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Randomized Trial of Drug Abuse Treatment-Linkage Strategies

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Randomized Trial of Drug Abuse Treatment-Linkage Strategies

## Abstract

A clinical trial contrasted two interventions designed to link opioid-dependent hospital patients to drug abuse treatment. The 126 out-of-treatment participants were randomly assigned to: (a) case management, (b) voucher for free methadone maintenance treatment (MMT), (c) case management plus voucher, or (d) usual care. Services were provided for 6 months. MMT enrollment at 3 months was: 47% (case management), 89% (voucher), 93% (case management plus voucher), and 11% (usual care); at 6 months enrollment was 48%, 68%, 79%, and 21%, respectively. Case management and vouchers can be valuable in health settings to link substance abusers with medical problems to drug abuse treatment.

Key words: randomized clinical trial, opioid use, case management, methadone treatment vouchers, substance abuse treatment

### Randomized Trial of Drug Abuse Treatment-Linkage Strategies

A significant gap exists between the number of people who need treatment for drug use and the number of people receiving it. The National Survey on Drug Use and Health (2002) indicated that, of the 7.7 million people who needed treatment for an illicit drug problem in the past year, only 18% (about 1.4 million) received treatment. Estimates are that only 20% of all drug abusers are enrolled in drug abuse treatment at any given time (Epstein & Gfroerer, 1998).

Hospitals care for many injection drug users (IDUs) who are not in drug abuse treatment. In 2002 there were an estimated 670,307 emergency department (ED) visits related to drug abuse in the United States (Substance Abuse and Mental Health Services Administration, 2004). Drug users are more likely than others to use the hospital ED for medical treatment, rather than receiving less costly outpatient care. For example, McGeary and French (2000) found that chronic drug use increased the probability of ED use by more than 30 percent, compared with casual or non-drug-using counterparts. Out-of-treatment drug users are more likely to use emergency services than those in drug abuse treatment (Stein & Anderson, 2003). In a 7-hospital study in Tennessee, Rockett, Putnam, Jia, and Smith (2003) found that less than 10% of ED patients who needed substance abuse treatment were receiving it. EDs usually are unsuccessful in linking substantial numbers of patients to drug abuse treatment. Lubeckis et al. (1991) found that less than 19% of IDUs seen in the ED were successfully referred to substance abuse treatment.

Recently several pilot or demonstration projects have aimed to forge links between hospital care and drug abuse treatment programs. Aszalos, McDuff, Weintraub,

Montoya, and Schwartz (1999) established an intensive ambulatory drug treatment program for heroin-dependent people hospitalized for other medical illnesses. After 6 months of treatment, clients were able to reduce illicit drug use, obtain medical coverage, and improve their living situation. Bernstein, Bernstein, and Levenson (1997) assessed Project ASSERT, an ED-based intervention that involved a 15-to-20-minute interview as a tool to link patients with substance abuse treatment. Clients demonstrated a reduction in the severity of their drug problems and a reduction in alcohol use. Witbeck, Hornfield, and Dalack (2000) piloted a linkage program providing intensive case management for substance-abusing or chronically mentally ill homeless individuals who frequently used emergency medical services, providing intensive case management. Those who utilized the linkage program showed a 58% reduction in emergency service use in contrast to the year before, while the comparison group did not decrease emergency service use.

Case management is a promising approach to connect IDUs with care. In case management a staff member (case manager) attempts to enroll patients in needed services and to coordinate the services patients require for their complex problems. With substance-dependent individuals case management has been used in two ways: (a) linking patients already in substance abuse treatment programs to additional services and (b) linking out-of-treatment substance users to treatment. Several studies indicated that case management holds promise when implemented in drug abuse treatment programs (Conrad et al., 1998; Drake, Yovetich, Bebout, Harris, & McHugo, 1997; Evenson, Binner, Cho, Schicht, Topolski, 1998; Jerrell & Ridgely, 1995; McLellan, et al., 1999).

The results of studies have been mixed when assessing case management programs that aim to link out-of-treatment substance abusers to drug abuse treatment. Two studies with positive results found that patients randomly assigned to case management were more likely to enter drug abuse treatment (Lidz, Bux, Platt, & Iguchi, 1992; Mejta, Bokos, Mickenberg, Maslar, & Senay, 1997). Mejta et al. (1997) found that 98% of the clients assigned to case management were admitted to a substance abuse treatment program whereas 57% of the comparison group clients were admitted. Additionally, clients who received case management were able to access treatment more rapidly than the comparison group clients. Lidz et al. (1992) found that a case management intervention was more effective than usual care in linking clients to treatment. Negative findings include a study of an expanded "brokerage model" versus a more intensive case management program with severely mentally ill substance abusers (Havassy, Shopshire, & Quigley, 2000) and an investigation of case management for substance abusers with HIV/AIDS (Sorensen et al., 2003). Havassy et al. (2000) found no significant differences in service use for substance users assigned to the brokerage model of case management versus the more intensive model. Sorensen et al. (2003) found no significant differences between services utilized by substance users randomized to case management versus those who were randomized to treatment as usual.

Vouchers for drug treatment are another approach, which has considerable face validity but limited empirical investigation. If drug abuse treatment were free or available at a low cost, drug users could enroll more easily: They could immediately enter treatment rather than needing a case manager to help them gain access to the front of the waiting line. Thus, providing vouchers for treatment may be a more parsimonious

linkage strategy. Several studies have evaluated the use coupons or vouchers to link drug users with treatment. At least five separate studies, each with positive results, had been published by the late 1990s (Sorensen, Masson, & Copeland, 1999). Most recently, Booth, Corsi, and Mikulich (2003) provided a coupon for 90 days of methadone maintenance treatment (MMT) to half of a sample of out-of-treatment drug injectors; fully 66% of those who received a coupon for free treatment entered MMT within 2 months, compared with 17% of those who did not receive coupons. All studies using vouchers to link drug users to treatment have used outreach strategies targeting untreated drug users in the community, rather than seeking patients from hospitals.

The present study was designed to test the efficacy of two treatment linkage strategies—case management and provision of vouchers for free MMT—among opioid users presenting for medical treatment at a county public hospital. These treatment linkage strategies are interventions that mental health professionals and public health system planners can use to better integrate substance abusers into the drug abuse treatment system.

## Method

### *Design Summary*

The study was a randomized controlled experiment with 126 participants, examining the impact of two interventions designed to enroll participants in MMT, enroll participants in medical and social service programs, and decrease opiate use. Patients appearing at the hospital were screened for possible opioid use disorders. Those who agreed to participate received a baseline interview and were then randomly assigned to receive either 6 months of case management, a voucher for 6 months of free MMT, case



management plus a voucher, or usual care. The usual care condition was intended to approximate what would happen to participants if the interventions were not available. The usual care or “treatment as usual” design is useful when comparing study interventions to the status quo (Areal & Alvidrez, 2002); other design options can compare interventions with minimal treatments or historical controls. This paper reports on follow-up assessments held 3 and 6 months after enrollment.

Four primary hypotheses were tested to address the primary aims of treatment enrollment and substance use outcomes: (a) More voucher participants would enroll in MMT than participants not receiving vouchers; (b) More participants receiving case management would enroll in other services (not MMT) than patients not receiving case management; (c) Participants receiving vouchers would demonstrate lower rates of opiate-positive urine toxicology at three and six months than participants not receiving vouchers; and (d) Participants receiving case management plus vouchers would demonstrate lower rates of opiate-positive urine toxicology at three and six months, compared with the other three interventions. Additionally, two secondary hypotheses were formulated: (a) Those who received case management plus vouchers would show improvements on a measure of physical health compared to those who did not receive either; and (b) more case management participants would enroll in MMT than those participants who received usual care.

### *Research Participants and Procedures*

*Inclusion and Exclusion Criteria.* All participants met the following criteria for study inclusion: (a) 18-65 years of age; (b) receiving medical treatment at San Francisco General Hospital’s (SFGH’s) ED, inpatient units, or an outpatient clinic, Integrated Soft

tissue Infection Services (ISIS), at time of recruitment; (c) willing and interested to enroll in case management or MMT; (d) met the state of California's Title 9-Code of Regulations eligibility requirements for MMT: (a) 2 years of heroin dependence, (b) 2 prior treatment attempts that ended more than 7 days prior to the screening date, (c) currently injecting heroin, which was confirmed via self-report at screening and at baseline with an opiate dipstick; (d) and provided informed consent to participate in the 18-month long study.

Participants were excluded from the study if they were: (a) unable to provide informed consent due to current psychotic disorder, severe medical complications, or intoxication, sedation, or being asleep; (b) in police custody or expecting incarceration; (c) imminently scheduled for or currently in case management or substance abuse treatment (excluding 21-day or 30-day methadone detoxification); (d) leaving the San Francisco area within 6 months; (e) using heroin less than 15 days out of the past 30 days; (f) or participating in a similar research study.

### *Recruitment Methods*

*Sources of Participants.* SFGH is a public hospital for the City and County of San Francisco and is the city's largest provider of acute medical care for uninsured individuals. The ED and inpatient units provide medical care to ill or injured IDUs. An outpatient clinic that serves many IDUs, ISIS, offers care to patients with soft tissue infections on a walk-in basis. In addition to medical services, ISIS provides counseling, access to substance abuse treatment, and social work services. SFGH also provides substance abuse treatment and consultation through the Psychiatry Department's Division

of Substance Abuse and Addiction Medicine (DSAAM). DSAAM services include an Opiate Treatment Outpatient Program that provides methadone treatment.

All participants were recruited from three sites at SFGH: the ED, inpatient units, and the ISIS clinic. Research assistants went to the ED and ISIS clinic regularly to screen potential participants. Research assistants also fielded referrals from the hospital's Substance Abuse Consultation Service and Primary Care Substance Use Services, which help patients with substance abuse problems in the inpatient and outpatient units, respectively. Finally, some patients contacted staff after seeing flyers posted in the ISIS clinic. Patients were recruited from June 2000 to October 2002.

*Initial Screening.* Once a potential participant was identified, the research staff would assess the patient for criteria of inclusion and exclusion to the study. Additionally, research assistants gathered socio-demographic information at screening. This included gender, self-identified ethnicity, age, marital status, years of education, and employment status. Also, some clinical information was collected, including age at first heroin use, HIV status, cigarette use, and the potential participant's reason for seeking medical treatment. With confirmed eligibility, the patient was asked to go to the research office located in SFGH for a baseline appointment usually scheduled within the next 3 working days.

*Baseline Appointment.* At the baseline appointment the research interviewer explained the study in detail and administered a written informed consent process. The UCSF Institutional Review Board approved all study procedures. The baseline interview was then administered.

*Randomization Process.* Following the baseline interview, participants were randomly assigned to an intervention in the order they enrolled in the study according to a computer-generated list. Additionally, randomization was stratified by the time of the day participants were recruited to participate in the study. Participants were either recruited in the day (7 am to 3 pm) or night (3 pm to 11 pm). At the completion of the baseline interview, the research assistant and participant opened a sealed envelope together that contained a paper slip, which informed them of the participant's random assignment to an intervention. The research assistant and participant were blind to this information up until that point.

If the participant was in the *case management* intervention, the research interviewer paged the case manager, who met with the participant before the participant left the interview area. If the participant was in the *voucher* intervention, the research interviewer called the Opiate Treatment Outpatient Program at the hospital to make an intake appointment, scheduled within a few days following baseline. Participants received an appointment slip and instructions on how to find the clinic at the hospital. As a precautionary measure, voucher participants had two photos taken of them, one for the research staff and one for the counselor. This ensured the positive identification of voucher participants, so that voucher use by non-participants was prevented. They were instructed to contact research staff immediately if they missed their intake for any reason, so staff could reschedule their clinic intake. If the second intake was missed, participants could schedule a third intake appointment. If intake was not completed within 2 weeks of the original intake date, the voucher could not be redeemed. Participants were not allowed to reschedule a fourth intake appointment. If the participant was in the *case*

*management plus voucher* intervention, procedures for both the interventions above were administered. If the participant was in the *usual care* intervention, the research interviewer offered to call the Substance Abuse Consultation Service (SACS) to have a consultant meet with the participant for a counseling and referral session. Generally participants were aware of SACS, and 28% of them had received such a consultation in the year before they joined the study. While interviewers offered to call, very few participants requested this service. Regardless of experimental intervention, participants received an appointment slip for their next research interview (in 3 months).

### *Experimental Interventions*

Both the case management and voucher interventions lasted for 6 months after participants were randomized.

*Case Management.* The structure of this specific intervention was adapted from Ballew and Mink (1986), who conceptualized case management in terms of the following six elements: (a) engagement, (b) needs assessment, (c) planning, (d) accessing resources, (e) monitoring, and (f) advocacy. For detail about the study's case management intervention, please refer to the manual by Sorensen, Jacob, and Roth (2004).

The goals of the case manager were to reduce substance use, by facilitating appropriate use of substance abuse treatment, and to encourage the participant's use of a network of medical and social services. The study's case manager also attempted to help participants remain in drug abuse treatment and ancillary services. We dubbed this a "linkage model" of case management because of the focus on connecting participants to needed services rather than providing primary mental health care. Two masters-level social workers, based at the SFGH research office, served consecutively as case managers

during the study, supervised by the first author. The same case manager served both participants randomized to the case management intervention along with those randomized to the case management plus voucher intervention. The caseload of the full-time case manager was about 15 participants throughout the study, including case management activities involving contact with participants and programs, as well as research responsibilities (e.g. staff meetings, making records of contacts). Case managers were available to work with participants in a variety of settings including the participant's residence, the case manager's office, inpatient ward, or elsewhere in the community. As noted in the measures section, the amount of time in case management services was measured, as well as the frequency and type of case management activities.

*Vouchers for Methadone Treatment.* Vouchers were redeemable for 6 months of treatment at the SFGH Opiate Treatment Outpatient Program. The program had been a site for research involving 6 months of MMT as a platform for delivering tuberculosis medications (Batki, Gruber, Bradley, Bradley, & Delucchi, 2002). In the present research the protocol was developed from the work of Batki et al. as well as Reilly et al. (1995), who developed a 6-month MMT intervention at the San Francisco Veterans Affairs Medical Center.

In general, the procedures involved daily methadone dosing with a methadone dose that was set individually for the participant's needs, monthly drug testing, and a minimum of 50 minutes of counseling per month. The participants received a stable dose for the first 3 months, and the dosage was gradually reduced during the last 3 months, so that participants would be ready for discharge after 6 months. Treatment goals were set individually, and with many participants the counselor worked to find a stable source of

methadone treatment so the participants could transfer to long-term MMT after the 6 months of treatment allowed by the voucher. The same counselor treated all study participants. The counselor was a Certified Addictions Treatment Specialist, supervised by the treatment program's clinical director (a licensed clinical psychologist). The caseload of the part-time counselor was about 15 participants throughout the study. Participants who were absent for 14 consecutive days were automatically discharged from the clinic, following clinic policy. A more detailed description of the treatment is available (Lin et al., 2004).

### *Measures*

Participants were interviewed using both published measures and measures created for the study. The published measures included the Addiction Severity Index (ASI; McLellan, Kushner et al., 1992), Beck Depression Inventory (BDI; Beck, Steer, & Brown, 1996), The Thoughts About to Abstinence measure (Hall, Havassy, & Wasserman, 1990; Wasserman et al., 1998), Medical Outcomes Study Short-Form Health Survey (SF-36; Ware, 1996), Texas Christian University AIDS Risk Assessment (ARA; Camacho, Bartholomew, Joe, & Simpson, 1997), Treatment Services Review (TSR; McLellan, Alterman et al., 1992), and urine toxicology. As the primary measure of substance abuse, a urine sample was collected at each research interview. Quest Diagnostics, a licensed laboratory in California, tested the urine for amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, ethanol, opiates, and phencyclidine using enzyme immunoassay. Since these measures are commonly available and published, they are not described further. Measures created for this study included a

methadone treatment database, the Health Care Utilization Survey, and case manager contact notes.

*Methadone Treatment Database.* This database was created to measure participants' use of methadone treatment. Participants' methadone treatment status was coded, for each month in the study, as being enrolled in: (a) detoxification (defined as treatment intended to last less than 6-months), (b) study-funded methadone (vouchers for 6-month MMT), or (c) long-term MMT (defined as treatment intended to last at least 6 months). For analysis purposes, we report results as "methadone maintenance" for the second and third categories listed above. Treatment status was determined by accessing information from the county's Community Substance Abuse Services (CSAS) database and from the participant's self-reported information in the Health Care Utilization Survey. If treatment was reported during a month in either the CSAS database or the Health Care Utilization Survey, it was recorded. If there was a disparity in treatment dates, the data from CSAS was used as the default. If a participant received at least one day of treatment in a given month, "in treatment" was recorded for that month. In instances where more than one type of methadone treatment was received within a month, coding priority was assigned for the treatment with the longest intended stay in the following order: MMT, study-funded methadone, and detoxification. For example, if a participant was enrolled in study-funded methadone for 3 weeks out of a month and was transferred to long-term MMT for the fourth week, the month was coded as MMT.

*Health Care Utilization Survey.* This unpublished survey asked participants to report use of health services from providers who do not report utilization to the CSAS or SFGH databases. The survey identified providers that reported to these systems, and then asked



participants for a self-report of medical, mental health, and substance abuse services from other providers. The survey asked participants to report all methadone treatment received, regardless of whether the treatment program reported to these data systems.

*Case Manager Contact Notes.* The case managers documented all of their activities involved in delivering the case management, including contact with participants and agencies, using a database adapted from a database developed in a prior study (Sorensen et al., 2003). This database contained information about the date, time, length, location and purpose of the case management activity, the type of contact made, and whether or not a referral was made or items provided to the participant.

#### *Times of Administration*

All standard instruments mentioned previously were administered at baseline, and 3-, and 6-month follow-up interviews. The Thoughts About Abstinence Form was administered only at the baseline interview to characterize the sample. The Health Care Utilization Survey was administered at 3- and 6- month follow-up interviews.

#### *Attrition from Screening*

A total of 314 people were screened during a 29-month period. Out of those screened, 219 were eligible. Attrition from screening to consent was 40%, with 126 people enrolling in the study. The people who did not enroll in the study did so for the following reasons: 51% (96 of 188) were not eligible, 44% (82 of 188) never came to the baseline interview, and 5% (10 of 188) came to the baseline interview but were unable to participate due to other reasons, for example, they were uncomfortable with the questions asked. Ineligible people could not participate in the study for the following reasons: 30% (29 of 96) were ineligible for MMT, 10% (9 of 96) were not heroin users, 28% (27 of 96)

were imminently scheduled for or currently in case management or substance abuse treatment, 10% (9 of 96) were using heroin less than 15 days out of 30 days, 10% (10 of 96) were not interested in treatment, 6% (6 of 96) were enrolled in a similar research study, and 6% (6 of 96) were ineligible due to other reasons.

### *Data Analysis*

The design of this study can be described as a 2-by-2 crossed design, but the analysis followed a cell-means approach. The reason is that, instead of testing all possible effects, we focused on the pre-specified hypotheses, which were based on theory and published studies on the use of vouchers and case management, which included comparisons of cell means (hypothesis 4). Prior to beginning recruitment a statistical power analysis was conducted to estimate the required sample size. Minimal power was set at 80% with a Type I error rate of 0.05. The study met and slightly exceeded its recruitment target based on the power analysis. As participants were randomized to intervention, comparisons at baseline were not tested (Senn, 1994).

Tests of the primary hypotheses were conducted by using single degree of freedom tests of the relevant outcome measures at the 3- and 6- month assessment points: enrollment in MMT, urine toxicology for the presence of opiates, and number of other services received (taken from the TSR, McLellan, Alterman et al., 1992). Other services include medical, employment, alcohol drug (not MMT), legal, family, and psychological care. Initially, the data were modeled via logistic and Poisson regression models, which included treatment intervention plus baseline demographic measures (age, gender, marital status, education and homeless status). Because these covariates were not statistically significant in any of the models, and participants were randomly assigned to intervention,

we tested the hypotheses, and report here, using two-group comparisons. Urine toxicology and MMT enrollment were tested using Pearson's chi-square test, and service use was tested using the Mann-Whitney-Wilcoxon test. For the first of the two secondary hypotheses, we estimated and tested the interaction term comparing the change from baseline to the 3-month assessment and, separately to the 6-month assessment, between the case-managed plus voucher condition versus usual care using a repeated measures analysis estimated via restricted maximum likelihood. For the second hypothesis we used Pearson's chi-square test to compare the proportion of participants who received case management versus usual care participants enrolled in MMT.

We conducted additional analyses to assess potentially more subtle intervention effects, as was observed in an earlier study of 6-month detoxification (Masson, et al., 2004). Treatment interventions were compared on cocaine use, the SF-36 Mental Component Summary scale, number of days of opiate use, HIV risk scores, and differences in engagement by site of recruitment. Also examined were the nature and amount of case management provided, and the nature and amount of voucher redemption.

## Results

A total of 126 participants enrolled and were recruited from three SFGH sites, 19 from the ED, 24 from inpatient units, and 83 from ISIS. Of these participants, 125 indicated whether they had been referred to the study: 38 were referred, 15 people were self-referred, and 72 were recruited directly by research staff in the ED and ISIS. The 126 participants were enrolled and randomized to a treatment intervention: 32 to case management, 30 to vouchers, 32 to case management plus vouchers, and 32 to usual care. Table 1 describes the participants at baseline within treatment intervention. They tended

to be homeless, heterosexual men averaging 43 years of age and had been using heroin 18 years on average. At the 3-month follow-up 89% (112 of 126) were assessed, and at the 6-month follow-up 90% (114 of 126) were assessed. Participant flow through the study is illustrated in Figure 1. There were no significant differences in follow-up rates by treatment intervention, and no differences among the linkage intervention groups were found on the mean number of days, measured from baseline, to when the scheduled follow-up assessments were actually conducted.

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 Insert Table 1 and Figure 1 about here  
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#### *Primary Outcomes*

As predicted by our first hypothesis, participants in the two interventions receiving vouchers for MMT were more likely to be enrolled in MMT at the 3 and 6-month assessments than those not receiving a voucher. Table 2 displays the outcome measures by intervention condition, and the results of hypothesis testing appear in Table 3. Differences in the percentage enrolled in MMT treatment were markedly strong as indicated by Table 3. Additionally, of those in the case management and voucher interventions who enrolled in MMT, 31% (17 of 55) participants were transferred to long-term methadone treatment (Lin et al., 2004).

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 Insert Tables 2 and 3 about here  
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The second primary hypothesis, that more participants in the case management interventions would enroll in services other than MMT, was not confirmed: No significant differences were found when comparing enrollment in other services between those receiving case management versus not (at 3-months  $p=0.57$ ; at 6-months  $p=0.80$ ). The third primary hypothesis was partially supported: Differences in urine toxicology for opiates reached statistical significance at 3 months, with fewer voucher participants testing positive for opiate use; there were, however no differences at 6 months. Regarding the fourth hypothesis, which compared the case management plus voucher intervention with the other three, the differences did not reach statistical significance.

#### *Secondary Hypotheses*

The first secondary hypothesis, comparing the case management plus voucher participants with usual care participants on physical health, was not supported: No significant differences were seen in the change from baseline to either the 3- or 6-month assessments between the case management plus voucher participants versus usual care participants on the Physical Component Summary scale of the SF-36

However, more participants in the two case management conditions enrolled in MMT than participants in usual care at both 3 and 6 months (3-months; 41 out of 59 (69%) versus 3 out of 27 (11%),  $\chi^2(1) = 25.2, p < .0001$ ; at 6-months; (37 out of 58 (64%) versus 6 out of 28 (21%),  $\chi^2(1) = 13.6, p = .0002$ ), providing support to the second secondary hypothesis.

#### *Secondary Outcomes*

*Self-report of heroin use.* A statistically significant effect for self-reported days of heroin use was found at the 3-month assessment for the comparison of the vouchers

versus no vouchers (Wilcoxon statistic = -3.06 (1),  $p= 0.002$ ), indicating fewer days of self-reported use among participants receiving vouchers.

*Cocaine urine toxicology.* A significant difference between those receiving vouchers and those not was found for cocaine use at the 3-month assessment and came close to significance at the 6-month assessment—both in an unexpected direction. Participants in the two voucher interventions tested positive for cocaine more often than those not in those interventions (65% (35 of 54) versus 38% (21 of 55) positive at 3 months,  $\chi^2 = 7.74(1)$ ,  $p= 0.005$ ; 58% (33 of 57) versus 41% (22 of 54) at 6 months,  $\chi^2 = 3.59(1)$ ,  $p= 0.058$ . No differences based on case management status were seen.

*SF-36 Scales.* No significant difference existed at either the 3- or 6-month assessments between the voucher interventions or the case management interventions on the standardized SF-36 Mental Component Summary scale.

*ARA.* The comparison of the needle risk index produced a statistically significant difference among the four interventions; at 3 months the voucher and the case management plus voucher intervention groups reported less risky needle-related behaviors than the other two interventions (Kruskal-Wallis  $\chi^2 (3) = 8.10$ ,  $p < 0.05$ ).

*Site effects.* In comparing the sites from which participations were recruited (ED, inpatient units, and ISIS clinic) on rates of enrollment in MMT and use of other services, no significant differences were found.

### *Process Measures*

Table 4 summarizes the contact notes recorded by the case managers. The case managers' activities were predominantly telephone calls (52% of activities) and visits (38% of activities). The most frequent activities originated with the case manager and

were directed to people other than the participant (46% of activities). The most frequent purposes were: Monitoring (43%), accessing resources (40%), and planning (22%). The per-participant activities for the 6 months in treatment averaged 19.8 ( $SD = 30.33$ ) (not shown) with a median value of 6. Ten percent of participants had 50 or more activities. Services occurred most frequently early in case management. Altogether, 66% of activities occurred in months 1-3 of the 6 months of case management.

Regarding the timing and nature of voucher redemption, 55 of the 62 vouchers were redeemed at the methadone program (89%), 44 on the first appointment and 11 on a rescheduled appointment. Vouchers were redeemed between 1 and 17 days ( $M = 6.5$  days) after the baseline interview.

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 Insert Table 4 about here  
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### Discussion

This study assessed whether participation in linkage interventions (case management or voucher for MMT) was associated with enrollment in MMT, lower rates of drug use, and other outcomes among hospital patients initially not in drug abuse treatment. Regarding MMT enrollment, both the case management and voucher interventions significantly influenced participants' likelihood of being enrolled in MMT both 3 and 6 months after randomization. Regarding substance use, only one of the differences in urine toxicology for opiates reached statistical significance at the .05 level, although participants receiving a voucher tested positive for cocaine significantly more often than those not in those interventions at 3 months. In addition, participants assigned to the

voucher interventions self-reported, fewer days of opiate use in the 30 days before the three-month follow-up interview, as well as less needle-related HIV risk at the three-month follow-up interview. Regarding other outcomes, case managers provided considerable services both to and on behalf of participants, but participants in the case management intervention did not report engagement in other services at a higher level than those not assigned to case management.

The results support the utility of case management as a linkage strategy. In comparison to usual care, case management was supported both as a single treatment-engagement strategy and in combination with a voucher. Thus this study builds upon two randomized trials (Lidz et al., 1992; Mejta et al., 1997), which found that case management is an effective strategy for linking drug users with substance abuse treatment. Specifically, this study extends these findings to a group of patients receiving care at a public hospital. However, the treatment-engagement rate was lower for participants assigned to case management when compared to the participants assigned to vouchers; there was no indication that recipients of case management used opiates or cocaine less often, and their reports of enrollment in other services did not differ from participants who did not receive case management.

The finding that over 90% of participants receiving vouchers were enrolled in MMT at 3 months is a key result of the present study. The result extends the work of Booth et al. (2003), in which vouchers engaged two-thirds of street-recruited drug users into MMT. The higher rate of treatment-enrollment in the current study may be due to several factors: The participants may have been amenable to change due to medical problems that brought them to the hospital, the MMT program was located at the same



institution where they were receiving medical care, and the voucher provided access to 6 months of treatment (compared to the 3-month vouchers used in the Booth et al. [2003] study). Further, the voucher participants in the present study indicated less injection-related HIV risk and less opiate use through self-report. Urine toxicology, however, revealed they were more likely to have used cocaine before the 3- and 6-month follow-ups. The possible reduction in opiate use can likely be attributed to the high rate of enrollment in MMT. Some research has found decreases in cocaine use related to methadone maintenance (Borg et al., 1999), especially later in the treatment process. Other studies have found, like this one, an increase in cocaine use among patients enrolled in MMT (Best et al., 2000), thought to be related to decreased heroin dependence creating more disposable income, an effort by participants to counteract the sedating effects of methadone, or to find an alternate way to achieve intoxication when a blocking dose of methadone was achieved.

Ability to generalize from this study is restricted by study limitations that include the use of exclusion criteria and the nature of the interventions. Of 314 people screened for the study, only 126 (40%) participated. Investigation of the pre-enrollment attrition by Mitsubishi et al. (2002) indicated no differential attrition by demographic background, but those recruited from the outpatient ISIS clinic were more likely to enroll in the research. Thus, participants who were recruited from inpatient or emergency settings would likely have lower rates of treatment engagement. Thirty-nine percent of pre-enrollment attrition was attributed to people not appearing for the baseline interview, which occurred several days after recruitment. We suspect that this hiatus served as a behavioral screen, eliminating potential participants who were less motivated or less reliable. Future

research could examine the impact of this procedure on treatment engagement and participant outcomes.

There is considerable geographic variation in availability and financial coverage for both methadone treatment and case management. The current study's findings regarding the efficacy of case management or vouchers might not generalize to states or communities where the full costs of these services for medically indigent individuals are covered by local, state or federal funding. In areas where there are long waiting lists for these services, such interventions could be particularly helpful from a public health perspective, especially in light of the finding that at the 3-month assessment those in the voucher plus case management and the voucher interventions demonstrated reduced HIV risk related to needle use.

The case management and voucher interventions were developed for the present study. While they approximate how these approaches would function in community settings, they have serious limitations. First, both provided only 6 months of services. Case management seldom has such a limitation in the community. Similarly, most MMT is oriented toward longer-term care than 6 months, reflecting an understanding that the problems of opioid dependence require much more time for stabilization to occur. The 6-month time frame is thus a limitation of the present study that could be explored in further research. Although the usual care intervention was intended to approximate what would happen if the interventions were not being tested, usual care participants may have experienced disappointment when they learned they would not receive an intervention. Fortunately, follow-up rates were no worse in the usual care group, yet future research would benefit from including a more carefully controlled comparison intervention using a

minimal intervention that better documents the services received by participants in the comparison group.

The longer-term outcomes and cost-outcomes of these linkage strategies are unknown. We are continuing to follow the participants and are gathering information on service utilization, in order to address some of these issues in the future.

In an era of scarce resources and integrated behavioral medicine, there is a need to direct patients to the services that can help them. In the present study the voucher for 6 months of MMT appears to have been particularly effective as a linkage strategy. One view of the results is that this patient population is in significant need of methadone treatment, and health planners could use a voucher approach to make treatment more available to this treatment-resistant population. Alternatively, the high rate of treatment engagement among voucher participants may be an example of the services that these patients would seek if greater funds were available for methadone treatment in the community. Whether the issue is patient resistance or societal under-funding, treatment engagement approaches such as those studied here can be valuable in health settings as a strategy to increase entry of substance users with medical problems into the drug abuse treatment system.

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Table 1

*Background of Participants Randomly Assigned to Linkage Strategies*

Variable	Case management (n=32)	Vouchers (n=30)	Case management + vouchers (n =32)	Usual care (n =32)	Total sample (N =126)
Age in years <sup>a</sup>	42.7±7.63	43.3±7.79	42.7±8.02	43.0±9.55	43 ±8.20
Years of education	12.4±2.89	11.0±1.82	12.4±2.12	12.6±1.74	12.8 ± 4.00
Gender (%) <sup>b</sup>					
Men	75	80	72	81	77
Women	25	20	28	19	23
Ethnicity (%)					
Caucasian	47	43	53	47	48
African-American	23	30	31	31	29
Latino	16	13	6	3	10
Asian	3	0	3	0	2
Other/Mixed	11	14	7	19	13
Sexual orientation (%)					
Heterosexual	84	90	84	91	87
Homosexual	9	3	13	3	7
Bisexual	7	7	3	6	6
Married (%)	9	0	0	19	7
Homeless (%) <sup>c</sup>	78	90	88	75	83

<sup>a</sup> Continuous variables are expressed as mean +/- standard deviation.<sup>b</sup> All percentages rounded to nearest whole number.

Variable	Case management ( <i>n</i> =32)	Vouchers ( <i>n</i> =30)	Case management + vouchers ( <i>n</i> =32)	Usual care ( <i>n</i> =32)	Total sample ( <i>N</i> =126)
Employed (full or part-time) (%)	3	3	6	0	3
Yearly income LT \$10,999 (%)	81	83	59	66	72
Thoughts about abstinence %)					
Ideal goal: Quit using heroin	88	73	84	88	83
Real expectation: Quit using	31	33	37	18	30
How hard to quit: very hard	66	50	56	59	58
Smoke cigarettes (%)	93	86	91	97	92
Age of 1 <sup>st</sup> heroin use	28.7±8.97	22.9±7.97	24.0±7.72	24.3±9.27	25 ±8.70
Years of lifetime heroin use	14.0±8.86	20.4±9.79	18.7±10.89	18.7±11.99	17.9 ± 10.60
Prior drug abuse treatment episodes	10.4±8.67	7.7±6.74	7.5±6.46	11.2±11.29	9 ±8.60

<sup>c</sup> Defined as no stable living arrangement, e.g. living on streets or in shelters.

Table 2

*Outcome Measures by Assessment and Treatment Condition: Percentages, Means, Standard Deviations, and Medians*

Outcome	Month	Case management	Vouchers	Case management + vouchers	Usual care
% MMT <sup>a</sup>	3	46.7	88.5	93.1	11.1
	6	48.3	67.9	79.3	20.7
% Opiate-negative <sup>b</sup>	3	27.6	52.0	41.4	26.9
	6	57.1	71.4	62.1	65.4
Mean (SD) median					
Other services <sup>c</sup>	3	2.3 (1.35) 2	2.5 (1.82) 2	1.9 (1.57) 1	2.1 (1.27) 2
	6	1.9 (1.26) 2	1.9 (1.41) 1.5	2.1 (1.42) 2	1.96 (1.35) 2
Physical health	3	43.9 (12.18)	38.6 (13.59) 41.1	46.1 (10.56)	43.6 (11.68)
		43.8		45.6	47.3
	6	45.3 (10.51)	40.4 (11.94) 38.9	44.0 (10.98)	42.1 (13.12)
		46.1		44.5	45.1

<sup>a</sup> MMT = methadone maintenance treatment

<sup>b</sup> Opiate-negative = opiate-negative urine toxicology

<sup>c</sup> Other services = medical, employment, alcohol, drug (not MMT), legal, family, psychological

Table 3

*Summary and Test Statistics for Primary Hypotheses*

Outcome	Hypothesis	Month	No voucher %	Voucher %	Pearson's $\chi^2$	p-value	OR (95% CI)
% MMT <sup>a</sup>	1	3	29.8	90.9	43.4	< .0001	23.5 (8.9 – 69.3)
		6	34.5	73.7	17.8	< .0001	5.3 (2.4 – 11.8)
% Opiate negative <sup>b</sup>	3	3	27.3	46.3	4.2	.04	2.30 (1.03 – 5.11)
		6	38.2	33.3	0.37	.54	0.79 (0.36 – 1.71)

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*Note.* All tests 1 *df*

<sup>a</sup> MMT = methadone maintenance treatment

<sup>b</sup> Opiate- negative = opiate- negative urine toxicology

Outcome	Hypothesis	Month	Other 3	Case	Pearson's	p-value	OR (95% CI)
			conditions%	management + vouchers %	$\chi^2$		
	4	3	35.0	41.4	0.37	.54	1.31 (0.55 – 3.13)
		6	64.6	62.1	0.06	.80	1.12 (0.47 – 2.68)
Mean N other services <sup>c</sup>	Hypothesis	Month	No case	Case	Wilcoxon		
			management %	management %	statistic		
	2	3	2.28	2.12	0.57	.5714	-
		6	1.94	2.0	-0.25	.8007	-

<sup>c</sup> Other services = medical, employment, alcohol, drug (not MMT), legal, family, psychological

Table 4  
Number of Activities Provided by Case Managers

Service Feature	Number	%
<b>Purpose</b>		
Engagement	204	4
Accessing resources	2,233	40
Legal	350	6
Needs assessment	411	7
Monitoring	2,437	43
Tracking	513	9
Planning	1,194	22
Advocacy	338	6
Emotional support	475	9
Crisis intervention	24	0
Other	88	2
<b>Activity type</b>		
Visit	2,135	38
Telephone	2,913	52
Letter	180	3
FAX	75	1
Record search	187	3
Other	97	2
<b>Direction</b>		
To participant	619	13
From participant	1,291	27
To other <sup>a</sup>	2,172	46

<sup>a</sup> Other includes: program, family member/friend, medical/psychiatric provider, attorney/police/bail bonds.

	From other <sup>a</sup>	647	14
<hr/>			
Time			
	Visit/effort	6,1504	81
	Travel	7181	9
	Tracking	7284	10
<hr/>			
Contact made (if applicable)			
	Yes	5,073	94
	No	299	6
<hr/>			
Referral made			
	Yes	344	6
	No	5,242	94
<hr/>			
Item provided <sup>b</sup>			
	Yes	519	9
	No	5,586	92
<hr/>			

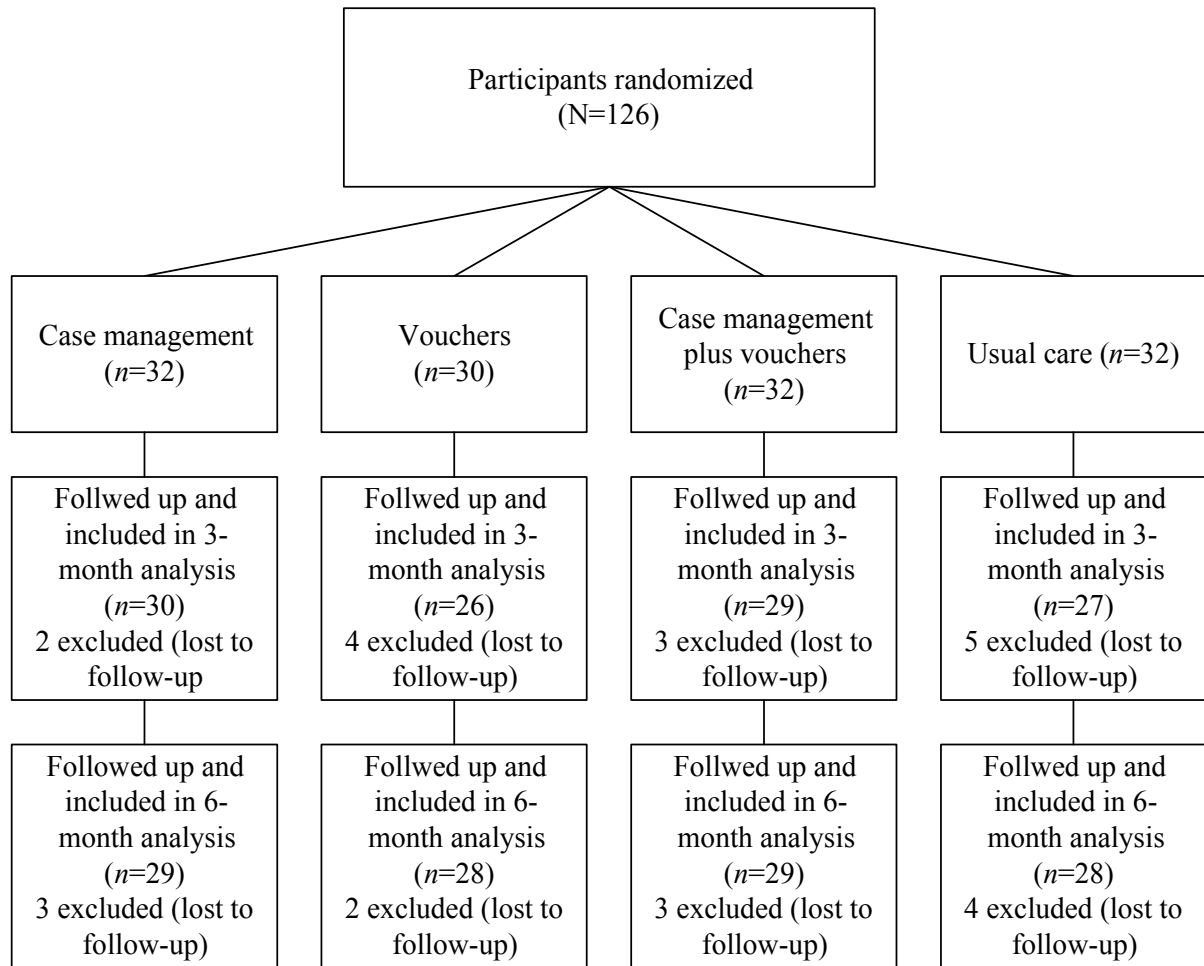
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<sup>b</sup> Item includes: food coupons, coffee, cookies, bus tokens.



Figure Captions

*Figure 1.* Participant flow through the study



CONSORT Checklist of items to include when reporting a randomized trial

PAPER SECTION And topic	Item	Description	Reported on Page #
<i>TITLE &amp; ABSTRACT</i>	1	<a href="#">How participants were allocated to interventions</a> (e.g., "random allocation", "randomized", or "randomly assigned").	3
<i>INTRODUCTION</i> Background	2	<a href="#">Scientific background and explanation of rationale.</a>	4-7
<i>METHODS</i> Participants	3	<a href="#">Eligibility criteria for participants</a> and the <a href="#">settings and locations where the data were collected.</a>	8-10
Interventions	4	<a href="#">Precise details of the interventions intended for each group and how and when they were actually administered.</a>	11-14
Objectives	5	<a href="#">Specific objectives and hypotheses.</a>	7-8
Outcomes	6	<a href="#">Clearly defined primary and secondary outcome measures</a> and, when applicable, any <a href="#">methods used to enhance the quality of measurements</a> (e.g., multiple observations, training of assessors).	8
Sample size	7	<a href="#">How sample size was determined</a> and, when applicable, <a href="#">explanation of any interim analyses and stopping rules.</a>	17
Randomization -- Sequence generation	8	<a href="#">Method used to generate the random allocation sequence, including details of any restrictions</a> (e.g., blocking, stratification)	11
Randomization -- Allocation concealment	9	<a href="#">Method used to implement the random allocation sequence</a> (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	11
Randomization -- Implementation	10	<a href="#">Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.</a>	11
Blinding (masking)	11	<a href="#">Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment.</a> When relevant, <a href="#">how the success of blinding was evaluated.</a>	11
Statistical methods	12	<a href="#">Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses,</a> such as subgroup analyses and adjusted analyses.	17-18
RESULTS Participant flow	13	<a href="#">Flow of participants through each stage</a> (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. <a href="#">Describe protocol deviations from study as planned, together with reasons.</a>	41
Recruitment	14	<a href="#">Dates defining the periods of recruitment and follow-up.</a>	9-10
Baseline data	15	<a href="#">Baseline demographic and clinical characteristics of each group.</a>	33-34
Numbers analyzed	16	<a href="#">Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat".</a> State the results in absolute numbers when feasible (e.g., 10/20, not 50%).	41
Outcomes and estimation	17	<a href="#">For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision</a> (e.g., 95% confidence interval).	36-37
Ancillary analyses	18	<a href="#">Address multiplicity by reporting any other analyses performed,</a> including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.	20-22
Adverse events	19	<a href="#">All important adverse events or side effects in each intervention group.</a>	NA
DISCUSSION Interpretation	20	<a href="#">Interpretation of the results,</a> taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated	22-26

		with multiplicity of analyses and outcomes.	
Generalizability	21	<a href="#">Generalizability (external validity) of the trial findings.</a>	24-25
Overall evidence	22	<a href="#">General interpretation of the results in the context of current evidence.</a>	23-24