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Inability to access buprenorphine treatment as a risk factor for using diverted buprenorphine

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Abstract

Background—As buprenorphine prescribing has increased in the United States so have reports of its diversion. The study purpose was to examine frequency and source of and risk factors for diverted buprenorphine use over a 6-month period in an Appalachian community sample of prescription opioid abusers.

Methods—There were 503 participants at baseline; 471 completed the 6-month follow-up assessment. Psychiatric disorders and demographic, drug use, and social network characteristics were ascertained at baseline and follow-up. Multivariable logistic regression was used to determine the predictors of diverted buprenorphine use over the 6-month period.

Results—Lifetime buprenorphine use “to get high” was 70.1%. Nearly half (46.5%) used diverted buprenorphine over the 6-month follow-up period; among these persons, 9.6% and 50.6% were daily and sporadic (1–2 uses over the 6-months) users, respectively. The most common sources were dealers (58.7%) and friends (31.6%). Predictors of increased risk of use of diverted buprenorphine during the 6-month follow-up included inability to access buprenorphine treatment (AOR: 7.31, 95% CI: 2.07, 25.8), meeting criteria for generalized anxiety disorder, and past 30 day use of OxyContin, methamphetamine and/or alcohol.

Conclusions—These results suggest that improving, rather than limiting, access to good quality affordable buprenorphine treatment may be an effective public health strategy to mitigate buprenorphine abuse. Future work should evaluate why more persons did not attempt to access treatment, determine how motivations change over time, and how different motivations affect diversion of the different buprenorphine formulations.

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Keywords

diversion; prescription opioids; buprenorphine; abuse; opioid dependence treatment

1. Introduction

Office-based opioid dependence treatment (OBOT) with buprenorphine (non-generic and generic buprenorphine tablets, and non-generic buprenorphine tablets and film) in the United States (US) has grown considerably since its Food and Drug Administration approval in 2002. In 2010 there were approximately 500,000 unique recipients of buprenorphine (Dart, 2011). However, with increased buprenorphine availability, there have been increased reports of buprenorphine misuse and diversion. Specifically, U.S. emergency department (ED) visits related to buprenorphine misuse/abuse according to the Drug Abuse Warning Network (DAWN) increased from 5025 visits in 2006 to 17,546 visits in 2009, National Forensic Laboratory Information System (NFLIS) seizures (representing diverted buprenorphine) increased from 446 in 2005 to 6722 in 2009, and Poison Control Center exposures increased from 765 in 2006 to 3212 in 2009. These increases were primarily, but not entirely, accounted for by the increased amounts of non-generic buprenorphine tablets sold over these years (Johanson et al., 2012). Specifically, there were an excess of 20 DAWN ED visits, 46 NFLIS seizures, and 23 Poison Control Center exposures per year for each additional million tablets sold per year.

Determining risk factors for use of diverted buprenorphine is a critical step in order to develop public health strategies to mitigate this adverse event. Studies in France show that prior drug use by intravenous and intranasal routes predict buprenorphine misuse via intravenous and intranasal routes, respectively (Roux et al., 2008a; Roux et al., 2008b; Vidal-Trecan et al., 2003). However, there are no prospective data regarding predictors of diverted buprenorphine use within the US. Thus, the purpose of this study was to prospectively evaluate the risk factors, frequency and source of buprenorphine used among a community sample of prescription opioid abusers. Both individual and social network-level characteristics were examined. Social networks influence drug use initiation and continuation (Valente et al., 2004), but their role in buprenorphine diversion has not yet been evaluated.

2. Methods

2.1 Study design and population

This prospective analysis is nested within an ongoing longitudinal cohort study of social networks and HIV risk among rural Appalachian drug users. Inclusion criteria included: 1) age 18 years or older; 2) residing in an Appalachian Kentucky county; and 3) recent (i.e., last 30-day) use of prescription opioids, heroin, cocaine and/or methamphetamine. Participants were compensated \$50 per study visit. The University of Kentucky Institutional Review Board approved the study.

2.2 Sampling

The cohort was recruited using Respondent Driven Sampling (RDS) that is effective in recruiting hard-to-reach populations, including rural drug users (Heckathorn, 1997; 2002; Wang et al., 2007). Initial recruits (i.e., seeds) were identified through community outreach, word-of-mouth, and flyers. Each seed was given three coupons with which to recruit their peers. Seeds received \$10 for each redeemed coupon. Recruited peers then were asked to recruit their peers and so on, until the desired sample size was reached (n=503).

2.3 Variables and Measures

Trained non-clinician interviewers conducted baseline and 6-month follow-up interviews. Baseline questionnaires included the Addiction Severity Index (McLellan et al., 1992) and the Mini-International Neuropsychiatric Interview (MINI), version 5.0 (Sheehan et al., 1998). Demographic variables, collected by the ASI, included gender, age, years of education, legal income, current marital (married/unmarried) and employment status (see Table 1 for categories), and race (white/non-white). ASI drug use variables included number of previous detoxification and drug treatment episodes, recent number of days with drug problems, recent number of days using several drugs (see Table 1 for specific drugs queried) received by illegal (i.e., not prescribed) and legal (i.e., prescribed) means. The MINI determined whether Diagnostic and Statistical Manual of Mental Disorders criteria were met for current major depressive disorder (MDD), generalized anxiety disorder (GAD) and antisocial personality disorder (ASPD). Participants also were asked “Have you ever attempted, but were unable to get into buprenorphine treatment?” A name-generating questionnaire determined the total number of persons in each participant’s social network with whom the participant used drugs (drug network), had sex (sex network) and counted on for social support (support network) in the past 6-months. These characteristics listed above served as independent variables for subsequent analyses. In addition, participants were queried about their primary source for buprenorphine.

At the 6-month follow-up visit subjects were asked if they had ever used buprenorphine (non-generic buprenorphine, generic buprenorphine tablets, and buprenorphine and naloxone to get high. If the answer was “yes,” frequency of non-prescribed (i.e., diverted) use was determined over the last 6 months and 30 days. The dependent variable analyzed was past 6-month use of diverted buprenorphine (yes/no).

2.4 Analytic Plan

Descriptive statistics are provided on the prevalence, frequency and source of diverted buprenorphine used. Chi-square tests and Wilcoxon rank-sum tests for categorical and continuous variables, respectively, were completed comparing characteristics of those who reported any past 6-month diverted buprenorphine use to those who reported none. As participants were nested within social networks, a variance component model evaluated whether diverted buprenorphine use differed across network components; results showed it did not. Thus, multivariable logistic regression was employed to model the risk factors (see Table 1 for list of independent variables) for any past 6-month diverted buprenorphine use. Variables significant at the $p < 0.10$ level in unadjusted models were entered into the multivariable logistic model one at a time from most to least significant. Only variables significant (i.e., $p < 0.05$) were retained in the final model. STATA, version 12.0 was utilized for all analyses.

3. Results

There were 503 participants at baseline; all reported past 30-day non-medical prescription opioid use “to get high.” Ninety-three percent ($n=471$) completed the 6-month follow-up interview and were included in the results reported here. The majority reported using buprenorphine “to get high” at least once in their lifetime (70.1%; $n=330$). Nearly half (46.5%; $n=219$) had used diverted buprenorphine between the baseline and 6-month follow-up visit; most (50.7%; $n=111$) were sporadic users, reporting 1–2 uses over this time period. Daily use was uncommon (9.6%; $n=21$). The median number of days of diverted buprenorphine use in the last 30 days was 1 (interquartile range: 0, 3). The most common primary sources of buprenorphine were: dealer (58.7%) and friends (31.6%), followed by

family (7.3%) and spouse/partner (1.4%). Physicians were rarely (0.9%) a primary source as expected.

Table 1 shows the baseline characteristics among those who did (n=219) and did not (n=252) report any past 6-month use of diverted buprenorphine. Median and interquartile range (IQR) of monthly legal income did not differ (p=0.781) between those who had used diverted buprenorphine [\$500 (IQR: 150, 900)] and those who had not [\$573 (200, 900)]. The only sociodemographic difference between these two groups was being on disability, which decreased the odds of having used diverted buprenorphine compared to the unemployed. Recent use of OxyContin, hydrocodone, methamphetamine and alcohol at baseline increased, while recent use of benzodiazepines decreased, the odds of having used buprenorphine. Injection drug use (IDU) and meeting criteria for GAD at baseline, and attempting but failing to access buprenorphine treatment (p=0.001) also were significant risk factors. Lastly, for each additional member of one's drug network, the odds of using diverted buprenorphine increased 5%.

In the adjusted model (Table 2), six variables emerged as significant predictors of diverted buprenorphine use over the 6-month period. The strongest predictor was attempting but failing to access buprenorphine treatment (Adjusted Odds Ratio [AOR]: 7.31, 95% Confidence Interval [CI]: 2.07, 25.8). Meeting criteria for GAD and recent use of OxyContin, methamphetamine, and alcohol at baseline also were independent risk factors. Recent benzodiazepine use was associated with decreased risk (AOR: 0.53, 95% CI: 0.31, 0.89). Drug network characteristics and being on disability were not significant variables in the adjusted model.

4. Discussion

This study prospectively evaluated risk factors for diverted buprenorphine use in a community-based sample of prescription opioid abusers in the US. Attempting but failing to access buprenorphine treatment was the strongest predictor of diverted buprenorphine use over the 6-month period, increasing the risk 7-fold. Notably, daily use of diverted buprenorphine was uncommon (i.e., n=21 of 471 or 4.5% of the sample).

The finding that the most robust risk factor for buprenorphine use was failing to access legitimate buprenorphine treatment has several important implications. First, it suggests that increasing, not limiting, buprenorphine treatment access may be an effective response to buprenorphine diversion among persons not in treatment. However, it is noteworthy that relatively few participants (n=19) overall attempted to access buprenorphine treatment suggesting a need to understand better why more persons were not attempting to access OBOT. One potential reason is that the cost of OBOT is too high for this sample; monthly legal incomes were approximately \$500 yet the cost of OBOT treatment in Kentucky (KY) is on average \$940/month [e.g., 16 mg/day of buprenorphine and naloxone film costs ~\$540 at KY Walmart stores and the largest provider of OBOT in KY charges ~\$400/month].

Other inventions also are likely needed to mitigate diversion. Dealers and friends were the most common source of diverted buprenorphine in this sample. Friends and family were the most common sources of non-medical use of prescription opioids in the National Survey on Drug Use and Health, but the majority of the friends and family had received them from doctors' prescriptions (SAMHSA, 2009). Thus, it is possible that doctors are an indirect source of diverted buprenorphine and could benefit from continuing educational activities targeted at improving current OBOT practices. For instance, there are data showing that doctors providing OBOT in Appalachia as well as other US regions have limited understanding of the legislation allowing for OBOT, the clinically relevant pharmacology of buprenorphine, and many were not engaging in currently recommended OBOT practice

behaviors (i.e., only 50% of doctors reported routinely inducing patients while in withdrawal; Lofwall et al. 2011). While OBOT physicians are regulated by the Drug Enforcement Administration (DEA), DEA regulation is not aimed at teaching or evaluating for quality OBOT practices. Importantly, quality care OBOT practices have been shown to reduce illicit opioid use and increase drug abstinence (Alford et al., 2011; Fiellin et al., 2008; Parran et al., 2010; Soeffing et al., 2009). Thus, OBOT has the potential to not only reduce buprenorphine diversion and misuse, but also diversion and misuse of the prescription opioid analgesics that have been associated with increasing unintentional overdose deaths (Hall et al., 2008; Paulozzi et al., 2006; Paulozzi and Ryan, 2006).

Recent oxycodone use also was a risk factor for diverted buprenorphine use. Oxycodone abuse is highly prevalent in Appalachia and associated with a more severe profile of drug problems compared to abuse of other prescription opioids (Havens et al., 2007a; Young and Havens, 2012). Thus, it may be that oxycodone use is an indicator of someone with a more severe drug use disorder that is trying to use buprenorphine to relieve withdrawal symptoms and/or treat their addiction as others have reported (Alho et al., 2007; Mitchell et al., 2009; Monte et al., 2009).

Methamphetamine and alcohol use also were predictors of buprenorphine use. This fits a general pattern of poly-drug use in this cohort that is consistent with other studies among rural Appalachian drug users (Shannon et al., 2011; Havens et al., 2007b). Another interesting finding was that those with GAD were more likely to have used diverted buprenorphine. It has been speculated, although not widely accepted or proven, that buprenorphine may be effective in treating anxiety (McCann, 2008), suggesting a self-medication hypothesis to explain the results here. However, this diagnosis was made by the MINI and was not confirmed by a clinical interviewer, which is a study limitation.

Lastly, recent benzodiazepine use is clearly *not* a risk factor for use of diverted buprenorphine in this sample. While it was associated with a lower adjusted odds ratio, it would be incorrect to say that benzodiazepine use is protective because benzodiazepine use was very high (>80%) among those who did and did not use diverted buprenorphine, far greater than other buprenorphine-treated populations (e.g., 46% for Lavie et al., 2009; 32% among those in the Bramness and Kornor, 2007; and 67% for Nielsen et al., 2007). This high prevalence of benzodiazepine use is concerning because the majority of deaths with buprenorphine have occurred when combined with other central nervous system depressants like the benzodiazepines, particularly by the intravenous route (Kintz, 2001).

While lifetime buprenorphine use “to get high” was specifically queried, the motivations for use of past 6-month and recent use of diverted buprenorphine were not systematically queried. Thus, it is possible that persons were using buprenorphine for a variety of reasons such as treating their own addiction and/or opioid withdrawal as others have reported (Alho et al., 2007; Mitchell et al., 2009; Monte et al., 2009). In fact, several subjects said they were using the medication to treat their addiction and withdrawal. Future research should more clearly evaluate motivations at each use along with route of use and the formulation of buprenorphine used (e.g., film, tablet, generic or combination products). Differences in motivations and routes of use of diverted medication may vary depending on the formulation as well as the subject population (e.g., opioid dependent or not). For example, if buprenorphine/naloxone is misused by a parenteral route in an opioid dependent individual, it produces more severe precipitated opioid withdrawal compared to buprenorphine alone (Stoller et al., 2001). However, among recently detoxified and non-dependent opioid abusers, there is no statistically significant difference in self-administration of buprenorphine/naloxone compared to buprenorphine alone (Comer and Cone 2002), and

naloxone does not significantly diminish buprenorphine's opioid agonist effects when administered intranasally or sublingually (Middleton et al. 2011; Strain et al., 2000).

4.2. Conclusions

The inability of nonmedical prescription opioid users to access buprenorphine treatment was the strongest predictor of diverted buprenorphine use. However, relatively few participants attempted to access treatment overall. Therefore, understanding why there were not more attempts to access OBOT and ensuring adequate access to quality, affordable OBOT are logical next steps in attempting to reduce diverted buprenorphine use; such actions also should decrease use of other diverted prescription opioids that have been associated with the US epidemic of unintentional overdose deaths.

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Table 1

Characteristics of Prescription Opioid Abusers (n=471) who Did and Did Not Use Diverted Buprenorphine over the 6-month Follow-Up Period

Baseline Variables	Bup Use n=219		No Bup Use N=252		p-value	Odds Ratio	95% CI
	n	%	n	%			
Demographics							
Female	103	47.0	104	41.3	0.209	1.26	0.87, 1.82
White	208	95.0	235	93.2	0.430	1.37	0.62, 2.99
Age in years, med (IQR) *	30 (26, 36)		32 (27, 38)		0.064	0.98	0.96, 1.00
Years of education, med (IQR)	12 (10, 12)		12 (10, 12)		0.426	1.00	0.99, 1.01
Married	54	24.7	66	26.2	0.703	0.92	0.61, 1.39
Employment:							
Unemployed	50	22.8	60	23.8	-	1.00	-
Full-Time	74	33.8	89	35.3	0.189	0.73	0.45, 1.16
Part-Time	66	30.1	58	23.0	0.236	0.73	0.44, 1.22
Disability	22	10.0	38	15.1	0.036	0.51	0.27, 0.95
Student/retired/military	7	3.2	7	2.8	0.819	0.88	0.29, 2.65
Past 30-day drug use, # days							
Legal (prescribed) methadone use	3	1.4	10	4.0	0.086	0.37	0.09, 1.24
Illegal (not prescribed) use of:							
Methadone	139	63.5	145	57.5	0.189	1.28	0.88, 1.86
OxyContin	167	76.3	162	64.3	0.005	1.78	1.19, 2.67
Other oxycodone	165	75.3	178	70.6	0.252	1.27	0.84, 1.91
Hydrocodone	188	86.2	197	78.2	0.024	1.79	1.07, 2.85
Benzodiazepines	178	81.3	222	88.1	0.039	0.57	0.35, 0.97
Alcohol	131	59.8	123	48.8	0.017	1.56	1.08, 2.25
Heroin	8	3.65	12	4.76	0.552	0.76	0.30, 1.89
Cocaine	58	26.5	49	19.4	0.069	1.49	0.97, 2.30
Crack cocaine	25	11.4	29	11.5	0.975	0.99	0.56, 1.74
Methamphetamine	12	5.6	3	1.2	0.008	4.81	1.33, 17.3
Marijuana	142	64.2	146	57.9	0.125	1.34	0.92, 1.95

Baseline Variables	Bup Use n=219		No Bup Use N=252		p-value	Odds Ratio	95% CI
	n	%	n	%			
1 day of IDU in past 6 months	137	62.6	132	52.4	0.026	1.52	1.05, 2.19
Treatment							
Tried and failed to enter buprenorphine treatment (tx)	16	7.3	3	1.2	0.001	6.54	1.87, 22.7
# Days drug problems, med (IQR)	10 (0, 30)		10 (0, 30)		0.467	1.00	0.99, 1.02
# Previous tx episodes, med (IQR)	1 (0, 2)		1 (0, 2)		0.834	1.01	0.95, 1.09
# Previous of detoxs, med (IQR)	0 (0, 1)		0 (0, 1)		0.543	1.05	0.97, 1.13
DSM-IV Disorders							
Major Depressive Disorder	55	25.1	68	27.0	0.645	0.91	0.60, 1.37
Generalized Anxiety Disorder	79	36.1	61	24.2	0.005	1.77	1.18, 2.63
Antisocial Personality Disorder	76	34.7	72	28.6	0.153	1.33	0.89, 1.96
Social Network							
# Persons in Drug Network	5 (3, 10)		4 (2, 8)		0.031	1.05	1.01, 1.09
# Persons in Sex Network	2 (1, 5)		2 (1, 5)		0.273	1.01	0.97, 1.06
# Persons in Support Network	2 (1, 3)		2 (1, 3)		0.242	1.10	0.95, 1.27

* Med= median and IQR=interquartile range.

Table 2

Factors Predictive of Diverted Buprenorphine Use

	Adjusted Odds Ratio	95% Confidence Interval
Tried and failed to access buprenorphine treatment	7.31	2.07, 25.8
Past 30 Day Use of Non-Prescribed:		
OxyContin®	1.80	1.18, 2.75
Benzodiazepines	0.53	0.31, 0.89
Methamphetamine	4.77	1.30, 17.5
Alcohol	1.60	1.09, 2.36
Generalized Anxiety Disorder	1.69	1.11, 2.56