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Buprenorphine Treatment Formulations: Preferences among Persons in Opioid Withdrawal Management

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Abstract

Background: In the current study, we examined factors predicting willingness to receive buprenorphine treatment and preferences for various buprenorphine formulations (oral, injection, implant) among persons in opioid withdrawal management.

Methods: Participants were three hundred thirty-eight persons entering brief inpatient opioid withdrawal management programs at two sites. We used t-tests and Pearson χ^2 – tests of independence to compare participants willing and unwilling to be prescribed buprenorphine in the future. Among persons willing to receive buprenorphine, we used multinomial logistic regression to estimate the adjusted effects of potential correlates of type of buprenorphine formulation preferred.

Results: Participants averaged 33.9 ($\pm$ 9.5) years of age, 70.4% were male, 82.8% were White, and 11.0% were Latino/a. In all, 55.6% of participants had been prescribed buprenorphine in the past, and 54.7% were willing to use prescribed buprenorphine in the future. Those reporting past month illicit buprenorphine use and prior overdose were more willing to use prescribed buprenorphine. Of these (n = 180), most preferred daily buprenorphine formulations (tablet or film) (48.6%) over a weekly or monthly injection (23.1%) or bi-annual implant (28.3%).

Conclusions: Past buprenorphine prescription does not predict future willingness to restart. Among those willing to use buprenorphine, newer formulations of buprenorphine appealed to more than half of the participants.

Keywords

Buprenorphine; Opioids; Heroin; Opioid agonist treatment

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1.0 INTRODUCTION

Opioid overdose rates continue to rise to unprecedented levels in the United States (Center for Behavioral Health Statistics and Quality, 2016a; Morbidity and Mortality Weekly Report, 2017). A primary treatment challenge of controlling the opioid epidemic is that addiction to heroin and other opioids are chronic relapsing disorders. Although opioid withdrawal management programs serve a substantial proportion of individuals with OUD, comprising over one-quarter of all treatment service admissions for heroin or other opiates nationally (Center for Behavioral Health Statistics and Quality, 2016b), opioid withdrawal management in itself is largely ineffective in preventing relapse (e.g., Gossop, Stewart, Browne, & Marsden, 2002).

For individuals completing withdrawal management, transitioning to opioid agonist treatment (OAT; e.g., methadone, buprenorphine, buprenorphine-naloxone) may be a particularly effective treatment protocol for maintaining long-term abstinence (see Connery, 2015 for review; Volkow, Frieden, Hyde, & Cha, 2014). Yet patients completing opioid withdrawal management often do not transition to OAT, fail to adhere to treatment protocol, or drop out of treatment once enrolled (see Connery, 2015 for review). Challenges to OAT effectiveness include structural barriers (e.g., time, transportation required to receive medication; Uebelacker, Bailey, Herman, Anderson, & Stein, 2016), lack of commitment to take at-home oral medication (Substance Abuse and Mental Health Services Administration, 2008), unwillingness to use certain formulations (e.g., unpleasant taste of sublingual formulation, Awgu, Magura, & Rosenblum, 2010; slow dissolution of tablet, Strain, Harrison, & Bigelow, 2011), and non-adherence, which is associated with an exponential likelihood for relapse (Tkacz, Severt, Cacciola, & Ruetsch, 2012). In an effort to enhance adherence and retention, and to curb diversion researchers have developed new formulations of OAT. However, it is not yet known how amenable persons with opioid use disorders may be to various formulations or what their preferences may be.

Relative to methadone, buprenorphine, a partial agonist approved to treat opioid use disorder as an office-based treatment in 2002 (Substance Abuse and Mental Health Services Administration, 2005), is similarly effective in reducing withdrawal and craving (Gowing, Ali, & White, 2009), but has a more desirable safety profile (Bell, Butler, Lawrance, Batey, & Salmelainen, 2009; Hser, Evans, Huang, & Anglin, 2004) and exhibits lower abuse liability (Johanson, Arfken, di Menza, & Schuster, 2012; Johnson, Strain, & Amass, 2003). Still, oral buprenorphine, which requires daily self-administration of tablets or film, is associated with nonadherence (e.g., not taking prescribed pills; Fareed et al., 2014), diversion (Alho, Sinclair, Vuori, & Holopainen, 2007; Moratti, Kashanpour, Lombardelli, & Maisto, 2010), and higher dropout rates than methadone (Bell, Trinh, Butler, Randall, & Rubin, 2009; Mattick, Kimber, Breen, & Davoli, 2008), often in the early phases of treatment (Hser et al., 2004). Longer-acting formulations of buprenorphine could hold promise for increasing treatment retention. The FDA recently approved a monthly buprenorphine injection (Sublocade) for opioid use disorder (Food and Drug Administration, 2017) and a second depot injectable formulation with 1 week and 4 week dosing is under review. Probuphine, an implantable buprenorphine that provides six months of internal

dosing without the need for in-office visits, has demonstrated efficacy in several trials (Ling et al., 2010; Rosenthal et al., 2013; White et al., 2009).

Little is known about persons' willingness to begin buprenorphine treatment or their preferences for these new formulations of the medication. In prior work (Stein et al., 2012), demographics (age, gender, race) did not predict buprenorphine preference (vs. methadone) treatment, although females, older persons, and whites were more likely to initiate OAT. In other work, prior heroin injection was associated with higher interest in injectable OAT (Ahamad et al., 2015). Cunningham and colleagues (2013) found that patients with prior buprenorphine experience—whether illicit or prescribed—exhibited better buprenorphine treatment retention than buprenorphine-naïve patients, but it is not known how this prior experience impacts one's willingness to begin a future course of buprenorphine treatment.

Our prior work (Bailey, Herman, & Stein, 2013; Uebelacker et al., 2016) showed that 63% to 78% of patients in opioid withdrawal management reported a desire for OAT following withdrawal, with more people favoring buprenorphine than methadone maintenance (Uebelacker et al., 2016). In the current analysis, years later in the opioid epidemic, we hypothesized first that a majority of persons entering a short-term withdrawal management program would be willing to receive buprenorphine treatment in the future. Based on existing literature, we hypothesized that injection drug use (IDU) and prior illicit or prescribed buprenorphine use would be related to greater willingness to receive buprenorphine. We also hypothesized that oral buprenorphine would remain the preferred choice of formulation among persons willing to receive buprenorphine treatment and wanted to identify the factors associated with formulation preferences so as to inform OAT services.

2.0 Methods

2.1 Recruitment

Between April and September 2017, we recruited consecutive persons seeking inpatient opioid withdrawal management at two sites—Stanley Street Treatment and Resources, Inc. (SSTAR) in Fall River, Massachusetts and Butler Hospital in Providence, Rhode Island—to participate in a one-time survey research study. SSTAR's program provides evaluation and withdrawal management using a methadone taper protocol, individual and group counseling, and aftercare case management. On average, admitted patients stay 4.9 days and are offered rapid linkage with outpatient buprenorphine and methadone maintenance care, assisted by case managers at the withdrawal management unit. The Alcohol and Drug Inpatient (ADI) Unit at Butler Hospital also provides detoxification under medical supervision, using clonidine, benzodiazepines and anti-emetics for symptom mitigation but no opioid agonists. The average length of stay at ADI is 5.3 days. During their stay, patients attend group therapy and are assigned a case manager to establish counseling and medical care upon discharge.

Of persons seeking care at SSTAR or Butler, 284 and 102, respectively, met Butler Hospital's Institutional Review Board-approved study eligibility criteria: 18 years or older, English speaking, and ability to provide informed consent. Twenty persons at SSTAR and twenty-eight persons at Butler refused study participation or were discharged before staff

could interview them. The remaining 264 (SSTAR) and 74 (Butler) persons completed a nonincentivized, face-to-face interview administered by non-treating research staff. Interviews lasted approximately 15 minutes.

2.2 Measures

In addition to age, sex, race/ethnicity, years of education, past year IDU, and past month heroin use, the following variables were assessed.

2.2.1 Employment status.—Respondents were asked if they were currently working. Those reporting that they worked full-time (> 35 hours) or part-time (< 35 hours) were coded as employed. Respondents reporting being currently unemployed, receiving disability, or being a full- or part-time student were coded as unemployed.

2.2.2 Homelessness.—Respondents were asked where they had slept/spent their nights in the past three months. Respondents spending any nights on the street or in a shelter were coded as homeless and all others not homeless.

2.2.3 History of overdose.—Respondents were asked if they had ever overdosed. We defined overdose (on any drug) as “you were unarousable (couldn’t be woken) with shaking or calling your name because of the drugs you consumed.”

2.2.4 Illicit buprenorphine use.—Respondents were asked, “In the past 30 days, how many days did you use buprenorphine (Suboxone) without a prescription?”

2.2.5 Prescribed buprenorphine use.—Respondents responded “yes” or “no” to ever having been prescribed buprenorphine.

2.2.6 Prescribed methadone use.—Respondents responded “yes” or “no” to ever having been enrolled in a methadone maintenance program.

2.2.7 Prescribed extended release naltrexone (Vivitrol) use.—Respondents were asked if they had ever been prescribed Vivitrol. Respondents were provided the following explanation: “Vivitrol is a medication-assisted treatment. It’s an injection (shot) of naltrexone that the patient receives once per month. Vivitrol works by blocking the ‘high’ one might experience from opiate use.”

2.2.8 Willingness to receive buprenorphine.—Respondents were asked if they would “be willing to be prescribed buprenorphine or Suboxone in the future?” Answer options were “yes” or “no.”

2.2.9 Willingness to receive various buprenorphine formulations.—Respondents were first told that buprenorphine (Suboxone) may be coming in different forms soon and asked about their likelihood for using various formulations, “assuming that all the forms are equally safe and effective and cost the same.” Respondents were asked about using buprenorphine a.) “if you had to see a doctor once a month to get a prescription for pills or filmstrips to use under your tongue every day?”, b.) “if you had to see a doctor

once a week to get a shot under your skin, but you didn't have to carry around or take a pill or film every day?", c.) if you had to see a doctor once a month to get a shot under your skin, but you didn't have to carry around or take a pill or film every day?", and d.) "if you had to see a doctor every 6 months, but you needed minor surgery to get an implant in your forearm that is less than one inch long and smaller than a toothpick, but you didn't have to carry around or take a pill or film every day?" We provided a 5-point Likert response and those responding "somewhat likely" or "very likely" were coded as willing to use the respective formulation and those responding "very unlikely," "somewhat unlikely," or "neutral" were coded as not willing to use the formulation.

2.2.10 Preferred buprenorphine formulation.—Respondents were asked which one of the above four options they preferred.

2.2.11 Willingness to receive buprenorphine while in withdrawal management.—For each of the four assessed buprenorphine formulations, respondents were asked if they would be willing to start the treatment "in detox." Those responding "yes" to at least one of the four questions were coded as willing to receive buprenorphine while in withdrawal management.

2.3 Analytical Methods

We present descriptive statistics to summarize the characteristics of the sample. T-tests for differences in means and the Pearson χ^2 – test of independence were used to compare persons willing or not willing to take buprenorphine in the future. Multiple logistic regression was used to evaluate the adjusted correlates of willingness to take prescribed buprenorphine, and willingness to use each of the 4 specific treatment formulations. We used multinomial logistic regression model to estimate the adjusted associations of potential correlates of buprenorphine formulation preference. Recruitment site was included as a fixed-effect control variable in all multivariate models. Confidence interval estimates and tests of significance were based on the robust Huber-White variance estimator. Additionally, we used contingency tables and χ^2 – tests of independence to evaluate the association of participants' treatment preference with willingness to initiate each individual buprenorphine formulation while in the managed opioid withdrawal program.

3.0 Results

Participants averaged 33.9 ($\pm$ 9.5) years of age, 70.4% were male, 82.8% were White, and 11.0% were Latino/a (Table 1). Mean years of education was 12.2 ($\pm$ 2.0). About 24.6% were employed either part- or full-time, and 19.4% had experienced at least one night of homelessness in the past three months. Two hundred forty-one (71.3%) had injected drugs in the past year and most (89.6%) had used heroin in the past month. Approximately 78.1% reported they had used non-prescribed buprenorphine and 55.6% said they had previously been prescribed buprenorphine. About 50.9% had previously been enrolled in a methadone maintenance treatment program and 20.4% had previously been prescribed extended release naltrexone. In total, 78.4% had received some form of medication treatment (prescribed

buprenorphine, methadone, or naltrexone). Over half (55.9%) had a lifetime history of overdose.

One-hundred eighty-five (54.7%) reported they would be willing to be prescribed buprenorphine in the future (Table 1). Persons willing to use prescribed buprenorphine were significantly ($\chi^2 = 5.05, p = .025$) more likely to report prior illicit buprenorphine use (82.7% vs 72.6%), significantly ($\chi^2 = 5.40, p = .020$) more likely to have overdosed (61.6% vs 49.0%), and significantly less likely to have been recruited at SSTAR (73.5% vs 83.7%, $\chi^2 = 5.04, p = .025$). Willingness to use buprenorphine in the future was not associated significantly with any of the other variables included in Table 1.

We estimated a multiple logistic regression model to evaluate adjusted associations of background characteristics with willingness to use buprenorphine. The model included all of the variables identified in Table 1. After adjusting for other variables in the model, the only significant correlates of willingness to take prescribed buprenorphine were non-prescription use of buprenorphine (OR = 2.14, $z = 2.67, p = .008$) and site. Participants recruited from SSTAR were significantly less likely to express a willingness to take buprenorphine in the future (OR = 0.51, $z = -2.13, p = .003$).

Among the persons willing to use prescribed buprenorphine in the future, 79.1% reported they would be somewhat or very likely to use it if they had to see a doctor once a month to get a prescription for pills or filmstrips, 40% said they would be somewhat or very likely to use if they had to see a physician weekly for a shot, 63.3% said they would be somewhat or very likely to use it if they had to see a physician monthly for a shot, and 50.6% said they would be will to use prescribed buprenorphine if they had to see a physician bi-annually for minor surgery to get an implant in their forearm.

We estimated logistic regression models to evaluate possible correlates of willingness to use buprenorphine for each treatment formulation. Correlates in the models were age, sex, race, ethnicity, years of education, employment status, homelessness, past month heroin use, past year IDU, ever prescribed extended release naltrexone, ever prescribed buprenorphine, past month illicit buprenorphine use, and recruitment site. Being willing to see a doctor monthly for pills or filmstrips, being willing to see a doctor weekly for a shot, and being willing to see a doctor biannually for an implant were not associated significantly with any of the variables in the model (no Table). The likelihood of being willing to see a doctor monthly for a shot was positively and significantly (OR = 1.21, $z = 2.08, p = .038$) associated with years of education but was not associated significantly with any other correlate evaluated in the models.

Participants were also asked which of the buprenorphine formulations they would prefer. Only 4 persons said they would prefer to see a physician every week for a shot; this was combined with seeing a doctor once a month for a shot under the skin. Valid data were available for 173 persons who said they would be willing to take buprenorphine in the future. Eighty-four (48.6%) said they would prefer to see a doctor monthly for pills or filmstrips, 40 (23.1%) said they preferred a shot, and 49 (26.6%) said they would prefer seeing a physician every 6 months for an implant under the skin. We estimated a

multinomial logistic regression model to evaluate the adjusted associations of background characteristics with buprenorphine preparation preference. Correlates in the model were age, sex, race, ethnicity, years of education, employment status, homelessness, past month heroin use, past year IDU, ever prescribed extended release naltrexone, ever prescribed buprenorphine, past month illicit buprenorphine use, and recruitment site. Relative to females, males were significantly ($OR = 0.28$, 95% CI 0.11; 0.70, $p = .007$) less likely to prefer a shot under the skin than seeing a doctor monthly for a prescription for pills or filmstrips. Treatment preference was not associated significantly with any of the other background characteristics, substance use behaviors, or treatment experiences evaluated in the multinomial logistic regression model (no Table). We note that unadjusted associations evaluated using ANOVA and χ^2 – tests were consistent with the multivariate model.

Formulation preference was associated with willingness to initiate that buprenorphine formulation while in opioid withdrawal management. About 94.1% of persons expressing a preference for pills or flimstrips, 97.4% of persons expressing a preference for a monthly shot, and 98.0% of persons expressing a preference for an implant reported they would be willing to initiate treatment with that treatment while still in managed opioid withdrawal management.

4.0 Discussion

In recent years, new formulations of buprenorphine treatment have been approved for the treatment of opioid use disorder. However, little is known about persons' willingness to use prescribed buprenorphine now that it's been available for fifteen years, or preferences for new formulations of buprenorphine just arriving in clinical settings. Extending our prior work (Bailey et al., 2013; Uebelacker et al., 2016) that showed most patients in opioid withdrawal management reported a desire for aftercare OAT, in the current sample of persons undergoing opioid withdrawal management, we found that approximately half were willing to use prescribed buprenorphine in the future. Although most preferred oral buprenorphine, respondents interested in future buprenorphine treatment were willing to use a variety of formulations (i.e., injections, implants) and to start their preferred treatment during a similar brief inpatient stay. Respondents' overall willingness to use injectable or implantable buprenorphine is promising given that these longer-acting formulations, relative to oral buprenorphine, may increase treatment retention and reduce risk for diversion.

The current findings support a model of care in which opioid withdrawal programs include, and indeed promote, OAT initiation. Study participants' overall willingness to use buprenorphine in the future offers important implications. Providing immediate withdrawal symptom relief with sublingual buprenorphine, evaluating and treating existing co-morbid mental health conditions, and then discussing various buprenorphine formulation options that can be delivered on-site may be effective in rapidly transitioning many patients to treatment that can aid long-term recovery.

Notably, however, nearly half of study participants were not willing to start, or restart, buprenorphine in the future. Participants offered this response prior to being prompted about new formulations of buprenorphine, although some may have known about such new

products. Consistent with Uebelacker's (2016) findings, but in opposition to Ridge's (2009) findings and our study hypotheses, prior buprenorphine treatment was not associated with willingness to try prescribed buprenorphine in the future. We did not assess if respondents' prior experience with buprenorphine was negative or positive, which would likely influence one's preference for buprenorphine in the future (Pinto et al., 2010). Qualitative research that examines what patients do not like about buprenorphine treatment and providers can shed light on aspects that could be improved upon. In contrast, respondents reporting prior use of illicit buprenorphine were more willing to use buprenorphine in the future. It is possible that patients using buprenorphine illicitly to control withdrawal symptoms have experienced the benefits of buprenorphine, without any logistical challenges or demands that might be associated with formal buprenorphine treatment. Patients reporting a prior overdose were also more willing to use buprenorphine, perhaps indicating that experiencing life threatening overdose may be associated with increased willingness to try any OAT. Surprisingly, past year IDU (an opioid use severity marker) did not predict willingness to use buprenorphine in the future. This cohort was already a "high severity" group given its near-daily frequency of opioid use and high rates of heroin use; therefore, IDU may not be a good marker of "severity" in this sample. Further, the great majority of this sample were injectors. One of the clinical sites was more likely to have patients willing to use buprenorphine. Although SSTAR offers both methadone and buprenorphine within their suite of outpatient treatment options, because SSTAR uses methadone during its brief inpatient program SSTAR patients may more easily transition to methadone, and thus disfavor buprenorphine, relative to ADI patients. However, because surveys were administered upon program entry, care received was unlikely to affect willingness, other patient differences between the sites may be at work. Reasons for site differences in buprenorphine interest is worthy of future study.

In general, buprenorphine formulation preferences did not differ by individual level factors. However, men were more likely to prefer oral buprenorphine than women. In prior work (Stein et al., 2012), sex did not predict buprenorphine preference (vs. methadone) treatment, although women were more likely to initiate OAT than men. Therefore, it is plausible that women are more amenable to novel treatments, and men may prefer well-established oral formulations. It is also possible that persons who prefer the oral formulation are those who prefer greater personal control of treatment, which allows for modifying the daily dose, taking treatment holidays, and perhaps diverting some doses for money.

4.1 Limitations

Although patients with preferences for buprenorphine are up to three times more likely to be prescribed buprenorphine than those without such preferences (Ridge et al., 2009), in this study we did not assess which type of buprenorphine treatment respondents received, if any, following discharge from their withdrawal management program. Future work should consider how withdrawal programs could influence one's willingness to engage in prescribed buprenorphine treatment. Second, we didn't assess respondents' previous knowledge about the formulations that are not yet widespread, although we provided brief explanations of a likely visit schedule. Third, the sample used in this study is limited to patients entering withdrawal management at two sites in the Northeast. Research is needed

that examines buprenorphine-related preferences in different regions as well as among patients seeking OAT, both of which may produce different findings. Fourth, we did not assess whether persons unwilling to use buprenorphine in the future were willing to use other medication treatments. Fifth, because those who responded they would *not* “be willing to be prescribed buprenorphine or Suboxone in the future” were not asked about any of the newer formulations of buprenorphine, the 54.7% rate of future buprenorphine interest likely represents a lower bound estimate. Finally, given the novelty of the research area, our measures assessing buprenorphine preferences were not established, validated measures.

4.2 Conclusions

In the current sample, a majority of people who used opioids were willing to receive prescribed buprenorphine in the future, and appeared amenable to receiving oral, injectable, or implantable formulations. Providing persons seeking managed withdrawal with education about novel buprenorphine formulations, if locally available, might increase the number of persons willing to use buprenorphine, although our study was not designed to answer this question. Shared decision-making models that emphasize joint patient-clinician treatment may be employed during withdrawal management to effectively transition patients to a suitable buprenorphine treatment regimen (Joosten, de Weert, Sensky, van der Staak, & de Jong, 2008; Joosten, DeFuentes-Merillas, et al., 2008). Education targeted at patients reporting prior overdose or recent illicit buprenorphine use may be particularly effective as patients with this profile appear amenable to pursuing prescribed buprenorphine treatment. Determining how to best transition patients from withdrawal management settings to long term buprenorphine treatment remains to be seen, but is critical during this epidemic of opioid addiction and overdose.

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Highlights

- About half the sample was willing to use prescribed buprenorphine (BUP-RX).
- Prior illicit BUP use and overdose were associated with willingness to use BUP-RX.
- BUP treatment was not associated with willingness to use BUP-RX.
- Oral BUP-RX was preferred over than injection or bi-annual implant.
- Men reported greater willingness to use oral BUP-RX than women.

Table 1.

Background Characteristics and Treatment History by Willing to Use Prescribed Buprenorphine in the Future.

	<u>Willing to Use Buprenorphine</u>			t or χ^2 (<i>p</i> =)
	Sample (n = 338)	No (n = 153)	Yes (n = 185)	
Age of Participant	33.9 ($\pm$ 9.5)	33.5 ($\pm$ 9.3)	34.3 ($\pm$ 9.7)	−0.84 (.399)
n (%) Male	238 (70.4%)	106 (69.3%)	132 (71.4%)	0.68 (.678)
n (%) White	280 (82.8%)	123 (80.4%)	157 (84.9%)	1.17 (.278)
n (%) Latino/a	37 (11.0%)	16 (10.5%)	21 (11.4%)	0.07 (.793)
Yrs Education	12.2 ($\pm$ 2.0)	12.4 ($\pm$ 2.0)	12.0 ($\pm$ 2.0)	1.64 (.102)
n (%) Employed	83 (24.6%)	42 (27.5%)	41 (22.2%)	1.26 (.261)
n (%) Homeless	65 (19.2%)	25 (16.3%)	40 (21.6%)	1.50 (.220)
n (%) Past Year IDU	241 (71.3%)	110 (71.9%)	131 (70.8%)	0.08 (.826)
n (%) Past Mo. Heroin Use	303 (89.6%)	134 (87.6%)	169 (91.4%)	1.28 (.258)
n (%) Past Mo. Illicit Bup. Use	264 (78.1%)	111 (72.6%)	153 (82.7%)	5.05 (.025)
n (%) Ever in Bup. Rx	188 (55.6%)	79 (51.6%)	109 (58.9%)	1.80 (.180)
n (%) Ever in Methadone Rx	172 (50.9%)	71 (46.4%)	101 (54.6%)	2.25 (.134)
n (%) Ever in ERN ^I Rx	69 (20.4%)	38 (24.8%)	31 (16.7%)	3.37 (.067)
n (%) Ever OAT	265 (78.4%)	117 (76.5%)	148 (80.0%)	0.62 (.433)
n (%) Ever Overdosed	189 (55.9%)	75 (49.0%)	114 (61.6%)	5.40 (.020)
n (%) Site A	264 (78.1%)	128 (83.7%)	136 (73.5%)	5.04 (.025)

^I
Extended release naltrexone