HEALTH POLICY

Increasing Access to Medications for Opioid Use Disorder in Primary Care: Removing the Training Requirement May Not Be Enough

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Background: Substance use disorders, including opioid use disorder (OUD), are understood as chronic diseases with a relapsing and remitting course and no known cure. Medications for OUD (MOUD) are well established with decades of evidence supporting their safety and efficacy; however, treatment access remains poor and inequitable. Buprenorphine is an MOUD that can be prescribed in a primary care outpatient setting, although regulatory and administrative challenges are a barrier to prescribing it. Recent regulatory changes offer an opportunity to expand the number of family doctors who treat OUD.

Methods: We offered free, easily accessible buprenorphine “x-waiver training” led by a team of primary care clinicians. In addition, we provided wrap-around support for MOUD clinical questions and administrative needs with experienced family medicine mentors.

Results: More than 400 clinicians attended our trainings, including medical students, residents, and attending physicians. Of the 101 attending physicians who completed our trainings, only 30 went on to apply for an x-wavier, and of those only 7 were currently prescribing when contacted 12 months later.

Conclusion: Our experience indicates that removing the training requirement is a necessary first step but is unlikely to result in major changes to rates of prescribing without other significant cultural changes. (J Am Board Fam Med 2021;34:1212–1215.)

Keywords: Access to Health Care, Buprenorphine, Continuing Medical Education, Family Medicine, Family Physicians, Health Policy, Opioid-Related Disorders, Opioids, Primary Health Care

Introduction

Although definitions of chronic disease differ between the Centers for Disease Control and Prevention (CDC), the World Health Organization (WHO), and many other groups, some experts argue for using the simplest description defining chronic disease as “continuing or occurring again and again for a long time.” As our understanding of substance use disorders (SUDs) and in particular opioid use disorder (OUD) increases, these conditions are widely considered to fall within the umbrella of chronic disease. OUD is heritable, is characterized by relapsing and remitting patterns of severity, has significant morbidity and mortality if untreated, and has no “cure.” Family medicine, with our history of patient-centered care and team-based, longitudinal disease management, serves as an ideal setting for long-term management of OUD. With COVID-19 we see a “dual pandemic” with never-before-seen rates of opioid overdoses and an even greater need to expand access to treatment.

There are 3 Food and Drug Administration (FDA)-approved, evidenced-based medications for opioid use disorders. These medications are buprenorphine, naltrexone, and methadone. Buprenorphine is a partial agonist μ- and δ-receptor ligand that reduces withdrawal symptoms and blocks the rewarding effect of opioids. Naltrexone is an opioid antagonist that blocks the opiates receptors, and methadone is a full agonist of μ-receptors with a long half-life.

In the United States, there are 141,000 prescribing clinicians, of which 10,000 are primary care family physicians. Buprenorphine is the most commonly used MOUD with 80% of MOUD prescriptions being written for buprenorphine. As of 2019, only 4,000 clinicians were approved to prescribe buprenorphine, of which 400 were primary care family physicians. The training required to prescribe buprenorphine is a comprehensive 8-hour “x-waiver training” that includes both didactic and clinical decision-making components. However, the required training for the x-waiver is frowned upon by many family physicians who cite the 8-hour didactic training as a barrier to providing MOUD. While some family physicians are trained in MOUD through fellowship programs, many family physicians feel the training does not adequately prepare them to provide MOUD. Additionally, we observe variation in the training that is provided in fellowship programs.

In 2018, the Substance Abuse and Mental Health Services Administration (SAMHSA) published a policy statement removing the requirement for the x-waiver training. This policy statement provides an opportunity to expand the number of family physicians who treat OUD. As a result of this policy change, we provided free, easily accessible buprenorphine “x-waiver training” led by a team of primary care clinicians. In addition, we provided wrap-around support for MOUD clinical questions and administrative needs with experienced family medicine mentors.

To serve as a model for expansion of MOUD in primary care, we decided to pilot a training program with the following goals: 1) to remove a barrier to MOUD training by providing easily accessible training led by experienced family medicine clinicians; 2) to establish a support system for MOUD clinical questions and administrative needs; and 3) to evaluate the effectiveness of the training intervention. This study describes our training initiative, including the methods and results of our pilot study.

Methods

We offered free, easily accessible buprenorphine “x-waiver training” led by a team of primary care clinicians. In addition, we provided wrap-around support for MOUD clinical questions and administrative needs with experienced family medicine mentors. This training was designed for family physicians, nurse practitioners, and physician assistants who treat patients with opioid use disorder (OUD). The team was composed of 10 primary care clinicians, including family medicine, general internal medicine, emergency medicine, and psychology.

The training included an interactive didactic component for physicians and non-physician providers. The didactic component consisted of 3 one-hour modules: an introduction to addiction and MOUD, training on buprenorphine dosing, and training on use of the buprenorphine/naloxone combination product (Suboxone: Indivior). The didactic component included a video lecture, case scenarios, and Q&A with experienced family medicine mentors. The didactic component was followed by a 1-hour interactive discussion with experienced family medicine mentors. Experienced providers were available throughout the training to answer questions and discuss MOUD clinical scenarios.

The training content was designed to provide a comprehensive understanding of MOUD and to familiarize clinicians with the particular challenges and strategies for prescribing buprenorphine in a primary care setting. MOUD clinicians face a number of challenges, including knowledge about treatment options, patient and family concerns, and knowledge about the risks and benefits of each option. Our training included modules on knowledge about treatment options, patient and family concerns, and knowledge about the risks and benefits of each option.

Results

In total, 437 clinicians attended our trainings, including medical students, residents, and attending physicians. Of the 101 attending physicians who completed our trainings, only 30 went on to apply for an x-waiver, and of those only 7 were currently prescribing when contacted 12 months later.

Discussion

The national guidelines for MOUD in primary care call for family physicians to have a good understanding of MOUD and to be capable of prescribing it. However, many family physicians cite the 8-hour didactic training as a barrier to providing MOUD. We believe removing the training requirement is a necessary first step in increasing MOUD prescribing. However, our experience indicates that removing the training requirement is unlikely to result in major changes to rates of prescribing without other significant cultural changes. We are encouraged by the 30 family physicians who applied for an x-waiver and 7 family physicians who are currently prescribing, but we believe there is still room for improvement.

Conclusion

Our experience indicates that removing the training requirement is a necessary first step but is unlikely to result in major changes to rates of prescribing without other significant cultural changes. (J Am Board Fam Med 2021;34:1212–1215.)

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OUD (MOUD), including opioid agonists (methadone and buprenorphine) and opioid antagonists (naltrexone). Decades of evidence in different settings and populations show that buprenorphine and methadone decrease the risk of opioid overdose death. Recent evidence confirms that treatment with medication should be first line as compared with more traditional nonpharmacologic behavioral health and counseling approaches. The DATA 2000 law allowed a new opportunity for office-based treatment of OUDs using buprenorphine if the physician met several criteria, most notably attending an 8-hour training course.

Only a small fraction of US primary care physicians (PCPs) have their “x-waiver” and even fewer of those with the waiver go on to prescribe MOUD. The American Academy of Family Physicians (AAFP), in a position article, details the barriers to prescribing MOUD and commits to working to reduce these barriers to increase the number of family physicians who treat OUD in their office. Commonly cited barriers to obtaining the waiver and prescribing buprenorphine include lack of training and mentors, fear of a Drug Enforcement Administration (DEA) audit, and lack of time and money to integrate these services into busy primary care offices.

Methods
In 2018, our program received a grant to increase the number of locally waivered clinicians by addressing these barriers. We provided free, conveniently located buprenorphine waiver training by a team of primary care clinicians with office-level administrative support to implement buprenorphine prescribing and mentoring with experienced clinicians once a waiver was obtained.

We used the American Society of Addiction Medicine (ASAM) and later the Provider Clinical Support System (PCSS) trainings when it became free to use. We received approval from both agencies to slightly modify their slides to add local data and include cases specifically directed to a primary care audience. We included anecdotes about our own personal experience with prescribing buprenorphine since 2014, including how we managed after-hours calls, challenging case scenarios, note writing, and billing. Many of our trainings were directed at primary care residents (including family medicine, internal medicine, and OB/GYN) as well as medical students. Since residents do not generally have their own DEA license, they cannot apply for the buprenorphine “x-waiver” until they graduate. In addition, many advance practice providers (APPs) participated but until recently needed to complete 16 hours of additional training. Thus, we excluded APPs, residents, and medical students from this evaluation as they were not able to prescribe buprenorphine at the end of the training.

Results
In a period of 3 years, approximately 400 individuals participated in 17 different waiver trainings led by our team. Of the 101 attending physicians who attended our trainings, only 30 went on to apply for an x-waiver, and of those only 7 were currently prescribing when contacted 12 months later (see Table 1 and Table 2 for details and breakdown by specialty).

Table 1. Attending Physician Participants

| Participated | % |
|-------------|---|
| Total       | 101 100% |
| MD          | 86 85% |
| MD, MPH     | 3 3% |
| DO          | 12 12% |
| Medically underserved* | 38 38% |
| Rural*      | 22 22% |
| Specialty   |     |
| FM          | 24 24% |
| IM          | 23 23% |
| OB/GYN      | 19 19% |
| EM          | 17 17% |
| EM/FM       | 1 1% |
| PSY         | 8 8% |
| MED/PED     | 5 5% |
| SUR         | 2 2% |
| ANT         | 1 1% |
| PED         | 1 1% |
| Waiver      |     |
| Yes         | 27 27% |
| Applied     | 3 3% |
| Plans to Apply | 4 4% |
| Maybe       | 1 1% |
| No          | 13 13% |
| Took course for knowledge | 1 1% |
| Moving out of NY | 1 1% |
| Unknown/no response | 39 39% |

*Not all participants reported.
Discussion

Our results are consistent with what is found in other programs, but we find them disappointing. Our program was designed to explicitly address the barriers noted in the literature, and yet only 7 clinicians went on to actively prescribe. The Trump administration issued an end-of-term announcement that the waiver was to be eliminated; however, this was quickly withdrawn by the Biden administration due to “significant legal and clinical concerns.” A new announcement allows an exemption for practitioners who are licensed under state law and who possess a valid DEA registration to submit a notice of intent (NOI) to prescribe buprenorphine with a patient limit of 30 without certifying to any additional training. Medical experts have noted that this requirement for additional training is unique to buprenorphine and is not required for other, much more dangerous medications.

We believe our experience provides further evidence that there are multiple levels of complex barriers to increasing access to MOUD in primary care. The most commonly cited reasons for not pursuing a waiver or actively prescribing among our participants was that clinicians did not see a need in their practice or that the opportunity had not arisen to prescribe. Our findings may be understood in the context of the capability, opportunity, motivation, and behavior model (COM-B). According to COM-B, a person’s capability, opportunity, and motivation influence whether they carry out a behavior. While our training addressed the capability (eg, waiver training), it did not address the opportunity and motivation to prescribe.

The ability to intervene on opportunity and motivation are complicated barriers that likely relate to discomfort with the unknown, pervasive stigma against people with SUDs, and concerns about administrative and legal regulations. Studies of PCPs and SUD treatment facilities have shown low understanding of effectiveness and at times active discouragement of the use of MOUDs. Adherence to or greater familiarity with a more traditional 12-step approach to treatment is negatively associated with acceptability of MOUD. In addition, there are regional differences in acceptability, education, and training. The direct experience of seeing OUD treatment successfully implemented in a primary care clinic may be the most efficient way to increase opportunity and motivation.

We believe that removing the requirement for additional training is an important first step in increasing access to long-term OUD treatment. However, equally important is normalizing the prescribing of buprenorphine in primary care settings and creating opportunities for clinicians at all levels of training to have direct experience seeing patients receive MOUD in a primary care setting. If the requirement is removed and clinicians are not motivated to obtain waivers, are not clear on the safety or effectiveness of MOUDs, or do not screen for opportunities to use them, then impact on access will be minimal.

Starting in undergraduate medical education, we must include instruction about the chronic disease model of SUD, expand interventions to decrease clinician-based stigma, and implement strategies to build trust around disclosure with patients in a primary care setting and better ways to screen for patient need and acceptance of treatment from a PCP. This is a cultural change in the way that substance use has traditionally been treated, and patients may not know, or may not trust, that they will receive adequate treatment in this setting. We need to educate both providers and patients that primary care is the right place

| Waiver† | % of Waiver | % of Participating‡ |
|---|---|---|
| Total | 30 | 100% | 30% |
| MD | 26 | 87% | 30% |
| MD, MPH | 1 | 3% | 33% |
| DO | 3 | 10% | 25% |
| Medically underserved* | 13 | 43% | 34% |
| Rural* | 6 | 20% | 27% |
| Currently prescribing† | 7 | 23% | NA |

*Not all participants reported.
†Waiver = yes/applied.
‡As of last contact 12 months from training.

Table 2. Attending Physician Participants Who Applied for Buprenorphine “x-Waiver”

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for long-term treatment similar to diabetes and hypertension.

Conclusion

National reforms that support having primary care access to substance use counselors and/or OUD care coordinators along with permanent removal of barriers and continuous medical education will help improve uptake and access to pharmacotherapy for OUD. Ultimately, however, cultural change in primary care toward OUD will be achieved through provider-to-provider conversations and exposure to the transformative experiences of treating OUD in primary care.

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To see this article online, please go to: http://jabfm.org/content/34/6/1212.full.

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