Physician–pharmacist collaborative care model for buprenorphine-maintained opioid-dependent patients

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Abstract

Objectives: To develop a physician–pharmacist collaborative practice for opioid-dependent patients designed to increase access to treatment, optimize patient care, reduce cost, minimize physician burden, and prevent diversion.

Setting: Suburban health department.

Practice description: Physician–pharmacist buprenorphine/naloxone maintenance practice.

Practice innovation: Traditionally, health department buprenorphine/naloxone patients have been referred to community physicians at considerable cost with varying outcomes. In this pilot project, patients were managed using a drug therapy management model. Intake assessments and follow-up appointments were conducted by the pharmacist. The pharmacist debriefed with the physician and documented each interaction, allowing for efficient assessment completion. The physician appended notes, when applicable, and cosigned each patient's record. The pharmacist prevented diversion by gathering data from outside providers, pharmacies, and laboratories.

Results: This health department program improved care by producing structure and expanding treatment options. A total of 12 patients completed full intakes with 135 follow-up appointments equating to an estimated savings of $22,000. The program demonstrated a 91% attendance rate, 100% 6-month retention rate, and 73% 12-month retention rate. Overall, 127 (98%) urine toxicology screens were positive for buprenorphine and 114 (88%) were positive for buprenorphine and negative for opioids.

Conclusion: Physician and pharmacist collaboration optimized care of buprenorphine-maintained patients. Data from this pilot were used to develop a permanent physician–pharmacist program and to obtain approval for the first state-approved opioid use disorder drug therapy management protocol.

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Opioid abuse has reached epidemic proportions in the United States. A 2007 National Institutes of Health study found that roughly 80% of the global opioid supply was consumed by Americans despite representing only 4.6% of the world's population.[1] The number of individuals diagnosed with pain reliever dependence or abuse showed a statistically significant rise from 1.5 million to 2.1 million between 2002 and 2012, and heroin dependence increased from 214,000 in 2007 to 467,000 in 2012.[2]

Worldwide, opioids have been the most frequently implicated pharmacologic class in drug-related deaths.[1] Opioid overdoses have developed as a serious public health issue in this country. Drug overdoses are now the leading cause of death by injury in the United States. [3] In 2010, 75% of prescription medication overdoses involved opioid analgesics.[4]

Opioid use disorder, a chronic, relapsing brain disease, can be managed in mainstream medical practice.[5–7] Buprenorphine and buprenorphine/naloxone are the only agonist therapy currently approved by the Food and Drug Administration for treating opioid dependence in the office-based setting.

Buprenorphine is a partial opioid agonist. It is effective in the management of opioid use disorder.[7–16] However, dosing can be complicated, involving three phases: induction, stabilization, and maintenance.[17] Initiation of buprenorphine is referred to as induction. Patients must experience mild to moderate opioid withdrawal symptoms before the medication is started. Guidelines recommend observed buprenorphine/naloxone administration, where a patient is directly monitored for opioid withdrawal and medication adverse effects during induction. The dose of buprenorphine/naloxone is adjusted over a 1- to 3-day period, requiring repeated appointments that can last up to 2 hours.[18]

Newer literature suggests that unobserved induction may be a safe and effective alternative.[19–21] Patients receive a few doses of buprenorphine/naloxone with specific instructions on initiation in a home setting. Once the medication has been successfully started, the patient enters the stabilization phase, during which the dose is further titrated to manage withdrawal and craving.[8]

Within a few days to weeks, the patient reaches the maintenance phase. At this stage, the medication dose does not generally fluctuate, but the patient must be closely monitored for relapse and diversion. Maintenance treatment may span months to years and requires weekly to monthly monitoring as well as regular substance abuse counseling. Medication discontinuation requires a dose taper, which can extend over several months.

Despite the demand for opioid substitution therapy, there continues to be a shortage of community treatment options, particularly for rural and indigent patients.[22–24] Improving access to opioid agonist treatment is considered a national public health priority.[25]

A host of reasons have been proposed as to why physicians choose not to treat opioid dependent patients: stigma associated with managing addictions, risk for diversion, concerns about medication safety, lack of staff support, difficulty obtaining counseling (a federal requirement for prescribing of buprenorphine), dosing/monitoring demands, financial constraints, limited time, and lack of expertise/interest in treating addiction or concurrent disorders.[5,22,24–27]

To help patients identify prescribers, the Substance Abuse and Mental Health Services Administration (SAMHSA) published a buprenorphine/naloxone provider locator list. However, a growing number of certified physicians opted not to have their identifying information published through SAMHSA, making their availability unknown to the general population.[22,24]

Survey results suggest that physicians would be more willing to prescribe buprenorphine, if barriers were reduced.[5] Collaboration with other health professionals could help to ease physician burden. To date, one publication has described physician collaboration with nurse practitioners.[7] Buprenorphine's monitoring demands, unique medication properties, and risk for diversion allowed for an important role for pharmacists.

Previously published studies show that by partnering with the treatment team, pharmacists can reduce physician burden, improve patient outcomes, and reduce cost by monitoring patients for efficacy, safety, and adherence and providing medication education.[28–32] Most states in this country have laws and regulations allowing collaborative practice agreements between pharmacists and physicians.[32]

Key Points

Background:

- Opioid use disorder is an important public health issue. Buprenorphine/naloxone is an effective medication used to prevent relapse.
- A limited number of waivered prescribers and treatment alternatives are available for managing this patient population.

Findings:

- Physicians and pharmacists can successfully collaborate to provide effective medication management for patients with opioid use disorder.
- Collaboration helps to reduce physician burden and optimize patient care.
- Pharmacists are well trained to assist in the management of buprenorphine/naloxone maintained patients by providing patient education, monitoring medication outcomes, and assisting in diversion prevention.

Objectives

In this article, we describe a physician–pharmacist collaborative practice designed to increase access to buprenorphine/naloxone treatment, optimize patient care, reduce treatment cost, minimize physician burden, and limit diversion.

Practice description

A physician–pharmacist collaborative buprenorphine/naloxone maintenance practice was piloted at a suburban health department for 12 months. The pilot program was structured to allow 6 hours per week of a contractual psychiatric pharmacist, 4 hours of a contractual medical assistant, and up to 4 hours of a health department–employed primary care physician. The physician (second author) was a residency-trained internist. The pharmacist (primary author) held a doctor of pharmacy degree, completed an American Society of Health-System Pharmacists–accredited psychiatric pharmacy residency training, and was certified in psychiatric pharmacy by the Board of Pharmacy Specialties.

Patients who were candidates for buprenorphine/naloxone therapy were identified by the health department intake program and referred to local outside providers for induction. Once induction was completed, substance abuse counselors were responsible for identifying referrals for the health department maintenance clinic. The clinic prioritized patients who were uninsured or underinsured.

The pharmacist's time was divided into approximately 4 hours for patient care and 2 hours for program administration. The pharmacist was allotted 60 minutes to meet with the patient and obtain a detailed medical, psychiatric, and substance abuse history. The pharmacist was also responsible for reviewing clinic procedures and completing a treatment contract and providing medication adherence education. The patient's urine toxicology, laboratory tests, and vital signs were collected by a medical assistant. The pharmacist then presented a case summary to the physician and documented the encounter. The physician allocated 30 minutes for case discussion, treatment planning, and documentation.

All patients were initially monitored weekly. Per protocol, monitoring was gradually reduced to monthly based on patient's treatment plan adherence and urine toxicology results. Follow-up appointments were scheduled in 15-minute increments, during which the pharmacist pre-interviewed the patient, confirmed all relevant vital signs and toxicology, and electronically documented the visit. The physician then briefly confirmed the history and treatment plan with the patient and added to the documentation as needed.

A professional relationship was established with a local independent community pharmacy. Patients were required to have their prescriptions filled at one pharmacy, preferably at this referral site. Prescriptions were either written by the physician or called in by the pharmacist (with physician authorization).

The project was reviewed by the Department of Health and Mental Hygiene Institutional Review Board and deemed not to be research.

Practice evaluation

From June 2012 to May 2013, a total of 25 appointment referrals were completed for 19 unique patients. Of these, 12 intakes were completed with 135 follow-up appointments. The patients were predominantly white men with a mean age of 30 years (range, 22–41).

Table 1 summarizes patient characteristics and appointment data. Patients attended a mean of 11 appointments (range, 2–25) with a 91% routine appointment attendance rate.

Mean patient duration in the pilot was 20 weeks (range, 2–52 weeks). Daily buprenorphine/naloxone doses ranged from 3 mg to 20 mg, with a mean dose of

Table 1. Patient characteristics and appointment data (n = 12)

Characteristics	No. (%)
Gender	
Men	11 (92)
Women	1 (8)
Race	
White	10 (83)
Hispanic	1 (8)
Black	1 (8)
Employment status	
Employed	3 (25)
Unemployed	9 (75)
Concomitant psychiatric disorders at intake	
Anxiety	2 (17)
Affective disorders (depression, bipolar disorder)	6 (50)
Attention-deficit/hyperactivity disorder	2 (17)
Appointments	
Completed intakes	12 (100)
Attended follow-up appointments (n = 141)	135 (91)

Table 2. Outcomes of patients with opioid dependence cared for in collaborative care pilot project

Patient outcomes	No. (%)
Patients successfully progressed from weekly to monthly monitoring (n = 12)	6 (50)
Urine toxicology screen negative for opioids and positive for buprenorphine (n = 129)	114 (88)
Urine toxicology screens positive for buprenorphine (n = 129)	127 (98)
Patients retained in pilot (therapeutic taper excluded)	
6 months (n = 6)	6 (100)
12 months (n = 11)	8 (73)
Patients discharged because of nonadherence with contract	
6 months (n = 6)	0 (0)
12 months (n = 12)	3 (25)

12 mg/d.

Table 2 summarizes patient outcomes. All urine toxicology screens positive for substances of abuse were sent for laboratory confirmation. The majority of screens were positive for buprenorphine. The two patients with negative screens had missed previous appointments and subsequently run out of their medication. There were no cases of suspected diversion.

Patients retained in clinic were defined as those enrolled and who remained at 6 and 12 months. Patients tapered per treatment plan were excluded. Of those not retained, 2 patients continued to abuse opioids/other substances and refused more intensive therapy, and 1 patient dropped out and was lost to follow up. One patient was successfully tapered after establishing opioid abstinence for more than 1 year.

Before the buprenorphine/naloxone pilot project, the health department paid for uninsured/underinsured patients to receive medication management from community physicians. The authors were provided with records of actual expenditures paid to induce and maintain patients on buprenorphine/naloxone in the county. A mean cost for community intake and follow-up appointments for maintenance patients was calculated using actual health department expenditures. A comparison of average community costs and pilot budget revealed that the health department was able to save $22,000 through this pilot program.

During this project, the health department continued to pay for all community inductions and some maintenance patients who had established outside care. Using actual expenditures for patients induced and maintained in the community during this 12-month pilot, the projected future savings for conducting all induction and maintenance appointments at the health department would be approximately $63,000 annually.

Discussion

The health department's internal buprenorphine/naloxone clinic improved patient care by providing a continuous structure. Some of the noted benefits to a physician–pharmacist collaborative model within a health department included enhanced communication, reduced physician burden, regular access to urine toxicology results, increased buprenorphine/naloxone maintenance treatment slots (particularly for indigent patients), enhanced monitoring for diversion, and cost savings. The success of this pilot led to the development of the first opioid use disorder drug therapy management agreement approved by the Maryland Boards of Pharmacy and Physicians.

One study of office-based treatment practices found that prescribers managed a median of 10 patients and a mean of 14.[5] The same study reported that 43% of patients completed inductions outside of the office.[5] In designing this pilot, community private physicians, who traditionally accepted health department buprenorphine/naloxone referrals, were informally interviewed. Physicians reported that offering take-home buprenorphine/naloxone induction was preferred to providing long-term maintenance treatment. Physicians cited reimbursement rates, scheduling difficulties, and greater workload associated with routine maintenance monitoring as reasons for their preferences. Consequently, the health department pilot was initially designed to provide maintenance monitoring, once induction had been completed within the community. The program managed 12 patients, which was consistent with published reports in office-based settings.

In this pilot project, 98% of urine toxicology screens were positive for buprenorphine. While routine urine toxicology data have been frequently reported in the literature, few studies included buprenorphine results. It is important that the practitioner regularly monitor urine toxicology to assess patient outcomes and prevent diversion. The screen should include all types of opioids (natural, semisynthetic, and synthetic).[6] Some routine urine toxicology tests assess for natural opioids such as heroin and morphine, but not semisynthetic opioids (buprenorphine).

The practitioner should also be aware of common detection times for substances of abuse. Heroin, morphine, oxycodone, marijuana (single use), and cocaine can generally be detected for 1 to 3 days, while some benzodiazepines and long-term marijuana produce positive results for up to 30 days after last use.[6,33] In addition, the cutoff limits and interacting substances vary based on the specific test. Positive immunoassay screens should be sent for confirmation testing using analyzers such as gas chromatography–mass spectrometry or high-performance liquid chromatography.[33]

Retention rates in most of the published studies were defined as continuous months in treatment and ranged from 39% to 59% at 6 months, 56.9% at 1 year, and 54% at 3 years.[9,14,15] Since the patients entered our care after having received buprenorphine/naloxone for varying amounts of time, we chose to report the number of patients who remained in treatment at 6 and 12 months in the pilot project. In all, 100% of our patients remained in treatment at 6 months and 73% continued at the 1-year point. While this percentage cannot be directly compared to the literature, the rate suggests that all patients in this pilot project chose to continue care in this program versus moving their care to another practice.

Pharmacy schools and residency programs have prepared pharmacists to provide patient care for psychiatric and substance abuse patients in hospital and ambulatory settings.[34] In this model, the pharmacist follows up with the patients regarding their substance use since last appointment, adherence with substance abuse treatment programming and self-help group attendance, response to buprenorphine (including craving and with-

drawal symptoms), medication adherence and adverse effects, substance use triggers, changes in social issues such as employment and housing, and psychiatric and medical stability. This monitoring is consistent with previous literature.[6]

In this pilot project, the pharmacist concisely shared relevant information with the physician and documented the encounter, which allowed for efficient patient monitoring and helped reduce physician burden. The pharmacist also routinely monitored health department substance abuse treatment notes and communicated relapses directly with the substance abuse counselors. Addiction counseling has been shown to be essential in establishing patient retention and was a legal requirement for prescribing buprenorphine.[15] The interactivity between the physician/pharmacist team and substance abuse counselors was a strength of this program.

Diversion of buprenorphine/naloxone has continued to be a national concern. Several procedural safeguards were implemented to prevent diversion. Patients were prescribed only the combination product, buprenorphine/naloxone. The manufacturer added naloxone to the formulation as an abuse deterrent. Health department patients routinely received urine toxicology screens, including buprenorphine monitoring, at every appointment. Positive urine screens were sent to the laboratory for confirmation and quantification testing. The pharmacist routinely reviewed and tracked urine screen and quantification data.

When planning this pilot, the clinical pharmacist reached out to a local independent community pharmacy with close proximity to the health department. The community pharmacists were introduced to the prescribing physician and clinical pharmacist and were provided with basic information about the pilot. This pharmacy served as the primary referral source for all patients receiving buprenorphine/naloxone prescriptions. Patients were required to have their buprenorphine/naloxone prescriptions dispensed at the same pharmacy, preferably the health department referral location. The physician, clinical pharmacist, and community pharmacists communicated on a weekly basis by telephone. The community pharmacists assisted in diversion monitoring and alerted the clinic to discrepancies in medication fill history. The relationship also benefited the patients, since the community pharmacy staff were familiar with them and were able to easily contact clinic providers, if there were insurance issues, questions, or discrepancies. This helped to reduce stigma and misunderstanding and ensured that patients were able to consistently obtain medications in a timely fashion.

The pharmacist and physician also completed periodic random medication checks, which patients agreed to as part of their treatment contract. Table 3 summarizes suggested adherence enhancement and diversion-reduction techniques.[35] A prescription drug monitoring program was not available during this pilot but has since been implemented on a state level. Once accessible, prescription data were regularly reviewed by the pharmacist.

Table 3. Tips for improving adherence and reducing diversion among patients with opioid dependence and treated with buprenorphine[a]

▮ Treat with buprenorphine formulations containing naloxone, except with pregnancy
▮ Monitor and address medication efficacy or adverse effect issues
▮ Use a treatment contract with treatment expectations including dismissal for diversion
▮ Obtain informed consent to contact all health care providers involved in patients care (including pharmacists) to allow for regular communication
▮ Require patients to consistently obtain buprenorphine/naloxone at a single pharmacy. Develop professional relationships with the local pharmacists
▮ Limit prescription length until patient's opioid dependence is stable
▮ Collect urine toxicology (including buprenorphine) at every appointment
▮ Implement random medication counts and/or urine toxicology screens
▮ Consult the state prescription drug monitoring program

Source: Reference 35.

Limitations

This pilot project had some inherent limitations.

The number of patients managed was lower than would have been expected, because patients referred by the health department for induction in the community did not always return for maintenance at the health department. Since developing this program, unobserved or take-home induction was added to the health department services to allow for better patient retention

The health department referral process was initially inefficient; 25 patient referrals resulted in 12 patient intakes. Counselors received specific written and verbal instruction to improve the referral process, resulting in more successful patient intakes as the pilot project progressed.

Conclusion

Physicians and pharmacists working collaboratively optimized the care of buprenorphine/naloxone-maintained patients. Data from this pilot project were used to establish a permanent physician–pharmacist buprenorphine/naloxone program and obtain the first state-approved opioid use drug therapy management agreement.

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