

Policy Brief on: *Treating Opioid Addiction in an Office-Based Practice*

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Introduction:

Opioid abuse and dependence remains a serious and growing public health problem in the United States. For decades heroin has been a primary opioid of concern and it continues to be regularly abused. In 2005 there were an estimated 379,000 heroin users nationwide. (<http://www.whitehousedrugpolicy.gov/drugfact/heroin/index.html>).

But adding to America's opioid problem has been a surge in problems related to prescription opioids such as Oxycontin, Vicodin and Percocet, a surge that has occurred in tandem with their growing medical use as painkillers. As of 2005, about 1.8 million Americans were believed to have engaged in some type of "non-medical use" of oxycodone and hydrocodone prescription opioids. (<http://www.oas.samhsa.gov/2k7/pain/pain.htm>).

In 2002 alone there were 5528 deaths attributed to an overdose of prescriptions opioids, exceeding deaths caused by either heroin or cocaine (Merrill, 2002). According to the federal Substance Abuse and Mental Health Services Administration (SAMHSA), in 2001 emergency room visits related to prescription opioids for the first time exceeded those involving heroin.

There is substantial evidence that opioid dependence, whether it involves heroin or prescription drugs, can be successfully treated with methadone and a newer medicine called Buprenorphine. Both of these treatments work by blocking the effect of the abused opioid and eliminating suffering related to withdrawal. Medication-assisted treatment of opiate addiction has been shown to enhance social productivity and to decrease drug use, overdose deaths, criminal activity and the spread of infectious diseases, including HIV (Salsitz et al., 2000). Oral doses of a medication called Naltrexone, which block the effects of illicit opiates and ease withdrawal, have been used to treat addiction. Oral Naltrexone is not used very often in the US due to limited effectiveness and poor adherence, (Merrill et al., 2005), (Weinrich and Stuart, 2000) though a monthly injectable form of Naltrexone has recently been developed and shows some promise (Brands et al., 2002).

However, there is a gap between treatment effectiveness and treatment access. Since the 1970's, federal and state regulations have generally restricted methadone availability to specially licensed methadone clinics, effectively preventing most private physicians from offering methadone for addiction treatment. There are fewer regulatory inhibitions on prescribing Buprenorphine, but impediments remain and in practice its availability in mainstream medical care is limited.

Recently, many experts have considered whether more patients could get help if methadone treatment could be provided by physicians in a general "office-based" setting (as opposed to a special clinic) through what have come to be known as "methadone medical maintenance" programs. There is also interest in broadening access to office-based treatment with Buprenorphine.

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Policy Implications:

Today, primary care physicians are seldom involved in treating opioid dependence with either methadone or Buprenorphine in an office-based setting.

For methadone, the lack of involvement is attributed to the fact that prescription powers are restricted by a complex web of federal regulations and state laws that tightly control dispensing. These measures appear driven by concerns that methadone itself could be diverted for illicit use and by the view that methadone simply replaces one addiction with another. There have been increases in emergency room visits and deaths related to methadone, though these increases appear to be tied to the rise in methadone use for pain treatment and not to methadone for addiction treatment (King et al., 2002). Restrictions on methadone have limited its use to government-approved opioid treatment programs (OTPs), which has had the practical effect of erecting barriers to medical methadone services.

Methadone treatment programs are limited in many states and localities and efforts to establish new ones are frequently scuttled by community residents who oppose treatment centers in their area. Programs are located in urban areas, limiting access for rural patients, and five mainly rural states currently have no methadone treatment programs at all. Also, there are a large number of people dealing with opioid dependency who are simply uncomfortable with the burdens of treatment in the methadone clinic environment, where on any given day hundreds of patients may be receiving their daily dose of methadone.

All of these impediments have created a situation where only a small number of people with opioid addiction get treatment with methadone. For example, there are estimates that only about 15 percent of those with heroin addiction receive methadone maintenance. In addition, patients who do gain access to programs routinely find that they must go elsewhere to get treatment for mental health problems and other medical issues that regularly accompany addiction.

Because it is viewed as safer and less likely to be abused, regulations for providing Buprenorphine are not as strict as those governing methadone. The federal Drug Addiction Treatment Act of 2000 allows Buprenorphine to be prescribed by physicians who have completed a special 8-hour training program, received certification in addiction medicine or addiction psychiatry, or participated in a clinical trial of Buprenorphine. Buprenorphine has the potential to increase physician interest in addiction medicine, make treatment less burdensome for patients by requiring fewer visits, and enhance treatment access by dispersing treatment opportunities geographically and providing treatment in the less stigmatized medical setting. But questions remain about whether Buprenorphine access will be limited by:

- physician interest and ability to acquire the skills and infrastructure needed to treat opioid addiction;
- reluctance on the part of public and private insurers to cover Buprenorphine treatment; and
- the imposition of additional regulatory constraints governing Buprenorphine use.

In an effort to make effective treatment more accessible to patients addicted to opioids, over the last 15 years researchers funded by SAPRP and others have explored whether methadone and Buprenorphine can be effectively administered to patients through mainstream, office-based medical practices. Their studies thus far suggest that office-based treatment programs can be as safe and effective as specialty clinics and are attractive to patients because they require fewer visits, thus making it easier to re-integrate into work, school and family.

In addition, federal regulatory changes have been enacted that seek to expand methadone treatment in office-based practices, but barriers to participating remain high. In 2001, federal authority over treatment programs was transferred from the Food and Drug Administration (FDA) to the Substance Abuse and Mental Health Services Administration (SAMHSA) and the old regulatory system was replaced with an accreditation model that could make it easier to create

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office-based methadone programs. Current federal regulations allow patients who have been successfully treated for two years to receive up to one month of take-home doses of methadone.

Despite the evolution in attitudes and regulations related to opioid abuse, research shows that significant challenges remain to providing methadone and Buprenorphine to America's growing and diversifying population of opioid-dependent patients.

Key Results

- Stabilized, long-term methadone maintenance patients can be treated safely in medical office-based practices (methadone medical maintenance programs) without adverse effects and with high rates of treatment retention and improved satisfaction.
- While stabilized patients appear to do well after switching to office-based treatment, international research shows that new patients also can successfully initiate treatment in such settings. However, research investigating the effectiveness of office-based treatment for new patients has been restricted in the United States.
- US-based methadone medical maintenance programs may fall short when it comes to enhancing access to addiction treatment because under the current regulatory structure, only a small proportion of methadone maintenance patients qualify for office-based services.
- Buprenorphine delivered in office based settings is effective for the treatment of opioid dependence and is likely comparable in effectiveness to traditional methadone maintenance treatment.
- Compared to patients receiving methadone maintenance treatment, patients receiving office-based Buprenorphine treatment in the United States are more likely to be younger, Caucasian, relatively affluent and dependent on prescription opioids.
- Office-based opioid treatment with methadone and Buprenorphine has been implemented slowly due to a combination of policy restrictions and the slow development of a physician workforce.

Merrill, J.; *Treating Opioid Addiction in an Office-Based Practice Knowledge Asset*, Web site created by the Robert Wood Johnson Foundation's Substance Abuse Policy Research Program; October 2007.

http://sapr.org/knowledgeassets/knowledge_detail.cfm?KAID=7