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Supportive alternate site provision of buprenorphine: Overcoming barriers and improving patient outcomes



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ABSTRACT

Background: Improving access to medications for opioid use disorder (MOUD) is a national priority; however, these efforts commonly focus on the provider. Access to buprenorphine through retail pharmacies and stigma associated with filling prescriptions for MOUD pose additional barriers for patients when embarking on their road to recovery.

Methods: This study performed a pre-post retrospective chart review to evaluate the potential positive impact on patient retention when providing buprenorphine at office visits instead of at pharmacies. Study staff reviewed electronic medical records to document patient retention in treatment at 6 months as the primary outcome. The study evaluated as secondary outcomes missed office visits, medication adherence, illicit drug use (that drug testing results identified), and drug-related emergency department (ED) utilization. Study staff documented outcomes for patients given their buprenorphine medication at their office visit (n = 154) compared with randomly selected patients prescribed buprenorphine from the same office-based opioid treatment clinic who had to go to retail pharmacies to fill their prescriptions (n = 154).

Results: Patients receiving buprenorphine at their office visit demonstrated a 52.2% higher retention rate after 6 months compared to the control group (p = .005). Patients were more likely to attend scheduled office visits (p = .046), less likely to test positive for nonprescribed/illicit drugs (p < .001), and less likely to utilize the ED for drug-related reasons (p = .018) when the program alleviated the need to fill buprenorphine prescriptions at retail pharmacies and began to offer the pharmacy services at office visits.

Conclusions: Provision of buprenorphine to patients at their treatment visit was associated with higher patient retention rates and better health outcomes compared with patients who filled their buprenorphine at pharmacies prior to the program's integration of medication provision at patient office visits. Understanding how alleviating barriers to medication access impacts retention in care has meaningful implications for opioid use disorder patients and treatment providers.

1. Introduction

Individuals who utilize medications for opioid use disorder (MOUD) are retained in treatment programs longer than those who do not and demonstrate better outcomes with abstinence from nonprescribed therapeutic and illicit drugs (National Institute on Drug Abuse, 2016). Medications including buprenorphine are effective for the treatment of opioid use disorder (OUD) and have become an essential component of ongoing treatment programs (Jerry & Collins, 2013). Treatment of OUD requires long-term management, and longer patient retention is correlated with decreased drug use, improved social functioning, enhanced

quality of life, and reduced mortality (Bart, 2012; Cicero et al., 2014; Schuckit, 2016). However, even with the effectiveness of buprenorphine and other MOUDs, less than a fifth of those diagnosed with OUD receive specialty care, and of those who do, only a third receive MOUD, with 6-month retention rates commonly under 30–50% (Williams et al., 2018). Studies have demonstrated considerable variability in retention rates observed across treatment settings and various interventions, ranging from 3 to 88% at 6-month follow-up (Timko et al., 2016).

Despite the strong evidence for the efficacy of MOUD in reducing morbidity and mortality, as well as increasing patient retention in treatment and well-being for individuals with OUD, numerous barriers

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prevent broader utilization of MOUD. Thus, research has placed much attention on expanding access to MOUD, making it a key priority nationwide. Many efforts have been prescriber-focused, such as increasing the number of providers able to treat OUD through buprenorphine in office-based opioid treatment (OBOT) settings and increasing maximum patient thresholds. Treatment programs have considered initiatives to overcome insufficient prescriber training and education, lack of clinician peer support, poor care coordination, associated provider stigma, reimbursement concerns, regulatory burdens such as the waiver process and record keeping requirements, as these obstacles contribute to providers declining to prescribe buprenorphine (Andrilla et al., 2018; Haffajee et al., 2018).

Aside from limitations at the provider-level, pharmacy barriers that exist for patients who have been prescribed buprenorphine may also negatively impact medication access and positive outcomes. One of the hopes of having buprenorphine treatment encompass filling prescriptions at a pharmacy, as opposed to a designated program (e.g., methadone), was to reduce the daily burden and associated stigma of participating in such a program for patients while being able to maintain their medication access (Substance Abuse and Mental Health Services Administration, 2020). Buprenorphine enabled physicians to treat patients with OUD in a similar manner to patients with other chronic diseases; thus, supporting a change in attitude toward OUD from both the medical community and society (Ling et al., 2012). However, OUD is still not always viewed in the same light as other chronic conditions. For example, research has shown that attitudes toward patients with substance use disorder (SUD) is significantly more negative than attitudes toward individuals with mental illness (Barry et al., 2014; Kennedy-Hendricks et al., 2017). The disconnection between prescribing provider and pharmacist exists for most chronic diseases and research has shown 20-30% of prescriptions written to treat these conditions are never filled (Viswanathan et al., 2012). Data on the success rate of patients diagnosed with OUD filling prescribed buprenorphine are limited; however, unlike patients treated for hypertension, diabetes, asthma, and so on in many instances, OUD patients are subject to stigma when seeking to fill their prescriptions and face uncertainty around whether their retail pharmacies even stock and dispense buprenorphine. In particular, a pharmacy's ambiguity around what the Drug Enforcement Administration (DEA) regulations are, inability to meet patient demand, wholesaler limitations, stigma from pharmacy staff associated with OUD, and fear of patient diversion can contribute to negative patient outcomes for those with OUD (Haelle, 2019). Furthermore, pharmacists report feeling disconnected from prescribers such that they are operating with inadequate information that hinders their confidence to provide appropriate, safe, and effective medication access (Bach & Hartung, 2019; Hagemeier & Pack, 2013; Hartung et al., 2018). Additionally, patients often cite transportation to a pharmacy that dispenses buprenorphine as a barrier to care (Samina et al., 2014).

2. Material and methods

2.1. Study setting

This study evaluated retention in care when providing buprenorphine to patients at their office visits at an OBOT clinic in urban Pierce County, Washington. The clinic's service model is an evidence-based, patient-centered treatment approach, and it offers a wide range of treatment options to patients. The services include intensive outpatient treatment, buprenorphine and naltrexone therapy, cognitive behavioral therapy, peer support, and primary care services. The clinic made the programmatic decision to provide buprenorphine at office visits as an extension of its treatment offering in November 2017 to help address the barriers that patients faced at pharmacies. Patients obtained medication at the time of their clinic visit as opposed to seeking to fill at pharmacies after their visits.

2.2. Patient selection

Inclusion criteria required patients in both the intervention and control groups to be diagnosed with OUD, prescribed buprenorphine, and within the first 90 days of their treatment plan at the start of the study. Analysis of each patient's start date in treatment compared with their earliest buprenorphine prescription in the respective time period that we studied classified whether or not a patient was within the first 90 days of treatment. Three-hundred and four unique OUD patients had their buprenorphine provided to them at their office visits via the pharmacy program studied between November 2017 and May 2018. One-hundred and fifty-four of these patients were within the first 90 days of their treatment regimen when first provided buprenorphine at their office visit and composed the intervention group. The study extracted patient office visit records between November 2016 and May 2017 to identify unique OUD patients treated at the same OBOT clinic prior to the pharmacy program. Three-hundred and forty patients met the inclusion criteria and composed the control population. The study used a computerized random number generator to randomly select a subset of 154 patients to represent the control group.

We performed chart reviews for each intervention patient beginning at the earliest buprenorphine fill date with the pharmacy program that provided their medication at their office visit between November 2017 and May 2018, and progressing for 6 months per patient. Likewise, each control patient's chart review began at the earliest buprenorphine fill date with a retail pharmacy between November 2016 and May 2017, and progressed for 6 months per patient.

We obtained IRB exemption prior to beginning the retrospective chart reviews. The study defined all data extracted from patient electronic medical records by a generic patient identification number and did not include any protected health information. This process made it such that any chart review information could not be linked back to a specific patient.

2.3. Targeted outcomes

The study performed a pre-post retrospective chart review analysis targeting patient retention in treatment, attendance at scheduled office visits, return to use and buprenorphine adherence via drug testing results, and drug-related emergency department (ED) utilization. We evaluated outcomes for OUD patients receiving buprenorphine medication at their office visit in comparison to OUD patients from the same OBOT clinic using offsite retail pharmacies to fill their prescriptions prior to the pharmacy services being available at the clinic. Patients receiving buprenorphine at their office visit had their prescriptions filled by a pharmacy that coordinated prescription drug monitoring program (PDMP) reviews, dispensing and delivery with the clinic's appointment schedule, such that a pharmacy representative gave each patient their prescribed buprenorphine at the time of their clinic visit. The pharmacy couriered medications to the clinic daily for the patients with appointments scheduled. Any medication not picked up was sent back to the pharmacy.

2.3.1. Retention

The study evaluated retention at 3 and 6 months after each patient's earliest buprenorphine fill date during the respective time frames studied, with 6-month retention as the primary study outcome. An extensive chart review process that focused on extracting patient office visit notes from electronic medical records determined retention. If a patient had attended office visits and received buprenorphine prescriptions progressing through the 3-month mark without any visit noted as "re-engagement" (meaning multiple consecutive office visits were missed prior to the patient returning to treatment), we defined the patient as retained. If a patient did not make an office visit at the 3-month mark but had enough days' supply of buprenorphine prescribed from the last appointment to be covered through the 3-month

mark, we noted the patient as retained. The same methodology applied to the evaluation of 6-month retention. In the event that a patient transitioned from buprenorphine to naltrexone treatment during their chart review, we considered them retained if they met the aforementioned criteria despite the change in medication. Over the course of each patient's 6-month chart review, study staff documented the number of scheduled, attended, and missed office visits.

2.3.2. Drug-related ED utilization

Additionally, the study documented the number of drug-related ED visits from patient electronic medical records. Drug-related visits included ED use due to overdose, abscess from injection site, injury while on drugs, sickness from withdrawal, fear or sickness while on drugs, as well as drug-seeking behavior and suicide attempts with documentation of illicit drug use or misuse of prescription medications in the diagnosis entry, testing data, or general visit notes from the ED.

2.3.3. Buprenorphine adherence and illicit drug use via drug testing results We recorded drug testing results, including both buprenorphine positivity to better understand adherence and nonprescribed/illicit drug positivity to allow for a view into the patient's return to use over the duration of each patient's 6-month chart review. Study staff documented results from observed urine drug screens performed at each patient's office visit, which tested for buprenorphine, amphetamine, benzodiazepine, cocaine, methadone, opiate and oxycodone drug classes via immunoassay methodology. The study staff documented the number of drug tests performed and number of drug tests positive for each of the tested drug classes per patient during the respective time frame studied. We defined an episode of return to use as a patient testing positive for an illicit or nonprescribed medication and documented this during the chart review.

2.3.4. Patient experience

Last, the study captured patient experience receiving buprenorphine medication at their office visit, via a voluntary and anonymous survey, to understand the patient's perspective of the program. Forty-five patients receiving their buprenorphine in coordination with their treatment appointment completed the short questionnaire. The survey consisted of an overall satisfaction rating, likelihood to recommend the program and to continue to use the service if given a choice, and a free text field to explain the best aspect of receiving buprenorphine medication in tandem with their treatment visit. Patient experience data were not available for the control patients.

2.4. Data analysis

The study used Chi-square tests to evaluate the statistical significance of study findings regarding patient retention at 6 months, missed office visits, medication adherence via buprenorphine positivity, return to use via nonprescribed/illicit drug positivity, and drug-related ED utilization. We used Excel for tabulating and evaluating data, with $\alpha=0.05$ for all tests performed. We calculated p values for each outcome evaluated representing the probability of obtaining an observed result. Due to the multiple tests we conducted for the outcomes targeted, we applied Bonferroni correction such that a p value less than 0.01 indicated strong evidence of statistical significance (Chen et al., 2017).

3. Results

3.1. Intervention and control patients

The study's evaluation of patient age, gender, insurance type and stage in treatment at the start of the study was not significantly different between the intervention and control groups (Table I). The majority of patients across both the intervention and control groups was over the age of 30, insured by Medicaid, and within their first 30 days of

treatment.

3.2. Patient retention in care

The observed 6-month retention rate was significantly greater for patients receiving their buprenorphine at the time of their treatment visit (Fig. 1). At the 6-month mark, 45.5% (n=70) of intervention patients compared to 29.9% (n=46) of control patients remained in treatment, $\chi 2(1,N=308)=8.0$, p=.005. Of the intervention patients, the study retained 59.7% (n=92) at the 3-month mark, compared to 49.4% (n=76) of control patients. The study retained 76.1% (n=70) of these intervention patients at the 6-month mark, whereas the study retained 60.5% (n=46) of these control patients at the 6-month mark. Patients were more likely to make scheduled appointments when the clinic provided their buprenorphine medication in coordination with their clinic visit. Specifically, intervention patients missed 9.7% (n=260) of scheduled office visits, compared with 11.5% (n=251) of scheduled office visits for control patients, $\chi 2(1,N=308)=4.0$, p=.046.

3.3. Buprenorphine adherence and illicit drug use via drug testing results

Intervention patients tested positive for buprenorphine and negative for nonprescribed/illicit drugs more frequently than control patients. The buprenorphine positivity rate for intervention and control patients was 92.5% (n=3026) and 85.8% (n=1774) of total samples tested, respectively, $\chi 2(1,N=3235)=38.7$, p<.001. Further, 29.2% (n=549) and 41.3% (n=559) of total samples tested were positive for nonprescribed/illicit drugs, for intervention and control patients, respectively, $\chi 2(1,N=3235)=50.8$, p<.001 (Fig. 2). Specifically, 15.1% (n=284) of samples tested from intervention patients were positive for opiates, compared with 27.9% (n=378) from control patients. The amphetamine drug class was the most frequently positive nonprescribed drug class that we observed for intervention patients and the second most for control patients. For intervention and control patient drug tests, 16.5% (n=311) and 23.2% (n=314), were positive for amphetamines, respectively.

3.4. Drug-related ED utilization

Fewer intervention patients visited the ED for drug-related reasons compared with control patients, $\chi 2(1,N=308)=5.6$, p=.018. Twenty-four intervention patients (15.6%) had at least one drug-related ED visit during the chart review time frame, corresponding to 43 visits, whereas 41 control patients (26.6%) had at least one drug-related ED visit during the chart review time frame, corresponding to 81 visits (Fig. 3).

3.5. Patient experience

The patient experience survey responses provided key insights into how removing the need to seek pharmacies to fill buprenorphine prescriptions directly impacted participating patients. All respondents (100%) reported that they would recommend receiving buprenorphine medication at the time of an office visit to others and, if given a choice, would continue to use the service. Categorizing the patient free text responses regarding what aspect(s) of receiving their buprenorphine at the time of treatment was most valuable centered on lack of judgment or perceived stigma (40.0%), convenience or removal of transportation barriers (28.9%), quick turnaround (28.9%), and communication with the pharmacy (20.0%). We chose select quotes to highlight patients' experience receiving buprenorphine medication at the time of their clinic visit:

"I love getting my prescription here. I don't have to deal with the hassle I deal with at most other pharmacies."

Table IDistribution of patient demographic information and treatment stage at start of study for intervention patients receiving buprenorphine medication at office visits and control patients filling buprenorphine prescriptions at retail pharmacies prior to programmatic switch.

| Characteristic | | Intervention, n (%) | Control, n (%) | p value ^a |
|-----------------------------------|----------------------------------|---------------------|----------------|----------------------|
| Age | ≤30 | 40 (26.0) | 52 (33.8) | .1352 |
| | >30 | 114 (74.0) | 102 (66.2) | |
| | Average | 38 | 36 | |
| Gender | Male | 74 (48.1) | 84 (54.5) | .2543 |
| | Female | 80 (51.9) | 70 (45.5) | |
| Insurance type | Medicaid | 108 (70.1) | 113 (73.4) | .9144 |
| | Medicare | 3 (1.9) | 2 (1.3) | |
| | Commercial | 36 (23.4) | 33 (21.4) | |
| | No insurance | 7 (4.5) | 6 (3.9) | |
| Treatment stage at start of study | Patients ≤30 days in Treatment | 112 (72.7) | 125 (81.2) | .2124 |
| | Patients 31-60 days in treatment | 33 (21.4) | 23 (14.9) | |
| | Patients 61–90 days in treatment | 9 (5.8) | 6 (3.9) | |

^a Chi square tests were utilized to evaluate differences in characteristics documented for intervention and control patient groups, with $\alpha = 0.05$ for all tests performed.

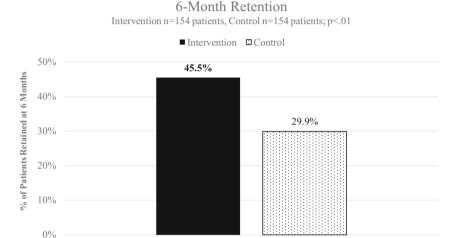


Fig. 1. 6-month treatment retention rate for intervention patients receiving buprenorphine medication at office visits and control patients filling buprenorphine prescriptions at retail pharmacies prior to programmatic switch.

"This has been perfect for me. I need to get in and out quickly so I can get back to work."

"This is so convenient. I wish my other doctors had this type of program." $\,$

"I like how quick and easy it is. At times there is a long wait to see the doctor so by the end of my appointment I am just ready to leave. My meds are already here and ready for me to sign and go."

"I love the privacy of it. Not having a long line of people hearing or judging."



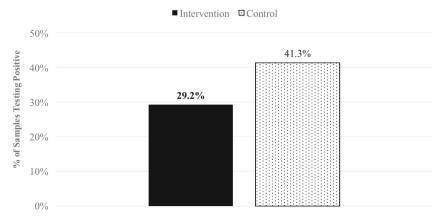


Fig. 2. Non-prescribed/illicit drug positivity rate for intervention patients receiving buprenorphine medication at office visits and control patients filling buprenorphine prescriptions at retail pharmacies prior to programmatic switch.

Drug-Related ED Visit Frequency

Intervention n=154 patients, Control n=154 patients; p<.05

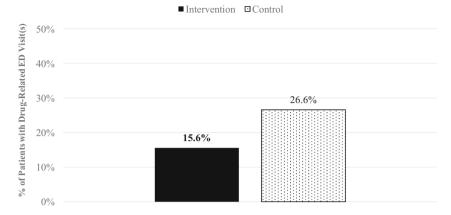


Fig. 3. Drug-related ED utilization frequency for intervention patients receiving buprenorphine medication at office visits and control patients filling buprenorphine prescriptions at retail pharmacies prior to programmatic switch.

4. Discussion

4.1. Buprenorphine patient retention and medication adherence

Provision of buprenorphine directly to patients at their clinic visit may improve patient outcomes. Patient retention, medication adherence, illicit drug use, and drug-related ED utilization all significantly improved following program implementation. Further, the survey of patients receiving buprenorphine at their clinic visit indicated high satisfaction with the program.

Longer retention in treatment for OUD has been associated with favorable patient outcomes; however, retention can be challenging, with many patients discontinuing treatment prematurely, within a few weeks or months after initiation (Weiss et al., 2015; Williams et al., 2019). Research has observed substantial variability in buprenorphine patient retention at 6 months, ranging from 19.1% to 64.0% of patients, with the median retention rate at 56.8% of patients (O'Connor et al., 2020). Prior studies evaluating the impact of various programmatic switches on patient retention, medication adherence, and illicit drug use commonly focus on treatment model interventions in tandem with prescribing MOUD, such as the integration of behavioral therapy, alternative counseling approaches, and psychosocial support (Carroll & Weiss, 2017, Fiellin et al., 2013, Gryczynski et al., 2014, Manhapra et al., 2018). Care coordination has been associated with improved health outcomes and patient satisfaction. Increased pharmacist involvement in care coordination for OUD patients has demonstrated positive patient outcomes, including high attendance and retention rates (DiPaula & Menachery, 2015). Further, a recent study evaluating the impact of integrating onsite pharmacies within community mental health centers revealed higher medication adherence rates as well as lower hospitalization and ED use for participating patients, translating into reductions in health care costs (Wright et al., 2016). However, research on the impact of clinic-based buprenorphine provision on retention in treatment and medication adherence is lacking.

One advantage of using buprenorphine to treat OUD is that patients are not required to report to the clinic for observed daily dosing; however, with the ability to independently dose comes added patient responsibility to travel to the pharmacy to fill buprenorphine prescriptions in addition to overcoming barriers that may exist to attend scheduled treatment appointments. Without their MOUD, patients cannot be adherent to treatment regimens, and the risk of relapse is significantly greater when patients are nonadherent (Bell & Strang, 2020, Lander et al., 2020). Coordinating the provision of buprenorphine to patients at the time of their treatment visit may be a motivating factor for attending

scheduled office visits and, thus, help to positively impact retention in care and medication adherence. Broader implementation of the clinic-based medication provision program studied here may benefit patients diagnosed with other diseases aside from OUD, such as SUD, mental health conditions, chronic pain, heart disease, diabetes, asthma, and so on, where office visits and pharmacy trips may be frequent and medication adherence is vital.

4.2. Provision of buprenorphine in coordination with patient office visits

Provision of buprenorphine in coordination with patients' office visits is a key tenet of a comprehensive managed program that establishes a direct, trusted relationship between the prescriber and pharmacist. The pharmacist is experienced in caring for patients who have been prescribed medications to treat OUD and is complemented by a compliance leader with regulatory expertise. Other key features of the program include:

- Pharmacy liaison present during clinic office hours to deliver medications and facilitate patient engagement as well as communication between clinic and pharmacy;
- PDMP review from the pharmacist on each patient, raising any irregularities prior to filling the buprenorphine;
- Review of drug testing results, ensuring buprenorphine was present and identifying any unexpected substances; and
- Lifesaving naloxone offered to each patient.

4.3. Limitations

The retrospective design of this study and confound of time between the control and intervention patient chart reviews are limitations of this study. The most significant change to operations and workflow during the study period was implementation of the clinic-based buprenorphine provision program; however, standard improvements in office management, unseen changes to routine policy or standard operating procedure to improve patient care, and secular trends within the patient groups studied coinciding with the implementation might influence outcomes and patient satisfaction. The providers treating the patients in November 2016 remained consistent throughout the duration of the study. Patients were automatically converted to receiving buprenorphine at their office visit in November 2017; however, patients were not prohibited from opting out. Providers highly encouraged patients to take part in the program and the majority of patients utilized the services. Due to the pre-post study design and although rare, the ability for

patients to opt out of the buprenorphine provision program, selection bias may be a limitation of the study. In addition, the urine toxicology testing that the OBOT performed over the course of the study was done via immunoassay screening. Thus, opiate testing results documented targeted morphine, so the test may not have detected the use of other opiates or opioids. Furthermore, the testing performed did not include fentanyl despite the surge in its use over the past few years and its status as an opioid of great concern on the illicit market. Additionally, despite many of the local EDs using the same electronic medical record interface system as the OBOT clinic, the study may not have captured patient ED utilization if the ED did not use the same software vendor. Last, as this study was limited to a single OBOT clinic, the findings may not be generalizable across patient populations; however, the results of this study serve as an indicator that coordinating the provision of buprenorphine with scheduled patient office visits may produce similar results in OBOT clinics treating similar patients.

5. Conclusion

This study found that provision of buprenorphine to patients at their treatment visit was associated with higher retention rates and better health outcomes compared with patients who filled their buprenorphine at pharmacies. The results of this study suggest that broader implementation of clinic-based buprenorphine provision may have significant benefits for OBOT clinics serving OUD patients, and they further support the value of care coordination between the prescriber and pharmacist to positively impact patient outcomes. Research should continue to shed light on the pharmacy-level obstacles that OUD patients face when seeking to fill their buprenorphine prescriptions at a pharmacy, and how programs trying to improve medication access, such as buprenorphine provision at office visits, impact patient retention in care and health outcomes.

CRediT authorship contribution statement

Asif Khan: Conceptualization, Supervision, Resources, Writing – Review & Editing. **Qudsia Khan:** Supervision, Resources, Writing – Review & Editing. **Elizabeth Kolb:** Methodology, Data Curation, Formal analysis, Writing – Original Draft.

Declaration of competing interest

Northwest Integrated Health (NWIH) and Cordant Health Solutions (Cordant) sponsored this study. NWIH is a client of Cordant and permitted the use of its data on a deidentified basis for this retrospective analysis. Study concept and design were contributed by A. Khan and Kolb. Kolb took the lead in data collection and data interpretation. The manuscript is written by Kolb, assisted by A. Khan and Q. Khan.

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