

COMMENTARY

Against Our Instincts: Decriminalization of Buprenorphine

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The rate of overdose deaths has increased dramatically over the past 2 decades. Recently, efforts have been made to expand access to medications for opioid use disorder, such as buprenorphine, by removing X-waiver training requirements. However, relieving such barriers has also raised concern about increasing diversion rates for buprenorphine use, defined as the use of buprenorphine for some purpose or by someone other than it was originally intended. Historically, diversion has been addressed through the criminalization of buprenorphine possession without a prescription. We argue that while buprenorphine diversion is not to be condoned, the benefits of such actions greatly outweigh the harms. Thus, criminalization of diverted buprenorphine represents a dangerous and wasteful response that threatens the progress made through expanded access to this lifesaving medication. (J Am Board Fam Med 2022;35:394–397.)

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Background

In June of 2021, Vermont and Rhode Island moved to become the first 2 states to decriminalize possession of buprenorphine, a partial opioid agonist used in the treatment of opioid use disorder (OUD), without a prescription from a provider. Buprenorphine, a partial opioid agonist used to reduce opioid craving and withdrawal symptoms, was originally approved for outpatient treatment of OUD with the federal Drug Addiction Treatment Act of 2000 (“DATA 2000”), which included a required 8-hour training course granting an “X-waiver” to prescribe buprenorphine. While initially intended to expand treatment for OUD to the outpatient setting, the X-waiver requirement eventually created significant barriers to accessing life-saving medications as the need for treatment dramatically increased during the overdose crisis.

In Vermont, Gov. Phil Scott signed a 2-year bill that allowed possession of a 2-week supply of buprenorphine without a prescription, while in Rhode Island, Gov. Daniel McKee signed a bill to exempt buprenorphine from the list of controlled substances that result in criminal penalties. Federally, the Department of Health and Human Services (HHS) recently moved to expand access to buprenorphine by removing training requirements for the X-waiver that typically governs its prescription in the outpatient setting. These progressive policy changes come against a harrowing estimation of over 93,000 deaths related to drug overdose in 2020.¹ This sharp increase in overdose mortality came during the height of the COVID-19 pandemic, which has created added barriers to accessing medical care for individuals with OUD.

Studies have consistently demonstrated the life-saving effects of buprenorphine for individuals with OUD, with 1 meta-analysis demonstrating a two-thirds reduction in all-cause mortality for patients currently taking the medication.² Despite these statistics, buprenorphine has been the center of controversy between public health, medical, and criminal justice officials throughout the ongoing overdose crisis. Before removal of training requirements, many have long avoided obtaining an X-waiver to prescribe buprenorphine, often citing a lack of belief in agonist therapy, a shortage of time for new patients, or insufficient compensation for such visits.³

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While many believe that decriminalizing buprenorphine and loosening regulations for its prescription will improve access to care, others worry about potentially harmful consequences of increased availability of these medications. In a statement responding to the actions of the HHS, a coalition of addiction psychiatrists and osteopathic physicians from multiple professional societies expressed worries that eliminating training requirements to prescribe buprenorphine would increase the risk of incorrect prescribing practices and in turn increase buprenorphine diversion—the use of buprenorphine *for purposes or by individuals* other than was originally intended.⁴ Although this concern has some merit, we believe that the criminalization of buprenorphine diversion leads to stigmatization of this essential medication is more harmful than buprenorphine diversion itself.

Is Buprenorphine Diversion Always Harmful?

At the outset, we want to acknowledge that even though it is hard to get high on buprenorphine, studies consistently demonstrate that some buprenorphine is diverted for recreational purposes.⁵ We also want to make clear that we appreciate the potential harms of recreational drug use and have grave reservations about buying and selling drugs “on the street.” Apart from the inherent risks of illegally procured drugs, unlike other opioids, buprenorphine rarely has life-threatening consequences when used alone. This is in part due to partial agonist properties of buprenorphine that create a ceiling effect limiting its agonistic effects at high doses.⁶ Furthermore, buprenorphine is most commonly co-formulated with naloxone, which deters intranasal and injection use by exerting antagonistic effects only when administered parenterally.

Estimation of the true rate of overdoses attributable to buprenorphine is difficult given inconsistencies and limitations in collection and reporting data on a national level. However, geographically limited case studies indicate that buprenorphine is detected in a few fatal overdoses and almost invariably combined with other substances. The 2021 Tennessee Buprenorphine Report indicated that less than 5% of overdose deaths were attributable to buprenorphine.⁷ Similarly, a study in New York City found that of 98 overdose deaths, only 2 had buprenorphine in the postmortem report.⁸

It is also important to acknowledge that most who use buprenorphine without a prescription are often

not using it to get high. In a meta-analysis of 17 studies of buprenorphine diversion, only 2 studies indicated that abuse (using to get high) was more common than use for therapeutic reasons, such as preventing withdrawal symptoms or reducing the use of other opioids.⁹ In this study, 1 commonly cited reason for using diverted buprenorphine therapeutically is the inability to access medically directed buprenorphine therapy.⁹ Barriers to accessing buprenorphine extend across socioeconomic, bureaucratic, and stigmatizing lines and include unemployment, insurance status, buprenorphine waiting lists, and most importantly, knowledge and physical access to providers who can and want to prescribe buprenorphine.¹⁰ Studies demonstrate that nearly half of surveyed individuals are motivated to initiate buprenorphine treatment, with more than 75% indicating interest in treatment if it were offered at low-threshold, easily accessible locations.¹¹ Combatting the rising opioid overdose deaths requires allocating limited resources toward low-threshold licit buprenorphine access to reduce the need for diversion.

Given the low risk of misuse and overdose as well as the therapeutic benefits of buprenorphine, diversion may act as a stand-in until it is possible to access medically directed buprenorphine therapy. One recent study demonstrated that increased use of non-prescribed buprenorphine—even when used less than once a week—conferred a relative reduction in risk of unintentional overdose in a multivariate analysis.¹² In addition, use of diverted buprenorphine may promote linkage to the health care system, demonstrated by associations between prior use of nonprescribed buprenorphine and willingness to engage in medically-directed treatment.¹³

Is Buprenorphine Criminalization Helpful?

Given the well-documented harms of criminalization and inadequacy of a carceral approach in stemming overdose deaths, we believe that devoting significant resources to preventing diversion represents an unwise allocation of resources. Maine created the Diversion Alert Program (DAP), a database of individuals arrested on charges related to possession or sale of controlled substances, to stop “prescription drug abuse” by leveraging health care providers’ ability to terminate treatment to prevent illegal “sale” of prescribed drugs.¹⁴ Following initiation of the DAP, buprenorphine became the third most reported drug implicated in arrests, potentially compromising these

individuals' ability to access this lifesaving medication. Meanwhile, overdose deaths continued to rise in the state.

Maine's story tracks with national trends—most people arrested for buprenorphine diversion are either arrested for possession without a prescription or distribution with a prescription.¹⁴ Such arrests can have life-threatening consequences in both the short-term and long-term. Despite many efforts to expand access to medications for OUD in institutionalized settings, many incarcerated individuals are unable to receive treatment. Over a 3-year period in the Cumberland County Jail in New Jersey, 6 people committed suicide while in the throes of opioid withdrawal because the jail would not prescribe buprenorphine, even though some of those who committed suicide had been prescribed buprenorphine before their arrests.¹⁵ In addition, transition out of correctional institutions is often marked by an incredibly high rate of overdose deaths. Post-release opioid-related overdose mortality is currently the leading cause of death for people leaving jail or prisons, mainly due to a lack of medications for OUD access after release, loss of respiratory tolerance to opiates, and social factors such as lack of housing or employment. One Massachusetts-based study found that when people who use drugs were released from prison, they suffered a 30-fold increased risk of overdose in the following year.¹⁶

In attempting to reduce the risks of harm from misuse of diverted buprenorphine, criminalization threatens the lives of the very individuals it purports to save. While expansion of substance use disorder treatment in carceral settings would stem the rise of overdose deaths during and post-incarceration, all by itself, it is not a comprehensive solution to the issues related to buprenorphine criminalization. Indeed, experience from Chittenden County in Vermont demonstrates that decriminalization of buprenorphine diversion as a part of a larger strategy to decrease overdose has the potential to save lives. In 2017, the county opted not to prosecute individuals for buprenorphine diversion, democratized access to buprenorphine at the local syringe exchange and emergency department, eliminated a waitlist for buprenorphine and lobbied to ensure comprehensive access to all medications for OUD in state prisons. After these endeavors, Chittenden County reported a 50% reduction in opioid-related overdose fatalities while overdose deaths were rising across Vermont.¹⁷

Conclusions

Given the current landscape of the overdose crisis, we must focus our efforts on dramatically expanding access to lifesaving medications, such as buprenorphine. While we acknowledge that many interventions (such as increasing access to harm reduction services, increased physician-training in addiction care, etc.) are needed to combat the overdose crisis, we believe that decriminalization of diverted buprenorphine represents an essential piece of these efforts by removing personal and bureaucratic barriers to this medication. In evaluating the effects of buprenorphine diversion, evidence suggests that buprenorphine holds a small risk of overdose compared with other frequently prescribed opioids; even infrequent use of nonprescribed buprenorphine reduces the risk of overdose death, and incarceration has extreme consequences for those arrested under these laws. As we look to the future of buprenorphine availability, we ought not to allow our instincts to protect our patients from buprenorphine diversion to interfere with efforts to expand access to this life-saving medication.

To see this article online, please go to: <http://jabfm.org/content/35/2/394.full>.

References

1. Ahmad F, Rossen L, Sutton P. Provisional drug overdose death counts. Published online 2021.
2. Santo T, Clark B, Hickman M, et al. Association of Opioid Agonist Treatment With All-Cause Mortality and Specific Causes of Death Among People With Opioid Dependence: A Systematic Review and Meta-analysis. *JAMA Psychiatry* 2021;78:979–93.
3. Huhn AS, Dunn KE. Why aren't physicians prescribing more buprenorphine? *J Subst Abuse Treat* 2017; 78:1–7.
4. Sevarino KA, Nielsen P, Kushner M, et al. Letter to Acting Secretary Norris Cochran and Acting Director Regina LaBelle. Published online February 18, 2021. <http://www.aatod.org/wp-content/uploads/2021/02/data2000.letter.coalition.pdf>.
5. Lofwall MR, Walsh SL. A Review of Buprenorphine Diversion and Misuse: The Current Evidence Base and Experiences From Around the World. *J Addict Med* 2014;8:315–26.
6. Walsh SL, Preston KL, Stitzer ML, Cone EJ, Bigelow GE. Clinical pharmacology of buprenorphine: Ceiling effects at high doses. *Clin Pharmacol Ther* 1994;55:569–80.
7. Tennessee Department of Health Office of Informatics & Analytics. 2020 Buprenorphine Report. Published

- online November 2020. https://www.tn.gov/content/dam/tn/health/documents/pdo/2020%20Buprenorphine%20Report_11.30.pdf.
8. Paone D, Tuazon E, Stajic M, et al. Buprenorphine infrequently found in fatal overdose in New York City. *Drug Alcohol Depend* 2015;155:298–301.
 9. Chilcoat HD, Amick HR, Sherwood MR, Dunn KE. Buprenorphine in the United States: Motives for abuse, misuse, and diversion. *J Subst Abuse Treat* 2019;104:148–57.
 10. Evans EA, Yoo C, Huang D, Saxon AJ, Hser Y-I. Effects of access barriers and medication acceptability on buprenorphine-naloxone treatment utilization over 2 years: Results from a multisite randomized trial of adults with opioid use disorder. *J Subst Abuse Treat* 2019;106:19–28.
 11. Fox AD, Chamberlain A, Sohler NL, Frost T, Cunningham CO. Illicit buprenorphine use, interest in and access to buprenorphine treatment among syringe exchange participants. *J Subst Abuse Treat* 2015;48:112–6.
 12. Carlson RG, Daniulaityte R, Silverstein SM, Nahhas RW, Martins SS. Unintentional drug overdose: Is more frequent use of non-prescribed buprenorphine associated with lower risk of overdose? *Int J Drug Policy* 2020;79:102722.
 13. Kenney SR, Anderson BJ, Bailey GL, Stein MD. Buprenorphine treatment formulations: Preferences among persons in opioid withdrawal management. *J Subst Abuse Treat* 2018;94:55–9.
 14. Piper BJ, Desrosiers CE, Fisher HC, McCall KL, Nichols SD. A New Tool to Tackle the Opioid Epidemic: Description, Utility, and Results from the Maine Diversion Alert Program. *Pharmacotherapy* 2017;37:791–8.
 15. United States Department of Justice Civil Rights Division, United States Attorney's Office District of New Jersey. Investigation of the Cumberland County Jail (Bridgeton, New Jersey). Published online January 14, 2021. <https://www.justice.gov/opa/press-release/file/1354646/download>.
 16. Larochelle MR, Bernstein R, Bernson D, et al. Touchpoints – Opportunities to predict and prevent opioid overdose: A cohort study. *Drug Alcohol Depend* 2019;204:107537.
 17. Pozo BD, Krasner LS, George SF. Decriminalization of Diverted Buprenorphine in Burlington, Vermont and Philadelphia: An Intervention to Reduce Opioid Overdose Deaths. *J Law Med Ethics* 2020;48:373–5.