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Medication-Assisted Treatment for Opioid Use Disorder in a Rural Family Medicine Practice

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Abstract

Opioid use disorder (OUD) is a cause of significant morbidity and mortality in the United States. Although efforts are being made to limit access to prescription opioids, the use of heroin and synthetic opioids as well as death due to opioid overdose has increased. Medication-assisted treatment (MAT) is the pairing of psychosocial intervention with a Food and Drug Administration (FDA)–approved medication (methadone, buprenorphine plus naltrexone) to treat OUD. MAT has resulted in reductions in overdose deaths, criminal activity, and infectious disease transmission. Access to MAT in rural areas is limited by shortages of addiction medicine-trained providers, lack of access to comprehensive addiction programs, transportation, and cost-related issues. Rural physicians express concern about lack of mentorship and drug diversion as reasons to avoid MAT. The prescribing of MAT with buprenorphine requires a Drug Enforcement Agency (DEA) waiver that can easily be obtained by Family Medicine providers. MAT can be incorporated into the outpatient practice, where patient follow-up rates and number needed to treat to effect change are similar to that of other chronic medical conditions. We describe a case of opioid overdose and a suggested protocol for the induction of MAT with buprenorphine/naloxone (Suboxone) for OUD in a rural family medicine outpatient practice. Treatment access is facilitated by utilizing the protocol, allowing office staff work to the extent allowed by their licensure, promoting teamwork and minimizing physician time commitment. We conclude that improved access to MAT can be accomplished in a rural family medicine outpatient clinic by staff that support and mentor one another through use of a MAT protocol.

Keywords

opiate, narcotic, substance, addiction, therapy, buprenorphine, primary care, clinic

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Introduction

An opioid use disorder (OUD) is defined as a problematic pattern of opioid use that leads to serious impairment or distress.[1] In the late 1990s, prescription opioid use increased in all regions of the United States, including rural areas.[2,3] Unfettered prescription opioid use was promoted, to a large extent, by the pharmaceutical industry, which had previously assured providers and patients that both long-acting forms of opioids and opioids prescribed for somatic pain were not addicting.[3] Misuse and diversion of these medications became widespread; by 2017, an estimated 1.7 million people in the United States suffered from substance use disorders related to prescription opioid pain medications and 652 000 suffered from a heroin use disorder (not mutually exclusive).[4] OUD is a cause of significant morbidity and mortality, and nearly 47 000 people died from an opioid overdose in the United States in 2018.[5] Overall deaths due to opioid misuse and abuse are also on the rise, primarily due to respiratory depression,[6] the risk of which is accentuated with the concomitant use of benzodiazepines.[7] The abuse of novel opioids, which are based primarily on the potent opioid fentanyl and mixed with heroin, has increased in recent years.[8]

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Opioids are highly addictive substances and misuse may result in fatal consequences, which disproportionately affects rural areas. The rate of increase in deaths due to opioid use in rural areas exceeds those in nonrural areas of the United States. From 1999 to 2015, there was a 325% increase in drug overdose in rural areas, compared with a 198% increase in urban populations.[9] The Centers for Disease Control and Prevention (CDC) reported in October 2017 that "persistent limited access to substance abuse treatment services in rural areas" contributed to the excess risk in rural areas and that interventions should include better education about the role of opioids in treatment of chronic pain as well as improved access to medication-assisted therapy (MAT).[9]

MAT has a substantial potential to offset consequences for patients with OUD, if only it were more widely accessed. Morbidity associated with OUD, as measured by ED utilization, is as common as 20.1% monthly.[10] MAT has been demonstrated to reduce ED utilization rate by 51%.[10] Additionally, MAT has been shown to result in decreased criminal activity as well as human immunodeficiency virus and hepatitis C infections.[11] Long-term data on the efficacy of MAT for OUD is limited; a randomized study of patients with OUD assigned to either methadone or buprenorphine/naloxone (Suboxone) demonstrated a 5-year abstinence from heroin rate of 33.2% (number needed to treat = 3) and 20.7% from all opioids.[12] Despite recognition of the importance of MAT, it is estimated that only 11% of patients receive a prescription for a Food and Drug Administration (FDA)–approved medication for their OUD.[13]

Access to MAT is a nationwide problem, but rural communities face unique and significant barriers to opioid addiction treatment. There are fewer facilities, limited services, and greater distances required to travel in order to receive care.[14] Overall, 88.6% of rural counties lack a sufficient number of opioid treatment programs.[15] Outpatient primary care practices that offer MAT are exceptionally rare in rural areas; nearly 30% of rural residents live in a county without a buprenorphine provider compared with 2.2% of urban citizens.[16] A survey of rural physicians found that lack of mentorship, concern about Drug Enforcement Administration (DEA) intrusion into their practice, and patient misuse of medications were barriers to offering MAT.[17]

A cornerstone of primary care–based programs in MAT is the use of buprenorphine/naloxone (Suboxone) in conjunction with careful patient assessment. Becoming a prescriber is not without its own barriers and limitations. Primary care physicians must both hold a valid DEA license and complete an 8-hour Substance Abuse and Mental Health Services Administration (SAMHSA)–approved course prior to applying for a DEA waiver in order to prescribe buprenorphine. Physician assistants (PAs) and nurse practitioners (NPs) are required to complete 24 hours of approved training. Providers should also be comfortable utilizing tools such as the Clinical Opiate Withdrawal Scale (COWS) to inform their patient assessment.[18] In the initial waiver year, the provider is limited to treating 100 patients. In years following, a provider may apply to SAMHSA for approval to treat up to 275 patients.[19]

Our health system provides primary care to 77 000 patients in 11 rural clinics in the Midwest United States. Of the 64 primary care providers, only 3 possess a DEA waiver to prescribe buprenorphine, and have collectively treated 20 patients. Following a simple process to complete inductions and follow-up appointments, patients are able to receive MAT in the normal workflow of our rural family medicine practice.

Case Report

Our patient was an otherwise healthy 43-year-old male who had intermittently taken prescription methadone, fentanyl, and oxycodone over a 14-year period of time for chronic low back pain. In the past 2 to 3 years, he used heroin after coming home from working his job during the night shift; he would inject heroin intravenously to relax and fall asleep, and later would join his spouse and daughter for dinner before going back to work. Aware of the severity and progression of his problem, the patient had reached out to several local addiction treatment programs. Upfront costs, required travel to a treatment center, and the inability to be away from work prevented him from participating in any treatment program.

On one occasion, the heroin he obtained was more potent than expected. He injected himself and fell asleep. When he did not answer his spouse's calls, she came home from work and found him unresponsive and apneic; this was just moments before their pre-teen daughter would have come home from school. His spouse, a layperson, was unable to locate naloxone in their home and performed cardiopulmonary resuscitation until first responders arrived, even though she does not work in health care herself. First responders administered 2 intranasal doses of naloxone as the patient was transported to the emergency department (ED) of the critical access hospital in the same town. There, he was medically stabilized and monitored overnight. Coincidentally, his family medicine physician, who cared for his entire family and was familiar with the patient, was working in the ED that night. He was aware of Suboxone therapy for OUD being offered by his colleagues in the outpatient practice and made an urgent referral to the MAT provider. The following morning, the patient was seen in the family medicine clinic. He was actively in withdrawal with a COWS score of 16, indicating moderate withdrawal. Suboxone therapy was initiated according to the MAT protocol, 2 mg initially and 2 mg every hour thereafter for a total of 4 doses. He was stabilized over several days of follow-up at a dose of 8 mg of Suboxone twice daily. Follow-up consisted of frequent

weekly visits for the initial 4 weeks, monthly visits for 6 months, and then continued office visits every 3 months thereafter.

At a follow-up visit after 6 months of MAT, the patient was motivated to share his positive experience with others and referred 2 people for MAT in our practice. One year after beginning MAT, he was still taking Suboxone at 8 mg twice daily and felt that he was ready to begin weaning to a lower dose. He was working, had received a promotion, was actively participating in family activities, and made it a point to attend all of his daughter's school events. He and his family remain in our family medicine practice and are otherwise physically and emotionally well.

Discussion

The case presented illustrates how a rural family medicine practice can increase accessibility to MAT treatment. Previously, access to MAT was limited by lack of flexibility of the few other options existing in this rural area. Alternative MAT programs either require admission to an inpatient facility with the risk to patients of losing employment or require daily travel for over an hour to a nearby larger city for enrollment in a methadone program. These barriers prevented the subject patient in this case from receiving MAT treatment sooner. This patient expressed that he truly believes that he would not be alive if not for the simplicity of going immediately from the ED to the outpatient clinic to initiate MAT treatment.

MAT can be offered to patients in several formulations, including methadone, buprenorphine with or without naloxone, and naltrexone, but Suboxone is the most effective and practical option for incorporating MAT into an outpatient family medicine practice. A large comparative effectiveness study that included 40 885 adults with OUD, examined 6 different treatment pathways and found that only treatment with buprenorphine or methadone was associated with reduced risk of both overdose and serious opioid-related acute care utilization compared with no treatment at 3 and 12 months of follow-up.[20] Between these 2 options, there are additional barriers for the outpatient primary care provider to prescribe methadone compared with Suboxone. For a practitioner to administer and dispense methadone for OUD, they must obtain a separate DEA registration as a Narcotic Treatment Program. This type of activity requires additional approval and registration of the Center for Substance Abuse Treatment (CSAT) within SAMHSA of the Department of Health and Human Services (HHS), as well as the applicable state methadone authority.[21] Given its relative effectiveness and practicality, Suboxone is the MAT treatment used our rural family medicine practice protocol.

A suggested clinic-based protocol developed and implemented in our rural outpatient family medicine practice to provide a pathway for patients with OUD to receive MAT with Suboxone is shown in the appendix. The scheduling staff and team registered nurse (RN) have a list of specific tasks to prepare the patient for an initial consultation with a physician. By the time the patient is seen, appropriate laboratory tests, including liver function tests, human immunodeficiency virus and hepatitis C screening, sexually transmitted infection testing and pregnancy testing, where appropriate, have been completed. The State Prescription Drug Monitoring Program (PDMP) database is queried, and the patient's consent is obtained to receive records from previous treatment providers. Contact is made with the patient's medical insurance company to determine if there is a preferred buprenorphine formulation and the cost of that medication to the patient. Prior authorization is obtained from the insurance company, to help ensure that the recommended product is available at the time of the initial clinic consultation. In addition, behavioral and social services covered by the patient's medical insurance company are ascertained.

Patients are typically placed on the provider schedule one week prior to their initial consultation, providing time to complete the pre-induction activities as above. Appointment slots early in the day and early in the week are preferred, to allow for monitoring during office hours and follow-up to occur during the work week. Urgent appointments are approved when acute detoxification has occurred and the patient is ready to begin therapy immediately.

The COWS is administered when the patient comes to the clinic. A COWS score of 13 to 24 indicates that the patient is in opioid withdrawal, and further withdrawal symptoms will not likely be precipitated by initiation of MAT.[18] If a patient has recently used opioids and is not yet in withdrawal, as indicated by a COWS score of less than 13, they are asked to return to the clinic or commence treatment the following day. Patients who have been abstinent from opioids for many days and are no longer in withdrawal, can start treatment immediately, or be discharged home for a home-based induction. Those patients that are sent home self-administer the medication and are contacted by the nurse via phone within 1 to 2 hours of the previously agreed-upon MAT initiation time. Home initiation follows the same dosing regimen as office-based initiation (appendix).

In our practice, office-based MAT initiation is required for those who have a functional status <4 METs (metabolic equivalents), atherosclerotic coronary artery disease, diabetes mellitus, multiple medical comorbidities, methadone transition (current methadone dose of <40 mg daily) and chronic pain disorders. MAT is initiated with 2 to 4 mg of the buprenorphine component given every hour until the patient is comfortable and cravings for opioids have resolved. Dosage is calculated using a morphine-equivalent dose of 1 mg of buprenorphine for 10 mg of oral morphine for those patients using prescription medication. Patients using heroin or with unknown opioid

use are started with a 4-mg first dose. During the initiation period, the RN and physician alternate in seeing the patient every 15 to 30 minutes, allowing the physician to continue with a normally scheduled practice. Since many patients have a comorbid pain syndrome and opioid withdrawal may include unmasking some chronic pain, the RN visit includes assessment of the general well-being of the patient, vital signs, COWS, and a pain assessment. When the patient is comfortable, typically after receiving 2 to 3 doses of buprenorphine, they are discharged. The patient is contacted by telephone within 24 hours of induction and seen again within 1 week for follow-up. Thereafter, the patient is seen in the clinic weekly for a month and monthly for 6 months. Patients who are stable in the long term continue to be seen every 3 months. Urine drug screens are done at initiation and randomly and are completed at least every 6 months during MAT treatment.

In the initial 2 years of our program, 16 of the total 20 patients have sustained abstinence, 4 patients have not continued on buprenorphine, and none have been lost to follow-up. The 4 patients who have not continued buprenorphine have been previously prescribed methadone (n = 1), tramadol (n = 1), or hydrocodone (n = 2) for chronic pain syndromes. Three of these patients were referred to MAT due to failed opioid therapy agreements, and each patient previously took more than 50 mg morphine-equivalents per day. These patients were transitioned off of buprenorphine and are currently taking 10 mg morphine-equivalents or less of a prescription opioid. The program is still relatively new and in its first few years of development. Since failure of MAT treatment can occur after months or even years of therapy, we do expect that more patients will not be able to sustain abstinence in the future.

A significant factor in the success of our program is that patients are able to be enrolled when they ask to be seen, throughout the week, and not just at a time set aside specifically for MAT. This means that patients may be seen on an urgent basis when they are actively in withdrawal or are ready for therapy on their terms. Because the induction process is not cumbersome to the provider's time in clinic, urgently referred patients can be accommodated into the schedule of the provider following the same preestablished processes for any patient with any health condition, whether being seen for an initial consultation, induction, or for follow-up. Remote telehealth appointments may be offered to patients after their MAT treatment plan has been adequately established.

In conclusion, improved access to MAT for OUD can be delivered in rural areas by groups of Family Medicine providers and trained staff, by incorporating MAT into the regular provision of primary care in their practice and community.

Appendix

Buprenorphine/Naloxone Protocol

Patient referral (Established patient in the clinic health system or new patient from adjacent counties only)

1. If the patient calls the clinic:
   a. Registration/scheduling staff sends a secure message through the electronic health record (EHR) to the nursing time with a request for an appointment
   b. Nurse contacts a provider from the list of providers with a buprenorphine/naloxone waiver to schedule an appointment
   c. Early morning and early in the week appointment times are preferred
   d. A 40-minute appointment slot is preferred, but urgent appointments can be approved
   e. Same day access is provided for patients on illegal drugs who are already detoxed and in withdrawal
2. Internal provider referral: The provider sends a secure message through the EHR to a provider with a buprenorphine waiver to initiate the scheduling process

Previsit

1. Nurse attempts to obtain a Release of Information for previous providers, especially addiction/pain providers or other providers previously prescribing opioids to the patient
2. Nurse determines if the patient is in counseling for opioid use disorder (OUD)
3. Provider requests laboratory tests: liver function tests, human immunodeficiency virus, hepatitis C, sexually transmitted infections, pregnancy test (if female)
4. Clinic staff verifies medical insurance coverage for the relevant medication and availability at the patient's preferred pharmacy
5. Criteria for having a Registered Nurse present to do assessments at time of induction:
   a. Functional status <4 METs, atherosclerotic coronary artery disease, diabetes mellitus, multiple medical comorbidities, methadone transition (current methadone dose of less than 40 mg daily) and chronic pain disorders.

Day 1 (Consultation day)

1. Patient completes the Substance Use Assessment form[a]
2. Patient completes the Opioid Risk Assessment Tool[a]
3. Patient completes the Buprenorphine/naloxone agreement[a]

4. Patient provides sample for urine drug screen
5. Nurse accesses the Prescription Drug Monitoring Program (PDMP) and sends a secure message via the EHR with the results to the provider.
6. Provider sends a prescription to the pharmacy for a one-week medication supply

Patient induction (Typically the same day as consultation)

1. Provider notifies Emergency Department provider of induction for patients identified with higher risk per Previsit 5a, above
2. Patient picks up their prescription at the pharmacy immediately before their appointment prior to arrival at the clinic
3. Rooming staff records vital signs: blood pressure, pulse, respirations and temperature
4. Patient completes the Clinical Opiate Withdrawal Score (COWS) assessment[b]
5. Provider gives the patient 2-4 mg of buprenorphine sublingually in the clinic
6. Rooming staff repeats vital signs after 15-30 minutes: blood pressure and heart rate
7. Patient completes COWS assessment again and vital signs are obtained again after 1 hour
8. At 1 hour from the first dose, provider gives the second dose of 1-4 mg buprenorphine
9. Rooming staff repeats vital signs after 15-30 minutes: blood pressure and heart rate
10. If the patient has stable vitals and acceptable COWS assessment, they may leave the clinic
11. At 2 hours from the first dose, and at 2-hour intervals, additional buprenorphine is administered as required

Patient follow-up

1. Patient is to be seen or contact clinic within 24 hours
2. Patient is to be seen again weekly for one month, monthly for 6 months, then a minimum of every three months. Urine drug screen is done at initiation and randomly, but at least every 6 months thereafter.

[a]Screening tools available via SAMHSA-HRSA. https://www.integration.samhsa.gov.[22]

[b]The Clinical Opiate Withdrawal Scale (COWS). *J Psychoactive Drugs*. 2003;35:253-259.[18]

Patient Consent

The patient provided authorization for use of their medical information for research purposes.

Declaration of Conflicting Interests

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