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DRUG COURT PRACTITIONER FACT SHEET

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Methadone Maintenance and Other Pharmacotherapeutic Interventions in the Treatment of Opioid Dependence

Overview

Drug Courts are being confronted with increasing numbers of opiate dependent offenders. From heroin to oxycontin, opioid dependence is a devastating reality facing many drug courts throughout the nation. Although opioid addiction presents many new challenges, it is a treatable disease with evidence-based treatment responses. This Fact Sheet is intended to dispel misperceptions and educate practitioners about the efficacy of medication-assisted treatment.

According to the Office of National Drug Control Policy, there were over 977,000 heroin dependent individuals in the United States in the year 2000. The Substance Abuse and Mental Health Services Administration's 2000 National Household Survey on Drug Abuse indicated that an estimated 104,000 persons used heroin for the first time in 1999.

There has been an increasing trend in new heroin use since 1991. A significant proportion of these recent new users were smoking, snorting or sniffing heroin. Most of these new users are under the age of 26 (SAMHSA/U.S. Department of Health and Human Services). According to SAMHSA's 2000 National Household Survey on Drug Abuse, the average age of first heroin use has steadily declined since 1989, from 24 to 19 years of age in 1999. The "Monitoring the Future" study indicated that approximately 1.4% of our nation's 10th grade students used heroin in 1998.

According to the DEA's Domestic Monitoring Program data, the national average for heroin purity has remained relatively stable (above 35% per pure milligram) since 1992. An analysis of these same data also indicate a steady decline in the average price per milligram for heroin since 1992 at both the retail and dealer level. According to 1999 FBI Uniform Crime Reports, arrests for drug abuse violations have steadily increased since 1991. There were 1.56 million drug-related arrests in 1998.

The Substance Abuse and Mental Health Services Administration's (SAMHSA) 2000 Emergency Department Data from the Drug Abuse Warning Network (DAWN) identified an increase in heroin/morphine mentions between 1999 and 2000 in eight of the 21 metropolitan areas in the reporting network.

Methadone Maintenance Treatment

Methadone is the most widely studied medication and treatment for any disease in the world. Opioid treatment programs provide the dependent individual with an array of rehabilitative services. Therapeutically prescribed doses of methadone and LAAM relieve withdrawal symptoms, eliminate opiate craving and allow normal functioning. The efficacy of these medications increases significantly with counseling and on-site medical and other supportive treatment services. Medical personnel supervise treatment and nurses administer the medication to patients, most typically on a daily regimen until the individual is

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stabilized. Patients also provide toxicology samples, which are tested for the presence of methadone and drugs of abuse.

Methadone has been used to treat opioid dependence for thirty-five years and like all medications, therapeutic dosing is contingent upon individual patient needs. The therapeutic dosage range is generally between 80 – 120 mg. Methadone is taken orally and is rapidly absorbed from the gastrointestinal tract, appearing in plasma within thirty minutes of being ingested. Methadone is also widely distributed to body tissues where it is stored and then released into the plasma. This combination of storage and release keeps the patient comfortable, free from craving, and feeling stable.

The General Accounting Office reported in 1990 that “The National Institute on Drug Abuse and the National Institute on Alcohol Abuse and Alcoholism, the federal government’s two primary agencies for researching drug and alcohol abuse issues, respectively, have concluded that methadone is the most effective method available for treating heroin addiction.”

SAMHSA’s Center for Substance Abuse Treatment (CSAT) has also reported the increasing use of oxycontin and that methadone maintenance treatment is an effective pharmacotherapeutic intervention if oxycontin dependent individuals meet existing federal admission criteria. A significant number of oxycontin dependent individuals were admitted to methadone treatment programs during 2001 and have improved with a stable medication treatment regimen, in addition to counseling and other medical services.

The Center for Substance Abuse Treatment has found, as of October, 2001, that more than 205,000 individuals are being treated in methadone treatment programs. The National Institutes of Health Consensus Development Conference on “Effective Medical Treatment of Opiate Addiction” (November 1997) concluded that it is necessary to

increase access to methadone treatment services throughout the United States and to increase funding for methadone treatment, including providing benefits to methadone patients as part of public and private health insurance programs.

The Pharmacology of Methadone Treatment

Some critics of methadone treatment believe that it represents substituting one drug for another. Such critics see no distinction between heroin as an illicit drug and methadone as a medication, which is used in conjunction with other treatment services. Research has proven the drug substituting assertion to be false. Heroin and methadone have completely different pharmacological properties.

Heroin has an immediate onset of action with a four to six hour duration. The route of administration is typically through injection, snorting or smoking several times each day. Very few individuals can achieve any kind of neurochemical stability through such a short-acting opiate.

Methadone is taken once per day and has a duration of action of between 24 and 36 hours. It is orally ingested and is released into the body over the course of time through the liver. This is why methadone maintenance does not cause euphoric effects in the stabilized patient.

Other critics of methadone treatment include people in recovery from other drugs of abuse, including alcohol. They claim that since they are able to be abstinent without pharmacotherapy that methadone maintenance does not represent a “true” state of recovery. Once again, science does not support this view. The National Institute on Drug Abuse has found through years of research that there are profound changes in the chemistry of the brain as a result of chronic use of exogenous opiates such as heroin. The biology of the brain changes and may never revert back to its pre-heroin use state for a number of heroin-dependent

individuals. While this may not apply to all heroin-dependent persons, it has been found that more than 80% of methadone maintained patients will relapse to heroin use when methadone maintenance is withdrawn within the first 12 months of treatment being terminated.

Methadone and Pregnancy

Women can conceive and have normal pregnancies and deliveries when maintained on methadone. When the methadone dosage is therapeutically prescribed for pregnant women, methadone treatment provides a non-stressful environment for the developing fetus. Because methadone crosses the placental barrier, some babies born to female methadone patients may be physically dependent on methadone at first and need to be weaned. It is also true that methadone maintained women give birth to babies who do not experience any withdrawal. The myth that methadone produces abnormality in fetuses has no basis in fact. Additionally, children born to methadone maintained women have been studied longitudinally and develop normally in good post-natal environments. Accordingly, it is medically contraindicated to withdraw pregnant methadone maintained patients.

Federal Oversight of Methadone Treatment

The Center for Substance Abuse Treatment within SAMHSA manages the new accreditation system for methadone treatment programs. Implemented on May 18, 2001, this system will ensure that every methadone maintenance treatment program in the country is accredited over the course of the next three years, providing better program accountability and improving treatment quality throughout the nation's 950 registered methadone treatment programs. All treatment programs, regardless of the source of their funding (private or nonprofit) will be subject to these quality-driven accreditation standards.

Impact of Methadone Treatment in Reducing HIV Infection, Treating Hepatitis C and Psychiatric Comorbidity

Studies of methadone treatment have consistently found dramatic declines in heroin use after admission to methadone treatment and further declines as the patient remains in treatment. The value of treatment retention cannot be overstated.

The relationship between intravenous drug use, needle sharing and HIV/AIDS exposure is also well documented. Methadone treatment has played a pivotal role in reducing the spread of HIV/AIDS, according to NIDA-funded studies.

We also know that more than 70% of methadone maintained patients across the country are HCV-positive. Accordingly, methadone treatment programs are providing support services to these patients, ensuring that they are followed for HCV in addition to other comorbidities.

There is also significant psychiatric comorbidity in the methadone treated population, cited in the Ball & Ross study "The Effectiveness of Methadone Maintenance Treatment", published in 1991. The study found a lifetime prevalence of serious depression and anxiety disorders in 48% of the patients in the study. Methadone treatment programs are able to treat such psychiatric comorbidity either through the methadone treatment program or by referral to psychiatric services.

Impact of Methadone Treatment in Reducing Crime/Cost Effectiveness

Methadone treatment is also associated with reducing crime in the offender population as patients enter and remain in treatment. It has been repeatedly demonstrated that 80% of the patients will reduce or eliminate crime as they remain in methadone treatment programs.

The cost savings to taxpayers are also well documented. A comprehensive examination of the economic benefits and cost of methadone treatment reveals the benefits to cost ratio at 4:1; \$4.00 in economic benefits for every \$1.00 spent.

The Institute of Medicine concluded that “methadone maintenance pays for itself on the day it is delivered, and post treatment effects are an economic bonus.” The average cost of outpatient methadone treatment is approximately \$5,000.00 per year and involves the use of medication in addition to medical care and counseling.

Methadone treatment programs are staffed by professionals with extensive medical, clinical and administrative expertise. Patients routinely meet with a primary counselor, attend clinic groups and access medical and social services within the program setting.

Methadone Treatment in Correctional Settings

According to NIDA’s October 1999 “Principles of Drug Addiction Treatment”: “Research is demonstrating that treatment for drug addicted offenders during and after incarceration can have a significant beneficial effect upon future drug use, criminal behavior and social functioning. The case for integrating drug addiction treatment approaches within the Criminal Justice system is compelling. Combining prison and community-based treatment for drug addicted offenders reduces the risk of both recidivism to drug-related criminal behavior and relapse to drug use.”

At present, Rikers Island in New York City is the only correctional system in the United States that treats heroin dependent inmates with methadone, referring them to treatment programs upon release. The intervention is called the Key Extended Entry Program (KEEP) and has been a part of the Rikers Island Health Services since 1987. The service combines pharmacotherapy and comprehensive therapeutic treatment.

The Rikers Island program treated 3,985 inmates with methadone in 2000. Approximately 70% of these inmates were men and 10% of the women in the program were pregnant. All inmates have been diagnosed as opiate dependent by medical staff and were charged with either a misdemeanor or low-grade felony, serving a misdemeanor sentence in order to qualify for the program. 76% of all inmate patients reported to their assigned programs for continued substance abuse treatment following their release from jail.

The average KEEP patient’s length of stay was 35 days at Rikers Island in 2000. The program has demonstrated statistically significant differences in decreased criminal recidivism. It makes sense to expand access to this kind of service for people under legal supervision, especially since Drug Courts sanction drug dependent individuals to correctional facilities for short periods of time. Consideration might be given to reframing the Rikers Island KEEP program as a “reentry” program so that heroin dependent individuals can gain access to methadone treatment services upon release from incarceration.

A number of correctional facilities have indicated an interest in using pharmacotherapeutic interventions in treating chronic opiate dependence, based on the success of the Rikers Island model. Additionally, such correctional facilities have been using Naltrexone and are likely to consider using Buprenorphine, when it is approved. The Rikers Island experience indicates that providing access to such medication assisted treatment in correctional facilities is an extremely effective method of reducing recidivism and ensuring that people get access to outpatient services when they are released from jail.

Buprenorphine

Buprenorphine is a partial agonist of the mu-opioid receptor that is currently in development for the treatment of opioid dependence. When available, it will be marketed as sublingual (SL) tablets. Two

forms of buprenorphine will be available – buprenorphine alone in 2 and 8 mg tablets and a combination of buprenorphine and naloxone as sublingual tablets containing 2mg of buprenorphine and 0.5 mg of naloxone or 8 mg of buprenorphine and 2 mg of naloxone.

As a partial agonist, rather than a full agonist such as methadone or morphine, buprenorphine has pharmacological properties that are similar to but different from those of methadone. It has a ceiling effect for most of the effects produced by opioid drugs, such as analgesia and respiratory depression. This makes buprenorphine safer, in terms of respiratory depression in case of an overdose, but also may limit its efficacy for some patients. From a variety of studies in opioid-dependent patients, it has been shown that buprenorphine, 4 – 8 mg SL, is as effective as 30 mg of methadone in suppressing opioid withdrawal signs and symptoms for approximately 24 hours.

For maintenance therapy, approximately 16 mg of buprenorphine SL is equal to approximately 65 mg of methadone. Further, buprenorphine is thought to occupy the opioid receptor for much longer than other agonists, such as methadone, and is very firmly bound to the receptor, making it difficult for other opiates to displace it. For these reasons, buprenorphine works very well for some or most patients who need agonist maintenance therapy. However, patients who require high agonist doses for stabilization may not be adequately treated with buprenorphine.

Further, for patients who are currently maintained on methadone or LAAM, it will not be appropriate or, often, possible to switch patients to buprenorphine. Because of the partial agonist qualities of buprenorphine, patients cannot simply be switched over from methadone to buprenorphine; the patient must first be stabilized on a daily dose of methadone of no more than 30 mg, then switched to buprenorphine. It must be remembered that many patients on higher doses of methadone have a great deal of difficulty

decreasing the daily methadone dose while maintaining stability in treatment.

When available, buprenorphine will be marketed as both the mono form and in combination with naloxone. The reason for the combination is that when buprenorphine has become available and distributed in the mono form, it has been abused. While buprenorphine, as a partial agonist, has a lower abuse potential than full agonists, it does have opioid effects and can be abused. In places where the medication has been abused, it has been by the injection, not the sublingual, route of administration. Naloxone is not readily available when taken by the sublingual route, but is readily available when injected. It is thought that adding the naloxone to the sublingual tablet will decrease diversion and abuse by the injection route. Studies have shown that the combination tablet is as effective in clinical trials as the mono form of SL buprenorphine.

LAAM

LAAM, levomethadyl acetate, is a long-acting mu-opioid agonist. It acts much like methadone in the treatment of opioid dependence, but offers some advantages for some patients. Because LAAM undergoes extensive metabolism to active and long-lasting metabolites in the liver, it can be dosed less than daily. Most patients will receive LAAM only on a thrice-weekly schedule, allowing better functioning in the workplace or in the family situation. While LAAM offers some advantages for some patients in terms of dosing frequency, it has recently been associated with cardiac side effects. It has been shown that LAAM may prolong the Q-T interval in some patients and, in order to prevent medical complications, patients must be monitored with ECGs before and during their treatment with LAAM.

Summary

Methadone medication is not a substitute for heroin and does not affect the individual in any similar

way. Methadone treatment has been rigorously studied for more than 35 years and the results are found to be uniformly positive.

Accreditation oversight will enhance the consistency and quality of treatment services throughout the nation's methadone treatment programs. It is expected to end the debate about the quality of care offered in publicly funded vs. privately financed treatment programs since all programs, public and private, will be accredited through CSAT's approved accrediting organizations.

While a number of people will continue to be critical of methadone treatment because the medication, as a pharmacotherapeutic agonist, has its own dependence producing qualities, the reality is that we do not have anything at the present time (including Buprenorphine), following years of exhaustive research by NIDA, that will be able to perform as methadone maintenance treatment does in normalizing brain function without having some dependency-producing characteristics.

Just as psychiatrists are not expected to withdraw depressed patients from their antidepressant medication and, as physicians do not withdraw their patients from cardiovascular or other life sustaining medications that stabilize the patient and enable him/her to lead a normal life without struggling through the debilitating effects of an illness, methadone patients should not be required to withdraw from a medication that improves their quality of life.

Heroin dependence is a form of addictive disease, and methadone maintenance is a well-researched therapeutic medication. The empirical evidence consistently supports its safety and efficacy. Methadone and alternative pharmacotherapeutic agents alone are not sufficient; they must be combined with other therapeutic services to be of value to the individual. It is important that the criminal justice system strengthen its commitment to evidence-based treatment and work to address ideological biases through continuing education.

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