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A new treatment approach frees addicts from methadone clinics and dramatically expands the number of those who can benefit.

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Illustration:
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23 NYU PHYSICIAN
FALL 2007

methadone

“Are you having a problem with prescription opiate drugs such as OxyContin, Vicodin...?” inquired the voice from Brian’s car radio—a public service ad for a study under way at Bellevue Hospital. He scribbled down the phone number. Today,

Brian

is part of the first large-scale, nationwide study designed specifically to treat people addicted to prescription painkillers. It goes by the name POATS, for Prescription Opioid Addiction Treatment Study. Brian, 32, is no stranger to addiction. Cocaine use in college became a decade-long problem that has left an indelible mark. “The middle of my nose is gone,” he says. “I can put a tissue in one side and pull it out the other.” At 30 he finally went into rehab, yet after only one year away from drugs he took up a new habit: prescription painkillers. With an annual income of more than \$300,000 from an online business that virtually ran itself, Brian had already entered his own version of early retirement: playing golf, dabbling in insurance sales, and doing drugs.

At first, Brian told himself he was taking the opioid Vicodin for migraines, or because his hip hurt. But as he sank into a warm, groggy bliss, all he wanted was to keep feeling that way. Soon Vicodin had no effect unless he took 20, and eventually 30, a day. Then he switched to something more potent, OxyContin, chopping up the pills and snorting them. By the spring of 2007, he needed a daily dose of 10 80-mil-

ligram tablets—at a street price of \$12,000 per month—just to feel “normal.” Even patients in severe pain are rarely prescribed more than 200 milligrams per day.

“Cocaine makes you very hyper,” Brian explains. “You can’t sniff cocaine and live a normal life.” With OxyContin, by contrast, he would be in a bit of a fog but essentially still functional. “That’s why it’s dangerous, you know?” he says. “Because you can hide it.”

In April 2007 Brian heard the radio ad for the POATS trial. The study is a timely one. Aside from marijuana, prescription opioid painkillers are now the most abused drugs nationwide, particularly among teens and young adults. Over the past decade, the number of addicts entering treatment has more than quadrupled. There may now be several times more Americans addicted to prescription painkillers than the estimated 1 million people addicted to heroin. POATS is designed to address this growing epidemic. Funded by the National Institute on Drug Abuse, it involves 11 research locations scattered throughout the country.

At the heart of the study is a prescription medicine called buprenorphine

(Suboxone), a hexagonal orange pill that’s dissolved under the tongue. It’s similar to methadone, but with several important twists. Like methadone, buprenorphine is a synthetic opioid that binds to certain opiate receptors in the brain in the place of drugs like heroin or OxyContin. This allows it to control an addict’s cravings and withdrawal symptoms. Unlike methadone, however, its effects reach a “ceiling,” making a fatal overdose highly unlikely. In 2002 the FDA ruled that Suboxone can be prescribed by any doctor after eight hours of special training and dispensed at any pharmacy.

Equally important is that Suboxone is very difficult to abuse. If an addict tries to pulverize the tablets and inject them, a second ingredient—an opiate receptor “antagonist” called naloxone—floods the brain, counteracting any pleasurable effects and throwing the user into withdrawal. There’s also a more gentle buffer against relapse: If a user tries to take any opioid while on Suboxone, he’ll feel nothing at all; buprenorphine binds so tightly to the brain’s opiate receptors that other molecules can’t muscle their way in.

FDA approval launched a quiet revolu-

tion in the availability of treatment for opiate addiction. Methadone can be legally dispensed only at special clinics, and there are currently some 250,000 methadone maintenance slots nationwide—not even enough for all the people addicted to heroin who want treatment, much less the ballooning number addicted to prescription pills. Yet opening a new clinic or expanding an existing one has proven nearly impossible. Politicians and community activists invariably insist: “Not in my backyard.” Six states have no methadone programs whatsoever. And even in New York City, the birthplace of methadone maintenance and home to more treatment slots than any other city, former Mayor Rudolph Giuliani announced in 1998 his

Berger Professor of Medicine, Professor of Psychiatry, and Director of the Division of General Internal Medicine, who spent the first decade of his career working to improve methadone treatment programs in the Bronx. Substance abuse, explains Dr. Gourevitch, is vastly underrecognized. “Many people with this problem come through the doors of doctors’ offices over the course of their lives,” he says, “and the issue is never touched upon.” Sometimes the patient is ashamed to ask for help; sometimes the doctor avoids the issue.

Suboxone, and a handful of similar drugs, has the potential to change all that. The hope is that this will eventually do for drug addiction what SSRIs like Prozac did for depression: convince both

the patient as never being ‘clean,’ because they’re still taking an opioid medication. But if you think of other medications they prescribe, they don’t have that same bias. Would you ask a diabetic to tough it out without insulin?”

Fortunately, though, Suboxone is likely to escape much of the dark cloud that hangs over methadone. “First, methadone has been used almost exclusively for street heroin addicts, which immediately stigmatizes it,” notes Marc Galanter, M.D., Professor of Psychiatry and Director of NYU’s Division of Alcoholism and Drug Abuse. “It also carries with it so many restrictions that, in a way, it has the same panache as being sent to jail.” Most methadone clinics, no matter how respectable in appearance, inevitably make patients feel as if they’re on parole by requiring frequent drug tests, counseling sessions, and a strict regimen of visits. For some addicts, such routine and supervision are exactly what’s needed to tame the chaos in their lives. But for others, Suboxone’s advantage is more obvious: it allows a person struggling with addiction to seek treatment in the privacy of a doctor’s office and to take his or her daily medication at home.

It’s Monday morning, and Sheldon, 28, is at Bellevue Hospital for his weekly POATS appointment. Though roughly the same age as Brian, Sheldon represents a fundamentally different kind of patient: one whose addiction to painkillers began not with recreational use, but with medical care. Addiction stemming from legitimate pain treatment is rare.

According to pain expert Howard Fields, M.D., Ph.D., Director of the Wheeler Center for the Neurobiology of Addiction at the University of California, San Francisco, fewer than 6 percent of patients who are not already using (or seeking) narcotics when they begin treatment will end up abusing them, and far fewer will become truly addicted. Still, it does happen.

As for Sheldon, he had broken his arm several times by age 12, and it had never quite healed. So when he started construction work at age 23, the old injury flared up, eventually requiring surgery. Others on the construction crew had similar problems with pain, and one of them recommended a doctor. Soon Sheldon was on 40 milligrams per day of hydrocodone—an opioid painkiller—a dosage he stayed on for more than six months. Apparently, the doctor had prescribed liberally for other patients as well. Returning one day for an appointment, Sheldon found that

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While Suboxone, like methadone, is dispensed in clinics, it is most often taken in the privacy of the patient’s home.



intention to eliminate them, though he did not succeed. Because of the stigma, many addicts in need of treatment stay away from methadone clinics; others languish on long waiting lists. What Suboxone now offers, for the first time, is discreet, convenient access to effective treatment.

NYU’s branch of the POATS study is run by Marc N. Gourevitch, M.D., M.P.H., the Dr. Adolph and Margaret

primary-care physicians and the public that addiction is a chronic brain disease, not a character flaw.

Of course, substituting one addictive drug for another—the “replacement therapy” that Suboxone offers—is not without controversy. It’s the same debate that has swirled around methadone for decades. “For many physicians it seems like a cop-out,” says Dr. Gourevitch. “They view

Sometimes the patient is ashamed to ask for help. Sometimes the doctor avoids the issue.

the doctor's practice had been shut down. "I had to start buying the pills on the street," he says. Over the next four years, Sheldon moved from Vicodin to four 80-milligram tablets of OxyContin per day. If that wasn't available, he would snort heroin. In this strange new world of the addict next door, legal drugs increasingly serve as a gateway to illegal ones.

"So, are there any important issues we should address today?" asks Sheldon's physician, Joshua Lee, M.D., Assistant Professor of Medicine, who is helping Dr. Gourevitch conduct the POATS trial at Bellevue. "Nah. Everything's going great," Sheldon tells him. "Really great." After a few minutes of conversation, Lee asks the big question: "You're about to start dropping down in two weeks," he says, referring to Sheldon's Suboxone dosage. "How do you feel about that?" Last time, as they both know, this did not go well.

Phase I of the POATS trial, which Sheldon has completed, is essentially a gentle detox, calling for two weeks on the medication followed by two weeks of tapering off. But Sheldon had been using drugs for so long, he just wasn't ready. "I got scared," he says. "When I have any kind of withdrawal, my mind starts to go crazy. So I did the first thing I knew, which was to use."

Fortunately for Sheldon, the researchers had anticipated this as a potential outcome, and designed POATS to have a phase II for those who quickly relapse. Sheldon is now receiving three full months of Suboxone treatment, which simulates how he might do on long-term maintenance. Meanwhile, Brian, who completed phase I a month ago, is doing surprisingly well drug-free, although he describes his first three weeks without Suboxone as "the worst three weeks of my life"—sleepless weeks of nausea, chills, diarrhea, apathy, and intense, uncontrolled cravings for opiates. (Withdrawal from any opioid, including methadone, involves similar symptoms.) "I can see why people go back to using drugs," he says. "I still don't feel normal. But every day gets a little better."

How patients like Brian and Sheldon will fare long-term remains an open question. Long-term studies of people addicted to prescription opioids simply don't exist.

Do they respond to treatment differently than heroin addicts? How long should they be maintained on Suboxone? No one



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Dr. Marc Gourevitch and Joshua Lee of Bellevue Hospital.

dramatic reductions in illicit drug use, criminal activity, and drug-related emergency room visits.

Of course, medication alone is rarely enough to get an addicted person's life back on track; behavioral therapy can be a crucial adjunct. To measure the value of counseling, POATS has divided patients into two groups. Both receive standard supportive interactions with their physician while taking Suboxone,

really has answers. "There's clearly a subset of patients who, as with methadone, can use buprenorphine for a few weeks to a couple of months, get themselves out of a bad habit, taper down their dosage, feel uncomfortable, and pick up and move on," says Dr. Gourevitch. POATS will help to define who they are. But Dr. Gourevitch doesn't expect that to be the rule. "For many patients, this is a chronic relapsing condition, and long-term treatment with buprenorphine—in some cases for life—will help them most. We've learned that from 40 years of experience with methadone." The benefits of ongoing treatment are likely to be similar, as well, including

and one group receives intensive individual counseling as well. Yet in the real world, Dr. Galanter warns, most doctors prescribing Suboxone will have limited experience treating drug addiction, and may not be equipped to provide this additional support. He is also concerned that these doctors will use Suboxone as a first line of defense for patients who are not severely addicted, and for whom behavioral therapy may suffice.

For many patients, though, the risks of continued drug use—declining health, missed work, troubled relationships, and criminal behavior—far outweigh any risks of Suboxone. "You don't want to offer

someone a dependence-forming medication if you can avoid it," says Dr. Gourevitch. "But compared to the alternatives, it can be a reasonable treatment to start relatively early for someone who is in really bad shape."

Despite its virtues, Suboxone treatment has so far reached a relatively small number of patients, which has experts puzzled. In New York City, for example, just 1,300 prescriptions are currently filled each month. Compare that to the 60,000 addicts the city's Department of Health and Mental Hygiene had hoped this medication would help bring into treatment by 2010 (or the 34,000 patients currently on methadone). Nationwide, while the number of Suboxone prescriptions filled annually has doubled since 2002, according to IMS Health, a healthcare information company, the current average is just 120,000 per month, far fewer than the number of patients on methadone.

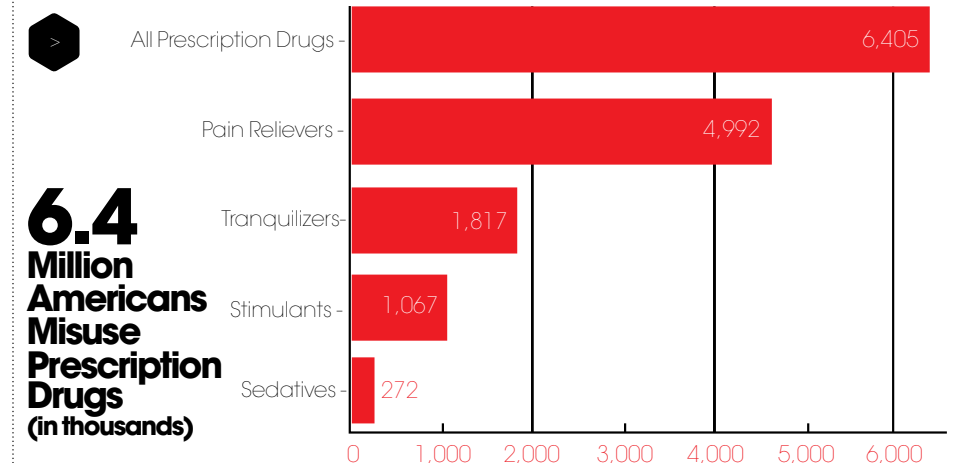
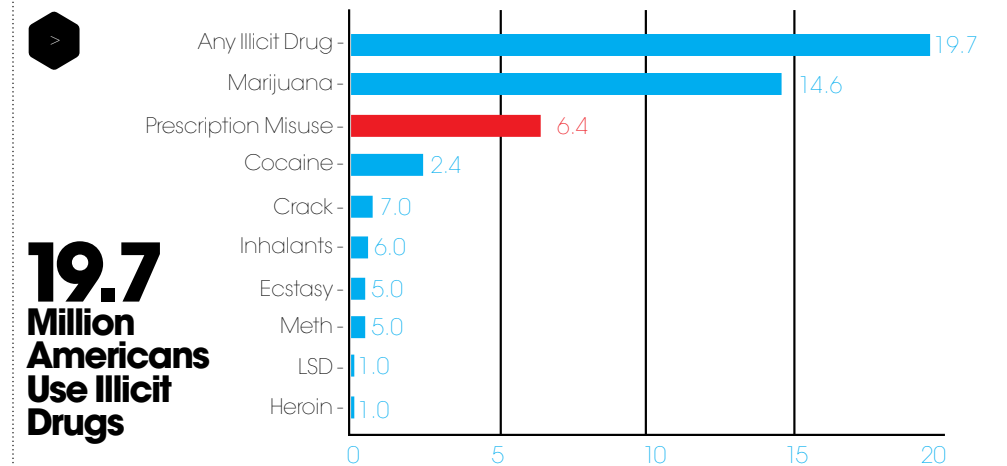
"Not everybody wants treatment," notes Dr. Gourevitch. And with no flashy television commercials urging patients to "Ask your doctor about Suboxone," most people have simply never heard of it. But there's another factor: cost. In fact, cost is the most common reason addicts cite for not getting the treatment they know they need, according to the 2005 National Survey on Drug Use and Health. No surprise, in a country where some 45 million people have no health insurance.

Before joining POATS, Sheldon had been on Suboxone twice before and quit both times. "You had to pay for a whole prescription at once, and, not having insurance, that was about \$500 to \$600," he recalls. "I just couldn't afford it any more." He's the first to admit, however, the faultiness of his logic, since his drug habit cost about \$120 per day—nearly 10 times the price of a day's dose of Suboxone. "An addict's mind," he explains, "is different than everybody else's."

With all of these real-world hurdles, it remains to be seen whether Suboxone treatment will be able to live up to its promise. Certainly for patients who can afford to pay out-of-pocket, or for those with health insurance, it has created an unprecedented opportunity: readily available treatment, in private, with dignity.

Yet Dr. Gourevitch hopes its use won't be restricted to these groups for long. Since last fall, he, Dr. Lee, and their colleague Ellie Grossman, M.D., M.P.H., Instructor in Internal Medicine, have been seeing opiate-addicted patients at Bellevue's Adult Primary Care Clinic every Tuesday, prescribing Suboxone

Illicit Drug Use in the U.S.



Source: Substance Abuse and Mental Health Services Administration (SAMHSA), 2005 National Survey on Drug Use and Health, Sept. 2006. Figures do not add up to totals because of multi-drug use by individuals.

Suboxone has created an unprecedented opportunity: readily available treatment, in private, with dignity.

while also attending to their other medical needs. By showing that this treatment can work successfully at a "safety net" hospital such as Bellevue, where patients are treated regardless of their ability to pay, Dr. Gourevitch hopes to inspire other public hospitals to follow his lead. Because of his dual role at the clinic, addicts

found ineligible for the POATS study have not been out of luck. "I can step out of my POATS research hat," Dr. Gourevitch explains, "and say, 'Well, I'm also a regular doctor, and I can help you with this condition.'" Thanks to Suboxone, more and more physicians can offer such encouragement. ●