

HHS Public Access

Author manuscript *Psychiatr Serv.* Author manuscript; available in PMC 2017 August 02.

Published in final edited form as:

Psychiatr Serv. 2017 March 01; 68(3): 295–298. doi:10.1176/appi.ps.201500501.

Integrating Buprenorphine Into an Opioid Treatment Program: Tailoring Care for Patients With Opioid Use Disorders

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Abstract

Objectives—This report identifies the institutional barriers to, and benefits of, buprenorphine maintenance treatment (BMT) integration in an established hospital-based opioid treatment program (OTP).

Methods—This case study presents the authors' experiences at the clinic, hospital, and corporation levels during efforts to integrate BMT into a hospital-based OTP in New York City and a descriptive quantitative analysis of the characteristics of hospital outpatients treated with buprenorphine from 2006 to 2013 (N=735).

Results—Integration of BMT into an OTP offered patients the flexibility to transition between intensive structured care and primary care or outpatient psychiatry according to need. Main barriers encountered were regulations, clinical logistics of dispensing medications, internal cost and reimbursement issues, and professional and cultural resistance.

Conclusions—Buprenorphine integration offers a model for other OTPs to facilitate partnerships among primary care and mental health clinics to better serve diverse patients with varying clinical needs and with varying levels of social support.

Death rates from opioid overdose in the United States have increased nearly fourfold since 2000 (1), and New York City has the highest rate of opioid use of any U.S. city (2). Patients with opioid use disorders who have comorbid disorders or who are at high risk of treatment complications require multiple treatment options to meet individual needs. Buprenorphine was introduced as the first office-based opioid maintenance treatment comparable to

The authors report no financial relationships with commercial interests.

methadone in effectiveness (3). Opioid treatment programs (OTPs), previously known as methadone programs, however, also offer access to psychosocial counseling, group therapy, and vocational rehabilitation. Previous research shows that supplementary counseling improves outcomes among patients who utilize methadone in OTPs (4) and that patients who use buprenorphine are willing to participate in counseling (5).

Office-based buprenorphine treatment is regulated by the Drug Addiction Treatment Act of 2000 (DATA 2000), which allows certified physicians to prescribe and dispense FDA-approved Schedule III, IV, and V narcotic medications in treatment settings other than a traditional OTP. In 2003, the Substance Abuse and Mental Health Services Administration (SAMHSA) announced an interim final rule that allowed OTPs, which traditionally provide onlymethadone treatment, to offer buprenorphine maintenance treatment (BMT).

However, the rule required OTPs that dispense buprenorphine to follow the same regulations governing methadone use as opposed to the regulations for office-based use of buprenorphine. Like patients receiving methadone, new OTP patients using buprenorphine were required to attend clinic no less than six days per week to receive a daily dose of buprenorphine during their first 90 days of treatment. Reductions inmandated attendance were incremental, based on progress and duration in treatment. In contrast, office-based physicians can prescribe up to a month of buprenorphine medication, irrespective of duration in treatment. OTPs that wished to dispense buprenorphine in a way that approximated office-based buprenorphine take-home prescriptions were required to obtain federal and state waivers for individual patients.

Historically, urban OTPs have received Medicaid reimbursements to provide methadone treatment for heroin users, whereas people who are addicted to prescription opioids have been privately insured and have sought treatment from office-based buprenorphine providers (6). Most buprenorphine patients are treated in for-profit, private physician practices (7) and may pay out of pocket for the medication (8). These types of structural, socioeconomic, and regulatory barriers may have contributed to disparities in access to buprenorphine (9) by discouraging OTPs from introducing buprenorphine as an additional treatment alternative.

Buprenorphine integration in OTPs offers additional options for individuals who wish to switch from methadone to buprenorphine and allows OTPs to accept referrals from office-based buprenorphine providers of buprenorphine patients who are decompensating in their care or who need more psychosocial support than they are currently receiving. In 2013, the federal government (42 CFR Part 8) and the New York State Office of Alcoholism and Substance Abuse Services (NYS OASAS) provided regulatory changes allowing for OTPs to dispense take-home doses of up to one month of buprenorphine to clinically appropriate patients, a practice that more closely approximates DATA 2000 regulations compared with the daily attendance requirements for new patients receiving methadone.

Our hospital is one of the largest in New York City with a potential to reach diverse patient populations. We treat a large population of patients with substance use disorders and have a track record of implementing innovative programs, including at-home induction of buprenorphine in primary care (10), BMT following release from jail (11), and mobile phone

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technologies as treatment interventions (12). Our OTP, with its integrated ancillary psychosocial treatment options, was an ideal setting to integrate flexible buprenorphine dispensing.

Prior to the 2013 federal regulation change, BMT could be colocated with OTPs. Colocation required physicians to maintain separate clinical practices and records for those prescribed buprenorphine. One OTP reported 60% retention rates after six months for patients in colocated BMT, with 13% of patients testing positive for opioids (13). Integration of buprenorphine dispensing differs significantly from colocation. Integrated settings dispense both medications in the same clinic. Almost no literature documents integration of buprenorphine into an OTP. In this report, we offer a unique perspective on the experience of one of the first public hospitals in New York City to implement new regulatory guidelines permitting the integration of buprenorphine as well as barriers to and advantages of integration.

METHODS

This case study reports on our experiences at the clinic, hospital, and corporate levels during efforts to integrate buprenorphine into a hospital-based OTP in New York City. The OTP clinical team was responsible for obtaining and implementing patient waivers for buprenorphine dispensing in the OTP. Our firsthand experiences inform the organization of this report. The report provides descriptive quantitative analysis of data on all hospital outpatients treated with buprenorphine (N=735) from 2006 to 2013 (Table 1); data were deidentified by using procedures approved by Bellevue's Institutional Review Board.

RESULTS

In 2011, our OTP received a clinicwide waiver from NYS OASAS that would allow buprenorphine dispensing in accordance with DATA 2000, a significant modification of the requirement that newly admitted patients attend no less than six days per week to receive buprenorphine. After a six-month period of internal regulatory coordination to implement buprenorphine ordering, accounting, and dispensing, we began directly offering buprenorphine to both established patients within the OTP as well as those being admitted for treatment. OTP physicians were trained and certified as buprenorphine prescribers, nurses were trained to dispense buprenorphine, and counselors were trained to provide individual and group therapy tailored for patients receiving buprenorphine.

The NYS OASAS waiver authorized take-home doses of buprenorphine as judged appropriate by clinical staff, in accordance with DATA 2000, without the need for the state to individually waive more rigid daily attendance requirements for patients on a case-by-case basis. Because the state waiver was granted before the 2013 federal waiver, OTP staff initially still needed to apply for an individual waiver from the federal government for each patient to receive take-home buprenorphine doses at any schedule less restrictive than methadone. In January 2012, we submitted and received our first waiver from the Center for Substance Abuse Treatment (CSAT) authorizing a less restrictive attendance schedule for a

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patient being treated with buprenorphine rather than methadone. In 2013 we would no longer need to apply to CSAT for individual patient waivers because of the aforementioned federal regulatory changes.

Our OTP was the first in the New York City public health system to fully integrate BMT, including direct dispensing of medication. Approximately 40% of our patient population comes from our hospital's detoxification unit. In addition, we have established a system of patient cross-referral in which the hospital's primary care and psychiatry clinics may refer patients in buprenorphine care who are experiencing continued relapse, elevated medication diversion risk, or other factors for which a higher level of care may be recommended. In its initial stages, less than 10% of our total OTP census received buprenorphine. During the initial 20 months of implementation, patients enrolled in OTP demonstrated lower rates of positive urine toxicology results for opioids compared with patients in primary care and outpatient psychiatry (Table 1).

As we built this new partnership among OTP, primary care, and psychiatry clinics to integrate buprenorphine, the main barriers encountered were regulations, clinical logistics of dispensing medications, internal cost and reimbursement issues, and professional and cultural resistance.

Referral and enrollment of buprenorphine patients in the OTP proceeded slowly, possibly because of both perceived stigma and strict attendance requirements associated with OTPs. However, attendance requirements for buprenorphine dispensing have become more flexible with SAMHSA's regulatory changes. Institution-specific barriers included buprenorphine toxicology tests, which were difficult to obtain and which took longer to analyze than toxicology panel tests. Verification of sublingual ingestion of buprenorphine is more timeconsuming than for liquid methadone. Medication cost differences and compatibility issues with methadone-dispensing software and hardware limited our choice of buprenorphine formulations to dispensing only the tablet form of buprenorphine.

Reimbursement for buprenorphine services in OTPs can be complex. New York State Medicaid reimburses for BMT within an OTP, but many other insurance plans may not. Until recently, Medicaid reimbursed our OTP according to weekly flat rates per patient regardless of intensity of services. An additional billing process was required for patients receiving BMT, given that the standard rate did not adequately reimburse for the higher medication cost of buprenorphine. Medicaid has now transitioned to ambulatory patient group reimbursement of individual services, which better accounts for medication differences and other variations in care.

At our OTP, patients are offered counseling sessions and the option of group attendance in addition to medical and psychiatric services. Long-term patients who require only intermittent visits may receive optimum treatment in a lower-intensity environment; their transfer to primary care clinics or other less-intensive treatments may be clinically appropriate and a better allocation of resources.

The partnership between the OTP and office-based practices enables us to transition appropriate patients to lower levels of care and enhances patient access to the optimal medication-assisted therapy option of either buprenorphine or methadone.

DISCUSSION

Many methadone providers feel that buprenorphine advocates have disparaged methadone and have failed to acknowledge that methadone is well established, safe, and effective. A more nuanced view is warranted by continuing to recognize methadone treatment as an important option for patients, including those who need the psychosocial supports of a comprehensive program, the benefits of more flexible dosing options available in BMT, and more recently buprenorphine OTP integration affording high-intensity treatment and ability to bridge patients from and to lower levels of care.

The benefits of integrating buprenorphine into an OTP setting became clear over time. OTPs can prescribe either medication, depending on which is more appropriate for a patient, and can transition patients from buprenorphine to methadone and vice versa, depending on the circumstances. OTPs offer built-in structures for serving a large volume of patients with opioid use disorders, considerations for diversion control, procedures to address safety concerns about supply storage, and medical monitoring for patients with comorbidities. Because OTPs dispense buprenorphine in take-home doses instead of writing prescriptions for pharmacies, some patients have better protection of confidentiality from employers, given that some clinics guard only in-clinic protected health information, not pharmacy-filling data. Further expansion of buprenorphine availability within OTPs also compensates for the shortage of buprenorphine prescribers, given that OTP-enrolled buprenorphine patients are not included in a physician's buprenorphine patient limits.

Adding BMT into OTPs promotes holistic recovery and patient choice. OTPs have an on-site network of nurses, medical counselors, and staff. Our OTP recovery model is one of medication maintenance integrated with individual psychotherapy, group therapy, vocational training, general medical care, and psychiatric care. These integrated services may contribute to the lower rates of opioid-positive toxicology results among patients receiving buprenorphine at the OTP compared with those at the outpatient psychiatry and primary care clinics, which did not offer these services on-site. Providing BMT in an OTP also offers patients the flexibility to transition between intensive, structured care and primary care or outpatient psychiatry according to need.

CONCLUSIONS

The integration of buprenorphine into an OTP setting offers patients a new treatment option with integrated psychiatric, general medical, and substance abuse care that does not require patients to switch from buprenorphine to methadone. Regulatory changes offer OTPs greater flexibility to dispense buprenorphine, allowing treatment at tailored levels of care and expanding the clinical and therapeutic resources for recovery. Medicaid reimbursement policies, which vary by state, remain a barrier to buprenorphine integration in some states, and strides toward nationwide Medicaid coverage should be made. In addition to regulatory

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changes, New York State's Medicaid buprenorphine coverage was one of the most significant facilitators to integrating treatment into our OTP. The integration of BMT at our hospital offers a model for facilitating partnerships among OTPs, primary care clinics, and mental health clinics to better serve diverse patients with varying clinical needs and with varying levels of social support. Although office-based BMT has proven successful, complete integration of BMT into OTPs should be further examined as a viable treatment option.

Further research is necessary to assess whether integrated BMT influences patient relapse, retention, and dropout rates. Documentation of changes in treatment access as a result of this integration is also needed: for example, because of the intermediary role played by OTPs in stabilizing and assessing patients, our primary care physicians are receiving referrals of patients who initially received buprenorphine induction on the inpatient detoxification unit. The experience of buprenorphine integration supports continued advances in OTPs that may include the introduction of extended-release naltrexone (Vivitrol) as a third treatment option.

Acknowledgments

Support for this work was provided by a National Institutes of Health grant (DA 032674032674). The authors acknowledge the crucial assistance of John Rotrosen, M.D., and Babak Tofighi, M.D., in conceptualizing this work.

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TABLE 1

Characteristics of patients receiving buprenorphine in an opioid treatment program (OTP), in an outpatient psychiatry clinic, or in primary care^a

	OTP	N=39)	Outpatient psychiat	ry (N=224)	Primary care	(N=472)
Characteristic	Ν	%	N	%	Ν	%
Male	37	95	168	75	398	84
Age (M±SD)	43 ± 11	45±11	47 ± 9			
Race-ethnicity						
Black	6	23	56	25	141	30
Hispanic	14	36	26	12	56	12
White	16	41	102	46	157	33
Other or unknown	0	I	40	18	118	25
Insurance						
Medicaid or other public	31	79	140	63	297	63
State agency	0	I	0	I	1.2	
Prisoner or shelter	0	I	16	L	3.6	
Commercial	3	8	6	4	35	L
Self-pay	0	I	55	25	133	28
Unknown	5	13	0	I	3.6	
Urine toxicology results b	677	1,308	6,174			
Opioid positive $^{\mathcal{C}}$	100	15	420	32	1,825	29.6
Methadone positive	19	3	259	20	442	7.2
Benzodiazepine positive	95	14	289	22	859	13.9
Cocaine positive	50	L	346	26	1,356	21.9
Average buprenorphine dose (mg)						
Buprenorphine/naloxone	12	na	na			
Buprenorphine	18.5	na	17.5			
Fime in treatment	М	SD	М	SD	М	SD
Months	7.2	6.2	8.1	12.7	18.4	20.0
Weeks	31.3	26.7 na	79.6	86.5		

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 b Urine toxicologies reflect number of tests, not number of patients.

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^COpioid toxicology result was positive; interpretation of the results was limited because of each clinic's differing policies on toxicology testing frequency and threshold detection.