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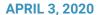
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The COVID-19 Pandemic: Practice And Policy Considerations For Patients With Opioid Use Disorder

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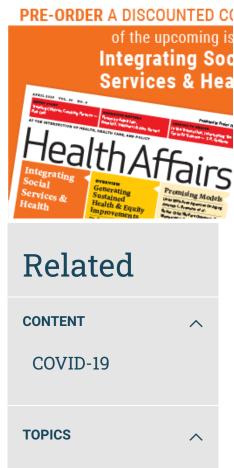




10.1377/hblog20200331.557887

A global pandemic does not abate other public health





emergencies. The COVID-19 crisis, paired with the unrelenting drug-related overdose epidemic, is likely to have profound impacts on people with opioid use disorder (OUD) and other drug use disorders. People with addiction are exceptionally vulnerable to the impacts of the COVID-19 pandemic due to persistent individual and structural discrimination and stigma. Increased COVID-19 risks for patients with OUD include: the medical segualae of opioid use (for example, respiratory depression); the criminalization of drug use leading to increased exposure to correctional facilities and homelessness (for example, close contact with others at risk); and, the convoluted legal and regulatory environment governing the opioid agonist therapy distribution system. Opioid agonist therapies (that is, methadone and buprenorphine) are well-established, lifesaving medications that require patients to gather in large groups and to attend frequent in-person visits with prescribers.

Addiction treatment providers, health system administrators, and government officials should anticipate that the necessary and appropriate public health interventions for "flattening the curve" and mitigating the spread of COVID-19—social distancing, self-isolation, quarantine, and shelter in place—will undoubtedly impact the ability of patients with OUD to access opioid agonist therapy and to use drugs safely. Decision makers need to consider urgently the impact of these actions and to implement newly released federal guidance, with specific attention to opioid treatment programs (OTPs), buprenorphine prescribing, telemedicine, hospital services and bridge programs, and harm reduction.

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"The COVID-19
Pandemic: Practice And
Policy Considerations For
Patients With Opioid Use
Disorder, " Health Affairs
Blog, April 3, 2020.
DOI:
10.1377/hblog20200331.
557887

Opioid Treatment Programs

Methadone, a Schedule II medication, can only be dispensed in federally approved OTPs; federal regulations require, for most patients, standing in a line in close contact with many other people for in-person daily dosing. To enhance social distancing, the Substance Abuse and Mental Health Services Administration (SAMHSA) issued guidance on March 16, 2020, enabling OTPs to increase access to 28-day, take-home supplies of methadone for all stable OTP patients. Prior to SAMHSA issuing the new guidance, federal rules required two years of OTP enrollment to receive a month's worth of take-home medication. Moreover, OTPs may permit a take-home supply of 14 days for less stable patients if the OTP determines it is safe—something that would normally only be permitted after one year in treatment. Per current rules, take-homes are not permitted for patients in short-term or interim treatment; thus, patients newly initiating treatment in the midst of COVID-19 may not be qualified for take-homes and will still need in-person visits. Moreover, on March 30, 2020, SAMHSA released additional guidance outlining the process for methadone receipt for OTP patients who are quarantined or isolated due to COVID-19—either through a surrogate take-home pick-up or "doorstep delivery."

Buprenorphine

In contrast to methadone, buprenorphine, a Schedule III medication, may be prescribed through pharmacies in the outpatient setting. However, the Drug Addiction Treatment Act of 2000 imposes additional regulatory requirements. Prescribers are required to have an "X-waiver" obtained through the completion of additional

training and special federal registration, and are limited as to the number of patients for whom they are allowed to prescribe. A call to end the X-waiver system, which many consider unduly onerous, is ongoing (X the X waiver), but to date, the federal government has not acted. The capacity of the buprenorphine prescriber system is currently insufficient—the number of X-waivered prescribers does not match clinical need, and, among providers who do have an X-waiver, the number actually prescribing buprenorphine is even lower. If buprenorphine prescribers become ill with COVID-19 or are reassigned into other critical care settings, the capacity of the X-waiver system will be further stretched.

Telemedicine

Another buprenorphine-related practice concern is that some prescribers and treatment programs require frequent visits (for example, weekly, bi-monthly) for prescription refills. As social distancing recommendations ramp-up, and non-critically ill patients are encouraged to stay away from health systems, telemedicine interventions are warranted. As of March 17, 2020, the Drug Enforcement Administration (DEA) now permits patients to be initiated on buprenorphine through a telemedicine visit without an in-person exam. This is a departure from the normally stringent federal regulations that require patients to be physically located at a DEA-registered facility or in the physical presence of a DEA-registered provider.

On March 17, 2020, the Office of Civil Rights announced, effective immediately, that it will waive potential penalties for Health Insurance Portability and Accountability Act (HIPAA) violations against health care providers using non-HIPAA compliant communication

technologies (for example, FaceTime, Skype) during the COVID-19 pandemic. SAMHSA issued additional guidance on March 19, 2020, to address questions related to opioid agonist therapy telemedicine practices. The agency reiterated that new OTP patients starting on methadone must continue to receive a complete physical evaluation in-person. In contrast, new OTP patients starting on buprenorphine may have their first visit over telemedicine, including phone only, if necessary. Moreover, follow-up OTP visits for existing patients on either methadone or buprenorphine are allowed to occur over telemedicine, including phone only. One of SAMHSA's guidance statements contradicted DEA rules -specifically, as to whether a buprenorphine prescriber outside of an OTP may use audio-only to initiate buprenorphine (see FAQ No. 4 of the March 19 SAMHSA guidance). However, on March 31, 2020, the DEA confirmed the veracity of SAMHSA's guidance, stating that OTPs and X-waivered prescribers may initiate buprenorphine for OUD treatment using audio-only visits -further expanding upon the regulatory relaxations of March 17.

Hospital Care And Bridge Programs

Hospital-based providers have an increasingly important role in initiating care and providing clinical services for patients with OUD. Best practices in the hospital setting call for opioid agonist therapy initiation and continuation following hospital discharge. Under normal circumstances, continuation of such therapy after hospitalization is challenging due to a confluence of internal and external barriers, particularly related to care coordination in the community or outpatient treatment programs. To meet the needs of recently hospitalized

patients with OUD who are unable to obtain care in the community, some hospitals have initiated "bridge clinics," which are low-barrier, rapid-access, addiction treatment programs. In a chaotic care environment, which will likely occur due to COVID-19, connecting patients to these low-barrier resources becomes critical. Bridge clinics may need to institute low-barrier telemedicine and additional social-distancing measures to ensure that patients and providers are safe, and patients are able to receive opioid agonist therapy.

Harm Reduction

Additional considerations for all providers to decrease harms for people with OUD during the COVID-19 crisis include: supporting drug use hygiene (for example, cleaning surfaces, not sharing pipes); treating or managing co-occurring polysubstance use (for example, nicotine replacement therapy for tobacco use disorder or mirtazapine for methamphetamine use) or referral to treatment for polysubstance use; for patients in quarantine or isolation, offering buprenorphine to treat withdrawal (for example, provide a one-month buprenorphine prescription with a home start); and, providing overdose prevention (for example, naloxone, fentanyl testing strips). The Harm Reduction Coalition has developed additional COVID-19—specific resources.

Next Steps And Conclusions

US federal health authorities are taking important steps to decrease barriers to opioid agonist therapy during this tumultuous time, but they can go further. There are lessons to be learned from Canada, where methadone is not administered through OTPs but instead prescribed and administered through daily dispensing at

pharmacies or as a take-home medication. Patients in British Columbia (BC), moreover, have access to a broader range of medications to treat and manage their OUD, including methadone; buprenorphine; slow-release, oral morphine; and injectable formulations of opioid agonist therapy (diacetylmorphine and hydromorphone). In an historic move, on March 26, 2020, BC health authorities announced that in light of the COVID-19 pandemic they will allow for "safe prescription alternatives to the illegal drug supply." Provincial guidance suggests prescribing oral hydromorphone and/or M-Eslon (12-hour release morphine) for patients using street opioids.

In a time of crisis, US federal and state health authorities should consider more aggressive action to ensure that people with OUD are able to access life-saving medications. First, each State Opioid Treatment Authority should request the new SAMHSA exemptions, and further, strongly encourage local OTPs to implement the new federal take-home guidance. Second, federal authorities could broaden their current recommendations to allow all patients to receive 28-day take-homes, including patients on short-term or interim treatment who are currently excluded from this option. Third, if OTPs close due to COVID-19, federal authorities could consider making an exemption to the Controlled Substance Act to allow for methadone prescribing in other health care settings. Currently, outside of OTPs, methadone may only be prescribed from pharmacies for chronic pain but not for OUD. Another option if closures occur could be to allow pharmacies to become urgent OTPs, such as is the model in Canada, and as was trialed in New Mexico.

Additional actions by the federal government to expand

buprenorphine access could include: eliminating X-waiver patient panel limits; suspending the X-waiver requirements to allow non-X waiver prescribers to prescribe buprenorphine; and permitting telemedicine prescribing of buprenorphine across state lines, which would benefit areas with a low number of X-waivered providers at baseline.

Structural barriers to care for people with OUD abound, and the COVID-19 pandemic further exacerbates issues of access and safety for patients with this condition. Additional federal action is urgently needed as the drugoverdose epidemic persists during this global crisis.

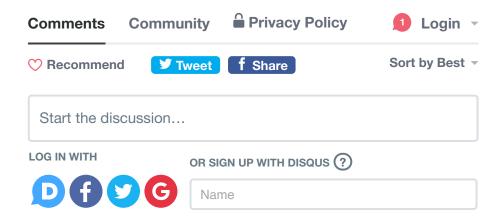
Author's Note

A special thanks to Dennis McCarty, PhD, for guidance and proofing of this post.

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