Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Journal of Substance Abuse Treatment 123 (2021) 108263

Contents lists available at ScienceDirect

Journal of Substance Abuse Treatment

journal homepage: www.elsevier.com/locate/jsat

Leveraging COVID-19 to sustain regulatory flexibility in the treatment of opioid use disorder

Kristi Lynn Stringer [a,b,*], Kirsten J. Langdon [c], Michelle McKenzie [d], Brad Brockmann [e], Phillip Marotta [b,f]

[a] Social Intervention Group, Columbia University, NY, New York, United States of America
[b] The Lifespan/Brown Criminal Justice Research Training Program on Substance Use, HIV, and Comorbidities, Center for Prisoner Health and Human Rights, Brown University, United States of America
[c] Department of Psychiatry, Rhode Island Hospital, United States of America
[d] The Miriam Hospital/Brown Alpert Medical School, United States of America
[e] Dept. of Health Services, Policy and Practice, Brown University School of Public Health, United States of America
[f] Washington University in St. Louis, United States of America

ARTICLE INFO

Keywords:
Opioid use disorder
Medications for opioid use disorder
Buprenorphine
Structural stigma
Regulations
Barriers to care

ABSTRACT

The U.S. government declared the opioid epidemic as a national public health emergency in 2017, but regulatory frameworks that govern the treatment of opioid use disorder (OUD) through pharmaceutical interventions have remained inflexible. The emergence of the COVID-19 pandemic has effectively removed regulatory restrictions that experts in the field of medications for opioid use disorder (MOUD) have been proposing for decades and has expanded access to care. The regulatory flexibilities implemented to avoid unnecessary COVID-related death must be made permanent to ensure that improved access to evidence-based treatment remains available to vulnerable individuals with OUD who otherwise face formidable barriers to MOUD. We must seize this moment of COVOD-19 regulatory flexibilities to demonstrate the feasibility, acceptability, and safety of delivering treatment for OUD through a low-threshold approach.

1. Regulatory frameworks as structural stigma

Methadone, buprenorphine, and extended-release naltrexone are highly effective medications that the United States (U.S.) Food and Drug Administration (FDA) has approved as medications to treat opioid use disorder (OUD; MOUD). Despite their efficacy, few people living with OUD initiate and remain engaged in treatment. The U.S. model of methadone treatment is characterized by strict regulations and high-threshold approaches that have demanding entry requirements, are abstinence-centric, require frequent urine drug tests, and mandate psychosocial support. Evidence suggests that nontraditional settings allow access to a broader, often more marginalized patient population that can result in increased initiation and retention rates and decreases in opioid use (Bachhuber et al., 2018; Champagne-Langabeer et al., 2020; Hall et al., 2014; Krawczyk et al., 2019) by offering recovery supports to reduce illicit drug use *without* mandating abstinence to receive MOUD (Payne et al., 2019; Snow et al., 2019; Weinstein et al., 2010; Weinstein et al., 2017).

The stigma associated with drug use, particularly heroin and other opioids, has resulted in policies that systematically discriminate against people who use drugs. Stigmatizing beliefs and attitudes toward drug use, in combination with some of the features of MOUD itself (e.g., the agonist nature of methadone and buprenorphine fuel the notion that MOUD "just replaces one addiction with another"), have incited stigma toward MOUD. Structural stigma refers to stigma that becomes codified into laws and regulatory frameworks that limit opportunities, resources, and well-being for stigmatized populations. As a health-related condition, structural stigma toward OUD is evident in the regulatory frameworks that govern the prescribing of MOUD (Jaffe & O'Keeffe, 2003).

Federal regulation of opioids and MOUD has a long history. Regulations governing methadone are the most stringent, requiring daily observed dosing in a certified opioid treatment program (OTP) and random drug screening. Regulations on buprenorphine prescribing are less stringent, but place an undue burden on providers who are required to register with the Drug Enforcement Agency (DEA), undergo additional training, and submit to DEA audits. The primary justification for

* Corresponding author at: Columbia University School of Social Work, 1255 Amsterdam Ave, Room 819D, New York, NY 10027, United States of America.
E-mail address: ks3592@columbia.edu (K.L. Stringer).

https://doi.org/10.1016/j.jsat.2020.108263
Received 16 June 2020; Received in revised form 13 October 2020; Accepted 22 December 2020
Available online 26 December 2020

these regulations is a desire to reduce diversion of buprenorphine, yet research indicates that diverted buprenorphine is mostly used by persons denied MOUD as self-medication to relieve withdrawal symptoms, not for the purpose of "getting high" (Lofwall & Walsh, 2014). Ironically, overregulation reduces access to buprenorphine and contributes to increased demand for it on the illicit market.

2. COVID-19-initiated regulatory flexibility

To slow the spread of COVID-19, the DEA has relaxed several of the regulatory obstacles described. For example, to reduce daily clinical encounters required for patients treated with methadone, states may now request blanket exceptions for all stable patients in OTPs to receive take-home doses.

Regulations around teleprescribing have also been meaningfully modified. Prior to COVID-19, regulations required an in-person medical evaluation prior to initiating buprenorphine. Strictly regulated video conferencing was permitted for follow-up visits. Pre-COVID regulations prohibited telephonic visits. Telemedicine for OUD was inaccessible for patients without access to devices with video conferencing capabilities. These new flexibilities allow telephonic visits, home-based buprenorphine induction (though methadone induction still requires a complete physical evaluation in person), and follow-up care. Additionally, the American Society of Addiction Medicine has recommended allowing continued access to medications without in-person drug testing (American Society of Addiction Medicine. Adjusting Drug Testing Protocols, 2020).

The greater flexibility to initiate MOUD via telehealth platforms has resulted in improved access to care, which in turn has led to increased treatment uptake. An outpatient addiction treatment center located in Providence Rhode Island, increased intake appointment completion rates from 50% (in-person) pre-COVID-19 to 69% (telehealth) during COVID-19. Additionally, opportunities to conduct follow-up visits through telehealth has allowed patients established in care to overcome concerns about community stigma and practical barriers such as transportation, childcare-related issues, and the burden of frequent drug screening, all of which has resulted in improved treatment retention rates.

Low-threshold access to MOUD is characterized by unobserved (home) induction, same-day treatment entry, prescribing in nontraditional settings, and a harm reduction approach to care that provides support for abstinence but does not mandate it (Haight et al., 2019; Jakubowski & Fox, 2020). However, buprenorphine and methadone require different strategies to increase access given the substantial differences in the regulatory frameworks of these two MOUD. Increasing access to buprenorphine is easier given its far superior safety profile compared to methadone. Although some of the low-threshold approaches such as home induction may be more risky with methadone, there are other aspects of the regulatory framework that could be reexamined, such as increasing the number of take-home doses, conducting home visits with a mobile clinic, and expanding clinic hours to allow for greater social distancing of patients.

The COVID-19 pandemic has also called for greater regulatory flexibility in access and availability of long-acting and injectable MOUD formulations, including injectable and implantable buprenorphine and naltrexone. OUD treatment facilities that offer implantable and injectable buprenorphine are critically needed. Long-acting MOUD formulations reduce the number of requisite visits to provider offices as well as the need to travel to pharmacies, thereby increasing the likelihood of adherence to treatment among people with MOUD.

3. Future directions and recommendations for evaluating change to MOUD in the context of COVID-19

As researchers and providers, we need to capitalize on this opportunity to engage people in care who have been reluctant to self-present for treatment. Whether individuals have forgone initiation of OUD due to stigma or a perceived inability to comply with the demands of low tolerance, high-threshold MOUD, clinicians should educate potential patients about the low threshold approaches currently available. Practitioners could achieve this by partnering with community-based organizations that may have a "touchpoint" with individuals in need of treatment and expanding care to nontraditional settings (e.g., mobile medication unit, MOUD within syringe exchange programs, and "transitions clinics" for people recently released from jail or prison).

We also have a duty to take advantage of this natural experiment to demonstrate the feasibility, acceptability, and safety of delivering treatment for OUD through a low-threshold approach. For maximum impact, employing quantitative methods that harness existing electronic medical records will allow for the assessment of patient-level outcomes pre- to post-COVID-19. Qualitative research with patients, clinical providers, and other stakeholders is also needed to capture perspectives and experiences with adapting to these rapidly evolving regulatory changes. Given the relatively rapid adjustments underway, we urge researchers to leverage mixed-methods and implementation science to identify factors that may facilitate or impede implementation and sustainability of low-threshold MOUD post-COVID-19. Rigorous data collection and analysis will be crucial to support the push for clinically informed and evidence-based approaches to treatment reform in the coming years.

While the government's declaration of the opioid epidemic as a national public health emergency has been successful at drawing attention to the extent of opioid-related harms, it was largely symbolic, as the major structural barriers to care have remained. The emergence of the COVID-19 pandemic presents an opportunity to remove regulatory restrictions that experts in the field have argued present barriers to patients for decades. We must take this opportunity to reexamine aspects of the regulatory framework that stand in the way of individuals with OUD receiving treatment. The regulatory flexibilities implemented out of a desire to avoid unnecessary COVID-related death must remain in place to improve access to evidence-based treatment and save lives. COVID-19 has motivated the adoption of low-threshold practices; however, these structural changes may only be temporary and will not reach the levels needed to truly reverse the trend in overdose deaths.

CRediT authorship contribution statement

Kristi Lynn Stringer: conceptualization, writing – original draft preparation; original and revision review & editing Kirsten J. Langdon: Writing – original draft preparation; original and revision review & editing Michelle McKenzie: Writing – original draft preparation; original and revision review & editing Brad Brockmann: Writing – original draft preparation; original and revision review & editing Phillip L. Marotta: Writing – revision draft preparation; revision review & editing.

Declaration of competing interest

The authors have no conflicts of interest to declare. This analysis was supported by Award Numbers 5T32DA037801 and R25DA037190 from the National Institute on Drug Abuse. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Mental Health or the National Institutes of Health.

References

American Society of Addiction Medicine. Adjusting drug testing protocols. (2020). ASAM COVID-19 Task Force recommendations caring for patients during the COVID-19 pandemic Accessed October 6, 2020 https://www.asam.org/Quality-Science/covid-19-coronavirus/adjusting-drug-testing-protocols.

Bachhuber, M. A., Thompson, C., Prybylowski, A., Benitez, J., Mazzella, S., & Barclay, D. (2018). Description and outcomes of a buprenorphine maintenance treatment program integrated within Prevention Point Philadelphia, an urban syringe exchange program. *Substance Abuse, 39*(2), 167–172. https://doi.org/10.1080/08897077.2018.1443541.

Champagne-Langabeer, T., Swank, M. W., & Langabeer, J. R. (2020). Routes of non-traditional entry into buprenorphine treatment programs. *Substance Abuse Treatment and Prevention Policy, 15*(1), 6. https://doi.org/10.1186/s13011-020-0252-z.

Haight, B. R., Learned, S. M., Laffont, C. M., Fudala, P. J., Zhao, Y., Garofalo, A. S., … Andersen, J. L. (2019). Efficacy and safety of a monthly buprenorphine depot injection for opioid use disorder: A multicentre, randomised, double-blind, placebo-controlled, phase 3 trial. *The Lancet, 393*(10173), 778–790.

Hall, G., Neighbors, C. J., Iheoma, J., et al. (2014). Mobile opioid agonist treatment and public funding expands treatment for disenfranchised opioid-dependent individuals. *Journal of Substance Abuse Treatment, 46*(4), 511–515. https://doi.org/10.1016/j.jsat.2013.11.002.

Jaffe, J. H., & O'Keeffe, C. (2003). From morphine clinics to buprenorphine: Regulating opioid agonist treatment of addiction in the United States. *Drug and Alcohol Dependence, 70*(2 Suppl), S3–11. https://doi.org/10.1016/s0376-8716(03)00055-3.

Jakubowski, A., & Fox, A. (2020). Defining low-threshold buprenorphine treatment. *Journal of Addiction Medicine, 14*(2), 95–98. https://doi.org/10.1097/ADM.0000000000000555.

Krawczyk, N., Buresh, M., Gordon, M. S., Blue, T. R., Fingerhood, M. I., & Agus, D. (2019). Expanding low- threshold buprenorphine to justice-involved individuals through mobile treatment: Addressing a critical care gap. *Journal of Substance Abuse Treatment, 103*, 1–8. https://doi.org/10.1016/j.jsat.2019.05.002.

Lofwall, M. R., & Walsh, S. L. (2014). A review of buprenorphine diversion and misuse: The current evidence base and experiences from around the world. *Journal of Addiction Medicine, 8*(5), 315–326. https://doi.org/10.1097/ADM.0000000000000045.

Payne, B. E., Klein, J. W., Simon, C. B., et al. (2019). Effect of lowering initiation thresholds in a primary care-based buprenorphine treatment program. *Drug and Alcohol Dependence, 200*, 71–77. https://doi.org/10.1016/j.drugalcdep.2019.03.009.

Snow, R. L., Simon, R. E., Jack, H. E., Oller, D., Kehoe, L., & Wakeman, S. E. (2019). Patient experiences with a transitional, low-threshold clinic for the treatment of substance use disorder: A qualitative study of a bridge clinic. *Journal of Substance Abuse Treatment, 107*, 1–7. https://doi.org/10.1016/j.jsat.2019.09.003.

Weinstein, L. C., Iqbal, Q., Cunningham, A., et al. (2010). Retention of patients with multiple vulnerabilities in a federally qualified health center buprenorphine program: Pennsylvania, 2017–2018. *American Journal of Public Health, 110*(4), 580–586. https://doi.org/10.2105/AJPH.2019.305525.

Weinstein, Z. M., Kim, H. W., Cheng, D. M., et al. (2017). Long-term retention in office based opioid treatment with buprenorphine. *Journal of Substance Abuse Treatment, 74*, 65–70. https://doi.org/10.1016/j.jsat.2016.12.010.