# Effect of Incarceration History on Outcomes of Primary Care Office-based Buprenorphine/Naloxone

*Emily A. Wang, MD, MAS[1,4], Brent A. Moore, PhD[2], Lynn E. Sullivan, MD[1,4], and David A. Fiellin, MD[1,3,4]*

[1]Department of Internal Medicine, Yale University School of Medicine, New Haven, CT, USA; [2]Department of Psychiatry, Yale University School of Medicine, New Haven, CT, USA; [3]Investigative Medicine Program, Yale University School of Medicine, New Haven, CT, USA; [4]General Internal Medicine, Yale University School of Medicine, New Haven, CT, USA.

***BACKGROUND:*** Behaviors associated with opioid dependence often involve criminal activity, which can lead to incarceration. The impact of a history of incarceration on outcomes in primary care office-based buprenorphine/naloxone is not known.

***OBJECTIVE:*** The purpose of this study is to determine whether having a history of incarceration affects response to primary care office-based buprenorphine/naloxone treatment.

***DESIGN:*** In this post hoc secondary analysis of a randomized clinical trial, we compared demographic, clinical characteristics, and treatment outcomes among 166 participants receiving primary care office-based buprenorphine/naloxone treatment stratifying on history of incarceration.

***MAIN RESULTS:*** Participants with a history of incarceration have similar treatment outcomes with primary care office-based buprenorphine/naloxone than those without a history of incarceration (consecutive weeks of opioid-negative urine samples, 6.2 vs. 5.9, p=0.43; treatment retention, 38% vs. 46%, p=0.28).

***CONCLUSIONS:*** Prior history of incarceration does not appear to impact primary care office-based treatment of opioid dependence with buprenorphine/naloxone. Community health care providers can be reassured that initiating buprenorphine/naloxone in opioid dependent individuals with a history of incarceration will have similar outcomes as those without this history.

*KEY WORDS:* buprenorphine/naloxone; incarceration; primary care; jail; prison.
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## BACKGROUND

The United States has the highest rate of incarceration worldwide.[1] In midyear 2007, 1.5 million were held in U.S. prisons, facilities designated for individuals serving sentences of greater than one year, and 700,000, in U.S. jails, which typically house those serving sentences of less than one year or awaiting trial. An additional 5 million individuals were under the purview of the criminal justice system, either on parole or probation, such that 3% of the U.S. population was under the control of the correctional system in 2008.[2] The prison population has grown steadily since 1980, largely fueled by harsher penalties for drug offenders. Between 50–80% of U.S. inmates have a history of substance use, with an estimated 12–25% reporting a history of opioid dependence.[3]

Opioid dependence is a chronic and often relapsing medical condition that frequently involves criminal activity, as those with this condition illegally obtain or use prescription and illicit opioids. Approximately 25% of all those dependent upon heroin (200,000 individuals) pass through the criminal justice system each year.[4] However, less than 0.5% of opioid dependent individuals receive treatment following admission to a correctional facility,[5,6] so that most individuals return to opioid use upon release.[7] Untreated opioid dependence is associated with criminal activity, HIV and hepatitis infection, re-incarceration, and death from overdose.[7–10] Although correctional facilities provide an important opportunity to engage individuals with opioid dependence in treatment, the typically short stay in jails and the bureaucratic barriers to opioid agonist treatment in prisons [5] make community providers a more likely source of treatment for opioid dependent individuals with a history of incarceration.[11]

While methadone has been the mainstay of community-based treatment of opioid dependence, its availability and, in some cases, its acceptance are limited among current and former inmates.[4] Methadone maintenance treatment slots are available for only 20% of opioid dependent persons, making linkage from correctional facilities to community methadone treatment even more challenging.[12] Buprenorphine/naloxone, a partial opioid agonist available for office-based treatment of opioid dependence since 2002, has important benefits for treating criminal justice populations, including heightened patient satisfaction and adherence,[13,14] reduced risk for misuse,[12] and perhaps, most importantly, the potential for initiation and maintenance in a primary care or office-based setting.

To our knowledge, there are no data on the impact of patient history of incarceration on treatment outcomes of primary care

office-based buprenorphine/naloxone. We hypothesized that those with a history of incarceration might have different treatment outcomes, including treatment retention or opioid abstinence, compared to those without, given the structural barriers that individuals face upon release from correctional facilities. Formerly incarcerated individuals, who are disproportionately poor compared to the general population, can face additional barriers to securing food stamps, public housing, and employment upon release,[15] which may increase their risk for buprenorphine/naloxone diversion or medication misuse, as a means of generating income. Provider concerns about diversion coupled with the stigma of incarceration[16,17] could promote discriminative practices among health care providers.[18,19] The purpose of this study is to determine whether having a history of incarceration affects primary care based buprenorphine/naloxone treatment response.

# METHODS

## Sample and Setting

This study is a secondary data analysis of a randomized controlled trial of three levels of psychosocial counseling and medication dispensing in conjunction with buprenorphine/naloxone maintenance treatment in a primary care clinic.[20] Briefly, adults seeking primary care based buprenorphine/naloxone treatment were referred for participation by area physicians, methadone clinics, and word of mouth. Individuals were excluded if they were dependent on alcohol, cocaine, sedatives, or benzodiazepines or had a medical or psychiatric disorder that precluded participation. Among those referred, 201 individuals, who met *Diagnostic Statistical Manual of Mental Disorders-IV* criteria for opioid dependence,[21] were eligible for participation and completed intake. Individuals who completed the 2-week induction period (N=166), during which participants were seen thrice weekly and titrated to 16 mg of buprenorphine/naloxone daily, were randomly assigned to receive one of three treatments: standard medical management and once weekly medication dispensing, standard medical management and thrice-weekly medication dispensing, or enhanced medical management and thrice-weekly medication dispensing. Successive increases to 20 mg and 24 mg were permitted depending on the participant's level of discomfort or evidence of ongoing (for three successive weeks) illicit drug use. The results of the trial did not demonstrate a difference in opioid abstinence between the three levels of counseling and medication dispensing. None of the participants were recruited directly upon release from correctional facilities.

## Analytic Variables

***Predictor.*** Incarceration history was obtained through the legal domain of the Addiction Severity Index (ASI), a structured interview that was administered to all randomized participants.[22] Participants were asked at baseline: "*How many months were you incarcerated in your life?*" Those who responded zero were categorized as never having been incarcerated; all others were defined as having a past history of incarceration. We chose this measure for our primary analysis given its utility in a primary care practice. Asking about a patient's history of incarceration is important to establishing risk for tuberculosis, HIV, hepatitis C, and other health conditions, in addition to drug dependence.[23] However, because we had access to variables which capture the range of participants' interactions with the criminal justice system, we also used other measures of delinquency from the ASI and the Treatment Service Review (TSR),[24,25] including history of arrest and conviction, as predictors in our analyses. Both instruments' legal and criminal justice domains have been previously validated.[26–32]

***Drug Use Outcomes and Treatment Retention.*** Illicit drug and prescription opioid use was measured weekly by urine toxicology testing. Urinalyses were conducted with the use of a semiquantitative homogeneous enzyme immunoassay for opioids and cocaine. To evaluate abstinence, two measures of the percent of weekly opioid-negative (based on a standard opiate test) and cocaine-negative urine toxicologies were computed, with missing samples counted either as positive or evaluating only provided urine samples. The maximum consecutive weeks of abstinence from illicit opioids and cocaine were also calculated, as were mean number of weeks retained in the study.

Participants who met one of three criteria were considered not retained in treatment and censored from further outcome analyses: (1) those who missed more than seven doses of medication (N=70), (2) those who missed three or more counseling sessions (N=8), and (3) those who met criteria for protective transfer (N=13). Participants with unremitting illicit-drug use (three consecutive weeks of urine specimens positive for opioids, cocaine, or both after the buprenorphine/naloxone dose had been increased for three weeks each to 24 mg) met the criteria for protective transfer and were offered transfer to methadone treatment programs.

***Potential Confounders.*** Sociodemographic, medical, psychosocial, drug use and treatment information was collected at baseline. Assessment instruments included the Center for Epidemiologic Studies Depression Scale (CES-D),[33] the Treatment Motivation Scale,[34] and the ASI. Current parole or probation status was also measured as a possible confounder between having a history of incarceration and buprenorphine/naloxone treatment outcomes.

***Data Analysis.*** We first compared individuals with a history of incarceration to those without on demographic, clinical characteristics, and history of drug use and treatment, using independent t-tests and chi-squared tests. Fisher's exact tests were used for estimated cell sizes less than five. Next, we estimated a propensity score as the conditional probability of a history of incarceration using logistic regression with all predictors that had a p value<0.1 in the univariate analyses.[35] We then compared unadjusted treatment outcomes between respondents with and without a history of incarceration and subsequently adjusted these analyses for the propensity score, so as to retain power that would otherwise be lost with adjusting for multiple covariates in traditional ANCOVA analyses.

## RESULTS

Thirty percent of participants reported a past history of incarceration (Table 1). Former inmates were more likely to be older, male, of an ethnic minority, and unemployed compared to those without a history of incarceration. They also were more likely to have longer histories of opioid dependence, have received methadone treatment, and have hepatitis C infection.

### Drug Use Outcomes and Treatment Retention

The mean dose of buprenorphine/naloxone for individuals with a history of incarceration was 17.9 mg±2.7 and for those without was 18.0 mg±2.2 (p=0.77). We were unable to detect a difference between treatment outcomes in participants with and without a history of incarceration. Participants with a history of incarceration were as likely to remain abstinent from opioids and cocaine and be retained in primary care buprenorphine/naloxone treatment compared to those who had never been incarcerated (Table 2). We also did not detect a difference between mean weeks of continuous opioid abstinence (6.2 vs. 5.9, p=0.74), mean weeks of continuous cocaine abstinence (7.2 vs. 7.3 p=0.9) and opioid-negative or cocaine-negative urines in the study population, even after adjustment for the propensity score. Similarly, we did not detect a difference in treatment

**Table 1. Baseline Sociodemographic, Medical, Psychosocial, and Legal Characteristics of Participants by History of Incarceration**

| Characteristics | Never Incarcerated (N=114) | Ever incarcerated (N=52) | P-value |
|---|---|---|---|
| Sociodemographics | | | |
| Age, mean (SD)[a] | 34.3 (9.6) | 39.7 (7.2) | < 0.001 |
| Male, % (N)[b] | 72 (83) | 88 (46) | 0.02 |
| White, % (N) | 88 (100) | 52 (27) | < 0.001 |
| Unemployed, %(N) | 33 (38) | 42 (22) | 0.30 |
| > = High school education, %(N) | 83 (94) | 77 (40) | 0.28 |
| Net income/month, mean (SD) | 1463(1560) | 1118 (1273) | 0.16 |
| % mo. income from illegal activity, mean (SD) | 10.6 (28.5) | 15.4 (33.8) | 0.35 |
| % income from illegal activity, % (N) | 14 (16) | 21 (11) | 0.25 |
| Never married, % (N) | 54 (62) | 63 (33) | 0.33 |
| Medical Characteristics | | | |
| ASI medical, % >0, % (N)[c] | .08 (.22) | .07 (.17) | 0.72 |
| Hepatitis C virus antibody positive, % (N) | 18 (21) | 48 (25) | < 0.01 |
| Psychosocial characteristics | | | |
| ASI employment, mean (SD) | .33 (.28) | .48 (.32) | 0.002 |
| ASI family/social, mean (SD) | .28 (.20) | .25 (.20) | 0.38 |
| ASI psychiatric, >0, % (N) | .05 (.09) | .05 (.08) | 0.96 |
| CESD, mean (SD)[d] | 16.7 (12.1) | 18.0 (10.8) | 0.52 |
| Drug use and treatment history | | | |
| Type of opioid use, % (N) | | | |
| Prescription opioid only | 21 (24) | 8 (4) | 0.07 |
| Heroin only | 63 (72) | 79 (41) | |
| Heroin and prescription opioid | 16 (18) | 14 (7) | |
| Intravenous drug use, % (N) | 30 (34) | 36 (18) | 0.48 |
| Years of opioid use, mean (SD) | 5.9 (6.0) | 12.8 (9.7) | < 0.01 |
| Opioid use in prior 30 days, mean (SD) | 28.0 (5.4) | 29.0 (2.3) | 0.18 |
| ASI Drug, > 0.3, % (N) | 71 (81) | 69 (36) | 0.81 |
| Treatment motivation scale, mean(SD) | 4.9 (0.5) | 5.0 (0.4) | 0.29 |
| Any drug treatment history, % (N) | 76 (86) | 90 (47) | 0.03 |
| Prior methadone treatment, % (N) | 29 (32) | 47 (24) | 0.02 |
| Use of other drugs in prior 30 days,%(N) | | | |
| Alcohol | 52 (59) | 42 (22) | 0.26 |
| Cocaine | 32 (37) | 46 (24) | 0.09 |
| Marijuana | 36 (41) | 23 (23) | 0.10 |
| Other | 18 (21) | 17 (9) | 0.86 |
| ASI Alcohol, % >0, % (N) | 52 (99) | 42 (22) | 0.26 |
| History of and Current Legal Issues | | | |
| Currently on parole/probation, % (N) | 7 (8) | 31 (16) | <0.001 |
| % ASI legal charges, mean (SD) | | | |
| Drug charges | 30 (34) | 65 (34) | <0.001 |
| Parole/probation violation | 3 (3) | 38 (20) | <0.001 |
| Charged with shoplifting/vandalism | 12 (14) | 36 (19) | <0.001 |
| Charged with Forgery | 1 (1) | 7 (5) | 0.005 |
| Charged with Weapons offense | 3 (3) | 17 (9) | 0.001 |
| Charged with Burglary, larceny, robbery | 8 (9) | 38 (20) | <0.001 |
| Charged with Arson | 1 (1) | 4 (2) | 0.23 |
| Charged with Rape | 0 | 0 | 1 |
| Charged with Assault | 6 (6) | 24 (18) | 0.001 |
| Lifetime months incarcerated, mean (SD) | | 20.2 (23.5) | |
| Days engaging in illegal activities for profit in prior 30 days, mean (SD) | 2.8 (7.5) | 5.1 (10.2) | 0.17 |

[a]*SD = standard deviation*
[b]*N = number*
[c]*ASI = Addiction Severity Index*
[d]*CESD = Center for Epidemiological Studies Depression scale*

Table 2. Treatment Outcomes of Groups by History of Incarceration

| Characteristics | Never Incarcerated (n=114) | Ever Incarcerated (n=52) | P-values | P's with adjustment* |
|---|---|---|---|---|
| Abstinence in the 2 weeks of induction, %(N) | 56 (64) | 44 (23) | 0.15 | 0.32 |
| Treatment completion, % (N) | 46 (52) | 38 (20) | 0.39 | 0.28 |
| Retention, weeks, mean (SD) | 17.6 (7.7) | 17.9 (7.0) | 0.79 | 0.42 |
| Percent opioid-negative urines with missing counted as positive, mean (SD) | 42 (34.3) | 43 (30.5) | 0.85 | 0.38 |
| Continuous opioid abstinence, mean no. weeks (SD) | 5.9 (6.0) | 6.2 (5.7) | 0.74 | 0.43 |
| Percent cocaine-negative urines with missing counted as positive, mean (SD) | 48.6 (33.3) | 50.5 (31.4) | 0.73 | 0.62 |
| Percent cocaine-negative urines of samples collected, mean (SD) | 76.9 (30.4) | 77.4 (29.6) | 0.94 | 0.99 |
| Weeks of continuous cocaine abstinence, mean (SD) | 7.3 (6.4) | 7.2 (6.2) | 0.90 | 0.17 |

*p values with adjustments for propensity score which includes all baseline characteristics p<0.10 (age, gender, race, HCV, ASI employment, years of opiates, drug treatment history, current parole status, prescription opioid use, and use of cocaine)

outcomes when participants were dichotomized by other measures, including having a history of arrest or conviction.

## DISCUSSION

Opioid dependent individuals with a history of incarceration who were receiving primary care office-based buprenorphine/naloxone showed similar rates of treatment retention and abstinence from opioids and cocaine compared to those never incarcerated. Participants with a history of incarceration were retained in treatment for a mean of 17 weeks and demonstrated continuous abstinence from opioids for 6 weeks and cocaine for 7 weeks. These findings are similar to other studies where methadone was initiated in either the community or prison;[36,37] studies evaluating buprenorphine/naloxone initiated in prison have not followed participants for more than 3 months but are similarly promising.[38,39] Given the evidence, all criminal justice settings, including prison, jail, parole, and probation, should consider initiating buprenorphine/naloxone for opioid dependent individuals or provide linkages directly to opioid agonist treatment programs in the community, but the reality is that most facilities have not actualized either. As such, individuals with a history of incarceration are apt to connect to treatment services upon release, possibly in office-based treatment programs. Our results should provide reassurance for community health care providers that initiating buprenorphine/naloxone in opioid dependent individuals with a history of incarceration will have similar promise for treatment success as in those without this history.

Compared to those who have not been incarcerated, former inmates are more likely to have hepatitis C infection and longer histories of opioid use, but have received past methadone treatment. This finding suggests that patients with a history of incarceration may not have had continued access to methadone while incarcerated or upon release.[5] Office-based buprenorphine/naloxone treatment can successfully retain and treat some opioid dependent patients with a history of incarceration and can be a potential avenue for referral to hepatitis C treatment and employment or vocational programs as patients become abstinent. Buprenorphine/naloxone treatment may be particularly attractive because it provides greater privacy, is less stigmatized than receiving methadone treatment, and is similar to treatment for other chronic medical problems. However, in spite of its appeal and efficacy, providers caring for individuals with a history of incarceration should be aware of potential financial barriers to paying for buprenorphine/naloxone,[40,41] as well as structural ones to continuing buprenorphine/naloxone in correctional facilities.[5]

A number of limitations of our study should be noted. Measurement of delinquency and incarceration was based on self-report from the legal domains of the previously-validated instruments, the ASI and TSR.[28,30–32,42] Alterman and colleagues used state documented arrests prior to treatment admission to measure the criterion validity of the ASI legal domain and found that recent legal problems correlated with past arrest ($r$=0.38).[31] In studies of opioid dependent individuals seeking treatment, the ASI legal elements had a correlation score of 0.43 with self-reported days spent gaining illegal profit and [27] a Cronbach's alpha of 0.74.[30] Moreover, a high score on the legal domain was associated with a 5 times increased odds of future criminal charges.[30] As for the TSR, Cacciola and colleagues studied 401 drug-dependent individuals and found that there was 100% test-retest reliability for days in jail and good discriminative validity between the various domains of the TSR.[28] While the validity of these instruments' legal domains has been studied, participants' true level of criminality cannot be known as no corroborating evidence of arrest or incarceration was gathered for this study; moreover, there is no gold standard against which to judge self-reported delinquent behavior.[43] There may have been social desirability and recall bias at play which would lead to underreporting of incarceration history, thus biasing our study to null findings. However, a minimum of 13 (21%) of the 62 individuals in the non-incarcerated group who did not complete treatment would have had to have been misclassified for there to be a statistically significant difference between the groups, such that those with a history of incarceration were less likely to complete treatment. Additionally, our measure of incarceration was relatively narrowly defined, asking about months of incarceration, rather than individual events that might have lasted less than a month. As such, individuals incarcerated for less than one month would be misclassified in the never incarcerated group. However, we performed additional analyses using less stringent measures, including history of arrest and conviction, and found similar results.

Our study demonstrates that having a prior history of incarceration does not adversely impact treatment outcomes

with buprenorphine/naloxone. For primary care practices based in communities with a high prevalence of incarceration, office-based buprenorphine/naloxone treatment may be an important way to engage formerly incarcerated individuals into primary care and reduce the negative health impacts of chronic addiction.

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***Corresponding Author:*** *Emily A. Wang, MD, MAS; General Internal Medicine, Yale University School of Medicine, Harkness Hall Building A 367 Cedar Street, Suite 410A, New Haven, CT 06510, USA (e-mail: emily.wang@yale.edu).*

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