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A 5-year evaluation of a methadone medical maintenance program

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Abstract

Methadone medical maintenance (MMM) is a model for the treatment of opioid dependence in which a monthly supply of methadone is distributed in an office setting, in contrast to more highly regulated settings where daily observed dosing is the norm. We assessed patient characteristics and treatment outcomes of an MMM program initiated in the Bronx, New York, in 1999 by conducting a retrospective chart review. Participant characteristics were compared with those of patients enrolled in affiliated conventional methadone maintenance treatment programs. Patients had diverse ethnicities, occupations, educational backgrounds, and income levels. Urine toxicology testing detected illicit opiate and cocaine use in 0.8% and 0.4% of aggregate samples, respectively. The retention rate was 98%, which compares favorably with the four other MMM programs that have been reported in the medical literature. This study demonstrates that selected patients from a socioeconomically disadvantaged population remained clinically stable and engaged in treatment in a far less intensive setting than traditional methadone maintenance.

Keywords

Methadone; Opioid-related disorders; Substance abuse; intravenous; Substance abuse treatment centers; Abstinence

1. Introduction

Methadone maintenance is the most widely accepted and best studied treatment for opioid dependence (Ball & Ross, 1991; Joseph, Stancliff, & Langrod, 2000; National Consensus Development Panel on Effective Medical Treatment of Opiate Addiction., 1998). Long-term methadone treatment has been shown to be more effective than short-term treatment (Sees et al., 2000) or nonagonist-based treatment for opioid dependence (Mattick, Breen, Kimber, & Davoli, 2003), and there is a high rate of relapse to opioid use when methadone is discontinued

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(Anglin, Speckart, Booth, & Ryan, 1989; Ball & Ross, 1991; Dole & Joseph 1978). Methadone maintenance treatment reduces morbidity and mortality from opioid addiction, societal costs from crime, and the spread of blood-borne diseases such as HIV infection (Barnett & Hui 2000; National Consensus Development Panel on Effective Medical Treatment of Opiate Addiction, 1998; Novick et al., 1990).

Methadone maintenance has been successfully implemented worldwide in a variety of clinical settings (Simoens, Matheson, Bond, Inkster, & Ludbrook, 2005). In the United States, however, the benefits of this therapy are achieved within a framework of intense federal and state regulations. The availability of methadone for the treatment of opioid dependence is restricted to specially licensed methadone maintenance treatment programs (MMTPs) to prevent its illicit sale and to ensure that substance abuse counseling is provided along with pharmacotherapy. Regulations require new clients to attend MMTPs daily for supervised methadone dosing; take-home doses are permitted only after clients have demonstrated treatment stability and safe methadone handling. Frequent contact with clinic staff facilitates engagement with counseling and vocational services, supporting recovery (Simpson, Joe, Rowan-Szal, & Greener, 1995).

As patients stabilize in treatment, the intensity of their service needs typically diminishes. Even extremely stable patients, however, are required by federal and state regulations to visit their MMTP much more frequently than is considered necessary for patients receiving care for other chronic medical conditions. For some patients, mandated frequent MMTP attendance may challenge or undermine sustained recovery by jeopardizing employment or social relationships (Joseph, 1995; Murphy & Irwin 1992). Contact with less stable MMTP patients or visits to the neighborhood where an MMTP is located can serve as unwelcome reminders of patients' substance abuse histories.

To better serve selected patients who have achieved long-term recovery while receiving methadone maintenance, physicians in several states have obtained federal approval to pilot a model of methadone treatment based in a private office setting rather than an MMTP (Fiellin & Barthwell, 2003). In the UK and Australia, this spectrum of opioid agonist treatment intensity across different settings is well established (Byrne & Wodak 1996; Luger, Bathia, Alcorn, & Power, 2000; Strang et al., 2005). Initial reports from such office-based initiatives in the United States (known as methadone medical maintenance [MMM]) demonstrated their feasibility and effectiveness (DesJarlais, Joseph, Dole, & Nyswander, 1985; Novick et al., 1994; Novick et al., 1988; Senay et al., 1993). Two randomized controlled trials demonstrating comparable outcomes at 6 months between the MMM approach and standard methadone maintenance have been published (Fiellin et al., 2001; King et al., 2002). Four additional MMM programs in the United States have been evaluated in the literature, including a specialized clinic (Senay, Barthwell, Marks, & Bokos, 1994), private offices (Salsitz et al., 2000; Schwartz, Brooner, Montoya, Currens, & Hayes, 1999), and a primary care clinic (Merrill et al., 2005). Physicians in these MMM programs either had extensive prior experience with methadone maintenance or received training and had access to more experienced methadone providers. These programs, however, typically served patients who have more social support and economic means than most patients receiving methadone treatment nationally.

The Division of Substance Abuse of the Albert Einstein College of Medicine (AECOM), which operates a network of traditional MMTPs, serves a very low income patient population (U.S. Census Bureau, Housing and Household Economics Division, Small Areas Estimates Branch, 2004): The Bronx reports the highest poverty rate (27%) and the lowest median household income (US\$26,361) of all New York City boroughs. In 1998, AECOM launched an MMM program affiliated with its MMTP network. We describe the characteristics and treatment outcomes of patients enrolled in the MMM program established to serve this economically disadvantaged patient population.

2. Materials and methods

2.1. Study setting

The Division of Substance Abuse at AECOM and the affiliated Substance Abuse Treatment Program at Montefiore Medical Center together serve approximately 4,500 patients who receive traditional methadone maintenance treatment at 12 MMTPs at six locations throughout the Bronx. Patients in this large MMTP network were the source of referrals to the MMM program we established.

2.2. Eligibility for MMM

In 1998, the AECOM Division of Substance Abuse received authorization from the United States Food and Drug Administration and the New York State Office of Alcohol and Substance Abuse Services to treat opioid dependence in selected patients using the MMM model. Initial criteria for entry to MMM included (1) employment; (2) no evidence of opioid, cocaine, or benzodiazepine abuse for the preceding 3 years; and (3) psychiatric stability as determined by the evaluating physician. Subsequently, patients who were unemployed by virtue of disability or retirement have been allowed to participate in MMM. Eligible patients are identified by system-wide review of urine toxicology data and clinical evaluation by MMTP clinic staff. Client interest and social and psychiatric stability are taken into account when enrolling patients in MMM.

2.3. MMM model

AECOM's network of MMTPs has a central pharmacy. For patients enrolled in our MMM program, the pharmacy distributes monthly supplies of methadone in tablet form to participating patients. The methadone is prescribed by a physician who meets with patients on a monthly basis in an office setting adjacent to the central pharmacy. MMM physicians provide substance abuse counseling and review patients' medical and mental health issues. A clinical note documenting the visit, including any changes in treatment or adverse events, is entered into the chart by the physician at every visit. The MMM clinical pharmacist, integral to the care provided by the program, also assesses patients for clinical and psychosocial stability. The pharmacist is available to program participants on a daily basis and is able to contact physicians as necessary. The physicians and pharmacist have extensive experience with methadone maintenance therapy and provide informal counseling and support to help patients maintain recovery and to identify triggers for relapse. Most ongoing treatment for medical and psychiatric comorbidities is provided outside the system through patients' traditional health insurance plans. Relapses to substance abuse are addressed with the patient by the MMM physician and pharmacist, who may recommend more intensive treatment including return to traditional MMTP. Patients pay for MMM at a monthly rate adjusted for their income. Safe handling and storage of methadone are emphasized in the intake interview. Scheduled monthly urine samples are obtained to monitor for illicit substance use and confirm use of methadone. Random urine samples may be taken more frequently as clinically appropriate. Urine samples are tested for opiates, cocaine, benzodiazepines, and methadone at a commercial laboratory using the enzyme-multiplied immunoassay technique. Steps taken to avert diversion include unannounced recalls of methadone to determine that patients are self-dosing properly and observed administration of a prescribed dose at the office visit to establish continued opioid tolerance.

2.4. Study design

In 2004, we conducted a retrospective chart review for selected demographic, drug use, and clinical parameters of all patients admitted to the MMM program since its inception in 1998. A single reviewer used a standardized chart abstraction instrument to gather data. The MMM

medical record of each patient, which included preadmission material from the MMTP from which the patient was referred, was reviewed. Demographic data were obtained from MMM admission forms. All patients were characterized as Hispanic (any race), Caucasian (not Hispanic), or African American (not Hispanic), according to admission data based on patient self-report. Clinical data, including HIV and hepatitis C infection status, were derived from the most recent physician notes. The reviewer, a physician with 1 year of clinical experience in methadone maintenance, was not a care provider in the MMM program. The AECOM Committee on Clinical Investigation approved the chart review instrument and study methods. We compared demographic characteristics of MMM patients with those of AECOM's traditional MMTP population, using 2002 data. Differences in the distribution of categorical variables (e.g., gender, ethnicity, hepatitis C infection, and history of injection drug use) across the two treatment programs were analyzed using the chi-square test. For continuous variables (e.g., methadone dose), the Student's *t* test for independent samples was used.

3. Results

One hundred twenty-seven patients were enrolled in MMM from January 1999 to July 2004. Mean duration of MMM enrollment was 2.7 years ($SD = 1.6$ years), for a total of 341 patient-years of treatment in MMM. Patient characteristics are summarized in Tables 1 and 2. Compared with patients in the traditional MMTPs, MMM patients were older (52 vs. 44 years), and a significantly larger proportion were male (72 vs. 59%, $p = .004$) and Caucasian (50 vs. 17%, $p < .001$). Ninety-two percent were employed on enrollment to MMM, and the remainder were either retired or permanently disabled. Seventy-one percent had at least the equivalent of a high school education. Mean monthly income was US\$2,700 at enrollment, derived from a wide variety of occupations (Table 3). Categories of employment roughly corresponded to educational level achieved. Sixty-two percent of MMM participants reported a history of arrest on initial enrollment into methadone treatment, and 75% were currently married or partnered. The mean age of first heroin use was 19 years, and patients had received methadone treatment for an average of 18 years before MMM enrollment.

There had been no adjustment in methadone dose since MMM enrollment for 91 patients (72%). Three patients (2%) had obtained dose reductions of 10 mg. Methadone doses increased by an average of 23 mg ($SD = 20$ mg) for 33 patients (26%). Three patients' doses increased by more than 50 mg; doses of the remaining 30 patients increased by an average of 18 mg ($SD = 9$ mg). Average methadone dose across the MMM population therefore increased slightly over the course of medical maintenance (from 66 to 72 mg) but remained significantly lower than the average dose of patients in the traditional MMTP system (100 mg; $p < .001$). Eighty-four percent of MMM patients reported a history of injecting drugs. Injecting was strongly associated with hepatitis C virus infection ($p < .001$), which was highly prevalent (84%; Table 1). Only 6% of MMM participants with known HIV status were HIV positive, compared with a 20% HIV prevalence among AECOM's traditional MMTP population. Fifty-eight percent of MMM participants were regular smokers.

Nine patients died while enrolled in MMM. Information in the chart indicated that four deaths were related to late complications of chronic hepatitis C infection, two were due to pulmonary disease, and one patient committed suicide. Exact causes of death of the other two could not be determined, but the patients were known to have multiple medical problems and to have died of natural causes. Although psychiatrically unstable patients were excluded from MMM participation, 25% of MMM patients reported some psychiatric morbidity. In the year preceding chart review, nearly half of these patients were not receiving mental health treatment or their source of mental health care was not recorded.

A single unannounced medication recall was conducted for 28% of MMM patients to confirm proper handling and self-dosing of methadone. There were no discrepancies at any of these recalls. Urine toxicology results were analyzed for the 3 years following MMM enrollment. The results indicate an extremely low level of illicit substance use: 0.8% of the aggregate urine samples were positive for non-prescribed opiates, and 0.4% were positive for cocaine. Seven patients accounted for all urine samples suggestive of illicit substance use. Approximately two thirds of the positive urine samples were derived from a single patient, who relapsed first with cocaine, then with opiates. Another patient developed worsening depression, employment problems, and relapse to heroin use. Both of these patients eventually returned to traditional MMTP clinics for more intensive treatment. The other five patients with positive urine toxicology results were counseled by the MMM physician and pharmacist and remained in MMM without further evidence of substance abuse. One patient left the program because of relocation to another state. Only three patients left MMM for any reason other than death, resulting in an overall program retention rate of 98%.

We compared the AECOM MMM program with the four other MMM programs that have been evaluated in the peer-reviewed literature (Merrill et al., 2005; Salsitz et al., 2000; Schwartz et al., 1999; Senay et al., 1994) and with two 6-month randomized controlled trials of MMM (Fiellin et al., 2001; King et al., 2002; Table 4). Two programs (one in Manhattan, Salsitz et al., 2000; another in Chicago, Senay et al., 1994) enrolled comparable numbers of patients, and two (Manhattan, Salsitz et al., 2000; and Baltimore, Schwartz et al., 1999) were evaluated for periods of more than 1 year. A substantially greater proportion of AECOM MMM patients have a minority background, and treatment retention (98%) compares favorably with that of other programs.

4. Discussion

This study demonstrates that selected patients from a socioeconomically disadvantaged population of persons receiving long-term methadone treatment remained clinically stable and engaged in treatment in a far less intensive setting than traditional methadone maintenance.

Our MMM participants represent a distinct sample with respect to the general MMTP patient population from which they were drawn. MMM participants' older age likely reflects their greater number of years receiving methadone maintenance treatment. Higher proportions of both men and Whites in our MMM sample may be due to the original admission requirement of employment, reflecting socioeconomic forces at play in the Bronx as in all U.S. cities. Alternatively, selection bias by MMTP staff may have contributed to observed demographic differences.

Methadone is most effective at relieving craving for opioids when properly dosed, often in the range of 80 to 120 mg daily (Dole & Nyswander 1965; Donny, Brasser, Bigelow, Stitzer, & Walsh, 2005; Faggiano, Vigna-Taglianti, Versino, & Lemma, 2003; Strain, Bigelow, Liebson, & Stitzer, 1999). It is interesting to note that the mean dose among all patients enrolled for more than 6 months in the traditional MMTPs was within this range, whereas the mean dose among MMM patients was significantly lower. Furthermore, methadone dose increased over the course of MMM treatment for 26% of the participants, suggesting that some patients may not have been optimally dosed prior to MMM entry. It is possible that some patients enrolled in MMM might have been reluctant to report symptoms of craving or withdrawal when they had been enrolled in the traditional MMTP, perhaps wishing to avoid appearing clinically "unstable." In the MMM setting, patients may have felt more free to acknowledge and discuss such symptoms, resulting in dose increases. Enhanced patient understanding of the relative benefits of proper methadone dosing may have reflected the integral role the clinical pharmacist plays in our MMM program.

The relatively low rate of HIV infection among MMM participants may reflect the demonstrated protective effect of methadone maintenance against acquiring HIV infection by needle use (Novick et al., 1990). It is also possible that patients with HIV infection were less likely to meet the original MMM eligibility requirement of employment. The high rate of hepatitis C infection among MMM participants is consistent with ready transmission of this virus early in the course of injection drug use (Garfein, Vlahov, Galai, Doherty, & Nelson, 1996), resulting in injectors being infected with HCV before first entering methadone treatment.

MMM programs described in the literature vary considerably with respect to treatment setting, populations served, and duration of observation. All demonstrate alternative models for providing methadone maintenance to opioid-dependent persons. The robust treatment retention rate we report after 5 years of operation suggests that the program we describe successfully meets its patients' needs. The MMM participants in our program are socioeconomically more diverse than those in other MMM programs. Patients' income levels and categories of employment suggest that the group is composed principally of middle- and working-class persons; only 14% had a college or postgraduate education. The stability of this group is perhaps not surprising given their mean duration of methadone treatment of 18 years. Our program demonstrates that methadone treatment in a low-intensity setting can achieve positive outcomes in diverse patient populations. The high degree of success demonstrated here suggests that eligibility and referrals to this MMM program may have been more restrictive than necessary; however, logistical constraints have limited the number of patients that can be accommodated.

Our study has several limitations. The retrospective design limits data collection to variables recorded in patients' clinical records. Inaccuracies and omissions in medical charts are possible. Although the low attrition rate suggests a high level of patient satisfaction, we do not have data directly addressing patients' perceptions of the program. Enrollment criteria were relatively strict; hence, we could not address whether MMM would be equally effective if offered to a broader sample of patients enrolled in traditional MMTPs.

In the United States, only a fraction (approximately 20%) of opioid-dependent individuals receive pharmacotherapy for this chronic condition (Fiellin & O'Connor 2002). Access to methadone maintenance therapy varies greatly by location, with limited availability of treatment slots resulting in waiting lists in many areas. Providing methadone to selected patients in physicians' offices and other less regulated settings may be an effective means of expanding access to treatment (Fiellin & O'Connor, 2002). Scarce addiction treatment resources could be allocated more effectively were it possible for more stable patients to migrate into less intensive opioid pharmacotherapy treatment settings. Buprenorphine, recently approved for out-patient treatment of opioid dependence, will enhance availability of such treatment options (Barnett, Rodgers, & Bloch, 2001; O'Connor et al., 1996; O'Connor et al., 1998). Some stable patients may successfully transition from methadone to buprenorphine therapy (Whitley, Arnsten, & Gourevitch, 2004); for others, methadone will remain the preferred treatment for their opioid dependence. The two randomized controlled trials to examine MMM (Fiellin et al., 2001; King et al., 2002) drew patients from populations similar to that treated in our program. The favorable outcomes they report complement our findings from a nonresearch setting, lending additional support to careful expansion of this model to more diverse populations with varying levels of clinical stability. Further research is needed to define long-term outcomes associated with more inclusive eligibility criteria for MMM and to assess the effectiveness of integrated and stand-alone MMM programs. More widespread adoption of the MMM model for eligible patients in traditional MMTPs is an important strategy for ensuring access to treatment and diminishing stigma for opioid-dependent persons.

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Table 1

Characteristics of MMM patients and patients enrolled in traditional MMTPs for more than 6 months

Characteristics	MMM (<i>n</i> = 127)	MMTP (<i>n</i> = 3,342)	<i>p</i>
Age in years, <i>M</i> (<i>SD</i>)	51 (7.2)	44	NA
Male, <i>n</i> (%)	91 (72)	1971 (59)	=.004
Hispanic, <i>n</i> (%)	49 (39)	1971 (59)	<.001
African American, <i>n</i> (%)	15 (12)	768 (23)	<.001
Caucasian, <i>n</i> (%)	63 (50)	568 (17)	<.001
HIV positive, <i>n</i> (%)	7 (6)	668 (20)	<.001
Hepatitis C antibody positive, <i>n</i> (%)	105 (84)	2005 (60)	<.001
Methadone dose on admission to MMM, <i>M</i> (<i>SD</i>)	66 (37)	—	—
Methadone dose at chart review, <i>M</i> (<i>SD</i>)	72 (39)	100 (57)	<.001

Note. NA, not available.

Table 2Selected characteristics of MMM patients ($n = 127$)

Characteristics	Value
Employed, n (%)	106 (92)
History of arrest, n (%)	71 (62)
Less than high school education, n (%)	32 (29)
High school graduate or equivalent, n (%)	79 (71)
College or postgraduate education, n (%)	14 (13)
Married or partnered, n (%)	85 (74)
History of injecting drugs, n (%)	96 (84)
Daily tobacco use, n (%)	71 (58)
Monthly income at enrollment to MMM (in US\$), M (SD)	2,700 (1,400)
Age of first opioid use, M (SD)	19 (4.7)
Age first injected, M (SD)	20 (4.7)
Number of methadone maintenance admissions, M (SD)	2 (0.9)
Total years on methadone before MMM, M (SD)	18 (7.7)

Table 3Type of employment at time of enrollment into MMM ($n = 127$)

Employment type	<i>n</i> (%)
Professional (lawyer, physician)	6 (5)
Health care (nurse, radiology technician)	5 (4)
Social worker/Educator	8 (7)
Computer/Technology related	2 (2)
Small business owner	6 (5)
Administrative/clerical (secretary, administrative assistant)	26 (23)
Skilled worker (electrician, plumber)	17 (15)
Construction	3 (3)
Building maintenance (porter, custodial worker)	19 (17)
Other	15 (13)
Unemployed	6 (5)

Table 4

Published studies on MMM

Program evaluations	Location	Number enrolled	% Minority	% Retained in MMM (duration of observation period)
Senay et al. (1994)	Chicago	130	38	69 (1 year)
Schwartz et al. (1999)	Baltimore	21	5	71 (12 years)
Salsitz et al. (2000)	Manhattan	158	18	84 (15 years)
Merrill et al. (2005)	Seattle	30	17	93 (1 year)
AECOM MMM program (current study)	Bronx	127	50	98 (5 years)
Randomized controlled trials	Location	Number enrolled	Number in MMM arm(s)	% Minority
Fiellin et al. (2001)	New Haven	46	22	22
King et al. (2002)	Baltimore	73	52	30