing providers</td>
<td>Recruit and train additional prescribing providers</td>
<td>Intervention team</td>
<td>X</td>
<td>X</td>
<td>X</td>
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</tr>
<tr>
<td>Support, host, or sponsor a waiver training</td>
<td>Support, host, or sponsor a waiver training</td>
<td>Intervention team</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Hold 2 annual meetings with community partners</td>
<td>Hold 2 annual meetings with community partners</td>
<td>Intervention team</td>
<td>X</td>
<td>X</td>
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**Stage: Implementation, Maintenance, Integration**

<table>
<thead>
<tr>
<th>Goal</th>
<th>Action Steps</th>
<th>Project Staff Responsible</th>
<th>Post-notice of award</th>
<th>Year 1</th>
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<tbody>
<tr>
<td>Track program outcomes and conduct quality assurance review</td>
<td>Track incoming referrals and community outreach</td>
<td>Data manager</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Track buprenorphine treatment and HIV Care</td>
<td>Track buprenorphine treatment and HIV Care</td>
<td>Data manager</td>
<td>X</td>
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<td>X</td>
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<tr>
<td>Document: diagnostic assessments, medical records of past hospitalizations or treatments by other providers, the treatment plan (including the treatment agreement and informed consent), authorization for release of information to other treatment providers, documentation of discussions with and consultation reports from other health care providers, medications prescribes and the patient's response to them (including any adverse events).</td>
<td>Document: diagnostic assessments, medical records of past hospitalizations or treatments by other providers, the treatment plan (including the treatment agreement and informed consent), authorization for release of information to other treatment providers, documentation of discussions with and consultation reports from other health care providers, medications prescribes and the patient's response to them (including any adverse events).</td>
<td>Data manager</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Track coordination with community referrals and patient navigators</td>
<td>Track coordination with community referrals and patient navigators</td>
<td>Data manager</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Conduct qualitative interviews with clinic staff</td>
<td>Conduct qualitative interviews with clinic staff</td>
<td>DEC</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Conduct qualitative interviews with intervention team</td>
<td>Conduct qualitative interviews with intervention team</td>
<td>DEC</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<td>Goal</td>
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<tr>
<td>Review and audit intervention forms for quality</td>
<td>Data manager, DEC</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
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<td>Conduct monthly data cleaning</td>
<td>Data manager</td>
<td></td>
<td>X</td>
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<tr>
<td>Map each piece of chart collection to a location in the EMR</td>
<td>Data manager</td>
<td></td>
<td>X</td>
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</table>
**Appendix D: Worksheet for DSM-V Criteria: Diagnosis of Opiate Use Disorder**

<table>
<thead>
<tr>
<th>Diagnostic Criteria*</th>
<th>Meets criteria</th>
<th>Notes/supporting information</th>
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<tbody>
<tr>
<td>(Opioid Use Disorder requires at least 2 within 12 month period)</td>
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<tr>
<td>1. Opioids are often taken in larger amounts or over a longer period of time than intended.</td>
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<td>2. There is a persistent desire or unsuccessful efforts to cut down or control opioid use.</td>
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<td>3. A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.</td>
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<td>4. Craving, or a strong desire to use opioids.</td>
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<td>5. Recurrent opioid use resulting in failure to fulfill major role obligations at work, school or home.</td>
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<td>6. Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.</td>
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<tr>
<td>7. Important social, occupational or recreational activities are given up or reduced because of opioid use.</td>
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<tr>
<td>8. Recurrent opioid use in situations in which it is physically hazardous</td>
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<tr>
<td>9. Continued use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by opioids.</td>
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<tr>
<td>10. *Tolerance, as defined by either of the following: (a) a need for markedly increased amounts of opioids to achieve intoxication or desired effect (b) markedly diminished effect with continued use of the same amount of an opioid</td>
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<tr>
<td>11. *Withdrawal, as manifested by either of the following: (a) the characteristic opioid withdrawal syndrome (b) the same (or a closely related) substance are taken to relieve or avoid withdrawal symptoms</td>
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* This criterion is not considered to be met for those individuals taking opioids solely under appropriate medical supervision.

Severity: Mild: 2-3 symptoms, Moderate: 4-5 symptoms. Severe: 6 or more symptoms.

Signed ______________________ Date ____________________

Appendix E: DSM-V Criteria for Substance Use Disorder
In the past 12 months, has your patient had at least two of the following occur:

1. **Risk of bodily harm** (drinking and driving, operating machinery, swimming, sharing injection equipment)
   a. Have you more than once driven a car or other vehicle while you were drinking (using drugs)? Or after having had too much to drink (while high)?
   b. Have you more than once gotten into situations while drinking/using or after drinking/using that increased your chances of getting hurt—like swimming, using machinery, walking in a dangerous area or around heavy traffic, or having unsafe sex?

2. **Relationship trouble** (arguments with partner, friends, physical fights while intoxicated)
   a. Have you continued to drink (or use drugs) even though it was causing trouble with your family or friends?
   b. Have you gotten into physical fights while drinking or right after drinking (or using drugs)?

3. **Role failure** or failure to meet obligations at home, work, school (absences, suspension, neglect of family or children)
   a. Have you had a period when your drinking (using drugs)—or being sick from drinking—often interfered with taking care of your home or family? Caused job troubles? School problems?

4. Shown signs of **withdrawal**:
   a. How do you feel when you don’t drink (use drugs)?
   b. When the effects of alcohol are wearing off, have you had trouble with sleep, feeling shaky, restless, nauseated, sweaty, had a racing heart or even a seizure?
   c. Have you found that when the effects of heroin/painkillers wear off, you had symptoms, such as muscle and joint aches, yawning, restlessness, nausea, stomach cramps/diarrhea, sweating, a racing heart, or anxiety? Or felt like you had come down with the flu?

5. Shown **tolerance** (needed to use a lot more to get the same effect):
   a. Have you had to drink more (or use more drug X) than you once did to get the effect you want?
   b. Or found that what you usually drank (or used) had much less effect than before?

6. Not been able to stick to intended drinking or drug using **limits** (repeatedly gone over them):
   a. Have you had trouble keeping to any drinking limits you set for yourself? How so?
   b. Have you had times when you ended up drinking (using drugs) more, or longer, than you intended? Tell me about that.

7. Not been able to **cut down or stop** (repeated failed attempts):
   a. Have you ever stopped or cut back before? What was that like?
   b. Are you able to stop using when you want to?
   c. Have you more than once wanted to cut down or stop drinking/using X, or tried to, but couldn’t?
8. Spent a lot of **time** (anticipating, or procuring, or recovering from substance):
   a. Some patients describe their drug use as a full-time job. Have you ever felt this way too?
   b. Have you spent a lot of time drinking (using drugs)? Or being sick or getting over its after-effects?

9. Kept using despite recurrent physical or psychological **problems** i.e. crack chest pain, alcoholic gastritis, speed psychoses, skin abscesses:
   a. Tell me about any medical problems you’ve had, if any, from drinking (using drug X)?
   b. Have you continued to drink/use even though it was making you feel depressed or anxious or adding to another health problem? Or after having had a memory blackout?

10. Spent **less time** on other matters (that had been important or pleasurable):
    a. What kinds of activities given up or cut back on – that were important or interesting to you, or gave you pleasure – in order to drink (use drugs)?

11. **Craving**, or a strong desire or urge to use substance.
    a. Have you had such a strong desire to drink (use drugs) that it was difficult to think of anything else?

If yes to 2 or more, then your patient meets criteria for a substance use disorder. (Mild 2-3, Moderate 4-5, Severe 6+)
Appendix F: Buprenorphine Treatment Agreement

This agreement has 5 parts:
Part 1: Tells you how and when to take your medicine
Part 2: Describes the goals of treatment
Part 3: List things that you and your doctor agree to do
Part 4: List things that could happen if you do NOT do the things listed in Part 3.
Part 5: Sign the form. You and your doctor must sign the form.

Part 1: My Medicine

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Breakfast</th>
<th>Lunch</th>
<th>Dinner</th>
<th>Bedtime</th>
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</table>

Part 2: Goals of Treatment
I understand that my cravings may not completely go away. I understand that buprenorphine may not work for me.
My goals for treatment include:

Part 3: Things I agree to do
I will:
- Only get buprenorphine from my doctor
- Tell all my other doctors that I am taking buprenorphine and cannot take any other opiate medications
- Tell my doctor about ALL of the medicines I am taking (over the counter, herbs, vitamins, those ordered by other doctors)
- Tell my doctor about all of my health problems
- Only get refills during my doctor appointment (refill requests may not be honored)
- Tell my doctor if I get pain medicine from another doctor or emergency room
- Keep my buprenorphine in a safe place AND away from children
- Only get my pain medicine from [insert pharmacy name, address, phone number]
- Bring all of my unused pain medicine in their original pharmacy bottles to my doctor visits if my doctor asked me to. He or she may count the number of pills left in my bottle(s)
- Allow my doctor to check my urine (pee) or blood to see what drugs I am taking
- Try all treatments that my doctor suggests, including social work and mental health referrals if necessary

I will NOT:
- Share, sell, or trade my buprenorphine with anyone
- Use someone else’s medicine
- Alter my urine sample (e.g. add water, use someone else’s urine)
- Change how I take my medicine(s) without asking my doctor
- Ask my doctor for extra/early refills if I use up my supply before my next appointment
- Ask my doctor for extra refills if my medicine or prescription is lost or stolen.
My doctor will:
- Work with me to find the best treatment for my addiction
- Refer me for additional help when needed

Part 4. I understand
- This is a controlled narcotic medication that may result in withdrawal symptoms when stopped immediately
- If I drink alcohol or use street drugs while taking my medicine:
  - I may not be able to think clearly
  - I could become sleepy
  - I may injure myself or overdose
- If I ever:
  - Steal
  - Forge prescriptions
  - Sell my medicine
  - Disrespect clinic staff
  My doctor will stop my buprenorphine treatment immediately

- If my goals in part 2 are not reached, my doctor may stop my buprenorphine treatment.
- If I do not follow this agreement, or if my doctor thinks that my medicine is hurting me more than it is helping me, my doctor:
  - Will continue to be my primary care doctor but will stop my buprenorphine treatment immediately
  - Will refer me to a specialist for treatment of pain and/or drug problems

I hereby authorize and give consent to the above named physician and/or any appropriately authorized assistants he/she may select, to administer or prescribe buprenorphine for the treatment of opioid use disorder.

The procedures to treat my condition have been explained to me. I understand that it will involve my taking the prescribed buprenorphine on the schedule determined by the treatment team.

It has been explained to me that buprenorphine itself is an opioid, but for some individuals it may not be as strong an opioid as heroin or morphine. Buprenorphine treatment can result in physical dependence. Buprenorphine withdrawal is generally less intense than that with heroin or methadone. If buprenorphine is suddenly discontinued, some patients have no withdrawal symptoms; others have symptoms such as muscle aches, stomach cramps, or diarrhea lasting several days. To minimize the possibility of opioid withdrawal, buprenorphine should be discontinued gradually, usually over several weeks or more.

For my first dose, I should be in withdrawal as much as possible. If I am not already in withdrawal, buprenorphine can bring on severe opioid withdrawal. For that reason, for the first few days I will be asked to remain at the clinic or pharmacy for a period of time after I take a first dose. After that, I will receive a prescription and return to the designated pharmacy to pick up the medication. I will comply with the correct dosing method for buprenorphine -- holding it under the tongue until it dissolves completely, without swallowing it. Swallowing the buprenorphine will lessen its effectiveness.
I understand that it may take several days to get used to the transition from the opioid I had been using to buprenorphine. I understand that using any other opioids (like heroin) will complicate the process of stabilization on buprenorphine. I also understand that other opioids will have less effect once I become stabilized on buprenorphine. Taking more opioids to try to override the effect of buprenorphine can result in an overdose. In addition, I understand that intravenous use of buprenorphine can produce serious problems including severe withdrawal, overdose, and even death.

I understand that I will not take any other medication without first discussing it with my primary physician because combining buprenorphine with other medications or alcohol may be hazardous. The combination of buprenorphine with Valium, Librium, or Ativan has resulted in death.

I understand that during the course of treatment, certain conditions may make it necessary to use additional or different procedures than those explained to me.

I realize that for some patients, treatment may continue for relatively long periods of time. I understand that I may withdraw from the program and discontinue use of buprenorphine at any time. In this event, I shall be transferred to medically supervised withdrawal treatment or to a methadone treatment program.

I will not allow any other individual to use my buprenorphine. It is dangerous for an individual not on buprenorphine to ingest the medication. Doing so may result in serious injury or even death for that individual.

For Female Patients of Child-Bearing Age:
To the best of my knowledge,
  □ I am pregnant at this time.
  □ I am not pregnant at this time.
If I do become pregnant, I will inform my medical provider or one of his/her assistants immediately.

For All Patients:
Alternative methods of treatment, the potential benefits of treatment, possible risks involved, and the possibility of complications have been explained to me. I certify that no guarantee or assurance has been made as to the results that may be obtained from addiction treatment.
Part 5: Sign the form
Sign your name and write the date.

Sign your name:
Date:
Print your name (First and Last):
Address:

Doctor Name:
Doctor signature:
Date:
Appendix G: Home induction protocol

- See PDF
Appendix H: Clinical Opiate Withdrawal Scale (COWS)

**Flowsheet for measuring symptoms over a period of time during buprenorphine initiation.** For each item, write in the number that best describes the patient’s signs or symptom. Rate on just the apparent relationship to opioid withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increase pulse rate would not add to the score.

| Patient’s Name: ___________________________ | Date: ___________
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Buprenorphine initiation:</td>
<td></td>
</tr>
</tbody>
</table>

Enter scores at time zero, 30min after first dose, 2 h after first dose, etc.

| Times: ______  ______  ______  ______ |

<table>
<thead>
<tr>
<th><strong>Resting Pulse Rate:</strong> (record beats per minute) <em>Measured after patient is sitting or lying for one minute</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>0 pulse rate 80 or below</td>
</tr>
<tr>
<td>1 pulse rate 81-100</td>
</tr>
<tr>
<td>2 pulse rate 101-120</td>
</tr>
<tr>
<td>4 pulse rate greater than 120</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Sweating:</strong> over past ½ hour not accounted for by room temperature or patient activity.</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 no report of chills or flushing</td>
</tr>
<tr>
<td>1 subjective report of chills or flushing</td>
</tr>
<tr>
<td>2 flushed or observable moistness on face</td>
</tr>
<tr>
<td>3 beads of sweat on brow or face</td>
</tr>
<tr>
<td>4 sweat streaming off face</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Restlessness Observation during assessment</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>0 able to sit still</td>
</tr>
<tr>
<td>1 reports difficulty sitting still, but is able to do so</td>
</tr>
<tr>
<td>3 frequent shifting or extraneous movements of legs/arms</td>
</tr>
<tr>
<td>5 Unable to sit still for more than a few seconds</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Pupil size</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>0 pupils pinned or normal size for room light</td>
</tr>
<tr>
<td>1 pupils possibly larger than normal for room light</td>
</tr>
<tr>
<td>2 pupils moderately dilated</td>
</tr>
<tr>
<td>5 pupils so dilated that only the rim of the iris is visible</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Bone or Joint aches</strong> If patient was having pain previously, only the additional component attributed to opioids withdrawal is scored</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 not present</td>
</tr>
<tr>
<td>1 mild diffuse discomfort</td>
</tr>
<tr>
<td>2 patient reports severe diffuse aching of joints/ muscles</td>
</tr>
<tr>
<td>4 patient is rubbing joints or muscles and is unable to sit still</td>
</tr>
<tr>
<td><strong>Runny nose or tearing</strong> Not accounted for by cold symptoms or allergies</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>0 not present</td>
</tr>
<tr>
<td>1 nasal stuffiness or unusually moist eyes</td>
</tr>
<tr>
<td>2 nose running or tearing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>GI Upset: over last ½ hour</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>0 no GI symptoms</td>
</tr>
<tr>
<td>1 stomach cramps</td>
</tr>
<tr>
<td>2 nausea or loose stool</td>
</tr>
<tr>
<td>3 vomiting or diarrhea</td>
</tr>
<tr>
<td>5 Multiple episodes of diarrhea or vomiting</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Tremor observation of outstretched hands</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>0 No tremor</td>
</tr>
<tr>
<td>1 tremor can be felt, but not observed</td>
</tr>
<tr>
<td>2 slight tremor observable</td>
</tr>
<tr>
<td>4 gross tremor or muscle twitching</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Yawning Observation during assessment</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>0 no yawning</td>
</tr>
<tr>
<td>1 yawning once or twice during assessment</td>
</tr>
<tr>
<td>2 yawning three or more times during assessment</td>
</tr>
<tr>
<td>4 yawning several times/minute</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Anxiety or Irritability</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>0 none</td>
</tr>
<tr>
<td>1 patient reports increasing irritability or anxiousness</td>
</tr>
<tr>
<td>2 patient obviously irritable anxious</td>
</tr>
<tr>
<td>4 patient so irritable or anxious that participation in the assessment is difficult</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Gooseflesh skin</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>0 skin is smooth</td>
</tr>
<tr>
<td>3 piloerection of skin can be felt or hairs standing up on arms</td>
</tr>
<tr>
<td>5 prominent piloerection</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total scores with observer’s initials</th>
</tr>
</thead>
</table>

**Score:**
- 5-12 = mild;
- 13-24 = moderate;
- 25-36 = moderately severe;
- more than 36 = severe withdrawal
Appendix I: Patient Handouts

- See PDFs
Appendix J: Additional Resources
National Alliance of Advocates for Buprenorphine Treatment
http://www.naabt.org/education/literature.cfm

Mutual Mistrust in the Medical Care of Drug Users: The Keys to the “Narc” Cabinet (Merrill et al.)
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1495051/

Confronting the Stigma of Opioid Use Disorder- and Its Treatment (Olsen and Sharfstein)

Patients with Addiction Need Treatment – Not Stigma (AMA Task Force to Reduce Opioid Abuse)

Coping with the stigma of addiction (Rosenbloom)
https://www.hbo.com/addiction/stigma/52_coping_with_stigma.html

Stigma Article Series: Part 1 – Patients with opioid addiction continue to face stigma (Goodheart)
http://atforum.com/2016/02/stigma-article-series-part-i-patients-opioid-addiction-continue-face-stigma/

Stigma Article Series: Part II – Watch Your Language! Stigmatizing Patients Who Have Addiction Disorders Can Worsen Clinical Care (Goodheart)

The ASM National Practice Guideline: For the Use of Medications in the Treatment of Addiction Involving Opioid Use (ASM, Updated May 2015)

The ASM National Practice Guideline: For the Use of Medications in the Treatment of Addiction Involving Opioid Use Pocket Guide (ASM)

Buprenorphine: An Office-Based Treatment for Opioid Dependence (The New York City Department of Health and Mental Hygiene)

Advisory: Sublingual and Transmucosal Buprenorphine for Opioid Use Disorder (SAMHSA)
http://store.samhsa.gov/product/SMA16-4938?WT.mc_id=EB_20160301_4938

SAMHSA Resources on Opioid or Opiates
http://store.samhsa.gov/facet/Substances/term/Opioids-or-Opiates?pageNumber=1

Overview of Harm Reduction (Harm Reduction Coalition)


Ingersoll K. The impact of psychiatric symptoms, drug use, and medication regimen on non-adherence to HIV treatment. AIDS Care. 2004;16(2):199–211.


