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Offering Emergency Buprenorphine Without a Prescription

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It is estimated that 2 million individuals in the United States have opioid use disorder (OUD) and an estimated 130 deaths from opioid overdose occur each day.[1] However, it is estimated that only 20% to 40% of individuals with OUD receive medications such as buprenorphine, methadone, and naltrexone to treat this disorder.[2]

In this Viewpoint, we discuss how allowing the sale of buprenorphine without a prescription in emergency circumstances could expand its use. and may benefit both individuals and the wider population.

Buprenorphine Prescribing for OUD

The Drug Addiction Treatment Act of 2000 allows physicians to prescribe buprenorphine, a schedule III medication, for outpatient treatment of OUD. In a populationwide study that included 17 568 patients, followed up for 12 months, buprenorphine use was associated with a relative reduction in all-cause mortality (adjusted hazard ratio, 0.63; 95% CI, 0.46–0.87).[3] Yet the steps required for a patient to initiate buprenorphine treatment are onerous.

The typical process may include several steps, including self-recognition of OUD, having motivation to seek treatment, making an appointment during normal business hours with a clinician who has a Drug Enforcement Agency (DEA) waiver to prescribe buprenorphine, waiting several days or weeks for that appointment, completing an intake assessment, waiting 1 to 2 days before buprenorphine induction (patients must be in withdrawal from opioids before they initiate treatment with buprenorphine), and starting the medication. Throughout this process, patients can lose motivation and never start the treatment they need, leaving them at risk for overdose and medical complications associated with OUD.[4]

The steps for prescribers to provide buprenorphine also are onerous. Clinicians must undergo special training, which is a standard not required for most other medications, receive a DEA waiver to prescribe, hire staff to help manage the patients, and handle

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confidentiality issues per the US Code of Federal Regulations (CFR; 42 CFR Part 2), including restrictions around disclosure of a substance use disorder (42 CFR §2.12) and specific requirements for patient consent (42 CFR §2.31).

Even after taking these steps, most clinicians who receive a DEA waiver still do not prescribe buprenorphine to allowable limits.[2] Therefore, it is not surprising that many patients who require buprenorphine are unable to access this medication.[5]

Prior suggestions for increasing patient access to buprenorphine have included eliminating the buprenorphine waiver,[2,6] removing buprenorphine from drug scheduling,[6] and improving the training of young physicians in addiction treatment.[2] Recently the National Academies of Sciences, Engineering, and Medicine issued a report that highlighted the need for improved treatment access, regardless of the availability of behavioral interventions, and have argued for access to all medications approved by the US Food and Drug Administration across any treatment setting.[5,7] These are important reforms; however, they are unlikely to be sufficient in addressing access issues.

Providing Buprenorphine Without a Prescription

Historically, medications have been made available without a prescription when they are relatively safe and effective and the public can easily comprehend indications for their use. Buprenorphine meets these conditions. Confining treatment to the offices and business hours of the medical community limits the ability of patients to receive needed treatment. It is time to consider novel and potentially controversial solutions.

Buprenorphine could be offered without a prescription, available behind the counter at pharmacies, in a model similar to that used for other medications. Buprenorphine could be available for those in need similar to emergency contraception, while limiting unrestricted access by setting age and quantity limitations similar to those used for pseudoephedrine. Limiting quantities (eg, 3-day supply) could encourage patients to seek long-term treatment from a clinician with a DEA waiver for their medical and psychosocial needs.

In addition, a behind-the-counter model could provide uninsured patients, who have the least access to clinicians, with needed treatment. Out-of-pocket costs may remain a barrier to access, but could serve as another incentive for patients to seek prescriptions, which would be more likely to be covered by insurers. In addition, pharmacists could observe the initial dose to ensure that opioid withdrawal symptoms are not precipitated by buprenorphine.

Emergency circumstances that would justify providing buprenorphine without a prescription would need to be clearly defined. Potential situations may include (1) when a person with OUD is waiting for an office-based treatment intake assessment or is having severe withdrawal symptoms, or (2) when a person who has successfully tapered off buprenorphine perceives that he or she is at imminent risk for relapse.[2] This model could potentially enable many persons with OUD to access and benefit from buprenorphine.

Challenges and Concerns

Several challenges and concerns with this proposal for providing buprenorphine without a prescription need to be considered.

The first concern is serious risk associated with use of buprenorphine. When taken alone without other medications, buprenorphine rarely produces serious adverse effects. However, just as the combination of acetaminophen (an over-the-counter medication) and alcohol can induce liver impairment and death, buprenorphine use has been associated with respiratory depression, sedation, and death. These adverse effects nearly always occur in persons who have taken buprenorphine with an additional sedating substance.[8] Such risks already appear on buprenorphine labels. A special consideration is unintentional poisoning in young children. The behind-the-counter model seeks to ensure children are safe from inadvertent buprenorphine exposure through monitoring and quantity limits.

A second concern is that buprenorphine might become a gateway drug. Buprenorphine can elicit euphoria in persons who do not already have physical dependence on opioids.[8] However, given that the chemical properties of buprenorphine produce only a modest euphoria (like pseudoephedrine or dextromethorphan), it is unlikely to become a recreational drug of choice. Recent literature has demonstrated that the use of buprenorphine likely signals an already existing OUD, rather than serving as a risk factor for the development of one.[9] Some persons without an OUD who experience severe pain could try buprenorphine, which, if effective, could lead to long-term misuse. The behind-the-counter model seeks to reduce this risk and, based on prior literature, it is reasonable to expect that nearly all use of nonprescription buprenorphine will occur in persons who are already physically dependent on opioids.

A third concern is that buprenorphine will be diverted. A considerable part of the illicit diversion of buprenorphine comes from patients who receive prescriptions and share or sell this medication to persons with OUD who are seeking to avoid overdose through self-management of opioid withdrawal.[9] It is likely that allowing buprenorphine to be available without a prescription could diminish the illicit market for buprenorphine because fewer persons with OUD would need to buy or borrow it from others.

Afourth concern is that buprenorphine requires physician monitoring. This concern is central to understanding the regulations around its prescribing. Monitoring allows physicians to ensure patients (1) experience a favorable risk-benefit ratio while receiving treatment and (2) are not diverting or overusing the medication. But when used in emergency situations, buprenorphine’s safety profile precludes the need for physician monitoring. Buprenorphine is seemingly safe to initiate without clinician oversight and some patients have reported starting treatment with diverted medication on their own. In the current model of prescribing, the burden of monitoring is on the physician; a behind-the-counter model would shift some of that burden to pharmacists, and the extent of a pharmacist’s liability risk regarding the dispensing of buprenorphine may depend on state law. As a result, this model would require increased pharmacist education regarding buprenorphine to improve effective counseling about the medication.

Conclusions

Wider buprenorphine availability could yield a high magnitude of benefit at both individual and population levels. At the individual level, patients could have withdrawal symptoms and cravings managed, possibly preventing further illicit opioid use.[8] At the population level, given the burden of OUD, increased buprenorphine access could lead to reduced health care costs, less drug-related criminal activity, and lower transmission rates for infectious diseases.[10]

The incidence of any risks related to buprenorphine is likely low for individuals and the population; however, the magnitude of risk is high (overdose death) when it does occur. On balance, this risk-benefit calculation favors making buprenorphine available under select regulation without a prescription.

A behind-the-counter model that does not require persons with OUD to find a physician who can and will prescribe buprenorphine could improve access to this medication. In addition, pharmacies could provide buprenorphine at night or during the weekend.

It is important to attempt to address the opioid epidemic in new, effective, and safe ways. Increasing access to buprenorphine, a relatively safe medication, without a prescription could prove helpful for treating persons with OUD.

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