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Scaling-up Interim Methadone Maintenance: Treatment for One Thousand Heroin Addicts

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Abstract

The objectives of this study were to determine: 1) the feasibility of expanding interim methadone treatment (IM); (2) the impact of IM on heroin and cocaine use; and (3) the effect of charging a modest fee for IM. Six clinics provided daily methadone plus emergency counseling only (IM) to heroin addicts on a waiting list for treatment. IM was provided for up to 120 days before transfer to regular methadone treatment. Drug testing was conducted at admission to IM and at transfer to MTP. Half the patients were charged \$10/week for IM. Logistic regression analysis was utilized to determine the effect of fee status and other variables on transfer. Of 1,000 patients enrolled in IM, 762 patients (76.2%) were admitted to a regular MTP. For those who transferred ($n = 762$), opioid positive tests decreased from 89.6% to 38.4%; cocaine, from 49.9% to 44.9% from admission to transfer. Logistic regression analysis indicated that fee status at baseline was not significantly associated with transfer. When limited public resources create waiting lists, IM can allow additional patients to sharply reduce heroin use while waiting for admission to MTP.

Keywords

heroin addiction; methadone treatment; interim methadone

1. Introduction

In the United States, where oral methadone has been used to treat addiction since 1965, federal and state regulations instituted in 1972 mandate the provision of various rehabilitative services along with medication. This requirement, originally based on the belief that methadone alone was not likely to have much impact on changing the behavior of heroin addicts, continues to be in effect under current program accreditation systems and substantially raises the cost of providing oral methadone to those addicts who might benefit from methadone alone. Over the past 30 years, the public's willingness to support rehabilitative services has waned, and in many parts of the U.S., MMT is now available only to those who can pay for it or whose private insurance will cover it. At present, more than one-third of methadone treatment programs

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(MTPs) are private, for-profit operations (Northrop Grumman Information Technology Health Solutions, 2006). The net effect of declining public support and the shift to for-profit programs is that many heroin users seeking entry to an MTP are placed on waiting lists until limited publicly subsidized openings become available (Des Jarlais et al., 1995; Lewis, 1999; Peterson et al., 2008).

Waiting lists for methadone treatment in the United States have existed for the past four decades (Friedmann et al., 2003; Patch et al., 1973; Wenger & Rosenbaum, 1994). The lack of access to methadone treatment is an international problem as well and waiting lists have been described in Europe, New Zealand and elsewhere (Adamson & Sellman, 1998; Fountain et al., 2000). In Baltimore at the time of the present study, individuals remained on waiting list prior to entering methadone treatment for approximately three months (Schwartz et al., 2006). In the 1980s when data indicated that MTP patients had a reduced likelihood of becoming infected with HIV, efforts were undertaken to reduce waiting lists or at least to provide oral methadone for those awaiting admission to MTPs. Drs. Vincent Dole and Donald des Jarlais obtained an Investigatory New Drug (IND) Application from the Food and Drug Administration that would allow the provision of methadone to heroin addicts who otherwise would have remained on waiting lists. A study conducted under this IND, which randomly assigned heroin-addicted individuals on an MTP waiting list to remain on the list for 30 days or to receive methadone without counseling (which these authors termed Interim Maintenance), found that individuals on IM had lower rates of heroin use at 30 days post-enrollment and were more likely to be enrolled in MTP at 16 month follow-up (Yancovitz et al., 1991). In an editorial Dole (1991) noted that although the Yancovitz study was a successful preliminary test of minimal service methadone, programs striving for a public health impact must be brought to scale to treat a significant proportion of the addicted population.

Calsyn et al. (1994), in a 3×2 factorial design, randomly assigned new MTP admissions to one of three counseling conditions: methadone only, methadone with standard counseling and methadone with enhanced counseling and one of two contingency contracting conditions (yes v. no). There was no effect of the level of counseling on 12 month treatment retention rates and no main effect of counseling level on the mean number of opiate or cocaine positive urine tests. Subsequently, new federal regulations permitted IM treatment (Federal Register, 1993) but were rarely implemented. A study in Baltimore demonstrated that individuals randomly assigned to IM as compared to remaining on a waiting list were significantly more likely to enter MTP, as well as reduce heroin use and self-reported criminal behavior (Schwartz et al., 2006; 2007). The present project was conducted following the trial in Baltimore in order to determine the feasibility of scaling up IM treatment in six different MTPs to treat over 1,000 patients and to determine the impact of charging a modest co-payment on treatment outcomes.

2. Methods

2.1 Participants

In Baltimore in 2005, heroin-addicted individuals seeking methadone treatment typically waited many weeks or months because of a relative shortage of publicly subsidized openings in existing programs (Schwartz et al., 2006). From January 2005 to June 2006, six Baltimore area MTPs admitted heroin-dependent patients to IM from their individual waiting lists. For admission to IM applicants had to meet criteria for entry into a MTP (Federal Register, 1993).

2.2 Exclusion

Pregnant women, and in some MTPs individuals with positive urine tests for benzodiazepines, were excluded from participation in IM; the former were admitted to the comprehensive MTP

and referred for obstetrical care while the latter were referred to detoxification from benzodiazepines if required or asked to return for an additional screening with a negative urine test for benzodiazepines.

2.3 IM procedures and additional assessments

All those individuals admitted to IM received the same medical, laboratory and baseline psychosocial assessments as those admitted to regular MTPs. IM treatment consisted of providing directly observed methadone administration and only emergency counseling. Methadone doses were provided following the same induction schedule used in the clinics for patients in their comprehensive methadone programs and generally began with 20 mg and increased roughly by 5 mg every day (or every other day) to a target of approximately 80 mg. Doses were then adjusted at the request of the patient through discussion with the medicating nurse and approval of any dose changes by physician order. Consistent with the federal regulations (Federal Register, 2001), there were no take-home doses and all clinics remained open Sundays and all holidays. Patients consented to methadone treatment and were provided an information sheet about the evaluation that was approved by the Friends Research Institute's (FRI) Institutional Review Board (IRB). Each program agreed to accept a certain number of IM patients over a period of 18 months. Three of the six MTPs charged a modest co-payment of \$10/week for the first half of their patients and the other three MTPs provided free treatment. After approximately half of their patients were admitted, each clinic changed its fee policy for new admissions with those clinics who had been charging \$10/week for providing IM switching to no charge and vice versa.

Patients were permitted to remain on IM for up to 120 days after which time, they were to be transferred to usual methadone treatment at their respective clinic and to participate in counseling on a regular (usually weekly) basis; they also were offered services that varied with the clinic and more frequent drug testing. However, clinics were permitted to admit patients to regular treatment as a treatment slot became available and program capacity allowed (see below). Patients were not permitted to refuse a treatment slot, although they were permitted to a dose taper to discontinue program participation.

At each clinic patients were assessed at baseline by MTP staff using the Center for Substance Abuse Treatment Government Program Results Act (GPRA) Client Outcome Measure for Discretionary Programs, as required by the Center for Substance Abuse Treatment (CSAT) which provided the funding for interim methadone treatment in this study. In addition, clinic patients provided a urine sample for drug testing. At the time of transfer to usual MTP, clinic staff was expected to obtain a specimen for urine drug testing. The clinic staff re-administered the GPRA to all patients still enrolled in treatment at 6 months from baseline. Project staff attempted to contact all patients who were not in treatment at 6 months, and when contact was successful, administered the GPRA either in person or by phone.

2.4 Outcome Measures

The GPRA measure, administered as described above, asks the number of days patients used heroin or cocaine in the past 30 days and whether they injected drugs in that time period. Baseline urine drug tests were analyzed by a local lab by EMIT for heroin and cocaine metabolites. A second urine drug test was obtained at the time of transfer to comprehensive methadone treatment from IM. The results of urine tests and the measure of days in treatment and successful transfer to usual methadone treatment were collected by the FRI staff from the six MTPs.

2.5 Explanatory Variables

The explanatory variables in the statistical model included the continuous variables measuring age and number of years of education, and the categorical variables measuring gender, race (Black v. White), current employment status (employed v. unemployed v. retired/disabled), past-30-day injection drug practices (yes v. no), fee status (fee v. no fee), baseline cocaine urine test results (positive v. negative), plus the interaction of fee and baseline cocaine urine test results.

2.6 Statistical Analysis

Logistic regression analysis was utilized to conduct the statistical analysis. The outcome variable in the statistical model was the binary variable of transfer to comprehensive treatment (no v. yes). Results for the full model, including all explanatory variables are reported in terms of the likelihood ratio χ^2 test and Nagelkerke R^2 , while odds ratios (*OR*) and 95% confidence intervals (*CI*) for the odds ratios are reported for each explanatory variable.

3. Results

Over a period of 18 months, 1,045 patients were admitted to IM at the six clinics. Complete data were available for 1,000 of these admissions. [Data were omitted for the 45 cases because one or more of key elements were missing from the records.] The demographic characteristics of the 1,000 participants are shown in Table 1. The mean age of the participants was 40.75 years, 56.4% were men, 71% were African American and 29% were White. Only 21% of participants were employed at treatment entry.

Of the 1,000 patients admitted to IM, 762 (76.2%) successfully entered comprehensive methadone treatment after a mean of 86.05 days of IM. Among those 762 IM patients who entered comprehensive treatment, the percentage that entered during the interval 0 -30 days was 9.0%; 31 – 60 days: 18.9%; 61 – 90 days: 18.9%; and greater than 90 days: 53.2%. As shown in Table 2, the rate of opioid positive urine tests dropped sharply from admission as compared to the time of transfer (89.6% v. 38.4%, respectively) while the rate of cocaine-positive drug tests over the same period decreased only modestly (49.9% v. 44.9%). Results of the logistic regression analysis indicated that the explanatory variables, as a set, predicted transfer to comprehensive treatment, $\chi^2(10) = 36.58$, $p < .001$; however, Nagelkerke $R^2 = .054$, indicating that the amount of variance explained in the transfer to comprehensive treatment by the explanatory variables as a set was modest. Two explanatory variables emerged as significant predictors of transfer to comprehensive treatment: Gender (*OR* = 1.42, 95% *CI* = 1.041 - 1.937, indicating that males were 42% more likely than females to fail to transfer to comprehensive treatment) and past-30-day injection drug practices (*OR* = 1.61, 95% *CI* = 1.174 - 2.213, indicating that the past-30-day injecting drug group was 61% more likely than the past-30-day non-injecting drug group to fail to transfer to comprehensive treatment). 70.9% of the group that was charged a \$10 weekly fee for IM was able to successfully transfer to comprehensive methadone treatment in contrast to 81.2% of the group that was not charged a fee.

Although not significant ($p = .055$), it should be noted that the results for fee suggest that fee group was at best only modestly more likely that the no fee group to fail to transfer to comprehensive treatment (*OR* = 1.52, 95% *CI* = .992 - 2.335).

4. Discussion

Three major questions were addressed in this demonstration. First, could IM be scaled-up at other outpatient methadone treatment programs? Second, would the decrease in heroin use be

as robust as observed in a previous study at a single clinic (Schwartz et al., 2006; 2007)? Third, would heroin addicts be willing to pay a modest fee to help support their treatment? All three questions were answered affirmatively.

The feasibility of bringing IM treatment to scale in Baltimore was successfully demonstrated as over 1,000 patients were treated in six different clinics. In fact, through this project funded through the Center for Substance Abuse Treatment, every not-for-profit MTP in the city that was open or was willing to remain open the required seven days per week participated in this effort and four clinics continue to provide IM through local funding beyond the conclusion of the original project. The current IM federal regulations proved to be the most problematic aspect of putting IM into place, as it took nearly six months after funding was authorized to obtain permissions from various State and Federal agencies for each clinic.

Under the IM federal regulations, an MTP wishing to provide IM treatment must first obtain a letter of support from the State's Chief Public Health Officer and from the federal Substance Abuse Mental Health Services Administration (SAMHSA [Federal Register, 2001]). For the purposes of the present evaluation, each of the six programs had to obtain permission from the local substance abuse authority, the State's Alcohol and Drug Abuse Administration, the State's Health Commissioner and SAMHSA. Another limitation of the federal IM regulations is that for-profit clinics are barred from providing IM treatment. This limits the number of programs available for IM given more than one-third of US MTPs are for-profit. Furthermore, MTPs that are closed on Sundays are not permitted to provide IM treatment. Another limitation is the requirement that patients remain on IM no longer than 120 days. In effect, this restriction limits the number of patients that can be drawn off the waiting list by the number of treatment slots that can accommodate IM patients at 120 days.

Urine tests for illicit drugs may overestimate drug use because they indicate solely the presence or absence of drug metabolite over a certain minimum concentration and may not reflect reduction in frequency or amount of use. That said, despite the absence of counseling or take home medications contingent on submitting urine specimens negative for illicit drugs, the patients receiving IM treatment showed large decrease in urines positive for illicit opioids. Over all, averaged across the 6 clinics, positive opioid specimens decreased from almost 89.6% to 38.4%. These data are supportive of our previous study of IM which showed a decrease in opioid positive drug tests from a baseline of 99% to 4-month follow-up of 56% (Schwartz et al., 2006). It is likely that the greater reduction in opioid positive tests found in the present sample as compared to the previous study can be attributed to the intent-to-treat design and the inclusion of drug testing results from IM drop-outs in the study by Schwartz et al. (2006). Also consistent with our previous findings, in the present study, cocaine-positive drug tests decreased only slightly from 49.9% to 44.9%.

While comparison to results from other studies must always be undertaken with caution, three studies of opioid agonist treatment with counseling in Baltimore in populations with remarkably similar characteristics to those of patients who participated in this IM demonstration project, showed comparable reductions of illicit opioid use to IM patients (Johnson et al., 1992; Johnson et al., 2000; Strain et al., 1999). Furthermore, in the UK and Australia, both of which allow general practitioners to prescribe methadone without there being a requirement for mandatory psychosocial services, self-reported reductions in illicit drug use among heroin users receiving only prescribed methadone are comparable to those typically found in structured MTP programs in the US (Gossop et al., 1999). We believe that these data as well as the data from previous studies of methadone only (Calsyn et al., 1994; Schwartz et al., 2006; ²⁰⁰⁷; Yancovitz et al., 1991) show that the impact of IM on heroin use is robust.

Since the lack of public funding is a major barrier to providing access to methadone treatment for patients unable to afford such treatment, it would be important to know whether treatment seeking patients would be able to support some of the cost of scaling up IM. In the present evaluation, charging a modest fee for IM treatment had, at best a modest effect on reducing entry into comprehensive methadone treatment. The \$10 weekly fee covered about one third of the estimated marginal cost of IM of about \$30 per week. No agreement was reached on a uniform policy for dealing with patients who were unable or unwilling to pay the fee; each clinic continued to follow its own policies with respect to fees. These policies varied considerably and may account for some differences observed in successful entry into regular treatment under the fee and no fee conditions. Nevertheless, charging a modest fee could permit the expansion of IM treatment capacity by making more funds available to support its already low cost, although such an approach may not be applicable to patients with Medicaid who may not be permitted to pay for services.

These data should not be used to argue that counseling and other psychosocial services are without value. There is sufficient evidence in methadone programs that when patients in MTPs develop a therapeutic alliance with skilled counselors there are significant improvements and that additional services can produce improvement in areas other than illicit drug use (McLellan et al., 1993; Woody et al., 1995). However, our findings do suggest that under current funding conditions, where patient contact with counselors may be infrequent (Hubbard, 1996; Kraft et al., 1997; McLellan & Weisner, 1996) and there is reliance largely on group treatment, the incremental benefits of the services beyond the provision of methadone and take home privileges contingent on negative drug tests are not substantial enough to justify the current regulatory impediments to the use of IM.

There are several limitations to the study. First, precise data on the number of patients who may have been discharged due to non-payment of fees was not available. Second, the GPRA questionnaire did not contain an item regarding the number of prior methadone treatment episodes. Therefore it was not possible to determine the impact of prior treatment on success in IM.

Our findings indicate that IM is an effective treatment for heroin addiction, which can increase entry into comprehensive methadone treatment, can be provided at low-cost, and can be scaled up to reach thousands of heroin addicts. Scaling up of effective treatment for heroin addiction can have significant public health impact in terms of reduction in heroin use, drug injection HIV infection and crime (Dolan et al. 2005; Metzger et al., 1993; Woody & Muñoz, 2000). Cogent arguments can be made that counseling and other services should be available for patients who find them valuable. However, requiring these services should not create a barrier to effective IM treatment for those heroin addicts for whom treatment would be otherwise unavailable. These findings support the argument that the current regulatory framework in the United States for providing opioid maintenance treatment is in need of revision. Permitting the use of IM by the relatively large number of for-profit MTPs and reducing the layers of governmental permission required prior to initiating IM would increase the likelihood that other cities would implement this effective approach to heroin addiction treatment.

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Table 1

Characteristics of 1,000 Interim Methadone Maintenance

Age, years (SD)	40.75 (8.68)
Male, n (%)	564 (56.4%)
Race	
Black, n (%)	710 (71.0%)
White, n (%)	290 (29.0%)
Employed, n (%)	218 (21.8%)
Unemployed, n (%)	690 (69.0%)
Retired/Disabled, n (%)	92 (9.2%)
Education, years (SD)	11.3 (1.8%)
Number of Days of Heroin Use in Past 30 days, n (SD)	24.83 (10.11)
Number of Days of Cocaine Use in Past 30 days, n (SD)	6.19 (9.47)
Baseline Positive Opioid Urine Test n (%)	904 (90.4%)
Cocaine	505 (50.5%)
Inject drugs in past 30 days, n (%)	574 (57.4%)
Number of Days in IM Treatment (Mean (SD))	86.05 (39.67)

Table 2

Outcomes of 753 Interim Methadone Patients who successfully entered MTP

Baseline Positive Opioid Urine Test, n (%)	289 (89.6%)
Transfer Positive Opioid Urine Test, n (%)	675 (38.4%)
Baseline Positive Cocaine Urine Test, n (%)	376 (49.9%)
Transfer Positive Cocaine Urine Test, n (%)	338 (44.9%)