Addiction to heroin and other opioids poses serious problems for communities, families, and individuals. Solutions sometimes seem uncertain, difficult, and controversial.

During more than 40 years since its development, methadone maintenance treatment (MMT) has helped millions of persons in recovery from opioid addiction; allowing them to improve their health, redeem their family and social lives, hold down steady jobs or return to school, and generally become productive tax-paying citizens in their communities. Yet, the merits and effectiveness of addiction treatment in general and MMT in particular have not been universally understood and accepted.

This booklet focuses on the evidence-based conclusions and educated commentary of credible sources to provide a current and balanced perspective on the treatment of opioid addiction with methadone.

Facts & Consequences of Opioid Addiction in America

Understanding Addiction As A Brain Disease

At one time, drug addiction was viewed as a failure of willpower or a flaw of moral character. It was not recognized as a disease of the brain, in the same way that mental illnesses previously were not viewed as such. Medical authorities have now accepted drug addiction as a chronic, relapsing disorder that alters normal brain function, just as any other neurological or psychiatric illness. Its development and expression are influenced by genetic, biological, psychosocial, and environmental factors. Outwardly, drug addiction is often characterized by impaired control over continued drug use, compulsive use despite harmful consequences, and/or intolerable drug craving.\(^1\)\(^,\)\(^2\)

Addiction to opioid drugs is particularly insidious because the brain produces its own opioid substances (e.g., endorphins) that are vital for survival. In effect, the brain is “tricked” by external, short-acting opioid agents into responding as if they are biologically essential. Once addiction sets in, brain chemistry becomes unbalanced, and the person becomes physically, emotionally, and mentally dysfunctional unless more opioid drug is regularly taken. Chronic opioid abuse causes physiologic derangements lasting months or years after the last drug-taking episode. So, even if opioid-abstinence is eventually achieved, relapses are common without ongoing therapy of some sort.\(^1\)\(^,\)\(^2\)
Medication-free therapies alone cannot stabilize the chemical upsets of opioid addiction.

Many public officials and healthcare providers have expressed a strong bias favoring “drug-free” treatment and eschewing the use of any medications during recovery.3 However, such therapies for opioid addiction alone cannot stabilize the chemical upsets associated with addiction and return brain function to a more normal state.

The common stereotype depicts opioid-addicted persons as social misfits and outcasts; however, such addiction is common throughout all segments of society and in every community.4 Widely available and affordable access to effective, community-based clinics providing methadone maintenance for the disorder provides a viable solution for helping to stem America’s opioid-drug addiction crisis.

Heroin Continues To Take A Toll

In the most recent reports, nearly 4 million Americans were classified as dependent on or abusing illicit substances, and heroin addiction has continued as a major concern.5 Heroin is derived from opium — as are morphine and codeine — a product of the poppy plant and classified as an opiate narcotic. A broader term, “opioid,” encompasses opium by-products and the many synthetic drugs (such as, oxycodone, hydrocodone, propoxyphene, and others including methadone) with properties similar to opium.6,7

The White House’s Office of National Drug Control Policy (ONDCP) has estimated that there are more than 800,000 untreated chronic heroin users in the United States, although this number is probably undercounted.3 Data on admissions to substance abuse treatment programs indicate that heroin dependence has surpassed cocaine in some cases to become the most common diagnosis behind alcoholism. Of interest, admissions for heroin use via inhalation have been increasing due to its higher purity.5,8

Reports from drug enforcement agencies indicate that during the past 2 decades heroin has become 30 times less expensive while its purity has increased more than 10-fold. A heroin “fix” can be purchased for as little as $5 and its purity exceeds 70% in some major cities.9-11 Availability of low-cost, high-purity heroin has fostered increased use, since it can be smoked, snorted, or otherwise inhaled without the need for injection needles. This has attracted many new users among youth, white, and middle class populations.5,9,11,12 Their experimentation eventually leads to injection and more severe addiction, and miscalculations of drug purity have led to fatal overdoses.3,13

The impact on public health has been severe. A typical intravenous-heroin abuser may inject 4 or more times each day and this has been associated with many serious communicable diseases, including: HIV/AIDS, hepatitis B and C, and tuberculosis. More than a third of all adult and adolescent AIDS cases reported in the U.S. have been associated with injection drug use.12,14 The prevalence of hepatitis C among intravenous-drug users ranges up to 90%,7,15 and two-thirds may be infected with hepatitis B.14 Drug abusers are from 2 to 6 times more likely to contract tuberculosis than nonusers,14 and almost half of the patients in some opioid addiction treatment programs have positive tuberculin skin tests.7 Finally, during the 1990s, heroin-related emergency department visits more than doubled and the annual death toll increased by 74%.3,16
Opioid Analgesics Are A Major Concern

One of the most troubling and increasing problems facing American communities is the abuse of opioid analgesic medications (painkillers), which has been associated with addiction, drug overdoses, and deaths. The prevalence of prescription-opioid abuse has surpassed illicit drug abuse.\textsuperscript{13,17} For example, in 2002 an estimated 4.4 million persons took pain relievers for non-medical purposes, compared with 3.9 million persons who abused an illicit substance, such as heroin, cocaine, etc.\textsuperscript{5}

Because methadone has become more widely prescribed as a potent and cost-effective analgesic, it has been misused along with other opioids like oxycodone, hydrocodone, and morphine.\textsuperscript{17} Consequently, throughout the past decade, there have been sharp increases in hospital emergency department visits associated with opioid analgesics (see graph),\textsuperscript{18} and also an upsurge in widely publicized overdose deaths attributed to these drugs.\textsuperscript{13,17}

As with any other opioid drug, methadone can be dangerous and life-threatening if improperly used, and there have been long-standing concerns about the diversion of methadone for illicit purposes.\textsuperscript{14} However, in 1995, a distinguished committee assembled by the Institute of Medicine concluded that, “the actual level of abuse and harm from illicit methadone falls short of its hypothetical potential for abuse... and is small relative to heroin and cocaine.”\textsuperscript{19}

Still, there were increasing reports of methadone-associated deaths in some communities during 2001 to 2003. MMT clinics were blamed as the source of diverted drugs and methadone was stigmatized as a “killer drug that should be curtailed.” In response, an expert panel convened by the government’s Substance Abuse and Mental Health Services Administration (SAMHSA) unanimously concluded that opioid analgesics in general, most often combined with other drugs or alcohol, were the major source of the problems. Methadone itself was documented as the sole and direct cause of death in relatively few cases, and the greatest source of the drug came from its prescription by physicians as a painkiller; not from MMT clinics.\textsuperscript{13}

In fact, MMT programs provide a valuable service to their communities by treating residents who, for one reason or another, become addicted to opioid painkillers. In one study, more than 80% of patients admitted to MMT programs had been using prescription opioid medications at higher than therapeutic dosages, with or without heroin (see pie graph).\textsuperscript{20} Nearly half had started their addiction by first misusing analgesics and 24% were being treated solely for opioid-analgesic dependency.

The majority of patients initiated opioid use due to ongoing pain problems, rather than recreational use.\textsuperscript{20} However, experts have cautioned that fears of producing dependency on opioid medications should not deter their appropriate prescription for patients in pain who would benefit from them. Pain is seriously undertreated in the U.S. and reducing the availability of opioid analgesics would exacerbate that problem.\textsuperscript{17}
Beneficial Effects Of Methadone For Opioid Addiction

Methadone was developed by German scientists in the late 1930s. It was approved by the U.S. Food and Drug Administration (FDA) in 1947 as a painkiller, and by 1950 oral methadone also was used to treat the painful symptoms of persons withdrawing from opioids, usually heroin.19,21,22

In 1964, researchers at Rockefeller University, New York – headed by Vincent Dole and Marie Nyswander – believed that opioid addiction was a “metabolic disease” that altered brain function and made it difficult for patients to remain drug-free.10,23 Dole’s team discovered that an ongoing, daily dose of long-acting oral methadone — maintenance treatment — offered a number of beneficial effects allowing otherwise debilitated opioid addicts to function more normally (see box).15,16,23-27

MMT was viewed as corrective therapy, rather than as a “cure” for opioid addiction, and it had no or only limited efficacy in treating dependence on other substances of abuse.22 Dole wrote, “the most that can be said is that there seems to be a specific neurobiological basis for the compulsive use of heroin by addicts and that methadone taken in optimal doses can correct the disorder.”23

Oral methadone has demonstrated a favorable safety profile when properly prescribed and used. No serious adverse reactions or organ damage have been specifically associated with continued methadone use extending more than 20 years in some patients. Minor side effects, such as constipation or excess sweating, may appear during early days of treatment and are easily managed. Women stabilized on methadone generally have more healthful pregnancies and their newborns do not suffer any lasting adverse consequences.15,26 Furthermore, methadone at appropriate dose levels does not hinder a patient’s intellectual capacities or abilities to perform work tasks.28

Adequate methadone dosing is critical for therapeutic success. Dole’s original research discovered that 80 to 120 milligrams of methadone per day, on average, was an effective dose. Dozens of studies since then have demonstrated that dosing in that range results in superior treatment outcomes, such as better retention of patients in treatment and less illicit drug use.9,26,27 For a variety of reasons — such as, high tolerance to opioids, physical condition, mental status, concurrent medications, or prior use of high-purity heroin — many patients require much higher daily methadone doses for treatment success; sometimes exceeding 200 mg/day or more.15,26,29 Patients maintained on inadequately low doses are much more likely to use illicit opioids and respond poorly to therapy.28

In 1997, an independent panel of experts convened by the National Institutes of Health (NIH) to reach a consensus on effective treatments for opioid addiction concluded that, “Of the various treatments available [for opioid addiction], MMT, combined with attention to medical, psychiatric, and socioeconomic issues, as well as drug counseling, has the highest probability of being effective.”16

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**How Methadone Maintenance Treatment (MMT) Works**

**Beneficial Effects Of Methadone For Opioid Addiction**

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**MMT Benefits**

- An adequate maintenance dose of methadone does not make the patient feel “high” or drowsy, so the patient can generally carry on a normal life. Daily drug-seeking to “feed a habit” ceases.
- Methadone can be taken once daily by mouth without the use of injection needles, which limits exposure to diseases like hepatitis and HIV.
- Methadone’s gradual, long-lasting effects eliminate drug hunger or craving.
- There is little change in tolerance to methadone over time, so it does not take more of the drug to achieve the same results.
- Euphoria-blocking effects of methadone make taking illicit opioids undesirable.
- Used properly, methadone is generally safe and nontoxic, with minimal side effects.
Ongoing MMT Is Essential & Cost Effective, But Capacity Is Insufficient

Time in treatment is a critical factor for addiction recovery. Typically, methadone-maintained patients must attend a treatment program each day to receive their oral dose of methadone; however, stable and compliant patients are usually allowed to take home a number of doses, thus reducing their clinic visits. Appropriate psychosocial therapy and other support services are integral components of ongoing MMT.

The NIH Consensus Panel and others concluded that patients treated for fewer than 3 months in MMT generally show little or no improvement. Studies have routinely demonstrated reductions in illicit opioid use of up to 80% or more after several months, with the greatest reductions for patients who remain in treatment more than a year. Patients often require MMT indefinitely, as would be expected with any chronic medical condition. Once a patient has been stabilized on MMT, withdrawal from methadone carries substantial risks. Virtually all who abandon MMT and do not pursue further treatment eventually relapse and potentially overdose.

Unfortunately, MMT is not available for all who might benefit, even though the number of patients in treatment has grown steadily and incrementally through the years. In 2004, there were about 1,100 MMT programs in 44 states; however, program capacity was sufficient to serve only a small fraction of opioid-addicted persons in this country who needed it; especially considering the additional numbers of persons addicted to opioid analgesics.

Methadone treatment is a cost effective alternative to incarceration or hospitalization. Studies have shown that it costs about $42,000 per year to leave a drug abuser untreated in the community, $40,000 if the offender is incarcerated, and only about $3,500 for MMT. Furthermore, the National Institute on Drug Abuse (NIDA) has reported that among MMT participants illegal activity declined by 52% and full time employment increased by 24%. Patients in MMT also earn more than twice as much money annually as opioid addicts not in treatment, which can enhance their value as taxpaying citizens in the community.

An often-quoted study of 150,000 patients — the California Drug and Alcohol Treatment Assessment (CALDATA) — found that for every $1 spent on addiction treatment more than $7 in future costs were saved. MMT was determined to be the lowest-cost, most effective treatment modality for opioid addiction; whereas, programs offering only opioid detoxification showed no long-term benefits at all.

Deaths and illness associated with addiction are financially draining on society. Untreated opioid addicts have a death rate 3 to 4 times greater than patients in methadone treatment. Furthermore, studies have consistently shown that the risk of communicable infections – HIV, hepatitis, tuberculosis – is significantly reduced by MMT, even in the absence of complete illicit-drug abstinence. If methadone clinics are closed communities pay a price. One study found that the costs for crime, justice system (e.g., arrests), and welfare services in a community that closed its MMT program were 17% higher when compared with a locality with an ongoing MMT clinic.

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Addiction treatment provides a 700% return on investment.
Past Practices And Misperceptions Have Hindered Progress

Through the years, MMT has fostered some negative attitudes and actions by critics. A segment of public opinion has opposed the use of methadone for treating opioid addiction and political initiatives have been enacted or proposed to thwart access to MMT. Many persons still perceive opioid dependence as a self-controllable “bad habit,” and dismiss MMT as an ineffective, addictive-narcotic substitution therapy.

However, it has widely and authoritatively been recognized that methadone is not merely a substitute for illicit opioids, and MMT does not simply replace one addiction with another. Although methadone can cause physical dependence, its steady and long-term action in the brain contrasts sharply with the disruptive cycle of “highs” and “lows” produced by short-acting opioids that lead to addictive behaviors. Methadone substitutes a stable existence for one of compulsive drug seeking and taking, criminal behavior, chronic unemployment, and high-risk sexual and drug-use behaviors.

Unfortunately, during the early days of MMT there were problems as a result of rapid clinic expansion in the face of decreased funding. A government report found that clinic policies, goals, and practices varied widely, and departures from recommended methadone doses, adopting a “less is more” approach, had pervaded many programs. Surveys since 1988 have observed that a majority of U.S. MMT clinics once provided average methadone doses far below the 80 mg/day recommended minimum. There have been improvements more recently, with most programs achieving average doses of 80 mg/day or more (see graph). However, many patients still receive inadequate amounts of methadone, and they often respond poorly to treatment, just as would any individuals prescribed insufficient drug therapy for a chronic medical disorder.

Regulations And Accreditation Promote “Best Practices”

MMT has been a tightly controlled medical specialty in the U.S. and methadone itself is a highly regulated drug. Fairly recently, in 2001, oversight of MMT programs was transferred to SAMHSA’s Center for Substance Abuse Treatment (CSAT). Revised federal regulations emphasize improved patient care and increased healthcare practitioner discretion in meeting patients’ needs; particularly, allowing more liberal methadone dosing and permitting qualified patients to take home doses for self-administration. However, state and local regulations may be more stringent, and they are in some cases.

As a component of the regulations, MMT programs must successfully complete an accreditation process similar to that required of much larger healthcare organizations. Best-practice guidelines and standards have been developed, reflecting the latest evidence promoting excellence in the treatment of opioid addiction. Results to date indicate that MMT program accreditation has been successful in improving patient care, safety, and treatment outcomes.
Meeting Challenges for Change in Communities

Quality care for opioid-dependent persons also involves promoting their reintegration, acceptance, and ongoing recovery from addiction in their communities. Toward those ends, MMT staff seek to develop an understanding of community values, needs, and resources; and, they strive to work collaboratively with community leaders and organizations at all levels.

Addiction treatment is sometimes viewed as a form of social welfare. However, from an MMT perspective, such treatment is a medical service that extends beyond benefitting opioid-addicted patients. Public safety, health, and eventually the local economy often are the greater beneficiaries of methadone maintenance treatment.3,37

Expanding Treatment

There is a provision in the revised federal regulations for office-based physicians, who have formal arrangements with established MMT programs, to provide methadone maintenance.30,45 This has been widely endorsed by government3,16,19,32 and medical33,46 organizations. It is estimated that at least 7% of patients in MMT clinic programs are sufficiently stable to be served in this manner – called methadone “medical maintenance” – and it would make additional MMT clinic capacity available for opioid addicts awaiting treatment. However, this approach has not been widely accepted and implemented.

In 2002, another opioid drug, buprenorphine, was approved by the government for prescription by qualified community-based physicians to treat opioid addiction.26,47 However, it has been recognized that “buprenorphine is unlikely to be as effective as more optimal-dose methadone, and therefore may not be the treatment of choice for patients with higher levels of physical dependence on opioids.”37,47 Also, without the close monitoring, psychosocial therapy, and other support provided by MMT clinics, the long-term benefits of buprenorphine for some patients could be questionable.

Overcoming Stigma, Prejudice, and Misunderstandings

The World Health Organization and others have recognized that the stigma, prejudice, and misunderstandings surrounding persons with addictive disorders is a major barrier to their treatment and proper care.14 In particular, these negative pressures have served as obstacles to persons entering methadone treatment, to doctors in treating opioid addiction, and to legislators and public health officials who could otherwise do more to make MMT widely available. Past policies have placed too much emphasis on protecting society from methadone and not enough on protecting communities from the epidemics of addiction, violence, and infectious diseases that MMT can help reduce.19

Rather than embracing MMT as a solution, some short-sighted communities have rallied against the opening of new MMT clinics – even in the midst of ever-increasing opioid addiction problems – and forcing their citizens to travel hours each day to other locales for methadone treatment. Hopefully, better, evidence-based information and education will succeed in overcoming all of the barriers facing MMT for the benefit of patients, their families, and their communities.

Stigma, prejudice, and misunderstandings surrounding methadone have served as obstacles to persons who would otherwise enter treatment, to doctors who might do more in treating opioid addiction, and to legislators and public health officials who could do more to make MMT available.