Buprenorphine and methadone maintenance in jail and post-release: A randomized clinical trial

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Abstract

Buprenorphine has rarely been administered as an opioid agonist maintenance therapy in a correctional setting. This study introduced buprenorphine maintenance in a large urban jail, Rikers Island in New York City. Heroin-dependent men not enrolled in community methadone treatment and sentenced to 10–90 days in jail (N=116) were voluntarily randomly assigned either to buprenorphine or methadone maintenance, the latter being the standard of care for eligible inmates at Rikers. Buprenorphine and methadone maintenance completion rates in jail were equally high, but the buprenorphine group reported for their designated post-release treatment in the community significantly more often than did the methadone group (48% vs. 14%, p<.001). Consistent with this result, prior to release from Rikers, buprenorphine patients stated an intention to continue treatment after release more often than did methadone patients (93% vs. 44%, p<.001). Buprenorphine patients were also less likely than methadone patients to withdraw voluntarily from medication while in jail (3% vs. 16%, p<.05). There were no post-release differences between the buprenorphine and methadone groups in self-reported relapse to illicit opioid use, self-reported re-arrests, self-reported severity of crime or re-incarceration in jail. After initiating opioid agonist treatment in jail, continuing buprenorphine maintenance in the community appears to be more acceptable to offenders than continuing methadone maintenance.

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1. Introduction

Opioid dependence/abuse represents a significant problem among the criminal justice population both in the U.S.A. and internationally. Urinalysis at booking from arrested felons in major cities nationally showed that the percentage of males and females, respectively, who tested positive for opiates ranged from 12% to 25% and 13% to 23% in 2003 (the last year of data) (National Institute of Justice, 2004). In France, 30% of prison inmates are heroin-addicted (Michel and Maguet, 2005); in Germany, 13% of prison inmates are injecting drug (presumably primarily heroin) users (Michels et al., 2007); and in Australia, 59% of prison inmates report injecting drug (primarily heroin) use histories (Butler et al., 2007). Heroin use among offenders has serious health and social consequences. Injection, which is still the primary route of administration among the general population of heroin users, is strongly associated with the transmission of HIV, hepatitis C and other blood-borne diseases (Amon et al., 2008; Beyrer, 2007). The relationship between heroin abuse and criminal activity has been extensively documented (Anglin and Perrochet, 1998; McBride and McCoy, 1993; White and Gorman, 2000). Offenders also have a high risk of death from opioid overdose within 2 weeks of release from incarceration (Binswanger et al., 2007; Bird and Hutchinson, 2003). Jails and
prisons offer prime opportunities to engage opioid-dependent offenders in treatment that can be continued into the community after release (National Institute on Drug Abuse, 1999).

Methadone maintenance has been the primary treatment for chronic opioid dependence since the 1970s. At least 20 countries provide methadone maintenance in prison or jails (Catania, 2003), including the Netherlands (Langendam et al., 1998), Australia (Hall et al., 1993; Dolan et al., 2003), Spain (Perez de los Cobos et al., 2004) and Canada (Haig, 2003); for a review, see Stallwitz and Stöver (2007). Methadone maintenance has not been generally available in correctional systems in the U.S., with only a half-dozen exceptions, including pilot programs (National Association of State Alcohol and Drug Abuse Directors, 2006; Magura et al., 1993; Kinlock et al., 2007). A national survey of U.S. jails found that 12% offered continuation of methadone for inmates who were in methadone treatment when incarcerated (Fiscella et al., 2004), but not for inmates out of treatment when incarcerated.

A major obstacle to expanded access to methadone maintenance for inmates in the U.S. is the unfortunate and undeserved stigma that has come to be associated with it, i.e., a common belief among the public (Blansfield, 1996), treatment providers (Kang et al., 1997), and public authorities, including the criminal justice system (Simpson and Knight, 1998; Westermeyer, 2000; McMillan and Lapham, 2005), that methadone “substitutes one addiction for another” and is not a true tool of recovery. For example, staff of a large Southwestern jail “described a tremendous amount of animosity towards drug addicts and lumped methadone maintenance treatment recipients together with heroin addicts and criminals.” They were also concerned about methadone’s euphoria-inducing potential: “methadone is just another crutch, a way to stay numb” (McMillan and Lapham, 2005). The federal Probation Manual contains specific anti-methadone statements (Administrative Office of U.S. Courts, 1994). Further, heroin-dependent people in general (Hunt et al., 1985; Goldsmith et al., 1984; Zule and Desmond, 1998) and offenders in particular (Rosenblum et al., 1991) express a great deal of ambivalence about long-term methadone maintenance, including fears about bone decalcification, overdosing and becoming unable to withdraw from the medication, as well as its persistent social stigma. Although many of these attitudes and beliefs are inaccurate, they have inhibited expansion of methadone maintenance in correctional settings.

Buprenorphine has certain potential advantages over methadone as a treatment for opioid-addicted jail inmates and other criminal justice populations. First, buprenorphine does not appear to carry the societal stigma attributed to methadone. Second, the criminal justice system is sensitive to potential objections that, through treatment, offenders might be rendered dependent on a drug that offers a “substitute high” and is “tough to kick.” In that regard, buprenorphine has lesser subjective agonist effects and milder medication withdrawal as compared with methadone (Lewis, 1985; Walsh et al., 1995, 1994; Eisenberg et al., 1997; Jasinski et al., 1978; Rance and Dickens, 1978). Finally, the combination buprenorphine/naloxone tablet is intended to precipitate withdrawal in opiate-tolerant persons when injected (Fudala et al., 1998; Alho et al., 2007) and, unless the person is in partial withdrawal already, when taken orally as well (Center for Substance Abuse Treatment, 2004: 50), making it relatively unattractive for diversion.

Buprenorphine appears to have been used as an opioid agonist therapy in prison only in France (Reynaud-Maurupt et al., 2005), Austria (Catania, 2003) and Puerto Rico (Garcia et al., 2007). The current study was a randomized clinical trial to compare the effectiveness of buprenorphine vs. methadone maintenance for opioid-dependent jail inmates. Methadone maintenance is the current standard of care for legally eligible opioid-dependent jail inmates in New York City. Research has shown that methadone and buprenorphine are both highly efficacious treatments for chronic opioid dependency (e.g., Johnson et al., 2000). The objective of the study’s comparison of these medications was to determine whether buprenorphine is at least as effective as methadone when initiated in a jail setting, since if would be difficult to recommend a medication that is less effective than the current standard of care, whatever its potential advantages for correctional systems.

2. Method

2.1. Setting

The setting of the study was the Key Extended Entry Program (KEEP) delivered by Prison Health Services with oversight by the New York City Department of Health and Mental Hygiene (DOHMH) within the Rikers Island jail complex in New York City. During FY2007 109,000 offenders were admitted to Rikers, of whom 15,838 received opioid withdrawal service using methadone and 4836 received methadone maintenance through KEEP within the jail. KEEP participants receive referrals to participating community methadone programs at the time of their release. The eligibility criteria for KEEP methadone maintenance are opioid dependence and (1) a sentence of up to 1 year of jail time or (2) being detained in jail on legal charges that will not result in a jail sentence of more than 1 year, if convicted (Tomasino et al., 2001). The study was conducted at the Eric M. Taylor Center (EMTC) facility for sentenced men at Rikers. The DOHMH indicated that it was not feasible in terms of staff time commitment to extend this pilot study to women inmates, who are housed in a separate facility. The study was given the operational title of Rikers Addiction Medication Study (RAMS).

2.2. Participants

Inclusion criteria:

• Inmates who were eligible for the Key Extended Entry Program (KEEP).
• 18–65 years of age.
• Sentenced to at least 10 days but less than 90 days of jail time. (This was more restrictive than KEEP, to allow time for post-release follow-up.)
• Expected to reside in New York City after release.

Exclusion criteria:

• Receiving methadone treatment in the community at remand to Rikers. (Such inmates are offered continuity of methadone maintenance by KEEP at the doses they received in the community.)
• Took non-prescribed “street” methadone within the previous 3 days.
• Currently receiving more than 20 mg/day of prescribed methadone.
• Current psychotic symptoms (e.g., schizophrenia, schizoaffective disorder) requiring referral for psychiatric intervention or currently treated with antipsychotic medication.
• HIV infection with T-lymphocytes less than 200/mm of blood and/or presence of a serious opportunistic infection requiring treatment, or receiving the HIV medication atazanavir.
• Unable to complete an English-language interview.
2.3. Recruitment

All inmates admitted to Rikers are evaluated for opioid dependence by KEEP intake staff. Those diagnosed as opioid-dependent and without medical contraindications are offered an opioid withdrawal protocol with methadone. If they accept, they are administered a dose of 20 mg of methadone. Inmates who initiate the withdrawal protocol are also evaluated for legal eligibility for methadone maintenance by KEEP intake staff. If inmates met the criteria for methadone maintenance and also appeared to be eligible for the present study, they were screened by the study’s research assistant. The research assistant explained the study to them, confirmed their eligibility for the study and, if the inmate was eligible and agreed to consider study participation, administered the informed consent. Study recruitment occurred from August 2006 to 2007.

2.4. Assignment to study conditions

Inmates providing informed consent were assigned either to the buprenorphine or methadone maintenance conditions, the latter being treatment as usual.
Pre-numbered envelopes were used with the treatment assignment inside the sealed envelopes. These envelopes were created by the project director using a random numbers generator; he was not involved in subject recruitment. When a treatment assignment needed to be made, the research assistant at Rikers opened the next consecutively numbered envelope to receive the assignment, which was immediately shared with the subject.

The great majority of subjects (87%) were assigned using simple random assignment at a 1:1 ratio. Due to the requirements of buprenorphine induction, however, 22% of the buprenorphine-assigned subjects were never medicated with buprenorphine, whereas all the methadone-assigned patients were stepped up to maintenance doses of methadone. Thus, in order to keep the mediated buprenorphine and methadone groups about equal in size, we also used treatment-adaptive randomization (Chow and Chang, 2007); specifically, we periodically adjusted the treatment allocation ratio to overweight buprenorphine assignment at 7:3. The reason not all buprenorphine-assigned subjects were mediated is as follows. Subjects assigned to methadone maintenance generally were stepped up from 20 to 30 mg. In contrast, subjects assigned to buprenorphine could rarely be medicated with buprenorphine on the day of assignment, since they already would have received a 20 mg methadone dose as part of the opioid withdrawal protocol at Rikers. The earliest that buprenorphine induction could occur was on the next day (at least 24 h after their last methadone dose). However, availability of medical staff to perform inductions was variable and often induction did not occur for 2 or 3 days. This was because study resources were not sufficient to supplement medical staff resources for buprenorphine induction and because other medical and correctional facility priorities sometimes pre-empted scheduled inductions. The consequence was that there was some attrition among the buprenorphine-assigned subjects before they could be medicated, including no-shows and changes of mind about participating (see Fig. 1, CONSORT diagram).

2.5. Interventions

**Methadone:** Subjects in the methadone maintenance condition received medication in the usual manner, waiting in a line at a window where liquid methadone was dispensed once daily. The usual initial maintenance dose was 30 mg/day which subsequently could be stepped up to a maximum of 70 mg/day if clinically indicated and the subject agreed.

**Buprenorphine:** The sublingual combination buprenorphine/naloxone tablet (Suboxone®) was used both for induction and maintenance. KEEP physicians prescribed the medication. Subjects received an initial dose of 4 mg which could be stepped up to a maximum of 8 mg on the first day. On subsequent days the subject could be stepped up to a maximum of 32 mg, if clinically indicated and the subject agreed. Subjects received their medication in a medical waiting area where they were observed by staff until verification that the medication was dissolved, usually in 5–10 min. Subjects were required to keep their faces and hands in view and not touch their mouths.

**Procedures:** Subjects received treatment until they became ineligible for further maintenance treatment, were discharged from Rikers, or voluntarily withdrew from treatment. Upon discharge buprenorphine subjects were referred to the buprenorphine treatment site of their choice from ten sites in New York City that had agreed to accept patients from Rikers, even if the patients did not have Medicaid or other insurance. Methadone subjects were referred to the methadone treatment site of their choice among 12 that were linked to the Rikers KEEP program. For the methadone condition, at least one treatment site was available in each of the five NYC boroughs (counties); for buprenorphine one or more treatment sites were available in all boroughs except Staten Island. KEEP staff provided patients due for release with a referral sheet and notified the named program or provider by telephone that the patient was being referred to them.

The study was approved by the Institutional Review Boards of National Development and Research Institutes (NDRI) and DOHMH. The ClinicalTrials.gov identifier is NCT00367302.

2.6. Assessments

Subjects completed a baseline psychosocial research interview conducted by the research assistant on the day of entry to the study or within the next several days; a brief exit interview within 1 week before their scheduled release date; and a follow-up interview 3 months after release. The baseline and follow-up interviews obtained data on the outcome measures as follows. Substance use was measured by asking subjects on how many days specific drugs were used in the 30 days prior to their arrest (baseline) or in the past 30 days (follow-up). If they had been re-arrested, they were asked about the 30 days prior to their re-arrest. Regarding re-involvement with criminal justice, subjects were asked, “since your release from Rikers on (date), how many times have you been arrested?” If re-arrested, they were read a list of specific offenses and were asked if any arrest led several inmates to reconsider buprenorphine treatment, whereas inmates in induction due to the requirements of buprenorphine and systemic obstacles were beyond the control of the inmates, as explained above, resulting in different rates of medication for the buprenorphine and methadone groups. The delay in induction due to the requirements of buprenorphine and systemic obstacles led several inmates to reconsider buprenorphine treatment, whereas inmates in the methadone condition experienced no delays and did not have an equivalent opportunity to reconsider. Further, inmates not medicated with buprenorphine did not receive referrals for buprenorphine maintenance in the community. Continuation of treatment in the community was a primary study outcome measure; inmates could not continue treatment if they never received treatment at Rikers in the first place. Consequently, interview follow-ups were attempted for 60 buprenorphine subjects, of whom 43 (72%) were interviewed at follow-up, and for 56 methadone subjects, of whom 38 (68%) were interviewed (see Fig. 1). The overall interview follow-up rate was 70%, with no statistically significant difference between the two conditions. Based on the locator information provided at baseline, subjects were contacted by telephone or mail. If they returned to Rikers in the interim, they were contacted at Rikers. The interviews were conducted as follows: telephone (46%), in-person at Rikers after re-arrest (47%), and in-person outside Rikers (7%). The study had no resources to conduct street searches. The primary reason for lack of follow-up interviews was inability to locate the subjects (see Fig. 1). Post-release treatment admission status (acquired from the assigned treatment program or provider) was obtained for all study subjects.

2.7. Follow-up

All subjects who were medicated with buprenorphine or who received maintenance doses of methadone were eligible for the 3-month post-release follow-up interview. Buprenorphine-assigned subjects who were not medicated were not followed-up and thus not included in the analysis. This is because buprenorphine induction presented special barriers in this correctional facility, which were beyond the control of the inmates, as explained above, resulting in different rates of medication for the buprenorphine and methadone groups. The delay in induction due to the requirements of buprenorphine and systemic obstacles led several inmates to reconsider buprenorphine treatment, whereas inmates in the methadone condition experienced no delays and did not have an equivalent opportunity to reconsider. Further, inmates not medicated with buprenorphine did not receive referrals for buprenorphine maintenance in the community. Continuation of treatment in the community was a primary study outcome measure; inmates could not continue treatment if they never received treatment at Rikers in the first place. Consequently, interview follow-ups were attempted for 60 buprenorphine subjects, of whom 43 (72%) were interviewed at follow-up, and for 56 methadone subjects, of whom 38 (68%) were interviewed (see Fig. 1). The overall interview follow-up rate was 70%, with no statistically significant difference between the two conditions. Based on the locator information provided at baseline, subjects were contacted by telephone or mail. If they returned to Rikers in the interim, they were contacted at Rikers. The interviews were conducted as follows: telephone (46%), in-person at Rikers after re-arrest (47%), and in-person outside Rikers (7%). The study had no resources to conduct street searches. The primary reason for lack of follow-up interviews was inability to locate the subjects (see Fig. 1). Post-release treatment admission status (acquired from the assigned treatment program or provider) was obtained for all study subjects.

2.8. Outcome measures

The primary outcome measures were treatment completion while in jail and reporting to the assigned treatment modality after release. Secondary outcome measures were: Intention to continue treatment after release; showing at any
medication-assisted treatment provider after release; re-incarceration; illicit opioid use after release; re-arrest; and severity of re-arrest charges. Adverse events were also documented.

2.9. Hypotheses and analyses

The study’s purpose was to determine whether buprenorphine and methadone maintenance initiated in jail would produce similar outcomes; thus no superiority hypotheses were proposed. Differences between the buprenorphine and methadone conditions were tested for significance by Fisher’s Exact Test, chi-square or analysis of variance. Continuous variables with skewed distributions were log-transformed prior to analysis. Significance was set at \( p < .05 \) (2-tailed) for all analyses.

3. Results

3.1. Characteristics of participants

There was only one significant difference between the methadone- and buprenorphine-assigned subjects on baseline characteristics—the buprenorphine-assigned group more often reported ever using buprenorphine before jail (Table 1). However, buprenorphine use history was not related significantly to any of the outcome variables. Thus, there were no baseline variables related significantly both to treatment condition and any of the outcomes.

3.2. Primary outcomes

Eighty-two percent of buprenorphine and 75% of methadone patients completed their assigned treatment while in jail; there was no significant difference between the conditions (Table 2). The median medication doses at release, for those not withdrawn before release, were 12 mg/day of buprenorphine (range 4–20 mg) and 30 mg/day of methadone (range 10–70 mg). Those not completing treatment in jail either voluntarily withdrew from medication (nine methadone vs. two buprenorphine patients, \( p < .05 \)) or were administratively withdrawn (see adverse events, below). Voluntary withdrawals from treatment included reasons such as not wanting to be “dependent on methadone,” saying “didn’t need it,” “wanted to kick on his own,” or wanted buprenorphine instead.

Methadone patients were in treatment at Rikers significantly longer than buprenorphine patients (31.8 days vs. 23.2 days, \( p < .05 \)), but the difference became non-significant when administratively discharged patients were excluded from the comparison, because buprenorphine patients were somewhat more likely to receive early administrative discharges (see adverse events for explanation, below).

The buprenorphine group reported for their designated post-release treatment in the community significantly more often than did the methadone group (48% vs. 14%, \( p < .001 \)) [Table 2].

3.3. Secondary outcomes

Before discharge from Rikers, buprenorphine patients stated an intention to continue treatment after release more often than did methadone patients (93% vs. 44%, \( p < .001 \)); which is consistent with the above post-release treatment-reporting pattern.

### Table 1
Baseline characteristics of study participants by treatment condition

<table>
<thead>
<tr>
<th></th>
<th>BUP (( n = 60 ))</th>
<th>Methadone (( n = 56 ))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>38.4 (7.9)</td>
<td>40.7 (9.1)</td>
</tr>
<tr>
<td>Arrests as adult</td>
<td>22.3 (16.2)</td>
<td>21.8 (18.2)</td>
</tr>
<tr>
<td>Substance use, no. days in last 30 before jail</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heroin or other non-prescribed opioid use</td>
<td>28.0 (6.4)</td>
<td>28.6 (4.8)</td>
</tr>
<tr>
<td>Heroin</td>
<td>27.9 (6.5)</td>
<td>28.6 (4.8)</td>
</tr>
<tr>
<td>Other non-prescribed opioid use</td>
<td>2.3 (4.5)</td>
<td>1.6 (3.4)</td>
</tr>
<tr>
<td>“Street” methadone</td>
<td>2.2 (4.5)</td>
<td>1.5 (3.4)</td>
</tr>
<tr>
<td>Other illicit prescription opioid use</td>
<td>0.4 (1.6)</td>
<td>0.9 (3.3)</td>
</tr>
<tr>
<td>Alcohol, heavy use (4 or more drinks per day)</td>
<td>4.4 (10.5)</td>
<td>4.4 (10.0)</td>
</tr>
<tr>
<td>Cocaine/crack</td>
<td>12.3 (13.5)</td>
<td>11.2 (13.1)</td>
</tr>
<tr>
<td>Sedative/tranquilizers</td>
<td>0.7 (2.2)</td>
<td>1.4 (5.1)</td>
</tr>
</tbody>
</table>

**Note:** No other comparisons were statistically significant.

* After methadone, the next most frequently reported prescription opioids were oxycodone and hydrocodone.

+ Prescribed or non-prescribed use. There were no reports of any buprenorphine use in the past 30 days before incarceration.

<table>
<thead>
<tr>
<th>Medication-Assisted Treatment History</th>
<th>%</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ever in community methadone treatment</td>
<td>45</td>
<td>48</td>
</tr>
<tr>
<td>Ever methadone treatment in jail in NYC</td>
<td>73</td>
<td>80</td>
</tr>
<tr>
<td>Methadone in jail, past 6 months</td>
<td>20</td>
<td>11</td>
</tr>
<tr>
<td>Ever prescribed buprenorphine</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>Ever used buprenorphine*</td>
<td>28</td>
<td>11*</td>
</tr>
</tbody>
</table>

Buprenorphine patients showed more often at a medication-assisted treatment provider than did methadone patients (48% vs. 23%, \( p < .005 \)). Five of the 56 methadone-assigned patients went to a buprenorphine provider rather than a methadone clinic after release, but no buprenorphine-assigned patients went to a methadone clinic.

There were no post-release differences between the buprenorphine and methadone groups in re-incarceration rates at Rikers, self-reported relapse to illicit opioid use, self-reported re-arrests, or the self-reported severity of re-arrest charges, as indicated by violent, property or drug possession offenses (Table 2).

3.4. Adverse events

No serious adverse events (SAEs) were observed or reported by subjects during the course of the study. The Social Security Death Master file (ssdmf.com) did not reveal any deaths between study intake and the post-release 3-month follow-up. However, as 30% of the subjects could not be interviewed at follow-up, it is possible that other kinds of SAEs might be underestimated, i.e.,
Table 2
Treatment outcomes

<table>
<thead>
<tr>
<th></th>
<th>BUP (n = 60)</th>
<th>Methadone (n = 56)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completed treatment in jail</td>
<td>82%</td>
<td>75%</td>
<td>ns</td>
</tr>
<tr>
<td>Reported to assigned treatment modality after release(a)</td>
<td>48%</td>
<td>14%</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Intended to continue treatment after release(b)</td>
<td>93%</td>
<td>44%</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Showed at a medication-assisted treatment provider after release</td>
<td>48%</td>
<td>23%</td>
<td>&lt;.005</td>
</tr>
<tr>
<td>Re-incarceration at Rikers</td>
<td>40%</td>
<td>50%</td>
<td>ns</td>
</tr>
<tr>
<td>3-Month follow-up interview (self-reports)</td>
<td>BUP (n = 43)</td>
<td>Methadone (n = 38)</td>
<td>p</td>
</tr>
<tr>
<td>Any heroin or non-prescribed opioid use, last 30 days</td>
<td>Mean = 13.7 S.D. = 14.3</td>
<td>Mean = 14.4 S.D. = 13.4</td>
<td>ns</td>
</tr>
<tr>
<td>Arrested after release(c)</td>
<td>53%</td>
<td>66%</td>
<td>ns</td>
</tr>
<tr>
<td>Arrested for a property crime(d)</td>
<td>26%</td>
<td>18%</td>
<td>ns</td>
</tr>
<tr>
<td>Arrested for drug possession(d)</td>
<td>14%</td>
<td>24%</td>
<td>ns</td>
</tr>
<tr>
<td>Arrested for a violent crime(d)</td>
<td>0%</td>
<td>0%</td>
<td>ns</td>
</tr>
</tbody>
</table>

Note: All analyses were re-run with the baseline variable, “ever used buprenorphine,” as a control in OLS or logistic regression analyses. Originally significant associations between treatment condition and outcomes remained significant and originally non-significant associations remained non-significant.
\(a\) Seven of the 60 BUP subjects were not referred to a specific community buprenorphine provider due to administrative miscommunication.
\(b\) Three subjects did not answer this question.
\(c\) Five methadone-assigned subjects showed at one of the buprenorphine providers.
\(d\) BUP (n = 42); one subject responded “don’t know” to arrest question.

hospitalizations due to medication side effects. There were some adverse events (AEs) during treatment in jail. Six buprenorphine subjects and one methadone subject were administratively withdrawn from medication due to suspicion of attempted diversion. One buprenorphine subject and one methadone subject discontinued treatment due to perceived side effects (headache and “nodding all the time,” respectively). One buprenorphine subject was administratively withdrawn because he insulted a nurse. Several subjects also were administratively withdrawn because they lost their eligibility for maintenance treatment, two because of transfer to another facility or program and two because charges in their cases had been upgraded making possible sentences of more than 1 year and transfer to prison.

4. Discussion

Although this clinical trial was uniquely feasible in the New York City jail system, its major implications are for correctional institutions nationally outside New York City as well as internationally. The study indicates that the outcomes of buprenorphine and methadone treatment initiated in a jail setting are similar in most respects; thus decisions about which to use (including using both) may be based on clinical and administrative considerations in specific jurisdictions.

Buprenorphine did appear to be more effective than methadone for offenders in one respect, which is the greater expressed interest and willingness of jail inmates who were not in methadone treatment at arrest to continue buprenorphine rather than methadone treatment in the community after release. These results were quite dramatic, with virtually all the buprenorphine group stating an intention to continue after release and one in two of the buprenorphine group vs. one in seven of the methadone group reporting to their assigned treatment after release. The necessity of receiving medication in highly regulated methadone programs, rather than through more flexible clinic- and office-based buprenorphine providers (flexibility allowed by the federal buprenorphine regulations), may help explain the higher rate of reporting for buprenorphine treatment after release. This finding for New York City may not be generalizable to other nations, however, depending on the nature of the dispensing regulations for methadone and buprenorphine in addiction treatment. (Note that persons enrolled in methadone treatment at arrest who receive methadone maintenance at the Rikers jail return to community methadone maintenance at a high rate [Magura et al., 1993]).

There were differences in the costs of administering buprenorphine and methadone. Medical/nursing staff and correctional officers devoted about 15 min per inmate per day in preparing for, dispensing and monitoring the ingestion of buprenorphine tablets during the post-induction period, as compared with 1–3 min in providing liquid methadone. Thus, Rikers KEEP administrators estimate that about ten times as many inmates can be served with methadone as with buprenorphine with the same staff resources. Since methadone is well-integrated in the medical care system at Rikers and is cost-effective, a general switch to buprenorphine would not be feasible or warranted there.

This is reinforced by the difficulty of having physicians reimbursed or adequately reimbursed for buprenorphine treatment for released inmates in New York. New York State policy dictates that inmates lose their Medicaid eligibility and must reestablish it after release (Freudenberg, 2001). This currently makes it impossible to provide continuity of buprenorphine treatment after release, except with a small number of community providers who do not require Medicaid coverage, at least not initially. In addition, many individual buprenorphine-certified physicians in New York City will not accept Medicaid coverage for buprenorphine treatment, because the rates are too low and the paperwork too arduous (Magura et al., 2007). The present study was able to establish a small network of providers who,
through various special arrangements and resources, were able to accept released jail inmates for buprenorphine treatment, but this is not a general solution.

Providing for continuity of buprenorphine maintenance for released jail or prison inmates in the community is likely to be a challenge in any jurisdiction, including in other countries. Adequate reimbursement arrangements for treatment must be in place and providers may need additional support to deal with the special issues presented by released offenders, who are also attempting to reintegrate economically and socially into the community (Freudenberg, 2001).

Buprenorphine (Suboxone®) is currently about ten times as expensive as generic methadone for equipotent doses. However, because both Suboxone® and Subutex® (the formulation without naltrexone) are scheduled to end their orphan drug exclusivity status on October 8, 2009, the cost of these medications vs. methadone is less likely to be an important consideration in the future (Food and Drug Administration, 2008). Of course this assumes that a generic version will be approved and found acceptable to clinicians and patients. Also it should be noted that buprenorphine could be administered on alternate days with no loss of efficacy (Amass et al., 2000), thus saving staff time to that extent.

More buprenorphine than methadone patients tended to be administratively withdrawn from medication due to suspected diversion attempts. The conditions of medication administration made it easier for buprenorphine patients to come under suspicion, since they needed to be observed for a period of time to allow the tablets to dissolve. A variety of actions, such as any movement of a hand to the face, could be grounds for suspected diversion. Methadone, in contrast, was administered in liquid form and the nurse did an immediate check to verify that it had been swallowed. Once any prospective patient population becomes more familiar with the buprenorphine protocol, these types of events should decrease.

Buprenorphine patients were significantly less likely to request voluntary withdrawal from medication at Rikers than were methadone patients. If suspected diversion incidents could be reduced for buprenorphine patients, then buprenorphine maintenance has the potential of significantly improving treatment completion rates for opioid agonist therapy in the jail setting.

The study has several limitations. Most of the methadone-assigned patients received sub-optimal doses of methadone (30 mg), although higher doses were available, which seemed primarily due to patient preference because most did not intend to continue treatment after release. This mirrors long-standing experience with KEEP patients (Tomasino et al., 2001). Informal comments from patients suggested they wished to avoid the risk of severe withdrawal from methadone after release. In addition, clinicians tended to advocate for higher doses only when observing symptoms of opioid withdrawal. It should be recognized that such issues are what distinguish effectiveness studies conducted under real world conditions from efficacy studies, where adequate dosing is paramount.

The sample size is modest due to the study’s limited funding mechanism. The 70% interview follow-up rate is only marginally adequate for behavioral research; because individuals not located for interviews may have poorer outcomes, the study results may be less favorable than reported. Future research should include sufficient funding for intensive follow-up efforts. The results are based on one jail setting and may not be generalizable nationally or internationally. Lastly, only men could be included in this study for administrative reasons.

On balance, these study results offer a promising new treatment option for chronic opioid-dependent, incarcerated offenders, both in the U.S. and internationally. A larger clinical trial of buprenorphine in a different setting with both genders would be a useful avenue for further research. Equivalent research in other countries would also be useful.

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Contributors

Dr. Magura was responsible for the study concept, the application for funding and overall scientific conduct of the study. Drs. Magura, Rosenblum, Joseph, Marsch, Lee, Hershberger and Ms. Shropshire were responsible for refining the design, planning for data acquisition, monitoring study implementation and data interpretation. Dr. Rosenblum managed the day-to-day conduct of the research at Rikers and in the community. Dr. Hershberger served as the study’s Medical Director. Ms. Shropshire administered the implementation of the interventions at Rikers Island. Dr. Magura wrote the first draft of the manuscript and Dr. Rosenblum conducted the data analysis. Drs. Hershberger, Joseph, Lee, Marsch and Ms. Shropshire made important intellectual contributions to the manuscript from the perspective of medication-assisted treatment providers or researchers. Dr. Joseph implemented the acquisition of data from the community programs. All authors contributed to and approved the final manuscript.

Conflict of Interest

The authors declare they have no conflict of interests.

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References


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