Office-Based Management of Opioid Dependence with Buprenorphine: Clinical Practices and Barriers

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BACKGROUND: Buprenorphine is a safe, effective and underutilized treatment for opioid dependence that requires special credentialing, known as a waiver, to prescribe in the United States.

OBJECTIVE: To describe buprenorphine clinical practices and barriers among office-based physicians.

DESIGN: Cross-sectional survey.

PARTICIPANTS: Two hundred thirty-five office-based physicians waived to prescribe buprenorphine in Massachusetts.

MEASUREMENTS: Questionnaires mailed to all waived physicians in Massachusetts in October and November 2005 included questions on medical specialty, practice setting, clinical practices, and barriers to prescribing. Logistic regression analyses were used to identify factors associated with prescribing.

RESULTS: Prescribers were 66% of respondents and prescribed to a median of ten patients. Clinical practices included mandatory counseling (79%), drug screening (82%), observed induction (57%), linkage to methadone maintenance (40%), and storing buprenorphine notes separate from other medical records (33%). Most non-prescribers (54%) reported they would prescribe if barriers were reduced. Being a primary care physician compared to a psychiatrist (AOR: 3.02; 95% CI: 1.48–6.18) and solo practice only compared to group practice (AOR: 3.01; 95% CI: 1.23–7.35) were associated with prescribing, while reporting low patient demand (AOR: 0.043, 95% CI: 0.009–0.21) and insufficient institutional support (AOR: 0.37; 95% CI: 0.15–0.89) were associated with not prescribing.

CONCLUSIONS: Capacity for increased buprenorphine prescribing exists among physicians who have already obtained a waiver to prescribe. Increased efforts to link waived physicians with opioid-dependent patients and initiatives to improve institutional support may mitigate barriers to buprenorphine treatment. Several guideline-driven practices have been widely adopted, such as adjunctive counseling and monitoring patients with drug screening.

KEY WORDS: opioid dependence; buprenorphine; medication assisted treatment.

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INTRODUCTION

Although opioid dependence is steadily increasing in the United States, the number of federally licensed methadone maintenance treatment slots is unchanged at approximately 250,000 and unevenly distributed geographically.¹ Buprenorphine is a safe, effective medication for opioid dependence that is associated with increased treatment retention, reduced illicit opioid use, reduced opioid craving, increased survival, and few adverse effects in research and community office-based settings.^{2–12} With the enactment of the Drug Addiction Treatment Act (DATA) of 2000 and the Food and Drug Administration's approval of sublingual buprenorphine for the treatment of opioid dependence in October 2002, office-based physicians in the United States, such as primary care physicians and psychiatrists, gained the opportunity to treat opioid-dependent patients with buprenorphine, commonly referred to as office-based opioid treatment (OBOT).¹³

To provide OBOT with buprenorphine, DATA 2000 requires physicians to obtain a waiver from the federal Center for Substance Abuse Treatment (CSAT). Prescribing physicians are responsible for providing patients with or referring patients to substance abuse counseling as well as developing linkages to other addiction treatment programs (e.g., methadone maintenance treatment). CSAT-issued guidelines form the core curriculum of treatment practices for the required 8-hour certification course.¹⁴ Sublingual buprenorphine is indicated for medically supervised taper (detoxification) or maintenance treatment in opioid-dependent patients. The guidelines recommend that dosing during the 1st day of induction be observed in a medical setting, such as the office. The guidelines recommend monitoring treatment adherence with drug toxicology screening, and pill counts. To decrease abuse and diversion, the use of the sublingual tablet coformulation of buprenorphine/naloxone ("combo" tablet) is recommended in all cases except for pregnant patients and during the first part of supervised induction for

patients who are dependent on long-acting opioids. In these cases, the sublingual tablet of buprenorphine alone ("mono" tablet) is indicated. Consistent with federal public health regulations that require specific protections of drug and alcohol treatment information,¹⁵ procedures should be established to ensure the privacy and confidentiality of patients treated with buprenorphine, such as storing OBOT records separately from other general medical information.

With buprenorphine as the first opioid agonist medication FDA-approved for OBOT, generalist physicians are taking on a new role in addiction treatment that requires additional guideline-driven training and certification. Because the system to certify and waiver physicians to prescribe buprenorphine is unique, it is important to examine the barriers waived physicians encounter in prescribing this medication and how practices compare to guidelines. Previous examinations of barriers to providing OBOT with buprenorphine were conducted within a year of its approval and were focused on addiction specialists.^{16,17} In September 2003, Kissin et al. surveyed a random national sample of 545 addiction specialists who had obtained a waiver, finding that 58% of those waived, prescribed. Significant predictors of prescribing included longer time since obtaining waiver, working in a solo or "individual" practice, and working in a specialty substance abuse treatment program. Predictors of not prescribing included being a psychiatrist.

Because of the substantial mortality and morbidity from opioid dependence,¹⁸ the Massachusetts Department of Public Health (MA DPH) surveyed all 356 waived physicians in October and November of 2005 about their practices and barriers to office-based opioid treatment with buprenorphine. This study advances current understanding because we surveyed both the barriers to prescribing buprenorphine and treatment practices among substantial numbers of physicians without addiction specialty certification who were waived to prescribe buprenorphine 3 years after it was initially available. We report the findings from this survey.

METHODS

Population

In October of 2005, MA DPH mailed two questionnaires, one for prescribers and one for non-prescribers, to all 356 physicians in Massachusetts waived by CSAT to prescribe buprenorphine. Non-respondents were sent a second mailing in November 2005. Mailings included a cover letter from MA DPH explaining that only one of the two mailed questionnaires should be completed based on whether or not the physician was currently prescribing buprenorphine. A self-addressed, stamped envelope was included in the mailing. No personal demographic information was collected and no compensation was offered for completing the questionnaires. Respondents who indicated on their questionnaire that they did not work in an office-based setting were excluded from analysis, because of our focus on describing OBOT.

Data Collection

Both questionnaires included questions about medical specialty, practice setting, addiction society certification, and barriers to prescribing. Respondents were asked about nine barriers to prescribing (for prescribers, "Have you experienced any of the following barriers to the provision of buprenorphine

treatment?" and for non-prescribers, "Why do you not currently prescribe buprenorphine?"), including stigma among office staff, "payment issues," "pharmacy issues," low patient demand for treatment, insufficient physician or staff knowledge, and lack of nursing, office, and institutional support. In addition, a space to specify "other" barriers was provided. The prescriber questionnaire inquired about the following treatment practices: the number of patients currently treated; prescribing indication (detox or maintenance); buprenorphine induction location (office versus home); the use of substance abuse counseling; the availability of methadone maintenance programs for referral of the use of monitoring practices, such as drug screens or pill counts; indication for the use of the mono tablet; and whether OBOT patient information is stored separately from other patient medical records. The non-prescriber questionnaire asked about past prescribing and plans to prescribe in the future.

Statistical Analysis

The dependent variable of interest was prescriber status (prescriber vs. non-prescriber). We performed frequencies and proportions for each of the questionnaire responses above, overall and by prescriber status. We dichotomized the medical specialty variable into psychiatrists and primary care physicians (general internists, family practitioners, or pediatricians), as these disciplines accounted for nearly all waived physicians. We also dichotomized the practice setting variable (i.e., group vs. solo), collapsing those who reported both group and solo practice into the group practice category. We conducted bivariate comparisons of these variables and the barrier variables for prescribers and non-prescribers using chi-square tests. To identify factors associated with prescribing buprenorphine, we fit multiple logistic regression models, including the following independent variables: medical specialty, practice setting, addiction society certification, and seven potential barriers to prescribing (insufficient nursing/office support, lack of institutional support, low demand, insufficient physician knowledge, insufficient staff knowledge, payment issues, and pharmacy issues). Correlation analyses were performed prior to performing regression analyses to identify potential variables that may be collinear ($r > 0.4$). Because of high correlation between the nursing support barrier and the office support barrier ($r = 0.56$), we combined these into a single variable (insufficient nursing or office support) for the logistic regression. We did not include the office staff stigma barrier in the regression, because no non-prescribers reported this barrier. This study was approved by the institutional review board at Boston Medical Center. All statistical analyses were done using SAS 9.1.

RESULTS

Of the 356 waived physicians who were sent a survey, 235 (66%) were included in our analysis. Of the 121 physicians who were excluded from analyses, 20 questionnaires were returned because of wrong address, 80 questionnaires were non-respondents, and 21 respondents were excluded because they did not practice in an office setting (Fig. 1). The survey response rate, excluding wrong addresses and non-office based physicians, was 75% (235/315).

Figure 1. Survey response.

Characteristics and Barriers Among Prescribers and Non-prescribers

Among the 235 physicians in the study sample, 156/235 (66%) were prescribers and 79/235 (34%) were non-prescribers. The characteristics and barriers reported by the total sample and by prescriber status are presented in Table 1. Respondents were from psychiatry (54%) and primary care specialties (44%), in some group practice setting (74%), or only solo practice (26%). Addiction society certification was held by 24%. The more common barriers among prescribers were payment issues, insufficient nursing support, insufficient office support, lack of institutional support, and pharmacy issues. The more common barriers for non-prescribers were insufficient office support, insufficient nursing support, lack of institutional support, insufficient staff knowledge, and low demand. About half of prescribers reported at least one barrier, whereas two-thirds of non-prescribers reported at least one barrier.

OBOT Practices

Results of the prescriber survey are presented in Table 2. Prescribers reported currently treating a median of 10 (interquartile range 3–25.5) patients and a mean of 14 patients. Only 8% of prescribers provided detoxification treatment alone. Forty-three percent of prescribers have at least some of their patients on complete buprenorphine induction at home (i.e., not directly observed). Substance abuse counseling was mandated by 79%, with 66% offering individual and 39% offering group counseling in their practice, and 57% referring to counseling elsewhere. To address opioid-dependent patients who failed or did not qualify for buprenorphine, 86% of respondents stated that they had the capacity to refer patients to methadone maintenance treatment and 40% had made such referrals. Monitoring practices for illicit drug use and appropriate adherence to prescribed medications included: pill counts (43%) and drug screens (82%), with over half reporting “observed” collection of drug screens. The “mono” tablet not co-formulated with naloxone was used by 29% for the following indications: 10% induction, 13% in pregnant patients, and 11% for “patient preference.” Only one-third reported maintaining

OBOT patient information separately from other medical information. Four-fifths of prescribers accepted insurance for OBOT.

Non-prescribers and OBOT

Of those non-prescribers who had never prescribed buprenorphine, 54% (33/61) reported they will prescribe in the future if the barriers are diminished. Reasons that respondents gave for not prescribing beyond barriers specifically queried included the following: the induction period was “too demanding,” the 30-patient limit, insufficient time or space in current practice, and lack of another physician for backup. Of the non-prescribers who had prescribed in the past, 67% (10/15) reported that they would prescribe in the future if barriers were diminished.

Factors associated with prescriber status

Results of logistic regression analyses modeling prescriber status are presented in Table 3. Being a primary care physician (OR 3.02 95% CI: 1.48–6.18) and being in a solo practice only (OR 3.01 95% CI: 1.23–7.35) were factors that significantly increased the odds of prescribing in adjusted analyses. Barriers significantly associated with decreased odds of prescribing in adjusted analyses included insufficient institutional support (OR 0.37 95% CI: 0.15–0.89) and low patient demand for buprenorphine (OR 0.04 95% CI: 0.01–0.21).

Table 1. Characteristics of 235 Office-Based Respondents Waivered to Prescribe Buprenorphine in Massachusetts, Overall and by Prescriber Status

	Total n (%)	Prescribers n (%)	Non- prescribers n (%)
Total	235 (100)	156 (66)	79 (34)
Specialty*			
Psychiatrist	126 (54)	74 (47)	52 (67)
Primary care†	102 (44)	78 (50)	24 (31)
Internist	61 (26)	45 (29)	16 (21)
Family medicine	32 (14)	27 (17)	5 (6)
Pediatrician	9 (4)	6 (4)	3 (4)
Other‡	6 (3)	4 (3)	2 (3)
Practice setting§			
Solo	58 (26)	46 (30)	12 (16)
Group	169 (74)	107 (70)	62 (84)
Addiction society certified¶	55 (24)	41 (27)	14 (18)
Barriers			
Insufficient nursing support	46 (20)	25 (16)	21 (27)
Insufficient office support	44 (19)	20 (13)	24 (30)
Lack of institutional support	38 (16)	19 (12)	19 (24)
Office staff stigma	11 (5)	11 (7)	0 (0)
Low demand	17 (7)	3 (2)	14 (18)
Insufficient physician knowledge	7 (3)	5 (3)	2 (3)
Insufficient staff knowledge	28 (12)	11 (7)	17 (22)
Payment issues	40 (17)	32 (21)	8 (10)
Pharmacy issues	19 (8)	18 (12)	1 (1)
One or more barriers	130 (55)	77 (49)	53 (67)

* N=234, 1 with missing data

†Primary care is the sum of internists, family medicine, and pediatricians. “Other” excluded

‡Other specialties included “anesthesia/pain medicine” × 2, “retired surgeon,” “ambulatory/urgent care medicine,” “outpatient addiction/mental health non-psychiatrist,” “emergency medicine”

§N=227, 8 with missing data

¶N=232, 3 with missing data

||N=235, none missing

Table 2. Treatment Practices of 156 Office-Based Buprenorphine Prescribers in Massachusetts

Treatment practices	N=156
Number of patients treated, mean	13.7
Median (interquartile range)	10 (3–25.5)
Detox or maintenance* n (%)	
Detox only	12 (8)
Maintenance only	62 (41)
Detox and maintenance	77 (51)
Induction site†	
Office only (observed)	71 (47)
Home only (unobserved)	31 (21)
Office and home	32 (21)
Inpatient only	15 (10)
Substance abuse counseling	
Mandatory counseling	120 (79)
Individual counseling offered in practice	100 (66)
Group counseling offered in practice	59 (39)
Offer referral to counseling	87 (57)
Methadone program available for referral	131 (86)
Made referrals to methadone program	61 (40)
Monitoring practices:	
Pill counts	67 (43)
Drug screens	128 (82)
Observed drug screens	68 (44)
Unobserved drug screens	60 (38)
Used mono tablet (buprenorphine alone) for:	
Induction	15 (10)
Pregnant patients	21 (13)
Patient preference	17 (11)
OBOT notes stored separate from other records	46 (33)
Accept insurance for buprenorphine	119 (80)

*N=151, 5 with missing data

†N=149, 7 with missing data

DISCUSSION

This survey of waived physicians in Massachusetts revealed several important findings about who is prescribing buprenorphine and how they are doing it. Given the median number of active patients among prescribers (i.e., ten), substantial treatment capacity among current prescribers remains. Thus, efforts to increase OBOT treatment could be directed to both waived physicians who already prescribe but have further capacity by regulations as well as those who do not prescribe. The lack of office and nursing support noted as common barriers by both prescribers and non-prescribers is evidence that for many providers adding OBOT with buprenorphine to one's practice requires increased administrative and clinical resources. An example of a successful collaborative care model was recently described.³ As prescribers commonly identified payment and

pharmacy issues as barriers, it is likely that increasing insurance coverage for buprenorphine and making it more available in pharmacies would help prescribers treat more patients. Increasing prescribing among non-prescribers will likely require improved top-down institutional support and improved systems that match patients seeking treatment to waived physicians.

Determining why psychiatrists were less likely to prescribe than physicians in primary care specialties warrants further investigation. This reluctance of psychiatrists to prescribe buprenorphine was noted previously in a national survey of 1,203 psychiatrists conducted before buprenorphine was released for OBOT, where four-fifths of all respondents, including 43% of those certified in addiction psychiatry, reported they would not be comfortable providing OBOT.¹⁹ The increased likelihood of prescribing we found among primary care physicians compared to psychiatrists may be evidence that the DATA 2000 legislation has encouraged office-based treatment beyond specialty practices and into primary care. According to the CSAT guidelines, DATA 2000 "promises to bring opioid addiction care into the mainstream of medical practice."¹⁴

We found that being in solo practice versus being in a group practice was also associated with prescribing buprenorphine. Wolinsky and Friedson have described a trade off between greater resources and greater autonomy for physicians who choose to work in group or solo practices, respectively.²⁰ We expected that group practices could provide more administrative support to waived physicians who would therefore be more likely to prescribe. However, it is likely that while group practices are better resourced, they present more bureaucratic or administrative barriers to instituting a new treatment such as OBOT. Furthermore, early regulations restricted not only each individual physician to 30 patients, but each group practice to 30 total patients, which likely reduced the incentive for group practices to support providing buprenorphine treatment over competing priorities.

Clinical practices of prescribers were largely consistent with the substance and spirit of buprenorphine training and the CSAT guidelines in that they conform to the 30-patient limit that was in effect at the time of this survey, substance abuse counseling was available and being offered, and monitoring of adherence and relapse through drug screens and pill counts occurred widely among prescribers.

Although these OBOT practices were CSAT guideline-driven, others were not. Substantial numbers of physicians use unobserved home induction where patients start buprenorphine at home, usually with telephone support from a nurse or physician. A successful home induction protocol has been described,³ but is

Table 3. Unadjusted and Adjusted Logistic Regression Models for Prescribing Buprenorphine Among Waived Physicians in Massachusetts*

	Unadjusted odds ratio	95% CI	P-value	Adjusted odds ratio	95% CI	P-value
Primary care vs. psychiatry	2.28	1.28–4.07	0.005	3.02	1.48–6.18	0.002
Solo vs. group practice	2.20	1.08–4.49	0.027	3.01	1.23–7.35	0.016
Addiction society certified vs. not certified	1.66	0.84–3.27	0.145	1.57	0.68–3.61	0.286
Barriers						
Insufficient nursing or office support	0.41	0.22–0.74	0.003	0.76	0.33–1.74	0.518
Lack of institutional support	0.43	0.22–0.89	0.022	0.37	0.15–0.89	0.026
Low demand	0.09	0.03–0.33	<0.001	0.04	0.01–0.21	<0.001
Insufficient physician knowledge	1.27	0.24–6.72	0.775	2.95	0.25–34.9	0.390
Insufficient staff knowledge	0.28	0.12–0.62	0.002	0.45	0.15–1.37	0.160
Payment issues	2.29	1.00–5.24	0.050	2.00	0.73–5.48	0.177
Pharmacy issues	10.17	1.33–77.7	0.025	7.76	0.88–68.3	0.065

*N=219 for this model. Complete data not available for 16 respondents. Adjusted odds ratios from model that includes all variables in the table

not part of the CSAT guidelines. Some physicians prescribe the mono tablet for "patient preference." This is not an appropriate indication because the mono tablet is more likely to be abused by crushing it and injecting it. Thus, it is more likely to be diverted and has a higher risk of contributing to overdoses.²¹ Only one third of prescribers store their notes separately from other medical information, which is a practice not specifically required, but may facilitate compliance with federal confidentiality requirements.

Because this study targeted all physicians eligible to provide OBOT with buprenorphine in a single state almost 3 years after buprenorphine was available, it adds to and supports previous examinations of treatment practices and barriers.²² We found that two thirds of waived physicians provided OBOT with buprenorphine, confirming preliminary national estimates.^{1,16,17} As in our study, Kissin et al. found that factors associated with not prescribing buprenorphine included being a psychiatrist and working in a setting other than a solo practice. Common barriers noted in this study included concern around the induction logistics, availability of the medication, and the 30-patient limit per physician and per practice that was in force at that time.

A survey of 375 physicians attending HIV educational conferences in 2006 found 25% had obtained a waiver to prescribe buprenorphine, but only 6% had ever prescribed.²³ As in our study, the provider specialty was significantly associated with likelihood of prescribing buprenorphine. Among the HIV providers, general internists were more likely to prescribe than family medicine or infectious disease physicians. Common barriers to providing care noted by waived respondents included deficits in knowledge about opioid treatment, lack of immediate telephone access to an addiction expert, inability to refer to a substance abuse treatment program, concern about resistance from staff or colleagues, and fear of taking on increased medicolegal risks, overly complicated patients, and issues of medication diversion. Similar knowledge deficits were not commonly reported in our study, though lack of nursing, office, and institutional support were.

The issue of lack of institutional support as a barrier deserves further study. Our survey did not clearly define lack of institutional support, whether it is a barrier from group practice, insurance carrier, hospital or clinic administration. Our findings do suggest that the impact of lack of institutional support is independent of whether a waived physician is in a solo or group practice. Potential improvements in institutional support are suggested by a 2003 survey of primary care and HIV clinic directors in New York examining the barriers to providing OBOT with buprenorphine.²⁴ This study found 60% would be likely to provide OBOT with buprenorphine if training was offered. Clinic characteristics associated with increased likelihood of prescribing included providing HIV specialty care, having a secure site to store narcotics, having immediate telephone access to an addiction expert, and receiving continuing medical education credits for training.

Our study has some limitations. First, the number of patients physicians are permitted to treat has evolved, and thus our results may not fully reflect current conditions. We conducted the survey 1 month after the 30-patient limit on each group practice was lifted. Thus, some group practices may have been unwilling to commit physician time or resources to so few patients at the time of the survey, which may explain why physicians in group practices were less likely to be prescribers. Furthermore, in January of 2007, the 30-patient limit per physician was

increased to 100 patients for approved physicians prescribing for greater than 1 year. As this Massachusetts sample shows that most prescribers are not close to the 30-patient limit, the impact of increasing the limit to 100 is unlikely to be immediate. Another limitation is that the survey instrument provided nine barriers for respondents to endorse, yet important barriers may not have been included on the list, such as the 30-patient limit. A third of the non-prescribers reported none of the barriers listed, and thus some barriers to prescribing were not identified in this study.

Addictive disorders, such as opioid dependence, are chronic relapsing brain diseases. Like methadone maintenance, OBOT with buprenorphine is probably most effective as a chronic therapy for opioid dependence.² Fully integrating this treatment for a chronic disease into mainstream medical practice is occurring among generalist physicians and will likely be enhanced with substantial systematic, multidisciplinary support. Prescribing practices are largely consistent with guidelines, though more education about home induction and the indications for the mono buprenorphine-only formulation should be incorporated into training. Our study provides evidence that utilizing the existing treatment capacity among physicians waived to provide OBOT awaits the improvement of nursing, office, and institutional support and the resolution of payment and pharmacy issues.

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Conflict of Interest: None disclosed.

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