

Community Treatment Programs Take Up Buprenorphine

Clinicians have been working out ways to incorporate buprenorphine into their treatment models. Representatives of three addiction treatment programs—a Veterans Affairs methadone clinic, a group of outpatient mental health centers, and a nationwide organization of therapeutic communities—talk about their plans and experiences.

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A VETERANS' METHADONE CLINIC IN NEW YORK CITY

Paul Casadonte

I have been working with and prescribing buprenorphine in a variety of settings since the early 1990s. I was principal investigator in two large buprenorphine research studies and study chairman for the NIDA-Veterans Affairs (VA) Office-Based Practice Study. That experience persuaded me that buprenorphine has potential as an alternative medication in methadone clinics for patients who need a clinic's structure and guidance but can benefit from the medication's special properties.

Our program is an integral part of the New York Harbor Healthcare System medical center, but is geographically separate from the VA hospital. At the time we signed our lease in the mid-1990s, this area of lower Manhattan was called the meatpacking district and considered undesirable. Then suddenly the area began to be redeveloped; it is now a historic district, and we have a methadone clinic in a very desirable area, surrounded by art galleries and some of the best restaurants in town. Our patient census at any time is about 200, all honorably discharged veterans. Many are Vietnam-era veterans; the median age is 47. Recently a number of older veterans have come in, people in their 60s who became addicted to pain medication in their 50s.

Patients must commit to a 60-day medicated stabilization. We no longer accept people who want only a quick heroin detoxification, because relapse as soon as methadone was tapered was significant.

During stabilization, patients get group therapy and counseling. If they do well—not necessarily stopping opiate use but keeping their appointments and showing other evidence of commitment to therapy—we offer them longer treatment. Patients who continue doing well for 90 days may receive methadone on a takeout basis. Patients who are doing poorly at 60 days are informed they have 30 more days to turn around or possibly face a taper of their medication or transfer to a higher level of care.

Of course we make every effort to engage patients in treatment, but we do not tolerate drug use for extended periods. We understand that it takes time to change behaviors, but since heroin use is dangerous, we put pressure on the patient to stop quickly. Just about all respond to our interventions, and retention is high.

Recently we had been stabilizing everyone on methadone—also using LAAM (levo-alpha-acetylmethadol hydrochloride) for over 10 years—but now we are offering buprenorphine. Patients have a choice. Now that LAAM is no longer available, buprenorphine is all the more welcome.

In a private office setting or primary care clinic, I'd be willing to offer buprenorphine to every opiate-dependent patient, especially those addicted to pain medications, and see who responded. Some may need methadone maintenance in a structured clinic, but buprenorphine is a good first choice. In our public clinics, we need to pay close attention to cost-effectiveness and perhaps initially reserve buprenorphine for patients most likely to benefit—working, younger, lower level of addiction. I will certainly offer it to individuals who started abusing opioids only recently, have had no previous methadone treatment or did not like methadone maintenance clinics, and are functioning relatively well, with homes and jobs and stability in their living situations and family obligations. These people can benefit from the more liberal take-home dosing that buprenorphine makes possible. We are offering three-times-a-week visits, as we did with LAAM. I would be less likely to offer buprenorphine to someone who's been abusing drugs for many years with multiple treatment failures, and has a history of incarceration, multiple medical and psychiatric problems, and so forth.

I do not suggest to patients who are stable on methadone that they transfer to buprenorphine. If someone wants to switch, we will make sure he is deter-

mined enough to weather the bit of discomfort the process requires. We would advise that he taper down his methadone dose and enter into withdrawal on the day we start the buprenorphine. Once through the transition, buprenorphine may not fully control discomfort and craving, especially for people who have been on high methadone doses. That said, responses are very individual. I have seen people stabilize on buprenorphine who were using \$100 per day of heroin. We have been converting a majority of our LAAM patients to methadone, since most of them have used methadone in the past, at least for detoxification. A few have wanted to try buprenorphine, and so far these transitions generally have gone well.

The patients who get buprenorphine will follow all the same clinic rules as everyone else, except they will be eligible for takeouts a little more rapidly—after 60 days, providing their urine tests are negative. I'm not going to give take-homes to people who are still abusing opioids, because buprenorphine will be sold and diverted onto the street. This is inevitable, even with Suboxone, the buprenorphine-naloxone combination product we will be using. Out-of-treatment opioid users won't seek Suboxone to inject, because that will make them sick; but they will buy it to stave off withdrawal when they can't get other opioids. In the clinical trials we saw patients selling doses or giving them away to friends for this purpose.

To minimize diversion, our nurses will monitor how much buprenorphine is going out, lost doses, and so on. However, directly observed treatment—actually watching patients to make sure they ingest the medication, as we do with methadone—is impractical with buprenorphine. The pills just take too long to dissolve, up to 5 to 8 minutes. By the way, I'm told they taste nasty.

The staff here is excited about buprenorphine. My own acceptance has generated interest and excitement about it. I've sent some staff members to trainings and have done many trainings myself, and that has aroused their scientific curiosity.

Staff buy-in for any new medication is critical and not automatic. Some of the staff may be concerned that buprenorphine, by allowing patients to come in only once a month, could jeopardize their jobs. To put this concern in perspective: We saw similar worries 10 years ago, when LAAM was introduced and patients began to be able to come in only three times weekly rather than daily. The fact is, there is

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plenty enough opioid addiction to keep everybody working. It is a good thing if treatment providers have to see individual patients less frequently, because it enables us to offer treatment to more patients.

In methadone clinics, as in other treatment settings, events and experience will determine how buprenorphine ultimately is used. At present, regulations inhibit methadone clinics from fully exploring buprenorphine's potential advantages, by requiring us to maintain these patients on the same attendance and monitoring schedules as our methadone patients. Hopefully that will change.

The current higher cost of buprenorphine compared to methadone may affect public and private methadone centers differently. At our VA clinic, we won't pass the extra cost on to our patients. Private clinics may pass on costs. If they do, some patients may think, "If I have to pay more out of pocket to get buprenorphine in a methadone clinic, why not go to an office-based practitioner instead?" So there are issues to be worked through; but fundamentally, I think buprenorphine should have a place in methadone clinics, both public and private.

A COMPREHENSIVE OUTPATIENT TREATMENT PROGRAM

George Kolodner

The Kolmac Clinic is an outpatient chemical dependency program in a mental health setting. We admit about 600 patients a year at 3 locations and maintain a census of 250 to 280 patients. We treat the full spectrum of chemical addictions, including alcohol and cocaine addiction.

Our program is both intensive and comprehensive, combining detoxification, rehabilitation, and followup care. Patients participate for up to a year and a half, after which they are encouraged to participate in support groups—usually either 12-step meetings or alternative programs like Smart Recovery. We are now beginning to offer buprenorphine as a support to the treatment of opiate addiction. Thus far we have treated 130 patients.

The program appeals primarily to people of moderate means who cannot afford the expense of long-term inpatient treatment, but who have insurance coverage and are anxious to avoid the stigma of a public clinic. Clinic sessions take place in the evenings, making it possible for working people to attend. We

have recently been approached by a managed care company that works specifically with Medicaid patients, and we are thinking of setting up a Medicaid pilot program to see if our model will work with that population.

We have been looking forward for many years to buprenorphine's approval. When the medication was in clinical trials all the researchers were reporting how much better it was, particularly for detox, compared to its nonnarcotic predecessors. Clonidine and diazepam were better than cold turkey, but not by much. Naltrexone looked like it worked, but patients wouldn't stay on it and they relapsed. Our completion rates were only about 10 percent for heroin addicts and 40 to 50 percent for prescription drug abusers.

We literally had patients dying—especially young, naïve heroin users who did not understand how tolerance works. They would get clean for a while, then relapse and die from an overdose because they had no sense of how their tolerance had changed. I was becoming reluctant to treat opioid addicts; on the other hand, some of them seemed to make it, and their needs were so acute that I didn't feel right turning them away. It was very frustrating to know there was a drug that had been proven safe but was not yet available.

We initially attempted to use buprenorphine for short-term detoxification. It worked, but our long-term recovery rates did not improve. We concluded that we did not want to use the medication as a short-term expedient. We physicians want to relieve suffering, but we don't want to set up revolving-door treatments. Our overall strategy is to use buprenorphine right from the beginning to facilitate withdrawal, to continue using it as a stabilizing medication, and to be very cautious about taking a patient off it.

With regard to patient selection for buprenorphine, I won't accept people who indicate that they just want to use the medication for detox. Patients have to commit to participation in our entire program, with buprenorphine being used as a support in the process. At this point I consider every active opioid addict who makes that commitment a potential candidate. The exceptions are a few people who come in who have already been through withdrawal and are 2 to 3 weeks past their last opioid use. I offer these people naltrexone instead of buprenorphine, because I have qualms about putting them back on a narcotic.

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Our patients' experiences with buprenorphine have been positive so far. Completion rates are up sharply over our past experience with opioid abusers. Patients who have used methadone in the past generally report that buprenorphine makes them feel much better—they're energetic, their heads are clear, they can function. Of course, the former methadone patients our clinic attracts are not from the very large population that thrives on methadone, but those who for some reason or another had a bad experience, relapsed, and don't want to try it again.

A number of our patients have attention deficit disorder. As far as we can tell, the buprenorphine does not necessitate a change in their dose of stimulant medication, and they seem to do as well as other buprenorphine patients.

We have had a few patients relapse while on buprenorphine, and uniformly they're telling me they don't get high. One of these was a lady who was given 20 Percocet (acetaminophen and oxycodone) in the ER and took them all in one day.

Patients generally enter our program wanting to use buprenorphine temporarily, with the goal of becoming drug free. While, as I have said, our personal experience indicates that removing buprenorphine too quickly invites relapse, we do not yet have sufficient research information to tell us when in the course of treatment we should offer or press our patients to taper off the medication. So we resort to trial and error, taking people off the drug when it appears reasonable to do so, and putting them back on if they relapse. But you hate to see people relapse. The scary thing is that things are working so well with buprenorphine, you don't want to rock the boat.

Because our clinic staff was already used to giving meds for detoxification, it was easy for them to accept the use of buprenorphine for that purpose. However, they were initially ambivalent about the idea of keeping patients on it after detox. Many of our staff are recovering from chemical dependence and are wary of medications. While they accepted naltrexone, buprenorphine, as an opioid, was a different matter. Some of the staff had also had negative experiences with drugs like diazepam and alprazolam, which the treatment community adopted enthusiastically, only to find that they were cross-addicting medications. I talked to the staff, and had someone from one of the better methadone programs come to talk to them. He had been on methadone himself for

many years and gotten off, so he was able to give them the perspective of someone whose life had changed in a positive way with opioid maintenance.

Ultimately, what really changed the staff's attitude was their experience with the patients. Having worked with opioid patients who were not being maintained on opioid agonists, they saw how the people on buprenorphine could do a higher level of work. If you were to walk into one of our groups, you would not be able to tell which patients are on buprenorphine. Now the staff is enthusiastic.

I use only Suboxone, the combination product that also contains the opioid blocker naloxone, partly to reduce the chances for buprenorphine diversion. If someone injects Suboxone while having an opioid other than buprenorphine on board, the naloxone will flush that opioid from the brain, thrusting the patient into withdrawal. However, there is uncertainty concerning whether or not someone can get high from injecting Suboxone when no other opioid is on board. Some researchers believe the naloxone will reach the brain first, and keep the buprenorphine from having any effect. But others are concerned that buprenorphine may overpower the naloxone in this situation and produce a high, albeit a relatively mild one. Time will tell.

We have been pleased that the insurance companies thus far have not balked at paying for buprenorphine. The medication's price is not exorbitant relative to the benefit it confers. All the major insurers in our area cover it; however, they do have several tiers of coverage. We are working to get the drug on the preferred list so that the copayments are reduced.

In summary, we are finding that buprenorphine fits very well into our program, both as a support for detoxification and for stabilization. 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.

PHOENIX HOUSE, A THERAPEUTIC COMMUNITY

Terry Horton and Suzanne McMurphy

Phoenix House was founded in 1967. Today we are the largest not-for-profit therapeutic community (TC) in the Nation. We operate some 90 drug treatment programs serving about 5,500 clients,

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primarily on the West and East Coasts. Our New York State program is distinguished by the fact we offer a full complement of primary care medical services within our abstinence-based residential program. We provide our own medical, dental, HIV, and optometry care.

At Phoenix House, we are looking at buprenorphine as potentially the long-awaited answer to a serious problem. In New York and elsewhere, the detoxification interval has historically raised a formidable barrier to successful integration of new opioid-addicted clients into TCs. For many years our State law allowed only hospitals to provide opioid detoxification services, so when patients came to us from the street we had to send them to an offsite medical center. Fewer than half came back. Those who did return were now several days—hard days—distant from the resolve that had originally brought them to our door. As well, many were still in withdrawal, because their detoxification treatments were inadequate.

Under those conditions, treatment engagement was difficult. Dropout rates within the first week were extremely high. The high dropout rates associated with offsite detoxification were financially damaging and ethically problematic. An induction bed given to a patient who drops out loses money for Phoenix House and—with half a million addicts in need of treatment in our city—wastes a vital resource.

About 5 years ago, State regulations changed to allow community-based medical detoxification. However, the medications available at the time were not well suited for TCs. Methadone carries an overwhelming regulatory burden. Clonidine has limited effectiveness, we believe, and certainly is not popular with addicts. So we continued to refer patients out.

Buprenorphine has finally provided us with the tool we have needed to bring detoxification services on site and integrate them with our other program offerings. Our enthusiasm for the new medication reflects firsthand experience. Phoenix House participated in Dr. Walter Ling and Dr. Leslie Amass's NIDA Clinical Trials Network (CTN) study comparing buprenorphine to clonidine for detoxification in residential settings. Buprenorphine looked like a winner for us: Although we treated only half a dozen patients, they liked the medication and tolerated it well; side effects were minimal and no serious adverse events occurred. The staff found buprenorphine efficacious and easy to administer. Based on monthly

phone conversations with the other participating programs, our positive experience seemed to be typical.

With the lessons of the study to guide us, in 2003 Phoenix House created a buprenorphine detoxification program that we call "First Step." Candidates are screened in any of our outreach centers, and with approval of our staff physician, are admitted to our Long Island City residential facility. After the physician completes his evaluation, the patient is prescribed and is observed self-administering the first of two initial doses of sublingual buprenorphine. Typically, clients become comfortable so quickly that they are able to participate in TC treatment right away, often within hours of the first dose. They are clear-minded; they do not nod off. Buprenorphine essentially serves as a treatment readiness drug, bridging the void between active drug use and drug-free treatment. From then on, the detoxification service functions essentially as an outpatient enhancement to a residential program. Patients participate fully in regular treatment activities. Twice a day they walk over to the health clinic for withdrawal symptoms assessment, dosing, and special motivational seminars.

First Step's protocols are based on the detoxification schedule used in the CTN clinical trial: 13 days of medication, building up to an 8-mg or 16-mg maximum dose and tapering back down to zero, followed by a final day of observation. Over time, we have learned to individualize treatment, changing the induction, stabilization, and tapering doses and schedules to best and most comfortably support patient needs. We've also begun treating clients on methadone and other long-acting opioids. No empirical studies have yet sorted out what the ideal time span for detoxification with buprenorphine should be, but an average of 2 weeks works well for us. That's ample time for clients to become engaged in the community environment, and for the staff to administer a curriculum of enhancements to support client motivation.

"Seamless continuum of care" is an overused phrase, but we honestly believe that's what we are achieving with First Step. Detoxification and induction are simultaneous and mutually reinforcing from the patient's Day 1. To date, more than 230 clients have passed through the program. Retention and completion rates have far exceeded our initial goals. When we first decided to go ahead with First Step, we imposed do-or-die criteria for viability. During the

first 6 months, we had to beat our baseline retention rates for opioid-addicted clients successfully making the transition from induction beds to long-term treatment. Moreover, the program had to be financially self-sustaining. Though the program has far surpassed its clinical performance goals, it has yet to achieve fiscal viability; however, we expect to reach necessary daily census targets within the half-year.

The first prerequisite for creating a service like First Step is having onsite medical services. A key concern is integration, structuring to take advantage of your assets—in our case, the community experience and group dynamics of self-help and mutual support. An important feature of First Step, for example, is that the nonmedical team also reports to the director of induction. That's an unusual paradigm, because medical models usually put everything under the medical director's authority. But it involves our induction director in the client's case from the very outset, and

keeps our focus on detoxification as a transitional rather than a preliminary or separate episode in the patient's care.

Some issues took us by surprise when we started First Step. Outreach was one: At first, we had trouble attracting clients. We found we were struggling against Phoenix House's rock-solid, formed-in-cement reputation. Throughout New York, people who refer street addicts for treatment were used to thinking, "Oh yes, Phoenix House, they're abstinence-based; the client will have to go to detox first." Even though providing medical detoxification is entirely consistent with the abstinence-based philosophy, some referral sources had trouble picturing us doing it. Over the past year we have placed a great deal of effort into contacting referral decisionmakers—social workers, judges, parole officers, and others—and saying: "Guess what? We have something new at Phoenix House. Have you heard about First Step?" &