



Buprenorphine Treatment for Opioid Use Disorder in HIV Primary Care

E2i Implementation Guide

An evidence-informed intervention, adapted for the Health Resources and Services Administration's Ryan White HIV/AIDS Program, to safely reduce opioid use disorder and improve HIV health outcomes among people with HIV.

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Table of Contents

	Executive Summary	1
	Introduction to the Implementation Guide	2
	Intervention Overview.....	7
	E2i Evaluation: Integrated Buprenorphine Treatment HIV Care Continuum Outcomes ...	10
	Core Elements	14
	E2i Evaluation: Integrated Buprenorphine Treatment Participation Outcomes	16
	Planning Activities.....	17
	E2i Evaluation: Integrated Buprenorphine Treatment Implementation Outcomes	26
	Implementation Activities	27
	E2i Evaluation: Challenges, Successes, Adaptations, and Lessons Learned.....	42
	E2i Program Spotlights	44
	Med Centro, Inc.....	45
	Greater Lawrence Family Health Center	48
	Appendices	51
	Appendix A. Implementation Science and Evaluation: Framework and Methods	52
	Appendix B. General Best Practices for Planning to Implement an Intervention Strategy	55
	Appendix C. Buprenorphine Treatment “Go Live” Worksheet	58
	Appendix D. Assessment, Eligibility, and Treatment Preparation Checklist.....	65
	Appendix E. DSM-5 Criteria for Opioid Use Disorder	67
	Appendix F. Sample Eligibility Criteria Checklist for Buprenorphine Treatment	68
	Appendix G. Sample Buprenorphine Treatment Agreement	69
	Appendix H. Sample Home Induction Protocol	74
	Appendix I. Additional Resources	76



EXECUTIVE SUMMARY

Buprenorphine Treatment for Opioid Use Disorder in HIV Primary Care (integrated buprenorphine treatment) is an evidence-informed intervention developed by HIV experts in collaboration with community members to improve health outcomes among people with HIV. In this intervention, clients receive treatment for opioid use disorder and HIV in a single setting, with the goals of reducing opioid use and overdose while improving client engagement in HIV care.

This Implementation Guide was developed for *Using Evidence-Informed Interventions to Improve Health Outcomes among People Living with HIV (E2i)*, which tested an integrated buprenorphine treatment program within Health Resources and Services Administration's (HRSA) Ryan White HIV/AIDS Program (RWHAP) settings and evaluated its impact. Additional easy-to-use implementation tools, tips, and resources to support replication of integrated buprenorphine treatment in the RWHAP and other HIV service organizations can be found in the [*Buprenorphine Treatment for Opioid Use Disorder in HIV Primary Care E2i Toolkit*](#).



INTRODUCTION TO THE IMPLEMENTATION GUIDE



INTRODUCTION TO THE IMPLEMENTATION GUIDE

What is Integrated Buprenorphine Treatment?

Buprenorphine/naloxone (hereby shortened to buprenorphine) is a safe and effective way to help people reduce opioid misuse and recover from opioid use disorder (OUD). By offering an integrated buprenorphine treatment program within an HIV service organization, clients with HIV can receive treatment for HIV and OUD in a single setting. Clients engaged in buprenorphine treatment may also receive counseling for any comorbid mental health or substance use issues, as well as case management services to address basic needs, such as housing and utility assistance.

Purpose of the Implementation Guide

The purpose of this Implementation Guide is to provide essential information and tools necessary for understanding, planning, and delivering integrated buprenorphine treatment within the Ryan White HIV/AIDS Program (RWHAP) and other HIV service organizations. This Guide is part of the [*Buprenorphine Treatment for Opioid Use Disorder in HIV Primary Care E2i Toolkit*](#), a comprehensive collection of helpful resources for implementing an integrated buprenorphine treatment program. The Guide is not designed for a small practice or single provider interested in treating small numbers of clients.

Other key resources for implementing and delivering buprenorphine in HIV care settings are:

- » [*Medication-Assisted Treatment website*](#) and [*Practice Guidelines for The Administration of Buprenorphine for Treating Opioid Use Disorder*](#) (Substance Abuse and Mental Health Services Administration/SAMHSA)
- » [*Treatment Improvement Protocol \(TIP 63\): Medications for Opioid Use Disorder*](#) (SAMHSA)
- » [*Dissemination of Evidence-Informed Interventions: Integrating Buprenorphine Treatment for Opioid Use Disorder in HIV Primary Care*](#) (HRSA HIV/AIDS Bureau, Special Projects of National Significance Program)
- » [*Training manual: Integration of Buprenorphine into HIV Primary Care Settings*](#) (HRSA HIV/AIDS Bureau, Integrating HIV Innovative Practices)

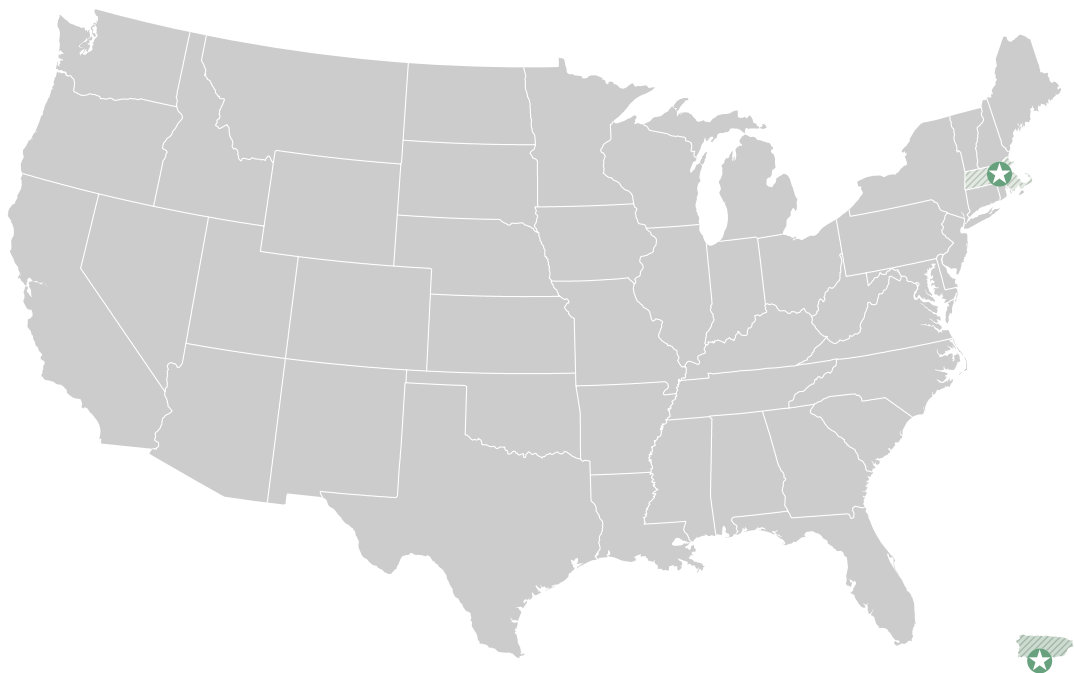
Implementation Guide Background

This Guide was developed as part of the RWHAP Part F Special Projects of National Significance (SPNS) Program *Using Evidence-Informed Interventions to Improve Health Outcomes among People Living with HIV (E2i)*, a four-year initiative (2017-2021) funded by the Health Resources and Services Administration's HIV/AIDS Bureau (HRSA HAB) of the U.S. Department of Health and Human Services. E2i was designed to improve HIV health outcomes for people with HIV who experience persistent gaps along the HIV care continuum, such as engagement in care, retention in care, adherence to antiretroviral therapy (ART), and viral suppression. Because OUD is associated with adverse effects on HIV health outcomes, people with HIV who have OUD are among those most in need of interventions that integrate behavioral health care within HIV care settings.

E2i chose to pilot the implementation of an integrated buprenorphine treatment program within HIV service organizations because of its demonstrated efficacy in improving health outcomes for people with HIV. Through a competitive request for proposals, two HIV service organizations in the HRSA HAB RWHAP were selected to implement integrated buprenorphine treatment between 2018 and 2020. These sites reported implementation and client outcome data to a team of evaluators who then analyzed these data. The stories, experiences, and evaluation outcomes of the sites are integrated and highlighted throughout this Guide.

The E2i Implementation Sites

FIGURE 1. Locations of the two sites that implemented integrated buprenorphine treatment through the E2i initiative.



Med Centro, Inc., (Ponce, Puerto Rico)

- Federally qualified health center
- RWHAP Part C recipient
- 40,000 total clients a year; <1% clients with HIV
- 32 employees provide HIV services
- Most common non-medical services accessed by clients with HIV: referral for health care (97%), other professional services (89%), health education (81%)

Greater Lawrence Family Health Center (Lawrence, Massachusetts)

- Federally qualified health center with a mobile health unit
- RWHAP Part C recipient; Part A subrecipient
- 58,000 total clients a year; <1% clients with HIV
- 26 employees provide HIV services
- Most common non-medical services accessed by clients with HIV: health education (100%), health insurance (77%), referral for health care (75%)
- Provides mobile health care and services to people experiencing homelessness

Implementation Science Evaluation

E2i used an implementation science approach to evaluate the intervention. The evaluation aimed to answer the following questions:

- » “What does it take to implement this intervention in an HIV service organization?”
- » “To what extent is successful implementation related to better HIV outcomes for the clients?”

E2i evaluators collected buprenorphine client data from the E2i implementation sites throughout the initiative to measure engagement in care, prescription of ART, retention in care, and viral suppression. They also collected and reviewed site staff surveys, client encounter forms, site visit reports, meeting notes, and other documents in order to learn more about: key factors for successful implementation; challenges encountered by the implementers; and adaptations to the intervention to achieve more successful implementation. The major findings from the evaluation are reported throughout this Guide. For additional detail on E2i’s theoretical approach and evaluation methods, see [*Appendix A*](#). See also the [*Buprenorphine Treatment for Opioid Use Disorder in HIV Primary Care E2i Toolkit*](#) for additional evaluation findings reported in manuscripts.



INTERVENTION OVERVIEW



INTERVENTION OVERVIEW

Goals

The primary goals of Buprenorphine Treatment for Opioid Use Disorder in HIV Primary Care are:

- » To reduce opioid misuse and overdose among people with HIV while improving client engagement in HIV and behavioral health care
- » To provide low barrier access to medications that treat OUD

Intervention Description

This intervention aims to systematically integrate a buprenorphine treatment program within an HIV service organization in order to address the overlapping epidemics of HIV and OUD. As such, a buprenorphine treatment program requires organizations to make changes to their staffing, equipment, and procedures, and to follow federal regulations for buprenorphine treatment. Organizations will also need to establish and strengthen partnerships with local community agencies that support basic and psychosocial needs for clients with HIV and OUD.

Using a client-centered approach, buprenorphine treatment teams support clients with HIV in progressing through buprenorphine initiation, stabilization, and maintenance. Clients may also receive adjunct counseling for comorbid mental health or substance use issues, and case management services to address basic needs, such as housing and utility assistance.

Priority Population

- » People with HIV and OUD



Buprenorphine Enrollment at the E2i Sites

20 clients

33-42 years old

70% male

70% Hispanic/Latinx

Rationale

- » There is a high co-morbidity of OUD among people with HIV.
- » OUD may interfere with adherence to ART, engagement in HIV care, and viral suppression.¹
- » Buprenorphine has several advantages over methadone, including:
 - More predictable drug-drug interactions with ART
 - Fewer side effects
 - Lower risk of dependency and misuse
 - Ability to be taken at home, making it more convenient, less stigmatizing, and less costly¹

Intervention Background

Previous evaluations of buprenorphine treatment delivered in HIV service organizations have found positive outcomes. Organizations have successfully integrated the programs into their overall systems. Clients with HIV were more engaged in both OUD treatment and HIV primary care, decreased their opioid use, and experienced improvements in linkage to care, ART use, retention in care, and viral suppression.²⁻⁸

¹ Cunningham CO. Opioids and HIV infection: From pain management to addiction treatment. *Top Antivir Med.* 2018;25(4):143-146.

² HIV/AIDS Bureau, Special Projects of National Significance Program. Integrating buprenorphine therapy into HIV primary care settings. Rockville, MD: U.S. Department of Health and Human Services, Health Resources and Services Administration; 2011. Available at: https://hab.hrsa.gov/sites/default/files/hab/About/RyanWhite/hab_spns_buprenorphine_monograph.pdf

³ Lucas GM, Chaudhry A, Hsu J, et al. Clinic-based treatment of opioid-dependent HIV-infected patients versus referral to an opioid treatment program: A randomized trial. *Ann Intern Med.* 2010;152(11):704-711.

⁴ Altice FL, Bruce RD, Lucas GM, et al. HIV treatment outcomes among HIV-infected, opioid-dependent patients receiving buprenorphine/naloxone treatment within HIV clinical care settings: Results from a multisite study. *J Acquir Immune Defic Syndr.* 2011;56 Suppl 1:S22-32.

⁵ Fiellin DA, Weiss L, Botsko M, et al. Drug treatment outcomes among HIV-infected opioid-dependent patients receiving buprenorphine/naloxone. *J Acquir Immune Defic Syndr.* 2011;56 Suppl 1:S33-38.

⁶ Korthuis PT, Tozzi MJ, Nandi V, et al. Improved quality of life for opioid-dependent patients receiving buprenorphine treatment in HIV clinics. *J Acquir Immune Defic Syndr.* 2011;56 Suppl 1:S39-45.

⁷ Walley AY, Palmisano J, Sorensen-Alawad A, et al. Engagement and substance dependence in a primary care-based addiction treatment program for people infected with HIV and people at high-risk for HIV Infection. *J Subst Abuse Treat.* 2015;59:59-66.

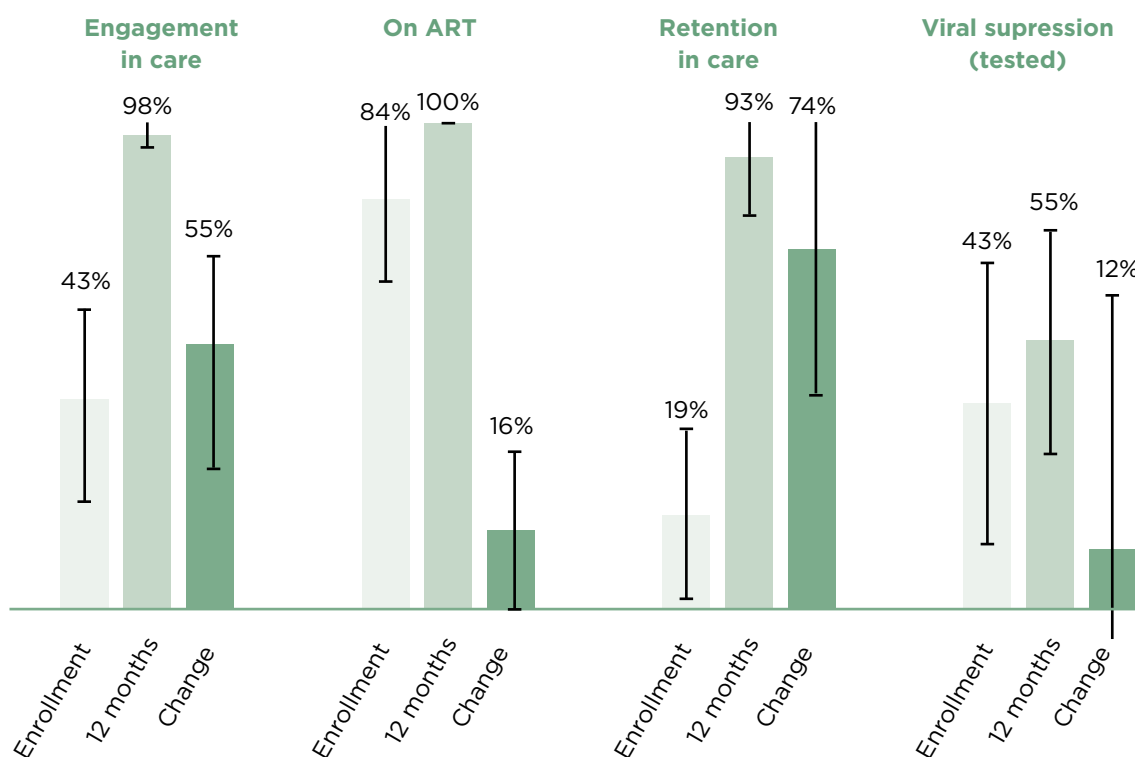
⁸ Tetrault JM, Moore BA, Barry DT, et al. Brief versus extended counseling along with buprenorphine/naloxone for HIV-infected opioid dependent patients. *J Subst Abuse Treat.* 2012;43(4):433-439.



E2i EVALUATION: INTEGRATED BUPRENORPHINE TREATMENT HIV CARE CONTINUUM OUTCOMES

- ◆ **Enrollment:** During a 9 to 12 month period, the E2i sites enrolled a total of 20 clients (9 at one site, and 11 at the other site) in integrated buprenorphine treatment. Clients were between the ages of 33 and 42 years old. Most were male (70%) and Hispanic/Latinx (70%).
- ◆ **Outcomes:** The E2i initiative measured HIV care continuum outcomes at the time of enrollment and 12 months later. Among the clients enrolled in integrated buprenorphine treatment, the percentage who were engaged and retained in HIV care increased significantly (by over 50%). There were no statistically significant changes in the other outcomes; however, 100% of clients were prescribed ART within 12 months of enrollment. Statistically significant changes may have been hard to detect in these outcomes due to small enrollment numbers.

FIGURE 2. HIV care continuum outcomes among the 20 clients enrolled in integrated buprenorphine treatment as part of the E2i initiative



Note: E2i used the following HRSA definitions for HIV care continuum outcomes:

- **Engagement in care** = At least one primary HIV care visit in the previous 12 months
- **On ART (adherence)** = Having been prescribed ART in the past 12 months
- **Retention in care** = At least two HIV care visits in the past 12 months
- **Viral suppression** = Having an HIV viral load test in the past 12 months AND having a result of less than 200 copies/mL at the last viral load test

Duration

- » Buprenorphine treatment in HIV primary care is a systems-level intervention that may continue indefinitely.
- » Clients stay on buprenorphine treatment for various lengths of time, based on their individualized needs.
- » Some clients may remain on buprenorphine treatment indefinitely.

Settings

- » Primary care or infectious disease clinics that provide HIV care
- » Settings may be:
 - Office-based
 - Mobile health units (recommended only for organizations that already have an established office-based buprenorphine program)

Mobile health units offer low-barrier settings for buprenorphine treatment.

Advantages include:

- **Accessibility:** *Mobile units can travel to areas where people live and congregate.*
 - **Drop-in service:** *Clients can walk in to get treatment “on demand.”*
-

Staffing

Treatment team

Integrated buprenorphine treatment programs require a multi-disciplinary team consisting of:

- » **Clinical Coordinator** (e.g., nurse, nurse practitioner, physician assistant, medical case manager, social worker, or certified alcohol and drug counselor):
 - Acts as the program champion, manager, and primary point of contact
 - Organizes team meetings for planning and sharing of information
 - Oversees recruitment, enrollment, informed consent, and retention
 - Supports the client and prescribers in buprenorphine induction, stabilization, and maintenance treatment procedures
 - Provides client education, screenings, and counseling

- Helps to make referrals to community providers for counseling or higher levels of care when needed
- Tracks clinical outcomes through chart documentation
- Keeps records that may be referenced for Drug Enforcement Agency inspection
- Applies harm-reduction principles
- Maintains therapeutic relationships with the client
- Requires at least 60% time

The two E2i sites were relatively small HIV care clinics based within large health centers. One site provided office-based buprenorphine. The other site provided buprenorphine services through their mobile health unit, which was an expansion of their office-based buprenorphine program. The mobile unit primarily served people experiencing unstable housing and homelessness.

» **Prescribing Providers** (e.g., physician, nurse practitioner, or physician assistant with requisite licensing to prescribe buprenorphine; note that teams need both a lead prescriber and a back-up prescriber for when the lead is unavailable):

- Diagnoses OUD and other psychiatric and medical conditions
- Orders laboratory tests
- Prescribes and titrates buprenorphine dosage
- Manages induction, stabilization, and maintenance of buprenorphine treatment
- Ensures appropriate documentation in medical charts
- Provides clinical guidance to the clinical coordinator

» **Behavioral health provider(s)** (e.g., licensed social worker or clinical psychologist):

- Provides cognitive behavioral therapy and/or group therapy to clients receiving buprenorphine treatment
- May be fully integrated, co-located, or provided by a partnering organization
- Counseling therapy is highly recommended for clients, but not required
- Support groups facilitated by behavioral health providers are also highly recommended

Additional recommended staff

Additional support from existing staff depends on each clinic's local context and needs. Many programs will need help from:

- » **Primary care providers and nurses:** To manage clients' other health needs and HIV care, if not provided by the buprenorphine prescribers
- » **Community health workers/Outreach specialists:** To conduct outreach, recruitment, community education about the program, support for harm reduction, etc.
- » **Substance use disorder counselor(s):** To provide individual and/or group counseling for buprenorphine clients (could be offered by a partner agency)
- » **Data coordinator:** To organize and store client assessment and all lab results and diagnoses in files and/or in the electronic health record; to track visits, retention, compliance, and overdose; and to oversee evaluation data collection, if applicable
- » **Billing staff/Benefits counselor:** To seek prior authorizations for insurance reimbursement and to help with reimbursement codes

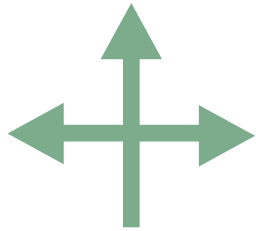
Office-based programs also typically receive support from:

- » **Office/Program administrator:** To hire staff, make agreements with community partners, and provide budget oversight
- » **Front desk and phone triage staff:** To talk to clients about the buprenorphine treatment program (training on how to do this is required)
- » **Medical assistants and nursing staff:** To support clients in withdrawal

Mobile unit programs also typically have:

- » **Mobile van driver(s)**
- » **Syringe service program staff:** To refer clients to the unit for treatment

In E2i, the office-based site staff consisted of a case manager, project manager, psychologist, and a physician. The mobile unit site was staffed by community health workers, nurses, case managers, and physicians.



CORE ELEMENTS



CORE ELEMENTS

Core elements are the “active ingredients” essential to achieving an intervention strategy’s desired outcomes. It is critical to closely follow the core elements when implementing an intervention in an HIV service organization; otherwise, the intervention may not work as intended.⁹ All other activities, such as staffing arrangements and clinical workflows, can be adapted to fit the unique circumstances of an organization and the priority population(s). However, adaptations should not compete with or contradict the core elements. **Integrated buprenorphine treatment has three core elements:**



1. Address the intersection of the HIV and opioid epidemics

- Many people with HIV use opioids to manage pain.
- People with persistent chronic pain may experience OUD.
- Injection drug use is a common route of HIV transmission.
- Buprenorphine treatment programs address the intersection of HIV and opioids by integrating buprenorphine treatment into HIV primary care.



2. Provide buprenorphine treatment

- The goal is to reduce the harm of opioid misuse and minimize the experience of withdrawal or cravings.
- The three main treatment stages are:
 - › **Induction:** medically monitored initiation of buprenorphine treatment
 - › **Stabilization:** increasing medication dosage until a client no longer has withdrawal or cravings and has not developed symptoms of opioid excess
 - › **Maintenance:** regular visits to the clinic to help clients maintain stability
- Clients often do not progress through the stages in a linear order.
- Adjunct behavioral health therapy is recommended but not required.



3. Adjust organizational systems

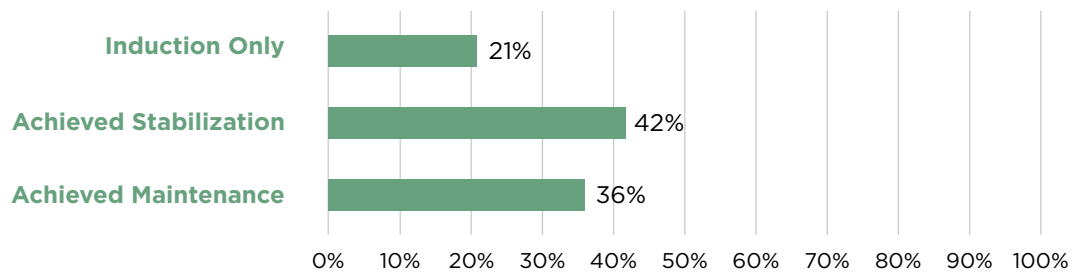
- Integrated buprenorphine treatment offers more than medication. The intervention requires organizations to assess and adapt their staffing, equipment, and procedures.
- Organizations need to identify community needs, establish or strengthen partnerships with other organizations, and follow federal and state buprenorphine policies.

⁹ Psihopoulos D, Cohen SM, West T, et al. Implementation science and the Health Resources and Services Administration’s Ryan White HIV/AIDS Program’s work towards ending the HIV epidemic in the United States. PLoS Med. 2020;17(11):e1003128.



E2i EVALUATION: INTEGRATED BUPRENORPHINE TREATMENT PROGRAM PARTICIPATION OUTCOMES

FIGURE 3. Participation outcomes among the 20 clients enrolled in integrated buprenorphine treatment as part of the E2i initiative.



◆ **Clinical encounters:** Clients had a median of 13 buprenorphine treatment encounters (IQR = 6-29)¹⁰ over 12 months. Encounters happened over a median of 147 days (IQR = 90-237).

◆ **Brief interventions and referrals:** Among the 20 clients enrolled in integrated buprenorphine treatment:

- 20% did not move beyond the initial induction phase
- 42% achieved stabilization
- 36% achieved maintenance

Clients spent the majority of their time (median of 88 days; IQR = 60-140) in the stabilization phase and less time in the induction phase (median of 15 days; IQR = 6-91) and maintenance (median of 28 days; IQR = 7-197) phases.

Among those who achieved maintenance, clients had a median of 6 (IQR = 5-9) transitions between phases. This means they moved back and forth among the phases, as needed, in order to re-establish stability.

¹⁰ IQR, or interquartile range, describes the 25th percentile and the 75th percentile of the data.



PLANNING ACTIVITIES



PLANNING ACTIVITIES

This section provides recommended activities for planning to implement integrated buprenorphine treatment. For helpful tools, see:

[Appendix B](#): General Best Practices for Planning to Implement an Intervention Strategy

[Appendix C](#): Integrated Buprenorphine Treatment “Go Live” Worksheet

Staff Roles and Training Needs

To ensure a smooth workflow, clearly delineate staff roles and responsibilities from the beginning, and adjust those roles as the program evolves. The most important role to define is the clinical coordinator, as this role can vary depending on the background of the person hired.

- » Prescribing providers must have a buprenorphine prescription waiver. Rules regarding training, certifications, and waivers are subject to change. For up-to-date information, see the [SAMHSA Medication-Assisted Treatment website](#).
- » All treatment team members must have experience or training in the assessment and management of substance use disorders (SUDs). For national training opportunities, see the [Center of Excellence for Integrated Health Solutions](#) and the American Society for Addiction Medicine (ASAM).

Recommended training

- » Identify a clinical mentor with expert knowledge and practical experience in buprenorphine treatment to provide additional support and strategies, and to help with challenging cases. The mentor can hold monthly case conferences with the team in-person or remotely. To find a mentor, access the [Physician Clinical Support System mentoring program](#).
- » All clinical staff can benefit from training on the basic features of SUDs, medication supported recovery, urine toxicology testing, confidentiality, motivational interviewing, polysubstance use disorders, and buprenorphine-specific subjects (e.g., client selection, induction, stabilization, documentation, forms, regulations, and case studies).

The E2i sites have inspired other organizations to start their own low-barrier buprenorphine programs and staff have grown professionally and evolved in their attitudes towards addictions.

- » In addition, all organizational staff can benefit from training on cultural responsiveness to reduce stigma and build trusting relationships with clients. This training can focus on:
 - Practicing empathy (e.g., be non-judgmental; understand others' feelings and perspectives)
 - Using language of change and recovery (e.g., use motivational interviewing techniques)
 - Using non-stigmatizing, person-first language (e.g., say person with HIV vs. AIDS victim; person with a substance use disorder vs. substance abuser)
 - Using harm reduction approaches (offer safer options vs. abstinence)
 - Recognizing the symptoms and effects of trauma and the benefits of creating a trauma-informed care environment
- » Over time, the treatment team should continue to build their skills to provide the most current standards of care.
- » For further resources on these topics, see the [*Addiction Technology Transfer Network*](#), [*TargetHIV*](#), [*AIDS Education and Training Center Program*](#), [*National LGBTQIA+ Health Education Center*](#).

Clinic Space and Equipment

If office based:

- » Identify a room for the clinical coordinator to meet with clients; a separate room may also be needed for inductions.
- » Equip the office with drug screening kits and computers with software for securing client logs and records.

If mobile-based:

- » Purchase or retrofit a mobile health unit; funding may be available through private, state, or federal grants. The unit requires an exam room, treatment room, lab station, and bathroom.
- » Equip the unit with furniture and supplies, such as point-of-care urine drug screens, emergency drug kits, Wi-Fi, and laptops with software for securing client logs and records.

Client Outreach and Recruitment Strategies

- » Review medical records to identify **existing clients with HIV** who meet OUD eligibility criteria. Some of these clients may include people taking opioids for chronic pain.
- » Set up a **clinic-wide internal referral system** with a protocol for discussing the program with these clients (who/what/when).
- » Universally **screen all new clients** with HIV for eligibility with diagnostic criteria for OUD from the Diagnostic and Statistical Manual of Mental Disorders (DSM-5).¹¹
- » Develop **recruitment materials** (brochures, flyers, etc.) to let the priority populations know about the program and how to get in touch.
- » Conduct **outreach in the community** (e.g., shelters, syringe programs, word of mouth, food banks, other community agencies).
- » Establish **bi-directional referral relationships** with partner agencies.

Partnerships and Referral Networks

- » Establish formal relationships and referral protocols with pharmacies, laboratories, and mental health and SUD treatment providers; consider writing up a Memorandum of Understanding with the agreed upon process to ensure smooth bi-directional referrals for clients.
- » As much as possible, integrate psychiatric and counseling services within the program. Services may include individual therapy, group therapy, psychiatric medication management, peer support, etc.
- » If full integration of behavioral health services is not possible, create a network of recovery support services with partnering agencies.

To identify clients for buprenorphine treatment, the office-based E2i site received referrals from case managers and other clinical providers. In addition, they developed bi-directional referral systems with local agencies, promoted the program on social media, and conducted outreach through their HIV rapid testing program. The mobile unit site identified clients through homeless shelters, the syringe service program, and referrals from case managers and hospital emergency departments. They also worked with the medical team to review charts for eligible clients.

¹¹ Diagnostic and Statistical Manual of Mental Disorders: DSM-5. 5th ed., American Psychiatric Association, 2013

Billing

- » Determine and document fees, payment plans, and policies, including the types of insurance to accept, and whether to apply to client assistance programs (coverage by public and private payors for medication and office visits varies).
- » Identify the staff person at the clinic who will be the point person for addressing issues related to insurance authorization.

Policies and Procedures

Workflow and scheduling

- » Determine a process for enrolling clients.
- » Determine the length of time required for each type of appointment (e.g., assessment, induction).
- » Develop a contingency plan to support clients outside of regular hours (e.g., on-call number, backup provider).
- » Create a plan for client registration and scheduling (office-based only).
- » Develop a plan for when clients see which staff (e.g., alternate visits between prescribing provider and clinical coordinator).
- » Develop a plan to manage a waitlist and minimize the wait time to initiation of treatment (a period of time that may be associated with higher risk of overdose; office-based only).
- » Develop a plan to manage clients transitioning from detox, residential treatment settings and/or incarceration.

Assessment

- » Determine which drug screening kits will be used and how frequently drug screening will be conducted, based on state, jurisdictional, and national regulation.
- » Determine which screening tools will be used to assess for co-occurring mental health and SUDs. Examples include:
 - *Patient Health Questionnaire (PHQ-9)* for mental health screening¹²
 - *ASSIST* (Alcohol, Smoking, and Substance Involvement Screening Test)¹³
 - *TAPS* (Tobacco, Alcohol, Prescription Medication, and other Substance Use tool)^{14,15}
 - *DAST-10/20* (Drug Abuse Screening Test)¹⁶

Treatment, prescription, and education

- » Develop clinic-specific protocols for buprenorphine treatment based on up-to-date clinical guidelines, as well as state and federal regulations.
- » Determine how prescribers will obtain buprenorphine for inductions. The process may differ depending on the setting and the resources available within your organization. For example:
 - If a pharmacy is onsite, providers can send the client or a staff member to the pharmacy before or during the induction visit to pick up the medication.
 - If no pharmacy is onsite, providers can write prescriptions to be picked up at a local pharmacy prior to the induction appointment.
 - Because clients may be in the early stages of withdrawal when they pick up their induction prescription, some prescribers may send the client's family members or close friends to pick up the induction doses.

¹² Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med.* 2001;16(9):606-613.

¹³ Humeniuk R, Ali R, Babor TF, Farrell M, et al. Validation of the Alcohol, Smoking and Substance Involvement Screening Test (ASSIST). *Addiction.* 2008;103(6):1039-1047.

¹⁴ Gryczynski J, McNeely J, Wu LT, et al. Validation of the TAPS-1: A four-item screening tool to identify unhealthy substance use in primary care. *J Gen Intern Med.* 2017;32(9):990-996.

¹⁵ McNeely J, Wu LT, Subramaniam G, et al. Performance of the Tobacco, Alcohol, Prescription Medication, and Other Substance Use (TAPS) tool for substance use screening in primary care patients. *Ann Intern Med.* 2016;165(10):690-699.

¹⁶ Skinner H. The Drug Abuse Screening Test. *Addict Behav.* 1982;7(4):363-371.

- Some providers are able to obtain limited supplies through their distributor and store them at their offices; however, there are strict Drug Enforcement Agency regulations governing this practice.
- Clinics or mobile units may use a courier service to deliver the medication from a pharmacy.
- » Order educational materials on buprenorphine to distribute to clients, such as those available from the [*National Alliance of Advocates for Buprenorphine Treatment*](#).

Record keeping

- » Follow federal and state mandates for record keeping practices, including maintaining a client log for each prescriber, ensuring secure medical record storage, and maintaining records for potential DEA visits. For more information, see: [*SAMHSA Record Keeping Requirements*](#).
- » Create guidelines that follow federal and state mandates regarding confidentiality of clients' electronic health records; coordinate with the IT department to better support documentation of client-level data.
- » Review 42CFR guidelines to determine how your practice will adhere to these guidelines. Refer to [*SAMHSA's Confidentiality Regulations*](#).

Referrals

- » Develop a protocol for accepting referrals (e.g., self-referred, referred only from within the clinic, or referred from other providers in the community).
- » Develop a protocol for referring clients to other providers and agencies for social services and treatment of co-occurring SUDs or other psychiatric disorders.

Safety

- » Develop policies that address safety and boundaries with clients including best practices for safely conducting outreach and home visits, as applicable. These policies are similar to policies on safety and boundaries pertaining to any other type of clinical care.

Natural disasters and emergencies

- » Develop alternative protocols for modifying procedures after disruption by a natural disaster or pandemic. For example, back-up data frequently, set up home-based and telehealth protocols, etc.

Effective team communication

- » Establish effective communication and supervision among treatment team members through regular meetings, for example:
 - Case conferencing meetings (weekly)
 - Supervision meeting between the clinical coordinator and prescribing provider (weekly)
 - Clinical mentor meeting (monthly or less often)

Sustainability and Reimbursement

Sustainability refers to the ability to maintain programming and its benefits over time. Achieving sustainability typically involves both applying for grants and accessing available reimbursement options.

Planning

A helpful resource for building capacity for sustainability is the [*Program Sustainability Assessment Tool*](#) developed at the Center for Public Health Systems Science at the Brown School, Washington University in St. Louis. Their Program Sustainability Framework identifies factors that can help strengthen an organization's capacity to maintain its program.

Sustainability planning involves the following steps:

1. Understand the factors that influence a program's capacity for sustainability
2. Assess your program's capacity for sustainability using the [*Program Sustainability Assessment Tool*](#)
3. Review results from your Assessment
4. Plan to increase the likelihood of sustainability by developing an Action Plan

For more information and downloadable tools, see sustaintool.org.

Reimbursement

Outpatient substance use treatment, including medication-assisted treatment, is an allowable core medical service under RWHAP funding. RWHAP-funded organizations can receive technical assistance on health coverage options from the [*Access, Care, and Engagement Technical Assistance \(ACE TA\) Center*](#).

Buprenorphine treatment for OUD is covered by Medicare and all state Medicaid programs. In addition, SAMHSA offers grants and incentives through state Medicaid programs to support providers to build comprehensive programs that offer medication supported recovery, including buprenorphine.

Program integration

Integrating buprenorphine treatment into the entire clinic setting will help create long-term sustainability. Strategies for integration include:

- » Develop a communication plan that outlines how information about the buprenorphine intervention is diffused throughout the clinic, for example:
 - Giving presentations at all-staff and department meetings to review the status of the intervention, discussing the treatment process, talking about client outcomes and cases, etc.
 - Writing a feature on the intervention for the clinic newsletter or blog
- » Meet with administrative leaders at least two times per year to discuss enrollment, outcomes, evaluation findings (if relevant), budget, programmatic needs, etc.
- » Keep internal referrals coming. Check in with providers to make sure they are screening and referring eligible clients for treatment.
- » Identify an intervention champion to support the intervention team in securing the internal and external supports necessary.
- » Recruit and train additional prescribing providers at the clinic site as you grow. The team can also consider hosting or supporting a buprenorphine prescription waiver training to grow a network of prescribing providers in the local area.



E2i EVALUATION: INTEGRATED BUPRENORPHINE TREATMENT IMPLEMENTATION OUTCOMES

To learn more about how the intervention was viewed by the leadership and staff members at the E2i sites, E2i collected data from the people implementing the intervention. The data included: (1) an organizational survey completed by site leadership once during the planning period, and every six months during implementation; and (2) review of site documents created during implementation, including site visit reports, meeting notes, and cost workbooks (see [Appendix A](#)).

Measure (definition)	Results at the E2i sites
Acceptability: how well staff and leadership regard the intervention	Both of the E2i sites found the intervention highly acceptable for the duration of the initiative. Each site believed that the intervention was a good fit for their organization's mission and goals.
Adoption: the intention, initial decision, or action to implement the intervention	One site reported lower adoption during the planning period, and then consistently high adoption after beginning service delivery. The other site reported high adoption for the entire initiative.
Appropriateness: the compatibility of the intervention to address a particular issue or problem	Both sites reported that buprenorphine was highly appropriate and filled a service need. Low enrollment into the interventions, however, raises questions about whether the intervention was appropriate for the population they hoped to serve.
Feasibility: the extent to which the intervention can be successfully carried out	Both sites considered buprenorphine highly feasible for the duration of the initiative.
Fidelity: the degree to which a site felt able to (a) implement the intervention as it was intended by the program developers, and (b) monitor progress	Both sites reported being able to maintain a full implementation team and assess fidelity throughout the initiative.
Penetration: the integration of the intervention within the organization	Both sites reported that buprenorphine activities were integrated into their organizational operations within a year of starting delivery of services.
Cost: the costs associated with planning and implementation, such as: personnel, training, supplies, incentives, and outreach activities	Costs included both direct and in-kind expenses. The average expenditures for each site were: • <i>Planning period:</i> \$23,814 • <i>Recruitment:</i> \$798 per client enrolled • <i>Implementation activities:</i> \$14,604 per client enrolled • <i>Supervision and management of intervention:</i> \$8,632 per client enrolled These numbers do not necessarily reflect what it would cost to implement buprenorphine at other HIV service organizations. Costs per client would be lower in settings where larger numbers of clients enroll in buprenorphine treatment.



IMPLEMENTATION ACTIVITIES



IMPLEMENTATION ACTIVITIES

The following activities describe the stages of buprenorphine treatment. **It is important to recognize that clients often do not progress through these stages in a linear order.** [*Appendix D: Assessment, Eligibility, and Treatment Preparation Checklist*](#) can be used to guide staff through each phase of treatment.

Activity 1: Initial Client Assessment

Goals of the assessment

The prescribing provider and clinical coordinator conduct an initial assessment at the client's first clinical encounter. The goals of initial assessment are to:

- » Determine the client's eligibility for buprenorphine treatment.
- » Develop treatment goals.
- » Assess potential barriers and facilitators to treatment.
- » Make plans to address those barriers.

Determine treatment eligibility

- » Discuss current opioid use and patterns, including type of opioid, method of administration, frequency of use, and last use.
- » Establish OUD diagnosis and severity using [*Appendix E*](#).
- » Conduct baseline urine drug screening, with the expectation of an opioid-positive screen (Consider adding fentanyl screening to your screening panel) and potentially other substances (e.g., methamphetamines, benzodiazepines, cocaine).
- » Document drug or needle use damage or complications.
- » Observe possible intoxication.
- » Ask about past and current use of other substances, including tobacco, alcohol, and benzodiazepines, as well as previous treatment experiences, and response to treatment (side effects and perceived effectiveness).

- » Screen for SUDs using DSM-5 criteria or a validated screening tool such as:
 - [*ASSIST*](#) (Alcohol, Smoking, and Substance Involvement Screening Test)¹³
 - [*TAPS*](#) (Tobacco, Alcohol, Prescription Medication, and other Substance Use tool)^{14,15}
 - [*DAST-10/20*](#) (Drug Abuse Screening Test)¹⁶
- » Review HIV-related lab work.
- » Check liver enzymes and consider ordering tests for hepatitis, syphilis, lipid profile, serum electrolytes, blood urea nitrogen and creatinine, complete blood count with differential and platelet count, and tuberculosis.
- » Take pregnancy serum or urine HCG and assess birth control methods (if applicable).
- » Complete the eligibility for treatment checklist. For an example, see [*Appendix F*](#).
- » If client is not currently eligible for treatment, discuss the reasons why, and reschedule for another time.
- » Consider an alternative treatment, such as a naltrexone or methadone.

Develop treatment goals

- » Discuss client's readiness to participate in treatment.
- » Discuss client's goals for engaging in treatment.
- » Provide education on overdose prevention and response.

Assess and address socioeconomic barriers to treatment

- » Identify how buprenorphine treatment will be paid for and coordinate prior authorizations.
- » Assess the client's living and recovery environment (e.g., housing, employment, social supports).
- » Support the client in obtaining referrals and creating a plan to access housing, legal, financial, or employment assistance, as needed.

Assess and address co-occurring medical conditions and psychiatric disorders

- » *Liver disease*: Clients with decompensated cirrhosis may require closer monitoring.
- » *Aspartate aminotransferase (AST), alanine aminotransferase (ALT)*: If AST or ALT are greater than five times the normal upper limit, clients may have increased risk of buprenorphine-induced hepatitis; care teams should weigh the risks and benefits of starting buprenorphine treatment on a case-by-case basis.
- » *Pain syndromes*: Clients who require high doses of full opioid agonist therapy (e.g., morphine, oxycodone, fentanyl) may require higher doses than typically used for treating OUD.
- » *Psychiatric Disorder*: Obtain mental health assessment and follow recommendations to promote mental health stability; this includes assessments for co-occurring mood disorders, anxiety disorders, eating disorders, trauma- and stress-related disorders, and psychotic disorders.
- » *Substance withdrawal*: Consider identifying and referring clients who need medically supervised withdrawal management from alcohol, benzodiazepines, or other sedatives prior to initiating buprenorphine.
- » *Medications metabolized by cytochrome P450 3A4 system (several HIV antiretroviral and psychiatric medications)*: 3A4 inhibitors may increase drug levels of buprenorphine causing symptoms of opioid excess (e.g., clients on ritonavir-boosted regimens may require a downward dose adjustment of buprenorphine, though this is not common).

Activity 2: Preparation for Treatment

Eligible clients can initiate treatment at the same visit as the assessment, or can return for a second visit, as long as the wait time to start treatment is minimized.

Educate client about what to expect

- » Educate the client on what to expect at each stage of treatment, and how to properly administer, safeguard, and discard medication.
- » Explain that clients must be in the early stages of withdrawal from opioids prior to induction; otherwise, they will experience precipitated withdrawal (which causes intense and acute symptoms). An opioid's half-life influences the time to withdrawal as noted in the examples below:
 - Heroin/fentanyl should be stopped at least 12 hours prior to induction
 - Methadone should be tapered down to 30mg/day prior to induction and should be stopped altogether 24-48 hours before induction.
- » Educate clients about the symptoms that accompany withdrawal. Reassure clients that buprenorphine is designed to help them feel better during withdrawal. Helpful handouts are available from the [*National Alliance of Advocates for Buprenorphine Treatment*](#).
- » Manage client expectations about buprenorphine, explaining that it is only one aspect of recovery, which is a lifelong process.
- » Educate the client on overdose prevention and response.

Discuss the treatment agreement

- » Discuss each component of a treatment agreement, including goals, risks and benefits, and the relationship between the client and the treatment team. See [*Appendix G: Sample Buprenorphine Treatment Agreement*](#).
- » Communicate with other providers in the client's circle of care about the treatment plan. This may require signed releases of information to exchange protected health information.

Prepare clients for induction

- » Determine whether it is better for the client to do clinic-based induction (i.e., in the office or mobile unit) or home-based induction, including microdosing.
 - *Clinic-based induction* is recommended for clients who: have not taken buprenorphine before; are transferring from methadone to buprenorphine (withdrawal symptoms are more likely in these clients); have worries about experiencing withdrawal; or have anxiety or difficulty following complex instructions.
 - *Home-based induction* has fewer barriers because it does not require clients to come to the clinic each day of induction.
 - *Microdose induction* is a multi-day, home-based process which involves prescribing buprenorphine in gradually increasing doses while the client is continuing their opioid use. Once a blocking dose of buprenorphine is achieved, concurrent opioid use is then stopped. Possible situations to consider for microdosing induction:
 - Failed attempt at either in office or home induction
 - Transitioning clients off of prescribed opioids
 - Transitioning clients off of fentanyl, which is more likely to cause precipitated withdrawal
- » Take a baseline screen of opioid withdrawal symptoms, using the 11-item [*Clinical Opiate Withdrawal Scale \(COWS\)*](#).¹⁷
- » Co-prescribe naloxone rescue kits, as available/allowable by law.

¹⁷ Wesson DR, Ling W. The Clinical Opiate Withdrawal Scale (COWS). J Psychoactive Drugs. 2003;35(2):253-259.

Consider dispensing “kick-packs” (optional)

Kick-packs contain small quantities of medications to relieve possible opioid withdrawal symptoms such as nausea, diarrhea, anxiety, myalgia, and rhinorrhea. Many clients will not need these medications. A kick-pack may include:

- » Clonidine 0.1mg to 0.3mg PO q4-6 hours PRN lacrimation, diaphoresis, rhinorrhea, piloerection
- » Loperamide (Imodium) 4mg PO x 1 PRN diarrhea, then 2mg PO PRN each loose stool or diarrhea thereafter, not to exceed 16mg/24h
- » OTC acetaminophen 500-1000 mg q 4-6 hrs, ibuprofen 600 mg q8 hrs, or naproxen 500 mg q12 hrs PRN myalgias or arthralgias

Activity 3: Induction

Induction is the medically monitored startup of buprenorphine treatment. The induction process usually lasts three days, though may take up to seven days. The goal of induction is to identify the lowest possible buprenorphine dose that will allow clients to reduce or stop their opioid use without experiencing withdrawal symptoms or uncontrollable drug cravings. Currently, sublingual buprenorphine is available in two formulations:

- » Buprenorphine hydrochloride (monotherapy)
- » Buprenorphine hydrochloride and naloxone hydrochloride in a 4:1 ratio (buprenorphine-naloxone; commercial name ‘Suboxone’) in a combination tablet or film. Buprenorphine-naloxone is often the preferred method of treatment because it reduces the likelihood that the medication will be injected rather than taken sublingually.

The most common side effects of buprenorphine include sweating, headaches, nausea, constipation, reduced sexual drive, drowsiness, and disrupted sleep. Clients with viral hepatitis may also experience mild increases in liver enzymes, particularly in ALT levels.

Clinic-based induction protocol (office or mobile unit)

Day 1: The prescribing provider conducts the initial induction visit, although it is helpful to have the clinical coordinator present as well.

- » Assess for baseline opioid withdrawal symptoms, using COWS.
- » Measure withdrawal symptoms: As noted earlier, the client must be in the early stages of withdrawal. The COWS (along with subjective measures) can identify if clients are experiencing adequate withdrawal to begin induction and avoid precipitated withdrawal. A COWS score of > 5 , but preferably > 12 , should sufficiently avoid precipitated withdrawal.
- » Check for signs of intoxication by other substances (e.g., alcohol odor, nystagmus, positive Romberg test, client disinhibition, or other altered mental status).
- » If clients do not meet the induction criteria, explain the reasons why and reschedule the appointment.
- » For clients who meet the induction criteria, the prescribing provider or clinical coordinator will:
 - **Start client on a 2-4 mg test dose** (use 4 mg for clients with stronger withdrawal symptoms). The tablet or film must dissolve completely under a moist tongue, which takes 5-10 minutes, and occasionally as long as 15 minutes. Stay with the client to ensure the medication is taken correctly and to put the client at ease.
 - **Evaluate client for reactions every 10-15 minutes**, for up to 3 hours. Most clients experience a reduction in withdrawal symptoms and cravings within the first 10-20 minutes.
 - **Give an additional dose of 2-4 mg (up to 16 mg total)** until withdrawal symptoms are significantly reduced.
 - **Send client home** with take-home doses and instructions for the next 1-2 days.

Day 2: Occurs in the clinic or from home by phone. The provider or clinical coordinator will:

- » Check for withdrawal symptoms (COWS) and cravings.
- » Titrate dosage upwards, not to exceed 16 mg/day.

Day 3: Occurs in the clinic or from home by phone. The provider or clinical coordinator will:

- » Check for withdrawal symptoms (COWS) and cravings.
- » Titrate dosage upwards, not to exceed 16 mg/day.
- » Prescribe a week's supply of buprenorphine

Home-based induction protocol (office or mobile unit)

Home-based induction occurs under the supervision of providers experienced with inductions; it is not recommended for newly waived providers and newly established sites. Home-based induction is best-suited for clients who have prior experience with buprenorphine, have reliable telephone access, and have demonstrated both comfort and skill at starting the medicine without clinical observation. Home-based induction can reduce barriers for clients, such as the stigma and discomfort of traveling to and attending a medical appointment while in withdrawal. Home-based induction also lessens the complications of getting a buprenorphine induction dosage to a mobile van or remote clinic.

Home-based induction involves the following steps:

- » Review the home induction protocol handout with the client ([*Appendix H: Home Induction Protocol Handout*](#)). The protocol includes information about how to take medication sublingually, how to track and record doses, and what clients should not do with buprenorphine.
- » Create a clear induction plan with the client that:
 - Explains when to stop opioids and begin induction.
 - Describes how to assess withdrawal symptoms.
 - Instructs when to take medication each day.
- » Provide enough medication to achieve a dose of 16mg per day until the first stabilization visit (in about a week).
- » Consider prescribing a “kick-pack” to treat symptoms of withdrawal.
- » Provide contact information for clients if they have questions or problems.
- » Check in with the client by phone to assess how they are doing.
- » Schedule the client's next appointment.

Notes on induction: Timing and amount of dosing is very important. 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 client non-adherence. A sudden exacerbation of opioid withdrawal symptoms after administering buprenorphine usually indicates precipitated withdrawal. Discuss symptoms with the client and review time of last opioid use. Give the clients a kick-pack of medications at the clinic for symptom management and instruct them to return the following day for re-evaluation.

Activity 4: Stabilization

Stabilization involves increasing the medication dosage until the client no longer has signs of withdrawal or cravings and has not developed signs or symptoms of opioid excess. Stabilization visits occur weekly for two to four weeks.

Stabilization involves the following steps:

- » **Assess withdrawal symptoms** using COWS. Review use of any adjunct medications for symptom management. Most clients will no longer be experiencing withdrawal but may continue to experience cravings.
- » **Increase daily dose** by 2-4mg until client achieves optimal relief of objective and subjective withdrawal symptoms and cravings. The median dose is 16mg daily, though the range can be from 8mg-24mg. Most clients reach their target dose within the first two weeks of treatment.
 - For clients with HIV who are on boosted atazanavir and other ritonavir-containing antiretrovirals, lower buprenorphine doses may be sufficient.
 - For clients on efavirenz-containing regimens, higher doses are often required.
- » **Review treatment agreement** with client. Remind them that diversion or misuse of buprenorphine may result in treatment discontinuation.
- » **Prescribe enough buprenorphine** for the next week (before next visit).

Throughout stabilization, clients need support, advocacy, and referrals. The clinical coordinator can do the following:

- » Encourage medication adherence.
- » Assist clients with using recovery-based supports (peer mentors, groups, friends, social events, etc.).
- » Discuss cravings and other challenges.
- » Discuss overdose prevention.
- » Remind clients to contact their medical team right away if relapse occurs.

Notes on stabilization: For many clients, the path to stabilization is not linear. It is not uncommon for a client to relapse during the first month or two. Clients may abruptly stop their buprenorphine medications, therefore requiring another induction. Some may stabilize for a few weeks, and then fall out of care. It is therefore important to develop a plan for “out-of-care” clients to rapidly re-engage in buprenorphine treatment.

Activity 5: Maintenance

The final phase of treatment is maintenance. Typically, maintenance visits occur once a month. However, clients with comorbid conditions and other high needs may need more frequent visits to maintain stability. For example, clients experiencing unstable housing or untreated mental health disorders can benefit from coming in every other week over several months. Treatment teams can use their discretion to determine a client’s visit frequency. After six months of maintenance, clients who remain highly stable can come every two to three months.

During a maintenance visit, the prescribing provider or clinical coordinator:

- » Assesses client’s functioning and stability.
- » Conducts toxicology screening.
- » Provides positive reinforcement for opioid-negative toxicology, and non-punitive counseling, intervention, and/or referral for positive screens.
- » Provides ongoing treatment adherence support.
- » Helps clients access the services they need to support their sobriety and overall health and wellbeing (counseling, housing, employment, etc.).

Addressing destabilization and relapse

When clients relapse or destabilize, the treatment team

- » Helps clients identify factors contributing to relapse.
- » Provides additional monitoring and support.
- » Refers clients to a higher level of care, if needed.

Schedule for Induction, Stabilization, and Maintenance

Induction	Week 1
	Clinic visits on days 1, 2, and 3 (or phone calls on days 2 and 3)
	OR Home-based (with initial visit to receive medication and instructions)
	Daily dose: start at 2-4mg; titrate up to 8-12mg (no > than 16mg)
Stabilization	Weeks 2 to 4
	Clinic visits weekly
	Check for withdrawal and cravings
	Toxicology testing
	Target dose: 12-16mg daily (up to 24mg)
Maintenance	Months 2 to 12
	Clinic visits monthly or twice a month (months 2-6); if doing very well, every 2-3 months through month 12
	Check for continued stability
	Toxicology testing
	Counseling once or twice monthly
	Adjust dosage as needed

Activity 6: Transition to Primary Care

Clients can stay on buprenorphine treatment indefinitely, but many can transition to working with just their primary care provider instead of the entire buprenorphine treatment team. The decision to transition clients can be done on a case-by-case basis. In mobile units, staff may try to encourage clients to transition to office-based care but can also allow clients to stay with the unit if they wish.

Activity 7: Terminating Treatment

The three primary reasons why a client may need to terminate treatment include: client's choice (voluntary); lack of clinical improvement or worsening clinical course; and violent and/or illegal behavior.

Voluntary termination

- » Some clients will wish to stop treatment. The ideal candidate for tapering off buprenorphine is socially and clinically stable, has developed supportive relationships with persons not using drugs, has discovered alternative ways of dealing with triggers for drug use, and is confident and motivated to stop treatment.
- » Clients should taper slowly (e.g., decrease dose by 10-25% each month), as slow tapers have been shown to be more successful than rapid tapers. The client and provider should decide together on the exact pace of the taper and monitor and adjust the taper as a team.

No significant improvement or worsening clinical course

- » When a client shows no significant improvement or a worsening clinical course, it may be due to physical or psychological stressors, inadequate or inappropriate treatment, or non-adherence with treatment.
- » The treatment team should work closely with clients during these times to help identify contributing factors and strategies to overcome them. Increase the frequency of monitoring and counseling with these clients.
- » If the current level of care cannot meet the needs of the client, outside providers or programs such as methadone maintenance, intensive case management, cognitive behavioral therapy, supportive housing, or residential treatment should be considered and offered.

- » If a client will transfer to a higher level of care, the treatment team should develop a Memorandum of Understanding with treatment partners and protocols to obtain consent to share client information. Transfer from office-based buprenorphine to more structured methadone treatment may be an option. If clients enter a residential treatment setting, buprenorphine can (and often should) be continued.

Illegal or violent behavior

- » The team should develop procedures to manage illegal or violent incidents, and determine which behaviors will result in involuntary detoxification and discharge.
- » Possible grounds for termination include: buprenorphine diversion (selling prescription medication); an indication of diversion may be the lack of buprenorphine and/or norbuprenorphine (a buprenorphine metabolite) in toxicology tests; an act or threat of violence against a client or clinic staff; possession of weapons; violation of the program rules and regulations; harassment of other clients or staff on the basis of gender, ethnicity, sexual orientation or gender identity; stealing or other illegal acts on the clinic grounds; duplicate registrations in opioid agonist treatment programs (methadone or buprenorphine); and tampering with toxicology samples.

Activity 8: Alternatives to Sublingual Buprenorphine

It is important for buprenorphine treatment programs to be aware of alternative treatment options, and to know where to refer clients if alternatives are not provided onsite.

Other forms of buprenorphine

- » Probuphine (buprenorphine implants) last about 6 months and are for clients who are stabilized on sublingual or buccal formulations. To provide implants, providers must receive specific training from the manufacturer on insertion and removal per the [*FDA-Approved Risk Evaluation and Mitigation Strategies \(REMS\)*](#).
- » Sublocade is a monthly extended-release buprenorphine subcutaneous injectable formulation for clients with moderate-to-severe opioid use disorder who have been initiated and treated with transmucosal buprenorphine for at least 7 days. Only health care settings with special certification per the [*FDA-approved REMS*](#) can order and dispense Sublocade.

Extended-release naltrexone (XR-NTX)

- » This is an opioid antagonist administered as a 30-day intramuscular injection. It works best for clients who have abstained from short-acting opioids for at least 7-10 days and long-acting opioids for at least 10-14 days. No waiver is required to prescribe.

Methadone

- » Only federally certified, accredited opioid treatment programs can dispense methadone to treat opioid use disorders; some clients are better served with this higher level of care and closer oversight.



E2i EVALUATION: CHALLENGES, SUCCESSES, ADAPTATIONS, AND LESSONS LEARNED

The E2i sites that implemented buprenorphine treatment encountered barriers and facilitators to achieving their integrated implementation goals. They also made changes to the original intervention to meet the specific needs of their clients and staff members. Here is a summary of adaptations and lessons learned. Additional information about the sites' experiences can be found in the Program Spotlights below.

- ◆ **Addressing recruitment challenges.** Both the office-based and mobile unit programs had lower than expected numbers of clients enroll in buprenorphine treatment. The reasons for low enrollment are not entirely clear. It is possible that clients preferred to receive methadone treatment, which was widely available in the same areas as the buprenorphine treatment. Site staff also noted that enrollment may have been negatively affected by clients with HIV moving away from their areas. In addition, stigma associated with OUD may have prevented people from accessing treatment. To address recruitment challenges, the E2i sites suggest that clients receive counseling on the pros and cons of methadone versus buprenorphine. Organizations can also consider pairing recruitment for buprenorphine with other outreach programs, such as community-based rapid HIV testing programs. Outreach workers from these programs can refer clients to the clinic for either pre-exposure prophylaxis (PrEP) to prevent HIV, or ART for HIV, depending on testing results. Once at the clinic, clients can be screened for OUD and referred to buprenorphine treatment as appropriate.
- ◆ **Adherence support needs.** To improve adherence to buprenorphine treatment, the office-based E2i site recommends scheduling weekly appointments for clients to meet with case managers and psychologists who help monitor and reinforce positive health behaviors.
- ◆ **Integrating mental health care.** A large percentage of clients with HIV and OUD at the E2i sites presented with a psychiatric disorder that could have impeded engagement with buprenorphine treatment. To address this widespread issue, E2i sites integrated individual psychological counseling into their buprenorphine programs and provided referrals to psychiatric treatment as needed.



E2i EVALUATION: CHALLENGES, SUCCESSES, ADAPTATIONS, AND LESSONS LEARNED

- ◆ **Insurance coverage for medication.** The E2i sites caution that clients who receive Medicaid need to pay close attention to medication coverage expiration dates. To prevent gaps in coverage, one E2i site created a log of expiration dates so they can alert clients a month in advance of expiration and help them renew their coverage. The site also found they needed to advocate for coverage with some carriers and offer a sliding scale for those who did not have coverage. They recommend looking for alternative funds to cover the medication payment in case it is not covered by insurance.
- ◆ **Reducing transportation and scheduling barriers.** Clients with inflexible schedules, lack of transportation, or who live at great distances from the clinic, often have difficulty attending appointments. To solve this issue, E2i sites used funds from Ryan White Part C to provide clients with transportation for appointments, offer early and late clinic hours, and offer home inductions, home orientations, home follow-up services, and home delivery of medications.
- ◆ **Accessing induction medications.** Getting induction medications in a timely manner to clients can be complicated (buprenorphine cannot be stored in the clinic). The E2i sites reduced barriers by having an onsite pharmacy technician and using a courier service to bring buprenorphine from the pharmacy. Home-based induction also overcomes this issue.
- ◆ **Keeping up to date with clients' changing phone numbers.** Because clients often change their phone numbers, one E2i site implemented a protocol to ask clients for their phone numbers at every visit, and to update the client database accordingly.



PROGRAM SPOTLIGHTS

PROGRAM SPOTLIGHT

Med Centro, Inc.



Organizational Background

Med Centro, Inc. (formerly Consejo de Salud de Puerto Rico) is a federally qualified health center located in Ponce, Puerto Rico, that serves more than 57,000 clients. For over 47 years, Med Centro has delivered comprehensive primary health care and supportive services to clients residing in the southern region of Puerto Rico. As a recipient of RWHAP Part C funding, Med Centro uses a team-based, multi-disciplinary approach to providing primary care, case management, nutrition, mental health care, infectious disease care, dental services, and outreach services for clients with HIV.

Implementation Goals and Context

Med Centro integrated office-based buprenorphine treatment into its existing HIV services with the twin goals of addressing OUD and helping clients engage in HIV care and treatment. The buprenorphine treatment program's core staff consists of a case manager in charge of client outreach, enrollment, and retention; a project manager who oversees administrative duties and hiring; a psychologist who assesses for OUD and other behavioral health problems; and a physician responsible for prescribing buprenorphine, managing induction and treatment, and recordkeeping. The buprenorphine team coordinates care with each client's primary care provider.

"As a professional, I am grateful to see the evolution and progress of our clients as they stabilize from opioid addiction and increase adherence to their HIV treatment." —Med Centro buprenorphine provider

Recruitment and Delivery

To identify existing Med Centro clients eligible for buprenorphine treatment, the team receives referrals from case managers and other clinical providers. All members of the HIV care team are located within the same physical location as the buprenorphine program, so referrals occur seamlessly. In addition, Med Centro developed agreements with local agencies that provide supportive services (e.g., housing) for bi-directional referrals, promotes the program on social media, and conducts outreach through Med Centro's community HIV rapid testing program.

Buprenorphine induction occurs at the clinic over a three-day period (home inductions are not allowable under Puerto Rican regulations). To ease the prescribing process, Med Centro collaborates with their onsite pharmacy to fill buprenorphine prescriptions during a client's induction appointment. Initially, clients had to wait 24-48 hours before starting induction because of prior authorization requirements under health insurance plans. During the COVID-19 pandemic in 2020, however, authorization requirements to prescribe buprenorphine became more flexible, reducing wait times and further easing prescribing practices. After induction, clients come weekly for stabilization and then every two to four weeks for maintenance.

Program Integration

Med Centro has effectively integrated the buprenorphine treatment program within their HIV primary care, behavioral health, and pharmacy departments. Over the course of the implementation process, all Med Centro staff have enthusiastically embraced the program and actively collaborated in providing wrap-around services. For continuation of the program after E2i funding ends, Med Centro has identified resources to cover costs not reimbursable by Medicaid.

Innovations, Adaptations, and Lessons Learned

- » **Partnership with detoxification program:** Southern Puerto Rico has a shortage of detoxification programs. To support clients who need help with detoxification, the Med Centro team established Memoranda of Understanding with treatment centers located on the north side of Puerto Rico.
- » **Therapy options:** Midway through implementation, Med Centro observed a need for buprenorphine clients to receive additional therapeutic and social support through group or individual therapy. The team coordinated with the site psychiatrist to try to make these options available to clients.



- » **Pharmacy technician:** Having a pharmacy technician inside the clinic provided greater agility in prescription processing and reduced client wait time.
- » **Co-management of treatment for mental health disorders:** Many clients with opioid dependence may also use benzodiazepines to manage anxiety. When benzodiazepines are combined with buprenorphine, they can have serious side effects if not managed correctly. Since Med Centro did not previously have protocols for co-prescribing these drugs, the prescribers worked with the clinic psychiatrist to develop a protocol to guide the management of buprenorphine clients also taking benzodiazepines.
- » **Developing empathy:** Med Centro staff have learned to build greater empathy for their clients, and to accept, without judgment, that some clients may not accept treatment, or may relapse while in treatment. The staff have changed their attitudes about OUD, and now understand substance use disorder as an illness.
- » **Building engagement, trust, and confidence:** Med Centro staff have found that treatment success depends on building trust and rapport with clients.
- » **Earthquakes and COVID-19:** In early 2020, Puerto Rico's southern coast was struck by several earthquakes that seriously damaged the region's infrastructure. Two months later, the COVID-19 pandemic created additional barriers to in-person access to care. In response to these challenges, the Med Centro team demonstrated flexibility, resilience, and commitment to their clients by adapting to telehealth care, providing further service coordination by telephone, and offering home visits and delivery of medications. Additionally, Med Centro continued to stay open and staffed for in-person visits throughout these crises. In light of COVID-19, Med Centro currently conducts client evaluations and medical follow-up via telephone call. In addition, the case manager follows up with clients via telephone to support adherence to buprenorphine and HIV treatment, identify patient needs, and provide support.
- » **Transportation:** A lack of transportation for clients who live in rural settings or have been affected by the earthquakes has been a critical barrier to care. Med Centro was able to leverage other funding streams to provide clients with transportation to the clinic and pharmacy.

Contact Information

Med Centro

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787.843.9393 Ext. 1056, 1058 • www.medcentro.org

A green spotlight icon at the top center of the page, casting a white beam of light downwards onto the 'PROGRAM SPOTLIGHT' text.

PROGRAM SPOTLIGHT

Greater Lawrence Family Health Center



Organizational Background

Greater Lawrence Family Health Center (GLFHC) provides comprehensive health care services that respond to the needs of a culturally diverse population, including people with HIV, across the Merrimack Valley in Massachusetts. GLFHC is a recipient of RWHAP Part C funding and a subrecipient of RWHAP Part A funding. In addition to its multiple locations, GLFHC has a mobile health unit (a truck-pulled trailer) for providing primary clinical care and supportive services to populations experiencing homelessness and other people who experience barriers to accessing office-based health care. GLFHC has offered medication supported recovery for OUD in a coordinated care setting for over a decade. In 2017, they began offering buprenorphine treatment for OUD as part of their mobile health unit services.

Implementation Goals and Context

After recognizing a dramatic rise in new HIV diagnoses among people who inject drugs and people experiencing homelessness, GLFHC applied for E2i funding to expand access to OUD treatment for people with HIV through their mobile unit. Their goals for the mobile unit buprenorphine program were to reduce opioid-related deaths and complications, and to improve continuity of HIV care for people with HIV and OUD.



Recruitment and Delivery

GLFHC uses a multi-disciplinary team-based approach to care that includes physicians, nurses, case managers, and community health workers. Due to its existing and robust office-based buprenorphine program, GLFHC did not need to hire new staff for the mobile unit.

Client recruitment for the program occurs at homeless shelters and through word-of-mouth, the syringe service program, and referrals from case managers and hospital emergency departments. GLFHC also implemented weekly huddles with multi-disciplinary team members to review charts for potentially eligible clients.

As a low-barrier entry to care model, the mobile unit program does not require clients to make appointments. When GLFHC first started the program, clients would come to the unit to be observed by a nurse while taking their induction dose. The provider would call the pharmacy to deliver the induction dose by courier, since buprenorphine cannot be stored on the mobile health unit. Later, GLFHC found that most clients could safely take their induction doses at their home or place of living. Clients need only return to the unit for stabilization and maintenance visits. Mobile unit staff maintain relationships with local methadone and detoxification facilities and refer clients to these organizations to meet individual client needs.

Program Integration

Because GLFHC already had an existing office-based buprenorphine program and a mobile unit for primary care services, integration of buprenorphine treatment into the mobile unit was seamless. Moreover, leadership and team members recognized the benefits to clients of further removing barriers to care and reducing harm.

After E2i funding ends, the program will continue with some changes in staffing time and effort. Fortunately, buprenorphine treatment is mostly sustainable through billing third-party insurance. The team has also secured other funding sources, including private, state, and federal funds to support the critical staff roles.

“This program is an unbelievable benefit for clients. It removes the barrier of a brick-and-mortar site, with no appointments or wait times, and allows us to provide low-barrier and client-centered care” —GLFHC mobile unit staff member



Innovations, Adaptations, and Lessons Learned

- » **Expansion of services:** Over time, GLFHC expanded its services by increasing the number of days they provide mobile buprenorphine services, bringing the mobile unit to an additional town in the region one day per week, and incorporating Hepatitis C treatment.
- » **COVID-19 pandemic:** During the COVID-19 pandemic, the mobile unit transitioned the bulk of its services to a telehealth platform but offered access to the unit five days a week for clients who did not have phones. Staff erected tents outside the mobile unit and used protective gear and safety precautions to minimize transmission risk of coronavirus. Despite multiple efforts by staff, maintaining contact with clients was very difficult.
- » **Home induction:** According to GLFHC staff, allowing clients to induce at home incorporates a harm-reduction and client-centered approach by acknowledging that clients are the best judge of their personal limitations and experience. Clients can also avoid challenges associated with coming into the unit during withdrawal for induction.
- » **Challenges with enrollment:** Enrollment in the program was negatively affected by clients moving away, by potential stigma associated with OUD and HIV, and by a shift in the drug supply chain from heroin to fentanyl. GLFHC found that for many clients who used fentanyl, as opposed to heroin, methadone was a preferred treatment option.
- » **Challenges with retention:** Clients with HIV and OUD experience complex barriers to staying in care. COVID-19 further complicated retention in care. Nonetheless, GLFHC makes multiple efforts to contact clients and has worked to create a client-focused environment where clients can readily re-access services whenever they are ready.
- » **Community impact:** By creating a low-barrier, on-demand, visible buprenorphine program, GLFHC was able to shift the perspective on treatment of substance use disorders among the greater clinical community. For example, emergency room doctors in the area have become more willing to provide buprenorphine to those who need it, and the nearby methadone clinic has started taking more of a harm-reduction approach.
- » **Increase in continuity of care:** The mobile unit was able to bring HIV care more directly into the community. For some clients, a fixed clinical site might not be the 'right fit'. Because GLFHC provides HIV primary care through its mobile unit, it can increase continuity of care for these clients.

Contact Information

Greater Lawrence Family Health Center (GLFHC)
100 Water St. Lawrence, MA
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APPENDICES

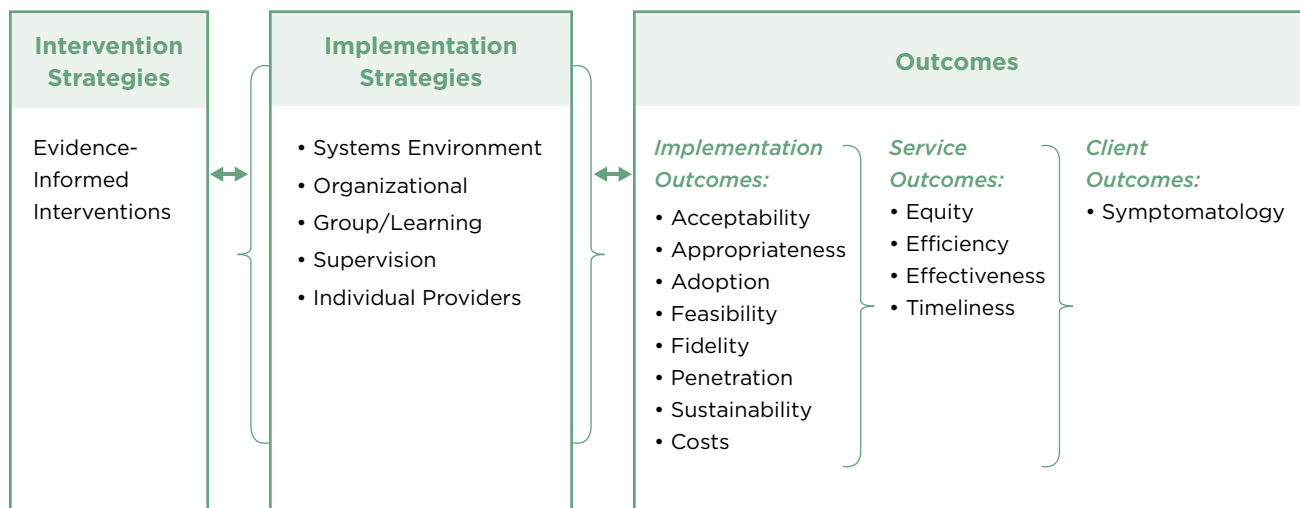


APPENDIX A. IMPLEMENTATION SCIENCE AND EVALUATION: FRAMEWORK AND METHODS

The Center for AIDS Prevention Studies (CAPS) at the University of California San Francisco conducted the evaluation of the E2i program implementation. The evaluation used the Proctor Model Framework for Implementation Research.¹⁸ This approach suggests that program assessment should include an understanding of the process of implementation and its impact on all people and systems that are involved in the implementation:

1. The core elements of the program (intervention strategies).
2. The efforts to put the program into place (implementation strategies).
3. How the program is viewed by the people involved (implementation outcomes).
4. How the program is delivered (service outcomes).
5. The impact on the participants (client outcomes).

The E2i Proctor Model



¹⁸ Proctor E, Silmere H, Raghavan R, et al. Outcomes for implementation research: Conceptual distinctions, measurement challenges, and research agenda. *Adm Policy Ment Health*. 2011;38(2):65-76.

Six types of information were gathered over the three years of E2i program implementation. These include:

Organizational Assessment: Every six months the program director completed a survey. This survey had questions about the organization (e.g., number of patients, types services provided, and staffing). It also included questions about program delivery and how the staff views the program.

Proctor Concepts

- » Implementation strategies (systems environment, organizational, group/learning, supervision)
- » Implementation outcomes (acceptability, appropriateness, adoption, feasibility, fidelity, penetration, sustainability, costs)

Document Review: Evaluators reviewed documents that were created during implementation and technical assistance activities. Documents were created by either the sites themselves or by The Fenway Institute/AIDS United and included: E2i funding applications, site visit reports, quarterly reports, monitoring call notes, cohort call notes, and presentations in meetings.

Proctor Concepts

- » Implementation Strategies (systems environment, organizational, group/learning, supervision, individual providers, individual patients)
- » Implementation Outcomes (acceptability, appropriateness, adoption, feasibility, fidelity, penetration, sustainability)

Observations: Sites participated in two Learning Session Meetings each year. Evaluators took notes on discussions and presentations. These notes focused on barriers and facilitators to implementation.

Proctor Concepts

- » Implementation Strategies (systems environment, organizational, group/learning, supervision, individual providers, individual patients)

Costing Data: Program managers and financial administrative staff completed two cost workbooks. One was for the three-month preparation/planning period and the first year of program implementation. The other was for the second year of program implementation. Costs included personnel and expenses paid for by E2i as well as in-kind donations.

Proctor Concepts

- » Implementation Outcomes (costs)

Intervention Exposure: Information was collected on clients who participated in the intervention between September 2018 and December 2020. Demographic information was collected on enrollment forms. Intervention exposure forms were collected whenever staff had program-related interactions with participants. These forms included information such as: date of the interaction, the staff person who had contact, type of interaction, activities completed, and outcomes of the activities.

Proctor Concepts

- » Service Outcomes (fidelity, penetration, equity, efficiency, effectiveness, timeliness)

Medical Records: Medical records were collected on participants for the 12 months before enrollment in the program and for the 12 months after enrollment in the program. The information was specific to HIV-related medical care, such as: appointment dates; prescription of ART; viral load test dates; and viral load test results.

Proctor Concepts

- » Client Outcomes (symptomatology)

Quantitative Analysis: Organizational assessment data was used to describe organization characteristics and readiness for implementation based on Proctor Concepts. Client level enrollment and intervention exposure data was analyzed using descriptive statistics to understand client demographics, proportions of clients receiving intervention services, and frequencies of exposures. When appropriate, proportion of clients completing the intervention was included. Repeated measures modeling methods were used to assess changes in HIV Care Continuum outcomes for clients enrolled in the intervention. This compared data from 12 months prior to enrollment to 12 months following enrollment. Costing data was analyzed to provide information on cost of intervention implementation per client enrolled.

Qualitative Analysis: Documents and observations were thematically analyzed using the Proctor Concepts. The intervention was the primary unit of analysis.



APPENDIX B. GENERAL BEST PRACTICES FOR PLANNING TO IMPLEMENT AN INTERVENTION STRATEGY

The following are general recommendations for planning to implement an intervention strategy in an HIV service organization.

Create a Planning Team

- » Assemble a team of staff “champions” who are invested in the success of the intervention: who will meet regularly to drive planning, implementation, and sustainability; and who will remain committed to overcoming hurdles and moving implementation forward.
- » Consider how to meaningfully involve at least one peer (a person with HIV who also represents the priority population) in the planning and implementation of the intervention (see [*AIDS United’s resources on meaningful involvement of people with HIV*](#)).
- » Hold weekly team meetings or daily “huddles” (i.e., short meetings at the beginning of the day to review client status and discuss recruitment and retention issues, etc.).

Engage Leadership and Staff

Implementing a new service into an established program may require changes in routines, job duties, and administrative procedures. It is essential to obtain buy-in and a firm commitment from the entire organization as early in the planning process as possible.

Meet with executive leadership to discuss:

- » How the intervention will support the organization’s mission and goals
- » The benefits of the intervention for clients and the organization as a whole
- » The resources needed to implement the intervention
- » The organizational systems and procedures that will be affected by implementation
- » The importance of leadership communicating their commitment to the intervention to all staff
- » How the intervention team will regularly share the status of the intervention with regard to planning, implementation, enrollment, and client outcomes



Meet with staff members directly and indirectly affected by the intervention to discuss:

- » The benefits of the intervention for clients and the organization as a whole
- » How staff can help with recruitment and referrals
- » Suggestions for outreach and implementation processes
- » How the intervention team will regularly share the status of the intervention with regard to planning, implementation, enrollment, and client outcomes

Assess Community Needs

Early in the planning process, organizations should consider conducting an informal or formal needs assessment to better understand the needs of the priority population(s) and how to best tailor the intervention to their needs. Engaging with the local community also helps to establish trust and grow your referral networks.

Community needs assessment strategies include:

- » Review existing client data on OUD among clients with HIV.
 - What does the data tell you about the needs of your client population?
- » Discuss the intervention with community members, providers, clients, and service agencies through informal or formal interviews or focus groups. Ask for their input on the intervention:
 - What might be barriers to implementation? What can be done to overcome these barriers?
 - What can the organization do to reduce stigma related to substance use disorders and HIV?
 - What community agencies would be a good fit for referrals?

Train All Staff

When implementing an intervention for people with HIV, it is important to train all organizational staff in reducing stigma, enhancing cultural humility, using a trauma-informed approach to care, and providing affirming, culturally-responsive care to all people with HIV, including Black, Indigenous, and other people of color, and including lesbian, gay, bisexual, queer, transgender, and gender diverse people. Training and resources are available from [*TargetHIV*](#), [*AIDS Education and Training Center Program*](#), and the [*National LGBTQIA+ Health Education Center*](#).

Conduct a Pilot Test

Prior to full implementation, it can sometimes help to conduct a pilot test under “real world” conditions to evaluate the feasibility and acceptability of the process flow, forms, and procedures.

- » Consider pilot testing with one provider’s client panel or with only new clients.
- » Use a [*validated quality improvement method*](#) to guide your pilot test.
- » After the pilot, communicate to all staff the results of the pilot: what worked, what did not work, and what changes were made to improve operations.



APPENDIX C. INTEGRATED BUPRENORPHINE TREATMENT “GO LIVE” WORKSHEET

Purpose

The purpose of the “Go Live” Worksheet is to:

1. Guide organizations in carrying out the intervention’s planning steps and activities
2. Monitor progress in meeting implementation goals
3. Serve as a tool for supervisors to provide feedback on intervention delivery

Instructions

The team that is leading the intervention should identify a team member to complete this worksheet over time. Use the worksheet to:

- » Develop and drive team meeting agendas
- » Document decisions made by the team
- » Track progress towards goals

Name of organization	
Name (Who is completing this worksheet?)	
Intervention goals	• To reduce opioid use and overdose among people with HIV while improving client engagement in HIV and behavioral health care • To provide low barrier access to medications that treat OUD
Core elements	1. Address the intersection of the HIV and opioid epidemics 2. Provide buprenorphine treatment 3. Adjust organizational systems
Eligible population	People with HIV and opioid use disorder
Planning and Implementation Activities	
Planning team (Who is on the planning team?)	1.
	2.
	3.
	4.
	5.
Priority population(s) to promote equitable access to treatment (How will you identify communities in need? Who will you engage?)	1.
	2.
	3.
	4.
Geographic catchment area(s) (From which communities will you recruit clients?)	1.
	2.
	3.

Language(s) (In what languages will you deliver the intervention?)	1.
	2.
Engaging staff (What strategies will you use to gain “buy-in” and feedback?)	1. Organizational Leadership
	2. Relevant Staff
Engaging community members and partners (What strategies will you use to gain “buy-in” and feedback?)	3. Community agencies
	4. Clients
Recruitment, in-reach, and outreach (What will be your recruitment and referral strategies?)	1.
	2.
	3.
	4.
	5.
Incentives (What non-cash incentives and vouchers, if any, will you give clients?)	

Intervention staff (Who will do what?)	Role/Task	Staff Responsible
	Clinical coordinator	
	Prescribing provider(s)	
	Behavioral health provider(s)	
	Outreach and recruitment	
	Enrollment	
	Data coordination	
	Substance use counseling	
	Billing codes/insurance help	
	Mobile van driver(s)	
	Others:	
Training (check if/when completed)	☐ Prescribing providers: prescription waiver training (required) ☐ Prescribing providers: meetings with clinical mentor ☐ Clinical coordinator: screening and management of substance use disorders (SUDs) ☐ All clinical staff: basic features of SUDs, medication supported recovery, and managing urine toxicology screening ☐ All staff: cultural humility ☐ All staff: trauma-informed care	
Space and equipment for Office-Based	☐ Where will inductions occur? ☐ Homes ☐ Exam room (which ones?) ☐ Do you have: ☐ Drug screening kits ☐ Software for securing client logs and records	

Space and equipment for Mobile units	Does your unit have: ☐ Exam room ☐ Treatment room ☐ Lab station ☐ Bathroom ☐ Furniture ☐ Point-of-care urine drug screens ☐ Emergency drug kits ☐ Wi-Fi ☐ Laptops ☐ Software for securing client logs and records
Partnerships (Who will you establish relationships and referral protocols with?)	☐ Pharmacy:
	☐ Laboratory:
	☐ Mental health:
	☐ SUD treatment:
	☐ Other:
	☐ Other:
Billing	☐ Billing and coding point person:
	☐ Client assistance programs:
Workflow (Describe the process for a client to go from recruitment, induction, stabilizations, to maintenance. Consider who, what, when, and where.)	
Assessment tools (What screening tools will you use for drug use, mental health, and substance use?)	1.
	2.
	3.
	4.
	5.

Implementation tools (What tools will you develop for enrollment, referral, tracking, client feedback, etc.?)	1.
	2.
	3.
	4.
	5.
Protocols and guidelines	Does your team have protocols for: ☐ Obtaining prescriptions from the pharmacy ☐ Record keeping ☐ Referrals to counseling, support groups, and psychiatric treatment ☐ Safety and boundaries ☐ Natural disasters and emergencies ☐ Team communication ☐ Addressing destabilization ☐ Addressing diversion ☐ Transitioning to primary care ☐ Terminating treatment ☐ Referring to alternative treatment ☐ Other:
Anticipated barriers (What barriers might you encounter for hiring, recruitment, and engagement? How can you minimize barriers?)	
Sustainability (What can you do to make your program sustainable?)	



SMART goals (What are your S pecific, M easurable, A chievable, R elevant, T ime-Bound goals?)	1.
	2.
	3.
	4.
	5.



APPENDIX D. ASSESSMENT, ELIGIBILITY, AND PREPARATION FOR TREATMENT CHECKLIST

Date(s): _____ Staff: _____ Client ID: _____

Instructions

- » Use this checklist to guide screening, enrollment, and induction of each client.
- » Supervisors can also use the checklist to monitor fidelity to the intervention and to provide feedback to staff on their performance.

Activities

Please leave a checkmark (✓) beside activities that are completed.

Assessment

- ☐ Assess for opioid use disorder and severity
- ☐ Screen for other substance use disorders; refer to services
- ☐ Assess for co-occurring medical and psychiatric conditions; refer to services
- ☐ Assess for social and basic needs; refer to services
- ☐ Conduct or review HIV laboratory tests
- ☐ Conduct or review tests for hepatitis, syphilis, lipid profile, serum electrolytes, blood urea nitrogen and creatinine, complete blood count with differential and platelet count, and tuberculosis
- ☐ Conduct or review urine drug screening

Eligibility

- ☐ Determine eligibility for buprenorphine treatment
- ☐ If not eligible, refer to alternative treatment (if applicable)

Prepare for Treatment

- ☐ Discuss client's treatment goals
- ☐ Provide education on buprenorphine treatment and overdose prevention and response
- ☐ Discuss clinic-based vs. home-based induction (if applicable)
- ☐ Conduct or review urine drug screening
- ☐ Review buprenorphine treatment agreement
- ☐ Assess for baseline withdrawal symptoms and cravings (using COWS)
- ☐ Dispense kick-pack and prescribe naloxone rescue kit (optional)
- ☐ Provide buprenorphine prescription

Treatment Support

- ☐ Discuss recovery environment
- ☐ Provide access to behavioral health counseling



APPENDIX E. DSM-5 CRITERIA FOR OPIOID USE DISORDER: WORKSHEET

Worksheet for DSM-5 criteria for diagnosis of opioid use disorder			
Diagnostic Criteria	Meets Criteria		Notes/Supporting Information
(Diagnosis requires at least 2 criteria within 12 months)	Yes	No	
1. Opioids are often taken in larger amounts or over a longer period of time than intended.			
2. There is a persistent desire or unsuccessful efforts to cut down or control opioid use.			
3. A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.			
4. Craving, or a strong desire to use opioids.			
5. Recurrent opioid use resulting in failure to fulfill major role obligations at work, school or home.			
6. Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.			
7. Important social, occupational or recreational activities are given up or reduced because of opioid use.			
8. Recurrent opioid use in situations in which it is physically hazardous.			
9. *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			
10. *Withdrawal, as manifested by either of the following: a. the characteristic opioid withdrawal syndrome b. the same (or closely related) substance is taken to relieve or avoid withdrawal symptoms			

**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 _____

Adapted from: Substance Abuse and Mental Health Services Administration. Medications for Opioid Use Disorder. Treatment Improvement Protocol (TIP) Series 63. Publication No. PEP20-02-01-006. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2020.

Content from: American Psychiatric Association. Diagnostic and statistical manual of mental disorders (5th ed., p. 541). Arlington, VA: American Psychiatric Publishing; 2013



APPENDIX F. SAMPLE ELIGIBILITY CRITERIA CHECKLIST FOR INTEGRATED BUPRENORPHINE TREATMENT

Inclusion criteria *(clients must meet ALL requirements to be eligible)*

- ☐ Confirmed HIV diagnosis
- ☐ Meets DSM-5 criteria for opioid use disorder
- ☐ Desires treatment
- ☐ Currently receives HIV primary care, or is willing to start primary care
- ☐ Age ≥18 years or emancipated minor able to consent for medical and substance use disorder treatment
- ☐ Able to comply with buprenorphine treatment program policies

Consideration for exclusion

(clients meeting ANY of these criteria MAY be considered ineligible)

- ☐ Severe hepatic dysfunction, i.e., AST and/or ALT ≥ 5x upper limit of normal
- ☐ Active suicidal ideation
- ☐ Psychiatric impairment that impedes ability to provide informed consent to make decision regarding own care (e.g., dementia, delusions, active psychosis)
- ☐ Methadone or opioid analgesic doses exceeding levels for safe transition to buprenorphine (methadone >30-60mg)
- ☐ Acute or chronic pain syndrome requiring chronic use of opioid analgesics
- ☐ Serious/uncontrolled/untreated medical problems (e.g., hypertension, hepatic failure, asthma, diabetes, etc.) or psychiatric disorders
- ☐ Requirement of a higher level of care than can be offered in the clinic (e.g., methadone maintenance or mental illness chemical addiction program)
- ☐ Has a known allergy/hypersensitivity to buprenorphine or naloxone

Regarding pregnant clients: Clinical guidelines for use of buprenorphine/naloxone during pregnancy are evolving. To stay up to date with recommendations, visit the [Substance Abuse and Mental Health Services Administration \(SAMHSA\) website](#).

Clients who are ineligible to begin treatment may be offered or referred to services to address certain issues (e.g., mental health treatment) and reassessed at a later date.



APPENDIX G.

SAMPLE BUPRENORPHINE TREATMENT AGREEMENT

Part 1: My Medicine

You and your treatment team have decided that buprenorphine may be a helpful medication for you. The best provider-client relationship comes from a place of mutual respect, honesty, and open communication.

When will you take your medicine? Write the medicine in the left column. Place a check mark under the meal or time of day that you will take the medicine.

Medicine	Breakfast	Lunch	Dinner	Bedtime

Part 2: Goals of Treatment

Buprenorphine is a medication which has proven to make life better for many people. Please note, everyone's experience with buprenorphine is different. For some, their cravings may not completely go away and for others, buprenorphine may not work.

My treatment journey goals include:

1.
2.
3.
4.
5.



Part 3: Things I Agree to Do

I will:

- » Only get buprenorphine from my provider
- » To ensure my safety, I will inform my medical team and any outside specialists about all medicines that I am taking, both prescription and over-the-counter
- » Tell my provider about all of my health problems
- » Only get refills during my provider appointment (refill requests may not be honored)
- » Tell my provider if I get pain medicine from another provider 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 medicines in their original pharmacy bottles to my provider visits if my provider asks me to. My provider may count the number of pills left in my bottle(s)
- » To ensure my safety and that I am taking my medication, I understand I need a urine drug screening. The medical team uses urine drug screens to support honest communication. If I am unable to provide a urine sample, it could prevent my prescriber from giving me my medication. Urine drug screenings are required by the federal government.
- » Try all treatments that my provider suggests, including social work and mental health referrals if necessary

I will NOT:

- » Use someone else's medicine or give my medicine to someone else
- » Change how I take my medicine(s) without asking my provider
- » Ask my provider for extra/early refills if I use up my supply before my next appointment
- » Ask my provider for extra refills if my medicine or prescription is lost or stolen.

My provider will:

- » Work with me to support me in my recovery process
- » Refer me for additional help when needed



Part 4: I Understand

I understand that:

- » Buprenorphine is a controlled narcotic medication that may result in withdrawal symptoms when stopped immediately.
- » If I combine buprenorphine with the illicit use of drugs and/or alcohol 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 provider will stop my buprenorphine treatment.

- » If I am unable to honor this agreement, my provider may stop these medicines. In this case, the dose of buprenorphine may be tapered before stopping completely.
- » If I do not follow this agreement, or if my provider thinks that my medicine is hurting me more than it is helping me, my provider:
 - Will continue to be my primary care provider 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 below-named provider and/or any appropriately authorized assistants they 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 people 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 people, 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.



To the best of my knowledge (select one option):

- ☐ 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 their assistants immediately.

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): _____

Provider name: _____

Provider signature: _____

Date: _____

Adapted from: HIV/AIDS Bureau, Special Projects of National Significance Program. Dissemination of Evidence-Informed Interventions: Integrating Buprenorphine Treatment for Opioid Use Disorder in HIV Primary Care. Rockville, MD: U.S. Department of Health and Human Services, Health Resources and Services Administration; 2020.



APPENDIX H. SAMPLE HOME INDUCTION PROTOCOL

What to Start With?

- » 4 buprenorphine (bupe) pills or films (8 mg)
(There are many different brand names and generic forms of bupe.)
- 6 Ibuprofen pills (200 mg) - for body pain, take 1-2 pills every 8 hours as needed
- 6 Clonidine pills (0.1 mg) - for anxiety, take 1 pill every 8 hours as needed
- 6 Imodium pills (2.0 mg) - for diarrhea, take 1 pill after each episode of diarrhea.
Max 6 pills per day

When Am I Ready to Start Bupe?

- » Use the list of symptoms on the right to see when you are ready to start bupe.
- » Wait until you have at least 5 symptoms to start bupe. If you don't have 5 symptoms, wait a bit longer and review the symptoms again. It is very important that you wait until you feel at least 5 symptoms before starting bupe!

Symptoms	Do I have this?
I feel like yawning	Yes
My nose is running	Yes
I have goosebumps	Yes
My muscles twitch	Yes
My bones & muscles ache	Yes
I have hot flashes	Yes
I'm sweating	Yes
I feel unable to sit still	Yes
I am shaking	Yes
I feel nauseous	Yes
I feel like vomiting	Yes
I have cramps in my stomach	Yes
I feel like using	Yes

Things *Not to Do* With Bupe

- » DON'T use bupe when you are high – it will make you dope sick!
- » DON'T use bupe with alcohol – this combination is not safe.
- » DON'T use bupe with benzos unless prescribed by a doctor who knows you are taking bupe.
- » DON'T use bupe if you are taking pain killers until you talk to your doctor.
- » DON'T use bupe if you are taking more than 60 mg of methadone.
- » DON'T swallow bupe – it gets into your body by melting under your tongue.
- » DON'T lose your bupe – it can't be refilled early.

How to Take Bupe?

- » Before taking bupe, drink some water.
- » Put bupe under your tongue.
- » Don't eat or drink anything until the bupe has dissolved completely.

Plan

- » Use your last heroin/methadone/pain pill at date:_____ time:_____
- » When you have at least 5 symptoms from the list, then you are ready to start.
- » Start with _____ pill or _____ film under your tongue.
- » Wait _____ minutes.
- » If you feel the same or just a little better, then take another pill or film.
- » Wait 2 hours—if you still feel sick or uncomfortable, take another pill or film.

Problems? Questions?

- » Call _____ at (____)_____.
- » Call _____ if you still feel sick after taking a total of ____pills or films (_____mg).

Next Steps

- » Appointment with _____ at _____.
- » Appointment with Dr. _____ at _____.

What I Took

	TIME	Amount of Pills or Films
Day 1	__:__ am/pm	
	__:__ am/pm	
	__:__ am/pm	
	__:__ am/pm	
Day 2	__:__ am/pm	
	__:__ am/pm	
	__:__ am/pm	
	__:__ am/pm	
Day 3	__:__ am/pm	
	__:__ am/pm	
	__:__ am/pm	
	__:__ am/pm	



APPENDIX I. ADDITIONAL RESOURCES

American Society of Addiction Medicine

Resources, training, and education on addiction medicine

www.asam.org

Harm Reduction Coalition

Training and resources focused on harm reduction policies and practices

harmreduction.org

National Alliance of Advocates for Buprenorphine

Educates the public about opioid addiction and buprenorphine treatment options and connects clients in need of treatment with qualified treatment providers

www.naabt.org

Providers Clinical Support System (PCSS)

Training for primary care providers in the prevention and treatment of opioid use disorder

pcssnow.org

Primary Care Guidance for Persons with Human Immunodeficiency Virus: 2020 Update by the HIV Medicine Association of the Infectious Diseases Society of America

Practice guidelines for providing primary care for people with HIV

www.idsociety.org/practice-guideline/primary-care-management-of-people-with-hiv