

TRAINING MANUAL



Integration of Buprenorphine into HIV Primary Care Settings

August 2012



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



Training Manual: Integration of Buprenorphine into HIV Primary Care Settings

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The Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (HAB) has developed the Integrating HIV Innovative Practices (IHIP) manuals, curricula, and trainings to assist health care providers and others delivering HIV care in communities heavily impacted by HIV/AIDS with the adoption of Special Projects of National Significance (SPNS) models of care. This IHIP training manual is part of that effort. Additional IHIP materials can be found at www.careacttarget.org.



A PROBLEM

If I was still under the addiction of [opioids] . . . I would jump up in the morning and I would forget about the HIV medicine and I would go out and get [high].¹

The intersection of opioid abuse, particularly injection drug use (IDU), and HIV is well documented; in fact, IDU is the second most frequent route of HIV transmission.² Injection drug use, either directly or via sexual contact with an IDU partner, accounts for one-third of the estimated AIDS cases since the beginning of the epidemic, and 18 percent of new infections in the United States.³

Opioids are natural, semisynthetic or entirely man-made drugs that bind to receptors in different parts of the body and are generally used as nonmedical painkillers. Heroin, morphine, fentanyl, codeine, oxycodone, buprenorphine, and methadone are opioids.

With an estimated 2.4 million opioid-dependent Americans,⁴ opioids are among the most frequently abused drugs.⁵ And nonmedical pain medication abuse has been garnering a lot of press. It's been featured in the *Chicago Tribune* and *The Baltimore Sun*, and on MSNBC. It was a front cover story of *USA Today* and a feature in *Time* magazine.

According to a 2010 Substance Abuse and Mental Health Services Administration (SAMHSA) national study, dependence/abuse of pain relievers ranked second

(after marijuana) among illicit drug use in the past year. Heroin ranked fifth.⁵

Prescription pain medications, such as hydrocodone (Vicodin), oxycodone (OxyContin, Percocet), and hydromorphone (Dilaudid), are highly addictive.⁶ According to the SAMHSA study, 5.3 million Americans reported nonmedical use of prescription pain relievers in the last month.⁷ And the consequences are growing: "Between 2004 and 2008, emergency department visits involving oxycodone, hydrocodone, and methadone increased 152%, 123%, and 73%, respectively, and the number of fatal overdoses due to opioid analgesics now exceeds those due to heroin and cocaine combined."⁸ In fact, mortality among illicit opioid users has been estimated at 13 times that of the general population.⁹

This problem is exacerbated among people living with HIV/AIDS (PLWHA) who may be using such medications for pain management.

- Receipt of prescription opioids to treat pain is not uncommon, particularly as HIV disease is associated with acute and chronic pain syndromes.¹⁰

- Pain threshold as well as drug tolerance may change in people who are addicted to opioids.¹⁰
- Greater pain severity has been observed in patients who have HIV disease and a mental health disorder.^{11,12}
- HIV-infected patients with drug histories are also more likely to have high higher levels of pain and symptom distress than non-drug-using PLWHA.^{13–15}

HIV care providers should, therefore, be aware of the increased abuse of prescription opioids.

High prevalence of co-occurring conditions among PLWHA requires a coordinated system of care. However, the number of opioid-dependent patients significantly outweighs the number of opioid treatment programs nationwide.¹⁰ In fact, only approximately 15 percent of substance users are in treatment.¹⁶ This is problematic, particularly as substance use is associated with increased risk of HIV transmission,^{10,17} and is a barrier to treatment adherence^{18–23} and therefore, viral control of HIV.^{22,24–26}

On a broader scale, the financial and social costs of untreated opioid dependence in the United States are estimated to be approximately \$20 billion per year, including \$1.2 billion in health care costs.²⁷

Opioid dependence is treatable—and buprenorphine is one available option. Drug addiction treatment correlates with decreased risk for HIV transmission and improved health outcomes.^{17,10}

Methadone’s effectiveness at reducing opioid abuse has been well established, and for many patients this may be the preferred form of opioid treatment.^{28–33} Methadone, however, may not be right for all HIV-positive patients seeking opioid abuse treatment. Some patients may have tried methadone and been unsuccessful, may have trouble adhering to the strict structure and regulations of methadone programs, and may feel stigmatized by going to a standalone substance abuse clinic. It may be more difficult for some patients to stay in care when HIV services and substance abuse treatment are fragmented (i.e., at separate locations).³⁴

UNDERSTANDING ADDICTION

What Do Opioids Do to the Brain, and Why Are They Highly Addictive?

Opioids release an excess of dopamine into the body. Dopamine is a neurotransmitter (brain chemical) involved

with learning, motivation, pleasure, and reward. Opioids change the amount and sensitivity of dopamine receptors and can make people feel euphoric; additionally, opioids can suppress pain and reduce anxiety. Eventually, users require an opioid to continuously occupy the opioid receptor in the brain, or they develop withdrawal symptoms.^{10,35,36}

Nerve receptors are likely to adapt and begin to resist the drug, causing the need for higher doses. The other side of this tolerance is a physical withdrawal reaction that occurs when the drug leaves the body and receptors must readapt to its absence.⁶

The American Society of Addiction Medicine defines *addiction* as a disease of brain reward, motivation, memory, and related circuitry.³⁷ Images of the human brain have shown that drug use can change the brain’s actual structure, function, and metabolism, sometimes long after drug use has ceased.

Dependence is the physiological change that occurs with drug use, resulting in the need to continue use—or increase dosage—to avoid withdrawal.¹⁶ Addiction, including opioid dependence, is considered a chronic, relapsing, brain-related disorder.^{10,27,38}

What Increased Risk Behaviors Are Tied to Opioid Abuse?

HIV-positive patients with substance use disorders have benefitted less from treatment than their non-substance-using peers.⁴ This is, in part, because opioid-dependent patients are less likely to be prescribed HIV antiretroviral (ARV) medications and, when they receive ARVs, are more likely to be involved in early discontinuation.^{4,39} In addition, substance use is associated with increased sexual risk behaviors, increased HIV risk, and poorer health outcomes, and contributes to destabilizing conditions, such as homelessness and mental illness.⁴⁰ As shown in Figures 1 and 2, approximately 18 percent of new HIV infections are attributed to IDU.³

What Is Medication-Assisted Treatment for Opioid Use?

Medication-Assisted Treatment (MAT) is defined as “the use of medication such as methadone or buprenorphine in combination with counseling and behavioral therapies to provide a whole-patient approach to the treatment of

FIGURE 1
Estimated Cumulative AIDS Cases by
Transmission Route, United States

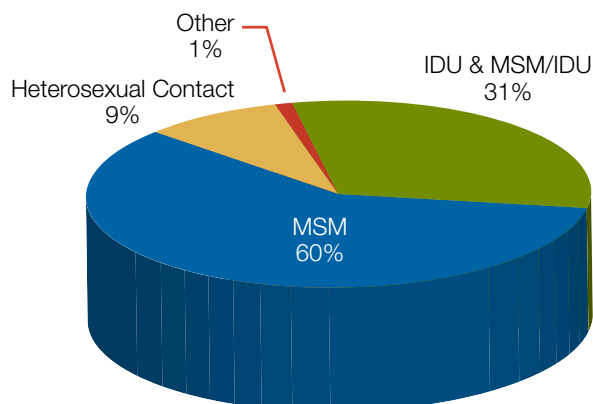
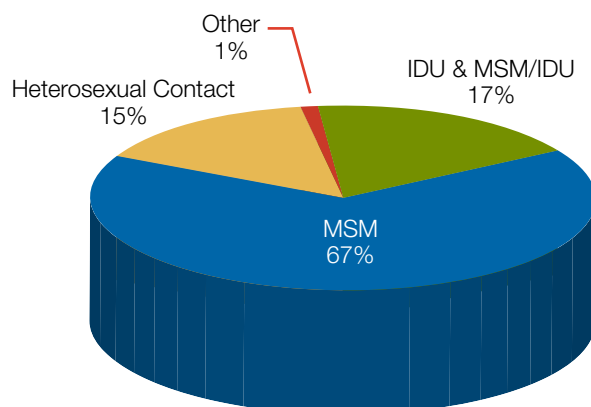


FIGURE 2
Estimated AIDS Cases by
Transmission Route, United States, 2010



Source: U.S. Centers for Disease Control and Prevention (CDC). HIV Surveillance Report. 2010(22). Table 2b. (Note, percentages may not add to 100 due to rounding).

opioid dependence.”⁴¹ According to an article in *JAIDS* by Dr. Cheever et al., MAT is an integral component of addressing heroin and prescription opioid abuse alongside HIV treatment and prevention services.¹⁰

Why Consider Medication-Assisted Treatment?

HIV primary care clinics facilitate access to opioid treatment in many ways. It can take the form of case finding outreach, referrals from partners and treatment programs in the community, availability of group support and counseling, and access to ancillary services. HIV primary care clinics and community health clinics are already treating many of the health care needs of their opioid-dependent patients. The prevalent model for managing patients with HIV and opioid dependence has been to treat their HIV and substance abuse independently of one another.⁴² Now, the integration of MAT under the umbrella of comprehensive HIV care services is not only

feasible but offers one more way to assist patient needs and create a truly medical home.⁴³

Treatment of opioid dependence results in significant public health benefits—and improved lives and livelihoods for people living with HIV. It allows providers to truly treat the whole person, a hallmark of the Ryan White HIV/AIDS Program. Inclusion of opioid treatment within an HIV primary care setting may also facilitate relapse prevention.⁴⁴

“A public health policy promoting integrated treatment for HIV [positive] individuals with opioid dependence is [considered] an essential strategy to curb the epidemic.”⁴⁵ This sentiment was included as part of the U.S. Centers for Disease Control and Prevention’s (CDC’s) Strategic Plan⁴⁶ and the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau’s (HAB’s) approach during a groundbreaking Special Projects of National Significance (SPNS) initiative.⁴⁷ (See “SPNS Initiative: Findings from the Field” on page 9.)



AN OPPORTUNITY

This integration of addiction and HIV treatment provides an opportunity to coordinate care of these 2 medical conditions in 1 setting, the HIV primary care clinic.⁴⁸

The Ryan White HIV/AIDS Program has led the way in creating comprehensive wraparound services and spearheading the notion of a medical home. The integration of substance abuse treatment within a Ryan White-funded clinic expands on this commitment and offers new hope.

“Developing effective integrated care models for complex patient populations, like HIV-infected drug users, is important for several reasons:

- First, integrated care dismantles barriers for disenfranchised patient populations.
- Second, integrated treatment models may foster better communication and collaboration among HIV care providers, psychiatrists, and alcohol and drug specialists.
- Third, data from randomized controlled trials have suggested that integrating services at a single site may improve both medical and substance abuse treatment outcomes.”⁴⁹

Many integrated service programs provide public HIV primary care. As these sites—whether HIV specialty or community health clinics—are already attending to a

BUPRENORPHINE AND THE NATIONAL HIV/AIDS STRATEGY

Two important components of HIV prevention are addressing transmission risk behaviors and improving adherence to ARVs. The integration of buprenorphine into HIV primary care settings achieves both of these goals—and the goals of the National HIV/AIDS Strategy. In fact, informing the greater HIV community about the feasibility and effectiveness of buprenorphine is an important component of the U.S. Department of Health and Human Services’ National HIV/AIDS Strategy Federal Operational Plan.

Source: U.S. Department of Health and Human Services (HHS). HHS operational plan: achieving the vision of the National HIV/AIDS Strategy. February 2011. Available at: <http://aids.gov/federal-resources/policies/national-hiv-aids-strategy/nhas-operational-plan-hhs.pdf>. Accessed December 12, 2011.

host of health issues in their patients, including HIV, and given the high prevalence of HIV and opioid dependence, including buprenorphine in the medical home model makes sense. It allows patients with chaotic lives to readily access services under one roof and providers to treat addiction as a chronic medical condition while addressing additional medical needs.

It also enables patients who have forged trusting and communicative relationships with their HIV primary care doctor to continue that relationship in the context of culturally competent care and now, to address their opioid dependence. Medication adherence and health outcomes are also optimized when HIV primary care is linked with substance abuse treatment.⁵⁰

This work is made possible thanks to the passage of the Drug Addiction Treatment Act of 2000, otherwise known as DATA 2000.

BUPRENORPHINE

What Is Buprenorphine?

Buprenorphine is a semisynthetic opioid.³⁶ *Subutex* is a white, oval tablet that contains only buprenorphine (and was discontinued as of January 1, 2012, by the original manufacturer, Reckitt Benckiser, although it is available generically).⁵¹ A coformulated version of buprenorphine and naloxone is called *Suboxone*. In tablet form, it's an orange, hexagonal pill with buprenorphine and naloxone in a 4:1 ratio.^{36,52} (As of 2010, Suboxone is also available as a sublingual film.) Whether as a film or tablet, buprenorphine opioid treatment is taken sublingually, meaning under the tongue.

There's an important distinction between Subutex and Suboxone: Suboxone is meant to discourage diversion

DATA 2000

The Drug Addiction Treatment Act of 2000 (DATA 2000) is the seminal legislation that made office-based treatment of opioid addiction possible. More specifically, it enabled *qualifying physicians* outside of opioid treatment programs (i.e., methadone clinics) to prescribe and/or dispense Schedule III, IV, and V opioid medications approved by the U.S. Food and Drug Administration (FDA). Buprenorphine is considered a Schedule III narcotic.

The promise of DATA 2000 is to help destigmatize opioid addiction treatment and to enable qualified physicians to manage opioid addiction in their own practices.

On October 8, 2002, the FDA approved two sublingual formulations: Subutex® (buprenorphine) and Suboxone® (buprenorphine/naloxone) tablets for the treatment of opioid addiction. (See "Getting Started" on page 14 to learn more.)

Together, these milestones paved the way for SPNS Buprenorphine Initiative grantees to prescribe Suboxone within their HIV primary care settings and thus created ever more comprehensive wraparound services for their patients.

On August 31, 2010, the FDA added another treatment option for addressing opioid abuse—Suboxone sublingual film. The film is administered similarly to Suboxone tablets; however, it dissolves more quickly under the tongue for speedier administration effectiveness. Additionally, Naltrexone, an extended-release injectable form of opioid treatment, is now available.

Though released after the conclusion of the Buprenorphine Initiative, these approvals extend the groundbreaking work first set forth in DATA 2000. (To read the full law, visit www.buprenorphine.samhsa.gov/fulllaw.html.)

Sources: Substance Abuse and Mental Health Services Administration (SAMHSA). Clinical guidelines for the use of buprenorphine in the treatment of opioid addiction: a treatment improvement protocol (TIP) series 40. DHHS publication no. (SMA) 07-3939. Rockville, MD: SAMHSA, 2004.

SAMHSA. Buprenorphine: physician waiver qualifications. n.d. Available at: http://buprenorphine.samhsa.gov/waiver_qualifications.html. Accessed October 25, 2011. Reckitt Benckiser. *Reckitt Benckiser Inc. received FDA approval for Suboxone® (buprenorphine and Naloxone) sublingual film C-III*. August 31, 2010. Available at: www.rb.com/FDA-Approval-for-Suboxone-Sublingual-FilmC-III. Accessed December 12, 2011.

as naloxone binds to—and blocks—opioid receptors.³⁶ By itself, naloxone is injected to reverse overdose. But when taken sublingually with buprenorphine, naloxone has no effect. This is because sublingual naloxone is not as well absorbed. Naloxone was added to buprenorphine to block the effects of heroin and other opioids—something it does very successfully.⁵³ If Suboxone is injected in an attempt to get high, it can initiate immediate withdrawal (otherwise known as “precipitated withdrawal”) in individuals who are on other opioids.³⁸ Because naloxone discourages use by injection, it makes Suboxone diversion less likely than methadone or Subutex (buprenorphine alone).^{54–57} (To read more about this, see “How Do I Identify Precipitated Withdrawal, and What Is It?” on page 26.)

As of 2012, manufacturer Reckitt Benckiser has suspended Subutex, stating that monotherapy of buprenorphine (without naloxone) increases diversion and misuse.

What Does It Do?

Buprenorphine stabilizes brain neurochemistry³⁸ because it displaces other opioids from their receptors and then occupies the same receptors, thus preventing withdrawal symptoms.⁵⁴

Because buprenorphine is a partial opioid agonist, it does not stimulate the same degree of activity at the brain’s opioid receptors as full opioid agonists do (e.g., heroin, morphine, OxyContin, fentanyl, and methadone). As a result, people using buprenorphine may still experience euphoria and become physically dependent, but to a lesser extent than with full agonists.³⁶

If patients use other opioids while already on Suboxone, buprenorphine will block the euphoria and other effects produced by opioids.³⁸ Providers have cited how lucid their patients are on buprenorphine and how dramatically it has improved their daily functioning.⁵⁴

Is Buprenorphine Addictive?

Buprenorphine does carry some risk for psychological and physical dependence,⁵⁸ although potential for addiction is considered generally low, certainly a lesser degree than full opioid agonists, and it seems easier to discontinue than methadone.^{53,59} That buprenorphine treatment may be easier to discontinue than methadone does not necessarily mean one medication-assisted addiction treatment measure is superior to another.⁶⁰ All patients

should be screened to see which treatment option may be best suited for them. If patients choose to stop using buprenorphine, they should be tapered off slowly to decrease risk of withdrawal symptoms and relapse to opioid use.

What Are Agonists and Antagonists and How Do They Relate to Buprenorphine?

Buprenorphine is considered a partial agonist–partial antagonist medication, meaning that it works by both activating and blocking opioid receptors.⁵⁵ The antagonist (or blocking) property provides a “ceiling effect” on buprenorphine’s ability to control pain and induce euphoria. Up to a certain dose, buprenorphine’s agonist (or activating) property predominates, and each dose increase is accompanied by an increase in the intensity of the drug’s analgesic and euphoric effects. Beyond a ceiling dose, however, the antagonist property of buprenorphine predominates. At that point, the effects of the drug level off and cannot be further enhanced—even with additional buprenorphine.⁵⁴

By contrast, heroin and methadone are full agonists: They have purely activating effects on opioid receptors and therefore lack buprenorphine’s ceiling effect. As a result, methadone is effective for addicts who require an extremely high dose of opioids to avoid withdrawal. Methadone may be more effective for some opioid-dependent patients, since they may need higher doses to stave off withdrawal and drug cravings.^{53,54,61}

Buprenorphine is considered to have sufficient agonist properties such that patients routinely describe the medication as allowing them to “feel normal.”⁶²

Is It Safe?

Buprenorphine is considered to have a safer profile than full agonists.⁶³ Suboxone, in particular, is considered to have an improved safety profile as compared with methadone or Subutex.^{2,34}

Suboxone has fewer adverse events associated with its use as well as fewer drug–drug interactions among HIV patients on ART than methadone.¹⁰ Risk of overdose on buprenorphine is also considered lower than overdose on methadone.⁵⁸

Worth noting, however, is the potential for overdose when benzodiazepines (i.e., medications used to treat insomnia and anxiety, such as diazepam [Valium] and

TABLE 1
Buprenorphine and Methadone Comparison

	Methadone	Buprenorphine
Method of Administration	Oral; pills, wafers, diskettes, or liquid	Sublingual; tablets or film
Coformulation	No	Yes, available both as monotherapy and in combination with naloxone
Method of Delivery	Through Federally certified Opioid Treatment Programs (OTPs)	Through qualified physicians in a primary care setting and OTPs
Dosing Frequency	Daily	Daily; also can be used on alternate days or thrice-weekly
Access	Limited by the number of programs and slots	Limited by the number of patients a physician can treat (100)
Cost	\$50 to \$300 per week for clinic visits; coverage by public and private payors varies	\$4 to \$19 per day, depending on dose; coverage by public and private payors for medication and office visits varies
Used for Detox	No	Yes
Addictive	Yes	Yes, although considered less addictive than methadone
Serious Side Effects/ Adverse Events	Cardiac conduction, respiratory depression, overdose, dependence	Respiratory depression, overdose, dependence
Pregnancy Category	FDA class “C” medication	FDA class “C” medication
Overdose Risk	Yes, by itself and when combined with other opioids and/or alcohol	Yes, when combined with benzodiazepines and/or alcohol

Source: Sullivan LE, Fiellin DA. Narrative review: buprenorphine for opioid-dependent patients in office practice. *Ann Intern Med.* 2008;148(9):662–70.

alprazolam [Xanax], or medications for seizures, such as phenytoin, carbamazepine, and valproic acid) are abused while a patient is taking buprenorphine.⁶⁴ Risk increases if buprenorphine is taken with large amounts of central nervous system depressants, such as alcohol or benzodiazepines.³⁶

Potential drug–drug interactions also exist between buprenorphine and other sedative drugs, opioid antagonists and agonists, and medications metabolized by the cytochrome P450 3A4 system.⁵³ Additional medications that affect this cytochrome include fluconazole and macrolide antibiotics; and inducers, such as phenobarbital, carbamazepine, phenytoin, and rifampicin.⁴⁵ (For a continuously updated list of P450 3A4 drug interactions, visit <http://medicine.iupui.edu/flockhart/table.htm>.)

Interactions between buprenorphine and psychiatric medications have not been studied in humans, except for citalopram (Celexa) and sertraline (Zoloft);

neither drug has clinically significant interactions with buprenorphine, so they can be safely coadministered.⁶⁵

Educating patients about the risk of overdose is imperative. Physicians should ensure patients receive drug screening prior to administration of buprenorphine. (See “Polydrug Use and Mental Illness” on page 30 for more information.)

How Does Buprenorphine Differ from Methadone?

There are several differences between buprenorphine and methadone, in addition to how and where they are administered. Methadone has been in widespread use for a longer period of time than buprenorphine, so more information is available on long-term safety and treatment outcomes. Since methadone is a full agonist, it is easier for people to overdose because the effects increase with higher doses. Buprenorphine is a partial agonist, so using

THE INTERNATIONAL EXPERIENCE

In France, more than 80,000 people have been treated with buprenorphine in their primary care clinic. Buprenorphine treatment within this setting has been shown to destigmatize drug treatment. French studies have shown improved individual, social, and economic benefits, including healthier patients, improved HIV medication adherence, lower viral loads, and better social function.

Buprenorphine treatment was also linked to dramatic decrease in drug overdose, including deaths from drug overdose.

Sources: Kaminski DM. AIDS Community Research Initiative of America. Buprenorphine: the new kid on the block. *ACRIA Update*. 2005;14(2):22.

Carrieri MP, Amass L, Lucas GM, et al. Buprenorphine use: the international experience. *CID*; 2006;43(Suppl 4): S197–215.

Emmanuelli J, Desenclos JC. Harm reduction interventions, behaviours and associated health outcomes in France, 1996–2003. *Addiction*. 2005;100(11):1690–700.

Gueye PN, Megarbane B, Borron SW, et al. Trends in opiate and opioid poisonings in addicts in north-east Paris and suburbs, 1995–1999. *Addiction*. 2002;97(10):1295–1304.

a larger dose will not heighten the effects of the drug. The propensity for drug–drug interactions with HIV medications is greater with methadone than buprenorphine.

But there are important similarities: Both drugs are known to improve addiction and health-related outcomes, and both are more effective when used in

combination with individualized counseling and behavioral therapy, an approach known as medication-assisted treatment, or MAT.

Is Buprenorphine Used for Detox and, if so, How?

Buprenorphine can also be used on an inpatient basis for medically supervised withdrawal (also called “detox”). This helps to reduce opioid withdrawal symptoms and, ultimately, brings the patient into a non-physically dependent state. During medically supervised withdrawal, patients receive buprenorphine daily for up to 10 days; it is discontinued 36 to 48 hours before discharge.

It should be noted, however, that SPNS grantees did not administer buprenorphine in this way. Rather, patients came into SPNS outpatient clinic sites while already in withdrawal and then subsequently received supervised induction of Suboxone.

What Do I Need to Know About Buprenorphine and Liver Enzymes?

Acute viral hepatitis and drug-induced hepatitis can harm the liver, helping to contribute to liver failure and liver disease. Due to the high rates of coinfection with hepatitis C virus (HCV) among those PLWHA who contracted HIV via IDU, routine monitoring of liver enzymes is important. The same is true for patients with previous histories of high alcohol use who may suffer from cirrhosis.^{9,66,67} (See also “What Are Some Side Effects of Buprenorphine?” on page 27.)

Though rare, buprenorphine-induced hepatitis is also possible. As such, patients should receive liver enzyme testing at baseline and 1 month post-treatment, as well as quarterly.⁹



SPNS INITIATIVE: FINDINGS FROM THE FIELD

For many years, the Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau (HAB) sought to improve services for HIV-infected substance abusers seeking care in Ryan White-funded programs. It has remained a HAB priority.¹⁰

—Dr. Laura Cheever,
Deputy Director and Chief Medical Officer of HAB

Buprenorphine is becoming increasingly available, and thanks to DATA 2000 guidelines it can now be integrated within general medical settings. This allows for more streamlined and comprehensive services for opioid-dependent people living with HIV disease. Ryan White-funded clinics are uniquely situated to address this range of patient needs.

To study opioid treatment among the HIV-infected population, HRSA's HIV/AIDS Bureau (HAB) funded an SPNS project entitled, "An Evaluation of Innovative Methods for Integrating Buprenorphine Opioid Abuse Treatment in HIV Primary Care" (Buprenorphine Initiative). This 5-year, national, multisite study involved 10 HIV primary care sites and more than 300 HIV-positive opioid-dependent patients. All sites used Suboxone tablets in the study, as Suboxone film was not yet available during the project period. All grantees were supported

by a technical assistance and evaluation center.² (To read more about the study, visit www.hab.hrsa.gov/abouthab/special/buprenorphine.html and www.hab.hrsa.gov/abouthab/files/hab_spns_buprenorphine_monograph.pdf.)

SPNS grantee sites were:

- community neighborhood health centers,
- university medical centers, and
- hospital centers.

Clinicians, whether at large institutions or at small clinic sites, can take on this work as proven by SPNS grantees.

The Buprenorphine Initiative represents *“the largest study addressing substance abuse among people living with HIV to date.”*⁶⁸

This landmark project helps pave the way for more HIV primary care physicians to better integrate services and offer ever more comprehensive care.

Currently, many Ryan White-funded providers are treating HIV disease among substance users. The promise in promoting opioid treatment within the context of the Ryan White HIV/AIDS Program is that it helps diminish opportunities for miscommunication between health care providers and reduction of drug–drug interactions.¹⁰ Similar strategies that HIV primary care providers are already employing in regard to motivational interviewing, harm reduction, and offering nonjudgmental care are all strategies that should continue as providers enter into opioid abuse treatment with patients.

BUPRENORPHINE TREATMENT MODELS

Existing programs for integrating buprenorphine treatment models include community health centers, hospital-based settings, and mobile health units.⁴⁵

The “HIV primary care model” involves the same physician administering HIV treatment and buprenorphine.⁴² This has been the most widely adopted model in the SPNS Buprenorphine Initiative.

This model is particularly attractive for rural settings, community health centers, and clinical settings where addiction specialists are difficult to access. This model also lends itself to adoption in clinical settings where patients may be distrustful of new providers, as it allows patients to access opioid treatment by their same physician.⁴²

The HIV primary care model approach may help decrease stigma associated with substance abuse treatment and may involve greater oversight on the part of the physician monitoring drug–drug interactions.⁴² Physicians may fear that if patients perform poorly in adhering to buprenorphine, it may put their relationship—and HIV care—in jeopardy.⁴² Based on SPNS Buprenorphine Initiative findings, this fear is, on the whole, unfounded. In contrast, patients felt they could open up about their substance abuse more readily and they received the same nonjudgmental harm reduction approach characteristic of Ryan White clinics.⁶⁹

Though HIV primary care physicians in the SPNS Buprenorphine Initiative were handling buprenorphine

administration, they certainly accessed mentorship opportunities and utilized staff such as the glue person to assist in many aspects of care support. In many grantee sites, the HIV primary care physician was responsible for induction of buprenorphine and writing prescriptions, but the glue person was responsible for many other aspects of care, such as counseling, assessments, maintenance, etc.⁶⁹ (To read a template introduction of the care coordinator glue person to prospective patients, visit www.careacttarget.org/library/bup/CORE_Buprenorphine_Program_Materials.pdf and see “The Glue Person” on page 21.)

Research has shown that medication-assisted addiction therapy decreases illicit opioid use while increasing retention in HIV primary care and adherence to HIV antiretrovirals.^{30,70–73} The SPNS project adds to the field of research supporting these findings.

The SPNS Buprenorphine Initiative found that “among the group who was at highest risk for an adverse clinical outcome—those not on ART at baseline—longer retention on [Suboxone] was significantly associated with higher rates of ART initiation and viral suppression.”⁷⁴ The greatest retention on ART was among subjects maintained on Suboxone for 3 or 4 quarters (9 to 12 months).⁴

“Buprenorphine is facilitating highly active antiretroviral therapy; it stabilizes patients, and we see their HIV RNA decline and their CD4 cell count rise,” explains Dr. Lynn Taylor, from Miriam Hospital, who participated in the SPNS Buprenorphine Initiative.³⁵

HIV clinicians at the majority of SPNS Buprenorphine Initiative sites had limited or no prior experience providing Suboxone to opioid-dependent patients before project initiation. According to Linda Weiss, evaluator of the SPNS Buprenorphine Initiative, physicians across sites found Suboxone treatment to be a good service to provide to their patients and found administration easier than expected and no harder than anything else they were currently overseeing within their clinics.

Prior to patient enrollment, providers attended an 8-hour training in conjunction with the American Society of Addiction Medicine (ASAM). In addition, each site had access to affiliated personnel with some experience in the use of Suboxone, underscoring the importance of a mentor with some addiction experience.⁶⁴ All sites stressed the importance of a care coordinator, or “glue person.” According to Weiss, to adequately address the needs of PLWHA and fully implement opioid abuse treatment, SPNS grantee physicians found

OTHER TREATMENT MODELS

While the HIV primary care model was adopted by the bulk of SPNS Buprenorphine Initiative grantees, success has been found through initiation of other treatment models, too. These include the following:

Onsite Addiction Specialist Model

This model includes a partnership between an HIV physician and an addiction specialist. The addiction specialist oversees induction, stabilization, and maintenance. Care is only “integrated” in the sense that patients receive both substance abuse treatment and HIV care within the same clinical setting.

It takes advantage of onsite specialized care and integrated electronic medical records within a single facility, and allows patients to continue to receive the full spectrum of care needs addressed under one roof. This model, however, requires patients to coordinate appointments through two separate physicians, which may add another barrier to care receipt.

This model was most applicable in HIV treatment centers within teaching hospitals where addiction care was easily accessible and HIV physicians had rotations only a few hours a week within the clinic.

Hybrid Model

This model utilizes an addiction specialist skilled in buprenorphine administration to handle the induction and stabilization phases and work with the HIV physician during the maintenance phase. The appeal of this model is that HIV physicians with reservations about full oversight of buprenorphine have increased support.

Conversely, this hybrid model initially fragments care and may require more coordination between physicians.

Also, patients may need to schedule and adhere to appointments with two providers rather than one.

Community Outreach Model

This model taps into the work being done by community health care mobile van units, particularly among marginalized populations. The van brings care services and treatment into the community to offer directly observed HIV treatment and buprenorphine therapy. This model may be helpful to individuals with difficulty keeping appointments and who are homeless.

However, this model requires an enormous amount of flexibility. It may create barriers to patients seeking care within the clinic setting and the community outreach van, and it offers less structure and potentially less autonomy than a clinic setting.

Drug Treatment Model

This model has been utilized in locations where substance abuse clinics offer HIV services onsite. Since patients are accessing buprenorphine therapy within the constructs of a substance abuse clinic, it offers easier transition to methadone therapy for those patients who need to be transferred to this more structured environment.

Disadvantages include the continued segregation of buprenorphine therapy from the patient’s traditional HIV physician (as patients would be referred to this new setting to address their HIV and opioid addiction). Substance abuse clinics are also often overburdened and may not be available in certain geographic locations. In addition, not all substance abuse clinics are well versed in HIV care, so this model is highly specific to a particular type of care setting.

Sources: Basu S, Smith-Rohrberg D, Bruce RD, et al. Models for integrating buprenorphine therapy into the primary HIV care settings. *Clin Infect Dis*. 2006;42(5):716–21.

HRSA, Special Projects of National Significance. *Integrating buprenorphine therapy into HIV primary care settings*. April 2012. Available at: www.hab.hrsa.gov/about/hab/files/hab_spns_buprenorphine_monograph.pdf.

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PATIENT EXPERIENCE: THE SPNS BUPRENORPHINE INITIATIVE

The SPNS Buprenorphine Initiative found that

Patients were overwhelmingly satisfied with the pharmacologic effects and treatment outcomes of Suboxone, including effectiveness in blocking cravings and controlling opioid use; decreased fear of withdrawal and/or missed doses; and an overall improvement in quality of life. Patients also described being more engaged with both their substance abuse treatment and HIV care, including greater ability to manage their own treatment, keep appointments, and adhere to antiretroviral medication regimes. . . . Nearly all were positive about their experience with integrated care, appreciative of an improved drug treatment environment, convenience, and quality of care.

Patients often described themselves as feeling “normal” on buprenorphine, like how they used to feel before they started using opioids. There was improved quality of life not only in health care outcomes but improved social status, too. Cravings for opioids were dramatically reduced.

As one patient described, “[I]f it wasn’t for Suboxone, I think I’d be dead, truly. . . . [Instead] it got me back to working. . . . I got my apartment, my son. He’s always loved me [but now] he respects me a lot more. . . . I start seeing hope for myself. And I start feeling I could fight HIV and there’s nothing that I can’t accomplish.”

Sources: Egan JE, Netherland J, Gass J. Patient perspectives on buprenorphine/naloxone treatment in the context of HIV care. *JAIDS*. 2011;56(Suppl 4):46–53.

they needed someone to assist in coordinating support services, address mental health issues, and work on any unforeseen psychosocial aspects that arose. This glue person was a mainstay, and the glue person’s work cannot be overstated. (See “Determine Staffing” section on page 21 to learn more.)

SPNS research supports integrating MAT—specifically Suboxone—into HIV primary care. According to one grantee site study among 93 HIV-positive, opioid-dependent patients who were assigned either to clinic-based buprenorphine and individual counseling or to case management with referral to drug treatment, people

in the buprenorphine group were significantly more likely to participate in treatment for opioid dependence (74 percent versus 41 percent), less likely to use opioids and cocaine, and more likely to attend their HIV primary care visits than were people in the group referred to drug treatment.⁷⁵

The SPNS Buprenorphine Initiative findings should provide encouragement to sites considering integrating opioid treatment into their HIV primary care clinics.⁶⁴ (To read SPNS grantee site case studies, visit www.hab.hrsa.gov/abouthab/files/hab_spns_buprenorphine_monograph.pdf.)

KEY FINDINGS: SPNS IN THE SPOTLIGHT

Patients and providers were overwhelmingly satisfied with the treatment and its results. The Buprenorphine Initiative:

- Allowed for integration—rather than fragmentation—of services, resulting in improved retention in care.
- Allowed initiation of ARVs among patients not previously on treatment.
- Improved drug and HIV treatment outcomes, particularly among those not previously on ARVs.
- Improved CD4 counts among patients participating in the project.
- Resulted in decreased heroin and other opioid use.
- Increased social stability.
- Decreased HIV transmission risk behaviors.
- Decreased stigma associated with substance abuse treatment.
- Was associated with improved mental and physical health-related quality of life.

Sources: HRSA, Special Projects of National Significance. *Integrating buprenorphine therapy into HIV primary care settings*. http://www.hab.hrsa.gov/about/hab/files/hab_spns_buprenorphine_monograph.pdf

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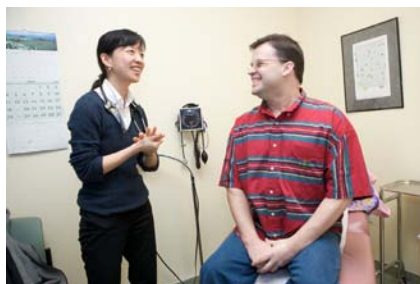
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PRESCRIBING BUPRENORPHINE

If Suboxone becomes routinely available in HIV primary care settings,
*“it has the potential to improve access to ART and reduce morbidity and mortality
among HIV-infected opioid-dependent patients who have traditionally
been less likely to access and adhere to ART.”*⁷⁶

GETTING STARTED

Who Can Prescribe Buprenorphine?

In order to prescribe buprenorphine, you must be a licensed physician (MD or DO) and receive a waiver from SAMHSA’s Center for Substance Abuse Treatment, and an accompanying ID number and Drug Enforcement Agency (DEA) registration number. (See “Qualify for a Waiver” on page 15.)

How Many Patients Can I Treat?

Authorized physicians may treat up to 30 patients at any one time for the first year. After 1 year, physicians may submit a second notification, this one to treat up to 100 patients.

To access and *email* notifications, visit: http://buprenorphine.samhsa.gov/pls/bwns/additional_notification_form?prefilled_or_online=ONLINE.

To access an online form to *fax* or *mail* in, visit http://buprenorphine.samhsa.gov/pls/bwns/additional_notification_form?prefilled_or_online=PREFILLED OR http://buprenorphine.samhsa.gov/SMA-167_Increase_Patients.pdf and send to the contact information below:

Substance Abuse and Mental Health Services
Administration
Division of Pharmacologic Therapies
Attention: Opioid Treatment Waiver Program
One Choke Cherry Road, Rm 2-1063
Rockville, MD 20857
Fax 240-276-1630
Phone 866-287-2728 (866-BUP-CSAT)⁷⁷

(To learn more about increasing patient limits, visit <http://buprenorphine.samhsa.gov/federal.html>.)

Conduct a Needs Assessment

Part of successful integration of opioid abuse treatment into your clinic is first identifying the level of abuse, including among those individuals potentially overlooked. The best way to do this is to implement screening programs to detect illicit drug use.

In cases where such screening isn't possible, providers may be able to utilize indirect estimates of illicit opioid use by using surrogate markers such as the number of patients with IDU as an HIV transmission category. Another surrogate marker is the number of clients receiving opioid prescriptions for chronic conditions.

National data, as well as clinical experience from [an SPNS Buprenorphine Initiative grantee] suggest that prescription opioid abuse may be proportional to the number of opioid prescriptions written.^{78,79}

Are There Any HIV Drugs That Should Not Be Taken With Buprenorphine?

Buprenorphine, along with several HIV drugs, is metabolized by the liver. Clinicians need to be aware of drug-drug interactions. Select appropriate antiretroviral agents and monitor patients accordingly. To assist in guidance, see Table 2. Drug-Drug Interactions.

What Happens If Someone Needs Pain Medication With Buprenorphine?

Should patients need the use of a full agonist for pain relief management, buprenorphine should be discontinued until pain is able to be controlled without the use of opioid pain medications. Physicians should recognize, however, that use of opioid pain medications by patients with opioid addiction may further increase tolerance and physician dependency—counter to the goals of buprenorphine treatment.⁵³

Can People on Methadone Switch to Buprenorphine?

Yes, people can switch from methadone to buprenorphine, especially if they are working with an experienced physician. Since methadone is a long-acting opioid, people who want to switch should initially be treated with buprenorphine monotherapy (to avoid withdrawal

symptoms from naloxone) before switching to buprenorphine and naloxone.

Before patients switch, they need to gradually taper their methadone dose (30 mg per day is recommended).⁵³ Physicians must contact the patient's Opioid Treatment Program (OTP) to ascertain the amount and time of the patient's last dose of methadone.

WHAT DO I NEED TO DO TO GET STARTED?

Qualify for a Waiver

Do you hold 1) a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties, OR 2) an addiction certification from the American Society of Addiction Medicine, OR 3) a subspecialty board certification in addiction from the American Osteopathic Association?^{57,80}

If yes to any of the above, see "Submit a Waiver" below. If no, see "Training" below.

Training

Physicians must complete 8 hours of approved training from a public or private certifying board in treatment management of opioid-dependent patients. This may be done in person or online. This was the most common route pursued by SPNS grantees. (To browse the list of qualifying physician trainings, visit <http://buprenorphine.samhsa.gov/training.html>, www2.aaap.org/buprenorphine, www.docoptin.com/physician/calendar.aspx, or www.buppractice.com.)

Addiction may also be "medicalized" like other chronic diseases and as such, principles of the chronic disease model that physicians may be using can also be applied.⁴⁵ Several SPNS grantees also underscored this point. (To read about the Chronic Disease Model, visit www.improvingchroniccare.org/index.php?p=the_chronic_care_model&s=2.)

Submit a Waiver

Physicians must receive a waiver from the special registration requirements of the Controlled Substances Act in order to prescribe medication-assisted opioid treatment.⁸⁰

TABLE 2
Drug–Drug Interactions

	Buprenorphine: effect on ARV level	ARV: effect on Buprenorphine level
Nucleoside Reverse Transcriptase Inhibitors		
Abacavir (Ziagen; Trivizir and Epzicom also contain abacavir)	Not studied; monitoring recommended due to potential interaction. ¹	Not studied; monitoring recommended due to potential interaction. ¹
Didanosine (ddI; Videx tablet or EC)	Buprenorphine has no effect on ddI. ²	ddI has no effect on buprenorphine. ²
Emtricitabine (FTC; Truvda, Atripla, and Complera also contain FTC)	Buprenorphine has no effect on emtricitabine. ¹	Emtricitabine has no effect on buprenorphine. ¹
Lamivudine (3TC, Epivir; Combivir, Epzicom, and Trizivir also contain lamivudine)	Buprenorphine has no effect on lamivudine. ²	Lamivudine has no effect on buprenorphine. ²
Stavudine (d4T; Zerit)	Buprenorphine has no effect on stavudine. ¹	Stavudine has no effect on buprenorphine. ¹
Tenofovir (Viread; Truvada, Atripla, and Complera also contain tenofovir)	Buprenorphine has no effect on tenofovir. ²	Tenofovir has no effect on buprenorphine. ²
Zidovudine (AZT, Retrovir; Combivir, and Trizivir also contain zidovudine)	Buprenorphine does not cause significant changes in zidovudine levels. ³	Zidovudine does not cause significant changes in buprenorphine levels. ³
Non-nucleoside Reverse Transcriptase Inhibitors		
Delavirdine (Rescriptor)	Buprenorphine does not cause significant changes in delavirdine levels. ⁴	Delavirdine increases buprenorphine levels but does not cause side effects/symptoms other than drowsiness. ⁴
Endurant (Rilpivirine; Complera also contains rilpivirine)	No data	No data
Efavirenz (Sustiva; Atripla contains Sustiva)	Buprenorphine does not cause significant changes in efavirenz levels. ⁴	Efavirenz lowers buprenorphine in bloodstream, but without causing withdrawal symptoms; although buprenorphine dose adjustment is unlikely to be necessary, monitoring for withdrawal symptoms is recommended. ⁴
Etravirine (Intelence)	Buprenorphine does not cause significant changes in etravirine levels. ⁵	Etravirine lowers buprenorphine levels; although buprenorphine dose adjustment is unlikely to be necessary, monitoring for withdrawal symptoms is recommended. ⁵
Nevirapine (Viramune)	Buprenorphine does not significantly change nevirapine levels. ⁶	Although nevirapine significantly lowers buprenorphine levels, buprenorphine dose adjustment is unlikely to be necessary. ⁶

(Table continues on the following page.)

TABLE 2
Drug–Drug Interactions

	Buprenorphine: effect on ARV level	ARV: effect on Buprenorphine level
Protease Inhibitors		
Atazanavir (Reyataz) Atazanavir/r	Buprenorphine does not significantly change atazanavir or atazanavir/r levels. ⁷	Atazanavir and atazanavir/r increase buprenorphine levels; buprenorphine dose adjustment may be needed if opioid toxicity/ side effects develop. ⁷
Darunavir/r (Prezista)	Buprenorphine does not cause significant changes in darunavir/r levels. ⁸	Darunavir/r increases buprenorphine levels; dose adjustment is not necessary, although clinical monitoring is recommended. ⁸
Fosamprenavir/r (Lexiva)	Buprenorphine does not cause significant changes in fosamprenavir/r levels. ⁹	Fosamprenavir/r does not cause significant changes in buprenorphine levels; dose adjustments unlikely to be needed. ⁹
Indinavir/r (Crixivan)	No data	No data
Lopinavir/r (Kaletra)	Buprenorphine does not significantly change lopinavir/r levels. ¹⁰	Lopinavir/r increases clearance of buprenorphine's main metabolite (called norbuprenorphine, or norBUP), but this does not cause side effects and buprenorphine dose adjustment is not necessary. ¹¹
Nelfinavir	Buprenorphine does not significantly change nelfinavir levels. ¹⁰	Nelfinavir does not significantly change buprenorphine levels. ¹⁰
Ritonavir (Norvir)	Buprenorphine does not significantly change ritonavir levels. ¹⁰	Ritonavir increases buprenorphine levels, but no dose adjustment is needed. ¹⁰
Saquinavir/r	No data	No data
Tipranavir/r (Aptivus)	Buprenorphine lowers tipranavir/r in the bloodstream by 19 to 25 percent; use with caution. Therapeutic drug monitoring may be needed. ¹²	Although tipranavir/r lowers the level of norBUP, this does not cause side effects, and buprenorphine dose adjustment is not necessary. ¹²
Integrase Inhibitors		
Raltegravir (Isentress)	Buprenorphine does not significantly change raltegravir levels. ¹³	Raltegravir does not significantly change buprenorphine levels; buprenorphine dose adjustment is not necessary. ¹³
Entry/Fusion Inhibitor		
T-20 (Enfuvirtide; Fuzeon)	No data	No data
Maraviroc (Selzentry)	No data	No data

Resource: For updated information about drug–drug interactions: www.hiv-druginteractions.org

A list of references for Table 2 is on the following page.

TABLE 2

Drug–Drug Interactions

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Waiver forms may also be accessed at <http://buprenorphine.samhsa.gov/howto.html> and mailed or faxed to the following address:

After the review process has taken place (typically, 45 days), approved physicians will receive an ID number and DEA registration number, which will need to be included on all prescriptions for opioid addiction therapy. (To learn more about waiver qualifications, visit http://buprenorphine.samhsa.gov/waiver_qualifications.html.)

Yes, physicians must be able to offer counseling services or have formal referral systems in place to link patients undergoing opioid treatment to counseling. (To view a grantee example of referral procedures, visit www.careacttarget.org/library/bup/UCSF_Buprenorphine_ProgramProtocols.pdf.)

Counseling as a part of substance abuse treatment typically results in greater reductions in opioid and other substance use and greater adherence to buprenorphine and other medical treatment.⁸¹ Counseling can be offered onsite or through referral to offsite mental health services partners in the form of individualized counseling or weekly group counseling. Regardless of where it is administered or the format in which it is delivered, patients who attend counseling consistently achieve better treatment outcomes than those with little or no counseling.^{82,83}

Patients with the most success had the following characteristics:

- access to therapy with a focus on comprehensive case management,
- a patient advocate with whom they felt they had good rapport and trust,
- medical and psychiatric care and counseling that were closely linked, and
- active engagement in their project participation.⁶⁹

Confidentiality

Records for substance abuse treatment have stricter standards than traditional medical records.^{84,85} “This means either keeping separate records for the substance abuse treatment components of care or identifying records concerning substance abuse treatment in a way that they are released only under appropriate circumstances.”⁸⁶ Use of electronic medical records, however, may assist in integrating HIV primary care records with opioid treatment records while still remaining in compliance with confidentiality regulations.⁸⁵

Federal regulations require physicians to obtain signed patient consent before disclosing any identifiable patient information to a third party. To avoid any confidentiality issues, physicians are recommended to have a separately signed form for each patient.

According to SAMHSA,

*It is particularly important to obtain patient consent when telephoning or faxing prescriptions to pharmacies, as this information constitutes disclosure of the patient's addiction treatment. When physicians directly transmit prescriptions to pharmacies, further redisclosure of patient-identifying information by the pharmacy is prohibited, unless signed patient consent is obtained by the pharmacy.*⁸⁷

This rule, however, does not apply if patients themselves deliver the buprenorphine prescription directly to the pharmacy.⁵³ Suboxone package labeling also contains information on Federal confidentiality and regulations.

In addition, it's particularly important to educate phone room and front desk staff or to develop policies and procedures in collaboration with front desk and phone room staff. This staff can also be helpful in giving screening forms to patients when they come in. If everyone fills out forms, it reduces any stigma associated with them and patients don't feel like they're being singled out.

Ensure Appropriate Storage

Suboxone was required to be in a locked cabinet for storage when onsite at the SPNS grantee clinic sites. According to Federal regulations, buprenorphine of any kind must be stored in a securely locked, substantially constructed cabinet whereby patients would not have easy access and clinicians can accurately record the amount of medication received and dispensed. Any theft must be reported to the local DEA office in writing within one business day.⁸⁸

Determine Available Clinic Space and Appointment Slots

SPNS grantees ensured they identified any structural changes that needed to be made to day-to-day operations of clinical services. This included assignment of clinic exam rooms and appointment slots in the clinic schedule. Patients need access to clinic space for the duration of their induction process as well as for routine check-ups.

Because medical interventions are rarely necessary during induction, regular office space could be used. Some grantees, however, found that offering induction in the same or similar area as future monitoring may be of assistance since patients are always returning to the same space.⁶⁹

Secure Buy-in

Stakeholders were considered patients, medical providers, clinic staff, clinic administration, and pharmacy (inhouse or within the community). SPNS grantees

found it was helpful to inform the community about their work. This allowed grantees to educate the community on buprenorphine and ensure this work was seen as a complement to—rather than a competition with—other available treatment alternatives, such as public and private methadone clinics, and residential detoxification and rehabilitation facilities, as well as substance-use treatment providers. Because of the cross-section of illegal opioid use and the criminal justice system, several SPNS grantees ensured outreach to their local jail services programs.⁶⁹

Higher level stakeholders included staff, directors, or administrators of State AIDS Drug Assistance Programs (ADAPs) and State Medicaid Programs (to discuss buprenorphine and its potential inclusion on formularies), as well as any State and local offices of AIDS services, and narcotic enforcement officials.⁶⁹

To continue support from personnel, SPNS grantee staff gave updates and case study presentations at monthly provider and clinic staff meetings. They also advertised the program by putting up flyers around the clinic and at affiliated partner sites. Clinic outreach workers also assisted with word-of-mouth advertising and education about the program in the community.

Patients who had successfully undergone buprenorphine induction were encouraged to speak to new patients about any fears they might have regarding the need to be in “withdrawal” at the time of induction. Hearing patient success stories helped alleviate fears.⁶⁹ Patient brochures and informational sheets were also created for this purpose and can be accessed here: www.careacttarget.org/library/bup/UCSF_Buprenorphine_ProgramRecruitment.pdf. Patient and provider flyer examples can be accessed here: www.careacttarget.org/library/bup/CORE_Buprenorphine_ProgramMaterials.pdf.)

Determine Staffing

Several roles emerged as essential to successfully implementing opioid abuse treatment. These roles may overlap or be assigned to different individuals within your clinic.

- Clinical champion within your clinic to serve as a resource throughout the implementation process.
- Front desk and phone triage staff coached on clients presenting in opioid withdrawal or contacting the office to request opioid abuse treatment.

THE COMMUNICATION HIGHWAY

SPNS grantees emphasized the importance of educating all staff about buprenorphine treatment. In particular, this assisted in cultural competency and improved communication and program success.

For example, some patients on opioid abuse treatment may be requesting opioid prescriptions (e.g., codeine, hydromorphone, morphine, oxycodone) from other health care providers that they see. As such, physicians integrating buprenorphine into their HIV clinics should be clear and communicative with others involved in patient care.

- Medical assistants and nursing staff prepared to work with patients in withdrawal.
- Coordinator to ensure things run smoothly; oversee referrals for housing, legal services, transportation, food pantry, clothing, individual counseling, and weekly buprenorphine support group counseling; and manage follow-up induction protocol.
- Office administrator responsible for correspondence, ordering supplies, and budget oversight.
- Substance abuse counselor with dedicated time for counseling clients who are seeking and receiving buprenorphine.
- Designated staff member to address benefits and insurance issues.

In many cases, these roles can be filled by existing staff who are already performing similar functions for other PLWHA within the clinic. Often, these responsibilities were part of the work assigned to what the SPNS Buprenorphine Initiative grantees came to call the “glue person.”

The “Glue Person”

Successful SPNS programs relied on a dedicated person who served as the face of the program within the clinic and the primary point of contact for issues related to buprenorphine. Providers—and patients—relied on this person deemed a “glue person,” although their background and training prior to the SPNS initiative varied from site to site. The glue person was not the primary

clinician administering buprenorphine. Nevertheless, the glue person was imperative to the success of the program. Together, the physician and glue person created the Dyad Model—a two-person team taking responsibility for the program.⁶⁹

Continuity, consistency, and stability are all essential components of addiction treatment, and the glue person helped provide that.

The glue person was cited as a critical aspect, particularly at clinics where clinicians may do rounds and not be available every day. Creating such a team approach was also imperative to achieving clinic buy-in. Successful sites offered informational trainings to counter misperceptions and address hesitation to the implementation of buprenorphine into their clinic. (To assist in such trainings, see accompanying buprenorphine “Curriculum” guide from HRSA.)⁶⁹

The glue person worked with the physician to develop and monitor individualized plans and track clinical outcomes. They provided patient education, conducted initial screenings and assessments for treatment eligibility, monitored and counseled patients during treatment (under the supervision of the clinician), and ran weekly patient support groups.⁶⁹

As described by the University of California, San Francisco SPNS grantee, the glue person’s “presence in the clinic afforded [them] familiarity with most of the patients and providers, and this knowledge contributed greatly to the visibility of the program and to patient support.”

Although the background and education of the clinical care coordinator, or “glue person,” varied from site to site, all had some sort of substance abuse training and experience working within the fields of HIV and mental

health. This was particularly helpful as co-occurring mental health issues are common among substance abusers. Clinic staff and patients alike were aware of the glue person’s role, and inclusion of that role helped support the success of these programs.

Identify a Mentor

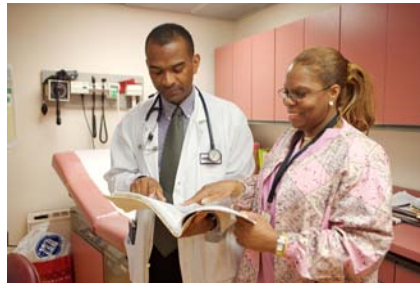
SPNS grantees underscored the importance of having a physician mentor, particularly during the planning and early implementation steps of integrating opioid abuse treatment into their clinics. Specifically, grantees accessed the SAMHSA-funded Physician Clinical Support System for Buprenorphine (PCSS-B), a free, nationwide program linking physicians interested in integrating buprenorphine into their practices with mentors for support. (To find a mentor or learn more about this program, visit www.pcassb.org or <http://ceitraining.org/bupren/>. To chat with other DATA waiver-approved physicians, join the free SAMHSA buprenorphine clinical discussion WebBoard, here: <http://bup-webboard.samhsa.gov/login.asp?target=default.asp>.)

Professional societies and HRSA’s AIDS Education and Training Centers also offer HIV-related support.

Pharmacy Care

At one clinic, Suboxone sublingual tablets were dispensed from the HIV clinic directly. Then, as the patient progressed and achieved a stable buprenorphine dose, prescriptions were transferred to a community pharmacy.⁶⁹

Several grantees found it helpful to tour a pharmacy to observe buprenorphine storage and dispensing practices. Grantees noted that onsite availability of a pharmacy and laboratory facilitated implementation and execution but were not prerequisites for success.



IMPLEMENTATION, STABILIZATION, AND MAINTENANCE

“The easy part is learning about and administering buprenorphine. The hard part is changing the clinic culture to say, ‘opioid dependence is a brain disease.’ We need to curtail the notion that these patients are different.”

—Dr. P. Todd Korthuis,
Associate Professor of Medicine and Public Health/Preventive Medicine,
Oregon Health and Science University HIV Program

Patients were often referred to opioid treatment from HIV medical care, psychiatry, mental health counseling, pain clinics, chemical dependency clinics, inpatient wards, community housing, and community drug treatment centers.

Eligible SPNS initiative patients had to meet the following criteria:

1. Be at least 18 years old.
2. Meet Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) criteria for opioid dependence. DSM-IV classifies opioid dependence as having three or more of the following within one year: tolerance; withdrawal; larger amounts/longer period than intended; inability to cut down or control use; increased time spent

obtaining opioids; social or occupational activities given up or reduced; and despite adverse consequences, opioid use persists.⁴⁵

3. If a female patient, not be pregnant, nursing, or trying to become pregnant. (Buprenorphine is classified by the FDA as a Pregnancy Category C medication similar to methadone.)
4. Be interested in receiving substance abuse services.
5. Be HIV-positive and receive HIV primary care at the site.

Prior to administration of Suboxone, patients receive education and counseling. Any patient assessment questions should be targeted and open-ended to solicit detailed responses beyond a simple yes or no. Providers

also discussed program expectations and answered patient questions. The initial assessment process was completed in one or two visits. Providers were also expected to have an emergency contingency plan for patients, such as an on-call number or backup system prior to program launch.¹⁶

(To access consent form, patient treatment agreement, and eligibility criteria checklist templates, visit www.careacttarget.org/library/bup/UCSF_Buprenorphine_ProgramTreatment.pdf; www.careacttarget.org/library/bup/TMH_PatientAgreementforSuboxoneTreatment.pdf; www.careacttarget.org/library/bup/SuboxoneTreatmentAgreement.pdf; and www.careacttarget.org/library/bup/CORE_Buprenorphine_ProgramMaterials.pdf.)

Grantees also had substance abuse counseling community linkages and collaborations, including onsite substance abuse counseling. Since “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” as well.⁶⁹

Exclusion criteria included:

1. uncontrolled or untreated psychiatric problems,
2. pregnancy,
3. serious uncontrolled or untreated medical problems (e.g., hypertension, asthma, diabetes, hepatic failure),
4. patient currently on more than 30 mg of methadone,
5. chronic pain disorder requiring high-dose opioid medication,
6. allergy or hypersensitivity to buprenorphine or naloxone,
7. benzodiazepine abuse or dependency (currently or within the past 6 months),
8. aspartate aminotransferase/alanine aminotransferase ratio of >5x upper normal limit,
9. binge drinking, and
10. requires greater program structure such as that involved in methadone maintenance.⁶⁹

Before physicians begin to prepare patients for treatment, they must answer four important questions:

- “1. Who is to perform the induction and stabilization of patients receiving buprenorphine?
2. How are patients to be maintained on buprenorphine treatment appropriately?

3. What forms of counseling are necessary?
4. How can care be coordinated between providers?”⁴²

PREPARATION FOR TREATMENT

Chart Work. All patients had to have a complete health history (including immunizations and tuberculin purified protein derivative status), recent physical exam documented in their medical charts, and pain evaluation.

Comorbidities. Providers reviewed their entire substance use history and any co-occurring medical conditions, particularly liver disease, pain syndrome, and mood disorders.

Medication Review. Patient medications were also reviewed. Worth noting, “many HIV antiretroviral and psychiatric medications are metabolized by the cytochrome P450 3A4 system and may necessitate buprenorphine and dose adjustments.”⁶⁹

Buprenorphine Access. Providers needed to ensure their onsite pharmacy or a community pharmacy was onboard with dispensing buprenorphine. In many cases, SPNS grantees worked with “benefits” workers to enroll study patients in Medicaid, Medicare, or State ADAP programs and to have buprenorphine added to formularies and obtain prior authorization for buprenorphine prescriptions (where possible).

Birth Control. Providers assessed female patients’ effective use of birth control.

Lab Work. Patients completed lab work to check liver enzymes, urinalysis, and for pregnancy. Their most recent HIV-related lab work was also reviewed to check HIV viral load, CD4 cell count, liver function tests, and hepatitis serologies.⁶⁹ Hepatitis screens, syphilis test, lipid profile, serum electrolytes, blood urea nitrogen (BUN, a measurement used as part of routine bloodwork and to diagnose or monitor kidney disease) and creatinine, a complete blood count (CBC) with differential and platelet count, and TB test may also want to be considered.⁵³

Toxicology Screening. Patients prescribed narcotics or benzodiazepines and those with substance abuse histories (including illegal opioid use and other drugs) were all screened.

Education. Patients were questioned about what they understood about buprenorphine treatment, and providers filled any “knowledge gaps.” Providers also reinforced patient goals, motivations, and readiness. One SPNS grantee utilized patient education slides, which

can be viewed here: www.careacttarget.org/library/bup/TMH_BuprenorphinePatientEducationSlides.pdf.

Agreements. Patients were asked to sign a contract that they would adhere to the program requirements and consent to treatment. Patients also signed an authorization to exchange health information. Lastly, patients were asked to sign a take-home dosage agreement. (To access examples of these documents, visit www.careacttarget.org/library/bup/UCSF_Buprenorphine_ProgramTreatment.pdf.)

Providers who did not have onsite substance abuse counseling, psychotherapy, or self-help programs of any kind were asked to create formalized agreements with providers to whom patients would be referred for counseling.

Kick Pack. SPNS grantees found it helpful to supply “kick packs” to patients. Since patients had to arrive at the clinic on the first day in an opioid-free state, these “packs” helped address any anticipated withdrawal symptoms, such as nausea, diarrhea, myalgias, and rhinorrhea.⁶⁹ To read about what specific medications were included in the kick packs prepared by the UCSF grantee, visit www.careacttarget.org/library/bup/UCSF_Buprenorphine_ProgramProtocols.pdf.

Manage Expectations. It’s imperative that patients understand what buprenorphine can and can’t do. There is no magic bullet for opioid dependence. Buprenorphine can dramatically assist opioid-dependent patients, but other interventions, such as harm reduction counseling, motivational interviewing, and behavioral counseling, should be used as well. It’s important that patients understand that recovery, whether still maintained on MAT or not, is a lifelong process.

Physicians were also asked to manage expectations and continue education with staff to keep them abreast of the program and ensure their buy-in and cultural competency in assisting patients undergoing opioid treatment.

Prescribing. On Suboxone prescriptions, clinicians must include patient’s full identification, including name, address, drug name, strength, dosage, quantity, and directions. As with other DEA-scheduled medications, prescriptions for Suboxone must be dated and signed on the date of issuance. The physician’s DEA registration number and physician DATA 2000 registration number must be included on prescriptions as well.⁸⁸

To keep track of prescriptions, one SPNS grantee utilized a Suboxone Treatment Record, which can be accessed here: www.careacttarget.org/library/bup/TMH_BuprenorphineTreatmentRecord.pdf.

INDUCTION

This phase is medically monitored, typically as observed therapy in a physician office for at least 2 hours. The induction phase begins with an initial “test dose” of buprenorphine.⁴²

The opioid-dependent person must have abstained from using opioids for 12 to 24 hours and must be in the early stages of withdrawal. Note, patients must be in early stages of withdrawal, otherwise buprenorphine will precipitate acute withdrawal. Many patients in the SPNS project were initially worried about having to be in “withdrawal” when they arrived their first day for Suboxone induction.

These worries were largely unfounded, and in fact, patients found the buprenorphine to work instantly. As one patient described, “With the bup . . . you’re not [feeling the heroin] . . . instantly you won’t feel it, but within a matter of a few days, maybe five days, you’re not having cravings, you’re just feeling normal. You just get up and you don’t miss it, nothing. This [stuff] works great.”

Inductions were scheduled on Mondays, Tuesdays, or Wednesdays to allow for two follow-up visits within the same week. The glue person was required to be at all patient appointments; however, the prescribing physician was required to be onsite only for the initial induction.⁶⁹

To view induction protocol in table form, see Figures 4-1 and 4-2 of “Treatment Protocols” at http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf.

HOW DO I IDENTIFY OPIOID INTOXICATION OR OVERDOSE?

Syndrome	Physical Findings
Opioid Intoxication	Conscious; sedated or drowsy; slurred speech; “nodding” or intermittently dozing; memory impairment; mood normal to euphoric; constricted pupils
Opioid Overdose	Unconscious; pinpoint pupils; slow, shallow breathing (i.e., respirations below 10 per minute); pulse rate below 40 per minute Overdose triad: apnea, coma, pinpoint pupils (with terminal anoxia; fixed and dilated pupils)

Source: Reproduced from SAMHSA. *Clinical guidelines for the use of buprenorphine in the treatment of opioid addiction: a treatment improvement protocol, TIP 40*. 2010. Available at: http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf. Accessed December 16, 2011.

How Do I Identify Precipitated Withdrawal, and What Is It?

Precipitated withdrawal is a more rapid and intense onset of symptoms. The purpose of induction is to safely suppress opioid withdrawal through dosing of buprenorphine. Longer-acting opioids, such as OxyContin and methadone, will require longer abstinence than shorter-acting opioids, such as heroin, Percocet, Vicodin, or oxycodone.⁸⁹

Providers should use only time of last opioid use to anticipate withdrawal. Patients must also be at adequate withdrawal phase before buprenorphine initiation.⁸⁹

To assess and assist with withdrawal, providers need:

- A penlight to assess pupil dilation,
- A stopwatch or clock to assess pulse rate, and
- A nearby bathroom, to ease the comfort of patients with active gastrointestinal and urinary symptoms associated with opioid withdrawal.

Withdrawal consists of predictable signs and symptoms resulting from the removal of or decrease in opioid use.⁵³ Clinicians in the SPNS Buprenorphine Initiative found the Clinical Opiate Withdrawal Scale (COWS) to be effective in measuring symptoms during induction.^{90,91} To access COWS and how to read and grade this scale, visit www.careacttarget.org/library/bup/COWS_ClinicalOpiateWithdrawalScale.pdf. Using the COWS scale allows clinicians to better identify whether patients are still experiencing opioid effects or are adequately in withdrawal to begin induction.

The University of California, San Francisco found the COW Scale in combination with the SOAP (Subjective data, Objective data, Assessment, Plan) Note Format on page 27 to be helpful.

While patients are undergoing induction, they should be engaged by health personnel. SPNS grantees found these patients needed interaction and direction from the moment they arrived to ensure a successful induction. Patient observation typically ranged from 2 to 4 hours following induction.

If patients experience precipitated withdrawal, clinicians should administer an additional 2- to 4-mg dose of buprenorphine hourly until symptoms resolve.⁹² Note, patients with cardiovascular disease or other severe conditions will need comanagement with the appropriate specialist.⁵³

How Long Does Buprenorphine Take to Start Working?

Patients typically feel relief within the first 5 to 15 minutes after Suboxone has been dissolved under the tongue. In the SPNS project, patients were given Suboxone tablets. Today, Suboxone film exists and dissolves faster, which may bring even faster relief.

For the SPNS project, treatment began with a sublingual dose of 2 mg (2 mg buprenorphine/.5 mg naloxone) for patients with mild withdrawal and 4 mg for patients with severe withdrawal⁶⁹ (Suboxone is also available in an 8 mg buprenorphine/2 mg naloxone formulation).⁹³ If patients experienced no change or only mild improvement of withdrawal symptoms, they were given an additional 2- or 4-mg dosage.⁶⁹

If administration of Suboxone resulted in precipitated withdrawal, patients were reviewed for their last opioid use, offered nonopioid symptom management, and told to return the following day for reevaluation.

Patients for whom administration of Suboxone was successful were provided an additional 2- to 4-mg dose to take later that evening, and take-home doses for the next 1 to 2 days, along with instructions and education about their use. Patients then returned in the next 1 to 2 days for evaluation and upward dose titration.

- Typical daily first week dose: 8 to 12 mg (not to exceed 16 mg).⁶⁹
- Typical daily second week dose: Some patients achieved stable dose between 12 and 16 mg daily from the second week thereafter; for others, dosage increased to as much as 20 to 24 mg during this time period.⁶⁹
 - Criteria for dose increases included significant opioid cravings, significant withdrawal symptoms, and positive urine opioid drug test.

Overall, most patients found optimal relief at 12 to 16 mg. Finding the appropriate therapeutic dose (usually by titrating the dose over time) is a hallmark of the stabilization phase, as is greatly reducing or ceasing opioid use without adverse effects or cravings. To achieve this, physicians may need to adjust dosages for patients still struggling. Behavioral intervention such as counseling may begin during this phase to help patients adapt to opioid-free living and adherence to buprenorphine.⁴²

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's 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 COWS.
- Observe for signs of substance intoxication, including but not limited to alcohol odor, nystagmus, positive Romberg test, disinhibition, or other altered mental status.
- Collect urine and send to 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 he or she 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.
- YES: Begin treatment with Suboxone and titrate to the target dose.

Source: Reproduced from HRSA, Special Projects of National Significance. *Integrating buprenorphine therapy into HIV primary care settings*. April 2012. Available at: www.hab.hrsa.gov/about/hab/files/hab_spns_buprenorphine_monograph.pdf.

For those on boosted atazanavir and other ritonavir-containing ARVs, lower doses were sufficient. For patients on efavirenz-containing regimens, higher buprenorphine doses were required.⁶⁹

Daily dosage of buprenorphine at 32 mg is considered the maximum, and the ceiling for which no further effects of craving or withdrawal are typically seen.⁹ Dosage at or below 24 mg, however, has been shown to help diminish concerns about hepatotoxicity.⁶⁴ (See also “What Do I Need to Know About Buprenorphine and Liver Enzymes?” on page 8.)

Recommended timing of induction and transition into stabilization and maintenance phases are outlined in the table on page 28.

What Are Some Side Effects of Buprenorphine?

The most common side effects associated with buprenorphine include sweating, headaches, nausea, constipation,

reduced sexual drive, and drowsiness and disrupted sleep (although less sedation than is associated with methadone). Patients with viral hepatitis may also experience mild increases in liver enzymes, particularly in alanine aminotransferase (ALT) levels; changes in ALT are most severe if buprenorphine is abused and injected intravenously.⁹

STABILIZATION

The stabilization phase begins after a person has discontinued—or greatly reduced—their drug use, no longer has cravings, and has few or no side effects. Buprenorphine dosage may need to be adjusted during this phase.⁶⁹ To view stabilization protocol in table form, see Figure 4-3 of “Treatment Protocols” at http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf.

TABLE 3
INDUCTION, STABILIZATION, AND MAINTENANCE

		Observation	Counseling	Prescription (Rx)
Induction	Day 1	Observe patient take one 8-mg Suboxone tablet* sublingually in clinic.	Week 1: Daily counseling.	Give patient 1 tablet to take home: No Rx.
	Day 2	Check criteria for dose increase. Observe patient take one 8-mg Suboxone tablet sublingually.		Give patient 1 tablet to take home: No Rx.
	Day 3	Observe patient take one 8-mg Suboxone tablet sublingually.		Give Rx for weekly supply.
Stabilization	Weeks 2–4	Once weekly: Check patient's symptoms for underdosing.	- 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 is >16 mg, give RX for biweekly supply.

Dose increase criteria: Significant craving, pain issues, withdrawal symptoms, or three consecutive toxicologies positive for opioids.

*For the SPNS Buprenorphine Initiative, Suboxone tablets were administered. A Suboxone sublingual film, however, may be used in lieu of tablets.

Source: Reproduced from HRSA, Special Projects of National Significance. *Integrating buprenorphine therapy into HIV primary care settings*. April 2012. Available at: www.hab.hrsa.gov/about/hab/files/hab_spns_buprenorphine_monograph.pdf.

Buprenorphine has a long half-life because it tightly binds to plasma proteins, and it assists in maintaining opioid levels in the brain. This allows for improved administration and less frequent dosing. For example, buprenorphine's effects may last anywhere from 1 to 3 days, depending on the individual and dosage.⁹³

If clinicians transfer patients to alternate-day dosing, this phase may need to be supervised in the physician's office or may take place at home with frequent monitoring during office visits.⁶⁹ Overall, induction and stabilization of buprenorphine were conducted over a 1- to 3-week period and maintenance continued as needed on a patient-by-patient basis. The SOAP Note Format described in the table above was used not only for assessing when to start patients on treatment but also in monitoring maintenance.

Record Keeping

Through opioid treatment, physicians should maintain patient records that outline:

- “Medical history and physical examination;
- Diagnostic, therapeutic, and laboratory results;
- Evaluations and consultations;
- Treatment objectives;
- Discussion of risks and benefits;
- Treatments;
- Medications (including date, type, dosage, and quantity prescribed and/or dispensed to each patient);
- A physical inventory of all Schedules III, IV, and V controlled substances on hand that are dispensed by the physician in the course of maintenance or detoxification treatment of an individual;
- Instructions and agreements; and
- Periodic reviews.”⁸⁸

Physicians must keep all records for a minimum of two years, should DEA decide to conduct an inspection. In addition, physicians are prohibited from releasing records without proper patient consent, court order, mandatory reporting of child abuse, or medical emergencies.⁸⁸

MAINTENANCE

The maintenance phase occurs when the person has been sustained on a steady dose of buprenorphine. In most instances, patients entered the maintenance phase of treatment within the first 2 weeks.

Medication visits were scheduled weekly, then tapered to biweekly and then to monthly. This was possible because up to a month of Suboxone may be prescribed at a time.¹⁶ Physician visits were scheduled once every 3 months. Urine drug testing was conducted throughout phases of treatment to aid in adherence and identify any continual drug use.

The total length of this phase was individualized. The SPNS Buprenorphine Initiative was 5 years long.

In evaluating patients, SPNS providers collected and examined information on multiple measures via chart abstraction. These included:

- Suboxone dosage prescribed.
- Number of Suboxone-related office visits (considered any visit relevant to Suboxone treatment, clinical care, or counseling, as well as urine collection and prescription pick up).

- Number of urine toxicology analyses performed. (Note, guidelines recommend monthly urine toxicology monitoring and more frequent monitoring among those with ongoing illicit drug use.)⁶⁴

Providers knew to include progress notes in each patient's medical record, and these notes were reviewed quarterly. The Buprenorphine-administering clinician or glue person notified primary care providers and others engaged in patient care about the patient's progress. Any treatment consent forms, authorizations, etc. were added to the medical record, as was any Suboxone dispensing.

Any patient on Suboxone who was clinically stable and wanted to discontinue treatment was tapered off buprenorphine slowly, as slow tapers have been shown to be more effective than rapid ones.⁶⁹

To ensure clinic success, several grantees instituted patient satisfaction surveys. These assisted in identifying any additional areas for improvement and helped sustain patient buy-in.



PATIENT SELECTION

The SPNS Buprenorphine Initiative grantees faced many of the same barriers to care delivery and treatment implementation.

POLYDRUG USE AND MENTAL ILLNESS

Polydrug use and mental illness are prevalent among opioid-using individuals. A variety of tools and approaches need to be considered for selecting—and preparing—patients for MAT with buprenorphine. Grantees used the Addiction Severity Index (ASI)-Lite, a validated self-report measure used to assess frequency—and severity—of drug and alcohol use, along with associated psychosocial impairment.^{64,94,95}

- ASI-Lite was given at baseline (lifetime and past 30 days) and at each followup interval (past 30 days).⁶⁴ (To view ASI-LITE, visit www.tresearch.org/resources/instruments/CTN_ASI_p1.pdf.)
 - Information collected on the form included use about opioids (including heroin, nonprescribed methadone, and nonmedical use of pain medications), cocaine, methamphetamines, alcohol, and sedatives/barbiturates (e.g., benzodiazepines).⁶⁴
- The Medical Outcomes Study Short Form Health Survey⁹⁶ and SF-12 Health Survey⁹⁷ were used by some grantees to assess patient health and quality

of life.⁴ (To access these, visit www.rand.org/health/surveys_tools/mos/mos_core_36item_survey.html and www.sf-36.org/demos/SF-12.html.)

- Center for Epidemiologic Studies Depression Scale⁹⁰ was used to assess depression among patients. (To view this scale, visit www.chcr.brown.edu/pcoc/cesdscale.pdf.) Patients with serious mental health conditions underwent an addiction psychiatry consult prior to initiating Suboxone.
- The buprenorphine “Patient Face Sheet” was used by some grantees as a checklist to assess which screenings had taken place. (To access the Patient Face Sheet, visit www.careacttarget.org/library/bup/TMH_BuprenorphineFaceSheet.pdf and www.careacttarget.org/library/bup/CORE_Buprenorphine_ProgramMaterials.pdf.)
- Alcohol Use Disorders Identification Test (AUDIT)⁴ was used to screen for alcohol use and is included in SAMHSA’s list of helpful addiction-screening instruments. SAMHSA also includes the Subjective Opiate Withdrawal Scale; Drug Abuse Screening Test (DAST-10); Clinical Institute Narcotic Assessment Scale for Withdrawal (CINA); CAGE Adapted to Include Drugs (CAGE-AID); Narcotic Withdrawal Scale; CAGE; Michigan Alcohol Screening Test (MAST); and Short Michigan Alcohol Screening Test (SMAST) as potential

screening instruments. All of these can be accessed in Appendix B of the following manual: http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf.⁵³

- Patients using cocaine before initiating Suboxone were found to be less engaged in treatment and less likely to be retained in treatment, with fewer weeks of continuous opioid-free toxicology tests.⁹⁹

SPNS project grantees used a harm-reduction approach to addressing substance use. In the case of polydrug use, some clients were allowed to enroll in the SPNS Buprenorphine Initiative if other substance use did not require acute intervention. These unique cases were reviewed on a weekly basis. In addition, increased frequency of counseling, 12-step meetings, and referral for an addiction psychiatry consult were recommended. For patients with severe polysubstance use, physicians should evaluate if buprenorphine is truly the best MAT option available or whether methadone or inpatient treatment may be preferable.

*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.*¹⁰⁰

PAIN MANAGEMENT ISSUES

As previously discussed, patients with HIV have a greater likelihood of suffering from chronic pain. This can add additional barriers to opioid treatment, as opioid medications are often used to manage chronic pain. (See also, “What Happens If Someone Needs Pain Medication With Buprenorphine” on page 15.)

To assist in addressing this, HRSA's AIDS Education and Training Center has produced a pain management toolkit and pain management and addiction management medication pocket guide. They can be accessed here: www.aidsetc.com/pdf/p02-et/et-03-00/painmgmt.pdf and www.aidsetc.com/pdf/p02-et/et-03-00/painmgmt.pdf.

JAILS AND INCARCERATION

The intersection of illicit substance use and incarceration is well documented. Some SPNS grantees work with their local jails to coordinate entry into HIV care services. Building on these relationships, a similar

protocol was adopted for buprenorphine. As one grantee describes,

*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 patients' 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.*¹⁰¹

To view a template of a jail health services transfer protocol, visit www.careacttarget.org/library/bup/UCSF_Buprenorphine_ProgramProtocols.pdf.

PREGNANCY

The amount of information on pregnant women on buprenorphine is scarce. Pregnancy was included as an exclusion criterion in the SPNS Buprenorphine Initiative. For female patients undergoing MAT with buprenorphine, providers should evaluate safe sex practices to prevent pregnancy. Should patients become pregnant during the course of buprenorphine treatment, physicians should weigh all the risks to reach a conclusive decision.⁵³ (See also Chapter 5, “Special Populations,” at http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf.)

COSTS AND REIMBURSEMENT

As Medicaid formularies vary from State to State, implementation of a buprenorphine treatment program must therefore take Medicaid's regulatory constraints into account.

Currently, there is no fee-for-service coverage of buprenorphine prescribed in outpatient settings. Buprenorphine may be covered in Medicare-certified programs or facilities for inpatient or emergency treatment; however, there are many variables. To read more about this, visit: <http://buprenorphine.samhsa.gov/faq.html#A25>.

ADAP formularies vary by State. Some SPNS grantees were able to work with their State ADAP administrators

and have Suboxone added to the formulary. This may not be true for all States and may be dependent on demand and resources.⁸⁵

HIV care and substance abuse treatment care have often been reimbursed through separate funding streams. Coordinating reimbursement for these services may require a little additional time, as reimbursement is not always the same for HIV services as for substance abuse services, even if both are being submitted to the same payor.¹⁰²

The University of California, San Francisco grantee found in the SPNS study that the approximate cost for a patient without an outside payor is about \$10 a day.¹⁰³ Costs may vary based on patient dose, and coverage by public and private payors for medication. Buprenorphine/naloxone medication can vary, typically from \$4 to \$19 per day.

Median labor and overhead costs of providing services for integrated care using national labor rates was \$136 per patient month; using local labor rates, the median was \$113. Toxicology analysis varied across the SPNS sites, with the median monthly cost being \$8.¹⁰²

CONCLUSION

Successful implementation of buprenorphine treatment into HIV primary care settings requires meeting patients

where they are; offering nonjudgmental, culturally competent care services; addressing the mental health and social support needs of patients; and securing buy-in from necessary parties. The inclusion of substance abuse treatment under the umbrella of comprehensive HIV care offers an incredible opportunity to better serve people living with HIV/AIDS—the goal of the Ryan White HIV/AIDS Program.

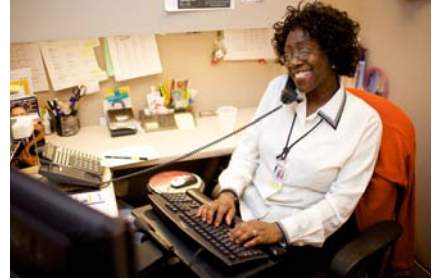
HRSA continues this commitment through the development of a buprenorphine monograph, help desk, email list, and forthcoming educational Webinars.

The SPNS Buprenorphine Initiative grantees are testament that this melding of services is not only feasible but effective, too!

As one grantee summarized,

*Is it worth it? Absolutely. First and foremost, it expanded our capacity to take care of folks who were previously on the margins of engaging in health care. . . . it also had this spill-over effect of raising our awareness of addiction issues in general.*¹⁰⁴

In the end, this work resulted in healthier patients, successful recovery, improved HIV and other health outcomes, and a clinic staff that realized not only was integrating buprenorphine easier than they thought, but more effective as well. So, what are you waiting for?



HELPFUL ONLINE RESOURCES

Integrated Buprenorphine Therapy into HIV Primary Care Settings and Appendices

(www.hab.hrsa.gov/about/hab/files/hab_spns_buprenorphine_monograph.pdf) and www.careacttarget.org/topics/buprenorphine.asp

Medication-Assisted Addiction Treatment Newsletter

www.hab.hrsa.gov/newspublications/careactionnewsletter/may2011.pdf

Substance Abuse Suboxone Treatment Program

www.careacttarget.org/2010_rw_grantee_meeting/papers/F-15.pdf

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

Buprenorphine: A Guide for Nurses, TAP 30, Technical Assistance Publication Series

http://buprenorphine.samhsa.gov/TAP_30_Certified.pdf

Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs: Inservice Training, Based on A Treatment Improvement Protocol, TIP 43

http://buprenorphine.samhsa.gov/tip43_curriculum.pdf

Patient Assistance Program

www.patientassistance.com/profile/reckittbenckiser-314/

Buprenorphine Physician & Treatment Program Locator

http://buprenorphine.samhsa.gov/bwns_locator/

State Substance Abuse Treatment Facility Locator

<http://findtreatment.samhsa.gov/>

Treatment Improvement Protocols

www.ncbi.nlm.nih.gov/bookshelf/br.fcgi?book=hssamhsatip; www.kap.samhsa.gov

Physician Clinical Support System

www.pcssmentor.org/ (primary care)
www.pcssb.org (buprenorphine)

Obtaining a Buprenorphine Waiver

http://buprenorphine.samhsa.gov/waiver_qualifications.html

National Alliance of Advocates for Buprenorphine Treatment

www.naabt.org/

State Methadone Programs

<http://dpt2.samhsa.gov/treatment/directory.aspx>

Screening Tools

www.hivguidelines.org/resource-materials/screening-tools/substance-use-screening-tools/
www.drugabuse.gov/nidamed/screening/

Opioids Glossary

<http://opioids.com/glossary/index.html>

Buprenorphine Treatment of Opioid Addiction: A Counselor's Guide

www.danya.com/dlc/courseprofile.asp?cid=7

Frequently Asked Questions

<http://buprenorphine.samhsa.gov/faq.html>
www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM191532.pdf

American Society of Addiction Medicine

www.asam.org

Association for Addiction Professionals Counselors

www.naadac.org

National Institute on Drug Abuse

www.nida.nih.gov

Reckitt Benckiser (manufacturer)

www.suboxone.com

Buprenorphine: A Guide for Nurses, TAP 30, Technical Assistance Publication Series

http://buprenorphine.samhsa.gov/TAP_30_Certified.pdf

California Society of Addiction Medicine

www.csam-asam.org

American Psychiatric Association

www.psych.org

Opioid Treatment Program Directory

<http://dpt2.samhsa.gov/treatment/directory.aspx>

Common Substance Use Screening Tools

www.hivguidelines.org/resource-materials/screening-tools/substance-use-screening-tools/
www.drugabuse.gov/nidamed/screening

Buprenorphine Treatment: A Training for Multidisciplinary Addiction Professionals (Blending Team Product)
www.ctndisseminationslibrary.org/display/85.htm

Buprenorphine Treatment for Young Adults (Blending Team Product)

<http://drugabuse.gov/blending/buprenorphineYoungAdults.html>

New York State Office of Alcoholism and Substance Abuse Services: Buprenorphine Information and Resources
www.oasas.ny.gov/AdMed/meds/bupindex.cfm

SAMHSA: Buprenorphine, Additional Resources
<http://buprenorphine.samhsa.gov/otherlinks.html>

Consumer Fact Sheet and Brochures

www.health.ny.gov/diseases/aids/harm_reduction/buprenorphine/docs/consumer_fact_sheet.pdf
www.kap.samhsa.gov/products/brochures/pdfs/buprenorphine_facts.pdf
www.health.ny.gov/publications/9555/

American Academy of Addiction Psychiatry

www.aaap.org

American Osteopathic Association

www.aoa-net.org

Buprenorphine and Primary HIV Care: Report of a Forum for Collaborative HIV Research Workshop
www.pcspbuprenorphine.org/pcss/documents2/Training/HIV%20Forum%20Report.pdf

International Center for Advancement of Addiction Treatment

<http://opiateaddictionrx.info/>

The Chronic Care Model

www.improvingchroniccare.org/index.php?p=The_Chronic_Care_Model&s=2

Advisory: An Introduction on Extended-Release Injectable Naltrexone for the Treatment of People With Opioid Dependence

<http://store.samhsa.gov/product/SMA12-4682>



NOTES

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