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 122 (2021) 108222

Contents lists available at ScienceDirect

Journal of Substance Abuse Treatment

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

Unprecedented need and recommendations for harnessing data to guide future policy and practice for opioid use disorder treatment following COVID-19

Nicholas A. Livingston [a,b,c,*], Victoria Ameral [d], Anne N. Banducci [b,c,e], Risa B. Weisberg [b,c,f]

[a] National Center for PTSD, Behavioral Sciences Division, VA Boston Healthcare System, Boston, MA, United States of America
[b] U.S. Department of Veteran Affairs, VA Boston Healthcare System, Boston, MA, United States of America
[c] Department of Psychiatry, Boston University School of Medicine, Boston, MA, United States of America
[d] Edith Nourse Rogers Memorial Veterans Hospital, Bedford, MA, United States of America
[e] National Center for PTSD, Women's Health Sciences Division, VA Boston Healthcare System, Boston, MA, United States of America
[f] Department of Family Medicine, Alpert Medical School, Brown University, Providence, RI, United States of America

ARTICLE INFO

Keywords:
COVID-19
MOUD
OUD
Opioid use disorder
Policy

ABSTRACT

The COVID-19 pandemic struck in the midst of an ongoing opioid epidemic. To offset disruption to life-saving treatment for opioid use disorder (OUD), several federal agencies granted exemptions to existing federal regulations. This included loosening restrictions on medications for OUD (MOUD), including methadone and buprenorphine. In this commentary, we briefly review policy and practice guidelines for treating OUD prior to the onset of the COVID-19 pandemic. We then outline specific MOUD treatment policy and practice exemptions that went into effect in February and March 2020, and discuss the ways in which these unprecedented changes have dramatically changed MOUD treatment. Given the unprecedented nature of these changes, and unknown outcomes to date, we advocate for a data-driven approach to guide future policy and practice recommendations regarding MOUD. We outline several critical clinical, research, and policy questions that can inform MOUD treatment in a post-COVID-19 era.

The opioid crisis in the United States has occurred in three waves, beginning with an increase in opioid pain medication prescribing, then rising rates of heroin use and overdose, followed by escalation of fentanyl poisoning the drug supply (Ciccarone, 2019). Currently, approximately two million Americans have an opioid use disorder (OUD; SAMHSA, 2019), and 46,802 died from an opioid overdose in 2018 alone, a fourfold increase from 2002 (Hedegaard et al., 2020). Aside from overdose and other adverse events, OUD is a highly debilitating and chronic condition for many (Dong et al., 2019; Rhee & Rosenheck, 2019). Medications for OUD (MOUD), primarily the opioid agonist methadone and partial agonist buprenorphine, are the gold-standard treatment for OUD and are life saving (Connery, 2015). Indeed, in the year following an overdose, death rates decrease by 59% among individuals receiving methadone and 38% among those receiving buprenorphine; however, less than one-third of individuals are prescribed MOUD (Larochelle et al., 2018). Arriving in the midst of this overdose epidemic, the COVID-19 pandemic led to rapid changes in MOUD delivery, with the federal government loosening MOUD guidelines to mitigate risk of exposure to COVID-19 and disruption to life-saving MOUD treatment. This commentary provides an overview of these changes to MOUD policy, and proposes a data-driven approach to evaluating their impact on MOUD treatment access, patient outcomes, and to guide future MOUD policy in the post-COVID-19 era.

Extensive federal, state, and local laws govern MOUD programs, especially programs providing methadone, with the Drug Enforcement Agency (DEA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) providing oversight. Current regulations for methadone and buprenorphine (i.e., Drug Addiction Treatment Act of 2000, 42 CFR 8, and the Ryan Haight Act of 2008 [DEA/DOJ, 2009]), which are schedule II and III controlled substances, are stricter than those for opioid medications prescribed for pain (e.g., Dilaudid, OxyContin) and nonscheduled medications including opioid antagonists (e.

* Corresponding author at: National Center for PTSD (116B2), VA Boston Healthcare System, 150 South Huntington Ave., Boston, MA 02130, United States of America.
E-mail address: nicholas.livingston@va.gov (N.A. Livingston).

https://doi.org/10.1016/j.jsat.2020.108222
Received 12 June 2020; Received in revised form 27 August 2020; Accepted 23 November 2020
Available online 3 December 2020
0740-5472/Published by Elsevier Inc.

g., naltrexone) and medications for other substance use disorders (e.g., alcohol use disorder), and they require prescribers to complete additional courses to obtain a DEA waiver. Due to these regulations, prior to the COVID-19 pandemic, practitioners had to perform in-person physical examinations of patients to initiate these medications (DEA/DOJ, 2009). Providers strictly limited methadone take-home doses to patients who had demonstrated medication adherence and stability in their recovery (SAMHSA, 2015). Guidelines for buprenorphine, while less burdensome, encouraged at least weekly in-person visits during early treatment or "initiation" (SAMHSA, 2004). For both, guidelines required regularly scheduled in-person medication monitoring, counseling, and/or group meetings.

Some experts have suggested that high quality medication management is sufficient for many, given mixed evidence in support of adjunctive psychotherapy (Carroll & Weiss, 2017). However, MOUD treatment demands make it difficult for many patients with OUD, especially patients in early recovery, to fully access and benefit from MOUD. Regular travel to treatment sites can be costly, time-consuming, and may conflict with other important life goals (e.g., employment, family responsibilities). Taken together, these restrictions are especially concerning for patients in early recovery, for whom treatment restrictions are the greatest, and risk for relapse, overdose, and death are disproportionately high. Such challenges are well-documented in the literature. For example, less than half of patients attend follow-up care after a detoxification admission (e.g., Spear, 2014), and very few patients hospitalized for overdose subsequently receive prescriptions for MOUD (e.g., Frazier et al., 2017; Larochelle et al., 2018).

Given this backdrop, the onset of the COVID-19 pandemic poses significant risks for individuals seeking MOUD. First, patients with OUD may be more physically vulnerable to COVID-19 itself (Slat et al., 2020). Second, social distancing guidelines and stay-at-home orders have impacted the social and economic well-being of Americans, and these stressors may put patients at greater risk for OUD relapse (e.g., added stressors, limited access to social supports and mutual self-help groups [Narcotics Anonymous]). Third, existing care models presented patients and clinics with the difficult choice between foregoing critical treatment or risking exposure to a deadly virus.

Fortunately, once the World Health Organization declared COVID-19 a global pandemic, care delivery systems made swift changes to offset disruption to life-saving treatment for OUD. On February 29, 2020, the Center for Disease Control (CDC) issued guidance to health care systems and payors to permit increased use of, and billing for, telehealth and telephone-only care, for both medication and therapy/counseling visits (CDC, 2020). On March 16, SAMHSA issued a directive permitting treatment programs to dispense buprenorphine without an initial in-person evaluation and granted states flexibility to provide 28- or 14-day take-home methadone supplies for stable and less stable patients, respectively (SAMHSA, 2020a, 2020b). These dramatic yet temporary exceptions aimed to offset disruption to essential MOUD treatment by loosening restrictions, expanding treatment options, and reducing the need for in-person visits.

Some suggest these COVID-19 MOUD policy changes should be made permanent to increase access to life-saving treatment and to remove existing barriers to care (Green et al., 2020), but data-driven results to inform such decisions do not yet exist. There is reason to be hopeful, given existing data in support of telehealth for MOUD in rural communities before the pandemic (Eibl et al., 2017). However, the current state of clinical care is complex, as worrisome signs of increasing overdose rates illustrate (Slavova et al., 2020). Given the potential for telehealth to expand treatment access, allowing telehealth visits for MOUD may result in improved treatment access and a reduction of adverse outcomes (e.g., relapse, overdose). Unfortunately, there are few published reports on the outcome of these MOUD policy changes. As such, it is critical that researchers, clinicians, and other policy and patient stakeholders consider the ways in which policy exemptions have affected key aspects of MOUD access, patient outcomes (Table 1) and clinics/systems. The swift action of the CDC and SAMHSA has created an unprecedented opportunity to study the effects of policy on MOUD treatment, patient outcomes, and the costs vs. benefits of former vs. current policies and practices. Although there are many outstanding questions regarding the impact of MOUD policy exemptions, we highlight a few here that we believe can guide next steps in policy and best-practice recommendations in the post-COVID-19 era:

Table 1
Suggested treatment access and patient outcome measures to guide policy recommendations, future research, and best-practices.

Treatment Access
Ease of finding a prescriber
Ease of obtaining and filling prescriptions
Ease of finding counseling
Retention in treatment (medication, counseling)
Provider flexibility regarding frequency of in-person treatment components (e.g., urine toxicology tests)
Access to overdose reversal medications
Access to mutual help meetings
Patient Outcomes
Overdose and mortality rates
Emergency department visits
Detoxification admissions
Medication compliance vs. diversion
Mental and physical health outcomes
Quality of life and functional outcomes

1. Has the COVID-19 pandemic and associated MOUD policy exemptions impacted patient care, in terms of prescriber and prescription access, counseling and behavioral treatments, and format of care (in-person vs. telehealth)? Has it reduced access to related resources, such as mutual help meetings and overdose reversal medications like naloxone (available through pharmacies and community-based organizations)?
2. Have MOUD policy changes impacted patient recovery and health outcomes, especially rates of overdose, ER visits, detoxification, or other adverse events (e.g., death)? If so, for whom?
3. What have been the barriers and facilitators of implementing CDC and SAMHSA practice recommendations across clinics and systems? Were some clinics and systems unable or unwilling to adopt these new guidelines? If so, what has been the impact on patient care and outcomes, and what is needed to support implementation in the future?
4. What types of innovative treatment delivery (e.g., mobile methadone vans; Knopf, 2020) have emerged in response to the pandemic, and what have outcomes looked like for these programs? What barriers have they encountered, and how will reinstating pre-pandemic guidelines impact their use and effectiveness moving forward?

These questions will help to evaluate what aspects of previous policy and practices should resume (e.g., requiring in-person care) versus what aspects of current policy and practice exemptions should continue (e.g., offering a choice of in-person vs. telehealth treatment and medication monitoring). Answers to these questions, which are accumulating within national health care claims, hospital, and outpatient clinic databases, may also guide resource allocation to assist clinics and systems to respond swiftly and effectively in response to the current or future pandemics, or other unanticipated events that might impact MOUD treatment. Whatever the case, the outcomes of the current policy exemptions, or any subsequent roll-back of these exemptions, will soon be realized. As such, it is critical to examine and document the impacts of these policy changes on OUD patient care and outcomes to ensure that guidance regarding future policies and practices are data-driven, and that the net result of these unprecedented policy exemptions, and any future permanent changes, are positive for OUD patient care.

Funding statement

Dr. Ameral's work on this project was supported, in part, by a fellowship funded by the Office of Academic Affiliations, U.S. Department of Veterans Affairs.

Declaration of competing interest

None.

References

Carroll, K. M., & Weiss, R. D. (2017). The role of behavioral interventions in buprenorphine maintenance treatment: A review. *American Journal of Psychiatry, 174*(8), 738–747.

Centers for Disease Control and Prevention (2020, February 29). Interim guidance for healthcare facilities : Preparing for community transmission of COVID-19 in the United States. Retrieved from https://stacks.cdc.gov/view/cdc/85502.

Ciccarone, D. (2019). The triple wave epidemic: Supply and demand drivers of the US opioid overdose crisis. *International Journal of Drug Policy, 71*, 183–188.

Connery, H. S. (2015). Medication-assisted treatment of opioid use disorder: Review of the evidence and future directions. *Harvard Review of Psychiatry, 23*(2), 63–75. https://doi.org/10.1097/HRP.0000000000000075.

Dong, H., Hayashi, K., Singer, J., Milloy, M. J., DeBeck, K., Wood, E., & Kerr, T. (2019). Trajectories of injection drug use among people who use drugs in Vancouver, Canada, 1996–2017: Growth mixture modeling using data from prospective cohort studies. *Addiction, 114*(12), 2173–2186.

Drug Enforcement Administration, Department of Justice. (2009). Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008: Interim final rule with request for comments. *Federal Register, 74*(64), 15595–15625.

Eibl, J. K., Gauthier, G., Pellegrini, D., Daiter, J., Varenbut, M., Hogenbirk, J. C., & Marsh, D. C. (2017). The effectiveness of telemedicine-delivered opioid agonist therapy in a supervised clinical setting. *Drug and Alcohol Dependence, 176*, 133–138.

Frazier, W., Cochran, G., Lo-Ciganic, W. H., Gellad, W. F., Gordon, A. J., Chang, C. C. H., & Donohue, J. M. (2017). Medication-assisted treatment and opioid use before and after overdose in Pennsylvania Medicaid. *JAMA, 318*(8), 750–752.

Green, T. C., Bratberg, J., & Finnell, D. S. (2020). Opioid use disorder and the COVID 19 pandemic: A call to sustain regulatory easements and further expand access to treatment. *Substance Abuse, 41*(2), 147–149. https://doi.org/10.1080/08897077.2020.1752351.

Hedegaard, H., Miniño, A. M., & Warner, M. (2020). *Drug overdose deaths in the United States, 1999–2018. NCHS data brief, no 356*. Hyattsville, MD: National Center for Health Statistics.

Knopf, A. (2020). DEA proposal for mobile methadone finally released. *Alcoholism & Drug Abuse Weekly, 32*(10), 3–4.

Larochelle, M. R., Bernson, D., Land, T., Stopka, T. J., Wang, N., Xuan, Z., … Walley, A. Y. (2018). Medication for opioid use disorder after nonfatal opioid overdose and association with mortality: A cohort study. *Annals of Internal Medicine, 169*(3), 137–145.

Rhee, T. G., & Rosenheck, R. A. (2019). Comparison of opioid use disorder among male veterans and non-veterans: Disorder rates, socio-demographics, co-morbidities, and quality of life. *The American Journal on Addictions, 28*(2), 92–100.

Slat, S., Thomas, J., & Lagisetty, P. (2020). Coronavirus disease 2019 and opioid use—A pandemic within an epidemic. *JAMA Health Forum, 1*(5), e200628.

Slavova, S., Rock, P., Bush, H. M., Quesinberry, D., & Walsh, S. L. (2020). Signal of increased opioid overdose during COVID-19 from emergency medical services data. *Drug and Alcohol Dependence, 214*, 108176. https://doi.org/10.1016/j.drugalcdep.2020.108176.

Spear, S. E. (2014). Reducing readmissions to detoxification: An interorganizational network perspective. *Drug and Alcohol Dependence, 137*, 76–82.

Substance Abuse and Mental Health Services Administration. (2004). *Clinical guidelines for the use of buprenorphine in the treatment of opioid addiction. Treatment improvement protocol (TIP) series 40. DHHS publication no. (SMA) 04-3939*. Rockville, MD: Substance Abuse and Mental Health Services Administration.

Substance Abuse and Mental Health Services Administration. (2015). *Federal guidelines for opioid treatment programs. HHS publication no. (SMA) XX-XXXX*. Rockville, MD: Substance Abuse and Mental Health Services Administration.

Substance Abuse and Mental Health Services Administration. (2019). *Key substance use and mental health indicators in the United States: Results from the 2018 National Survey on Drug Use and Health. HHS publication no. PEP19-5068, NSDUH Series H-54*. Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration.

Substance Abuse and Mental Health Services Administration. (2020a). FAQs: Provision of methadone and buprenorphine for the treatment of opioid use disorder in the COVID-19 emergency. Retrieved from https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf.

Substance Abuse and Mental Health Services Administration. (2020b). *Opioid treatment program (OTP) guidance*. Rockville, MD: Substance Abuse and Mental Health Services Administration.