Published in final edited form as:
J Offender Rehabil. 2010 February ; 49(2): 91–109. doi:10.1080/10509670903534951.

Developing and Implementing a New Prison-Based Buprenorphine Treatment Program

Timothy W. Kinlock, Ph.D.[1,2], **Michael S. Gordon, D.P.A.**[1], **Robert P. Schwartz, M.D.**[1], and **Terrence T. Fitzgerald, M.D.**[3]

[1]Friends Research Institute, Inc.

[2]University of Baltimore, Division of Criminology, Criminal Justice, & Social Policy

[3]Glenwood Life Counseling Center

Abstract

Research suggests that buprenorphine treatment may be a promising intervention for incarcerated individuals with heroin addiction histories. However, its implementation varies from corrections-based methadone because of unique challenges regarding dosing, administration, and regulation. Describing the first randomized clinical trial of prison-initiated buprenorphine treatment in the United States, this manuscript focuses on how these obstacles were overcome through collaboration among correctional, treatment, and research personnel. Building on the present authors' work in developing prison-based methadone treatment, and considering the lack of experience in implementing corrections-based buprenorphine programs in the United States, this manuscript may serve as a guide for interested corrections officials, treatment providers, and researchers.

Keywords

Prison; Substance Abuse; Buprenorphine

Introduction

The number of adults incarcerated in the United States has escalated dramatically since 1980 (Kinlock & Gordon, 2006), with approximately 2.4 million in prison or jail at the end of June, 2008 (Minton & Sabol, 2009; West & Sabol, 2009). An estimated 12-15% of these individuals have histories of heroin addiction (Karberg & James, 2005; Mumola & Karberg, 2006). Most such individuals do not receive drug abuse treatment, either during incarceration or upon release (Smith-Rohrberg, Bruce, & Altice, 2004). As a consequence, re-addiction to heroin typically occurs within one month of release from incarceration (Kinlock, Battjes, & Schwartz, 2005a), increasing the likelihood of death from overdose (Binswanger et al., 2007; Farrell & Marsden, 2008); HIV infection [Centers for Disease Control (CDC); 2006]; hepatitis B and C infections (Hagan et al., 2002); increased criminal activity (Kinlock, O'Grady, & Hanlon, 2003); and re-incarceration [Substance Abuse and Mental Health Administration (SAMHSA); 2000]. Therefore, access to effective drug treatment interventions needs to be improved for inmates with heroin addiction histories.

Despite extensive evidence of effectiveness (Johnson et al., 2000; Kleber, 2008) and its use in correctional facilities throughout the world (Jurgens, 2004), opioid agonist maintenance has

Trial Registration: ClinicalTrials.gov, NCT00574067

rarely been implemented in jails and prisons in the United States. A New York City jail methadone maintenance treatment program (MMT) which starts heroin-dependent inmates on MMT and maintains arrestees already enrolled in community-based treatment has been found effective (Magura, Rosenblum, Joseph, & Lewis, 1993; Tomasino, Swanson, Nolan, & Shuman, 2001). Unlike jail-based programs, opioid agonist maintenance programs for pre-release prison inmates are fewer and have been slower to develop. The present authors conducted two studies of prison-initiated opioid agonist maintenance with male pre-release inmates with pre-incarceration heroin addiction. A small-scale intervention with Levo-alpha-acetylmethadol (LAAM) was found to be feasible and facilitated post-release treatment entry (Kinlock et al., 2005a). A larger clinical trial showed that prison-initiated and community-initiated MMT were more effective than counseling only in terms of heroin use and treatment entry over the course of 12-months post-release (Kinlock, Gordon, Schwartz, Fitzgerald, & O'Grady, 2009).

Despite the above experiences, large-scale surveys of jail officials (Fiscella, Moore, Engerman, & Meldrum, 2004) and prison medical directors (Rich et al., 2005) in the United States found that 12% and 33%, respectively, provide MMT (the latter only to pregnant women). Preference of abstinence-based treatment and the existence of security concerns with the implementation of MMT seem to be the main reasons why many correctional personnel oppose the use of MMT in their facilities (Albizu-Garcia et al., 2007; Rich et al., 2005).

Buprenorphine in Prison

Because of these concerns regarding MMT, additional, alternative opioid agonist treatment interventions for prison and jail inmates need to be considered. LAAM was taken off the market in the United States by its manufacturer and is no longer available. Buprenorphine is highly effective in reducing heroin use in the community (Mattick et al., 2003; Montoya et al., 2004) and retaining patients in treatment (Strain, Stitzer, Liebson, & Bigelow, 1994). Buprenorphine has advantages over methadone, including less associated stigma; fewer regulations, which permit its use outside opioid treatment programs; and lower risk of overdose (Albizu-Garcia et al., 2007). Its combination with naloxone reduces the likelihood of intravenous abuse of the medication. Buprenorphine is safe and effective for alternate-day dosing instead of daily dosing [Center for Substance Abuse Treatment (CSAT), 2004], which may increase its patient adherence (Amass, Kamien, & Mikulich, 2000) and might make it less likely to interfere with security procedures in a prison setting (Smith-Rohrberg et al., 2004).

Initial examinations of buprenorphine in correctional settings in France (Levasseur, Marzo, Ross, & Blatier, 2002) and Puerto Rico (Albizu-Garcia et al., 2007) found that it is feasible and facilitated post-release treatment entry; the latter study also reported that it reduced heroin use post-release. A subsequently conducted randomized clinical trial comparing buprenorphine and methadone involving newly-admitted, heroin-dependent male jail inmates in New York City showed that while treatment completion rates in jail were similar, buprenorphine patients were significantly more likely to enter community-based treatment after release than methadone patients (Magura et al., 2009). At 3-months post-release, there were no group differences regarding self-reported heroin use or arrests. However, unlike most prisoners in the United States, the participants in this study, and the majority of the participants in the research conducted in Puerto Rico were opioid-dependent at the time of study entry. Because of these circumstances, and in view of findings from the study of pre-release MMT (Kinlock et al., 2009), it was important to determine if buprenorphine provided to both male and female prison inmates who were not tolerant to opioids would be feasible and effective as a pre-release strategy in reducing addiction and criminality and facilitating community-based treatment entry and retention.

Although buprenorphine treatment in a correctional setting may be promising, its implementation is associated with a number of unique challenges and obstacles. They differ from those of methadone because of variations in dosing, administration, and regulations. The focus of this manuscript is on how these unique challenges were overcome, particularly by effective and continuing collaboration among correctional, treatment, and research staff. Building on the authors' experiences in setting up and operating MMT programs within a correctional setting (Kinlock, Schwartz, & Gordon, 2005b), and in view of the lack of experience in implementing and evaluating buprenorphine treatment in jail and prison settings in the United States, this manuscript may serve as a useful guide for interested corrections officials, treatment providers, and researchers.

Rationale

Because most incarcerated individuals with pre-incarceration heroin dependence in the United States appear not to be using opioids while incarcerated to the point of maintaining or developing tolerance to opioids, (Smith-Rohrberg et al., 2004), it is recognized that providing opioid agonist therapy to individuals who were previously, but not currently, heroin-dependent is unconventional. However, the approach is consistent with longstanding federal regulations regarding the provision of opioid maintenance therapy to prevent relapse. Furthermore, the present authors' recently conducted studies showed that this approach is feasible and facilitates post-release treatment entry and retention and reduced heroin use and crime (Kinlock et al., 2005a; 2009). A major lesson learned from these two studies is that such innovative programs must have the strong support and continued collaboration of correctional, treatment, and research personnel in order to be feasible and effective.

Dosing

As in the authors' previous study of methadone in prison, the dosing approach had to be modified to account for the participants' lack of tolerance. Thus, it was necessary to begin at low doses (1 mg) and to increase dosage slowly and gradually (1 mg per week). Dose induction in non-tolerant participants is challenging because: (1) buprenorphine treatment with non-tolerant individuals in prisons and jails had previously not been conducted and therefore there were no established procedures in the United States to follow as a guide; (2) individual response to the medication varies considerably and the nursing and medical staff must monitor participants for side effects such as sedation or constipation; and (3) because violence is often used in the prison environment to settle disputes and establish and maintain one's reputation (Prendergast & Wexler, 2004), inmates feeling “high” from the effects of the medication may feel more vulnerable to violent victimization. Because of these circumstances, all participants are informed at the outset of medication that they should notify the medical staff as soon as possible if they have any side effects of the medication so that the dose can be adjusted accordingly. [Thus far, slightly over half of the participants who have received buprenorphine in prison have reported any side effects, with 50% reporting constipation, 17% reporting sweating, 17% reporting drowsiness, and under 10% reporting feeling “high”(the latter instances typically occurred at 1-3 mg)], In addition, each participant completes a form on a weekly basis indicating whether he/she has experienced constipation, drowsiness, sweating, or any other specific symptoms attributed to the medication. Furthermore, all program participants are clearly told by treatment staff that they may discontinue treatment at any time without penalty and receive a gradual dose reduction.

Medical Staff Training

The study physician had obtained the waiver from SAMHSA to be licensed to prescribe buprenorphine and he had served as medical director during the MMT study. It was also helpful that the nursing supervisor had administered medication to participants in the MMT study. The

nursing staff were trained in the administration of buprenorphine by another nurse with considerable experience working with buprenorphine.

Planning

As in the present authors' previous work with LAAM (Kinlock et al. 2005a), methadone (Kinlock et al., 2009) and buprenorphine (Albizu-Garcia et al., 2007), the current study, described below, was planned by involving correctional, treatment, and research personnel from the very beginning. Because each of these agencies has different priorities and agenda, and disparities often arise when rehabilitation interventions occur in prison (Miller, Koons-Witt, & Ventura, 2004), frequent meetings between all parties involved and the partnership between the research team and local correctional agencies strongly contributed to the successful implementation of the above mentioned studies. The partnership began in 1999 during the planning stages of the LAAM study. At that time, research, corrections, and treatment personnel wanted to interrupt the vicious cycle of relapse, recidivism, and reincarceration among many Baltimore inmates with pre-incarceration heroin addiction. While treatment and research personnel wanted to replicate the New York City jail MMT program in Baltimore's detention center, corrections preferred the pre-release prison as an intervention site because the jail handled a much larger volume of inmates and the jail's warden was philosophically opposed to opioid agonist maintenance. Additional resistance in that regard occurred among a number of corrections officers during the LAAM and MMT studies, and directives from key administrators indicating that the projects would take place as planned served to alleviate, but not eliminate, such resistance (Kinlock et al., 2005b). Corrections-research partnerships regarding the conduct of corrections-based drug abuse treatment evaluations have been discussed previously in the literature (e.g., Miller et al., 2004; Welsh & Zajac, 2004), but they remain unusual with respect to opioid agonist maintenance specifically.

Therefore, regularly scheduled meetings with corrections, treatment, and research personnel occurred in the current study to work out how implementation issues will be handled. Specific concerns in the initial stage of the study involved meeting with the staff of the women's prison regarding orientation to study procedures and working out procedures for the ordering, storing, and administration of the medication as well as logistical concerns. (Because the pre-release facility for men served as the setting for the previous studies with LAAM and MMT, such orientation meetings were less intense).

A crucial initial step was to secure the cooperation and ongoing support of the Maryland Department of Public Safety and Correctional Services (DPSCS). Obtaining approval from the office of the Secretary, to which all wardens must report, facilitated the cooperation of not only the wardens, but also of other correctional administrators, case managers, correctional health personnel, chiefs of security, and line staff. Correctional officers have daily contact with inmates, writing passes and escorting them to treatment interventions, and such personnel can influence, favorably or unfavorably, inmate participation in treatment (Miller et al, 2004). Furthermore, actions on the part of various key correctional administrators could adversely impact research and/or treatment procedures.

Obtaining Approval from Federal and State Regulatory Agencies

The first major challenge to project implementation was obtaining appropriate licenses from the United States Drug Enforcement Agency (DEA) and the Division of Drug Control of the Maryland Department of Health and Mental Hygiene Drug Control Unit (MDHMH). This required ensuring that procedures for the delivery, storage and dispensing of the medication in each pre-release facility are compatible with the standards of the DEA and the MDHMH. Several important steps were required in order to achieve this goal. After the study physician completed required application forms describing the nature of the study, plans for coordinating

with corrections officials in setting up the medication site, and proposed procedures regarding the handling of the medication, the DEA and MDHMH had to approve them. This required several modifications and clarification of procedures. First, a safe for each facility was identified and inspected by the DEA and MDHMH according to their specifications. Next, the DEA and MDHMH inspected both facilities to determine whether the medication area was sufficiently secure and compliant with existing regulations. Once this was done, the DEA and MDHMH had to assign each medication site a registration number in order for participant recruitment to begin.

It was decided to obtain a research license to permit storage and administration of buprenorphine. It would have also been possible to obtain an opioid treatment program satellite license of the community treatment program or to obtain a separate opioid treatment program license; but the requirements are much more complicated and involve accreditation by an appropriate agency under standards that are not always appropriate for relatively short term treatment in a prison. It may have been possible for the prison health physician to prescribe buprenorphine through their waiver and have it directly administered by pharmacists (or nurses) on a daily basis. This approach would be less problematic than obtaining a license for an opioid treatment program (OTP) but the study involved an outside drug abuse program which would have made such an approach more difficult.

Logistics

It was very helpful that the same key staff of the men's prison who served as liason to the buprenorphine study had served in this capacity in the MMT study. Therefore, they were already comfortable with logistical procedures developed in that study as to the location of the medication station, the hours of medication, and the times and locations for physical examinations, group orientation sessions, individual screening, and administration of informed consent and baseline assessment. Similarly, the main project liaison was already familiar with the process of receiving information on those inmates meeting eligibility criteria, described below, regarding Baltimore residence and prison time remaining to serve as well as performing the complex procedures needed to screen out inmates with pending parole hearings and/or unadjudicated charges. On the other hand, because women were not included in the MMT trial and were included in the current study in order to address long-overdue questions about what factors and program components may be related to positive treatment outcomes for women as well as for men (Pelissier & Jones, 2005), the case management staff at the women's prison required additional time to learn to perform the screening procedures, and additional meetings were held to review these procedures and study eligibility criteria in detail as well as to establish times and locations for participant screening, assessment, and medical examinations. Furthermore, because Maryland Division of Correction procedures require that a female physician or nurse practitioner accompany the study physician, who is male, while conducting the physical examinations, designation of that person and orienting her to study procedures was necessary.

The Present Study

The current study is a randomized clinical trial in which male and female pre-release prison inmates with pre-incarceration histories of heroin addiction and 3-6 months remaining on their prison sentences who meet criteria for opioid agonist treatment are randomly assigned to one of four conditions: (1) buprenorphine treatment and counseling in prison, with referral for continued treatment at an OTP upon release; (2) buprenorphine treatment and counseling in prison, with referral for continued treatment at a Community Health Center (CHC) upon release; (3) counseling only in prison, with referral for buprenorphine and counseling at an

OTP upon release; and (4) counseling only in prison, with referral for buprenorpine and counseling at a CHC upon release.

At release from prison, participants are advised by treatment staff to report to their designated OTP or CHC as soon as possible. Before release, they are informed that if they report within 10 business days after release, they will be guaranteed admission into the treatment facility. But if they arrive after that, they will receive treatment subject to the program's usual admission procedures, including being placed on a waiting list. The study was reviewed and approved by the Friends Research Institute Institutional Review Board (IRB).

Participants are assessed at study entry (baseline) regarding their demographic characteristics and histories of substance use, drug abuse treatment experiences, criminal activity, criminal justice system involvement, and legitimate employment. In addition, participants are assessed at 1-, 3-, 6-, and 12-months post-release regarding drug abuse treatment entry and retention, heroin use, cocaine use, and criminal activity. Urine samples are tested for opiates and cocaine as part of each follow-up assessment along with self-report information on treatment participation, heroin use, cocaine use, and criminal activity. Arrest data are obtained at the end of the study from the DPSCS..

Participant Eligibility Criteria

To be eligible for entry into the study, an inmate must meet the following criteria: (1) 3-6 months remaining to serve before planned release; (2) history of heroin dependence [meeting Diagnostic and Statistical Manual of Mental Disorders (DSM-IV; American Psychiatric Association, 1994) criteria of dependence at the time of incarceration] and manifesting physical dependence during the year before incarceration; (3) suitability for buprenorphine treatment as determined by the results of medical evaluation and the judgment of the study physician; (4) willingness to receive buprenorphine treatment; and (5) having a Baltimore address and planning to live in Baltimore after release. Inmates who do not meet the heroin-dependence criterion will be eligible if they had been enrolled in an OTP during the year prior to incarceration. Inmates with one or more of the following conditions are excluded from the study: (1) evidence of kidney failure; (2) evidence of liver failure; (3) history of psychosis; (4) unadjudicated charges that could result in transfer to another facility and/or additional prison time; and (5) (women only) pregnancy.

Participant Recruitment Procedures

Selection of study participants involves a complex multiple-level screening process involving corrections, research, and medical personnel. First, Maryland Division of Correction (DOC) personnel in their Research and Statistics department determine which inmates in each pre-release facility have Baltimore addresses and 3-6 months left to serve on their prison sentences. Second, the DOC identification numbers of all inmates in each facility who meet these first two criteria are sent to a case manager at each facility who serves as the primary liaison for this study. Third, that case manager schedules project orientation appointments with research staff for these qualifying inmates. Fourth, group orientation sessions are conducted at each pre-release prison in which research staff explain study procedures and eligibility requirements to these inmates and screen them for pre-incarceration heroin dependence and initial interest in study participation. Fifth, case management personnel at each pre-release center will review the criminal justice records, including FBI records, of all individuals who meet criteria for heroin dependence and indicate potential interest in participating in the study in order to screen out any individuals with pending parole hearings and/or unadjudicated charges that could result in transfer to another facility and/or extension of prison time. Sixth, potentially interested inmates will then meet individually with research staff for an in-depth discussion of the

purposes and procedures, as well as risks and benefits, of study participation, and to make a preliminary determination of eligibility, subject to confirmation during the medical history and physical examination (see below). The research assistant and potential participant review the informed consent document, questions are answered, and the individual signs the consent form if he/she chooses to participate in the study. (The informed consent form indicates that inclusion in the study will be dependent on examination by the project medical staff.) Inmates who refuse study participation are provided with a list of the locations and contact information for publicly funded substance abuse treatment facilities in Baltimore.

After each potential participant completes a baseline assessment, the study physician determines whether the participant is medically eligible for buprenorphine treatment based on a review of his/her medical record and the results of a medical history, physical examination, and laboratory tests. To be medically eligible, an individual must have a history of heroin dependence in the year prior to incarceration, no liver and/or kidney failure; no history of psychosis; and no other medical/psychiatric condition that in the physician's judgment would make the individual unsuitable for buprenorphine treatment. Individuals who do not meet medical eligibility or do not wish to initiate buprenorphine treatment following a discussion of the risks and benefits of such treatment with the study physician will have their enrollment in the study terminated at this point. Individuals who are determined medically eligible and are still interested in participating in the study then are randomly assigned to one of the four treatment conditions. The study physician opens an envelope assigning the participant to a particular treatment condition after the successful completion of the physical examination. The study physician does not know the group assignment until the envelope is opened.

Medical Examination

It was helpful that the study physician in the current buprenorphine study had served in that capacity throughout the methadone study. Therefore, he was familiar with the logistical procedures and routines developed in that study regarding medication and physical examinations in the prison for men. However, several obstacles were encountered regarding the medical examination. As part of the informed consent process, participants provide the study physician with access to their corrections medical charts which sometimes could not be easily located. A series of meetings with the study physician and the prison physicians served to alleviate this problem. Also, it was sometimes difficult to locate inmates for the physical examination. This was more likely to occur at the women's prison, where staff members were less familiar with study procedures and when inmates received assignments that required them to leave the prison, such as work release, or work training. As a consequence, the medical examinations had to be re-scheduled. Unfortunately, several female potential participants were released to the community before the re-scheduled medical examination because of the tendency to release some inmates earlier than expected as experienced in the authors' previous studies. (Because inmates receive credit in the form of reduced prison time for following rules, this circumstance may have contributed to selection bias). A series of meetings were held with case management staff of the women's prison to work out further the issue of letting research staff know which potential participants were on work release or work training and when to ensure that the inmate would be in the facility and therefore available for the scheduled physical examination. This was resolved with the help of corrections nursing staff, who arranged that an inmate would be held in the facility the day of the medical history and physical examination.

Medication

Another procedure that is involved with the use of buprenorphine-naloxone and not with methadone concerned ordering of the medication. While methadone could be brought in to the prison by the staff of the community-based facility that provided treatment, buprenorphine-

naloxone was ordered by filling out a form designating the quantity of medication shipped and needed for the entire study. The form had to be approved by the study's Program Official at the National Institute on Drug Abuse (NIDA), as well as a NIDA scientist in their Medications division. The form was sent to the designated scientist, who then approved for its delivery. It was crucial to obtain information on how the medication was shipped as well as the tracking number and estimated time of arrival and the telephone number of the individual transporting the medication. Unlike deliveries sent to community-based treatment programs, who obtain such medication on a regular basis, there were no established procedures for reception of the medication at the pre-release prisons. Since the prison medical personnel were not responsible for treatment of study participants, they could not receive the medication; therefore, the study's physician or nurse had to go to the prison at the anticipated time of medication delivery to sign for the medication.

Finally, unlike methadone, which is ingested by swallowing under the observance of medical staff, buprenorphine tablets are dissolved under the tongue. Nursing staff must observe each patient to make sure that the medication is dissolved and attempts are not made to take the medication away from the nursing station. This procedure can take up to 10 minutes per participant. Because of these circumstances, and the need to ensure that each inmate reports to the medication station, a time of day must be chosen to not interfere with ongoing routines at the prison.

Diversion

Another important issue concerning medication administration in a jail or prison involves the need to prevent diversion of medication. Each inmate is informed by the study physician and nurse at the beginning of buprenorphine treatment that he or she will be gradually taken off the medication should there be any evidence of attempted diversion of the medication. The nurse administering medication must watch each patient carefully to make sure that it is dissolved under the tongue and to confront any patient immediately when diversion is suspected.

Prior to the beginning of buprenorphine treatment, correctional, treatment, and research staff agreed on how participants who attempted to divert medication were to be handled. At initial meetings with prison security and case management staff, it was agreed that the study physician and nurse would take the responsibility of terminating such individuals from treatment, and, consistent with requirements regarding the protection of privacy of research participants, the prison officials would not be informed of such incidents. (The only inmate behaviors that required us to notify prison personnel occurred when a participant engaged in or expressed a desire to engage in physical harm to him/herself or other persons). Any inmates who were found by our astute nursing staff attempting to take the medication out of their mouths were terminated from treatment during the prison phase of the study. In each case, a buprenorphine tablet was found in the inmate's hand. While nursing staff in correctional institutions (as well as psychiatric hospitals and methadone programs in the community) who administer medications are vigilant about potential medication diversion, it is important to note that participants' attempts to divert medication may be more frequent with buprenorphine than with methadone. In their study of male jail inmates, Magura et al. (2009) found that 10% of buprenorphine patients and only 1% of methadone patients attempted to divert these medications. Those results are consistent with our previous findings in that no participants in our methadone study were terminated from treatment for attempted diversion.

Space

In the men's prison, medication is administered at the prison hospital. Physical examinations are also conducted in the evenings at the prison hospital. The study physician reviews all

medical records of potential participants and uses the hospital rooms to conduct the physical exam. So as not to interfere with the prison operations, an analogous space had to be secured at the women's prison. In the men's prison, medication is stored in a combination safe that is only accessible to treatment staff. The medication is dispersed behind secure bars. The inmates line up outside the medication window to receive their medication. In the women's prison, the medication is stored in a safe accessible only by research medical staff. It is administered to the inmate seated at a desk with the program nurse. The different arrangements result from the different physical plants and different levels of security.

Although securing space for conducting physical examinations has not been a logistical problem, such challenges have arisen with regard to space needed for group orientation sessions relating to participant recruitment as well as for conducting counseling intakes and group counseling sessions. A main reason for this challenging situation in the men's prison has been that other research and counseling programs have projects and interventions occurring in the same buildings as the present study. Meetings with the primary liason to this project were necessary to resolve these conflicts.

Inmates Transferred to Other Correctional Facilities

An important lesson learned in the LAAM study (Kinlock et al., 2005b) was that the presence of unadjudicated charges is not easily determined, requiring a careful review of an inmate's criminal justice system records, including the FBI data base, by the prison's case management staff. As a consequence, a thorough review of criminal justice system records is conducted on each potential participant prior to study enrollment. Second, to assure sufficient time to initiate and stabilize participants on methadone or buprenorphine, potential participants are recruited at an earlier point prior to their scheduled release. Furthermore, inmates can be transferred to other prisons and/or receive additional prison time because they are found guilty of prison rule violations. Therefore, the informed consent documents in both the methadone and buprenorphine studies have clearly indicated to potential participants that they will become ineligible for study participation should they receive a transfer to another prison and/or more prison time because of misconduct. These procedures have served to alleviate, but not eliminate, the problem of transfer and additional prison time because of unadjudicated charges and/or inmate rule violations. In the authors' MMT study, nine of 211 (4%) inmates who were randomly assigned to one of the three treatment conditions had to discontinue study participation because of these circumstances.

Release from Prison

Considerable and continuous collaboration between correctional, treatment, and research personnel is required in order to facilitate a smooth transition between prison release and community re-entry. This is an exceptionally challenging task in the current buprenorphine study for several reasons. First, unlike the authors' prior studies (Kinlock et al., 2005; Kinlock et al., 2009), treatment in prison and treatment in the community are not being delivered by the same community-based provider. Second, instead of having a single post-release treatment provider, the present study is employing two different providers in order to address the question of which one, an OTP or a CHC, will have higher treatment entry and retention rates and thus better outcomes with respect to addiction and criminality.

Several steps have been undertaken to facilitate participant post-release treatment entry. First, exit interviews are planned in which both the counselor and research assistant emphasize to the participant the importance of promptly reporting to their designated post-release treatment facility. Cards are given to each participant just prior to release. These cards contain information about the community-based treatment program they are to attend—contact person(s), address, hours of operation, hours of medication, and telephone number. Research staff have worked

out procedures with the community-based OTP and CHC with regard to sending each soon-to-be released participant's in prison study records. These records include the participant's physical exam results and information on medical problems experienced in prison and resulting treatment by the study physician, dosage of buprenorphine, the rationale for any dose changes, and counseling attendance and participation.

A major obstacle encountered with respect to this process occurs when participants are released from prison on Friday afternoons after the OTP and CHC have closed. Weekend and holiday hours of medication and counseling are limited in both facilities. The CHC is not open on weekends and the OTP is open only for limited hours on Saturdays and Sundays. A system has been worked out in which the study physician makes arrangements for participants released on weekends in all treatment conditions to be medicated as “guests” at the OTP, since it is not feasible to provide newly-released inmates with “take home doses” of study medication. For treatment programs in jails or prisons that are operating under a physician's license to prescribe buprenorphine, it might be feasible to provide a prescription for newly-released inmates; however, such individuals would require health coverage or funds to fill the prescription.

Release to Half-Way Houses

During the MMT study, the authors established relationships with Dismas House East and West, two DOC -operated half-way houses that allowed inmates to receive medication. Two male inmates have been released early and the authors have coordinated with the staff of each facility so participants can receive medication. This is a complex process for several reasons. First, because residents of these halfway houses are required to be legitimately employed, it has to be ensured that each participant can be medicated at the designated OTP and CHC at a time that does not conflict with the hours that the participant spends at his job. Second, transportation to and from the OTP and CHC has to be secured. Third, during the first two weeks at these facilities, inmates are on a “lock-down” status and are not supposed to leave the facilities at all. Agreement has been reached that allows the inmates to travel to the treatment site for intake processing and for medication, but the inmate must account for all time when he returns to the Dismas House site.

Temporary Closing of the Women's Prison

Perhaps the most formidable obstacle to successful study implementation was the unexpected temporary closing of the female pre-release center because of state budget cuts. As a result, the authors had to negotiate with corrections officials to secure cooperation of the warden and key medical, security, and case management staff of the only other prison in Maryland that housed female pre-release inmates. First, the authors convened a series of meetings with these individuals to enlist their cooperation and then to work out logistical concerns of where the medication would be stored, the hours of medication, and locations and times for project orientation and screening, informed consent, assessment, and counseling sessions. The strong and continued support of the DPSCS was instrumental in facilitating this process. Another challenge was that this facility was located 15 miles from Baltimore, requiring additional travel time and compensation for the medical and counseling staff of the community-based OTP responsible for the prison treatment. While the study physician and one of the nurses agreed to travel to this facility to treat patients, the other nurses and the counselor refused because of the time and distance involved. Thus, additional personnel had to be hired and trained. Further, the DEA had to inspect and approve the medication site and procedures for securing the medication, and the addition of another participant recruitment site had to be approved by the investigators' organizational IRB. All of these procedures took seven months to complete; during that time no female participants were recruited. One female inmate who was randomly assigned to a treatment condition and two others who were consented and awaiting the physical examination at the time the prison closed could not proceed with further study involvement.

Discussion

Many incarcerated individuals in the United States have histories of heroin addiction but do not receive treatment, either while in jail or prison or upon release. As a result, they typically become re-addicted shortly after release to the community, being at high risk for overdose death, spreading lethal diseases such as HIV and hepatitis, and subjecting many persons to criminal victimization. Opioid agonist maintenance programs, found effective in community settings, appear to be a promising intervention for reducing relapse to heroin addiction and its concomitant adverse health and criminogenic consequences. Specifically, the use of methadone and buprenorphine maintenance in jail and prison settings have been strongly endorsed by the Office of National Drug Policy (2001), the American Association for the Treatment of Opioid Dependence (2004), the World Health Organization, the United Nations Office on Drugs and Crime (UNDOC) and the Joint United Nations Programme on HIV/AIDS (UNAIDS).

However, it must be emphasized that implementing such treatment within a correctional setting is far from an easy task. First and foremost, treatment, corrections, and research personnel need to collaborate continually to develop, implement, and evaluate such new interventions effectively (Kinlock et al., 2005b; Miller et al., 2004). In such endeavors, all parties should agree on the basic design and implementation of the study, particularly details regarding logistics and space, and ensuring that study intervention, recruitment, and assessment do not interfere with ongoing routines at the jail or prison. Furthermore, the development of a specific letter of agreement or memorandum of understanding at the beginning of the study can help make clear the roles of key personnel, contributing to fewer problems with study implementation. If such an agreement is not made at the outset the result can be a climate of intolerance, and weaker support for the project. Under such circumstances, corrections and treatment staff are much less likely to respond to urgent problems and obstacles during study implementation (Miller et al., 2004). Also, it is important to update letters of support, especially if there is a change in personnel at the collaborating corrections and treatment agencies.

In addition, it must also be noted that while buprenorphine programs may have potential advantages over MMT with regard to frequency of dosing and less stigma, there are unique challenges associated with corrections-based buprenorphine interventions that appear greater than those associated with corrections-based MMT. One seemingly greater disadvantage to prison- and jail-based buprenorphine treatment is that patients may be more likely to try to divert a tablet of buprenorphine than liquid methadone. In both the present authors' experience and that of Magura et al. (2009), attempted diversion appears to be more frequent with buprenorphine than with methadone. Other challenges to the implementation of buprenorphine programs for inmates involve ensuring that research, treatment, and correctional staff work out complex procedures for ordering and shipping medication with key officials from various agencies.

Finally, it is recommended that researchers, treatment providers, and corrections officials should not be limited to reporting outcomes on the effectiveness of their interventions, but on the unique challenges they faced and how they overcame them. These efforts are valuable in that they serve as a guide for subsequent corrections-treatment partnerships. Although research, treatment, and corrections agencies personnel may have different priorities and agenda, they can agree that heroin addiction and its adverse consequences are serious problems that can be reduced with careful planning and collaboration.

Acknowledgments

This study was funded by the National Institute on Drug Abuse (NIDA), Grant R01DA021579, awarded to the first author (PI: Kinlock). The authors would like to thank the Maryland Department of Public Safety and Correctional

Services and the staff at Glenwood Life Counseling Center, REACH, and Total Health Care for their collaboration on this study. In addition, we would like to thank the project staff: Kathryn Couvillion, Amy Watts, and Melissa Morsell for their efforts related to this study. In addition, we wish to thank Redonna K. Chandler, Ph.D., Chief, Services Research Branch, Division of Epidemiology, Services, and Prevention Research at NIDA and Akiva Liberman, Ph.D. , Program Official at NIDA.

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