What's Going on @SPNS

AN UPDATE FROM HRSA, HIV/AIDS BUREAU,
SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE

MARCH 2008

Buprenorphine: Making Opioid Treatment a Primary Concern

The impact of drug abuse on HIV infection has been well documented; the Centers for Disease Control and Prevention (CDC) have estimated that since the epidemic began, more than one-third of all AIDS cases in the United States have been related to injection drug use.[1]

Opiates are among the most frequently abused drugs.[2,3] Opiates, also referred to as opioids, are extracted from opium poppy seeds or created synthetically in laboratory settings. These synthetic derivatives include prescription pain killers such as hydrocodone (Vicodin), oxycodone (OxyContin, Percocet), hydromorphone (Dilaudid), and heroin (diacetylmorphine).[4] In 2006, an estimated 5.2 million Americans were recent abusers of prescription pain relievers, and 338,000 were recent heroin users.[5]

Despite the prevalence of opiate abuse in the United States, relatively few treatment options have emerged. For decades, methadone has been the primary and, until recently, one of the only medical treatments for opiate addiction in the United States. Opiates release an excess of dopamine into the body; eventually, users require an opiate to continuously occupy the opioid receptor in the brain, or they develop withdrawal symptoms. Methadone is an agonist drug that treats opiate addiction by occupying this receptor and initiating the same reaction typically generated by the binding of an opiate; it thereby reduces the cravings and blocks the highs associated with opiate abuse.[6]

In addition, opioid addiction treatment is highly regulated and is generally limited to roughly 1,200 opioid treatment programs nationwide (some States have no such programs).[7] About 1.6 million, or 20.3 percent of people needing treatment for their illicit drug use, were able to receive treatment at a specialty facility in the past year; 6.2 million people needed treatment but did not receive it.[8]

The lack of drug treatment services in the United States has placed increased pressure on Ryan White HIV/AIDS Program providers because they must address substance abuse as well as HIV issues to sustain people in care over time.[9] That said, programs that integrate medical care and drug treatment have shown great promise in improving health and substance use–related outcomes.[10] Moreover, research has shown that treating addiction to drugs can reduce the risk for acquiring HIV as well as promote adherence to HIV treatment regimens.[11] At the same time, isolating opioid treatment from HIV treatment increases the opportunities for negative drug interactions to occur and for the patient's recovery to be delayed or even halted.

In October 2002, the U.S. Food and Drug Administration's (FDA's) approved buprenorphine (Subutex and Suboxone) for the treatment of opioid dependence in a primary care setting. Buprenorphine is well suited for a less regulated environment than methadone because it carries less risk for psychological or physical dependence.[12] Of the two types of buprenorphine tablets approved, Subutex contains only buprenorphine and is used infrequently, primarily in pregnancy or under directly observed treatment. Suboxone, a fixed-dose combination of buprenorphine and the opiate antagonist naloxone, is the primary medicatin used in the treatment of opiate addiction. Naloxone guards against intravenous abuse of buprenorphine and is defined as an antagonist because it acts within the body to reduce the physiological activity of opiates by combining with and blocking its receptor in the nervous system.[13,14]

DATA 2000

The path to the groundbreaking approval of buprenorphine was paved by the Drug Addiction Treatment Act of 2000 (DATA 2000), which allows physicians who meet certain requirements to treat opiate addiction with FDA-approved narcotic medications. Under the new law, opiate treatment can be provided by specially trained physicians in a primary care setting, allowing consumers to have greater access to treatment. "We really try to provide one-stop shopping for our patients," says J. Kevin Carmichael, MD, chief of service at El Rio Special Immunology Associates, a Special Projects of National Significance (SPNS) Buprenorphine Initiative grantee in Tucson, Arizona. "So it seemed like a logical extension to address substance abuse and particularly opiate issues in this setting instead of sending patients to a methadone clinic or somewhere else to get this kind of care."

U.S. Department of Health and Human Services
HRSA
Health Resources and Services Administration

SPNS Buprenorphine Initiative

In September 2004, the SPNS program, through the Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau (HAB), designed the Buprenorphine Initiative to determine the effectiveness of integrating buprenorphine opioid abuse treatment into HIV primary care settings. The initiative funded 10 model demonstration programs around the country (see box).

The sites are supported by an Evaluation and Support Center administered by the New York Academy of Medicine. The center provides ongoing technical assistance to the demonstration sites through support in program design; clinical training and consultation; and the development of policy and procedures that address regulatory, ethical, and clinical concerns.

Purpose of the Initiative

The Buprenorphine Initiative's primary purpose is to evaluate and then promote the sustainability and replication of its model programs. Findings from the evaluation will be broadly disseminated to a range of audiences, including physicians, administrators, addiction treatment providers, AIDS service organizations, policy makers, and funders. The lessons will be translated into publications and tools that meet the particular needs of these diverse audiences.

Buprenorphine Initiative Grantees

- CORE Center, Cook County Bureau of Health Services, Chicago, IL
- El Rio Santa Cruz Neighborhood Health Center, Tucson, AZ
- Johns Hopkins University School of Medicine, Baltimore, MD
- The Miriam Hospital Immunology Center, Providence, RI
- Montefiore Medical Center, Bronx, NY
- Oregon Health and Science University, Portland, OR
- Organization to Achieve Solutions in Substance Abuse (OASIS), Oakland, CA
- UCSF Positive Health Program, San Francisco, CA
- University of Miami School of Medicine, Miami, FL
- Yale University School of Medicine; New Haven, CT
- New York Academy of Medicine (Evaluation Center) in partnership with David A. Fiellin, MD.

For additional information on the SPNS Buprenorphine Initiative, visit the Evaluation and Support Center's Web site at www.bhives.org/.

Although conclusive findings will be presented at the end of the study in 2009, grantees have already identified and applied important steps for successfully implementing a buprenorphine program in the primary care setting, described in the sections that follow.

Steps to Success

1. Develop a Team Approach to Treatment.

When establishing a program like those modeled in the SPNS Buprenorphine Initiative, "the first step is to make a commitment to treat opioid addiction in the clinic," says Carmichael. "That is a big, big step, because physicians often get a mixed message about this problem. One message is that pain, often treated with opiates, is chronically undertreated. The other message is, 'Don't be taken advantage of by narcotics addicts, and don't get your patients addicted to narcotics.'" These preconceptions make it all the more important for providers to ensure that their staff are all willing to address the issue.

Building a united front means ensuring that staff have opportunities to be involved in the process of implementing the opiate treatment program. "We had several meetings in which we asked staff about some of the barriers to buprenorphine treatment," says Jennifer Mitty, MD, MPH, medical director at Brown University's Miriam Hospital in Providence, Rhode Island. "We were able to use this same team effort to conduct education sessions on treatment," she adds. "This has really upped our buy-in from staff."

2. Understand Barriers to Treatment.

Understanding the barriers to buprenorphine treatment means understanding that many patients are struggling with more than drug addiction—and more than HIV infection. Common issues include mental illness and chronic pain.

Mental Illness

Mental illness plays an influential role in the lives of many HIV-infected addicts. To that end, "we have two psychotherapists and a full-time psychiatrist at our clinic," notes Carmichael. "We are here to provide quality comprehensive health care to people living with HIV/AIDS, regardless of their ability to pay—and we define comprehensive care to include both physical and mental health."

Nevertheless, Carmichael acknowledges that 70 percent of patient deaths from AIDS occur among patients who are not taking their medications as prescribed. "It's not because we are unable to prescribe them or we can't get them," he asserts. "The obstacle is where people are in their lives, and substance abuse and mental health are big parts of that. So when we heard about [the Buprenorphine Initiative], we found the opportunity to be able to treat people here in our clinic—to get all of their services in one place—to be very appealing," he adds.

Chronic Pain

Comorbid chronic pain also can prove to be a hurdle for buprenorphine opiate treatment. Even people who are already on methadone but would

For More Information . . .

For additional information on the SPNS Buprenorphine Initiative, visit http://hab.hrsa.gov/special/bup_index.htm.

The SPNS Project Officers for the initiative are

- Pamela Belton (301.443.9481; pbelton@hrsa.gov),
- Adan Cajina (301.443.3180; acajina@hrsa.gov), and
- Katherine McElroy (301.443.0214; kmcelroy@hrsa.gov).

like to transition to buprenorphine for their opiate treatment are unable to do so if they have pain syndromes and are using opiate analgesics to treat their pain. Buprenorphine in certain circumstances can cause withdrawal in patients receiving pain medication, and in other circumstances it can block the effects of pain medication. This characteristic makes it difficult to use in patients who require opioid medication for pain control.

Chronic pain in the context of addiction and HIV care is a complex issue. "Certain patients have chronic back pain, joint disease, and other things like that that are probably not HIV-related. And then there are things that clearly are HIV-related like peripheral neuropathy and postrepetic neuralgia," says Carmichael. The difficulty for providers is in trying to distinguish pain related to physical conditions from pain related to chronic opiate abuse, which can alter patients' pain perceptions.

3. Establish Full-Time Support for Patients.

Flexibility and timeliness of care are big factors in adherence to both opiate and HIV treatment. Ensuring that staff are accessible is a critical consideration for all buprenorphine programs, particularly because many highly specialized physicians work at various hospital and clinic sites throughout the course of a work week. In the context of buprenorphine treatment, this may mean that a patient's treatment needs must be scheduled around the physician's schedule, rather than their own. And for those patients already battling drug addiction and HIV, this obstacle can prevent them from being able to adhere to treatment.

Recognizing this pitfall, Miriam Hospital employs two near-peer outreach workers who work part-time on buprenorphine treatment to ensure that, even when a doctor might not be available, someone is able to address patients' concerns and observe treatment adherence. The outreach workers share the same neighborhoods as many of the project's patients, allowing them to truly meet patients "where they are." Outreach workers can help ensure that patients are receiving proper care and support in their addiction recovery.

At the CORE Center in Chicago, Illinois, a full-time intervention coordinator devotes her time to patients in the buprenorphine program. The CORE Center also typically maintains at least one clinician on the site throughout the week as well. "We hypothesize that our staff presence has made our patients feel that—if they have relapsed or they need some other form of treatment—there is somebody here to help them," notes Jeffrey Watts, MD, principal investigator at the CORE Center.

In some cases, patients may desire even more flexibility in their treatment, particularly if they are doing well on buprenorphine. "If they are stable enough to give them a month's worth of Suboxone tablets to take home at a time, we will," says Carmichael. "But the reality is that, it's hard to get to that point so the patients that we have that are doing the best are on a 2-week schedule."

4. Aggressively Screen for Opiate Abuse.

Many patients hide their opiate abuse from their physicians because of stigma or legal concerns, among other reasons. To uncover opiate abuse that may have gone unnoticed, El Rio began regularly administering an instrument called the Global Assessment of Individual Need (GAIN), which evaluates patients for depression, substance abuse, and mental illness. "I always thought that I knew a lot about my job and I knew a lot about my patients," says Carmichael, "but the results of this tool drove home the point that you really need to look for it if you are going to find it because it's pretty easy for people to not talk about it. And then if everybody doesn't talk about it, it doesn't exist."

Barriers to Overcome

Medicaid

Medicaid, a program designed to help the medically needy access care, can inadvertently provide obstacles to buprenorphine treatment as well. Because Medicaid programs vary from State to State, health care coverage under the program also varies. In Arizona, where El Rio is located, Medicaid is provided through the Arizona Cost Containment System (ACCS), which is essentially a network of small HMOs.

Because of the intricacies of the Arizona Medicaid program, patients' medical needs are treated separately from psychiatric needs. "I may have a patient with a serious mental illness like bipolar disorder, and I see the patient to take care of the medical needs, but the patient is required to go to a different clinic funded by a regional behavioral health system to get his mental health care," says Carmichael. In most cases, substance abuse falls into the behavioral health system in Arizona, making it very difficult for providers to treat patients for both opiate addiction and HIV-related medical needs. "It's a tough system to work with because clearly, physical and mental health are inextricably interrelated," adds Carmichael.

Implementing a buprenorphine treatment program, then, must take into consideration Medicaid's regulatory constraints as they manifest themselves in the program's State. The profiled providers agree that Medicaid regulations can be a challenging hurdle to overcome in setting up a treatment program, and it is one of the most daunting tasks ahead in sustaining their programs success after the SPNS Initiative is complete.

DATA 2000 Patient Limits

Although DATA 2000 opened many doors for opiate treatment, it also barred some. Original DATA 2000 legislation placed a 30-patient limit on the number of patients that a physician was allowed to treat with buprenorphine and required special Drug Enforcement Administration (DEA) registration for the use of buprenorphine. Those measures were designed to provide further safety precautions for use in the primary care setting.[15] Recently, however, the Office of National Drug Control Policy Reauthorization Act of 2006 changed the restrictions on a number of patients a physician authorized under DATA 2000 may treat. Now, an authorized physician who submitted the notification for initial authorization at least 1 year ago may apply to treat up to 100 patients, greatly increasing the opportunities for primary care opiate treatment.

Sustaining a Future

When the SPNS Buprenorphine Initiative ends in 2009, the Evaluation and Support Center will assess which care models best deliver buprenorphine treatment in the HIV primary care setting. The lessons learned by grantees in the Initiative will be assessed and incorporated into guidelines for delivering buprenorphine care across the Ryan White HIV/AIDS Program community—bringing HRSA one step closer to achieving its mission to provide truly seamless, truly comprehensive care.

Endnotes

1 Centers for Disease Control and Prevention. 2002. Drug-associated HIV transmission continues in the United States. Available at: www.cdc.gov/hiv/resources/factsheets/idu.html. Accessed December 12, 2007.

2 Substance Abuse and Mental Health Services Administration (SAMHSA). 2007. Results from the 2006 National Survey on Drug Use and Health: National findings (NSDUH Series H-32, DHHS Pub. No. SMA 07–4293). Rockville, MD: SAMHSA. Available at: www.oas.samhsa.gov/NSDUH/2k6NSDUH/2k6results.cfm#Ch7. Accessed December 20, 2007.

3 National Institute on Drug Abuse. 2005. Opiates. In: Mind over matter: the brain's response to drugs teacher's guide. Rev. ed. (NIH Pub. No. 05–3592). Available at: www.drugabuse.gov/MOM/TG/momtg-opiates.html. Accessed December 20, 2007.

4 Harvard Medical School. 2005. Treating opiate addiction, Part 1: Detoxification and maintenance. Harvard Medical School Family Health Guide. Available at: www.health.harvard.edu/fhg/updates/update0405a.shtml.

5 SAMHSA, 2007.

6 Office of National Drug Control Policy. 2000. Methadone. Drug Policy Information Clearinghouse Fact Sheet. Available at: www.whitehousedrugpolicy.gov/publications/factsht/methadone/index.html. Accessed December 31, 2007.

7 Food and Drug Administration (FDA). October 8, 2002. Subutex and Suboxone approved to treat opiate dependence. Press release. Available at: www.fda.gov/bbs/topics/ANSWERS/ 2002/ANS01165.html. Accessed December 11, 2007.

8 SAMHSA, 2007.

9 HRSA, 2006.

10 New York Academy of Medicine (NYAM). 2007. Integrated Buprenorphine and HIV Care Evaluation and Support Center. Available at: www.bhives.org/. Accessed December 18, 2007.

11 NYAM, 2007.

12 Merriam-Webster's Medical Dictionary. Agonist. Available at: http://medical.merriam-webster.com/cgi-bin/medical. Accessed December 20, 2007.

13 FDA. October 8, 2002.

14 Merriam-Webster's Medical Dictionary. Antagonist. Available at: www.m-w.com/dictionary/antagonist. Accessed December 20, 2007.

15 FDA, 2002.