

Integrating Buprenorphine Therapy Into HIV Primary Care Settings

April 2012



U.S. Department of Health and Human Services
Health Resources and Services Administration
HIV/AIDS Bureau
Special Projects of National Significance Program



INTEGRATING BUPRENORPHINE THERAPY INTO HIV PRIMARY CARE SETTINGS

U.S. Department of Health and Human Services
Health Resources and Services Administration
HIV/AIDS Bureau
Special Projects of National Significance Program

April 2012

Integrating Buprenorphine Therapy Into HIV Primary Care Settings is not copyrighted. Readers are free to duplicate and use all or part of the information contained in this publication; however, the artwork is copyrighted by ImageZoo Illustration/Veer, and permission may be required to reproduce it. Citation of the source is appreciated. The document is available online at www.hab.hrsa.gov.

Suggested citation: 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.

CONTENTS

Introduction	1
Chapter 1	
Report From: University of California, San Francisco, Beehive Program	9
Chapter 1 Resources	30
Chapter 2	
Report From: CORE Buprenorphine Project	31
Chapter 2 Resources	44
Chapter 3	
Report From: Portland Integrates Care for Opioid-Dependent HIV/AIDS Patients Demonstration Model	45
Chapter 3 Resources	53
Chapter 4	
Report From: Miriam Hospital Buprenorphine Program	54
Chapter 4 Resources	64
Additional Resources	65
Grantee Involvement	66



INTRODUCTION

Since the beginning of the HIV/AIDS epidemic, 36 percent of all AIDS cases in the United States have been directly or indirectly linked to injection drug use (IDU).¹ Use of prescription and illicit opioids (natural, semisynthetic or synthetic drugs that bind to and activate opioid receptors) is prevalent among both injection drug users and users of noninjection drugs. Diacetylmorphine (heroin), hydromorphone (Dilaudid), hydrocodone (Vicodin), oxycodone (Percocet), morphine, oxycodone (OxyContin), methadone, and buprenorphine all are opioids. In 2010, the Substance Abuse and Mental Health Services Administration (SAMHSA) reported that more than 2 million opioid-dependent people were in the United States.²

Opioid dependence can be successfully treated. Experts favor medication-assisted treatment (MAT), a combination of pharmacotherapy, individualized counseling, and behavioral therapy, because it has proven to be more effective than using a single approach.^{3,4} For decades, methadone was the only option for MAT for opioid dependence. Methadone is a synthetic full opioid agonist: It binds to and triggers opioid receptors. At lower doses, methadone blocks withdrawal symptoms; higher doses reduce the craving for and effects of other opioids.

Methadone-based MAT has many benefits for individuals and society; it has been shown to lower injection-related risk for HIV and viral hepatitis, reduce criminal activity, and improve physical and mental health.^{5,6} But methadone treatment has limitations. For example, drug-drug interactions can complicate treatment of common comorbidities, such as depression and HIV infection, and increase the risk for drug overdose.⁷⁻⁹ Because methadone is a full agonist, however, it can cause severe withdrawal symptoms unless the dose is gradually tapered over a period ranging from months to years.

Despite the prevalence and consequences of opioid dependence in the United States — and the proven benefits of methadone-based MAT — access to methadone is limited when compared with need for such treatment. For example, the number of people needing methadone treatment continues to exceed the number of program slots available. In 2010, SAMHSA reported that 1.9 million people were dependent on prescription pain relievers and 397,000 were heroin dependent, totaling 2,259,000 people.² As of 2008, however, an estimated 1,200-methadone programs in the United States administered MAT to 266,900 people.¹⁰

In addition, Federal regulations require methadone to be provided only by accredited, certified opioid treatment programs (OTPs), which are freestanding entities. Although some OTPs provide primary care, usually services are not co-located under one roof.

In October 2002, another MAT option became available. Buprenorphine, a semisynthetic partial opioid receptor agonist, was approved by the U.S. Food and Drug Administration (FDA) both in tablet form as monotherapy (Subutex[®]) and in combination with naloxone (Suboxone[®]) to treat opioid addiction. Buprenorphine monotherapy and buprenorphine/naloxone combination therapy tablets and—as of August 2010—buprenorphine/naloxone film (Suboxone film) are the only FDA-approved medications for opioid addiction, other than methadone. Both tablets

and film are administered sublingually (under the tongue). Buprenorphine monotherapy* is used less frequently than combination therapy, primarily in pregnancy or under directly observed treatment. Buprenex, an injectable form of buprenorphine, is indicated for pain management only.

Buprenorphine works by knocking other opioids in the brain off their receptors, then binding tightly to the same receptors, thereby blocking other opioids from reaching them. Buprenorphine allows opioid-dependent people to avoid withdrawal symptoms and drug cravings after they reduce or discontinue use of other opioids.

Because buprenorphine is a partial agonist, its effects plateau within a 16- to 32-mg dose range. This “ceiling effect” makes overdose less likely with buprenorphine than with full agonists such as morphine, methadone, oxycodone, hydrocodone, heroin, codeine, and fentanyl. Higher buprenorphine doses will block the effects of full opioid agonists and can precipitate acute withdrawal symptoms if used by opioid-dependent persons when full opioid agonists are in the bloodstream.

Naloxone is a full opioid antagonist; it blocks opioid receptors, causing the rapid onset of withdrawal symptoms. By itself, naloxone is administered by injection to reverse opioid overdose. Naloxone was co-formulated with buprenorphine to discourage diversion, because injecting co-formulated buprenorphine and naloxone can cause withdrawal symptoms in opioid-dependent patients. Sublingual buprenorphine and naloxone use does not precipitate withdrawal symptoms, because sublingual naloxone has poor bioavailability. Buprenorphine has moderate bioavailability when given sublingually, so the effect of buprenorphine predominates and naloxone does not precipitate withdrawal symptoms in opioid-addicted persons.

MAT with buprenorphine can be an effective alternative to methadone.¹¹ However, buprenorphine is also addictive, and overdose remains a risk, particularly with concomitant use of alcohol and benzodiazepines.^{12,13}

NEW OPPORTUNITIES FOR TREATMENT OF OPIOID DEPENDENCE

Until 2000, MAT for opioid dependence could only be administered through federally approved treatment programs. Methadone and levo- α -acetylmethadone (LAMM)[†] were the only pharmacotherapies that could be dispensed through

OTPs. In May 2003, Federal OTP regulations (42 C.F.R. Part 8) were amended, and buprenorphine and buprenorphine/naloxone were added to the list of approved opioid medications that may be used in federally certified and registered OTPs, offering patients another MAT option.

The Drug Addiction Treatment Act of 2000 (DATA 2000) made it possible to expand access to MAT for opioid dependence. DATA 2000 allowed qualifying physicians to administer office-based addiction treatment with medications specifically approved by the FDA for that indication. To date, buprenorphine tablets and buprenorphine/naloxone tablets and film are the only medications to have received an indication for MAT outside of OTPs.

DATA 2000 thus provided opportunities to integrate primary medical care for people living with HIV/AIDS (PLWHA) with treatment for opioid dependence. Integrating primary medical care and MAT for opioid dependence offers great potential for improving health- and addiction-related outcomes among people who use drugs, because it provides an opportunity to address health-related consequences of IDU, such as chronic viral hepatitis, HIV infection, endocarditis, and cellulitis.^{14,15}

When DATA 2000 was passed, nothing was known about implementing MAT programs for opioid dependence in HIV care settings within the United States, because they had never been attempted. What was their cost, and would they be cost-effective? What effects would they have on health and substance use among PLWHA? And what impact would the programs have on providers, institutions, and local addiction treatment networks? To answer these and other questions, in September 2004 the U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (HAB), funded a Special Projects of National Significance (SPNS) Program initiative to evaluate the integration of buprenorphine opioid abuse treatment into HIV primary care settings.

The HRSA/HAB SPNS Program advances knowledge and skills in the delivery of health and supportive services to underserved populations with HIV infection. The 5-year SPNS initiative created demonstration programs integrating HIV/AIDS primary care with buprenorphine treatment for opioid dependence. It sought to determine the feasibility and effectiveness of integrating MAT with

* Subutex was discontinued by its manufacturer, Reckitt Benckiser, in September 2011, but it is available in generic form.

† LAAM, a long-acting formulation of methadone, was discontinued in the United States in 2004 as a result of cardiac safety issues.

BOX 1. SPNS BUPRENORPHINE INITIATIVE GRANTEES

Brown University/Miriam Hospital (Providence, RI)
El Rio Santa Cruz Neighborhood Health Center (Tucson, AZ)
The Hektoen Institute, LLC/CORE Center (Chicago, IL)
Johns Hopkins School of Medicine (Baltimore, MD)
Montefiore Medical Center (Bronx, NY)
OASIS (Oakland, CA)
Oregon Health and Science University (Portland, OR)
University of California, San Francisco, Positive Health Program at San Francisco General Hospital (San Francisco, CA)
University of Miami AIDS Clinical Research Unit (Miami, FL)
Yale University AIDS Program (New Haven, CT)
Evaluation and Support Center: The New York Academy of Medicine (New York, NY)

buprenorphine into HIV primary care settings with the ultimate goal of improving the health of PLWHA.

A total of 10 SPNS-funded demonstration programs in geographically diverse areas were established (Box 1). Grantees were charged with developing and evaluating programs that integrated HIV primary care and buprenorphine-based MAT. In addition, SPNS funded the Office of Special Populations at the New York Academy of Medicine to serve as an evaluation and support center (this center was later named Buprenorphine & HIV Evaluation & Support, or BHIVES). Each grantee conducted its own program evaluation, and BHIVES conducted a multisite evaluation across the 10 sites. The New York Academy of Medicine operated the Evaluation and Support Center; Yale School of Medicine staff were part of the evaluation team.

DATA 2000 REQUIREMENTS

All the SPNS grantees were subject to the Federal regulations governing MAT with buprenorphine. Under DATA 2000, qualifying physicians can obtain a waiver allowing them to administer buprenorphine for opioid dependence. Eligible physicians must submit a waiver notification form documenting the physician's qualifying information to the Center for Substance Abuse Treatment (CSAT). On receipt of this notification, the Drug Enforcement Agency (DEA) issues an identification number, known as a waiver or "X number," that is to be included on all buprenorphine prescriptions in addition to the physician's regular DEA number. Figure 1 depicts the process.

Physicians may take one of several paths to qualify for a waiver. Federal regulations require licensed physicians

to hold subspecialty board certification or to obtain at least 8 hours of approved training in the treatment and management of opioid-dependent patients through a public or private certifying board. This training may be done in person or online. A calendar of training opportunities by geographic region is available at the SAMHSA buprenorphine Web site (<http://buprenorphine.samhsa.gov/pls/bwns/training>). Other trainings are sponsored by the American Academy of Addiction Psychiatry (www2.aap.org/buprenorphine) and the American Society of Addiction Medicine (www.buppractice.com/).

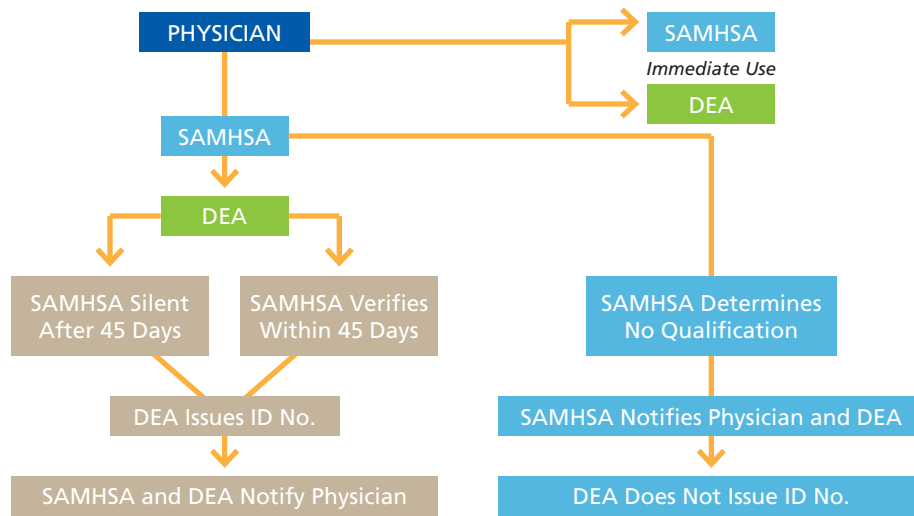
Although DATA 2000 broadened access to MAT for opioid-dependent patients, the original legislation limited the number of buprenorphine patients per authorized physician to 30. In 2006, The Office of National Drug Control Policy Reauthorization Act allowed physicians to submit a second notification, one year after submitting their initial notification, stating the need and intent to treat up to 100 patients. This legislation greatly increased opportunities for integrating MAT for opioid dependence into primary care.

BUPRENORPHINE TREATMENT

Policies and Procedures

As required by DATA 2000, SAMHSA, in collaboration with a team of independent substance abuse treatment professionals, the National Institute on Drug Abuse (NIDA), DEA, and FDA, has developed best practice guidelines for treatment and maintenance of opioid-dependent patients. The resulting Treatment Improvement Protocol (TIP) *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction* is available at

FIGURE 1. OFFICE-BASED TREATMENT NOTIFICATION REVIEW



Source: Substance Abuse and Mental Health Services Administration, CSAT Buprenorphine Information Center. *Physician waiver qualifications*. Available at: http://buprenorphine.samhsa.gov/waiver_qualifications.html. Accessed September 7, 2011.

http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf.¹⁶ The TIP provides information “beyond the general medico-legal responsibilities that govern most other types of medical practice” to help clinic staff implement MAT with buprenorphine.¹⁶

As an example of policies specific to addiction treatment, measures must be taken to protect patient confidentiality in addition to established medical confidentiality and privacy regulations. SAMHSA confidentiality regulations (42 C.F.R. Part 2) mandate that addiction treatment information in the possession of substance abuse treatment providers be handled with a greater degree of confidentiality than general medical information. Physicians must have a signed consent form before disclosing any individually identifiable information to third parties. For example, a signed consent form is required for faxing or telephoning buprenorphine prescriptions to pharmacies. Additional information on addiction treatment and privacy regulations is available at: www.samhsa.gov/HealthPrivacy/.

Buprenorphine MAT Phases

Buprenorphine therapy has three phases: induction, stabilization, and maintenance. Buprenorphine is also used during medically supervised withdrawal to help patients break physical dependence and move to a physically non-dependent state. However, detoxification without any additional rehabilitation is not effective for treating addiction; MAT is generally preferable.

Induction

The goal of induction is to identify the lowest possible dose needed to enable patients to reduce or altogether stop use of opioids without experiencing withdrawal symptoms, side effects, or uncontrollable drug cravings. Induction begins when patients discontinue use of other opioids and switch to buprenorphine under medical supervision. Buprenorphine is administered after opioid-dependent patients have abstained from opioid use for 12 to 24 hours and are in the early stages of opioid withdrawal, because buprenorphine can precipitate acute withdrawal in people who have opioids in their bloodstream.

Initial induction is conducted in the physician’s office, where patients can be closely monitored for at least 2 hours. Many clinicians use the Clinical Opioid Withdrawal Scale (COWS) to measure withdrawal symptoms during buprenorphine induction.¹⁷ Information on precipitated withdrawal and induction is provided as Resource A of this volume, and the COWS is provided as Resource B. The induction phase usually lasts for a week, during which time patients are closely monitored for withdrawal symptoms and side effects and the buprenorphine dose is adjusted as needed. Buprenorphine dosage is titrated over time to reach a dose that stabilizes the patient.

Some patients with a history of opioid dependence may want to undergo MAT with buprenorphine or buprenorphine/naloxone even though they are not physically dependent

on opioids. MAT with buprenorphine may be a good option for patients who have been unsuccessfully treated for opioid dependence with other modalities, want to stop using opioids, and have concerns about relapse. For those patients, the lowest possible dose of buprenorphine/naloxone should be used for induction.

Stabilization

The stabilization phase, which usually lasts for 1 to 2 months, begins when a patient has discontinued or greatly reduced use of other opioids, uncontrollable drug cravings have subsided, and the patient is experiencing few or no side effects. During stabilization, weekly office visits allow for monitoring and dose adjustments, if necessary; treatment can be intensified if the patient continues to use illicit opioids. In some cases, patients may switch to alternate-day buprenorphine dosing once they are stabilized.

Maintenance

The maintenance phase occurs once patients are on a steady dose of buprenorphine, giving them the opportunity to focus on psychosocial and addiction-related issues. The length of the maintenance phase is individualized for each patient; the SPNS initiative followed patients for 5 years.

If stabilized patients want to discontinue buprenorphine use, daily (or alternate-day) dosing should be gradually tapered according to an individualized schedule. Although medically supervised withdrawal can be accomplished over a short period, this approach is not recommended in the absence of an urgent need to discontinue buprenorphine or buprenorphine/naloxone.

Because of its opioid agonist effects, buprenorphine may be abused or diverted for street resale, particularly by people who are not physically addicted to opioids, because it will produce a high. To decrease the likelihood of diversion and abuse of the product, the combination of buprenorphine/naloxone is preferred in treatment settings, although buprenorphine monotherapy is usually used on the first day of induction and in pregnant women. Although it was not available during the SPNS initiative, some patients may prefer the film formulation of buprenorphine and naloxone, because it dissolves more quickly than the co-formulated tablets.

BARRIERS TO MAT WITH BUPRENORPHINE

The SPNS grantees faced several common barriers, including State AIDS Drug Assistance Program formulary restrictions and Medicaid requirements, which vary from State to State; patients with chronic pain; and regulatory requirements.

Medicaid

Medicaid, a program designed to help the medically needy access care, can inadvertently present obstacles to buprenorphine treatment. Medicaid formularies vary from State to State, and health care coverage under the program also varies. In some cases, patients' medical needs are treated separately from behavioral health needs (e.g., substance abuse treatment), making it difficult for providers to treat patients for both opioid addiction and HIV-related medical needs. Implementation of a buprenorphine treatment program must take into consideration Medicaid's regulatory constraints.

Chronic Pain

Chronic pain is prevalent among PLWHA, especially those with co-occurring psychiatric and substance use disorders.^{18,19} Chronic pain in the context of addiction and HIV care is a complex issue. Long-term opioid abuse can alter patients' perception of and tolerance to pain.^{20,21}

Co-management of chronic pain complicates buprenorphine MAT. Buprenorphine itself and in combination with nonopioid analgesics may be insufficient to treat chronic pain. Buprenorphine and buprenorphine/naloxone can precipitate withdrawal or block the effects of pain medication and are thus not recommended for people with chronic pain that is managed with other opioids.

Regulatory Requirements

As described earlier, physicians are required to obtain special waivers before prescribing buprenorphine. For some programs, especially those with large numbers of midlevel practitioners providing HIV primary care, this requirement limits both the number of providers who can prescribe buprenorphine and the number of patients who can receive treatment from their primary care providers.

LESSONS LEARNED

Several key strategies seemed to underlie the success of the programs, including use of a "glue person," a dedicated point person who "owned" the program and served as the face of the program within the clinic; a dyad model; a team approach; continual screening for opioid abuse; and ongoing support for patients.

Glue Person

Several programs relied on a glue person, who was the key point of contact for all issues related to buprenorphine treatment. Providers and patients were able to rely on the glue person to meet the daily needs of the program. This

person had different titles among the programs, such as “clinical coordinator” or “buprenorphine nurse,” but in all cases, the glue person had substance abuse training and experience working within the fields of HIV and mental health (co-occurring mental health issues are common among substance abusers). Physicians, clinic staff, and all patients were aware of the glue person’s role and how to easily access that person. The glue person was a critical component for enrolling and maintaining patients in care.

Dyad Model

Program implementation was a team effort that commonly consisted of a nonphysician service provider (i.e., the glue person) and a prescribing physician. Each site in the SPNS demonstration project used this dyad model, but the background and experience of the nonphysician service provider depended on the available staff at each site.

Team Approach

When establishing a program like those modeled in the SPNS Buprenorphine Initiative, buy-in is critical. Clinics initiating a buprenorphine program should involve all clinicians and staff in the implementation of the program and elicit from them and address their perceptions of the barriers and challenges in office-based treatment for opioid addiction. The projects in the SPNS initiative found a team approach to be important to their success.

Screening for Opioid Abuse

Patients may hide their opioid abuse or dependence from their physicians because of stigma or legal concerns or to obtain opioid analgesics for diversion. To uncover opioid abuse that may have gone unnoticed, many SPNS sites administered screening questionnaires or conducted interviews.

Ongoing Patient Support

Flexibility and timeliness of care are significant factors in adherence to both opioid and HIV treatment. Ensuring accessibility of staff is essential for all buprenorphine programs, particularly because many physicians work at various hospital and clinic sites in the course of a work week. Consequently, in the context of MAT, a patient’s treatment needs often must be scheduled around the physician’s schedule. For those patients already battling drug addiction and HIV, this obstacle can prevent them from being able to adhere to treatment.

The SPNS projects took several approaches to ensuring access for patients. Peer outreach workers are one approach; the glue person described previously was another avenue. The goal was to ensure that even when

a doctor was not available, someone was able to address patients’ concerns and observe treatment adherence.

PURPOSE OF THIS VOLUME

HRSA produced this monograph in order to assist Ryan White HIV/AIDS Program grantees in designing or refining the delivery of public health services to include the integration of buprenorphine-HIV treatment services/programs. The source of the material found throughout this document is derived from the demonstration projects of four SPNS grantee sites that yielded many positive results and lessons. The projects highlighted in this monograph were found to be highly effective — as determined by HRSA and SPNS Program staff — and offer the greatest likelihood for replication (Box 2 provides brief descriptions of the projects).

HRSA staff developed the basic outline of this monograph, identifying the issues and themes that would be highlighted in each chapter. Then, working with staff from the featured demonstration projects, HRSA staff oversaw the development of the content of each chapter in an iterative process of approving the detailed outline of each chapter, and reviewing initial content provided by the grantees which in most cases stemmed from monthly progress reports to the Government. All chapters included in this manual benefitted from continuous HRSA input, editing, review, and clearance channels.

Each chapter in this monograph describes how one of the four programs developed its integrated buprenorphine model of care. The chapters explain each program’s organizational structure, target population demographics, and local HIV and substance abuse data. They also explain why integrating buprenorphine opioid treatment into the HIV primary care setting resulted in better medical care. The chapters outline the processes the programs needed to put in place, including meeting DATA 2000 regulatory requirements, achieving institutional buy-in, implementing staff training requirements, and evaluating processes and outcomes. Readers may be particularly interested in the lessons learned described in each chapter, such as how barriers were overcome, and how the sites leveraged sustainability of their program or components of the program.

This monograph includes links to resources consisting of forms, training materials, and brochures that the grantees found particularly helpful. (Note that logos and other graphic elements have been removed from the materials.) The resources are available at the TARGET Center (Technical Assistance Resources, Guidance, Education

BOX 2. GRANTEES CONTRIBUTING TO THIS VOLUME

University of California, San Francisco

The University of California, San Francisco's (UCSF's) Beehive Program at San Francisco General Hospital cared for a diverse, urban, low-income, and often homeless population in a comprehensive HIV primary care setting at the public safety net hospital in San Francisco. The program grew out of a multidisciplinary effort between UCSF's Department of Medicine, the Division of Substance Abuse and Addiction Medicine in UCSF's Department of Psychiatry, and the San Francisco Department of Public Health's Community Behavioral Health Services to provide clinician education and training on addiction, integrated services, and the use of office-based buprenorphine treatment. This collaboration also developed policies and procedures to deliver buprenorphine treatment in HIV clinical settings. The program's process and outcome evaluation focused on the implementation and effectiveness of an integrated HIV–buprenorphine treatment intervention compared to stand-alone buprenorphine treatment services offered by the public health department.

Miriam Hospital Immunology Center (Providence, RI)

The Miriam Hospital Immunology Center's program targeted HIV-infected substance abusers receiving primary care at the center. The program evaluated the effectiveness of integrating buprenorphine treatment into HIV primary care and examined whether the program helped decrease HIV risk behaviors, increase adherence to HIV medications and/or substance abuse treatment, and improve quality of life. In evaluating the program, staff assessed substance abuse, HIV risk behaviors, adherence to HIV medications, quality of life, patient satisfaction, and follow-up with primary care and substance abuse treatment visits at 1, 3, 6, and 12 months; HIV viral load and CD4 data were obtained through chart review.

CORE Center (Chicago, IL)

The CORE Center focused on a wide range of opioid-dependent HIV-positive patients. The program's goal was to determine the effectiveness of a clinical/psychiatric model that included buprenorphine treatment. Outcome indicators included patient acceptance, improved health outcomes, and retention in care. The CORE program identified opioid-dependent patients during assessment in primary care clinics and relied on a clinical and psychiatric model based on a tightly coordinated team consisting of a psychiatrist and a chemical dependency counselor, who administered buprenorphine treatment. Evaluation focused on a comparison of participants enrolled in the standard model of care (i.e., the HIV/cognitive–behavioral model, which included detox, residential treatment, and methadone) with participants in the new clinical/psychiatric model. Outcome indicators focused on health status and retention in care.

Oregon Health and Science University (Portland, OR)

Like the other grantees, the Portland Integrates Care for Opioid Dependent AIDS Patients (PICODAP) program targeted opioid-addicted patients in primary care HIV clinics. The goal was to integrate buprenorphine treatment and substance abuse counseling with HIV care; improvements were anticipated in medication adherence, attendance in substance abuse counseling, and health outcomes. PICODAP established teams comprising a physician, a nurse, a physician assistant, a counselor, and a patient advocate to coordinate and make decisions about buprenorphine integration at the clinic. The teams also monitored patients and ensured that they were provided with appropriate services. The evaluation compared outcomes of participants involved in the integrated buprenorphine–HIV treatment model with those of participants who received buprenorphine treatment according to Federal guidelines for methadone.

& Training Center for the Ryan White community) Web site, at www.careacttarget.org.

Readers desiring additional information on the programs described in this volume or about any of the other SPNS Buprenorphine Initiative grantees should contact

the grantee program directly. They may also contact the Evaluation and Support Center at the New York Academy of Medicine. Additional information on buprenorphine and buprenorphine treatment programs is available at <http://buprenorphine.samhsa.gov/> and http://buprenorphine.samhsa.gov/bwns_locator/.

References

1. U.S. Centers for Disease Control and Prevention. *Drug-Associated HIV Transmission Continues in the United States*. Fact Sheet. 2002. Available at: www.cdc.gov/hiv/resources/factsheets/PDF/idu.pdf. Accessed December 13, 2011.
2. Substance Abuse and Mental Health Services Administration (SAMHSA). *Results from the 2010 National Survey on Drug Use and Health: summary of national findings*. NSDUH Series H-41, HHS Publication No. (SMA) 11-4658. Rockville, MD: SAMHSA; 2011. Available at: www.samhsa.gov/data/NSDUH/2k10NSDUH/2k10Results.htm
3. Amato L, Minozzi S, Davoli M, et al. Psychosocial and pharmacological treatments versus pharmacological treatments for opioid detoxification. *Cochrane Database Syst Rev*. 2011;9:CD005031.
4. Mattick RP, Breen C, Kimber J, et al. Methadone maintenance therapy versus no opioid replacement therapy for opioid dependence. *Cochrane Database Syst Rev*. 2009;3:CD002209.
5. Gowing LR, Farrell M, Bornemann R, et al. Brief report: methadone treatment of injecting opioid users for prevention of HIV infection. *J Gen Intern Med*. 2006;21:193-5.
6. Lawrinson P, Ali R, Buavirat A, et al. Key findings from the WHO collaborative study on substitution therapy for opioid dependence and HIV/AIDS. *Addiction*. 2008;103:1484-92.
7. Gruber VA, McCance-Katz EF. Methadone, buprenorphine, and street drug interactions with antiretroviral medications. *Curr HIV/AIDS Rep*. 2010;7:152-60.
8. Kapur BM, Hutson JR, Chibber T, et al. Methadone: a review of drug-drug and pathophysiological interactions. *Crit Rev Clin Lab Sci*. 2011;48:171-95.
9. Saber-Tehrani AS, Bruce RD, Altice FL. Pharmacokinetic drug interactions and adverse consequences between psychotropic medications and pharmacotherapy for the treatment of opioid dependence. *Am J Drug Alcohol Abuse*. 2011;37:1-11.
10. SAMHSA. *Medication-assisted treatment for opioid addiction: 2010 State profiles*, 2011. Rockville, MD: SAMHSA. Available at: http://dpt.samhsa.gov/pdf/MedicationAssistedTreatmentForOpioidAddiction_2010StateProfiles03.pdf.
11. Wesson DR, Smith DE. Buprenorphine in the treatment of opiate dependence. *J Psychoactive Drugs*. 2010;42:161-75.
12. Häkkinen M, Launiainen T, Vuori E, et al. Benzodiazepines and alcohol are associated with cases of fatal buprenorphine poisoning. *Eur J Clin Pharmacol*. Epub 2011 Sep 17. Available at: <http://dx.doi.org/10.1007/s00228-011-1122-4>
13. Reynaud M, Petit G, Potard D, et al. Six deaths linked to concomitant use of buprenorphine and benzodiazepines. *Addiction*. 1998;93:1385-92.
14. Lloyd-Smith E, Kerr T, Hogg RS, et al. Prevalence and correlates of abscesses among a cohort of injection drug users. *Harm Reduct J*. 2005;2:24.
15. Que YA, Moreillon P. Infective endocarditis. *Nat Rev Cardiol*. 2011;8:322-36.
16. Center for Substance Abuse Treatment. *Clinical guidelines for the use of buprenorphine in the treatment of opioid addiction*. Treatment Improvement Protocol Series 40. DHHS Publication No. (SMA) 04-3939. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2004. Available at: http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf.
17. Wesson DR, Ling W. The Clinical Opiate Withdrawal Scale (COWS). *J Psychoactive Drugs*. 2003;35:253-9.
18. Merlin JS, Cen L, Praestgaard A, et al. Pain and physical and psychological symptoms in ambulatory HIV Patients in the current treatment era. *J Pain Symptom Manage*. Epub 2011 Nov 22. Available at: <http://dx.doi.org/10.1016/j.painsymman.2011.04.019>
19. Tsao JC, Soto T. Pain in persons living with HIV and comorbid psychological and substance use disorders. *Clin J Pain*. 2009;25:307-12.
20. Compton P, Charuvastra VC, Kintaudi K, et al. Pain responses in methadone-maintained opioid abusers. *J Pain Symptom Manage*. 2000;20:237-45.
21. Younger J, Barelka P, Carroll I, et al. Reduced cold pain tolerance in chronic pain patients following opioid detoxification. *Pain Med*. 2008;9:1158-63.



CHAPTER 1

REPORT FROM: UNIVERSITY OF CALIFORNIA, SAN FRANCISCO, BEEHIVE PROGRAM

The Beehive Program is an integrated buprenorphine treatment service offered to patients of the University of California, San Francisco (UCSF) Positive Health Program's (PHP's) HIV/AIDS clinic at San Francisco General Hospital (SFGH). The program was created in 2004 to address the critical need for opioid addiction treatment among people living with HIV/AIDS (PLWHA) in San Francisco by demonstrating an innovative and effective model of HIV care that integrates office-based treatment for opioid abuse into the HIV primary care setting.

The Beehive intervention model was achieved in partnership with seasoned collaborators who provided expertise and provider training in office-based opioid agonist treatment (OAT), buprenorphine therapy, and psychosocial interventions for opioid users as well as program evaluation. The Beehive Program treatment team included one clinical nurse coordinator (i.e., the “glue person”) and at least one buprenorphine-prescribing physician per patient. The treatment team worked with patients to develop and monitor individualized treatment plans and to document clinical outcomes. Patients could be treated by a primary care physician meeting Drug Addiction Treatment Act of 2000 (DATA 2000; Pub. L. 106–310) requirements or referred for treatment to the Beehive physician. The clinical nurse coordinator provided patient education about buprenorphine and conducted initial assessments of treatment eligibility. In addition, she monitored and counseled patients during their treatment under the supervision of the physician and ran weekly psycho-educational patient support groups. Buprenorphine/naloxone sublingual tablets were typically dispensed initially from the HIV/AIDS clinic directly, and then prescriptions were transferred to a community pharmacy when the patient achieved a stable buprenorphine dose.

In collaboration with the Division of Substance Abuse and Addiction Medicine (DSAAM) in the UCSF Department of Psychiatry at SFGH and the Community Behavioral Health Services (CBHS) of the San Francisco Department of Public Health (SFDPH), the PHP took steps in 2004 to expand its integrated service model of comprehensive HIV primary care to include office-based buprenorphine treatment. The PHP clinic served as a platform for provider education and training and for development of policies and procedures for delivering buprenorphine treatment to eligible clinic patients. The Beehive Program was 1 of 10 demonstration sites funded in 2004 by the Health Resources and Services Administration (HRSA), HIV/AIDS Bureau, through its Special Projects of National Significance (SPNS) Program to develop and evaluate programs that integrated HIV primary care and buprenorphine treatment for opioid dependence.

Organizational History and Structure

A detailed description of the history and structure of the three collaborating organizations, PHP, DSAAM, and CBHS, that made the Beehive Program possible is provided next. The sections that follow describe the participating organizations at the time of the program. The organizations have changed since, but those changes are not reflected in this chapter.

Positive Health Program

The PHP is a collaborative effort of the SFDPH's Community Health Network (CHN) and the UCSF Department of Medicine at SFGH. The UCSF AIDS program is recognized throughout the medical community as a world leader in the areas of clinical care and basic clinical research. Founded in 1983, the clinic provides more than 2,000 patient visits per month to patients in primary and specialty care as well as urgent care. The PHP has been ranked as the top facility in the country for AIDS care by *U.S. News and World Report* for many consecutive years. Its mission is "to explore, learn, teach, heal and comfort." It views HIV/AIDS as a primary care disease and is committed to the care and treatment of PLWHA regardless of race, ethnicity, sexual orientation, country of origin, or ability to pay.

The structure of the clinic is based on an integrated service model of comprehensive primary care, which brings together a range of services around primary health care with the goal of stabilizing clients and enabling them to access and remain in care. The rationale for the integrated service model is that PLWHA, who have complex medical needs and significant comorbidities, will have better health outcomes and improved quality of life when they have uninterrupted access to primary medical care and critical support services. A spectrum of specialty health and social service delivery programs designed to support the patient are arrayed around a core of primary care services and are coordinated by a multidisciplinary team of more than 75 providers in a centralized location.

The PHP's scope of clinical activities emphasizes outpatient primary and specialty HIV care; rapid availability of routine and urgent care; psychosocial support from a spectrum of social services; integration of patient care with clinical research; and ongoing education for patients, providers, and the community. Urgent care services provide same-day, drop-in management of acute medical conditions to nearly 700 patients per month. Pharmacy services provide medication refills, and medication adherence counseling and aid in the management of adverse drug events and interactions. Two psychiatrists with HIV specialty training provide onsite psychiatric services. Other specialty clinics and services include oncology, hematology, dermatology, infusion services, diet and nutrition counseling, anal dysplasia, neurology, cardiology, pulmonary, sickle cell, and obstetrics and gynecology.

The PHP social services program plays a critical role in the coordinated care of patients with substance use and

mental health disorders. A staff of five full-time social workers is involved in all new patient intakes. Social workers conduct mental health and substance use assessments as well as individual counseling and referral. Social workers assist patients with crisis intervention and management, provide benefits advocacy, and coordinate peer advocacy and outreach services. The staff is knowledgeable and effective in making culturally appropriate referrals for community services such as housing, substance abuse and mental health treatment, transportation, home care, and case management. The lead social worker is a motivational interviewing trainer. Other social support services (e.g., access to emergency housing; vouchers for transportation, food, and household goods) enhance access to care and enable clients to stay in care.

The main clinic occupies the entire sixth floor (Ward 86) of Building 80 at SFGH and contains 15 patient examination rooms, a pharmacy, a clinical laboratory, a modern three-bed treatment room for transfusions and drug administration, conference and office space for non-physician and physician staff, and a reception and patient waiting area. The PHP at SFGH has extensive computer-related hardware and software that support the Beehive Program, including access to the SFDPH Intranet site, which houses the San Francisco Office-Based Opiate Addiction Treatment (OBOT) Web site.

Division of Substance Abuse and Addiction Medicine, UCSF Department of Psychiatry at SFGH

DSAAM is located in the UCSF Department of Psychiatry at SFGH and consists of several programs located at SFGH and within the community:

- HIV Prevention and Intervention Program
- Methadone Van
- OBOT
- Opiate Treatment Outpatient Program (OTOP)
- Stimulant Treatment Outpatient Program (STOP)
- Stonewall Project.

HIV Prevention and Intervention Program. Clients in OTOP methadone detox, OTOP methadone maintenance, the OTOP van, or the Stonewall Project receive, as needed, HIV testing, HIV risk-reduction counseling (reducing transmission or progression of HIV), and HIV medication-adherence coaching. Services are provided at SFGH Ward 93, at OTOP van sites, and at the Stonewall Project site.

Methadone Van. The Methadone Van provides methadone dosing and counseling services at three neighborhood sites: Walden House in the Mission, a community church in Bayview/Hunters Point, and a community site in Sunnydale. The van provides services to patients in their neighborhoods, reaching opioid-dependent patients who might otherwise not be able to access methadone maintenance treatment.

Office-Based Opiate Addiction Treatment Program. OBOT patients receive opiate maintenance through OBOT at their primary care or psychiatric or methadone clinic. DSAAM counselors provide the counseling at the CHN sites, currently Tom Waddell Health Center and Potrero Hill Health Center. DSAAM provides clinical coordination and quality monitoring at all sites, currently the two CHN health centers as well as Bay Area Addiction Research and Treatment (10 methadone slots) and the Harm Reduction Center (5 methadone slots). Roughly half of the patients receive methadone and half receive buprenorphine.

Opiate Treatment Outpatient Program. OTOP, located at Ward 93 at SFGH, provides methadone maintenance dosing and counseling to opiate-dependent clients in conjunction with medical and psychiatric services. Since the onset of the AIDS epidemic, DSAAM has been involved in combating HIV disease among injection drug users (IDUs) through research, prevention, treatment, and medical care. It has been designated as the county methadone treatment provider for the most medically and psychiatrically compromised opiate addicts. OTOP is licensed to provide methadone to 750 clients daily through combined maintenance and detoxification services.

Stimulant Treatment Outpatient Program. STOP provides outpatient treatment for methamphetamine and cocaine abuse or dependence and any co-occurring substance use or psychiatric disorders. A STOP counselor staffs the HIV/AIDS clinic of the PHP. STOP staff help participants clarify their needs and goals using motivational interventions and guide them in behavior change (i.e., harm reduction, cessation of use, relapse prevention). Participants receive one or more of the following services:

- Drop-in group and individual counseling
- Assessment of addiction severity and development of an individualized treatment plan
- Individual counseling once a week, including couples and family sessions as needed
- Group counseling 1 to 5 days a week

- Random urine testing as needed
- HIV and sexually transmitted infection risk reduction and medication adherence support
- Psychiatric medication management
- Referrals and service coordination.

Stonewall Project. The Stonewall Project is a counseling program that provides harm reduction-based treatment to gay and other men who have sex with men (MSM) who have drug and alcohol problems. The Stonewall Project's counseling services are based on a participant-centered perspective and integrate substance use, mental health, and HIV prevention and education. The overarching treatment goal is to reduce the harm caused to participants and their loved ones by substance use. Individual participant treatment goals vary and range from complete abstinence to controlled or safer use. The Stonewall Project is no longer part of DSAAM, but it was at the time of the grant.

Current and former DSAAM faculty members have played significant contributing roles in the Beehive Program's provider trainings, induction services, and ongoing clinical consultation on office-based buprenorphine treatment. Provider education and training (on addiction, addiction treatment, integrated services, OAT, and the use of buprenorphine) was a central activity of this integrated HIV-buprenorphine treatment service. Education, hands-on training, and ongoing support and consultation are necessary ingredients in identifying and addressing the concerns of prescribing physicians and other providers. Members of the OBOT core group advised the PHP on the development and implementation of buprenorphine treatment guidelines for HIV primary care settings and played roles in quality assurance and improvement. Drawing on his expertise as a psychologist, the OTOP program director developed and supervised the psychosocial component of the Beehive intervention.

Community Behavioral Health Services, San Francisco Department of Public Health

CBHS, an agency of the SFDPH, was established to provide a substance abuse and mental health delivery system accountable to consumers and the public. It administers publicly funded substance abuse services in San Francisco. The mission of CBHS is

- To assess the nature and magnitude of mental illness, alcohol, and other drug-related problems in San Francisco;

- To ensure provision of quality, culturally competent, cost-effective mental illness, alcohol, and other drug prevention, treatment, and recovery services to individuals, families, and communities affected by substance abuse and mental illness; and
- To promote cooperation and collaboration among public and private service systems and agencies to reduce the level of mental illness, alcohol, and other drug problems in San Francisco.

Formerly the independent Community Substance Abuse Services and Community Mental Health Services, CBHS has a long history of developing and administering innovative substance abuse services, including programs for high-risk IDUs. CBHS administers 146 substance abuse treatment programs housed in more than 50 agencies in San Francisco and has received several Center for Substance Abuse Treatment grants, including funding for a Targeted Capacity Expansion program for community-based, medically supported detoxification services; OBOT; the San Francisco Practice Improvement Collaborative; and the Impact of Treatment Demand.

San Francisco Office-Based Opiate Addiction Treatment Pilot Program. The SFDPH is the first public health agency in the country to receive Federal and State approval to initiate an OBOT program. The city began mobilizing in the mid-1990s to develop and implement responses to its heroin problem. The Treatment on Demand Planning Council focused on overall drug problems, whereas the Heroin Subcommittee, formed in 1999, focused specifically on heroin abuse. Planning for the San Francisco OBOT (SF OBOT) began in 1997, initiated through a board of supervisors resolution that authorized SFDPH to develop a plan and seek necessary waivers to commence office-based methadone services. Using a community-based planning process that included methadone treatment providers, David Hersh and Alice Gleghorn developed a best practice model for the treatment of indigent opioid-dependent patients by physicians in primary care, mental health, and other community clinic settings.

Treatment at the SF OBOT involves coordination of medical, counseling, dispensing, and administrative services among the primary care setting, a community pharmacy, and an evaluation/quality management team. At one clinic, a full-time registered nurse coordinates the OBOT program. She interfaces with the physicians and the core OBOT team, does quality assurance, and arranges

trainings. The treatment protocols rely on a Web-based database for confidential and efficient communication among OBOT sites.

San Francisco Buprenorphine Treatment Initiative. With the U.S. Food and Drug Administration's (FDA's) approval of buprenorphine, the SF OBOT program was expanded to include a buprenorphine option. In 2003, the Outpatient Buprenorphine Induction Clinic (OBIC) was developed for the initiation and stabilization of patients on buprenorphine to alleviate physician discomfort with the buprenorphine induction process. A treatment protocol was developed and implemented to prepare patients for induction. Although patient numbers were initially small, OBIC physicians found that the buprenorphine induction process was feasible and went well. They induced patients with many years of heroin use, high-dose heroin use, methadone use, and cocaine use.

Epidemiology

The UCSF PHP at SFGH is one of the oldest and largest HIV/AIDS clinics in the United States. The PHP clinic provides primary medical care to 2,565 patients. Approximately 81 percent are men, 17 percent are women, and 2 percent are transgender. The racial/ethnic composition of the patients is 48 percent White, 24 percent Black, 6 percent Asian/Pacific Islander, 1 percent Native American, and 19 percent multiracial or unstated. Twenty-five percent are Hispanic by ethnicity. Fifty-six percent of the patients are less than 45 years old.

The Beehive Program focuses on two populations: patients and their providers. The target provider population consists of HIV primary care providers who care for patients with opioid abuse and dependence. The target patient population consists of PLWHA who meet *Diagnostic and Statistical Manual of Mental Disorders*, fourth edition (*DSM-IV*)¹ criteria for opioid dependence. An eligible patient for the Beehive Program (1) meets *DSM-IV* criteria for opioid dependence, (2) expresses an interest in receiving substance abuse treatment services, and (3) receives HIV primary care from the PHP.

The initial focus of the intervention was to provide physician and staff education and training on the office-based provision of buprenorphine treatment. A core group of primary care physicians and clinic staff was identified to participate in the first year of intensive training and preparation for the intervention; they would see opioid-dependent patients together on a weekly basis, attend

monthly multidisciplinary case conferences, and continue to receive expert consultation and support throughout the project period. Enrollment of additional physicians and staff in the buprenorphine integration program was planned, but it did not occur to the degree hoped. Greater success occurred with staff enrollment. Although several nurse practitioners completed buprenorphine waiver trainings and had DEA licenses for prescribing Schedule II medications, nurse practitioners are not currently eligible for the “X licenses” that would permit them to prescribe buprenorphine, a Schedule III medication. This barrier was a source of frustration.

The second focus of the project was to enhance the existing model of comprehensive HIV primary care at the PHP by (1) preserving the existing integrated service model of onsite substance abuse counseling and referral services and peer support groups and (2) integrating new office-based buprenorphine treatment policies and procedures into the primary care clinic. A clinic-based treatment team consisting of a physician and a clinical nurse coordinator evaluated patients for eligibility. Participating patients received education and counseling before being prescribed buprenorphine. Substance abuse counseling can be provided by any member of the care team to help clients make necessary lifestyle changes.

Local HIV/AIDS Epidemiologic Data

HIV/AIDS profoundly affects San Francisco. Few people in the San Francisco Bay Area have not experienced the loss and suffering associated with this illness. A cumulative total of 28,114 San Francisco residents were diagnosed with AIDS through December 31, 2008.² This number accounts for 18 percent of all AIDS cases in California and 3 percent of all cases in the United States. Compared with cases reported in California and in the United States as a whole, AIDS cases in San Francisco are more likely to be male, White, and MSM, including MSM who are also IDUs (Table 1-1). Among women with AIDS, the most frequent exposure category is injection drug use.

As of December 31, 2008, 9,248 San Francisco residents were living with AIDS; 781 (8 percent) were non-MSM IDUs.² The number of PLWHA increased from 14,247 in 2003 to 15,757 in 2008 and continues to increase as a result of the combination of ongoing incidence of HIV and an increase in survival after AIDS.

Many HIV-infected IDUs progress to AIDS and death in San Francisco. More than 18,866 San Francisco residents have died from HIV/AIDS.² The annual death rate

from HIV/AIDS-related causes declined from 15.7 per 100 persons per year with AIDS in 1995 to 1.8 per 100 persons per year with AIDS in 2006. The drop in death rates beginning in 1996 reflects the remarkable impact of effective antiretroviral therapy (ART). The proportion of deaths in which HIV/AIDS was listed as the underlying cause of death decreased from 81 percent (1995–1998) to 66 percent (2003–2006), but the proportion of deaths associated with substance abuse (drug overdose, mental disorders due to substance use) increased over time.²

For AIDS cases diagnosed between 1996 and 2008, 5-year survival was 85 percent for MSM, 81 percent for heterosexuals, 74 percent for MSM IDUs, and 66 percent for heterosexual IDUs.² The poorer survival among IDUs partly reflects higher death rates from causes associated with drug use, such as overdose, liver disease, and other infections.

Survival after an AIDS diagnosis has been better for MSM and heterosexuals than for MSM IDUs and heterosexual IDUs in San Francisco. Between 1995 and 1998, people exposed to HIV through injection drug use lived the shortest amount of time (37 months) compared with other exposure categories (63 months for MSM, 45 months for MSM IDUs, and 56 months for “other”).³ These findings may be attributable in part to lower access to medical care and to adherence issues. When the SFPD looked at the use of ART among PLWHA in 2000—one index of medical care access—IDUs were less likely to be on ART (54 percent among IDUs versus 69 percent among MSM exposure categories).² As of December 31, 2008, 70 percent of HIV-positive San Francisco residents without AIDS who were eligible for treatment received ART, but IDUs had the lowest proportion of ART use (59 percent).²

Local Substance Use Epidemiology

Substance use is an epidemic in San Francisco. Historically, San Francisco has ranked in the top five cities in the United States for emergency department drug episodes for the past decade.⁴ During 1999, 12,000 drug- or alcohol-related hospitalizations occurred in San Francisco.⁵ At SFGH alone, 3,945 emergency department discharges and inpatient admissions occurred for injection drug use–related skin and soft-tissue infections in FY 1999–2000.⁶ Skin and soft-tissue infection was the most common primary diagnosis for medical/surgical admission at SFGH during the same year. Medical billing records for patients with opioid-use diagnoses receiving ambulatory care, emergency, and inpatient medical services at SFGH are 2.5 times greater than the average national per-patient charges.⁷

TABLE 1-1. CHARACTERISTICS OF CUMULATIVE AIDS CASES IN SAN FRANCISCO, CALIFORNIA, AND THE UNITED STATES

	San Francisco (N = 28,114)		California (N = 152,318)	United States (N = 1,030,832)
	n	%	%	%
Gender				
Male	26,563	94	91	80
Female	1,160	4	9	20
Transgender*	391	1	<1	—
Race/Ethnicity				
White	20,090	71	55	39
African American	3,610	13	18	40
Latino	3,305	12	23	19
Asian/Pacific Islander	918	3	2	<1
Native American	149	1	<1	<1
Other/unknown	42	<1	<1	<1
Exposure Category				
MSM	20,901	74	67	44
IDU	2,150	8	10	23
MSM IDU	4,195	15	9	7
Heterosexual	432	2	6	14
Transfusion/hemophilia	166	<1	2	2
Other/unidentified	270	1	6	11

Notes: San Francisco data are reported through March 9, 2009, for cases diagnosed through December 2008; California data are reported through December 2008. U.S. data are reported through December 2007 and may be found in the CDC *HIV/AIDS Surveillance Report, 2007*, Vol. 19. Percentages may not add to 100% due to rounding. Transgender data are not reported by the United States. MSM = men who have sex with men; IDU = injection drug users.

Source: San Francisco HIV/AIDS Epidemiology Annual Report 2008, p. 1.²

At the end of the 1990s, San Francisco consistently ranked among the top four cities in heroin-related hospital admissions relative to other U.S. metropolitan areas.⁴ In addition, San Francisco led California in the number of heroin-related problem indices and consistently possessed 3 times the number of heroin-related hospital admissions and heroin-related deaths relative to the State average.⁸ Approximately one-half of the people who died from nonalcohol, drug-related causes in San Francisco never received drug treatment services from the public health system.⁹ Reliable estimates at that time placed the number of active heroin users in San Francisco between 15,000 and 17,000;¹⁰ however, the City and County of San Francisco's treatment capacity consisted of only 2,695 methadone

maintenance slots and 815 methadone detoxification slots funded through public, Federal, and private sources.³ Demand for treatment remains high, and most methadone programs are operating at capacity.

Although in recent years heroin-associated deaths and emergency department visits in San Francisco have declined to national levels, prescription opioid abuse has skyrocketed.¹¹ Opioid analgesics often are prescribed to treat pain in PLWHA and were a mainstay of AIDS care in the era before highly active antiretroviral therapy (HAART). Greater pain severity has been observed in dually diagnosed patients with concurrent HIV/AIDS and mental health disorders.^{12,13} In addition,

HIV-infected patients with histories of problem drug use are more likely to have higher levels of pain and symptom distress than those without drug-use histories.¹⁴⁻¹⁶ Today, with reductions in HIV/AIDS mortality from HAART, HIV care has evolved from a palliative care model to chronic disease management. Many PLWHA, however, still struggle with disability and dysfunction related to the adverse sequelae of chronic pain and substance dependence. HIV providers are challenged to keep pace with the clinical skills and knowledge to prescribe opioid medications safely and effectively.

Substance use disorders are common in HIV care settings. In an informal survey of PHP primary care clinicians in 2004, providers estimated that an average of 20 percent of their HIV-infected patients were opioid dependent. In an anonymous waiting-room survey of 262 PLWHA at SFGH in 2007, 204 patients (78 percent) reported ever using street or illicit prescription drugs and 182 (two-thirds) reported drug or alcohol use in the prior 12 months.¹⁷ Among these 182 patients, the prevalence of substance use was as follows: 51 percent alcohol, 47 percent methamphetamines, 42 percent crack cocaine, 29 percent cocaine, 26 percent heroin, 20 percent nonprescribed use of prescription opioids, and 16 percent nonprescribed use of benzodiazepines.

In the same waiting-room study, among the 234 patients ever prescribed opioids for pain, 80 (34 percent) reported prescription opioid misuse (“ever using opioid pain medications for reasons other than pain”). Reasons for misuse included to sleep better (78 percent), to soothe anxiety (46 percent), to prevent opioid withdrawal (33 percent), to come off stimulants (31 percent), and to keep from feeling sad (24 percent). Although misuse was greater among heroin users, the reasons offered for misuse also suggest that a significant proportion of HIV-infected patients in this clinic may be self-medicating unrecognized or untreated mental health symptoms and addictive disorders.

Why Integrate Buprenorphine Into the HIV Primary Care Setting?

From an HIV primary care perspective, uncontrolled substance use not only interferes with medication access and adherence but also may contribute to HIV pathogenesis, increase transmission risk, and destabilize patients’ sources of social and financial support. Local public health programs lack sufficient substance abuse treatment facilities and other resources to meet the critical needs of this high-risk population.

One strategy for increasing the availability of opioid treatment services is expansion of methadone maintenance treatment (MMT) slots for PLWHA. Additional scale-up of methadone clinics can be costly, however, given methadone’s strict regulation as a Schedule II drug by Federal and State laws. MMT programs and their clients must comply with substantial requirements, including minimum standards regarding specific dosing schedules, urine toxicology screening, counseling, and documentation. Office-based buprenorphine treatment is an alternative strategy. As a Schedule III drug, buprenorphine can be prescribed in the primary care setting to more patients than could be enrolled in a methadone program.

Integrated service programs provide most of the public HIV primary care and substance abuse services in San Francisco. HIV care in San Francisco is designed to be client centered, to increase access to care, and to eliminate disparities in health outcomes among all affected populations and communities. The accessibility of the continuum of care is dependent on the funding available for each component. Primary care and case management are widely available, but housing, mental health care, and substance abuse treatment are not adequately funded by any funding stream. Ryan White HIV/AIDS Program funds help make services accessible but are not enough to make them universally available. Primary care is the center of the continuum of care, and PLWHA access it through various mechanisms. Providers in the San Francisco Bay Area include community health clinics, private medical practices, and public and private hospitals. Some of the greatest challenges are to help stabilize patients’ lives so they can consistently access care and to provide comprehensive, quality care to those whose lives remain chaotic. The integrated service model in San Francisco brings clients into care and helps them manage medications and stay in the system of care.

Medication adherence and treatment outcomes are optimized when linked with substance abuse treatment.¹⁸ As a Ryan White-funded primary care provider, the PHP clinic has historically provided substance abuse counseling and access to substance abuse treatment for its patients through multiple community linkages and collaborations. Substance abuse services at the PHP have been coordinated by a large staff of five full-time social workers. Services include onsite substance abuse counseling, referrals to inpatient and outpatient substance abuse treatment programs, and a strong linkage to OTOP on the hospital campus. With the addition of the Beehive Program, the PHP has been able to introduce new and

needed opioid-use treatment services for its patients by supporting the integration of office-based buprenorphine treatment into existing primary care practices.

Provider Requirements and Training

In San Francisco, the UCSF DSAAM and SFDPH CBHS sponsored several local trainings to assist physicians with meeting DATA 2000 requirements. Before the Beehive Program was established in 2004, three PHP faculty physicians had participated in at least 8 hours of approved training in the treatment and management of opioid-dependent patients offered through a public or private certifying board. One physician had obtained a waiver from opioid treatment program registration requirements so that she could prescribe Schedule III controlled medications approved by the FDA for the treatment of opioid addiction. The other two physicians received their waivers in 2005. Although no additional attending physicians obtained waivers during the project period, two clinical fellows and two senior residents obtained waivers and at least five nurse practitioners, two nurses, and a social work associate participated in 8-hour buprenorphine waiver trainings.

Getting Started

Getting started required clinic administration approval and space allocation, a reliable source of continuing medication for patients, provider orientation and training, and open lines of communication with other substance use treatment programs. Continuous, effective, and client-centered communication with all parties was critical to successful implementation. Keeping multiple key stakeholders in the clinic, institution, and local community informed about the development of policies, procedures, and agreements for treating patients was essential.

Clinic Administration Support

To build a strong foundation for the provision of buprenorphine at our clinic, we sought and received support for the demonstration program from the clinic's administrative leadership. We received letters of support from both the PHP medical director and the SFDPH director of health, who volunteered once weekly as a primary care provider at the PHP. We identified structural changes needed to integrate buprenorphine into the day-to-day operations of clinical services, including appointment slots on the clinic schedule, assignment of clinic exam rooms, clinic staff orientation, and pharmacy issues. We secured a minimum of one exam room 3.5 days per week for the Beehive Program and permission to use other areas of the clinic at other times, including the treatment room for brief

interim assessments and dosing adjustments. We sought and received approval from the clinic's nurse manager to post flyers in each exam room to inform patients about the Beehive Program and to distribute buprenorphine patient brochures in the clinic waiting room and in exam rooms (Resource 1A). Exam rooms also were supplied with Beehive Program information for providers, including a laminated referral card (Resource 1A). We also held an in-service breakfast about buprenorphine treatment at the monthly clinic staff meeting prior to beginning treatment services. A description of the Beehive program for Ward 86 providers is in Resource 1C.

Medications and Pharmacy

Initially, we met jointly with the head of our hospital pharmacy, the head of the SFDPH's CBHS pharmacy, and the PHP clinical pharmacist to discuss the practical issues of storing and dispensing buprenorphine to PHP patients. We also met separately with the San Francisco Jail Health Services pharmacy director to develop jail medication protocols, including inventory control and packaging of medications for patients incarcerated in and later pending release from the county jail system. We drafted an agreement with the SFDPH's CBHS pharmacy to secure a defined amount of buprenorphine that would permit us to provide free treatment to a small number of medically indigent patients. Within the community, we identified two neighborhood pharmacies that were willing to submit Treatment Authorization Request (TAR) applications for Medi-Cal approval of reimbursement for buprenorphine on behalf of our Medicaid patients. These HIV/AIDS specialty pharmacies were able to dispense buprenorphine weekly in either vials or medisets that also contained patients' antiretroviral medications. These pharmacies also offered home deliveries for patients with disabilities.

In September 2005, Reckitt Benckiser, the manufacturer of buprenorphine, agreed to provide medication for all indigent patients participating in the SPNS project. This generous donation alleviated the logistical problem of securing a reliable source of buprenorphine for our medically indigent patient population. We subsequently were able to dispense donated medication directly from our clinic during induction and stabilization phases of treatment. Prescriptions were transferred to a community pharmacy when the patient achieved a stable buprenorphine dose. Because buprenorphine was not on the hospital formulary, we were not allowed to store the medication in the Omnicell automated medication dispensing system with other clinic medications. Instead, we were required to acquire a locked

cabinet in a locked office to store the donated medication. With the support of the CBHS pharmacy, we set up a system to monitor and report all buprenorphine that we administered and dispensed to patients at the clinic, as required by the California State Controlled Substance Utilization Review and Evaluation System (CURES) prescription drug monitoring program.

Provider and Staff Training

One of the main goals of our program was to provide training, education, and support to a core group of clinic providers (including physicians, nurses, social workers and counselors, and administrative staff) in the provision of office-based buprenorphine opioid-abuse treatment. An onsite training curriculum was developed for Beehive Program staff by the OBOT program. Topics ranged from general information on addiction treatment (e.g., overview of addiction and addiction treatment, overview of OAT, urine toxicology, confidentiality issues, motivational interviewing) to buprenorphine-specific subjects (e.g., patient selection, induction, stabilization, documentation, forms, regulations, and case studies). Other topics included how to access prompt clinical consultation from addiction specialists at the SF OBOT program and OBIC. Treating providers participated in a clinical practicum at OBIC to gain hands-on experience in induction procedures with their own patients and toured the CBHS pharmacy to observe a model for buprenorphine storage and dispensing practices. Prescribing physicians also had access to the Substance Abuse and Mental Health Services Administration (SAMHSA)-funded Physician Clinical Support System for Buprenorphine (PCSS-B), a free, nationwide program designed to assist practicing physicians with incorporating buprenorphine treatment into their practices. The PCSS-B mentors provided monthly telephone discussion forums and e-mail support to our treatment team and other SPNS grantees.

Substance Abuse Treatment Program Communication

Local substance use treatment program directors and counselors in our community (e.g., residential treatment programs, methadone clinics) demonstrated low levels of knowledge regarding buprenorphine therapy, its mechanism of action, and potential interaction. At some for-profit narcotic treatment programs, the new buprenorphine treatment service risked being viewed as a business competitor. We anticipated that we would encounter methadone-maintained patients who would be interested in transferring from methadone to buprenorphine, and we took a proactive approach to communicating with other substance use treatment providers in the community. We

created a program-specific Authorization to Exchange Health Information form (Resource 1B). We offered and conducted buprenorphine in-services for the staff of a large therapeutic community residence and for the SFGH OTOP methadone clinic staff. Specifically, we worked with OTOP leadership to develop written recruitment and referral procedures for SFGH OTOP methadone clients who wished to transfer to the Beehive Program (Resource 1C).

Human Resources and Staffing Needs

The Beehive intervention model was achieved in partnership with seasoned collaborators who provided expertise and provider training in office-based OAT, buprenorphine therapy, psychosocial interventions for opioid users, and program evaluation. Given a supportive environment and highly accessible clinical consultation locally and nationally, actual staffing needs were minimal.

The Beehive Program treatment team included one clinical nurse coordinator and one buprenorphine-prescribing physician. Together, they assessed and educated patients, developed and monitored patients' individualized treatment plans, and documented clinical outcomes. Patients were treated with buprenorphine by their X-licensed primary care physician or were referred for treatment to the Beehive physician by the patient's primary care provider or a member of the social work team.

The clinical nurse coordinator played critical provider- and patient-support roles. This position was part time (60 percent) and was held by an experienced registered nurse who also worked as the PHP clinic's urgent care triage nurse (40 percent). Her daily presence in the clinic afforded her familiarity with most of the patients and providers, and this knowledge contributed greatly to the visibility of the program and to patient support. She provided patient education about buprenorphine and conducted initial assessments of treatment eligibility. Under the supervision of the prescribing physician, she monitored and counseled patients during their treatment and ran weekly support groups. She assisted qualifying physicians in submitting their DATA 2000 waiver notifications and promoted and delivered provider trainings in the clinic and in the community. Her expertise as a psychiatric nurse with many years of experience working in the OTOP methadone clinic as both a counselor and a triage nurse was of great additional benefit to the Beehive Program.

Implementation

We developed written clinical guidelines for the implementation of the Beehive model in collaboration

with the SFPDPH OBOT program and the Integrated Buprenorphine Intervention Service (see “Clinical Guidelines for Prescribing Buprenorphine in the Office-Based Treatment of Opioid Dependence at the UCSF Positive Health Program” in Resource 1C). The implementation protocol was written when buprenorphine was donated by the manufacturer and was stored at and dispensed from the clinic. CURES required the submission of monthly dispensing reports (Resource 1B). Effective January 1, 2009, the CURES reporting system transitioned to an online, weekly reporting system. California clinics planning to dispense buprenorphine directly to patients should consult the CURES Web site for current regulations (<http://ag.ca.gov/bne/cures.php>).

Patient Selection

Patients received information about buprenorphine therapy and program expectations (Resource 1C) before an initial assessment of clinical eligibility for buprenorphine treatment (Resource 1A). The initial assessment process provided an opportunity for the treatment team and the patient to gather information to decide whether the program was likely to meet the patient’s needs and expectations and to prepare for the induction visit. The initial assessment process could be accomplished in one or two visits, depending on the patient’s preference.

Each patient’s suitability for buprenorphine treatment was confirmed, including a diagnosis of opioid dependence and review of other inclusion and exclusion criteria. We used the following inclusion criteria:

- Patient is at least 18 years old.
- Patient meets *DSM-IV* criteria for opioid dependence (see worksheet in Resource 1B).
- Patient, if female, is not pregnant, is not trying to become pregnant, and is not nursing. (Buprenorphine has been classified by the FDA as a Pregnancy Category C medication.)
- Patient is eligible for medical care at a Department of Public Health site.

Our exclusion criteria were as follows:

- Patient has serious uncontrolled or untreated psychiatric problems (e.g., suicidality, active psychosis).
- Patient has serious uncontrolled or untreated medical problems (e.g., hypertension, hepatic failure, asthma, diabetes).

- Patient takes more than 30 mg per day of methadone.
- Patient has a chronic pain disorder for which high-dose opioid analgesic medication is required (evaluated on a case-by-case basis).
- Patient uses alcohol in a chaotic manner (i.e., binge drinker).
- Patient uses high doses of nonprescribed or misuses prescribed benzodiazepines, sedatives, or hypnotics.
- Patient requires the structure of a higher level of care (i.e., methadone maintenance).
- Patient has a known allergy or hypersensitivity to buprenorphine or naloxone.

Clinical Assessment

All eligible patients had a complete health history and recent physical exam documented in their medical chart prior to treatment initiation. We obtained a substance use history (e.g., current opioid habit, other substance use, previous opioid treatment) and reviewed co-occurring medical conditions (e.g., liver disease, pain syndromes, mood disorders) and lab work (liver enzymes; urine, drug, and pregnancy tests). Active medications were reviewed carefully because many HIV antiretroviral and psychiatric medications are metabolized by the cytochrome P450 3A4 system and may necessitate buprenorphine dose adjustments. For female clients of childbearing age, we assessed and documented effective use of birth control. A physical exam documented any signs of opioid withdrawal, substance intoxication, and sequelae of drug or needle use.

Preparation for Treatment

In preparing a patient for treatment, we elicited what the patient knew about buprenorphine treatment and provided additional information to close any knowledge gaps. We discussed the patient’s goals, motivations, and readiness for treatment and noted potential barriers to success as well as strengths. The patient reviewed and signed an authorization to exchange health information, treatment consent, and take-home dose agreement (Resource 1B). To reduce the risk of precipitated withdrawal during buprenorphine induction, we instructed patients to arrive at the clinic on the first day of treatment in an opioid-free state. To help them achieve this state, we offered our patients a “kick pack” of nonopioid medications tailored to treat their specific anticipated withdrawal symptoms (e.g., nausea, rhinorrhea, diarrhea, myalgias).

BOX 1-1. ASSESSING SYMPTOMS OF OPIOID WITHDRAWAL FOR BUPRENORPHINE INDUCTION: SOAP NOTE FORMAT

Subjective Data

- Elicit symptoms of opioid withdrawal: cravings, anxiety, discomfort, pain, nausea, hot or cold flushes. Include patient subjective rating of these symptoms (mild, moderate, or severe).

Objective Data

- Document signs of opioid withdrawal, including autonomic excitation (elevated blood pressure, increased heart rate), mydriasis, tremors, agitation or restlessness, yawning, rhinorrhea, piloerection, hot and cold flushes, diaphoresis, lacrimation, vomiting, and muscle fasciculations. Utilize the Clinical Opiate Withdrawal Scale (COWS; see Resource B of this volume).
- Observe for signs of substance intoxication, including but not limited to alcohol odor, nystagmus, positive Romberg test, disinhibition, or other altered mental status.
- Labs: Collect urine and send to the SFGH clinical lab for routine toxicology and, for female patients, pregnancy testing.

Assessment

- Is the patient in opioid withdrawal? YES or NO. Include severity (mild, moderate, severe) based on COWS score. The patient should exhibit objective signs of at least mild withdrawal and have a COWS score >5 prior to receiving the first dose of buprenorphine.

Plan

- **NO:** If the patient appears intoxicated or exhibits no signs of withdrawal, then she or he should not be started on buprenorphine. Reschedule the patient for a later date or time. Counsel the patient on the importance of presenting in some withdrawal for a more comfortable overall induction. An exception may be made for patients described in the *Special Populations* section on page 19.
- **YES:** Begin treatment with buprenorphine/naloxone and titrate to the target dose per clinical guidelines protocol.

Induction, Stabilization, and Maintenance

Induction, stabilization, and maintenance on buprenorphine treatment were conducted over a 1- to 3-week period in accordance with published treatment guidelines¹⁹ supplemented by a growing body of literature specifically concerning buprenorphine treatment in HIV/AIDS patients.²⁰⁻²²

We used a SOAP note format (Subjective data, Objective data, Assessment, Plan) to assess physical dependence (symptoms of withdrawal) and for starting and maintaining patients on buprenorphine (Box 1-1).

We began treatment with a sublingual dose of 2 mg for patients exhibiting mild withdrawal and 4 mg for moderate to severe withdrawal (Resource 1C). Most patients experienced relief of opioid withdrawal symptoms within the first 5 to 15 minutes after tablet dissolution. We

administered an additional dose of 2 to 4 mg if patients experienced no change or only mild improvement in their withdrawal symptoms. We provided patients with another 2 to 4 mg to take as needed later that evening and with take-home doses for the next 1 to 2 days. A sudden exacerbation of withdrawal symptoms after the first buprenorphine dose often suggested precipitated withdrawal. In this case, we reviewed the patient's last opioid use, provided nonopioid symptom management, and instructed the patient to return the following day for reevaluation.

Patients returned to the clinic in the next 1 to 2 days for reevaluation and upward dose titration. Typical daily doses during the first week of induction ranged from 8 to 12 mg and did not exceed 16 mg. In the second week, typical daily doses might increase to 20 to 24 mg. Criteria for dose increases included (1) significant opioid craving,

(2) significant opioid withdrawal symptoms, and (3) urine drug testing that was persistently positive for opioids.

We defined a stable dose as that which results in the optimal relief of objective and subjective opioid withdrawal symptoms. This expected range was 12 to 16 mg daily, although much lower doses were sufficient for patients on boosted atazanavir and other ritonavir-containing antiretroviral regimens. Patients on efavirenz-containing regimens did not require higher buprenorphine doses. The maximum daily dose is 32 mg, which we only rarely exceeded in cases in which patients reported that split dosing resulted in substantial relief of chronic pain syndromes.

Maintenance Phase Monitoring

Most patients achieved a stable target dose within the first 2 weeks and entered into a maintenance phase of treatment. Medication visits were scheduled initially weekly, then every 2 weeks, and then monthly for clinically stable patients. Stable patients were expected to see the prescribing physician at least once every 3 months.

Urine drug testing was conducted throughout all phases of treatment as a consensual diagnostic test to document treatment adherence, aid in the diagnosis and treatment of continued or other substance abuse, and support patient advocacy in family and social issues. The frequency of urine drug testing ranged from once weekly during induction and stabilization to monthly in clinically stable patients. Patients with opioid-negative urine tests received affirmation and other positive reinforcements. Drug-positive urine tests were treated as opportunities for counseling and brief intervention.

At the SFGH clinical lab, buprenorphine was not included in the routine urine assay for drugs of abuse, but we occasionally observed cross-reactivity with the lab's opioid screen. Buprenorphine confirmation testing could be requested from the Lab Medicine resident within 1 week of testing. (In 2010, the SFGH clinical lab began to offer urine assays for buprenorphine and norbuprenorphine [the primary active metabolite of buprenorphine] as a write-in lab order.) Point-of-service drug kits offer specific buprenorphine tests and may be useful in settings where diversion is suspected.

Medication Dispensing and Prescribing

Buprenorphine is a Schedule III controlled substance and does not require a security prescription. Therefore, when medications were not dispensed directly by the Beehive

Program, maintenance prescriptions could be called in or faxed with an original signature to the CBHS pharmacy or community pharmacies.

Counseling

Treatment programs that provide regular, frequent, and structured counseling focused on substance use have consistently achieved better treatment outcomes than those that provide little or no counseling.^{23,24} Although patients are likely to reduce their nonmedical or illicit use of opioids with OAT alone, the addition of counseling in the treatment typically results in greater reductions in opioid and other substance use.²⁵ We conducted brief counseling during medication visits and offered individual counseling onsite with trained PHP social workers or through referral to offsite mental health services partners. We offered weekly group counseling for support and relapse prevention tools. The Beehive clinical nurse coordinator facilitated buprenorphine support groups and psychoeducational groups about psychosocial, behavioral, and medical conditions. Common topics included coexisting medical conditions (e.g., hepatitis C virus), medication and treatment adherence, nutrition, pain management, sexual risk reduction, and coping skills for symptoms of depression and anxiety.

Record Keeping and Communication

We documented each Beehive Program patient visit as a progress note in the patient's primary care electronic medical record, and these notes were reviewed quarterly by the Beehive medical director. In addition, we personally notified primary care providers of their patient's progress through the induction and stabilization stages of treatment and provided regular updates on maintained patients. Copies of treatment consents and authorizations were added to the medical record, and all buprenorphine dispensed from the clinic was documented in the CURES reporting log.

Special Populations

We observed lower effective buprenorphine doses and slower upward titration needed among incarcerated patients. Because jailed patients typically were not referred for treatment until after they had gone through detoxification, they were usually (but not always) opioid free several days to several weeks at the time of presentation for treatment. Their presenting symptoms were typically craving or those of "prolonged abstinence syndrome" rather than frank physical manifestations of opioid withdrawal. Opioid effects (i.e., feeling "high") were reported consistently among incarcerated patients with daily doses as low as 2 to 4 mg.

We also observed that at or just prior to the time of release from jail, drug cravings increased even among patients stabilized in jail on buprenorphine. Because cravings triggered by environmental cues or even mild stress are predictors of relapse, we often considered a small dose increase prior to release from jail. In the Beehive Program, we recommended that jail health staff dispense at least 2 days of discharge buprenorphine medication in patient's property (see jail protocol in Resource 1C). Because an incarcerated patient's release date is unpredictable, we made sure that patients knew where they could go for follow-up care if they were released unexpectedly.

Buprenorphine-experienced patients are another special population. Patients who have previously been treated with buprenorphine are usually quite knowledgeable about its effects. They also are familiar with their own withdrawal syndromes and craving symptoms and demonstrate both comfort and skill at restarting the medicine without direct clinical observation. These patients may be appropriate for home induction with buprenorphine, a practice that has been reported with select patients as both safe and effective.^{26,27} At the Beehive Program, buprenorphine-experienced patients were given telephone or pager access to the clinical staff for advice and coaching through the home induction, if needed.

Other Issues

Contingency Planning, On-Call and Back-up Systems, and Clinical Consultation. When a patient shows no significant improvement or a worsening clinical course, it may be due to progression of the illness, additional physical or psychological stressors, inadequate or inappropriate treatment, or noncompliance with treatment. Our treatment team worked closely with these patients to help identify contributing factors and strategies to overcome them, and we increased the frequency of monitoring and counseling. When the level of care could not meet the needs of the patient, outside providers or programs such as intensive case management, day treatment, supportive housing, or residential treatment were considered. Transfer to OTOP for more structured methadone treatment was another option, and the Beehive care team could access the OTOP "warm line" for real-time consultation on challenging cases and for patient case conferences.

We also developed policies and procedures for on-call and back-up systems. All PHP patients have access to an HIV provider during clinic hours and through an answering service at nights and on weekends. In addition, the

Beehive physicians and nurse carried pagers to field project-specific queries and concerns from participating patients. Finally, an OBOT-OBIC on-call addiction specialist is available by phone and pager for warm line consultations concerning buprenorphine dosing, eligibility, counseling, and stabilization.

Patient Termination. On some occasions, a patient decides to discontinue buprenorphine treatment. The ideal candidate is socially stable, has developed supportive relationships with non-drug users, has discovered alternative ways of dealing with the precipitants to drug use, and is confident and motivated to taper off opioid agonist therapy. Buprenorphine-maintained patients who were clinically stable and wanted to discontinue treatment were tapered slowly. Slow tapers have been shown to be more successful than rapid tapers.²⁸ The pace of a voluntary taper was determined by the patient and could be halted or reversed at the patient's request.

Diversion, theft, and threatening behavior or violence were viewed as serious breaches of program rules. If diversion was suspected, the prescribing physician was notified immediately. Witnessed diversion activity usually resulted in involuntary detoxification and discharge. Other reasons for termination from the Beehive Program included an act or threat of violence against a patient or clinic staff; possession of weapons; violation of the program rules and regulations; harassment of other patients or staff on the basis of gender, ethnicity, or sexual orientation; stealing or other illegal acts on the clinic grounds; duplicate registrations in this and other OAT programs (methadone or buprenorphine); and tampering with urine toxicology samples.

Program and Process Evaluation

Beehive Program Evaluation

Multisite outcome evaluation activities were determined in collaboration with HRSA and the Coordinating Center at the New York Academy of Medicine, and a local evaluation team conducted a process evaluation. The process evaluation examined the configuration, implementation, and performance issues of the Beehive Program, whereas the multisite outcome evaluation focused on progress in the treatment of each patient's addiction, health, mental health, and psychosocial status. These findings have been published in the *Journal of Acquired Immunodeficiency Syndrome*.²⁹

Process Evaluation

The goal of the process evaluation was to document how the program was implemented. The process evaluation

documented the project's fidelity to the proposed service model and reported the extent to which the project accomplished its stated goals and objectives. A formative evaluation was conducted during the first project year, and an annual program chronology tracked qualitative and quantitative data on successive stages of implementation. We asked the following questions:

- What is the level of provider (or patient) acceptance of integrated care?
- What are the barriers and facilitators for HIV primary care physicians successfully providing integrated buprenorphine opioid abuse treatment and HIV primary care?
- What clinical and ancillary support services are needed to provide high-quality, effective, and integrated care?
- What are the barriers and facilitators for clients successfully engaging in integrated buprenorphine opioid abuse treatment and HIV primary care?

The evaluation team described the intervention and the characteristics of providers, clinicians, and agencies that participated in the intervention. They documented the number of patients served by each provider in the program, the recruitment and retention into buprenorphine treatment, utilization of program counseling, and the use of alternative treatment modalities and other support services. They also monitored staff training and turnover, the utilization of consultation services, and other challenges. Evaluators also documented organizational structure, system influences, and other contextual factors that affected how the project was implemented and how long implementation took. The evaluators described differences between design and implementation and identified problems in the program's operations early in the implementation phase so that modifications could be made to achieve program goals and objectives. The process evaluation examined critical aspects of the program, such as recruiting strategies, eligibility criteria, patient characteristics, treatment-duration and patient-attrition rates, and the ability of the program to meet its objectives. Measures of accomplishment were drawn from program records, patient enrollment and discharge data, provider participation in trainings, and patient outcomes, as documented by project forms, medical records, and follow-up interviews. Data sources were relevant file documents, the project's data collection instruments, electronic patient records, SFDPH database records, observation of services, interviews with patients and former patients, and interviews with key staff.

Monthly implementation meetings were held during which the evaluation team presented its observations and made recommendations to the program staff and consultants. These meetings provided the opportunity to review and discuss what was working and to identify areas that required strengthening or modification.

Buy-in From Stakeholders and Providers

The most important local stakeholders in this intervention were the patients, medical providers, clinic staff and administration, and hospital pharmacy. Additional stakeholders in the community were other substance use treatment providers, including public and private methadone clinics and residential detoxification and rehabilitation facilities, and the criminal justice system (i.e., the Forensic AIDS Program and the San Francisco Jail Health Services). Higher-level stakeholders included the SFDPH; the California State Office of AIDS, which oversees the AIDS Drug Assistance Program (ADAP); and the California Bureau of Narcotic Enforcement.

We were fortunate to have the full support of our clinic administration and local public health department before embarking on this intervention. We were least successful in obtaining buy-in from our hospital pharmacy and our State ADAP, and we attributed this difficulty to a severe statewide economic downturn that resulted in statewide work furloughs and budget cuts. The most challenging stakeholders were the HIV medical providers, specifically physicians.

Physician Buy-In

One of the biggest challenges integrating buprenorphine into our HIV primary care clinic was our own physicians' lack of familiarity with a new medication and discomfort with induction procedures. In an informal survey of HIV primary care physicians at the PHP, provider-perceived barriers were lack of skill or knowledge about induction, lack of clinic infrastructure, and chronic pain management. The part-time nature of most physicians' involvement in HIV primary care at our institution contributed to the low dose and uptake of buprenorphine training, certification, and practice. With typically only one-half day per week spent in the clinic, most PHP physicians preferred to refer their patients for buprenorphine treatment rather than invest in the training and waivers to provide treatment themselves. By contrast, midlevel practitioners (i.e., nurse practitioners) cared for the majority of primary care patients in our clinic but were not eligible under current Federal laws to obtain waivers to prescribe buprenorphine.

To address physician concerns about induction, we offered a phased-in approach to induction training. Waivered physicians could participate in a clinical orientation and practicum at OBIC before treating their first patients. At this hands-on training, which might consist of one morning to several days, according to their preference, physicians observed and then practiced OBIC induction protocols with an OBIC provider.

Critical to any integrated buprenorphine treatment program is the ability to develop and sustain an active dialogue about opioid-use disorders with clinic providers, front-line staff, and administrative leadership. Our activities included scheduled program updates and discussions at monthly provider and clinic staff meetings about opioid analgesic use and misuse, given that so many of our clinic patients receive prescriptions for chronic pain. We conducted addiction case presentations at HIV/AIDS grand rounds and medical grand rounds and at national HIV continuing medical education courses. We also engaged in individual consultation with providers to help them assess their opioid-dependent patients for buprenorphine eligibility and to provide frequent communication during buprenorphine treatment phases. We streamlined our Beehive referral procedures to allow providers to refer their patients directly through appointments made at the front desk and eliminate the need for referral phone calls or for filling out consultation request forms. Providers were able to contact the Beehive physician in person by pager, telephone, or e-mail.

Other activities we pursued that have the potential to affect provider buy-in include a series of inquiries designed to better elucidate providers' opioid-prescribing practices. A Quality of Opioid Prescribing workgroup was convened when it was noted that a significant number of opioid-dependent patients were not considered or referred for buprenorphine treatment because they were prescribed high doses of opioid analgesics for chronic pain by their HIV providers. With the clinic administration's support, we conducted clinic-level assessments of the quality of opioid prescribing for PHP patients.

In a supplemental and voluntary online survey, "Quality of Opioid Prescribing in HIV Primary Care," we asked a national sample of HIV providers about their demographics, experience, and patients. We assessed provider practices and attitudes about chronic opioid therapy, addiction, and confidence in recognizing opioid analgesic abuse. Responses were received from 106 providers, who

reported that 28 percent of their patients had chronic pain, 21 percent received opioid analgesics, 37 percent were HIV-infected by injection drug use, and 12 percent were addicted to prescription opioids. Few providers followed recommended guidelines for chronic opioid therapy in managing nonmalignant pain. Mean provider confidence was 6.3 on a scale of 10. Higher confidence was associated with male provider sex ($p = .04$), patient volume ($p < .03$), discussing substance use, ($p = .03$), urine toxicology ($p = .01$), prescribing longer-acting opioids ($p = .001$), and prescribing buprenorphine ($p = .009$). We concluded that HIV providers seldom follow recommended guidelines for opioid prescribing and have limited confidence in their ability to recognize opioid analgesic abuse.³⁰

Because clinical practices developed to reduce misuse and increase early detection and treatment of opioid dependence are associated with higher confidence, we initiated the groundwork to develop evidence-based clinical guidelines to assist providers in managing pain for their opioid-dependent patients with HIV/AIDS.

Steps to Success: Overcoming Barriers and Promoting Factors Contributing to Adherence

We took steps to address other challenges to buprenorphine treatment: provider uptake, patient acceptance, pain syndromes, and medication costs.

Provider Uptake

Provider barriers that impair the broad delivery of integrated HIV-buprenorphine services include the limited clinical duties of faculty physicians in academic medical centers, a lingering hospice-model approach to pain management dating to the pre-HAART era, clinical naïveté in recognizing and diagnosing opioid-use disorders, and personal discomfort addressing drug use. Potential prescribing physicians also expressed disappointment when they learned that buprenorphine was not available through the hospital outpatient pharmacy for medically indigent patients.

To overcome some of these provider barriers, we took frequent opportunities to expose a larger group of PHP clinic providers to problem-based learning about addiction, chronic pain management, opioid addiction treatment, and appropriate use of buprenorphine. We provided onsite training and education to early-career medical professionals, including nursing students, medical students, resident physicians, and clinical fellows. Two HIV Clinical Scholar's Fellows received their buprenorphine waivers (2006–2008),

and one became actively involved as a prescriber in the Beehive Program following her fellowship and until her departure for another institution in 2010. We also provided trainings to community providers, including OTOP methadone clinic staff and county jail staff. Two jail health physicians are buprenorphine prescribers, and we trained a jail nurse to evaluate and monitor incarcerated buprenorphine patients. We drafted a nurse practitioner protocol describing the nurse practitioner's role in buprenorphine treatment, and the protocol was approved by the SFDPH for use in all of its CHN clinics. We are providing skills-based training to resident physicians and nurse practitioners to reduce provider discomfort with substance use discussions.

The success of the Beehive Program also depended on a wider network of outreach and education to local community substance use treatment providers and other service providers about buprenorphine and the medical management of opioid dependence. Regular reports to PHP providers as well as to other community clinics and service organizations promoted valuable feedback and generated clinical interest in referring patients to office-based buprenorphine treatment.

Patient Acceptance of Buprenorphine

Just as physicians must be trained and well prepared to prescribe buprenorphine, patients must be equally trained and have clear expectations of all stages of buprenorphine treatment. We identified five patient factors that influenced program participation and treatment adherence, as follows:

1. **Treatment readiness.** Some patients reported and demonstrated ambivalence about drug cessation. One of our patients chose to return to a methadone maintenance program because she “just liked to get high” once in a while. She could achieve an opioid euphoria by using heroin on top of methadone but not on buprenorphine. Another chose to return to the sedating side effects of methadone treatment because she “couldn't handle the reality” of being awake on buprenorphine.
2. **Fear of opioid withdrawal.** Other patients feared the potential discomfort of needing to be in opioid withdrawal on the day of induction and the potential for precipitated withdrawal during the induction process. Others had the misperception that the naloxone component of the combined formulation would precipitate withdrawal if they used opioids in the presence of buprenorphine. One patient reported she kept waiting for “the Narcan [naloxone] to kick in” during

her induction. Another potential patient declined to transfer from a very low 18-mg daily methadone dose to buprenorphine because she thought that naloxone worked like disulfiram. She believed that consuming any alcohol, even that used for cooking, would activate the naloxone component of the medication and put her into withdrawal (e.g., an Antabuse-like effect).

3. **Disorganization.** Many of our patients were more marginalized and impaired than the general HIV/AIDS patient population in San Francisco. They had greater difficulty keeping appointments and required intensive case management. Indeed, out-of-treatment patients that present for buprenorphine office-based treatment may be more disorganized and less stable than those able to enroll and attend methadone maintenance programs.
4. **Competing priorities.** Many patients contend with a daunting array of competing priorities, such as obtaining food and housing, frequent incarceration, severe mental illness, and a thriving underground economy based on the diversion and resale of prescription opioids and sedative-hypnotics. One potential patient reasoned, “Why give up my OxyContin prescription for buprenorphine, when I can support my crack habit and buy Christmas presents for my family?”
5. **Concurrent opioid use.** Many HIV-infected patients in San Francisco take full-agonist opioid medications, whether receiving methadone from a narcotic treatment program, obtaining prescription opioids from their primary care provider for chronic pain, or making street purchases for recreational use. SFGH has been identified as a source for many of the street narcotics confiscated by police officers in San Francisco.

To address these patient-related challenges, we continued to assess and revise our patient education, orientation, response, and support processes. We learned to address readiness for behavior change more effectively through motivational interviewing techniques that were designed to elicit, explore, and resolve ambivalence. Consistent, effective, patient-centered communication with patients through cycles of recovery, ambivalence, and relapse was critical to our success. Patients who dropped out often returned when we invested in developing a more empathetic patient-provider relationship or guiding style of provider consultation.³¹

We also observed that buprenorphine induction does not precipitate intolerable opioid withdrawal symptoms among

patients who have prepared sufficiently for induction. Once they have been stabilized on a maintenance dose, patients appear to prefer buprenorphine. However, some patients who may be eligible for buprenorphine treatment may not know enough about it or may have preconceptions about the induction process or buprenorphine's effects or interactions with other drugs and medications. To address this challenge, we developed patient education brochures and information sheets that can be used by individual physicians and members of the treatment team in the exam room during primary care visits (Resource 1A).

Peer testimony is a valuable adjunct to written patient education materials and provider explanations to support patients in their new experiences with buprenorphine. Patient support groups with peer cofacilitation can provide this forum. We began a weekly support group open to patients in different stages of buprenorphine treatment, including those still contemplating starting treatment. This format was based on a similar model that our clinic developed for patients with chronic hepatitis C virus infection. The group is structured to talk patients through the treatment process, address mental health issues, support adherence, enlist allies in care, and promote peer support.

We created an open-door policy for our most disorganized patients and worked closely with intensive case management agencies to enhance the stabilizing forces in patients' lives (i.e., housing, food sources, mental health treatment). We identified and began outreach to other community-based organizations that do not provide primary medical care to PLWHA. Specifically, we undertook a collaboration with the Jail Health Services' Forensic AIDS Project of the City and County of San Francisco to provide integrated HIV-buprenorphine treatment for incarcerated patients and linkages to integrated primary HIV care and buprenorphine treatment at the PHP after jail release.

Acute and Chronic Pain Syndromes

Acute and chronic pain syndromes are commonly seen with HIV infection. Although parenteral buprenorphine at low doses is an effective analgesic for mild to moderate pain, the doses used in the treatment of opioid dependence (and given in the sublingual form) do not provide significant pain relief for the majority of patients on chronic opioid therapy. In addition, buprenorphine will block the analgesic effects of any additional opioids, including prescribed analgesics. Patients who desired buprenorphine treatment but received high-dose chronic opioid therapy for pain presented a significant challenge.

To address the clinical issue of managing new acute or chronic pain in buprenorphine-maintained patients, we received technical assistance from Dan Alford, who introduced us to useful clinical algorithms utilizing buprenorphine and methadone. We also cared for patients with mild to moderate pain who chose to undertake a trial of buprenorphine in divided doses. With the support of our clinic's medical director, we (1) conducted an anonymous waiting-room survey of patients in 2007 regarding the treatment of their pain and their substance use, (2) requested and received raw data from the clinic's electronic medical record to examine provider prescribing patterns and documentation of pain and substance use problems, and (3) developed and administered a multisite provider survey of providers' attitudes and behavior concerning pain management and substance-using patients.

In the patient waiting-room survey, we compared responses between patients reporting heroin or nonprescribed opioid use in the past month (active users) and patients reporting no illicit opioid use in the prior month (nonusers). Variables included demographics, pain characteristics and treatment, patient satisfaction, and provider relationships. Of the 262 patients who responded, 81 percent were male, 46 percent were White, mean age was 44 years, and 24 percent met criteria as active users. Most respondents (89 percent) reported ever having a problem with pain, and 59 percent reported chronic pain, defined as pain for more than 3 months. Compared with nonusers, active users were more likely to report any history of pain ($p = .03$), current pain ($p = .02$), and chronic pain ($p = .03$).

Preliminary analysis of a 2006 dataset from our electronic medical records ($n = 957$ unduplicated patients) examined the prevalence of HIV patients in our clinic with chart documentation of (1) an opioid-use disorder, (2) opioid analgesic prescriptions, or (3) a pain disorder. Sixty percent of patients with an opioid-use disorder also had a pain diagnosis in their medical chart, 40 percent of patients with an opioid-use disorder were prescribed opioid analgesics, and 18 percent of patients prescribed opioid analgesics had an opioid-use disorder charted. Because these data derive from a clinical database relying on providers to enter diagnoses and prescriptions, it likely underestimates the true prevalence of these conditions.

Finally, we participated in a citywide pain task force that was formed to address the systemwide issues of pain

management, prescription opioid analgesic abuse, and diversion. We have now treated several PHP clinic patients with buprenorphine for prescription opioid dependence.

Medication Costs

The cost of buprenorphine for patients without an outside payor source was approximately \$10 per day. Consequently, another challenge was consideration of the costs of buprenorphine for patients, who are mostly indigent and on very limited incomes. Although the State Medicaid program approved TARs for buprenorphine patients, many other patients did not qualify for Medicaid benefits. To address this challenge, we initially set aside program funds to purchase a limited amount of medication for indigent patients and worked with the SFDPH CBHS to request product support from the manufacturer while we advocated for the addition of buprenorphine to the list of medications covered by our hospital's outpatient formulary and the California ADAP formulary. Subsequently, we negotiated with the CBHS pharmacy director to provide free buprenorphine medication for five medically indigent patients at the start of the program. We were fortunate in the following years to receive free medications from the manufacturer for the remainder of the SPNS project period. Since the end of the SPNS funding, medically indigent patients have been able to receive medication again from the SFDPH's CBHS pharmacy for an unknown period of time, and Medicaid continues to approve TAR applications. To date, no one has been turned away from treatment because of a lack of funds, but finding a reliable and stable source of buprenorphine for our poorest patients remains a significant challenge.

Leveraging Sustainability

Since the end of SPNS project funding in 2009, we made significant changes to maintain the program's sustainability and to promote office-based opioid dependence treatment in general.

Service Provision

Three HIV/AIDS physicians in the PHP continued to prescribe and manage an active buprenorphine practice in their HIV primary care clinics. Our practice is conducted on a smaller scale primarily as a result of the absence of our clinical nurse coordinator, who was funded by the SPNS project and has now retired. We no longer store and dispense buprenorphine onsite at the clinic, because we no longer receive donated medication from the manufacturer and do not have the clinical nurse coordinator

support to submit weekly CURES reports. Our own hospital has not added buprenorphine to its outpatient formulary, although Medicaid patients may obtain the medication with preauthorization from community pharmacies and the CBHS pharmacy operated by the SFDPH. Consequently, we have made the following adjustments in our Beehive Program protocol:

- Patients may fill their first prescription and bring the medication back to the clinic for onsite induction.
- Selected patients who demonstrate a good understanding of the medication's pharmacodynamics may receive detailed written instructions and a prescription for a small quantity of buprenorphine for home induction.
- Patients requiring more preparation and clinical support may be referred to OBIC for induction and stabilization and then return to the PHP clinic for maintenance treatment by a buprenorphine-prescribing physician.

Our providers remain committed to offering continued office-based buprenorphine treatment. Medically indigent patients who are unable to obtain Medicaid or private health insurance to pay for buprenorphine are referred to OBIC and the CBHS pharmacy for treatment subsidized by the SFDPH. In 2010, an experienced addiction psychiatrist started to see PHP patients on a volunteer basis once weekly. She provides yet another venue for HIV-infected patients to receive buprenorphine at our clinic.

Provider Training

We drafted new policy and procedure documents describing the training and role of nurse practitioners in buprenorphine treatment. These documents were adopted in 2008 by the credentialing committees of SFGH and the SFDPH CHN. Although nurse practitioners are still not allowed to prescribe buprenorphine, they care for the majority of PHP patients and may play a significant role in the evaluation and monitoring of buprenorphine-treated patients. We continue to train and mentor nurse practitioners at the PHP and other CHN clinics, according to the approved policy. We continue to recruit and mentor other physicians and nurses to participate in 8-hour trainings and buprenorphine treatment, and we support qualifying physicians in obtaining their waivers.

In addition, we received funding from a SAMHSA cooperative agreement to train resident physicians at SFGH on

how to conduct screening, brief intervention, and referral to treatment (SBIRT) for their patients with or at risk of substance use disorders. We view this new program as a natural extension of the work that was begun in the area of provider training in this HRSA-funded SPNS project. A lesson learned from this project is the impact of a limited or absent addiction medicine curriculum in undergraduate and graduate medical education on future providers' comfort and willingness to provide OBOT. Consequently, we have included training about opioid-use disorders and buprenorphine in our intensive SBIRT curriculum at SFGH. Medical residents visit our methadone and buprenorphine clinics, and we support senior residents' participation in the required 8-hour DATA 2000 trainings to receive their buprenorphine waivers. In early 2011, 55 resident physicians and other clinicians in internal medicine and family medicine participated in a 4-hour self-study and 4-hour face-to-face training at SFGH, which we offered in collaboration with the PCSS-B.

The role of SBIRT in HIV/AIDS clinics is the subject of a feasibility study for which we received funding in 2009 from the American Recovery and Reinvestment Act of 2009. By increasing the detection and diagnosis of opioid-use disorders at the PHP through the implementation of SBIRT procedures programmed in our electronic medical record system and introduced to HIV primary care providers and social work teams, we have sustained the clinical discourse on opioid-use disorders and triggered greater recognition by providers of office-based buprenorphine training and treatment.

SPNS program funding helped maintain Beehive Program clinical activities during the project period—specifically, the funding of the clinical nurse coordinator, who played a vital role in day-to-day implementation of the Beehive Program. Dissemination activities have demonstrated the majority of HIV primary care provided by nurse practitioners and the potentially beneficial role they can play in integrated buprenorphine treatment. Finally, dissemination activities have helped secure other Federal funds for buprenorphine exposure at the level of graduate medical education and pilot studies to test interventions that may increase the detection and treatment of opioid-use disorders at our HIV/AIDS clinic.

Resources

The chapter resources reproduce the tools, forms, and materials either developed or utilized by our integrated buprenorphine-HIV/AIDS program. In addition, the

following Web sites may be helpful to clinicians desiring to implement a buprenorphine treatment program for their patients with HIV/AIDS:

- BHIVES Integrated Buprenorphine and HIV Care Evaluation and Support Center, <http://www.bhives.org/bhives/index.php>
- SAMHSA Buprenorphine Web site, <http://buprenorphine.samhsa.gov/index.html>
- PCSS-B, <http://www.pcssb.org/>
- National Alliance of Advocates for Buprenorphine Treatment, <http://www.naabt.org/>
- Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction: A Treatment Improvement Protocol, TIP 40, http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf
- Technical Assistance Publication 30: Buprenorphine: A Guide for Nurses, http://buprenorphine.samhsa.gov/TAP_30_Certified.pdf

Conclusion

Uncontrolled opioid-use disorders interfere with life-saving HIV antiretroviral medication access and adherence, may contribute to HIV pathogenesis, increase HIV transmission risk behavior, and destabilize patients socially and financially. Office-based buprenorphine treatment for HIV-infected patients with opioid dependence is an alternative to MMT programs and can be included in an integrated care model to HIV primary care clinics. Although the daily presence of a clinical nurse coordinator (i.e., a glue person) permits a larger-scale and more comprehensive delivery system for office-based opioid treatment, individual prescribers can implement treatment protocols successfully in their own practice and with patients referred by nonwaivered colleagues. The number of active prescribers at a clinic is a significant rate-limiting step, and we anticipate that efforts to train and waiver more qualified clinicians, including resident physicians, fellows, and midlevel practitioners, will contribute to higher adoption and acceptance of buprenorphine treatment in HIV care settings.

Our own Beehive Program has benefited greatly from a supportive public health department that provides induction services, hands-on provider training opportunities, and free medications for medically indigent patients. The PCSS-B also provides practical clinical consultation to providers nationwide. At SFGH's PHP, an active clinicwide

dialogue about opioid-use disorders and concern about safe opioid prescribing have helped raise awareness about and sustain the practice of office-based buprenorphine treatment in our HIV primary care practice. In a health care environment where effective, evidence-based

opioid-use treatment is not always easily available to those who need it and for whom it may make all the difference in the world, including office-based buprenorphine treatment in a menu of integrated HIV services is sensible, feasible, and needed.

References

1. American Psychiatric Association, *Diagnostic and statistical manual of mental disorders* (4th ed., text rev.). Arlington, VA: Author; 2000.
2. San Francisco Department of Public Health, HIV Prevention Section. *HIV/AIDS epidemiology annual report: HIV Epidemiology Section, 2008*. Available at: <http://sfhiv.org/documents/AnnualReport2008.pdf>.
3. San Francisco Department of Public Health, HIV Seroepidemiology and AIDS Surveillance Section. *HIV/AIDS epidemiology annual report, 2000*. Available at: http://sfhiv.org/files/data_reports/hiv_aids_annual_rpt/HIVAIDSAnnRpt2000.pdf.
4. Substance Abuse and Mental Health Services Administration, Drug Abuse Warning Network. Major drugs of abuse in ED visits, 2001 Update. *DAWN Report*, October 2002. Available at: www.oas.samhsa.gov/dawn.htm.
5. San Francisco Department of Public Health, Community Programs Division. *2002 overview of health: who we are, how we live, our health*. Available at: [ww.sfdph.org/dph/files/reports/StudiesData/OvrViewHlth/OvrviewHlth02/OvrviewHlth02All.pdf](http://www.sfdph.org/dph/files/reports/StudiesData/OvrViewHlth/OvrviewHlth02/OvrviewHlth02All.pdf).
6. Centers for Disease Control and Prevention. Soft tissue infections among injection drug users—San Francisco, California, 1996–2000. *MMWR*. 2001;50:381–4.
7. Masson CL, Sorensen JL, Batki SL, et al. Medical service use and financial charges among opioid users at a public hospital. *Drug Alcohol Depend*. 2002;66:45–50.
8. Cunningham JK, Thielemeyer MA. *Heroin/opioid-related hospital admissions: trends and regional variations in California (1986–1995)*. Irvine, CA: Public Statistics Institute; 1997.
9. Meredith L, Abramowitz A. *San Francisco substance abuse indicator data: problems and their treatment in context*. San Francisco, CA: San Francisco Department of Public Health Community Substance Abuse Services; 1995.
10. San Francisco HIV Prevention and Planning Council. *2001 San Francisco HIV prevention plan*. San Francisco, CA: San Francisco Department of Public Health AIDS Office; 2001.
11. Compton WM, Volkow ND. Major increases in opioid analgesic abuse in the United States: concerns and strategies. *Drug Alcohol Depend*. 2006;81:103–7.
12. Tsao JC, Dobalian A, Naliboff BD. Panic disorder and pain in a national sample of persons living with HIV. *Pain*. 2004;109:172–80.
13. Rosenfeld B, Breitbart W, McDonald MV, et al. Pain in ambulatory AIDS patients. II: impact of pain on psychological functioning and quality of life. *Pain*. 1996;68:323–8.
14. Vogl D, Rosenfeld B, Breitbart W, et al. Symptom prevalence, characteristics, and distress in AIDS outpatients. *J Pain Symptom Manage*. 1999;18:253–62.
15. Del Borgo C, Izzi I, Chiarotti F, et al. Multidimensional aspects of pain in HIV-infected individuals. *AIDS Patient Care STDS*. 2001;15:95–102.
16. Tsao JC, Stein JA, Dobalian A. Pain, problem drug use history, and aberrant analgesic use behaviors in persons living with HIV. *Pain*. 2007;133:128–37.
17. Asher A, Little S, Lum PJ. *Treating pain and assessing substance use at an HIV/AIDS clinic*. Paper presented at: the 20th Annual Conference of the Association of Nurses in AIDS Care; 2007; Orlando, FL.
18. Fiellin DA, O'Connor PG. Clinical practice. Office-based treatment of opioid-dependent patients. *N Engl J Med*. 2002;347:817–23.
19. Center for Substance Abuse Treatment. *Clinical guidelines for the use of buprenorphine in the treatment of opioid addiction. Treatment Improvement Protocol (TIP) Series 40*. DHHS Publication No. (SMA) 04–3939. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2004.
20. Lum PJ, Tulskey JP. The medical management of opioid dependence in HIV primary care settings. *Curr HIV/AIDS Rep*. 2006;3:195–204.
21. Bruce RD, Altice FL, Gourevitch MN, et al. Pharmacokinetic drug interactions between opioid agonist therapy and antiretroviral medications: implications and management for clinical practice. *J Acquir Immune Defic Syndr*. 2006;41:563–72.
22. Sullivan LE, Bruce RD, Haltiwanger D, et al. Initial strategies for integrating buprenorphine into HIV care settings in the United States. *Clin Infect Dis*. 2006;43(Suppl 4):S191–6.

23. Ball JC, Ross A. *The effectiveness of methadone maintenance treatment*. New York: Springer-Verlag; 1991.
24. McLellan AT, Arndt IO, Metzger DS, et al. The effects of psychosocial services in substance abuse treatment. *JAMA*. 1993;269:1953–9.
25. Yancovitz SR, Des Jarlais DC, Peyser NP, et al. A randomized trial of an interim methadone maintenance clinic. *Am J Public Health*. 1991;81:1185–91.
26. Lee JD, Grossman E, DiRocco D, et al. Home buprenorphine/naloxone induction in primary care. *J Gen Intern Med*. 2009;24:226–32.
27. Gunderson EW, Wang XQ, Fiellin DA, et al. Unobserved versus observed office buprenorphine/naloxone induction: a pilot randomized clinical trial. *Addict Behav*. 2010;35:537–40.
28. Senay EC, Dorus W, Goldberg F, et al. Withdrawal from methadone maintenance. Rate of withdrawal and expectation. *Arch Gen Psychiatry*. 1977;34:361–7.
29. Weiss L, Netherland J, Egan JE, et al.; BHIVES Collaborative. Integration of buprenorphine/naloxone treatment into HIV clinical care. *J Acquir Immune Defic Syndr*. 2011;56(Suppl 1):S1–104.
30. Lum PJ, Little S, Botsko M, et al.; BHIVES Collaborative. Opioid-prescribing practices and provider confidence recognizing opioid analgesic abuse in HIV primary care settings. *J Acquir Immune Defic Syndr*. 2011;56(Suppl 1):S91–7.
31. Rollnick S. Consultations about changing behavior. *BMJ*. 2005;331:961–3.

CHAPTER 1 RESOURCES

Resource 1A. Beehive Program Recruitment Materials

<http://www.careacttarget.org/topics/buprenorphine.asp>*

San Francisco Department of Public Health Integrated Buprenorphine Intervention
Services Brochure
Beehive Patient Brochure
Beehive Patient Flyer
Beehive Program Exam Room Laminate Card

Resource 1B. Beehive Program Treatment Forms

<http://www.careacttarget.org/topics/buprenorphine.asp>*

Beehive Program Authorization to Exchange Health Information
Beehive Program Consent to Treatment With Buprenorphine
Beehive Program Take-Home Dose Agreement
Beehive Program Documentation of Clinical Eligibility
Beehive Program Worksheet for *DSM-IV* Criteria for Diagnosis of Opioid Dependence
Prescribers' Direct Dispensing Log Information

Resource 1C. Beehive Program Protocols

<http://www.careacttarget.org/topics/buprenorphine.asp>*

Beehive Program Description for Ward 86 Providers
Beehive Program Provider–Patient Expectations
Referral Procedures for HIV/AIDS Patients From SFGH OTOP to the Beehive Program
Clinical Guidelines for Prescribing Buprenorphine in the Office-Based Treatment of Opioid
Dependence at the UCSF Positive Health Program
San Francisco BHIVES–Jail Health Services Buprenorphine Inventory and Transfer Protocol

* This publication lists non-Federal resources in order to provide additional information to consumers. The views and content in these resources have not been formally approved by the U.S. Department of Health and Human Services (HHS) or the Health Resources and Services Administration. Listing these resources is not an endorsement by HHS or HRSA.



CHAPTER 2

REPORT FROM: CORE BUPRENORPHINE PROJECT

The Buprenorphine Project (BUP) at the Ruth M. Rothstein CORE Center had much success in enrolling, engaging, and retaining HIV-positive, heroin-dependent patients in care. What follows is a “how to” guide for agencies, clinics, and institutions planning similar projects. In addition to information on our implementation process, we have included details on challenges, barriers, and lessons learned along the way to help guide future integration projects.

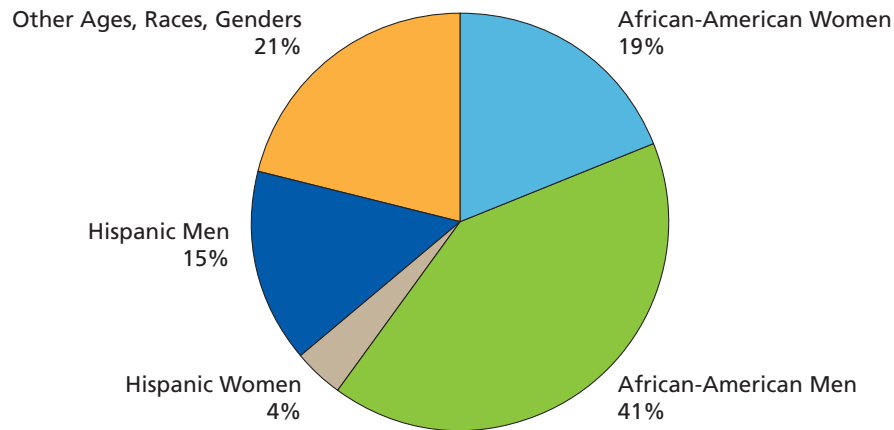
CORE Center Clinic

The CORE Center, an entity of the Cook County Health and Hospitals System, provides health care for patients throughout the Chicago metropolitan area. The services at the CORE Center are guided by its mission: “to provide the highest quality of care for persons affected by infectious disease with respect, dignity and compassion, without regard to the ability to pay; to ensure a patient centered and consumer guided environment; and to seek to better understand and to prevent these diseases through education and research.”

The health system first began providing comprehensive HIV-specific primary medical care and social support services in 1983 through the Cook County HIV Primary Care Center. In October 1998, the program moved from the Fantus Clinic of the Cook County Hospital into the CORE Center. The CORE Center is a recipient of Ryan White HIV/AIDS Program funding (Parts A–D) and is part of the Pediatric AIDS Clinical Trial Group Network and the Adolescent Trials Network. Our combined programs have a large patient capacity; in 2007, they provided more than 32,000 primary care visits to 4,133 unduplicated HIV-positive patients.¹ With the “one-stop shopping” model of care, the CORE Center provides comprehensive multidisciplinary care, including HIV primary care and specialty care (e.g., hematology/oncology, nephrology, neurology, obstetrics/gynecology, hepatitis C care, dental care). Our infectious disease attending physicians, who are expert clinicians with HIV/AIDS treatments, assign all patients to the nearly 75 primary care providers who rotate each week at the CORE Center. In addition, the CORE Center has an onsite pharmacy, a key component in buprenorphine integration. This four-story clinic building serves as a center for HIV care and research in Chicago’s medical district.

The CORE Center has two generous clinic areas with examination rooms and separate counseling rooms for case managers, chemical dependency counselors, mental health counselors, resource infectious disease physicians, a clinical pharmacist, and a benefits manager. The women’s treatment clinic has a separate children’s playroom staffed with child-life specialists. In addition, mental health and psychiatry occupy another section of the building with individual offices, and the chemical dependency department has other individual offices and group meeting rooms for up to four groups at one time. Since its doors opened in 1998, the CORE Center has integrated case management, mental health care, and substance abuse care into its treatment model. This initiative provided 4,519 outpatient substance abuse services (individual and group) and 2,205 psychiatric visits for approximately 750 unduplicated HIV-positive patients in 2007.²

FIGURE 2-1. DEMOGRAPHICS OF HIV-POSITIVE CORE PATIENTS >AGE 24 YEARS, 2007
(N = 4,133 UNDUPLICATED PATIENTS).



For the past decade, the CORE Center has offered mental health counseling for individuals, couples, and groups and substance abuse counseling consisting of a State-accredited intensive outpatient program and aftercare program. All mental health and chemical dependence counselors are licensed clinical social workers, psychologists, or certified alcohol and drug counselors and have an average of 8 years treating the target population.

In 2000, a clinical psychiatrist joined the CORE Center staff and began onsite psychiatric assessments and medication maintenance. With the addition of a psychiatric nurse practitioner in 2003 and a bilingual HIV internist/psychiatrist in 2006, CORE psychiatrists have provided quality care to more than 2,000 unduplicated patients. Psychiatry, mental health, and chemical dependency services work together to provide integrated care.

CORE Community

Although the CORE Center offers a variety of services onsite with the comprehensive care model, it remains a strong partner with city community agencies. The Social Security Administration, the Illinois Department of Children and Family Services, the AIDS Legal Council of Chicago, the Illinois Department of Corrections, and the Illinois Office of Rehabilitative Services all have staff that work at the CORE Center to coordinate among agencies for the benefit of the target patients, focusing on the indigent, the poorly educated, and the disenfranchised. We work with the Midwest AIDS Training and Education Center and the Great Lakes Addiction Technology Transfer Center to provide and receive

specific training in co-occurring HIV and substance use disorder (SUD).

Residential substance abuse treatment centers, methadone clinics, and recovery homes partner with the CORE Center to offer treatment for mutual patients. Many of these programs, such as the Haymarket Center, the Pilsen Wellness Center, and the Women's Treatment Center, provide much needed support and care to minority HIV-positive patients and have been past recipients of the Center for Substance Abuse Treatment (CSAT) Targeted Capacity Expansion (TCE) grants. Housing programs such as Bonaventure House, Interfaith House, and Chicago House provide housing in the HIV community for patients who receive their medical care at the CORE Center. Predominantly Hispanic agencies, such as El Rincon, CALOR, and Healthcare Alternative Systems, connect hard-to-reach clients with HIV care at our center.

CORE Demographics

Illinois ranked sixth among States in cumulative reported AIDS cases, and the City of Chicago is the epicenter for the HIV epidemic in Illinois.³ The Chicago Department of Public Health (DPH) estimates that 26,238 PLWHA live in the City of Chicago, which had nearly 1,200 new infections and 1,000 new AIDS diagnoses in 2006.³ Consistent with national trends, African-Americans and Hispanics in Chicago continue to be increasingly and disproportionately affected by HIV. A total of 4,133 unduplicated patients received treatment for HIV at the CORE Center in 2007: of the adult patients older than age 24, 65 percent were African-American, 19 percent were Hispanic, and 28 percent were women (Figure 2-1).¹

The majority of AIDS cases reported to the Chicago DPH have been among racial/ethnic minority populations since 1990. By 2005, nearly 55 percent of newly diagnosed cases of AIDS were among African-Americans and 16 percent were among Hispanics, although those groups represent 36 percent and 26 percent of the city's population, respectively. African-American men are 1.5 times more likely than their White counterparts to have HIV, and African-American women are more than 8 times more likely than White women to be infected.⁴ This disproportionate impact of HIV disease on the city's racial/ethnic minority populations is also reflected in the geographic distribution of the disease: Twenty-five percent of AIDS patients were among residents of eight mostly minority (greater than 80 percent) and economically disadvantaged areas on the west and south sides of the city.³

Clinic Population

The CORE Center's general population is composed of medically indigent PLWHA in the Chicago metropolitan area. Across from the John H. Stroger, Jr. Hospital of Cook County, in the heart of Chicago's medical district, the CORE Center is geographically placed to capture the underserved and impoverished African-American, Hispanic, and immigrant populations of Cook County. The CORE Center is the central referral site for HIV specialty care for Cook County—the second largest county in the Nation—and for the surrounding five counties and Cook County Jail. Most of our clients reside in 11 of 22 community areas on the south and west sides of Chicago. In those communities, rates of unemployment, poverty, and dependence on public assistance are more than 10 times the Federal averages.⁴ Within this HIV-positive treatment population, the racial, ethnic, and gender distributions mirror the underserved communities served by our health system.

In addition, past studies and current site data indicate alarming rates of SUD within minority HIV patients. Through a research project funded by HRSA, the Substance Abuse and Mental Health Services Administration (SAMHSA), and the National Institute on Drug Abuse, 2000–2002 screening data of new CORE Center adult patients revealed that 460 (51 percent) of 903 new patients had SUD (alcohol or drug) symptoms and 374 (42 percent) had both SUD and mental health symptoms.⁵ Most patients were either African-American (77 percent) or Hispanic (9 percent). This information was gathered using the Alcohol Use Disorders Identification Test

(AUDIT),⁶ AUDIT and drug-related items, the Center for International Disease Information⁷ screener, and the Structured Clinical Interview for *Diagnostic and Statistical Manual of Mental Disorders*, fourth edition (*DSM-IV*) disorders⁸ screening components. Over the past 3 years, data from screenings conducted at Ryan White HIV/AIDS Program case management intakes revealed the following rates of active abuse or dependence for patients entering care at the CORE Center: 10.2 percent for cocaine/crack, 3.8 percent for heroin, 0.8 percent for methamphetamine, 14.8 percent for alcohol, 1.0 percent for hallucinogens, and 11 percent for marijuana.⁴ These data were entered as self-reported “drug of choice” for patients entering and reentering care, with each patient selecting only one drug of choice. Both CORE Center data sources reveal similar rates of SUD (41 to 51 percent) for patients entering HIV primary care at CORE.

Social, legal, and mental health issues place minority HIV-positive patients at even greater peril. Ninety-one percent of our patients have incomes at or below the Federal Poverty Level, and of those for whom employment status is known, 72 percent are unemployed. Closely related to low income and unemployment is the lack of third-party insurance or other payer source for health care. Twenty-three percent of our clients receive Medicaid or Medicare benefits, 3 percent are privately insured, and 47 percent are uninsured or self-pay. Nearly 45 percent of our patients report that they lack permanent housing.¹ These patients need active linkage with and advocacy for housing, work rehabilitation services, and public entitlements.

Why Integrate Buprenorphine Into the HIV Primary Care Setting?

This demonstration project was an opportunity to treat addiction as a chronic medical condition within the construct of primary care. It demonstrated to providers and patients that addiction must be addressed and should be treated as a chronic, recurrent illness. Supporting the heroin statistics noted in the previous section, the ongoing use of heroin by many of our patients was evident from the methadone referrals by our substance abuse staff, the consistent reporting of intravenous heroin as the risk factor for primary HIV infection, the high rates of hepatitis C coinfection (28 percent) in our HIV patients,¹⁰ and the high recidivism rate of drug-dependent patients in our HIV inpatient wards at Cook County Jail.¹¹ The data impressed on our administration the need for something new or different to treat our patients.

TABLE 2-1. BUP PROGRAM REQUIREMENTS

Sector	Requirements
Pharmacy	Internal: Buprenorphine added to the CORE Center formulary External: Buprenorphine added to the State formulary for Medicaid coverage
Personnel	Full-time clinic coordinator, part-time physician (2 hours per day, 2 days per week), part-time administrative staff
Clinic space	One office, one counseling room, waiting area
Laboratory	Urine toxicology, liver function test (aspartate aminotransferase or alanine aminotransferase)

Something Old

Although our providers and clinic had seen successful use of methadone maintenance treatment or residential treatment with no agonist therapy, these treatments entailed limitations and barriers for a substantial number of our heroin addicts. With methadone maintenance, our opioid-dependent patients frequently complained about difficulty accessing treatment, frequent “pick ups” at the clinic, increasing doses with subsequent “nodding” or sedating effects, and interference with productive activities (e.g., work, child care). From the provider perspective, extensive drug–drug interactions with methadone, additional requests for other narcotics, and nodding off during clinical examinations gave many of our providers concern about the utility of methadone maintenance.

In addition to offsite methadone maintenance for our HIV-positive patients, other patients desired no agonist if methadone was the sole choice. Few patients who chose acute detoxification and subsequent residential treatment were able to remain relapse-free for extended periods; this pattern reflects what we know from the literature.¹²

Something New

For the CORE Center and our patients, DATA 2000 was quite exciting. Our physicians would be able to provide co-located care for HIV and heroin dependence and integrate substance abuse treatment with HIV primary care. At the time of this project’s inception in 2005, the City of Chicago offered limited options for patients in need of buprenorphine. The number of prescribers was minimal, and many physicians filled their 30-limit rosters with impaired health care professionals, many of whom had private insurance. (Initially, qualifying physicians were

able to treat no more than 30 patients for opioid dependence in their practice, but this limit was subsequently expanded to 100 patients for providers receiving CSAT approval.) Buprenorphine treatment options for our patient population were limited. From the methadone referrals, new patient intake data, and general psychiatric treatment data, our providers knew that patients had an immense need for “something new”; integrating existing clinic treatment (e.g., brief interventions, intensive outpatient groups) with onsite pharmacotherapy was an exciting prospect. Moreover, buprenorphine use in the HIV/AIDS population had additional advantages as a partial mu-receptor agonist with extremely favorable pharmacokinetics (strong binding, half-life, and slow dissociation), lower rates of side effects, lower overdose potential, and predictable drug–drug interactions with antiretrovirals.

Getting Started

Before initiating the BUP at the CORE Center, we needed to identify the necessary elements for successful program integration. To do so, we relied on national trainings with the American Society of Addiction Medicine, local mentoring by an experienced buprenorphine provider, and written recommendations from the CSAT Treatment Improvement Protocol Series 40 on buprenorphine.¹³ Within the clinic environment, staffing, medication availability, space requirements, and laboratory monitoring emerged as the critical elements for our integration project (Table 2-1).

Pharmacy and Medication Access

A common barrier for all SPNS buprenorphine demonstration sites and most clinics was acquiring and dispensing the medication (i.e., buprenorphine). An onsite

pharmacy at the CORE Center supplies nearly one-third of our HIV patients with antiretrovirals; another third of our patients receive their HIV medications through local or home-delivery pharmacies and use Medicaid or Medicare entitlements. The final third of our patients participate in the State AIDS Drug Assistance Program (ADAP) and receive their prescriptions through home delivery or the CORE Center pharmacy. Other medications, including psychotropics, for the majority of patients are dispensed by the CORE Center pharmacy.

During our first project year, our team leaders submitted a comprehensive request to have combined buprenorphine/naloxone (Suboxone) added to the Cook County and CORE Center formulary list. Because of the advantages of naloxone for preventing abuse by injection, our clinic chose to use only combined buprenorphine/naloxone. With the aid of our assistant project director (and clinic medical director), we received approval and, eventually, budgetary inclusion for providing buprenorphine/naloxone in our onsite CORE Center pharmacy. This initial work proved invaluable in helping our patients with opioid withdrawal and in enhancing our study retention with onsite dispensation of medication.

During our project, the Cook County Health and Hospitals System underwent substantial budget cuts to eliminate a \$100 million deficit at the county-government level. The CORE Center, as part of this health system, focused on pharmacy costs as a major source of funding cuts, and the CORE medical director instructed our study staff to reduce the costs of buprenorphine in the CORE Center pharmacy budget. In response to those directives, the CORE BUP worked with clinic “benefits” workers to enroll all eligible study patients for Medicaid, Medicare, and ADAP entitlements. Staff registered Medicaid patients individually with Illinois Medicaid to obtain prior authorization for buprenorphine prescriptions. This labor-intensive plan for shifting patients to entitlements proved essential in providing buprenorphine to a greater number of patients in need.

During the past 4 years, we have been able to shift the costs of buprenorphine/naloxone from our health system (indigent pharmacy budget) to third-party insurers for 77 percent of our cases. This dedication and work enabled us to continue to provide onsite “free” buprenorphine to new patients and to keep buprenorphine costs at a minimum for our health care system. Without this billing and cost shifting, the CORE BUP would have been

limited to a maximum of 20 to 30 patients at any one time. Because this dispensing change had implications for monitoring and accessing study patients, we encouraged patients to use pharmacies that would deliver to our internal onsite pharmacy for redispensing and handling. Through this recommendation, we minimized the impact of external dispensing of buprenorphine on patient contact and study retention.

Clinic Space

At the inception of this project, the plan was to undertake all buprenorphine inductions within adjacent clinical space in our primary care clinics on the CORE Center’s third floor. Patients awaiting induction were in opioid withdrawal and required interaction and direction from the moment of arrival to successfully complete induction. As we began to engage more patients, we found it more convenient to use space within the chemical dependency area on the CORE Center’s first floor, where simultaneous induction and monitoring could occur in two adjacent clinical spaces.

Because of the medical nature of the induction, we assumed that a clinic room with medical and emergency equipment would be required. Ultimately, patients rarely required medical intervention; therefore, regular office space could be used. A penlight (for assessment of pupil dilation) and a stopwatch or clock (for assessment of pulse rate) were the only devices used on a regular basis in determining the severity of opioid withdrawal. For the comfort of the patients and the active gastrointestinal and urinary symptoms associated with opioid withdrawal, a nearby bathroom is strongly recommended. Because a physician participated in all inductions, any medical triage needs could be addressed immediately.

Laboratory and Toxicology Testing

At the CORE Center, phlebotomy services are available onsite; laboratory samples are sent to our affiliated hospital. Liver function tests, a urine pregnancy test (if applicable), and urine toxicology were performed before BUP patients were scheduled for induction. HIV-associated markers (i.e., HIV viral load, CD4 lymphocyte count, hepatitis serologies) were checked as part of HIV primary care, but results did not alter the induction schedule or treatment. Subsequent laboratory and urinalysis tests were performed only if clinically indicated or if required as part of the study protocol. The need arose for immediate toxicology results in cases of possible diversion, abuse of benzodiazepines (e.g., alprazolam and diazepam) or

methadone, or uncertain withdrawal states. We ultimately began to use urine dipsticks for clinical guidance with a customized toxicology panel for benzodiazepines, methadone, buprenorphine, and “other opioids.” (The dipsticks are available with a variety of different drug panels or can be ordered with customized panels, depending on the target population).

Human Resources and Staffing Needs

The quality, quantity, and skill sets of the staff are critical to any new intervention. Mentoring from experts as well as live and online trainings recommended a dyad consisting of a prescribing physician and an accessible service provider. For the prescriber component of the integration, we needed qualified physicians who were addiction specialists or who had completed required certification (an 8-hour training module) in opioid agonist therapy. Like other SPNS sites, we used the dyad model. At the CORE Center, our “glue person” was our clinical coordinator, who was a substance counselor with certification in mental illness and substance abuse and vast experience in substance abuse treatment, mental health counseling, and case management. Table 2-2 lists the recommended staffing used at our center for HIV primary care and substance abuse treatment.

At the CORE Center, 30 to 50 percent of patients receive primary care services from midlevel providers (nurse practitioners or physician assistants). Many physicians

rotate for only a half day per week or less in the CORE Center. Because continuity, consistency, and stability are essential components of addiction treatment, it was important to identify a core group of providers who would offer continuity of care throughout the week, Monday through Friday. Because psychiatric services and substance abuse treatment at the CORE Center had been historically linked by mutual patients and by an onsite intensive outpatient program, it seemed logical and more feasible to incorporate buprenorphine into primary care through the onsite psychiatric service. The psychiatric team underwent the required buprenorphine training and certification through live and online training modules.

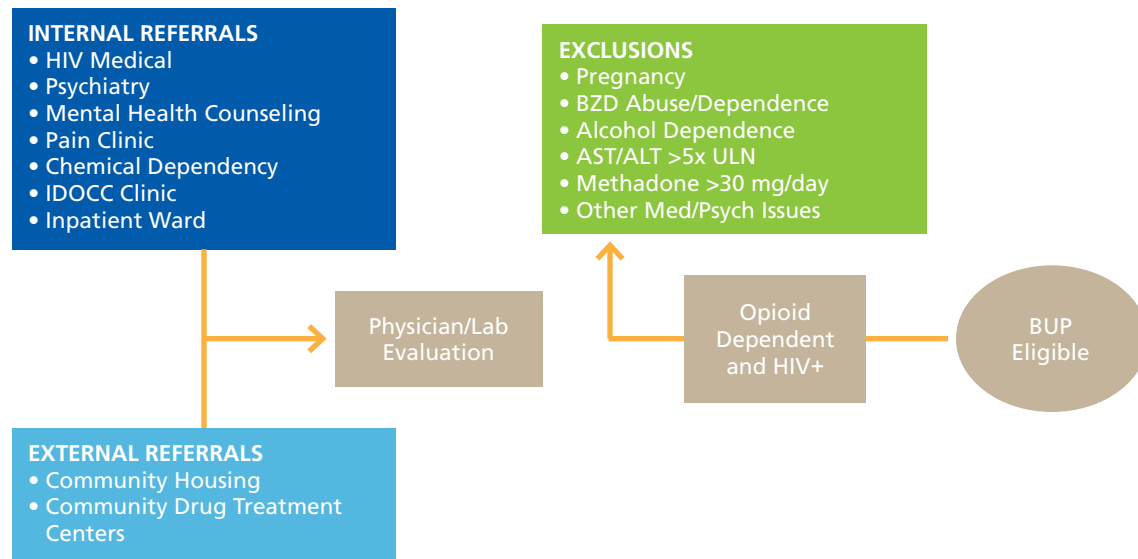
Implementation

Once we established how we would integrate the buprenorphine service, we developed a screening, assessment, and treatment algorithm for providing buprenorphine at the CORE Center. Eligible patients for the BUP were identified by primary care providers, other CORE center staff, outside community partners, the inpatient hospital ward, and self-referral. Any patient who reported substance abuse was referred to the BUP. Heroin dependence was the primary criterion that led to referral to the clinical coordinator for assessment. Abuse of prescribed opioids (e.g., codeine, hydrocodone, and oxycodone) generated some referrals from prescribing providers, but addicted patients with pain disorders rarely wanted treatment with our program.

TABLE 2-2. RECOMMENDED CLINIC STAFFING

Providers	Service	Description
Medical (MD, nurse practitioner)	HIV-specific primary care	HIV care, referral to other medical specialty services
Psychiatry (MD)	Psychiatric care, buprenorphine induction	Evaluation and treatment for comorbid Axis I disorders, opiate withdrawal and buprenorphine induction
Administrator	Office management	Correspondence, ordering supplies, budget oversight
Clinical coordinator	Social services, substance abuse screening and referral, substance abuse group, buprenorphine induction	Referrals for housing, legal services, food pantry, clothing, identification cards; referral to BUP or other agencies; individual counseling and weekly BUP group (1 hour); manage follow-up induction protocol

FIGURE 2-2. BUP ENROLLMENT PROTOCOL



Note: AST/ALT = aspartate aminotransferase/alanine aminotransferase ratio; BZD = benzodiazepine; IDOCC = Illinois Department of Corrections Clinic; ULN = upper limit of normal.

Informing the Referring Providers

To inform the primary care providers as well as other CORE staff members and community partners about this ongoing project, we used a multitude of educational materials. We posted BUP flyers with tear-off strips with BUP contact information throughout the CORE Center and in the medical offices. Another flyer was targeted to HIV providers and included medical information regarding buprenorphine. We also prioritized information sessions with various onsite provider groups (e.g., pharmacists, case managers, intake nurses) and offsite substance abuse providers (e.g., methadone clinics, residential programs, halfway houses).

Screening and Assessing the Patients

Once referred, the patient would meet with the clinical coordinator, who would often conduct a screening immediately. The screening process entailed two steps: (1) establishing the *Diagnostic and Statistical Manual of Mental Disorders*, fourth edition, text revision⁹ diagnosis of opioid dependence and (2) determining whether the patient met inclusion or exclusion criteria (Figure 2-2).

As part of the clinical assessment, the clinical coordinator reviewed medical charts and electronic medical records for information about medical issues, psychiatric issues,

highly active antiretroviral therapy (HAART), and any other medications (Resource 2A). This screening and assessment information was then reviewed on a case-by-case basis with the buprenorphine physician prior to scheduling the inductions.

Establishing the Glue Person

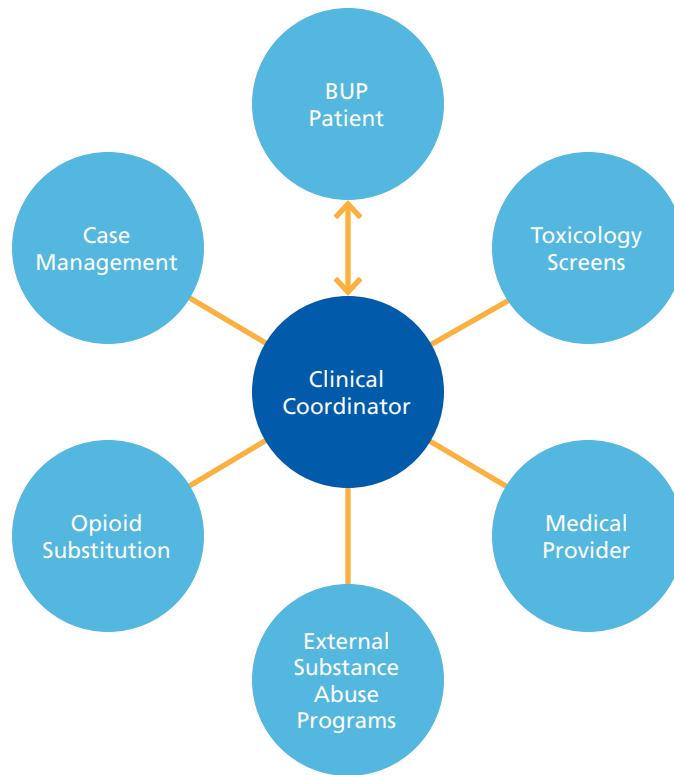
Because our multiple prescribers of buprenorphine had limited time, an accessible central figure who could engage patients at every level of care, at any location within the clinic setting, was crucial. This part of the treatment dyad, the clinical coordinator, was also known as the “glue person” and served many roles (Figure 2-3).

Our clinical coordinator attended preclinic meetings for face-to-face contact with our primary care providers and carried a pager so she could be contacted directly during clinic hours to take referrals and answer any questions regarding the project.

Induction Schedules

Once patients were engaged and informed about buprenorphine treatment, inductions were scheduled on Mondays, Tuesdays, or Wednesdays to allow for an induction day and two subsequent follow-up days within a normal work week. The availability of space and of the glue person every

FIGURE 2-3. ROLE OF THE GLUE PERSON



day of the week was necessary, but the prescribing physician needed to be onsite only for initial inductions in the mornings at the beginning of the week. Table 2-3 highlights recommended schedules, from our clinical experience, for buprenorphine inductions, stabilization, and maintenance with specific information about prescriptions.

Program and Process Evaluation

Multiple evaluation processes were used to identify patient-centered issues as well as systematic barriers to success. System-level evaluations included

- An annual report of data to Federal oversight agencies;
- An annual report of procedures and review of consents with local institutional review board;
- At least quarterly review of pharmacy issues, costs, and average doses;
- A process evaluation log book; and
- Intervention staff meetings (weekly, then monthly, and eventually quarterly).

Among these program-level assessments, the annual reviews as part of our institutional review board regulatory assessments were always helpful in ensuring patient privacy and confidentiality in this vulnerable population. In addition, the monthly intervention meetings were critical to maintain appropriate staffing levels, modify the screening process, hone the timing and dosing for inductions and stabilizations, and calculate pharmacy costs.

Patient-centered evaluations as part of the clinical or research components included

- Weekly meetings (in person or by phone) between the clinical coordinator and the physician for patient coordination, scheduling of inductions, and follow-ups;
- Medical chart review;
- Review of quality-of-care indicators (CD4, viral load, assessment of risk behaviors, immunizations, liver function tests, tuberculin purified protein derivative status, hepatitis screening); and
- Patient satisfaction surveys.

TABLE 2-3. RECOMMENDED TIMING FOR BUPRENORPHINE INDUCTION

		Observation	Counseling	Prescription (Rx)
Induction	Day 1	Observe patient take one 8-mg buprenorphine/naloxone tablet sublingually in clinic	Week 1: Daily counseling	Give patient 1 tablet to take home: No Rx.
	Day 2	<ul style="list-style-type: none"> • Check criteria for dose increase • Observe patient take one 8-mg buprenorphine/naloxone tablet sublingually 		Give patient 1 tablet to take home: No Rx.
	Day 3	Observe patient take one 8-mg buprenorphine/naloxone tablet sublingually		Give Rx for weekly supply.
Stabilization	Weeks 2–4	Once weekly: Check patient’s symptoms for underdosing	<ul style="list-style-type: none"> • Week 2: Once or twice weekly • Weeks 3 and 4: Once weekly 	Give Rx for weekly supply.
Maintenance	Months 2–12	Monthly check depending on clinical stability and dose	Months 2–12: Once every 2–4 weeks	Give Rx for monthly supply; if dosage >16 mg, give Rx for biweekly supply.
Dose increase criteria	Significant craving, pain issues, withdrawal symptoms, or three consecutive toxicologies positive for opioids			

Although many patient-focused assessments were included as part of our study’s research design, the constant evaluations and contact between the physicians (psychiatrists in our case) and the counselor ensured optimal care for our patients while building the essential trust between the prescribing physicians and the more available counselor. Health maintenance testing (e.g., hepatitis, TB, pregnancy, immunizations, Pap smears) and HIV monitoring (CD4, viral load) is not necessary for buprenorphine treatment, but the integration of substance abuse treatment and HIV primary care resulted in improvement in our patients’ overall health and HIV disease. The use of psychiatrists as the primary prescribers, unlike other SPNS grantee sites, also allowed us to enroll patients with comorbid chronic mental illness (e.g., schizophrenia, bipolar disorder) and heroin dependence. Monthly intervention meetings reviewing general program components and current patient issues permitted an ongoing analysis of exclusion and inclusion criteria for severity of medical problems, psychiatric illness, and nonopioid drug abuse.

Buy-in From Stakeholders and Providers

Despite the need and demand for alternative substance abuse treatments, several barriers continued to prevent the integration of buprenorphine into primary care. The Federal grant award from HRSA provided much leverage in terms of administrative buy-in for staff and space allocation. In addition, the well-understood impact of heroin dependency on HIV retention and engagement in HIV care highlighted the need for this specialized service.

Despite the drawbacks and costs of this integration project, the benefits to the patients and providers in addressing the addiction component within the treatment model convinced the stakeholders that the project was worth the effort. Many of the disadvantages related to direct costs to our clinic, including space allocation, medication cost, and access, required training, labor, time, and management of opioid withdrawal. The advantages seemed to be either patient centered or health system associated: improved HIV and substance abuse outcomes, easier access to agonist treatment, reduction in overdose deaths,

reduction in emergency room and inpatient visits, retention in HIV care, possible improvement in adherence to HAART, integration of HIV care with substance abuse treatment, and improvement in quality of life. These issues were addressed directly with CORE Center administrative leaders, and we decided to move forward with our grant proposal and then with our integration implementation.

Steps to Success

Our prescribing physician–clinical coordinator dyad worked well; however, an element of nonintegration persisted with HIV primary care because the primary care provider was involved only in the referral and subsequent monitoring. We came away with the following key lessons learned:

- Accessibility of buprenorphine, including transportation and low or no cost for medication, is critical for treating indigent opioid-dependent populations.
- HIV primary care providers have not been as involved in buprenorphine treatment as a result of laws against nurse practitioners and physician assistants prescribing this Schedule III drug.
- A two-person dyad with a counselor and a physician works well as long as trust exists between the physicians and the counselor and the counselor is available every day for problem solving and patient recruitment.
- The onsite availability of a pharmacy, a laboratory, and medical care facilitated implementation and execution.
- All providers in a clinic need to be educated about the pharmacologic properties of buprenorphine. Many patients continue to request opioid prescriptions (e.g., codeine, hydromorphone, morphine, oxycodone) after buprenorphine treatment, and because of a lack of knowledge about buprenorphine pharmacokinetics, many providers continue to prescribe the drugs. Patients either sold these prescriptions or used them to get high after discontinuing buprenorphine.
- High rates of psychiatric comorbidity (more than 45 percent) in this target population necessitate availability of psychiatric services.
- The two-person model (with one full-time staff person) and the transitioning of medication costs to third-party payers make this service cost-effective and affordable for many clinics.
- Buprenorphine works! Patients noted improved functioning and ease of administration, and providers

noted increased HIV care adherence and mental coherence in patients.

- Housing and shelter are key elements in a patient's ability to maintain sobriety and avoid the drug-related industry (selling and buying drugs, prostitution).

To address some of these lessons or barriers, particularly psychosocial issues, we relied on our clinical coordinator a great deal to assist with housing and transportation issues. Other SPNS sites relied on available case management services or AIDS service organizations to provide needed assistance to stabilize the patient and his or her environment.

Diversion (selling of prescribed medication) also became an issue as our project evolved. Within Chicago's indigent heroin-dependent populations, buprenorphine is not readily available, so diversion was not much of a factor at project onset. Eventually, we developed a general diversion policy that included monitoring prescriptions, pill counts, and urine toxicologies. Despite buprenorphine's known blockade at the mu opioid receptor and associated mild analgesia, many patients continued to request additional opioids from other prescribers. These medications were either sold for profit or used by the patient to get high after a few days off buprenorphine. Because of a lack of knowledge about buprenorphine's pharmacokinetics, many providers in our clinic obliged patients' requests, despite active enrollment in the buprenorphine program. Urine dipstick analysis for buprenorphine assisted in identifying whether patients were taking the medication themselves or selling it to others.

Factors Contributing to Adherence

Adherence for our psychiatrist-staffed study in an HIV primary care clinic related to six areas: (1) HIV primary care; (2) HIV antiretroviral adherence (if applicable); (3) health maintenance monitoring (as noted previously); (4) psychiatric care, counseling, and psychotropic adherence (when applicable); (5) substance abuse engagement, including intensive outpatient care, 12-step groups, and onsite recovery care; and, finally, (6) buprenorphine adherence. Critical factors for our patients included

- Rapport, engagement, and trust;
- Availability of medical treatment, psychiatric care, and counseling;
- Availability of routine and crisis care for substance abuse treatment;

- Accessibility without stigma relative to HIV, mental illness, or substance abuse;
- Patients' active participation;
- Supportive therapy with a focus on comprehensive case management; and
- Patient advocacy.

Clearly, our patients were invested in receiving comprehensive treatment, including HIV primary care and substance abuse treatment; however, the availability and access to concomitant psychiatric assessment and treatment (onsite, in our case), case management (e.g., housing assistance, food pantry referrals), and patient advocacy (e.g., public aid assistance, legal aid for children and family services, parole and probation documentation) dramatically enhanced adherence while building long-lasting trust in our intervention team members with this vulnerable target population. To this day, "our" patients who previously enrolled in our HIV BUP still reach out to our psychiatrists and substance abuse counselor for reengagement with HIV primary care, case management, legal aid, or mental health counseling.

Leveraging Sustainability

As the end of BUP approached, we hoped to continue our successful program for opioid-dependence treatment in HIV/AIDS patients. Our transition plan involved several key elements, including opioid dependence assessment and treatment referral, buprenorphine availability, onsite buprenorphine inductions, onsite buprenorphine maintenance, coordinated case management, and psychiatric evaluation and ongoing treatment. We had considered several options, including a combination of Federal and local funding that was yet to be realized.

HRSA funding for the CORE BUP ended in August 2009. In September 2009, Hektoen Institute, as agent for the CORE Center, was awarded a SAMHSA CSAT TCE/HIV service grant to increase substance abuse treatment services for minority patients. The HIV Substance Treatment and Recovery Project (H-STAR) continues opioid dependence assessment and treatment referrals as a portion of its services for patients with addictions to all illicit substances. H-STAR also has additional Matrix Model groups and includes treatment for monolingual Spanish-speaking patients and those with co-occurring mental illness. The original BUP staff, supplemented by two substance abuse counselors and

additional part-time psychiatrists, have been able to expand the successful elements of the BUP, including coordinated case management, psychiatric evaluation, and medication management, including buprenorphine treatment for opioid-addicted patients, to an even larger population of clients.

Because of the increased services for the patients needing psychiatric care, the delivery of psychiatry services will be different for some patients, who will be seen in the 4th-floor psychiatry offices. Coordinated case management⁶ and addiction-specific psychiatric treatment⁷ services will continue in the former BUP space.

With regard to buprenorphine availability, our aggressive efforts to minimize the financial burden on the Cook County pharmacy budget has allowed us to maintain a number of patients (a maximum of 20 to 25) on buprenorphine through our pharmacy at any one time. This capacity has continued beyond the end of the SPNS initiative because we have the same clinical coordinator, who is familiar with the process of quickly transitioning patients into medication benefits (Medicare and Medicaid).

The actual task of prescribing for, scheduling, and monitoring of patients on buprenorphine was viewed as the greatest obstacle in continuing the CORE BUP. Our clinic coordinator has been relentless in identifying, assessing, and scheduling appropriate patients for inductions. She also manages postinduction education on Days 1, 2, and 3. An overarching need, the certification of more of our infectious disease attending physicians and primary care physicians in prescribing buprenorphine, must still be accomplished. We will continue to notify center clinicians about local buprenorphine trainings.

BUP Training

In July 2010, with carryover funds from the BUP, a Half and Half training, sponsored by the American Academy of Addiction Psychiatrists and led by two physicians experienced with buprenorphine was held at the CORE Center. This session was attended by 20 physicians. To date, 18 of them have applied for and received the SAMHSA waiver to prescribe buprenorphine. Only one infectious disease attending physician is in this group.

Our plan to have one of our psychiatrists conduct the induction and then transfer the patient to his or her primary care provider (if a physician) for buprenorphine

maintenance is still unrealized. The co-director of H-STAR has clinic hours 1 morning per week to augment the continuation of the two morning clinics run by the project's addiction psychiatrist and provide monolingual Spanish psychiatric evaluations and ongoing medication management. Additional hours provided by part-time BUP trained psychiatrists assist in the continued inclusion of BUP prescription for opioid-addicted patients.

Resources

We developed and used various patient education materials and clinical documentation forms:

- Screening Face Sheet (Resource 2A)
- Script (Resource 2B)
- BUP Patient Flyer (Resource 2C)
- BUP Provider Flyer (Resource 2D)
- Patient information flyers from the buprenorphine manufacturer.^{14,15}
- Video on BUP.¹⁶

These materials and forms contributed to the success of our program.

Conclusion

In summary, the CORE Center BUP with the Cook County Health and Hospitals System completed a successful SPNS demonstration project. Through SPNS funding and dedicated staff, we integrated substance abuse care, HIV primary care, and specialty psychiatric care for opioid-dependent HIV-positive patients. With the addition of buprenorphine to our health system formulary and

ongoing pharmacy cost management, we have been able to maintain up to 80 patients with this novel and beneficial treatment. Our clinicians' experience with buprenorphine and trust between the previously mentioned staffing dyads resulted in an efficient, successful, and safe treatment algorithm. Through screening, induction, stabilization, and maintenance phases, we minimized the amount of direct staff time required; we highly recommend our algorithm in similar treatment populations. Contributing to our program's success were our strong relationships with designated pharmacies (our onsite pharmacy and a delivery pharmacy) and our focus on comprehensive case management. In our impoverished, often homeless population with frequent legal involvement, these factors supported engagement, retention, and monitoring throughout the demonstration period.

With a well-timed CSAT grant award for substance abuse treatment in HIV/AIDS patients, our site avoided abrupt discontinuation or drastic reduction in this integrated care. We continue to provide the key elements of our demonstration project in the new service grant and are gradually transitioning and incorporating staffing components into long-term funding (Ryan White funding and funding from the Cook County Health System). With ongoing program success and significant changes in our patients' lives, we continue to share these stories through presentations at policy and stakeholder meetings and national professional conferences and through publications in international medical and substance abuse journals. It is through this sharing and dissemination that we hope not only to maintain our current program but also to inspire other agencies and clinics to provide this critical new service to their HIV patients.

References

1. Health Resources and Services Administration, HIV/AIDS Bureau, Division of Science and Policy. *The CORE Center: 2007 Ryan White HIV/AIDS program data report*. October 22, 2007. Rockville, MD: Author.
2. CORE Center. Chicago Antimicrobial Research Project. CARP Database. Accessed February 2008.
3. Illinois Department of Public Health. HIV/AIDS. Available at: www.idph.state.il.us/aids/default.htm. Accessed March 15, 2008.
4. Chicago Department of Public Health. *Public health*. Available at: www.cityofchicago.org/city/en/depts/cdph.html. Accessed December 22, 2009.
5. Soto T. Co-occurrence of substance abuse and psychiatric symptoms among HIV-infected urban adults in primary care clinics. Poster presented at: International Association of Physicians in AIDS Care International Conference on HIV Treatment Adherence; 2003; Barcelona, Spain.
6. Babor TF, de la Fuente JR, Saunders J, et al. *AUDIT, The Alcohol Use Disorders Identification Test: guidelines for use in primary health care*. (WHO Pub. No. PSA/92.4). Geneva, Switzerland: World Health Organization; 1992.
7. Robins LN, Wing J, Wittchen H-U, et al. The Composite International Interview: an epidemiologic instrument suitable for use in conjunction with different diagnostic systems and in different cultures. *Arch Gen Psychiatry*. 1988;45:1069-77.

8. First MB, Spitzer RL, Williams JBW, et al. *Structured Clinical Interview for DSM-IV (SCID-I) (User's guide and interview)*. Research version. New York: Biometrics Research Department, New York Psychiatric Institute; 1995.
9. American Psychiatric Association. *Diagnostic and statistical manual of mental disorders* (4th ed., text rev.). Arlington, VA: Author; 2000.
10. CORE Center. Data on hepatitis C/HIV comorbidity. 2006. Unpublished.
11. Pulvirenti J, Muppidi U, Glowacki R, et al. Changes in HIV-related hospitalizations during the HAART era in an inner-city hospital. *AIDS Read*. 2007;17:390–4, 397–401.
12. Connock M, Juarez-Garcia A, Jowett S, et al. Methadone and buprenorphine for the management of opiate dependence: a systematic review and economic evaluation. *Health Technol Assess*. 2007;11:1–171, iii–iv.
13. Center for Substance Abuse Treatment. *Clinical guidelines for the use of buprenorphine in the treatment of opioid addiction*. Treatment Improvement Protocol (TIP) Series 40. DHHS Publication No. (SMA) 04–3939. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2004.
14. Reckitt Benckiser. *Help may be as close as this doctor's office* [patient information]. Richmond, VA: Author; 2007.
15. Reckitt Benckiser. *Embrace treatment, regain control* [patient information]. Richmond, VA: Author; 2007.
16. Reckitt Benckiser. *Treating opioid dependence—What you need to know about treatment with Suboxone* [product information video]. Richmond, VA: Author; 2007.

CHAPTER 2 RESOURCES

Resource 2A. BUP Patient Face Sheet

<http://www.careacttarget.org/topics/buprenorphine.asp>*

Resource 2B. BUP Script

<http://www.careacttarget.org/topics/buprenorphine.asp>*

Resource 2C. BUP Patient Flyer

<http://www.careacttarget.org/topics/buprenorphine.asp>*

Resource 2D. BUP Provider Flyer

<http://www.careacttarget.org/topics/buprenorphine.asp>*

* This publication lists non-Federal resources in order to provide additional information to consumers. The views and content in these resources have not been formally approved by the U.S. Department of Health and Human Services (HHS) or the Health Resources and Services Administration. Listing these resources is not an endorsement by HHS or HRSA.



CHAPTER 3

REPORT FROM: PORTLAND INTEGRATES CARE FOR OPIOID-DEPENDENT HIV/AIDS PATIENTS DEMONSTRATION MODEL

The Portland Integrates Care for Opioid-Dependent HIV/AIDS Patients (PICODAP) demonstration project was a collaboration between two HIV clinics that sought to implement office-based buprenorphine/naloxone (Suboxone) treatment in HIV clinic settings for opioid dependence. Oregon Health and Science University (OHSU) and the Multnomah County HIV Health Services Center (HHSC) were the two project partners.

OHSU provides comprehensive HIV care to people living with HIV/AIDS (PLWHA) both inside and outside the Portland Transitional Grant Area (TGA). The Portland TGA consists of Oregon's Clackamas, Columbia, Multnomah, Washington, and Yamhill counties and Washington's Clark County. The program serves more than 500 active adult and pediatric PLWHA and employs five full- and part-time clinicians (three nationally certified HIV specialists, one psychiatrist, and one pharmacist). Clinic providers also supervise medical trainees (students, residents, and fellows) in HIV care delivery. Additional services include onsite mental health, addiction treatment, dermatology, and case management. The clinic's physicians serve as statewide AIDS Education and Training Center trainers and provide statewide patient consultation and HIV care for rural clients. They also provide direct medical care and consultation to PLWHA who are incarcerated in the Oregon State Department of Corrections. The OHSU HIV Clinic receives Ryan White HIV/AIDS Program Part A funds; accepts CareOregon (Oregon's managed Medicaid program), Medicare, and private insurance; and serves uninsured PLWHA. The university implemented the electronic medical record system EpicCare in 2005.

The HHSC, the largest HIV care provider in Oregon, has been in operation since 1990. Its five full- and part-time clinicians care for an estimated 900 active adult PLWHA. HHSC provides the full range of primary care services and is supported by multiple funding streams. Ryan White HIV/AIDS Program Part A, B, and C funds bridge the gap in access to medical care and services for uninsured clients not covered by other resources, including an onsite pharmacist, case managers, and part-time mental health services. HHSC accepts CareOregon and private insurance. HHSC implemented the EpicCare system in 2008.

The target population during implementation of the demonstration model was HIV-positive adults at least 18 years old who met *Diagnostic and Statistical Manual of Mental Disorders*, fourth edition (*DSM-IV*)¹ criteria for dependence on heroin, other non-prescribed opioids, or prescription opioids. Men and women of any racial or ethnic group were included. Other inclusion criteria included eligibility to receive primary care services at the participating HIV clinics. Women with childbearing potential were required to agree to use birth control for the duration of participation.

Potential participants were excluded if any of the following conditions were present:

- A medical condition that would make study participation medically hazardous
- Known allergy or sensitivity to buprenorphine or naloxone
- Acute severe psychiatric condition in need of immediate treatment, or imminent suicide risk
- Dependence on alcohol, other depressants, or stimulants requiring immediate medical attention
- Current pattern of benzodiazepine abuse that would preclude safe participation in the study
- If female, being pregnant, lactating, or planning to become pregnant
- Taking more than 30 mg methadone per day.

The buprenorphine–naloxone formulation (Suboxone) was used to limit the abuse potential of buprenorphine alone, as discussed in the U.S. Department of Health and Human Services (DHHS) Treatment Improvement Protocol Series 40 (TIP–40) guidelines.² If taken parenterally rather than sublingually, the naloxone component precipitates withdrawal symptoms in individuals dependent on full agonists.

Epidemiology

Portland HIV clinics applied for Special Projects of National Significance (SPNS) Program funding in 2004 in response to the local incidence of HIV among substance users, particularly injection drug users (IDUs). Data from the time showed a 21.6 percent increase in people living with AIDS and a 24.8 percent increase in people living with HIV between 1999 and 2002 (a total of 4,250 PLWHA in the Portland TGA)³ IDUs (including men who have sex with men) accounted for 21.7 percent of HIV/AIDS cases through 2002 and made up 22.7 percent of new HIV/AIDS cases. IDUs were the second largest group of PLWHA in the Portland metropolitan area.^{4,5}

U.S. Census data estimated a total population of 2,214,943 for the six counties of the Portland TGA in 2010.⁶ As of December 31, 2010, an estimated 4,211 people in the Portland TGA were living with AIDS (2,618) or HIV (1,593).^{7,8} Recent data suggest an IDU prevalence of 14.5 percent among PLWHA in the Portland TGA (compared with 1.0 percent in the general population) and 14.9 percent for other substance

use (compared with 17.7 percent in the general population).⁴ In the general Oregon population, prescription pain relievers have been identified as the fourth most frequently abused substance (behind alcohol, tobacco, and marijuana).⁹ A 2002 study of Oregon’s Medicaid-insured PLWHA showed that 30 percent had been treated for a substance abuse issue and 20 percent had been treated for both substance abuse and mental health issues between 1999 and 2000.⁵

Despite Portland’s needle exchange program, sharing needles was the main source of HIV infection among adult IDUs. An estimated 21 percent of IDUs who had injected in the previous 12 months had shared needles or “works,” as reported in a 2003 study by the Oregon Department of Human Services.¹⁰

Why Integrate Buprenorphine Into the HIV Primary Care Setting?

We saw three main benefits to integrating buprenorphine into our HIV clinics: improving access to treatment for PLWHA, expanding the provider treatment arsenal, and adopting the chronic care model for substance abuse treatment.

Although opioid dependence is common, only approximately 15 percent of opioid-dependent people access methadone maintenance.¹¹ Integrating buprenorphine therapy into HIV clinic settings provides an opportunity to engage patients who have relapsed following methadone maintenance and to expand access to opioid treatment for those who have not previously sought other treatment options for opioid dependence. In addition, integrating buprenorphine/naloxone therapy expands provider treatment options for opioid-dependent patients. Prior to integration, only referral for methadone maintenance or detox programs was available to HIV clinic patients in the Portland TGA.

HIV clinics have long adopted a chronic care model for HIV infection management. In contrast, substance abuse has historically been seen as an acute issue requiring intervention rather than as a chronic, relapsing–remitting medical condition. Incorporation of buprenorphine/naloxone treatment acknowledges opioid dependence as a chronic medical condition requiring longitudinal, multidisciplinary team management over a patient’s lifetime.

Provider Requirements and Training

At the outset of the PICODAP project, prescribing HIV physicians, midlevel providers, alcohol and drug counselors, and clinical pharmacists all attended a 1-day training session to qualify for Drug Addiction Treatment Act of

2000 (DATA 2000; Pub. L. 106–310) waivers. Over time, streamlined online training became available. Providers and staff joining the clinic in the past 2 years have completed this abbreviated online training.

In addition, we conducted periodic brief refresher trainings during lunch breaks and team meetings for all staff. All clinical staff were encouraged to participate in buprenorphine trainings, although only prescribing physicians are allowed to apply for DATA 2000 waivers. Making buprenorphine training available to all staff facilitated change in the organizational culture so that staff and providers of all training levels came to view opioid dependence as a chronic, treatable medical condition.

Getting Started

Before training and implementation, we took time to focus on several areas we thought would be key to a successful project, including needs assessment, buy-in from staff, quality management, and program scope. The sections that follow describe our approach.

Conduct Needs Assessment

Begin by estimating the need for opioid-dependence treatment services. The best way to obtain data is to implement screening programs to detect illicit drug use. In clinics where such programs are not available, indirect estimates of illicit opioid use may be derived using surrogate markers, such as the number of clients with intravenous drug use as HIV transmission category (data are available in most HIV treatment organizations). A commonly overlooked surrogate marker for opioid abuse and dependence is the number of clients receiving opioid prescriptions for chronic conditions. National data, as well as clinical experience from the PICODAP project, suggest that prescription opioid abuse may be proportional to the number of opioid prescriptions written.¹² Implementation of routine, random urine drug screening and monitoring of early refill requests may identify a subset of prescription opioid users who may have opioid dependence requiring treatment. This marker was not readily apparent to HIV clinic providers before implementation of these screening procedures at the PICODAP demonstration sites, but it quickly became an important means of identifying patients in need of treatment.

Use Existing Quality Management Systems

Most HIV clinics maintain ongoing quality assessment and improvement plans. Implementing buprenorphine as a quality improvement initiative (i.e., moving toward an integrated treatment model) may facilitate integration

into the local organizational culture. Using existing rapid-cycle process improvement approaches (e.g., “Plan–Do–Study–Act” cycles) may help address early barriers and challenges to implementation.

Consider Desired Scope of Services

Early consideration of the appropriate scope of services is essential, particularly with regard to clients already receiving methadone maintenance therapy (MMT). In the PICODAP project, many such clients wanted to be switched to buprenorphine because of a perceived increased convenience for dosing and appointments. National guidelines advise against attempting transition from methadone to buprenorphine at methadone doses greater than 30 mg per day; most clients in methadone treatment are maintained at much higher doses, and methadone tapers frequently precipitate relapse. The PICODAP demonstration sites decided not to offer buprenorphine to opioid-dependent patients who were doing well on stable methadone maintenance.

Human Resources and Staffing Needs

Several personnel roles are essential for implementing office-based buprenorphine, although roles may overlap and may be filled by multiple staff members:

- A clinical champion who can serve as a resource to other HIV clinic staff and providers throughout the implementation process
- Front desk and phone triage staff coached on what to expect from clients presenting with opioid withdrawal or calling to request buprenorphine
- Medical assistants and nursing staff prepared to work with patients in withdrawal
- A designated coordinator to make sure things run smoothly
- A substance abuse counselor who has dedicated time for counseling clients who are seeking and receiving buprenorphine
- A designated staff member to address buprenorphine insurance issues.

In most cases, these roles may be filled by existing staff members, who often already perform similar functions for other HIV-infected clients.

Implementation

The leadership team of the PICODAP project comprised an HIV provider who served as clinical champion, an

addiction psychiatrist who served as training director, and a substance abuse counselor who served buprenorphine clients at both HIV clinic sites. The implementation team conducted a series of physician, staff, and community partner trainings on the use of buprenorphine/naloxone; promoted awareness of availability of buprenorphine treatment among potential clients; supported change teams in each clinic site; and monitored compliance treatment with national treatment recommendations (e.g., DHHS TIP-40).

Each HIV clinic assembled a “change team” composed of key players across all points of service. Typically, this team included one HIV provider, a nurse or medical assistant, a clinic administrator, and front desk staff. The implementation leadership team met with change teams periodically for ongoing training and support. Change teams identified barriers and solutions for day-to-day implementation challenges, promoted practitioner ownership of the project, and examined structural changes in the linkages between addiction medicine and HIV primary care. They also provided ongoing support for patients and practitioners. Clinic operations were examined to assess strategies for ensuring that patients initiated and maintained counseling relationships as soon as the patients were stabilized on medication.

The PICODAP training director assisted each provider during the first buprenorphine induction and regularly provided phone consultation support and feedback for subsequent patient-management issues. Trainings for all HIV clinic staff were conducted prior to initial implementation, and 1-hour refresher courses were conducted periodically.

Potential opioid-dependent clients were identified by HIV clinic staff and providers or were referred from community-based service agencies and correctional facilities. Buprenorphine services were advertised in local alternative publications and with flyers placed in locations frequented by local heroin users. The substance abuse counselor screened all potential clients for *DSM-IV* opioid dependence and other buprenorphine eligibility criteria as well as for eligibility for care at the HIV clinic (mainly confirming HIV status) and verified insurance coverage for buprenorphine/naloxone. Once it was confirmed that a client met the inclusion criteria, he or she next met with an HIV primary care provider for baseline physical assessment. For eligible clients, an appointment was scheduled for induction within 4 weeks of initial screening; frequently, this appointment took place within a few days of screening. Patients were scheduled for at

least weekly follow-up visits after induction for medication, including counseling and urine toxicology analysis, for the first month. Follow-up took place every 2 weeks for the second month and then at least monthly in accordance with clients’ clinical stability. The implementation leadership team met at least monthly to review progress and to suggest potential changes in medication and counseling management for all clients receiving buprenorphine.

Program and Process Evaluation

The PICODAP project relied heavily on feedback from clinic change teams regarding ongoing implementation progress, challenges, and lessons learned. The implementation leadership team reviewed issues raised by the change team at least weekly and recommended an array of responses, including quick phone calls to treating clinicians or clinic administrators and providing additional training sessions. The implementation leadership team tracked lessons learned and shared them with HIV clinic staff and providers during scheduled lunchtime clinic meetings. The implementation leadership team also tracked patient progress. Measures of progress included client urine drug screens (collected at each visit) and self-reported substance use, adherence with counseling sessions, and assessment of engagement in HIV medical care (as determined by number of visits attended). Feedback regarding treatment recommendations was quickly relayed to treating providers.

The implementation leadership team monitored clinic performance of urine drug screens, buprenorphine/naloxone dosing, and client adherence to scheduled counseling and medical visits throughout the course of the demonstration.

Buy-in From Stakeholders and Providers

Achieving buy-in from clinic staff, administration, payers, and community-based organizations serving PLWHA prior to implementation of buprenorphine treatment is one of the most important requirements of a successful program. We conducted numerous meetings with each stakeholder group to introduce the rationale for integration of buprenorphine treatment, to answer questions and concerns, and to solicit advice regarding implementation roll-out.

We conducted formal and informal lunchtime staff trainings in HIV clinics to help with buy-in among clinic staff. Providers were individually approached regarding participation in DATA 2000 waiver training by a local buprenorphine provider “champion,” who continued to be available for phone consultations. Providers joined staff during lunchtime refresher trainings. In addition,

providers needed time to become comfortable with inductions and treatment and to see successful outcomes among other patients.

Clinic administrators were made aware of the clinic space and flow requirements for the buprenorphine program. Clinic flow must account for time needed for counseling, insurance verification, or urine toxicology analysis. Space must be available for 2 to 4 hours to keep clients under observation following induction. Alternative strategies may decrease clinic resources required for induction. A recent study demonstrated that self-managed home inductions with buprenorphine are safe and effective compared with clinic-based inductions.¹³

We also met with key payers who provide prescription coverage for many of our patients, including local AIDS Drug Assistance Program (ADAP) leaders and CareOregon administrators. Neither organization provided coverage for buprenorphine prior to implementation. As implementation proceeded, we were able to report patient successes and share data regarding potential effects on cost of care. Ultimately, both agencies added coverage for buprenorphine to their formularies.

Community-based service organizations, such as case management and social services organizations, can be invaluable in linking potential clients to office-based buprenorphine. Again, we met with local agencies to inform them of buprenorphine implementation plans. Local detox centers and treatment programs should also be informed of an HIV clinic's plans to implement buprenorphine treatment because HIV-infected clients can often transition directly from those services to office-based care. Likewise, local correctional facility health care liaisons may be able to transition inmates at high risk for relapse directly to office-based treatment on release from jails or prisons.

Steps to Success: Overcoming Barriers

Successful integration of office-based buprenorphine/naloxone into the Portland HIV clinic demonstration sites required overcoming several barriers. Many of the issues are ongoing challenges that require continual monitoring and day-to-day problem solving. Examples of those barriers and ways to overcome them in clinical practice follow.

Insurance Coverage and Cost

In expanding capacity for PICODAP, the biggest early barrier was ensuring buprenorphine/naloxone prescription drug coverage. At the time of initial program

implementation, prescription drug coverage was limited for the majority of Portland's HIV-infected clients. Neither Ryan White Part B (i.e., ADAP) nor Medicaid—the two main sources of prescription drug coverage for PLWHA in Oregon—included buprenorphine/naloxone on their formularies. The implementation leadership team gave multiple formal and informal presentations to key staff at these agencies and ultimately negotiated the addition of buprenorphine/naloxone to both formularies. ADAP now offers coverage to Ryan White-eligible clients who have no other prescription drug coverage for buprenorphine/naloxone. CareOregon will approve prescriptions for buprenorphine/naloxone through its prior-authorization process. Prior-authorization approvals are most easily obtained for patients who have previously relapsed after attempting methadone maintenance.

Polydrug Use

Treatment with buprenorphine/naloxone may not diminish clients' use of other substances. The PICODAP project used a harm-reduction approach to allow clients with polysubstance use to enroll in office-based buprenorphine if other substance use did not require acute intervention. Although many clients curtailed or stopped using other substances, some did not. These cases were reviewed at least weekly by the leadership team. In cases of limited use of other illicit drugs or alcohol, increased frequency of counseling and 12-step meetings and referral for an addiction psychiatry consult were recommended. Patients with more severe polysubstance use, including repeated failure to curtail other substance use over time or increasing risk for adverse events due to other substance use, were referred for inpatient or outpatient treatment or MMT, and buprenorphine treatment was suspended. HIV treatment organizations seeking to implement office-based buprenorphine will need to address the full spectrum of patients' substance abuse issues, recognize that addressing all issues will be a long-term endeavor, and individually tailor treatment plans to address polysubstance use over time.

Mental Illness

Co-occurring mental illness was common in the PICODAP population, as it is for many PLWHA with substance abuse issues. Each client considering buprenorphine was screened for mental health conditions by the HIV provider and the substance abuse counselor. Clients with serious mental conditions were referred for an addiction psychiatry consult before initiating treatment, and the addiction psychiatrist was available to prescribing HIV providers for "curbside" informal consultations. HIV clinics seeking to

implement office-based buprenorphine should be prepared to screen and treat mental health conditions onsite or refer for mental health professional consultation.

Lack of Support in the Treatment Community

The PICODAP project built close linkages with local inpatient and outpatient addiction treatment programs. Some inpatient treatment programs did not accept clients on buprenorphine maintenance, and some outpatient treatment programs encouraged patients to stop using maintenance therapy; this discrepancy made transitions to and from office-based buprenorphine treatment problematic.

It is important to communicate clearly with the staff of treatment facilities or support groups to be sure that programs are compatible with treatment plans. The HIV clinic demonstration project's substance abuse counselor facilitated communication with the treatment programs.

Timing of Readiness for Appointment and Inability to Offer Treatment on Demand

Many clients had difficulty preparing to be in withdrawal for scheduled induction appointments in the HIV clinic. HIV providers in Portland HIV clinics adopted a relatively flexible approach to scheduling induction appointments. Providers added patients to their schedules to accommodate those who were in the critical withdrawal window. This flexibility helped increase access to buprenorphine/naloxone for those who were just starting to engage in treatment.

Transitions to and From Jail

Many clients seeking buprenorphine treatment were facing legal issues that can complicate induction and maintenance therapy. When the substance abuse counselor first met each patient to discuss buprenorphine, she asked whether he or she had any impending court dates or sentencing. This information helped shape the patient's treatment plan for timing induction before or after a jail sentence. Scheduling an appointment with the substance abuse/medical team immediately following release from jail (preferably the same day) can help patients maintain the sobriety typically attained while incarcerated.

Home Inductions

Many clients have difficulty timing the opioid withdrawal required for buprenorphine induction and request buprenorphine/naloxone prescriptions for home induction. Although the practice is outside current TIP-40 guidelines, the role of home inductions is evolving, and a recent study demonstrated the safety and efficacy of

home inductions.¹³ This approach may be reasonable, particularly for patients with prior experience using buprenorphine/naloxone.

Steps to Success: Additional Elements

In addition to taking steps to overcome the barriers described, we found that several other elements were important to the success of the PICODAP project, as described in the sections that follow.

Get the Word Out That Buprenorphine/Naloxone Treatment Is Available.

Identifying eligible clients during the demonstration period required a citywide referral network of HIV clinic providers, local narcotic treatment and outreach programs, community-based outreach programs, OHSU hospital inpatient wards, jail discharge planners, and emergency room providers. The Portland implementation team also posted flyers and placed advertisements in strategic locations to notify potential clients about the study. The desired effect was to spread knowledge in the community about treatment with buprenorphine and to initiate patient-provider discussions about the feasibility or appropriateness of treatment.

Establish Appropriate Infrastructure to Facilitate a Team Effort Around Treatment With Buprenorphine.

Once a client was enrolled in our buprenorphine program, it took the combined effort of the substance abuse counselor, the HIV provider, the addiction psychiatrist, and clinic staff to provide education, coordinate appropriate care, and retain the client in treatment. The implementation leadership team met weekly to formally discuss each patient's progress, and each team member was available for informal consultations as the need arose. It was also essential to ensure that the medical assistants, nurses, and case managers supporting the clinics were aware of treatment protocols to anticipate side effects and to generally support each patient's recovery effort.

HIV clinics seeking to implement office-based buprenorphine should consider adding treatment team members. We experienced a need for couple and family counseling that we could not meet with our given resources. Peer mentorship (i.e., a person in recovery who has taken buprenorphine) would be helpful for recruitment and retention, especially when first engaging a person in treatment or when a patient is struggling. We were able to provide support groups in response to patients' desires to meet with people who were sharing their experiences.

Identify and Empower a “Glue Person.”

Although program implementation was a team effort, the onsite HIV clinic substance use counselor’s role evolved to become the “glue,” the critical component for enrolling and maintaining patients in care. This person was the main point of contact for patients seeking buprenorphine treatment and for connecting and coordinating care among the patient and the HIV/buprenorphine providers and clinic staff and other resources. Ryan White HIV/AIDS Program Part A grantees should prioritize funding for onsite HIV substance abuse counselors who can fill this role in integrated settings.

Be Flexible and Patient With the Change Process.

To encourage enrollment and retention, PICODAP sites allowed open appointments, provided direct phone lines to buprenorphine providers, and allowed home inductions when appropriate. The implementation team discovered that some patients took longer to stabilize on buprenorphine/naloxone than initially anticipated. It also took time to achieve full buy-in from providers (especially those without addiction training) as they learned to identify problematic opioid use among their patients and to become comfortable with the process of buprenorphine/naloxone induction and maintenance. A treatment approach that features increasing amounts of structure and accountability as a patient stabilizes has worked at our two sites.

Anticipate Insurance Issues.

As previously discussed, prescription coverage for buprenorphine/naloxone evolved over the implementation period. Along with negotiating the addition of buprenorphine/naloxone to ADAP and managed Medicaid formularies, the implementation team took advantage of medication assistance programs sponsored by the manufacturer. The substance abuse counselor became the de facto insurance coordinator. In this role, the counselor helped patients and support staff navigate the requirements of insurance companies and medication assistance programs, including filing timely prior authorizations and documenting certain criteria (e.g., clean urine analyses, income restrictions).

Recognize the Potential for Relapse and the Need to Plan for Follow-Up.

Buprenorphine programs should minimize punitive measures and work with clients if they remain engaged in care. Point-of-care urine drug screens helped verify patients’ self-reported drug use, facilitate patient-provider discussions about drug use or abstinence, and guide tailoring of individual treatment plans.

Anticipate Pain Management Issues.

Clients taking buprenorphine/naloxone will occasionally require elective or emergency surgeries that require aggressive pain management. The PICODAP team asked patients to notify us of upcoming medical procedures that would require pain management so that the team could coordinate care. Depending on the extent of the procedure, buprenorphine/naloxone was withheld on the morning of the procedure and resumed when acute pain management requirements had subsided. Clients were counseled that non-narcotic analgesics could be used concomitantly with buprenorphine with their HIV provider’s approval.

Cultivate Relationships With Other Agencies.

The treatment team should ensure that an appreciation of different treatment philosophies is in place with the agencies (e.g., corrections, insurance, rehabilitation and housing facilities) to which patients are referred or with which patients are shared. Communication is essential so that the team can work with an agency to best meet the needs of referred patients, particularly in situations where there is resistance to using medication-assisted recovery.

Factors Contributing to Adherence

We found that the following factors were instrumental in patients’ adherence to buprenorphine:

- Thorough prescreening for readiness
- A “glue person” to keep in touch with the patient
- Prescribing physician available for support or questions following induction
- A buprenorphine treatment policy in place to encourage accountability and educate the patient about the clinic’s expectations
- Positive results that patients can see and use to focus on improving other aspects of their lives
- A harm reduction approach that keeps patients who relapse in the care system and allows repeated attempts at recovery and better adherence in the future.

Leveraging Sustainability

The PICODAP model has continued beyond the end of the SPNS funding. PICODAP has had a long-term impact on the HIV/AIDS treatment community in the following ways:

- Prescribers serve as a resource for others in the medical community interested in starting their patients on buprenorphine.

- Local and State Medicaid and ADAP payers have added buprenorphine to their formularies.
- Over the years, prescribing Suboxone in both HIV clinics has become a routine and normal part of treatment for substance use. Having had experience treating with Suboxone, physicians have felt comfortable accepting the latest innovations in treatment, including home inductions and extended-release naltrexone.
- The model of a glue person to coordinate care has transferred to other high-needs clinic patients (e.g., connecting homeless patients with housing services).
- The PICODAP team has sponsored three annual communitywide conferences on various aspects of buprenorphine management, has raised awareness of opioid abuse in the community, and has facilitated communication among various community stakeholder groups.

References

1. American Psychiatric Association. *Diagnostic and statistical manual of mental disorders* (4th ed., text rev.). Arlington, VA: Author; 2000.
2. Center for Substance Abuse Treatment. *Clinical guidelines for the use of buprenorphine in the treatment of opioid addiction*. Treatment Improvement Protocol Series 40. DHHS Pub. No. (SMA) 04-3939. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2004.
3. Oregon Department of Human Services. *Oregon epidemiology profile of HIV/AIDS, 2002*. Available at: <http://public.health.oregon.gov/Teamsite/Documents/hiv/data/docs/2002epi.pdf>.
4. Portland Area HIV Services Planning Council. *Comprehensive care plan, 2009-2011*. Portland, OR: Author; 2008.
5. Program Design and Evaluation Services. *Estimated prevalence of mental health and substance abuse issues among HIV-positive Oregonians*. Portland: Oregon Public Health Division; 2002.
6. U.S. Census Bureau. 2010 Census data. Available at: <http://2010.census.gov/2010.census/data/>. Accessed May 13, 2011.
7. Oregon Health Authority. *Epidemiological profile: preliminary data*. Portland, OR: Author; 2011.
8. Seattle and King County Public Health. *HIV/AIDS epidemiology semi-annual reports: 2010-2nd Half*. Seattle, WA: Author; 2011.
9. Oregon Health Authority, Addictions and Mental Health Division. *Oregon's epidemiological data on alcohol, drugs, and mental health*. Portland, OR: Author; 2011.
10. Dowler D, Lindstrom S, Rumptz M, et al. *We listened: 2002 survey for people living with HIV and AIDS in Oregon*. Portland, OR: Program Design and Evaluation Services; 2003.
11. Becker WC, Fiellin DA, Merrill JO, et al. Opioid use disorder in the United States: insurance status and treatment access. *Drug Alcohol Dependence*. 2008;94:207-13.
12. Substance Abuse and Mental Health Services Administration. *Results from the 2008 National Survey on Drug Use and Health: National Findings*. Rockville, MD: Office of Applied Studies; 2009.
13. Lee JD, Grossman E, DiRocco D, et al. Home buprenorphine/naloxone induction in primary care. *J Gen Intern Med*. 2009;24:226-32.

Resources

PICODAP drew from existing resources available through the California Society of Addiction Medicine Web site (www.csam-asam.org) for patient educational materials regarding buprenorphine and management forms. We also created a buprenorphine treatment agreement that the counselor or provider would review with the patient prior to initiating buprenorphine (Resource 3A).

Conclusion

The PICODAP Demonstration Model achieved its goal of implementing a sustainable model of office-based buprenorphine into local HIV clinics. Both HIV clinics continue to offer buprenorphine to their patients with opioid dependence. Keys to successful implementation include achieving buy-in from community and clinic stakeholders, conducting appropriate training with providers and staff, and identifying a glue person to coordinate buprenorphine care for opioid-dependent, HIV-infected patients.

CHAPTER 3 RESOURCE

Resource 3A. Suboxone Treatment Agreement

<http://www.careacttarget.org/topics/buprenorphine.asp>*

* This publication lists non-Federal resources in order to provide additional information to consumers. The views and content in these resources have not been formally approved by the U.S. Department of Health and Human Services (HHS) or the Health Resources and Services Administration. Listing these resources is not an endorsement by HHS or HRSA.



CHAPTER 4

REPORT FROM: MIRIAM HOSPITAL BUPRENORPHINE PROGRAM

The Miriam Hospital, a Brown University teaching affiliate, is a 250-bed nonprofit hospital in Providence, Rhode Island. The Miriam Hospital Immunology Center has a strong track record of providing comprehensive primary care for people living with HIV/AIDS (PLWHA) in Rhode Island in general and, in particular, in inner-city communities that traditionally have had difficulty accessing medical care. The clinic is recognized as an important provider of medical care for HIV-positive inmates being released from prison. The Miriam Hospital has a strong working relationship with the methadone maintenance programs in Rhode Island as well as with outpatient, short-term, and residential substance abuse treatment programs.

The Miriam Hospital Immunology Center is the largest provider of HIV/AIDS care and research in southeastern New England. The center's mission is threefold:

1. To promote better understanding, through research, of HIV care and prevention
2. To provide HIV care and prevention to PLWHA and to those who are HIV negative and at risk, with a focus on women and hard-to-reach populations
3. To provide HIV education to fellows, medical students, residents, and community providers.

Care is provided to all patients regardless of their ability to pay for services. Staff at the Immunology Center provide primary care and consultation services at multiple sites, including the Rhode Island Department of Corrections, a supportive housing facility funded by Housing Opportunities for People With AIDS, and community health centers. The Immunology Center clinic received funding from Ryan White HIV/AIDS Program grants to support staffing, laboratory testing, provision of pharmaceuticals not on the AIDS Drug Assistance Program (ADAP) formulary, client transportation, case management, mental health and HIV counseling, testing, and referrals. Client participation is encouraged through periodic focus groups, patient satisfaction surveys, and membership on community advisory boards.

The Immunology Center has an excellent record of collaboration with all the major providers of addiction services, such as detoxification facilities, methadone maintenance treatment centers, and agencies providing inpatient and outpatient counseling. Several sober houses provide group living focused on recovery for people who have completed inpatient programs. Patients who are in recovery are encouraged to become active in 12-step programs to provide them with additional support and an outlet for sober social activities.

The Miriam Hospital Immunology Center is regarded as the primary provider of HIV/AIDS care in the southern New England region, which in this context includes southeastern Massachusetts and northeastern Connecticut, and offers a nonjudgmental, supportive care center for people living with addictions. The staff and providers at the center have extensive

experience working with substance users, and the broader community recognizes and appreciates the services provided by the center to address the health and welfare of the HIV-positive population.

Epidemiology

Rhode Island, in southeastern New England, is the smallest of the United States but the second most densely populated State. U.S. Census data from 2000¹ reported a total population of more than 1 million with 86 percent residing in urban areas.

Substance use has a tremendous impact on the Providence metropolitan area. The Substance Abuse and Mental Health Services Administration (SAMHSA) reported that in 2000, an estimated 7.4 percent of all Rhode Islanders (i.e., 78,000 people) were dependent on or abused alcohol or illicit drugs.² Of the Rhode Islanders treated for illicit drug use in 2000, 37 percent were not independently housed, 44 percent had no documented income, and 79 percent earned less than \$300 per week. Just 24 percent had their drug treatment funded with some form of insurance, including Medicare and Medicaid.³

Rhode Island is a low HIV-prevalence area, and cases are concentrated primarily in the Providence metropolitan area. The estimated number of PLWHA in Rhode Island in 2007 was between 3,766 and 4,295. Between January 1, 2000, and December 31, 2007, 1,102 Rhode Island residents were newly diagnosed with HIV and were reported to HEALTH-RI, the State department of health.⁴ This number provides only a minimum estimate of HIV infection because it does not include people who are HIV infected who have not been tested yet or those who get tested anonymously. Of the 1,102 HIV cases diagnosed and reported to HEALTH-RI from January 1, 2000, to December 31, 2007, men accounted for 72 percent, and the majority of cases were between ages 30 and 39 (39 percent). Among men, Whites accounted for the majority of cases (50 percent), followed by African-Americans (25 percent) and Hispanics (23 percent). Among women, African-Americans accounted for the majority of cases (39 percent), followed by Hispanics (28 percent) and Whites (28 percent).⁴

The local epidemic in Rhode Island has several significant differences from the epidemic in the United States as a whole. Most notably, the primary mode of HIV transmission in Rhode Island is injection drug use, which was the exposure category for 34 percent of cumulative AIDS cases between 1982 and 2007.⁴

The number of Immunology Center patients who are heroin users has not been tracked, but anecdotal evidence indicates that opioid intoxication and withdrawal are seen daily in the clinic and referrals for substance abuse treatment are common. A full spectrum of recovery services for drug dependency are available in Rhode Island, including inpatient detoxification and outpatient follow-up care. The number of people seeking treatment frequently exceeds the number of available treatment slots, regardless of modality.

The demand for services at the Miriam Hospital Immunology Center is growing. The number of patients receiving services increased from 858 in 2001 to an estimated 1,300 in 2008. The racial and ethnic composition of the clinic population in 2008 was 20 percent Hispanic/Latino, 30 percent African-American, 47 percent White, 2 percent Asian, less than 1 percent Native American (19 percent of patients report more than one race). Women are 33 percent of the clinic population.⁵ Transgender people also have received services at the center. The major comorbidity within the clinic population is hepatitis C, and more than one-third of patients are coinfecting with hepatitis C and HIV.

Why Integrate Buprenorphine Into the HIV Primary Care Setting?

Establishing a comprehensive primary care program that integrates HIV care with opioid abuse treatment using buprenorphine/naloxone (Suboxone) can lead to increased social stabilization, which can ultimately increase engagement and retention in medical care, thereby decreasing morbidity and mortality. Providing substance abuse treatment in the primary care setting can help address issues of opioid withdrawal and drug interactions while allowing for coordinated referrals to mental health and case management services.

In addition, our experience has shown us far less tangible reasons for service integration that lead to increased success in both substance abuse treatment and HIV care. HIV primary care providers are extraordinarily sensitive to issues surrounding stigma and often address many personal and intimate topics with their patients. Most providers in the HIV primary care setting have had to explicitly or implicitly confront issues surrounding substance use among their patients. These relationships and conversations are useful places from which to extend comprehensive care. In providing HIV care, it is essential to build trusting relationships between care providers and

patients. Once those relationships are established, they can serve as a springboard for other care, such as substance abuse treatment.

HIV care and substance abuse treatment can complement one another. Addressing substance use and accessing treatment can lead to increased engagement in HIV care and adherence to HIV treatment.

Provider Requirements and Training

The Drug Addiction Treatment Act of 2000 (DATA 2000; Pub. L. 106–310) requires physicians to hold subspecialty board certification or to obtain 8 hours of specialized training in buprenorphine therapy before prescribing it. Our prescribing physician providers met those requirements through both in-person and online courses.

Our experience has shown a tremendous programmatic advantage to training additional clinic staff on buprenorphine and other issues related to substance use treatment and working with substance users. The program incorporated a “buprenorphine nurse” as well as outreach workers. The buprenorphine nurse completed the qualifying buprenorphine training required under DATA 2000, and the outreach workers completed non-DATA 2000-qualifying buprenorphine trainings. In addition, throughout our integrated buprenorphine treatment program, the buprenorphine nurse and/or the outreach workers completed multiple trainings sponsored by The Miriam Hospital, Brown University, and nonprofit and community-based organizations. Recommended trainings to complement the qualifying buprenorphine training are listed in Box 4-1.

Didactic training and experience working with patients being induced and maintained on buprenorphine as well as with substance users in general have led to a cadre of staff who are well prepared to face the challenges associated with the integration of buprenorphine into the HIV primary care setting.

Getting Started

Our experience integrating buprenorphine treatment into our HIV primary care center has helped us to better understand the foundation required for such a program and the expectations for changes that will need to occur for full and successful integration into the clinic. HIV treatment programs seeking to implement a buprenorphine component should prepare for broad changes in clinic culture and operating paradigms, as described in the sections that follow.

Paradigm Shift

Integrating buprenorphine treatment into the HIV primary care setting goes far beyond physicians prescribing the drug. Organizations need to begin to look at practical ways in which they can address a menu of options for opioid-addicted patients and simplify access to different modes of substance abuse treatment. Alternatives to buprenorphine (e.g., referrals for methadone maintenance therapy, referral and support for inpatient and outpatient detoxification and rehabilitation programs, community-based 12-step programs) need to be available. Support services, such as case management and mental health services (provided either onsite or by referral) also are likely a critical factor for success. Substance use treatment will be part of the comprehensive care addressed by the HIV primary care center team, and it will require access to these additional options to support treatment more fully.

BOX 4-1. RECOMMENDED CORE TRAINING TOPICS TO COMPLEMENT THE QUALIFYING BUPRENORPHINE TRAINING

- Opiate Replacement Therapy
- Polysubstance Abuse: Interactions Between Opiates, Benzodiazepines, Alcohol, Cocaine, and Other Substances
- Toxicology Screening: Practical Uses and Limitations
- Integrating Substance Abuse Treatment and HIV Care
- Sustaining Recovery: Use of Community-Based Resources
- Mental Health Diagnoses and Treatment in the Midst of Substance Abuse
- Treating Hepatitis C Virus Among Substance Users

Clinics and providers need to rethink how they approach substance use within the context of HIV care. Specifically, clinician–patient interactions should include

- Identification of opioid use or “finding” opioid-addicted patients,
- Routine toxicology screening for patients prescribed narcotics or benzodiazepines and for those with a history of substance use,
- Interviews with patients consisting of open and frank discussions of substance use,
- Medication review, and
- Pain evaluation.

Experience has taught us the importance of managing expectations. Implementation will not be a seamless path for all (or even most) patients, and providers should recognize that relapse will be part of the process. Build flexibility into the program, and anticipate that both providers and patients will need to think creatively about lifelong success with recovery. It may take patients a long time to accept the full spectrum of needs for a successful “recovery”; these often go beyond traditional substance abuse treatment and incorporate a range of medical, social, and interpersonal issues. Providers should maintain an open door and accept patients throughout all phases of treatment and relapse. In addition, provider–patient communication should routinely include the presentation of the full range of treatment options available through the clinic and in the community to complement or supplant buprenorphine treatment.

Space, Personnel, and Availability of Physicians

For a buprenorphine program to begin in an HIV primary care setting, three components are essential:

1. **Physical space.** In our center, a dedicated office (dubbed the “Bup Lounge”) was secured down the hall from the HIV clinic exam rooms. This space was equipped with comfortable furniture and resources for administrative and clinical tasks. The lounge was a critical piece of the buprenorphine program because it allowed patients and staff to feel as though the program had a stable “home,” and it became a center of activity within the clinic.
2. **Prescribing physicians.** Availability of prescribing physicians is a concern, particularly in centers where individual physicians staff a limited number of clinic sessions per week. Programs must ensure that a

prescribing physician is available or accessible during all hours that clinics are in session because patients may not always present for care or treatment at scheduled appointment times. Flexibility is a cornerstone of our program, but when deciding to see patients outside of planned visits, a system must be in place for medical coverage during clinic hours. The number of certified physicians in a given center can influence the manner in which coverage is provided, whether the coverage is onsite or on call. In addition, mentorship and support for prescribing physicians (and their program teams) should be identified prior to program implementation. In the event that questions or needs arise during the induction or maintenance of a patient on buprenorphine treatment, a clear plan should be in place for expert consultation.

3. **Additional personnel.** Although prescribing physicians play a key role in the implementation of the buprenorphine program, additional staff and personnel are the daily “face” of the buprenorphine program. Clinic-specific program protocols will dictate the exact positions and staff necessary for implementation, but appropriate staff must be identified to serve in key program roles; those staff will likely undergo a significant shift in responsibilities and daily duties. Note that staff throughout the entire clinic can be affected by the change in services. Finally, staffing plans need to consider the impact of the buprenorphine program on the flow of the clinic.

Training for All Levels of Staff

A strong foundation in substance use is necessary before integration begins. Preparation is key, and training of staff at multiple levels within the center is critical so that patient needs can be appropriately addressed and triaged. Although specialized buprenorphine training may not be required for staff members who are not providing direct services, clinic staff should be familiar and comfortable with procedures for buprenorphine treatment and substance use services. All staff should be aware of the various roles that everyone in the clinic can play to comprehensively address substance use among patients.

Referral Mechanisms

Multiple options exist for identifying the “appropriate” population for a clinic’s buprenorphine program. Clinics will need to determine whether buprenorphine treatment will be available only to the clinic population or whether additional sources of referral can be used to identify patients

desiring to initiate buprenorphine therapy within an HIV primary care setting. Potential sources of referral include

- Government sources, such as the SAMHSA Web site or a local department of health;
- Nonprofit sources, including the National Alliance of Advocates for Buprenorphine Treatment (www.naabt.org), local substance use treatment facilities, and AIDS service organizations; and
- Industry sources, including the Web site of Reckitt Benckiser Pharmaceuticals, the manufacturer of Suboxone (and previously Subutex).

In our experience, however, most patients learned about the program through word of mouth.

Forecasting and Reevaluating

To some extent, an integrated substance use treatment program will create an additional burden on an HIV primary care center and will require record keeping and communication with community partners, such as pharmacies where patients may be procuring buprenorphine. The center should anticipate an additional burden but also should reassess the true demand of the program throughout the first year and periodically thereafter to best allocate resources.

Forecasting and planning includes several steps:

- **Keeping count of patients.** A single point person should be responsible for tracking the number of patients treated by all prescribing providers, both for ongoing program evaluation as well as for ensuring compliance with DATA 2000 regulations related to the number of patients who can be treated by a prescriber or group at a given time.
- **Reassessing providers' feelings about the program.** General sentiments of prescribing and nonprescribing physicians at the clinic, as well as of other clinic staff, should be discussed periodically. This discussion can occur either in group forums or in individual discussions with program managers, clinic directors, or buprenorphine program staff.
- **Surveying pharmacies.** Local corporate and independent pharmacies are critical partners in the successful implementation of a buprenorphine treatment program. In our experience, an in-house pharmacy was not available to store and distribute buprenorphine for patients. Relying on a local branch of a chain pharmacy

was essential, and the strong working relationship with that pharmacy required periodic communication in advance of program implementation to discuss pharmacy utilization by program patients. Clinical liaisons from Reckitt Benckiser Pharmaceuticals are able to support and assist with the development of these important relationships.

Funding and Insurance

Significant costs to patients (as well as to clinics) are associated with the integration of buprenorphine treatment into the HIV primary care setting. Prior to implementation, the financial resources required and available to support this treatment option must be assessed:

- **General funding.** Is buprenorphine included on the jurisdiction's ADAP formulary? Is mental health funding available to support this treatment option? Does State Medicaid support buprenorphine treatment (as it does in Rhode Island)? What resources exist to support the uninsured? Does the center have an indigent care fund that might help defray some of the costs?
- **Insurance.** Programs should expect that some dedicated effort may be needed to address coverage issues, even among insured patients. Requirements for prior authorizations can delay induction and provide a barrier to initiation of treatment. Even when patients are insured, in our experience preapproval is usually required and must be reviewed every 3 to 6 months. In addition, plans must be made to ensure that appropriate interactions with insurance companies take place to prevent lapses in coverage. Experience and conversations with colleagues in other jurisdictions suggest that some insurance providers have placed limits on the buprenorphine dosage and duration of treatment covered.

Expect that the involvement of uninsured patients (which likely will be the case) will present challenges, and tough decisions may have to be made throughout the process.

Human Resources and Staffing Needs

The human resources and staffing plan for an individual program should be based on the number of patients anticipated throughout the first year of the program and in subsequent years as well as on the variety of services provided to patients. For example, following the success of active outreach in HIV treatment programs at our center, the buprenorphine model we adopted involved a nurse working closely with a team of outreach workers to maintain patients in care. When planning for staffing patterns,

remember that after the time-consuming startup phase and each patient's induction period, most patients fit into the normal flow of the clinic. Necessary questions when determining a staffing plan and identifying specific people to serve in those roles include, Can the current staff absorb the buprenorphine patients? Who is interested in providing this care? Who is capable of providing this care?

Our experience, as well as that of our colleagues in other jurisdictions, has led us to consider the following key human resources:

- A point person, or “glue person”—a dedicated point person who “owns” the program and serves as the face of the program within the clinic—is critical. Providers and patients will be able to rely on this person to meet the needs of the program. In our setting, a nurse with substance abuse training and extensive experience working within the fields of HIV and mental health fills this role. Physicians, other clinic staff, and all patients are aware of her role, and she is known to all as the key person to contact for all issues related to buprenorphine treatment.
- Nurse clinics, where nurses are the primary points of contact and providers of patient care, are common among sites integrating buprenorphine into HIV care and have worked well in many settings. In our experience, this element has been key to success. The nurse clinic, with access to physicians and support staff, is extraordinarily successful within the context of the HIV primary care clinic because it allows for the comanagement of addiction in a supportive manner.
- Dedicated outreach workers provide positive social support at places outside the clinic and may include case managers, adherence outreach workers, family members, friends, sponsors, therapists, and substance abuse counselors. These workers can be there for patients when things are going well or, conversely, when things are going poorly. They need to be flexible (meeting patients “where they are at”) and work with patients in an individualized manner to keep them engaged or bring them back into care. When people outside the clinic serve in this capacity, a signed release of medical information may be required to allow for the exchange of protected health information between providers.
- It is essential to make use of social and community resources: The clinic cannot do everything! AIDS service organizations, community-based organizations, substance use treatment programs, and 12-step

programs all are available to the buprenorphine program and should be used to fully support patients in the recovery process.

Implementation

In our experience, five key program elements are required for the successful integration of buprenorphine opioid treatment in the HIV primary care clinic:

1. ***Acknowledgement of substance use in the overall care plan.*** Ongoing substance use as well as substance use treatment plans should be accounted for and addressed in comprehensive HIV care plans; substance use should be viewed as a comorbidity that is relevant to the care of the patient.
2. ***Conduct of routine toxicology screening.*** Nonpunitive toxicology screening of patients with a history of substance use, patients prescribed narcotics or benzodiazepines, and patients on buprenorphine provides clinicians with a tool from which to initiate conversations regarding substance use and to appropriately tailor treatment on the basis of substance use patterns.
3. ***Completion of contracts with patients on pain and psychiatric medications.*** Clear guidelines and expectations should be outlined and agreed on by providers and patients when pain and psychiatric medications are prescribed; these contracts may delineate visit and prescription frequency.
4. ***Availability of a glue person and clinic-based, community-based, and mentoring resources for patients.*** Appropriate staff and resources need to be dedicated to the integration of buprenorphine into the clinic; ownership of the program by a single staff member should be complemented by a variety of services provided in-house and throughout the community.
5. ***Tolerance and acceptability of the challenges and “chaos” that active substance users bring to a program and a clinic.*** Care of active substance users can sometimes require providers to offer care in a more flexible manner; this increased flexibility may increase demands on time and lead to more challenging interactions.

In addition to the importance of these components (all of which relate to an openness in addressing substance use within the clinic) and the issues discussed under “Getting Started” (p. 102), our experience has taught us two important lessons related to program implementation:

1. *Psychological barriers must be overcome swiftly.* Significant psychological barriers may exist with regard to physicians prescribing buprenorphine, and some physicians may find it difficult to “feel ready” to prescribe buprenorphine for the first time. Our recommendation is that after becoming certified, the physician should “just start” and begin prescribing buprenorphine when a program is in place and then address issues as they arise.
2. *The importance of mentoring cannot be overstated.* Identify a mentor—a clinician with experience (preferably one who is a higher volume prescriber) who can provide guidance and troubleshoot problems when they occur. In our experience, a local clinician with extensive experience was available to provide mentorship. Successful mentoring can occur by telephone or electronic modes of communication. The Physician Clinical Support System mentoring system can be a wonderful resource. When nurse clinics are part of the organizational structure, a nurse clinician can be identified as an important primary mentor.

Program and Process Evaluation

The integration of buprenorphine into HIV primary care requires ongoing evaluation and continuous quality improvement efforts. At the patient level, this effort requires additional charting of clinical services and substance abuse treatment plans. At a programmatic level, the evaluation process involves a wide range of quantitative and qualitative methods, and program “success” should be defined in broad terms.

Standard operating procedures and program manuals should reflect program guidelines, and all revised versions should reflect the rationale for changes in the program. Program-specific quality indicators that address buprenorphine treatment-specific activities and outcomes need to be determined, as do global measures of integrated care. When determining quality indicators, acknowledge that many patients will start and stop buprenorphine with some frequency. This variability should not be viewed as a failure of the program. In addition to tracking ongoing retention in care, reengagement in treatment (and care, as appropriate) should be reviewed. Databases and program logs are critical tools in tracking program involvement.

Qualitative methods through which to evaluate the buprenorphine program (and care on an individual level) include understanding the level of patients’ involvement

in their substance abuse treatment plan. Patients often are involved in negotiating their buprenorphine dose (increasing or decreasing), whether formally or informally, and this negotiation requires a level of engagement and control related to treatment. The literature supports “ramping up” to a dose and maintaining treatment at that level, but experience shows that patients start and stop buprenorphine as well as increase and decrease dosage. In our opinion, this variability does not constitute failure. Individual discussions with patients surrounding substance use relapses, lapses in treatment, and engagement in care can provide insight into the unmet needs of the population that the program and the clinic may need to address more fully either onsite or through referral.

Clinic staff and program personnel should continue to discuss the positive and negative effects of the buprenorphine program on the clinic in general. These discussions, which should occur on at least a semiannual basis, should address shortcomings and barriers as well as bolster successes. In our setting, ongoing program meetings allowed for real-time program adaptations.

Buy-in From Stakeholders and Providers

Buprenorphine is a part of comprehensive treatment for PLWHA who are addicted to opioids, and the key to success is dedicated staff within the clinic. For successful integration (and successful treatment), clinics and patients should have providers who view integrated substance abuse treatment and HIV care as a mission. Clinics should take the time to integrate substance abuse treatment into the clinic as a whole as well as into comprehensive care plans for individual patients. Opinion leaders in the clinic, who may be medical directors, the most “active” clinicians, department chiefs, long-tenured providers, or strongly valued providers, need to be supportive of a shift in the clinic’s culture to allow for full integration. At minimum, at least one opinion leader should agree with rethinking the way in which substance abuse can be addressed within the clinic. Ideally, opinion leaders should champion the cause and help the clinic take on culture change as a mission.

The greatest stakeholders are the clinicians. Opinion leaders must work with clinicians to discuss the value of substance use treatment within the HIV setting. This process should detail what treatment in this setting may entail and what resources the clinic would need to dedicate. Providing clear examples of the benefits of integrated care, including improved HIV and substance use

outcomes, may be a sound approach with many clinicians. Others may be interested in ways in which anticipated challenges may be prevented. In-service training specific to buprenorphine and addressing substance use with patients can also be useful.

Clinic staff need to be part of the culture shift. Nurses often handle calls related to substance use issues such as escalating narcotic use, emergency room visits, and overdoses. Responsibilities need to be balanced when changes come to the clinic. Including all clinic staff in conversations during the planning and implementation stages helps prevent otherwise unforeseen challenges.

Early discussions with community-based substance abuse treatment providers related to working constructively and collaboratively can best serve the population in need. Once the community-based providers understand that the clinic will be working with a small segment of the population, partnerships for mutual referrals can develop and any sense of competition among providers is diminished.

Steps to Success: Overcoming Barriers

Although multiple factors led to the successful integration of buprenorphine opioid treatment into HIV primary care, three primary indicators are related to the true shift in culture within the clinic:

1. A staff member (i.e., the buprenorphine nurse, also known as the glue person) who is dedicated to addressing substance abuse and is knowledgeable about buprenorphine therapy changed the culture of the clinic. This person made the clinical setting more accepting and open to addressing substance use and treatment of substance users. Because substance use is a chronic, relapsing condition, a staff member who is medically knowledgeable is valuable. In our setting, she proved to be the critical component in facilitating the integration of substance abuse and HIV treatment. Program success was contingent on this staff member.
2. Toxicology screening was initiated as a routine part of the buprenorphine treatment program and of individualized buprenorphine treatment plans. This approach opened the door for the increased utilization of toxicology screening within the clinic overall. This screening is now a routine aspect of HIV care for patients with a history of substance use and those who have been prescribed narcotics or benzodiazepines as well as patients on buprenorphine.

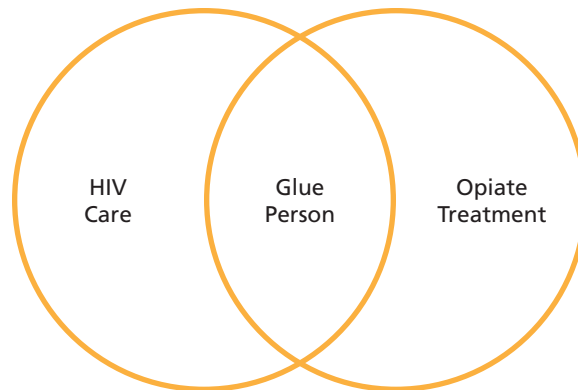
3. The focus on integrated resources allowed for the engagement of patients who would not otherwise be in care. This approach allowed not only clinicians certified to provide buprenorphine but all physicians in the clinic to accommodate substance users in their practices. Having the resources available to address the needs of active substance users promoted continuity of care for both HIV and substance use. In the absence of dedicated resources and a flexible, accommodating model of care, active substance use and relapse would prevent continuity and reengagement in HIV and substance use care.

The culture shift at our center resulted in staff seeing buprenorphine substance abuse treatment as one component of the HIV care provided rather than as an isolated substance abuse treatment program operating within the clinic. Dedicated staff and external grant funding helped bring the program to our center, but full integration, benefits of treatment, and minimal provider burden allowed for the continuation of the program.

Before initiation of the program, some staff and stakeholders had tremendous concerns related to the possibility of diversion of buprenorphine onto the streets. In our experience, this concern was unfounded. Although the potential still exists for diversion, the anticipated fears were unnecessary. To address potential diversion, buprenorphine toxicology screening is conducted. If a patient prescribed buprenorphine has a negative buprenorphine screen, more frequent follow-up and shorter, more frequent prescriptions are incorporated into the care plan. In addition, frank and open discussions about escalating substance use may result in more frequent monitoring and referral to outside substance abuse treatment services.

The development of an individualized treatment plan with each patient is critical to the patient achieving his or her own goals. Buprenorphine may not be the best treatment option for some patients, so having a menu of available services is essential to help patients develop an appropriate care plan. Entering treatment is a big step in the lives of patients, and recovery is a nuanced concept. Dedicated program staff work closely with individual patients to shift their mindsets about recovery. Ideas surrounding “being clean” and the role that pharmacotherapy can play in blurring that line may need to be addressed by program staff. Buprenorphine is a prescribed treatment, which is accepted by the “Big Book” on which 12-step programs rely; an integrated care program can work with 12-step programs toward the goal of recovery.

FIGURE 4-1. ROLE OF THE GLUE PERSON.



Factors Contributing to Adherence

With more potent, longer-acting antiretroviral options now available, adherence and missed doses are no longer as important as they once were. Our experience has taught us that our view of adherence to treatment should be much broader. Our goals for both HIV and substance abuse care should focus on the full spectrum of *linkage, engagement, and maintenance*. In an integrated program, this view includes acceptance that at any given time, patients may be at any point on the spectrum and may receive care for both HIV and substance use, for either HIV or substance use, or for neither HIV nor substance use. Clinics should maintain an open door so that patients have the ability to reengage in care without penalty at any time.

Far greater than adherence, the critical factor to success (defined as overall health and wellness) may well be the patient's remaining in care and staying engaged in the whole package of care services. Those services may include HIV clinical care and substance abuse treatment at the clinic, community services, 12-step programs, positive social support, and formal mental health services from community providers.

The glue person can support engagement and continuation in care. As part of the clinic staff, he or she can bring patients back into both HIV and substance abuse treatment when they fall out of care (Figure 4-1). The strong supportive and caring relationship between the glue person and the patients develops and promotes this open door, allowing for flexible, patient-centered approaches to care.

Leveraging Sustainability

For buprenorphine opioid treatment programs in HIV primary care settings to be sustainable, dedicated funds need to be committed by sources other than demonstration program and evaluation streams. Obtaining this funding requires championing the program's importance at multiple levels (organizational, local, State, Federal). Ryan White HIV/AIDS Program funding is a reasonable way in which to provide this service in a cost-effective manner over the long term, and staff should be able to be supported within this context.

In Rhode Island, buprenorphine is available on the mental health formulary, allowing some access for uninsured persons. One of the greatest successes and outcomes from our demonstration project was the resultant addition of buprenorphine to our State's ADAP. This change was considered a key element of long-term accessibility for our patients and was the result of dedicated lobbying over several years of this program. This addition was later rescinded as a result of a wide range of political and budgetary decisions. Providers throughout the community and advocates within the health department still strongly support including buprenorphine in the ADAP formulary, and efforts to reinstate the coverage will continue.

Program evaluation data can be used to rally additional support, and perseverance in voicing the need for support for buprenorphine and associated substance abuse treatment services at multiple levels can be accomplished through attendance at planning committee meetings, written communication with policy makers, and presentations in national forums.

BOX 4-2. MATERIALS DEVELOPED FOR THE MIRIAM HOSPITAL BUPRENORPHINE PROGRAM

Patient and Family Education Materials

- Talking With Your Doctor About Opioid Use (brochure)
- Buprenorphine Maintenance Treatment: Patient Information (informational pamphlet)
- Buprenorphine Maintenance Treatment: Information for Family Members (informational pamphlet)
- Patient education/information session checklist

Clinical and Substance Abuse Treatment Tools

- Worksheet for *Diagnostic and Statistical Manual of Mental Disorders*, fourth edition,⁶ criteria for diagnosis of opiate dependence
- Intake history and physical examination page

Resources

We developed and implemented a variety of patient and family education materials and clinical documentation forms:

- Patient education/information session checklist (Resource 4A)
- Patient agreement to participate in Suboxone treatment (patient-provider contract) (Resource 4B)
- Integrated care face sheet (Resource 4C)
- Suboxone treatment record (Resource 4D)
- Patient education PowerPoint presentation (Resource 4E).

These materials provided our center with additional tools necessary for the successful execution of an integrated

buprenorphine program. Other materials we developed are listed in Box 4-2.

Conclusion

Our experience has demonstrated that establishing a comprehensive primary care program that integrates HIV care with opioid abuse treatment using buprenorphine/naloxone (Suboxone) is possible but involves a shift in the culture of a clinic. Both providers and patients must learn to think comprehensively of the individual and structural-level issues surrounding substance abuse treatment and definitions of “success.” The establishment of trusting relationships can lead to truly integrated and complementary care for both HIV and substance abuse treatment.

References

1. U.S. Census Bureau. *2000 census of population and housing, population and housing unit counts*. PHC-3-41, Rhode Island. Washington, DC: Author; 2003.
2. Wright D. *State estimates of substance use from 2000 National Household Survey on Drug Abuse: volume II. Supplementary technical appendices*. (DHHS Publication No. SMA 02-3732, NHSDA Series H-16). Rockville, MD: Substance Abuse and Mental Health Services Administration, Office of Applied Studies; 2002.
3. Rhode Island Department of Mental Health and Retardation and Hospitals, Division of Behavioral Health Care, Chemical Treatment Services. *Statistical report, July 1, 2001–June 30, 2002*. Providence, RI: Author; 2002.
4. Rhode Island Department of Health, Division of Community and Family Health Equity, Office of HIV/AIDS and Viral Hepatitis. *Epidemiologic profile of HIV/AIDS*. Providence, RI: Author; March 2010.
5. Gillani FS, Zaller ND, Zeller K, et al. Changes in demographics and risk factors among persons living with HIV in an academic medical center from 2003–2007. *Med Health Rhode Island*. 2009;92(7):237–40.
6. American Psychiatric Association. *Diagnostic and statistical manual disorders* (4th ed., text rev.). Arlington, VA: Author; 2000.

CHAPTER 4 RESOURCES

Resource 4A. ORACLE Education/Information Sessions

<http://www.careacttarget.org/topics/buprenorphine.asp>*

Resource 4B. Patient Agreement to Participate in Suboxone Treatment

<http://www.careacttarget.org/topics/buprenorphine.asp>*

Resource 4C. The Miriam Hospital Buprenorphine Program Patient Face Sheet

<http://www.careacttarget.org/topics/buprenorphine.asp>*

Resource 4D. Suboxone Treatment Record

<http://www.careacttarget.org/topics/buprenorphine.asp>*

Resource 4E. Patient Education Slides

<http://www.careacttarget.org/topics/buprenorphine.asp>*

* This publication lists non-Federal resources in order to provide additional information to consumers. The views and content in these resources have not been formally approved by the U.S. Department of Health and Human Services (HHS) or the Health Resources and Services Administration. Listing these resources is not an endorsement by HHS or HRSA.



ADDITIONAL RESOURCES

Resource A. *Precipitated withdrawal: What it is. How to avoid it.* (National Alliance of Advocates for Buprenorphine Treatment)

<http://www.careacttarget.org/topics/buprenorphine.asp>*

Resource B. Clinical Opiate Withdrawal Scale (COWS)

<http://www.careacttarget.org/topics/buprenorphine.asp>*

* This publication lists non-Federal resources in order to provide additional information to consumers. The views and content in these resources have not been formally approved by the U.S. Department of Health and Human Services (HHS) or the Health Resources and Services Administration. Listing these resources is not an endorsement by HHS or HRSA.



GRANTEE INVOLVEMENT

The following individuals helped in providing the original content for this publication.

University of California, San Francisco, Beehive Program

- Paula J. Lum, MD, MPH, Associate Professor of Medicine, HIV/AIDS Division, University of California, San Francisco, and San Francisco General Hospital, San Francisco, CA
- Jacqueline P. Tulskey, MD, Professor of Medicine, HIV/AIDS Division, University of California, San Francisco, and San Francisco General Hospital, San Francisco, CA
- David Hersh, MD, Medical Director, Opiate Treatment Services, San Francisco Department of Public Health, Community Behavioral Health Services, San Francisco, CA

CORE Buprenorphine Project

- Jeff Watts, MD, Chairman, Department of Psychiatry, Cook County Health and Hospitals System, Chicago, IL
- Melody Bather-Gardner, MA, MISA II, MAATP, Clinical Coordinator, BUP Project, The CORE Center, Chicago, IL
- Virgilio Arenas, MD, Assistant Professor, Director, Division of Addiction Psychiatry and Addiction Psychiatry Training Program, Northwestern Memorial Hospital
- Pamela Vergara-Rodriguez, MD, Attending Physician, Internal Medicine and Psychiatry, Division Chief of HIV Psychiatry, The CORE Center, Cook County Health and Hospitals System, Chicago, IL

Portland Integrates Care for Opioid-Dependent HIV/AIDS Patients Demonstration Model

- P. Todd Korthuis, MD, MPH, Associate Professor of Medicine and Public Health/ Preventive Medicine, Oregon Health and Science University HIV Program, Portland
- Sarann Bielavitz, Research Coordinator, Oregon Health and Science University HIV Program, Portland
- Michael S. MacVeigh, MD, HIV Clinic Medical Director, Multnomah County Health Department, Portland, Oregon

Integrating Buprenorphine Therapy Into an HIV Primary Care Setting in Providence, Rhode Island

- Timothy P. Flanigan, MD, Professor of Medicine, Brown University/Alpert Medical School
- Cynthia Macleod, ACRN, Clinical Coordinator, The Miriam Hospital
- Helen Loewenthal, MSW, Senior Project Director, The Miriam Hospital
- Jennifer A. Mitty, MD, MPH, Assistant Professor, Brown University
- Lauri Bazerman, MS, Project Director, The Miriam Hospital

“Glue People”

- Melody Bather-Gardner, MA, MISA II, MAATP, Clinical Coordinator, BUP Project, The CORE Center, Chicago, IL
- Marilyn Blake, RN, Clinical Nurse Coordinator, University of California, San Francisco, and San Francisco General Hospital
- Kristen Meyers, CADC 1, Multnomah County Health Department HIV Health Services Center, Portland, OR (formerly of Oregon Health and Science University HIV Program)
- Cynthia Macleod, ACRN, Clinical Coordinator, The Miriam Hospital