Scottsdale, Ariz. — At a recent workshop on office buprenorphine prescribing, the first question addressed was: Is the 30-patient limit likely to be revised? The urgency of the question is another sign that physicians who choose to become waiver-qualified to treat patients addicted to narcotics under the Drug Addiction Treatment Act of 2000 continue to find that the demand surpasses their ability to provide care.

Currently, about 5,000 physicians have the waiver to prescribe buprenorphine for addiction treatment, said Dr. Laura F. McNicholas, who led the workshop, which was held at the annual meeting of the American Academy of Addiction Psychiatry. It has been reported that fewer than half that number regularly prescribe, however.

Those who do prescribe tend to be swamped with patients. Many of the specialists who attended the workshop said that they would like to be able to refer patients they have gotten stabilized to create more room on their rosters, but they have been unable to find other physicians to take those patients.

Last year, federal officials relaxed the limit set on the number of patients who could be treated from 30 patients at any one site to 30 patients per waiver-qualified physician. This has led many to question whether further relaxation is forthcoming.

Among those familiar with the machinations of the federal government, the sense is that Congress may be amenable to the idea of loosening the limits further because federal officials are satisfied with the way the program has been working. But some limits will stay in place, at least for the time being, said Dr. McNicholas, who recently chaired a panel that developed office buprenorphine guidelines for the Substance Abuse and Mental Health Services Administration.

The medical groups involved have not come to a consensus about the new limits they should seek from Congress, but discussions have begun, she added.

A recent assessment document on the buprenorphine prescribing program shows that even the Drug Enforcement Agency is satisfied with the program, said Dr. McNicholas, of the University of Pennsylvania Treatment Research Center, Philadelphia.

The document, which has been discussed but not yet finalized or published, says that, as expected, the program is reaching a different demographic of narcotics addicts than has traditionally been involved with methadone programs and other kinds of treatment. Those prescribed buprenorphine are more middle class and less likely to be addicted to heroin.

Figures in the report, which covers 3 years, indicate that about 60% of the patients treated through the program had never been in drug treatment before, and about 40% had been abusing diverted prescription medications, such as OxyContin, Dr. McNicholas said.

The report also says that while there has been diversion of buprenorphine, it does not appear to be a major problem. In fact, it notes that many of the cases have involved patients giving the medication to friends, who then find it so efficacious that they seek out treatment for themselves.

Another topic of discussion during the workshop involved the side effects that clinicians were seeing that were not particularly noted in the early trials of buprenorphine.

Several of those who attended the workshop said that some of their patients have headaches when they start the medication and some complain of feeling fatigued. Dr. McNicholas said experience is suggesting that 20% of patients experience headaches when they first go on buprenorphine, but that the condition always resolves in a few days.

Regarding the fatigue issue, Dr. McNicholas said she was skeptical of those complaints because, kinetically, the drug should not have that effect. However, when pressed by several of those who said that they did have fatigued patients, she allowed: “I am not saying it is not real, but I certainly haven’t seen it—and we have no data.”

“I hear things, frankly, that we did not see during the studies,” one of which was occurrence of headaches, she added.

There continue to be no worrisome reports of drug-drug interactions with buprenorphine. Such interactions were expected because it is given by sublingual administration; this is done so that large amounts do not assault the liver, but it means that most of the medication goes to the brain first.

Many of the buprenorphine diversion cases have involved patients giving the drug to friends, who then find it so efficacious that they themselves seek treatment.

Buprenorphine Demand Surpassing Patient Limit

BY TIMOTHY F. KIRN
Sacramento Bureau

The demand is such that Congress may be amenable to questions about further relaxation of the number of patients permitted to be treated.

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Detox With Buprenorphine More Lasting Than Clonidine

BY TIMOTHY F. KIRN
Sacramento Bureau

Scottsdale, Ariz. — Opiate addicts who go through withdrawal using buprenorphine are nine times more likely, to complete their withdrawal regimen than are patients who use clonidine, a large National Institute on Drug Abuse-sponsored trial shows.

In addition, buprenorphine might be that much-sought-after key to getting more opiate abusers involved in their longer-term psychotherapy treatment, Dr. Leslie Amass, Ph.D., said at the annual meeting of the American Academy of Addiction Psychiatry.

Regarding the fatigue issue, Dr. McNicholas said experience is suggesting that 20% of patients experience headaches when they first go on buprenorphine, but that the condition always resolves in a few days.

The study involved 344 opiate-addicted subjects who were randomized to either a 13-day schedule of tapered withdrawal using buprenorphine-naloxone (Suboxone) or a tapered withdrawal using clonidine patches. The patients came from 12 centers; 113 patients were detoxified as inpatients and 231 as outpatients. Most were heroin abusers, and many had been in treatment before.

No problems were found with the early doses of buprenorphine. All of the patients took and tolerated their first day’s dose of 8 mg, and 90% completed the induction phase of treatment. During that phase, the dose was increased to 16 mg before being cut back, said Dr. Amass, a principal investigator with the Friends Research Institute Inc., Los Angeles.

Overall, 68% of the buprenorphine-detoxified patients completed the full process, compared with only 30% of the clonidine patients.

Moreover, 77% of the inpatient, buprenorphine-detoxified patients completed and tested negative for illicit opiate use on day 14, compared with 22% of the inpatient, clonidine-detoxified patients. The success was true for 28% of the buprenorphine-treated outpatients and 5% of the clonidine-treated outpatients.

Fewer adverse events occurred in the buprenorphine-treated patients, and most were related to withdrawal. They included insomnia (62%), arthralgia (34%), and anxiety (26%). Only one of the serious adverse events was deemed potentially related to buprenorphine: a case of hematemesis that might have been a general opioid reaction.

‘The big message here is that if you are going to pursue a short-term intervention focused on medical withdrawal for opiate addiction, buprenorphine is the way to go,’’ Dr. Amass said.

Longer follow-up of these patients has been difficult, as is typical with drug-treatment patients. But there is good reason to think that buprenorphine serves as a better bridge to long-term treatment for more patients, Dr. Amass said.

Several studies have tried to document this influence, including a recently reported investigation of buprenorphine among adolescents. The study found that almost two-thirds of the adolescents treated with buprenorphine alone completed a 4-week course and transferred to naloxone maintenance. But only 5% of those treated with clonidine had done so (Arch. Gen. Psychiatry 2005;62:1157-64).

‘‘That’s unheard of in the treatment of adolescents,’’ Dr. Amass said.

The centers involved in the National Institute on Drug Abuse study had such a positive experience with buprenorphine and have continued to lead to long-term treatment that almost all have continued their programs, she said.

The exceptions have been the study’s methadone clinics, which are legally prohibited from changing drug treatments.

Two of the centers that have continued with buprenorphine are very prominent treatment centers that previously have eschewed pharmacologic detoxification of this kind: the Betty Ford Center in Rancho Mirage, Calif., and Phoenix House in New York.

Phoenix House notes that, of the first group of patients admitted to its buprenorphine withdrawal program, 90% completed detoxification and 76% continued into long-term treatment.

In a coordinated study at Phoenix House, almost 50% of 38 patients admitted to the program, completed a full 3-month treatment regimen. That compared with about 60% of 37 nonopiate drug abusers. Historically, the retention rate of opiate users is significantly lower than that of other drug or alcohol abusers.

The staff at Phoenix House attributes its better retention partly to the condition of its patients during the initial days of their stays. Phoenix House patients tend to be well enough during those early days to absorb the message delivered by counselors that recovery requires more than simply detoxification, Dr. Amass said.

The remaining contribution to retention probably has to do with the pharmacology of buprenorphine: ‘‘Buprenorphine ‘is the single best predictor of retention, regardless of setting,’’ Dr. Amass said.