Medication-Assisted Treatment for Opiate Addiction and the Public Financing of that Treatment

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Introduction

Defining Characteristics of Opiate Addiction and Dependence

Opiate dependence, often referred to as addiction, is defined in the Diagnostic and Statistical Manual of Mental Disorders as follows:

“…compulsive, prolonged self-administration of opioid substances that are used for no legitimate medical purpose or, if a general medical condition is present that requires opioid treatment, that are used in doses that are greatly in excess of the amount needed for pain relief. Persons with opioid dependence tend to develop such regular patterns of compulsive drug use that daily activities are typically planned around obtaining and administering opioids.”

The core concept of dependence is a strong desire or compulsion to take a drug. Addiction to or dependence on prescribed or illegal opiates—such as OxyContin®, Vicodin®, or heroin—is considered by the National Institute on Drug Abuse and other experts to be a chronic illness. Opiate dependence is a complex syndrome that includes neurobiological, genetic, psychological and social components. This disease, which affects both brain and behavior, can be treated effectively with a combination of appropriate medications, concurrent evidence-based therapy and continuing recovery support.

Dependence and Tolerance

Those who have opiate dependence or addiction experience tolerance, a physical state that reflects the brain's and body’s need for increasing doses of opiates to achieve the same result. People who use prescribed painkillers that contain opiates develop tolerance over time, but rarely become truly addicted. For them, opiate use generally occurs as part of an appropriate medical treatment plan created by a qualified physician to address acute or intractable pain. Patients who develop tolerance to opiates can slowly withdraw under their physician’s guidance, or they can participate in medically supervised withdrawal or detoxification programs, if this is clinically preferred.
According to the U.S. Center for Substance Abuse Treatment’s Treatment Improvement Protocol\(^4\), detoxification does not constitute a complete substance abuse treatment; patients need to go directly from detoxification programs to substance dependence treatment services.

Because of the chronic neurobiological component of opiate addiction, medication-assisted treatment, appropriate counseling and psycho-social treatment are considered the most effective way to manage this chronic illness and prevent acute recurrences of the addiction.\(^2\,^3\) Specific psycho-social counseling therapies—such as motivational interviewing and cognitive behavioral therapy—have been judged to be effectively to use with addicted patients.\(^4\) These therapies may be included in other counseling strategies for opiate-addicted patients.

**State Coverage and Funding Issues in the Public Sector**

Some opiate-dependent patients find that medication-assisted treatments, experienced providers and other therapies or recovery services are hard to find. Medicaid coverage of addiction medications varies greatly in the states. In addition, since substance abuse treatment is an optional benefit under Medicaid, state Medicaid programs may not cover the necessary counseling and recovery support services that will best support the opiate treatment medications. Even if a state or county Medicaid plan covers these medications and treatments, the state or county may contract with a managed care vendor to manage and monitor the services and the medication. These vendors may impose substantial limits and controls on service use unless the state, as the payer and policymaker, explicitly requires that access to treatment and counseling be a priority and that care management be available to encourage treatment.

Other funding sources vary too. State substance abuse or other block grant funding, state general revenues, county revenues and special appropriations for substance abuse treatment may not include funding for medication-assisted therapies and/or medications for opiate addiction.

Although funding is more available now than when methadone, naltrexone and buprenorphine treatments were introduced, it is changing slowly due to state budget concerns, the rise in Medicaid costs and the lack of information or stigma about these treatments or about opiate dependent patients.

Criminal justice systems often do not provide medication-assisted treatment for opiate-dependent individuals. Criminal justice system administrators have recently begun to acknowledge the existence of opiate dependence among offenders and the potential effectiveness of medication-assisted treatment in combination with appropriate psycho-social counseling. Funding has not yet been allocated in most instances.
Medication-Assisted Treatment for Opiate Dependence: Definition and Description

Medication-assisted treatment for opiate dependence refers to the use of buprenorphine, methadone or naltrexone to treat opiate dependence, in combination with counseling and recovery support services. As with other substance abuse treatment, however, long-term treatment and formal or informal recovery support is critical for patients to obtain the greatest cost benefit. If patients leave treatment too early or do not receive simultaneous, evidence-based counseling and recovery support services to prevent recurrence, they tend to return to acute addiction. Few opiate-dependent people recover permanently if they use only self-help techniques or detoxification alone. Although the cost of appropriate treatment for opiate-addicted people is significant, the cost of nontreatment or inappropriate treatment is far greater to society, states, communities and individuals.³

Funding Services for Medication-Assisted Treatment for Chronic Opiate Addiction

Thomas McLellan, Ph.D. and his colleagues⁶ have shown that, like diabetes, addiction to opiates is a lifelong, chronic medical condition that can be managed and treated effectively. Individuals who can pay for approved medications and therapy for opiate addiction or who have (often limited) commercial insurance benefits may be able to purchase the necessary medications, therapies and recovery support services on their own. Often, however, the initial income, savings or private treatment benefits that support use of these interventions is quickly exhausted, difficult to access or non-existent. Thus, these individuals—as well as low-income people and those who depend upon public health care benefits and services—may be forced to use whatever substance abuse interventions are free, subsidized and easily available and these may not be the services that are most appropriate or least expensive for their specific condition.⁷

Costly services frequently used by opiate-dependent individuals include emergency and trauma centers, urgent care centers, crisis services, detoxification centers, psychiatric emergency services or hospitals, or public inpatient units throughout the health care system. Since not all patients have identified dependence, misdiagnosis and mistreatment may occur.

Merely episodic use of available services—compared to services that are indicated for opiate addiction—may not help patients achieve lasting recovery or the maximum value for the public money spent. Patients’ use of more efficient and effective public services could occur if opiate addiction medications and therapy was more readily available to those who need it.

Private and public sector insurance plans, public health clinics, state-funded programs, the criminal justice system and the federal Substance Abuse Prevention and Treatment (SAPT) block grant programs may offer fragmented coverage or even no coverage to opiate-addicted patients.
Addiction Trends and Treatment Obstacles

Estimates of the number of people with opiate dependence are based on national surveys such as the National Survey on Drug Use and Health, discussed below. It is difficult to ascertain in a national survey the full number of opiate-addicted persons since many practitioners may miss the diagnosis, especially if the patient denies or is unaware of the dependence.

Prescription Pain Relievers

Prescription drug dependence is growing quickly amongst adolescents and elderly patients. The National Survey on Drug Use and Health (2006) indicates that about 12,649,000 people—5.1 percent of the U.S. population age 12 and over— reported non-medical use of prescription pain relievers during the past year. These individuals represent about 59.5 percent of those who reported use of illicit drugs other than marijuana in the past year. Not all of this use occurs amongst people who are dependent on or abuse these drugs. But the same 2006 study estimated that 1,635,000 individuals age 12 and over in this country reported that they were dependent upon or had abused prescription pain relievers during the past year.

As the figures above demonstrate, a substantial amount of opiate dependence is not just heroin addiction but is dependence on prescription painkillers such as OxyContin®, Lortab®, Darvon® and even methadone prescribed for pain. Recent media coverage has traced opiate addiction in the mines and along the highways close to the Appalachian Trail, which not only is a significant distribution route for opiates and other drugs but also is close to population centers that apparently are vulnerable to them. Such distribution routes also exist in other areas of the United States (see the High Intensity Trafficking Areas program managed by the Office of National Drug Control Policy). Those who are addicted to opiates also tend to abuse alcohol and other drugs, including nicotine, methamphetamine, “designer” drugs and other substances. Opiate-dependent people often have other mental health disorders and multiple serious medical disorders that are challenging to treat in the context of addiction.

Heroin

In 2006, the National Survey on Drug Use and Health found that an estimated 323,000 people were dependent on or abused heroin, representing about 0.8 percent of the total U.S. population age 12 and over.

The percentage of patients who are addicted to heroin (in contrast to prescribed opiates) has not increased substantially nationwide recently, despite its continuing prevalence in the Northeast and large cities such as Chicago, Los Angeles, Houston, New York and Baltimore.
**Special Populations**

Recent studies widely disseminated by the White House Office of National Drug Control Policy show that prescription drug abuse, dependence and addiction are increasing rapidly among older adolescents and older adults. Dependence in these prospective patients is not necessarily identified or treated. In addition, HIV/AIDS/STD and Hepatitis C patients often have high rates of opiate addiction that may not be treated, even if they regularly receive other medical services.

**Treatment and Criminal Behavior**

The National Institutes of Health (NIH) concludes that opiate dependence in the United States is unequivocally associated with high rates of criminal behavior. More than 95 percent of opiate-dependent people report committing crimes during an 11-year at-risk interval. While these crimes range from homicides to crimes against people and property, theft in order to purchase drugs is the most common criminal offense. Multiple studies conducted during the past two decades show that effective treatment of opiate dependence and other substance dependence disorders markedly reduces the rates of all criminal activity.

For example, a major study funded by the U.S. Substance Abuse and Mental Health Services Administration found that drug abuse treatment reduced drug use and criminal behavior. This finding was determined through a survey of 1,799 people (71.4 percent male and 28.6 percent female) who abused or were dependent on various drugs. A substance abuse history of each client was provided by a nationwide sample of 99 drug treatment facilities. The 1,799 clients were interviewed five years after their discharge from drug abuse treatment. Major findings included:

- Substance abuse among those who remained in treatment the longest was reduced or eliminated.
- Survey results confirm previous studies that showed substance abuse treatment can significantly reduce crime.
- Most criminal activity—including breaking and entering, drug sales, prostitution, driving under the influence and weapons use—declined by between 23 percent and 38 percent after drug treatment.
- Physical abuse and suicide attempts declined following treatment.
- There was a noticeable shift toward regaining and retaining child custody after drug abuse treatment.
- More reliable housing was secured following treatment.
Contemporary Medicine and Opiate Dependence: Methadone, Buprenorphine and Naltrexone

Opiate Dependence Treatment Medications

Medications that currently are FDA-approved and used to treat opiate dependence are described briefly below. It is important to note that while medications are an important component of treatment they must be accompanied by counseling and recovery support services. This practice provides the highest benefit to the patient and the commercial and public sector payers—such as Medicaid and the taxpayers who provide federal state and county funding—for investing in opiate dependence treatment.

Methadone

One of the first opiate treatment medications to be widely available in the United States was methadone, developed in Germany in 1937 as a pain medication. Studies at Rockefeller University in New York in 1964 by doctors Vincent Dole and Marie Nyswander established methadone's effectiveness in treating heroin addiction. Methadone has been available legally in the United States since 1972 for opiate addiction treatment. It is available only in nationally accredited clinics overseen by the DHHS/Center for Substance Abuse Treatment and the Drug Enforcement Administration.

People with opiate dependence receive methadone and required counseling in 1,203 U.S. methadone clinics. Some clinics treat private patients, some treat public sector patients and others treat both. A significant gap exists between those who report opiate addiction that could be treated with methadone and those who actually receive methadone treatment. Five states do not offer methadone treatment, and in other states it is available only in treatment programs offered at state or county methadone clinics. Methadone is the only medication currently approved by the FDA to treat pregnant opiate-dependent women, although clinical trials are under way for buprenorphine to treat pregnant women. Some public methadone clinics also offer buprenorphine or naltrexone but many do not provide them as yet.

Clinically, methadone is a “full agonist” that stimulates opiate receptors in the addicted brain and negates the need to use heroin or other opiates. Methadone is now a generic medication that is safe and effective when used appropriately but is lethal in large doses. Frequent evaluations of methadone as an opiate addiction treatment show it to be safe when used as indicated.

Buprenorphine

Buprenorphine (Suboxone® or Subutex®), a newer prescription medication approved by the FDA in 2002, is also available in the United States for opiate addiction treatment. Because it does not fully stimulate opiate receptors in the brain (“partial agonist”), it is safer and has a ceiling to its effects. To address the national treatment gap for opiate dependence, buprenorphine was approved by the FDA as an additional opiate treatment medication. Under the aegis of DATA 2000, physicians who are trained in its use can obtain a waiver to
prescribe buprenorphine products in their offices. Buprenorphine can be provided by trained physicians in methadone clinics or by qualified physicians in other treatment programs. As soon as buprenorphine was approved in late October 2002, the secretary of DHHS commissioned an evaluation of its effectiveness. The secretary’s report\textsuperscript{16} indicated no substantial diversion and abuse of the medication or additional public health problems but it is fair to say that all opiates need to be safeguarded in order to deter illegal diversion of the medications.

Like methadone, buprenorphine is widely available to treat opiate addiction but more often in the private sector than in the public sector. This is changing now. Both medications can be used to treat individuals with HIV/AIDS/Hepatitis C as long as patients are monitored for negative interactions with prescribed anti-retroviral medications. Buprenorphine has been used particularly to treat opiate-dependent patients with cardiac disease, younger users, newer addicts and adolescents age 16 to 18 who can receive methadone treatment only with a special waiver.

Buprenorphine is approved in every state, but is not covered in all states by public funding. Like methadone, buprenorphine cannot produce the best results unless appropriate counseling and recovery support services also are provided and covered by public funding sources.

State publicly funded substance abuse treatment systems show many differences in their emerging coverage of buprenorphine treatment. Actual patient access to this treatment depends on many factors; coverage in a formulary or benefit plan may not be sufficient. Buprenorphine is on many state and county Medicaid formularies, for example, but prior authorization is necessary for each prescription for each patient. Medicaid funding or benefits may not be available for the necessary counseling or support. Since Medicaid regulations specify that substance abuse treatment is an optional benefit, some states cover methadone and buprenorphine only for emergency detoxification under their medical plans.

Like methadone and other opiates, buprenorphine can be abused and diverted. Suboxone\textsuperscript{®}, the formulation of buprenorphine used for treatment (not detoxification) in the United States, is a combination sublingual tablet that contains buprenorphine and naloxone, an opiate antagonist, to deter diversion. If Suboxone\textsuperscript{®} is crushed and injected, the naloxone causes unpleasant withdrawal. As with other prescribed medications, buprenorphine must be monitored and managed. According to the DHHS Secretary’s Determinations report mandated by Congress, some non-medical use appears to involve attempts of addicts to self-medicate with buprenorphine when other drugs or formal treatment are not available.\textsuperscript{17}

\textit{Naltrexone}

Naltrexone (brand names Revia\textsuperscript{®}, Depade\textsuperscript{®} or Vivitrol\textsuperscript{®}), another prescribed medication, is an older opiate antagonist medication that is frequently used as a narcotic detoxification agent. It is sometimes prescribed as an oral, implanted or injected opiate medication following detoxification. Naltrexone can be safe and effective if the patient continues to take it as long as it is intended and receives counseling and recovery support. However, reports indicate
that opiate-addicted patients treated with oral naltrexone often leave treatment. Naltrexone may not be given in conjunction with methadone to patients who are actively undergoing treatment for opiate dependence.

Once monthly injectable naltrexone that lasts for 30 days (marketed as Vivitrol®) is sold primarily to treat alcohol dependence, although its manufacturer has also conducted clinical trials on naltrexone as an opiate or cocaine treatment medication. Several states indicate they cover naltrexone on Medicaid formularies or with other public funds. Again, they may do so without funding the associated treatment. Injectable naltrexone is on one state’s Medicaid formulary and is listed as a covered opiate dependence treatment service, but funding for this treatment is “frozen.” That state’s Medicaid program covers the medication with a treatment authorization request for each patient, although counseling and recovery support services are available and covered only from providers other than the physicians who offer the medication.

**Regulating Opiate Dependence Treatment Medications**

A unique regulatory regime applies for methadone and buprenorphine used to treat opiate dependence. Physicians may prescribe buprenorphine or methadone for pain, just as they may prescribe any other opiate medication for that reason. But special – and different - regulations apply when methadone and buprenorphine are used to treat opiate dependence.

Oversight of medications to treat opiate dependence involves the states, SAMHSA and the Drug Enforcement Administration. When methadone is used to treat opiate dependence, it must be dispensed by a federally certified opiate treatment program. SAMHSA oversees nationally accreditation of these programs, which also are state-licensed and monitored.

Although buprenorphine is occasionally used to treat post-surgical pain, the FDA-approved formulations for opiate dependence are Subutex® and Suboxone®. Subutex® is most commonly used for detoxification in the U.S. Suboxone®, used to treat opiate dependence, is a combination sublingual tablet that contains buprenorphine combined with naloxone, an opiate antagonist, to deter misuse and diversion.

To prescribe Subutex® and Suboxone® for opiate dependence treatment, a physician must have specialty qualifications, undergo training and apply for a special waiver. Only physicians who are appropriately qualified in addiction treatment are eligible to apply for a waiver; SAMHSA oversees the program.18 Physicians who receive a waiver are assigned a special identification number by The Drug Enforcement Administration, the number appears on buprenorphine prescriptions so that these can be monitored. The purpose of these regulations is to help ensure that medication-assisted treatment with buprenorphine is as safe, effective and medically appropriate as possible.
Notes

8. See http://www.oas.samhsa.gov/ndaud/2k6ndaud/2k6Results.cfm#TOC.
10. See http://www.oas.samhsa.gov/ndaud/2k6ndaud/2k6Results.cfm#TOC
12. See http://www.oas.samhsa.gov/sros/httoc.htm
13. See http://wwwdsasis.samhsa.gov/06sats/NSSATS2k6Tbl2.3.htm.
14. These states are Idaho, Montana, North Dakota, South Dakota and Wyoming.
18. For more information about the SAMHSA waiver program, see http://buprenorphine.samhsa.gov/waiver_qualifications.html.