



The Addiction Technology Transfer Center Network
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ADDICTION *Messenger*

Ideas for Treatment Improvement

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NIDA/SAMHSA Team Up to Create Resources for Providers

BUPRENORPHINE

New Options in Treating Opioid Dependency

The National Institute on Drug Abuse and the Substance Abuse and Mental Health Services Administration have combined forces to foster the adoption of research-based practices and interventions by community providers. This special issue of the AM focuses on the first NIDA/SAMHSA-ATTC Blending Initiative product: Buprenorphine Awareness. For more information about training and other resources see page 7.

Dr. Greene:

"I'm Dr. Deborah Greene. I work at the O.A.S.I.S. Clinic in Oakland, and I'm here to talk with you about boop-eh-noh - blah!"

Patients:

"Bee bee bee... bee ba-dee ba-dee ba-dee... Bupe-oh-what?" mug O.A.S.I.S. patients.

Dr. Greene:

"Most of my patients and everyone I know," says Dr. Greene, "They just call it 'bupe.'"

So begins the *Put Your Smack Down* video on buprenorphine (byoo'-preh-nohr-feen), a new medication

for treating opioid addiction. The colorful video, starting with galloping, twangy, electronic music that melds into a hip background beat, features people talking about their recovery from heroin addiction using buprenorphine, and is one of the components of a newly-released curriculum developed by NIDA and SAMHSA as part of their Blending Initiative—blending science and practice.

Why buprenorphine? Methadone Maintenance Treatment (MMT), coupled with a comprehensive treatment plan, has been the most effective approach over the past 30 years for treating opioid addiction. However, despite MMT's proven effectiveness, data reveal alarming increases in opioid misuse over the past decade, coupled with a huge gap in treatment, calling for additional treatment strategies.

Buprenorphine Helps Address Treatment Gap

Buprenorphine, like methadone, is an opioid replacement therapy. However, unlike methadone, which can only be dispensed in the highly structured environment of an Opioid Treatment Program (OTP), buprenorphine is the first opioid replacement therapy available by prescription from a physician, in primary care and other office-based settings. Not everyone

can or wants to show up for a daily dose of methadone and for them, buprenorphine may be the answer.

“I think there are people getting Suboxone (buprenorphine) in a physician’s office that would never come out to a methadone clinic,” says Ron Jackson, Executive Director of Evergreen Treatment Services (ETS), an OTP in Washington State. *“They would feel the stigma much more acutely waiting in line for methadone. They would have to get a whole lot worse first.”*

Arthur Van Zee, M.D., describes how buprenorphine expanded treatment for his patients, and how it addresses the needs of those who are addicted to opioids other than heroin:

“We are looking to buprenorphine as a possible solution to a very difficult situation. Our clinic is in the heart of Appalachia, in the southwestern corner of Virginia. Until about three years ago we had no large-scale opioid addiction, but the OxyContin epidemic changed that. There are now tens of thousands of new opioid addicts in our region. Methadone treatment programs may be two hours away by car. Try to imagine a 23-year-old single mother getting her daughter up at 4:30 every morning to drive to Tennessee to get a methadone dose. Because of these difficulties, prior to buprenorphine, I would just detox patients and set them up with our local counseling team. Now, I can offer them comprehensive treatment with an effective medication.” (Doot et al, 2004)

Patients from the *Put Your Smack Down* video describe the benefits of buprenorphine in their own words:

“I had to go to the methadone clinic every single day of my life... I couldn’t do anything... It’s great not to have to go to the clinic where you see all the other drug addicts and get back into it.... If you’re late, if you miss your (methadone) dose, there’s drug dealers – bam – right there to sell... You don’t have to hang around with people who are still using. You can take it home and use it like any other prescription.”

Buprenorphine is not expected to replace methadone in treating opioid dependency – there are advantages and disadvantages to both. But it represents a new

option that will increase patient access to opioid treatment, and help reduce stigma by medically mainstreaming treatment. As Ron Jackson, ETS Executive Director, notes:

“Methadone is stigmatized and doctors don’t know how to even ask questions about addiction. The conundrum of substance abuse is it’s easier to treat in earlier stages, but people don’t talk about it and won’t until it fulminates and they have to go to a specialty clinic. Now (with buprenorphine) they may be willing to talk about it and get treatment earlier.”

Buprenorphine - A Safe and Effective Medication

In 2002, the FDA approved buprenorphine as the first medication for treating opioid addiction in office-based settings. Research from NIDA clinical trials showed buprenorphine to be safe and effective for both opioid maintenance and medically assisted withdrawal (detoxification). More trials are being conducted with various populations and settings, but, in general, research has shown buprenorphine to be as effective as methadone at moderate doses.

It is also safer. As the dose of buprenorphine is increased, the effects of the drug levels out, called the “ceiling effect”. When the dose is adjusted adequately, buprenorphine provides a positive, but moderate, psychoactive effect that reduces craving and helps patients adhere to medication regimens. Patients report feeling better physically within an hour (or less) after taking their first dose, feeling fewer side effects than with methadone, less of a euphoric effect, and less drowsiness or sedation. As one of the patients in the *Put Your Smack Down* video describes it, “Bupe does not get you high; it takes the craving away and makes you want to enjoy life – that’s what I’m doing now, enjoying it.” Others used descriptors such as “clear headed” and “feeling normal”.

There are other advantages as well. Overall, buprenorphine causes a lower level of physical dependence and milder withdrawal symptoms than methadone, which makes it a better medication for use in detoxification. However, this may also make it easier for patients to discontinue treatment and return to opiate use. Buprenorphine’s high affinity for opioid receptors also has advantages. While methadone requires daily dosing, buprenorphine can be taken as infrequently as three times per week. Also, buprenorphine is “packaged” to discourage street diver-

sion. It is available in two different tablet formulations: Subutex contains buprenorphine only, while Suboxone, the most commonly prescribed form, contains buprenorphine plus naloxone. When Suboxone is taken sublingually as prescribed, and no other opiates are on-board, the Naloxone has little effect; but when Suboxone is injected by an opioid-addicted person, the Naloxone blocks the effects of other opioids and can precipitate withdrawal, a strong deterrent to misuse.

Physicians and Counselors Working Together

Research has clearly shown that when medical interventions are used for substance abuse treatment, combining them with psychotherapeutic and other services offers critical advantages in recovery and relapse prevention. However, while physicians must meet very specific criteria and obtain a license waiver from CSAT to dispense buprenorphine, federal regulations do not require a counseling component of buprenorphine treatment. Ongoing care coordination among physicians, addiction and mental health counselors, community support service providers, and self help/12-step programs is key to providing effective buprenorphine treatment. Perhaps the greatest challenge in providing effective care lies in bridging the gap between physicians and other providers, creating a multidisciplinary team where none may have existed before.

“We are finding that buprenorphine fits very well into our program,” says George Kolodner, of Kolmac Clinic, an outpatient chemical dependency program in Maryland. *“(However) it is a matter of serious concern that the medication, which has so much potential, could fail because it may be prescribed in isolation and not as part of a comprehensive treatment program.”* (Casadonte et al, 2004)

Recommendations for Co-Managing Buprenorphine Treatment

Successful care coordination includes several important attributes:

Maintaining Ongoing, Effective Communication: To best serve patients receiving buprenorphine, addiction professionals may need to be proactive, at least initially, in reaching out to physicians and developing strong linkages. Some members of the medical community may not be aware of the unique, and important, types of therapy

and support that addiction professionals can provide to their patients.

Effective communication strategies are particularly critical when different providers are not co-located. Scheduling periodic meetings, issuing and sharing reports and memoranda, creating both formal and informal communication loops, will help ensure that all members of the treatment team are in synch. Obtaining a signed release of information is necessary to facilitate communication between addiction professionals and the treating physician.

Familiarization with the Roles, Procedures, and Organization of Other Providers Agencies and Offices: One benefit of coordinated care is the linkage to other individuals/agencies with the necessary expertise to treat various aspects of the patient’s condition. Being clear about roles not only allows effective use of resources, but, importantly, helps ensure that all providers stay within ethical and legal parameters. The roles of certain providers may vary by state, depending upon the identified scope of practice for each profession, so it is important to become familiar with local guidelines and regulations. And, as the descriptions of provider roles below illustrate, there is potential for duplication of efforts which can best be minimized by clear understanding of roles and responsibilities.

Roles of the Physician. In order to prescribe buprenorphine, physicians must qualify and obtain a waiver from SAMHSA. Again, while physicians must be able to refer patients for counseling, they are not required to do so. The physician will screen, assess (medically and possibly psychosocially), diagnose opioid addiction, prescribe buprenorphine to the patient, and provide patient education. The physician may also focus on alleviating the discomforts of withdrawal by helping the person taper off of opioids or providing medication to help them stabilize, and they may also conduct urinalysis testing and provide recovery support.

Roles of the Addiction Counselor. Substance abuse counselors will provide screening services similar to the physician’s, focusing on a psychosocial assessment. Counselors should be familiar with patient selection criteria, highlighted below and covered thoroughly in the NIDA/SAMHSA Blending Initiative curriculum. Counselors also typically provide patient education, psychosocial treatment, urinalysis testing, recovery support, and case management/coordination. Regarding referrals, SAMHSA’s

Physician locator offers a state-by-state directory at http://www.buprenorphine.samhsa.gov/bwns_locator/aboutphysician.htm. Since qualified physicians are not required to be listed in the registry, a little sleuthing may be needed to find a physician in your area.

Supporting Treatment—Counselor Attitudes and Resistance: Counselors should review and consider their own treatment philosophy before accepting referrals from physicians prescribing buprenorphine, or referring clients for treatment. It is important to work with, not against, the medication. Counseling with a focus on “getting off” buprenorphine can convey the idea that the medication is a necessary evil and somehow wrong. Instead, counselors should focus on supporting patients’ medication compliance, framing it as one component of a comprehensive treatment plan.

There are other options and effective treatment can occur without medications, but talking with the patient about the realities of withdrawal and the low success rate of people who attempt withdrawal without medical assistance is important. Buprenorphine may be needed longer-term to prevent withdrawal symptoms and help a person function normally, while accompanying behavioral treatments can address other recovery issues. Even simple, yet important, things such as referring to buprenorphine as a medication, not a drug, will help send patients the correct message.

Additionally, if you have questions or concerns about the medication, speak directly with the physician, not the patient. Some patients may engage in “splitting” counselors and physicians, by saying such things as, “I like you, and you understand me; (s)he doesn’t understand me.” Such divisions among therapeutic staff should be avoided.

Patient Selection

Although the physician will ultimately determine suitability for buprenorphine treatment, counselors (and other addiction professionals) should also be knowledgeable about patient selection and suitability issues for several reasons: the patient’s appropriateness for use of buprenorphine may change during the course of treatment; patients or other treatment providers may ask the counselor about appropriateness for treatment; and useful and informed communication with the physician is enhanced by a knowledge of the entire treatment process.

Accurately assessing patients’ suitability for buprenorphine and determining the most suitable location for treatment (office versus OTP [if available]), is critical, and should be based on a careful evaluation, including the following criteria: 1) *Does the person have a diagnosis of opioid addiction?* 2) *Is the patient interested in office-based treatment?* 3) *Is the patient aware of the other treatment options?* 4) *Does the patient understand the risks and benefits of buprenorphine treatment and that it will address some aspects of substance use (for example, withdrawal suppression and blockade) but not all aspects (such as triggers and cravings that may be elicited by events and circumstances in the environment)?* 5) *Is the patient expected to be reasonably compliant? Can they follow safety procedures?* 6) *Is the person psychiatrically stable?* 7) *Are the psychosocial circumstances of the patient stable and supportive?* 8) *Are there resources available to ensure the link between physician and treatment provider?* 9) *Is the patient taking other medications that may interact with buprenorphine, such as naltrexone, benzodiazepines, or other sedative-hypnotics?*

A patient may be a less likely candidate for buprenorphine treatment if they have high-dose dependence on depressants or opioids, significant psychiatric comorbidity, suicidal or homicidal ideation, frequent previous relapses, current high risk of relapse, and poor support systems.

Similarly, certain medical conditions are considered *relative* contraindications for buprenorphine treatment (meaning there is not enough data pertaining to these particular conditions, so physicians will need to exercise clinical judgment in determining if buprenorphine is appropriate). These include seizures; HIV and STDs; hepatitis and impaired hepatic function; pregnancy; use of alcohol, sedative-hypnotics, and stimulants; and alcohol/other dependency.

Critical Areas for Physician Consultation

While ongoing care coordination and regular consultation with the physician is important, counselors should be particularly diligent about seeking consultation for the following issues:

1. *Any medical or health-related matters regarding the patient. When in doubt, refer the patient back to his or her treating physician.*

2. *Use of alcohol, sedative-hypnotics, and stimulants, and/or poly-drug addiction:* Combinations of other drugs should be carefully evaluated, and brought to the attention of a physician if discovered. Reported overdoses have been related to a combination of central nervous system depressants; for example, the combination of benzodiazepines and buprenorphine (especially if injected in an overdose attempt) may result in death; and patients should also be cautioned to avoid alcohol use while taking buprenorphine. Addiction to other drugs (such as stimulants or sedatives) is common among opioid-addicted individuals and may interfere with overall treatment adherence, though this is not an absolute contraindication to buprenorphine treatment; however, persons with multiple addictions may need to be referred for further or more intensive treatment.

3. *HIV and STDs:* Patients with these conditions often take a variety of medications and, therefore, the potential for medication interactions may exist.

4. *Hepatitis or impaired liver function:* Medication interaction is a concern here, as well. Ongoing studies are assessing the changes in liver enzymes related to treatment with Suboxone (buprenorphine with naloxone).

4. *Multiple previous opioid treatment episodes with frequent relapse.* While this would not exclude the option of buprenorphine treatment, understanding what led to previous treatment failures should help shape the current treatment plan.

5. *High risk for relapse based on psychosocial environmental conditions and/or a poor support system.*

6. *High level of dependence on high doses of opioids:* Level of opioid use needs to be evaluated carefully to determine if buprenorphine is appropriate, and if so, the best way to transition the person onto the medication. This is a medical decision, but optimally the addiction professional should bring all the information that they have to the physician and work with him or her in the development of the treatment plan. More research is needed to determine if buprenorphine is generally as effective as methadone for people with longer-term/higher-dose opioid addiction. However, some people who failed at methadone treatment have succeeded on buprenorphine, so, as with other medications, there is some unpredictability involved in selecting best candidates.

Special Populations

Co-occurring Psychiatric Disorders: Opioid users frequently demonstrate concurrent psychiatric diagnoses, ranging from anxiety or depressive disorders to antisocial personality disorders. Because drug use effects and withdrawal symptoms can sometimes mimic psychiatric symptoms, consideration must be given to the duration, recentness, and amount of drug use when making a psychiatric diagnosis. Counselors should consult the DSM-IV as well as review the patient's psychiatric history and consult with the buprenorphine-prescribing physician and other mental health providers. Any of the following should prompt further evaluation and appropriate action: suicidal thoughts or plans, extreme changes in mood, extreme changes in sleep or activity patterns, hyperactivity, paranoid thinking, hallucinations, unresponsiveness, and/or confusion.

Pregnancy: Buprenorphine is not currently approved for the treatment of opioid-addicted pregnant women. Clinical trials are ongoing, but for now pregnant women should be treated with methadone. If withdrawal is indicated, most physicians will likely urge the patient to wait until after delivery. If a patient on buprenorphine becomes pregnant, the physician will determine if buprenorphine or methadone is the best treatment strategy.

Opioid-Addicted Adolescents: Buprenorphine is not currently approved for the treatment of adolescents, although researchers are studying the safety and efficacy of buprenorphine treatment for this population.

Phases of Buprenorphine Treatment

Induction. Induction refers to the procedures used to transition someone from opioids onto buprenorphine. During induction the physician works with the patient to determine the most effective dose so that he/she can stop other opioid use with minimal withdrawal symptoms. While the physician primarily guides this process, the multidisciplinary team is critical in providing supportive care and counseling.

Stabilization. Once the patient is on buprenorphine, the next step is to make sure he or she is stabilized, meaning not experiencing any negative symptoms or craving. At this point, the decision can be made to either move on to the maintenance phase, or to medically assisted withdrawal (detoxification).

Withdrawal. Tapering off of buprenorphine is a medical

decision to be handled by the treating physician in consultation with the patient. Not all patients are appropriate for withdrawal from medications. Unstable living situations, multiple relapses, previous failed detoxification attempts, or lack of desire to withdraw from opioids may indicate that maintenance is a better treatment option. Many providers believe that treatment requires abstinence from all drugs. However, many opioid users cannot tolerate the withdrawal experience, and even if they can, may be drawn back to using. It is very important to understand that physical dependence is not the same thing as addiction, which is defined by the pathological behaviors and compulsivity of use, not by the body's adaptation to a medication. The goal of any treatment is the same - helping a person stop the negative and compulsive behaviors associated with drug use so they can lead a functional, normal life. Using a medication such as buprenorphine as a component of opioid treatment - to assist with the withdrawal process or to prevent people from going through withdrawal - can be an important method for helping people achieve this goal.

If withdrawal is deemed appropriate, a smooth transition from a physically dependent to non-dependent state is the goal. Withdrawal may take place either in inpatient or outpatient settings. Detoxification is accomplished by transitioning the patient onto a long-lasting opioid like buprenorphine, then tapering him or her off over a period of time (a few days to weeks depending upon the program). Clonidine and other non-narcotic medications may be used to manage withdrawal symptoms. Medically supervised withdrawal should be accompanied with and followed by psychosocial treatment, including supportive wraparound services, and sometimes medication treatment (i.e., naltrexone) to minimize risk of relapse.

Maintenance. During this phase the treatment professional should continue to address issues such as psychiatric co-morbidity and psychosocial domains (employment, legal, family/social, etc.). Goals of this phase include helping the patient stop and stay away from alcohol and illicit drugs, monitor cravings to prevent relapse, and address psychosocial and family issues.

Therapy and Counseling Models

Buprenorphine can be combined with other evidence-based practices, a few of which are highlighted below, to target and increase effectiveness at various stages of

treatment:

Motivational Interviewing and *Motivational Enhancement Therapy* may be used to help assess readiness for and to resolve ambivalence toward medication therapy.

Relapse Prevention techniques can help patients learn how to deal with triggers and cravings, understand addictive behaviors and thinking, and avoid relapse drift. Opioid-dependent patients are particularly likely to discount the importance and relevance of other drug or alcohol use, so may need help in recognizing how use of these drugs might act as relapse triggers.

12-Step Facilitation approaches may need tailoring for this patient population. The philosophy of some 12-Step meetings may be that abstinence does not include drug therapies. Counselors can remind patients that there is no need to disclose their medical history or medications in 12-Step meetings; they may also link patients up with 12-Step support people (including sponsors) who are supportive of their buprenorphine treatment; and/or they may develop special support groups for patients being treated with buprenorphine and attending 12-Step meetings.

Limitations

Buprenorphine is much more costly than methadone. According to the only current manufacturer of this medication (Reckitt Benckiser Pharmaceuticals, Inc.) Suboxone, at 16 mg/day, costs about \$288 for a month's supply, as compared to around \$30 for a month's supply of methadone at the usual doses. At present, many insurance programs do not reimburse for buprenorphine, but physicians and treatment providers can ask insurance companies to add this medication to their formularies, often done as a result of demand.

Physicians are limited to treating 30 patients with buprenorphine at any given time. This restriction was imposed by Congress to ensure that patients received counseling, to prevent individual doctors from becoming addiction treatment clinics, and to address concerns about diversion. As more physicians are approved to treat patients with buprenorphine this limitation will become less and less of an issue. Originally this cap also restricted entire group practices (e.g., hospitals and health maintenance organizations) to 30 patients total, but Congress lifted this restriction in July, 2005.

Buprenorphine Awareness Training Is Available

NIDA and SAMHSA have joined forces to offer buprenorphine awareness trainings to educate counselors and other non-physician providers about this medication. The training provides a broad overview of the medication, its effects, and the role of non-physician practitioners in providing and supporting buprenorphine treatment. Contact Wendy Hausotter at NFATTC for more information: 503-378-8516 or hausotte@ohsu.edu.

Looking Ahead

Offering buprenorphine in office-based settings expands the platform of opioid addiction treatment and represents an important advance in opioid treatment. It is not expected or intended to replace methadone, but it holds the potential to reach a much wider group of patients, including those whose use of pain medications has led to addiction and those who are more comfortable seeking treatment from a physician rather than at a methadone clinic.

The success of buprenorphine treatment hangs heavily on the ability of physicians and addiction professionals to forge effective collaborations and work in multidisciplinary teams. Providers who develop skill and experience working with office-based buprenorphine treatment, who forge strong linkages in supporting patients on buprenorphine, will provide a valuable service patients, the medical community, the opioid-addiction treatment field, and—ultimately—our community at large.

Thanks to Lynn McIntosh at the University of Washington Alcohol and Drug Abuse Institute for writing this issue of the AM.

References and Resources

Curricula:

Buprenorphine Treatment: A Training for Multidisciplinary Addiction Professionals: developed by NIDA/Pacific Southwest ATTC; includes *Put Your Smack Down* video. (Order free directly from PSATTC at 310-445-0874 x319 or contact your local ATTC).

Buprenorphine Treatment of Opioid Addiction: A Guide for Counselors. An on-line course produced for the Danya Institute/Central East ATTC by Omnipress. (Order and pay on-line at: <http://www.danyalearningcenter.org/courseprofile.asp?cid=7>).

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NIDA/SAMHSA-ATTC Blending Initiative: <http://www.nida.nih.gov/CTN/dissemination.html>.
SAMHSA Buprenorphine Information: <http://buprenorphine.samhsa.gov/> or 1-866-287-2728.
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