Leveraging pharmacists to maintain and extend buprenorphine supply for opioid use disorder amid COVID-19 pandemic

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Purpose. Strategies for deploying clinical pharmacists to increase access to buprenorphine in inpatient, outpatient and transitional care, and community practice settings are described.

Summary. Access to medications for opioid use disorder (MOUD) is essential, but patients face many barriers when pursuing treatment and MOUD. The coronavirus disease 2019 (COVID-19) pandemic has compounded the opioid crisis and worsened outcomes by introducing new barriers to MOUD access. Many strategies to ensure continued access to MOUD have been described, but the role of leveraging pharmacists during the opioid/COVID-19 syndemic to improve medication access and outcomes remains underappreciated. Pharmacists, while both qualified and capable of liberalizing access to all forms of MOUD, may have the strongest impact by increasing access to buprenorphine. Herein, we present progressive strategies to maintain and extend buprenorphine access for patients with OUD through deployment of clinical pharmacists, particularly in the context of the COVID-19 pandemic, during which access may be further restricted.

Conclusion. Leveraging pharmacists to extend access to MOUD, particularly buprenorphine, remains an underutilized strategy that should be implemented, particularly during the concurrent COVID-19 global pandemic.

Keywords: buprenorphine, COVID-19, opioid epidemic, opioid-related disorders, opiate substitution treatment, pharmacists

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The coronavirus disease 2019 (COVID-19) pandemic has negatively impacted the opioid crisis and has worsened outcomes for people with opioid use disorder (OUD) as opioid-related overdoses have surged during the global COVID-19 pandemic.[1-4] Medications for opioid use disorder (MOUD), including buprenorphine, methadone, and extended-release (XR) injectable naltrexone, are essential in reducing mortality and facilitating recovery.[5] Changes to healthcare delivery to combat the spread of COVID-19 significantly threaten access to and continuity of MOUD therapy in this underserved population, which heavily relies on face-to-face interactions with both prescribers and pharmacists. The most concerning access restrictions are for opioid agonist treatments (OAT), buprenorphine (a partial opioid agonist), and methadone (a full opioid agonist), given their superiority to other MOUD in decreasing opioid-related mortality.[6] Additionally, OAT maintain opioid tolerance, so without regular access patients may experience withdrawal symptoms, which could destabilize OUD treatment progress. To maintain and advance progress made in improving treatment initiation and retention, in addition to preventing opioid-related deaths, targeted strategies as well as broad policy change are needed to optimize access to OAT

during the COVID-19 pandemic and beyond (Box 1).

While regulatory bodies relaxed restrictions and provided specific guidance for opioid treatment programs (OTPs) to facilitate continued access to methadone early in the pandemic,[7] processes pertaining to management of buprenorphine use for OUD vary widely across inpatient and ambulatory care settings. Pharmacists have been identified as key healthcare professionals to expand the psychiatric treatment workforce,[8] and they are well positioned to expand the addiction treatment workforce as well. Pharmacy-based methadone administration and dispensing would decrease driving times for patients, particularly in rural areas with a shortage of OTPs,[9] and is currently being investigated in a feasibility study.[10] However, Drug Enforcement Administration (DEA) regulations restricting methadone dispensing for OUD to OTPs will prevent a significant pharmacy-driven increase in access to methadone in the foreseeable future. Contrarily, pharmacists could potentially increase buprenorphine access immediately. While clinical or advanced practice pharmacists with psychiatric, pain management, or ambulatory care specialty training may already provide care for patients with OUD, pharmacists across all community and clinical practice settings and specialties are uniquely positioned and qualified to bridge the gap in buprenorphine access and advocate for this population. Herein, we describe barriers to buprenorphine access in various treatment settings during the COVID-19 pandemic and potential solutions to maintain and extend supply, many of which include incorporating pharmacists into the interprofessional care of patients with OUD.

KEY POINTS

- There is an urgent need to expand access to medications for opioid use disorder (MOUD), particularly the opioid agonists methadone and buprenorphine, which are superior to other treatment options in reducing mortality and facilitating recovery.
- The COVID-19 global pandemic has exacerbated this unmet need, yet pharmacists remain underutilized in efforts to expand MOUD access, particularly access to methadone and buprenorphine, due to restrictive laws that overregulate access.
- Pharmacists can maintain and extend buprenorphine access across healthcare settings amid the COVID-19 pandemic by implementing the progressive strategies discussed herein.

Inpatient setting

Access to buprenorphine in emergency departments (EDs), urgent care centers, and inpatient settings can compensate for disruption of outpatient treatment pathways by the COVID-19 crisis. Addressing existing barriers, including provider stigma, lack of clinician training, and Drug Addiction Treatment Act of 2000 (DATA) waiver requirements, which have impeded universal adoption of buprenorphine protocols initiated in ED and inpatient settings, should be a priority for healthcare administrators and policymakers to promote rapid adoption of alternative access strategies. Chills, muscle aches, and gastrointestinal distress are common symptoms of both opioid withdrawal and COVID-19.[11,12] Therefore, viral testing with rapid results reporting to enable triage of patients with OUD to the appropriate care level should be considered for all patients with OUD due to symptom overlap combined with an elevated risk of COVID-19 transmission.[13] Existing DEA exceptions pertaining to ED initiation of buprenorphine (ie, the "three-day rule") and management of withdrawal secondary to hospitalization for medical indications allow DEA-licensed providers to administer buprenorphine in the absence of a DATA waiver.[14] While hospital-based practitioners should optimize use of these existing exceptions, federal policymakers should further reduce barriers by permitting prescribing of initial short-term medication supplies independent of a DATA waiver. Inpatient opioid withdrawal protocols should prioritize a shift to earlier initiation of scheduled buprenorphine regimens as opposed to symptom-triggered approaches, which may prolong length of stay and increase nursing staff exposure (along with personal protective equipment utilization) resulting from frequent withdrawal symptom scale assessments.[15-17] In critically ill patients with OUD receiving buprenorphine who are hospitalized for COVID-19 and mechanically ventilated, treatment interruption should be avoided and sublingual or intravenous buprenorphine should be continued (with or without adjunctive use of a full opioid agonist such as fentanyl or hydromorphone as needed for severe pain, analgesia-associated sedation, and withdrawal prevention) to eliminate the need for buprenorphine reinduction, which may complicate and prolong hospitalization.[11,18-20] Instances of successful microinduction of buprenorphine in critically ill patients without precipitation of withdrawal are increasingly being reported, and this approach can provide another useful tool to treat patients with OUD hospitalized for COVID-19 who have received full agonist opioids.[21] Buprenorphine microdosing is also an important option when converting a hospitalized patient from methadone to buprenorphine therapy due to lack of methadone access or tolerability concerns.[22]

Interprofessional collaboration to enable continued access to buprenorphine after hospitalization may take the form of bedside delivery of discharge medications and proactive communication with community pharmacies to confirm availability and

Box 1. Key Strategies for Optimizing Access to Buprenorphine During Covid-19 Pandemic

1. Promptly initiate buprenorphine for take-home induction in emergency or urgent care settings, and initiate inpatient inductions during hospitalizations, with a "warm handoff" to maintenance treatment providers.
2. Continue buprenorphine during hospitalizations and titrate to manage acute pain and OUD; if use is COVID-19 related, continue buprenorphine during period of potential intubation along with adjunctive full opioid agonists if needed.
3. Ensure close coordination in discharge planning, with buprenorphine delivery at bedside or coordinated prescription fills at a community pharmacy.
4. Utilize locked medication boxes or buprenorphine XR, with option of pharmacist administration, to improve medication security.
5. Remove DEA-mandated community pharmacy ordering limitations on buprenorphine to ensure adequate supply is available.
6. Enhance funding sources and third-party billing to increase access to buprenorphine, with allowances for verbal authorization or web-based signature.
7. Support pharmacist prescribing of buprenorphine for treatment of OUD and inclusion as eligible prescribers under DATA waiver (optimal buprenorphine access expansion will require removal of the DATA waiver requirement).
8. Foster partnerships between the criminal justice sector, community resources, and clinics to ensure all patients, including new patients, have access to care and buprenorphine prescription fills while incarcerated and immediately after to prevent overdose-related death.
9. Facilitate broad access to naloxone and nonprescription syringe sales by advocating for policy changes related to moving naloxone to nonprescription status and removing inequitable drug paraphernalia and syringe possession laws in order to enhance syringe sales.[a]

Abbreviations: XR, extended-release subcutaneous injection; COVID-19, coronavirus disease 2019; DATA, Drug Addiction Treatment Act; DEA, Drug Enforcement Administration; OUD, opioid use disorder.
[a]This strategy is not directly related to expanding access to buprenorphine but is directly related to improving patient outcomes.

reimbursement of buprenorphine to avoid potential lapses in treatment. Hospitals may experience a better return on investment by covering the costs of initial and "bridge" supplies of buprenorphine in cases where private or public reimbursement cannot be secured, as opposed to accepting the likelihood of readmission and hospitalization. Furthermore, rapid consideration of injectable subcutaneous buprenorphine XR as an addition to hospital formularies, with creative use of outpatient billing upon discharge and increased third-party reimbursement, may provide a financially viable treatment option for more patients. Establishing the safety of buprenorphine XR initiation prior to the recommended 7-day period of stabilization on daily buprenorphine might make inpatient initiation prior to discharge possible without prolonging length of stay. Patients who are hospitalized for long durations of intravenous antibiotic therapy, such as those receiving a 6-week regimen for infective endocarditis, present a unique opportunity for transmucosal buprenorphine stabilization and conversion to buprenorphine XR injection before discharge.

Outpatient and transitions of care settings

Lack of access to buprenorphine exacerbated by the COVID-19 pandemic will worsen outcomes for patients with OUD. Patients need care from professionals capable of continuing, assessing, and improving use of medications that are proven to reduce fatal overdoses and extend treatment retention. As the COVID-19 crisis threatens to increase rates of opioid withdrawal, relapse, and overdose, pharmacists in outpatient settings (clinics, community pharmacies, and hospital-based outpatient settings) are accessible resources for buprenorphine initiation and management. Among healthcare providers, pharmacists are the highest-trained clinicians who remain unable to obtain a DATA waiver to prescribe buprenorphine for OUD despite being able to prescribe controlled substances, including buprenorphine, for pain in some states pursuant to DEA licensure.[23] Pharmacists should be included as DATA waiver–eligible providers; however, elimination of the DATA waiver requirement would foster broader access to buprenorphine through pharmacists and other clinicians and is, therefore, a more critical goal.[24-27]

Emergency policies enacted now allow DATA-waivered providers to prescribe buprenorphine via telehealth rather than requiring an initial in-person visit and have already been associated with positive outcomes.[28] Pharmacists could be deployed to conduct interim telehealth visits to evaluate buprenorphine effectiveness and assess the need for medication titration, optimization, or escalation of care. This increased access could reduce in-person appointment burden for patients as well as appointment burden for DATA-waivered prescribers. This

enhanced access to care should be coupled with less restrictive quantity limits (eg, limits on total days' supply) and drug testing policies. While periodic drug testing may be beneficial in certain settings (such as in conjunction with contingency management strategies), routine testing increases the risk of virus exposure and further compounds COVID-19 hardships such as difficulty maintaining employment and childcare. Clinicians should be mindful to avoid drug testing in situations where results are used for punitive purposes or irrelevant to the treatment plan. Additionally, coordination of all medication prescription fills and access to curbside or home delivery can minimize pharmacy visits, particularly for patients in transitional housing structures such as homeless shelters and sober living facilities, which may have imposed leave restrictions. Pharmacists are well equipped to work with patients and insurers to assist with medication refill consolidation, and provider status on the federal level would align payment to incentivize such services. Lastly, patient assistance programs to cover medication costs for individuals who have lost wages or prescription insurance as a result of shelter-in-place orders should allow medical emergency exceptions and relaxed confidentiality requirements similar to those authorized under Code of Federal Regulations Section 42, Part B, whereby disclosure of substance use disorder records for program eligibility and coordination of care can be provided without written signature during telehealth visits.[29,30]

For some patients with OUD, especially those with unstable housing, management of larger medication quantities may be difficult. In cases where daily buprenorphine may impede transitional or supportive recovery housing, use of locked medication boxes or buprenorphine XR can address medication security concerns. In addition to minimizing diversion and preventing accidental overdose, buprenorphine XR is a valuable tool to overcome unstable prescriber access due to COVID-19. Despite many state regulations allowing pharmacists to administer other long-acting injectable products, such as antipsychotics, pursuant to a medication order, few states allow for pharmacists to administer buprenorphine XR. With overall access to healthcare professionals being reduced during the global COVID-19 pandemic, pharmacists can be the most accessible healthcare professionals and play a key role in extending these treatment services to patients. To increase access, pharmacists should be permitted to administer all long-acting injectable medications in all states after sufficient training and credentialing.

Transitions of care services are invaluable for the continuity of buprenorphine during the pandemic. Use of clinical pharmacists for interim telemedicine follow-up during transitions from acute to maintenance treatment can positively impact postdischarge treatment retention, ED visits, and rehospitalization.[31] Amid the COVID-19 pandemic, the potential for incarcerated persons to be released early for infection control, combined with the high incidence of overdose death after release, accentuates the relevance of offering medications to all incarcerated patients with OUD prior to release. Proactive outreach to local jails and prisons to foster partnerships enabling buprenorphine initiation prior to release and continuation in the community is critical to prevent overdose deaths. Pharmacists should be deployed to conduct these outreach calls and provide education and MOUD options, with the capability of initiating medications. Due to the inconsistency of state laws and regulations in this area, urgent legislative changes are required to leverage pharmacists' deployment in treating patients with OUD and improving access to care.[32]

Community setting

COVID-19–related regulatory changes aimed at increasing access to MOUD, and subsequent liberalization of buprenorphine prescribing practices, have the potential to exacerbate existing barriers encountered during the dispensing process at community pharmacies. Pharmaceutical distributors selling controlled substances have faced lawsuits for perceived failures in their past oversight of irregular and inappropriate opioid ordering among select community pharmacies. As DEA scrutiny has increased in recent years, these distributors have in turn increased their scrutiny of pharmacy ordering practices. A recent study indicated that buprenorphine orders are not distinguished from those for other opioid medications, and an increase in buprenorphine ordering may trigger audits or restrictions on controlled substance ordering privileges for some pharmacies.[33] Buprenorphine ordering caps coupled with stigma, fear of unwarranted regulatory oversight, and gaps in education among some pharmacists appear to be leading to problematic "gatekeeping." Examples of such gatekeeping may include a pharmacy restricting buprenorphine dispensing to existing patients, refusing to fill new buprenorphine prescriptions for large quantities, and in some instances refusing new patients altogether. Additional gatekeeping can occur in the form of stigmatizing comments and exacerbation of patient shame. Regulatory agencies such as DEA and state boards of pharmacy can quickly respond to make buprenorphine an exception under controlled substance ordering restrictions and widely distribute COVID-19–specific buprenorphine prescribing practice guidance. Community pharmacists should anticipate an increase in buprenorphine-containing medication prescription volume, as well as increases in the overall quantity written for each prescription, and must ensure an adequate supply is readily available.

In addition to exacerbating longstanding barriers to obtaining buprenorphine, the COVID-19 crisis may destabilize the supply chain for illegally obtained opioids. This destabilization has the potential to increase patients' risk of exposure to illicitly manufactured fentanyl and subsequent

fatal overdose, highlighting the crucial role of community pharmacists in providing direct access to naloxone, especially at a time when increases in return to illicit drug use and overdose are expected. However, substantial variation in state-level laws and regulations, as well as individual pharmacy policies, pertaining to pharmacists' authority in this area contributes to poor pharmacy-based naloxone accessibility.[34-37] Legislators, regulators, and pharmacy leaders should seek to standardize procedures across states and embrace direct authority for pharmacists to prescribe naloxone, given the association of this approach with a reduction in opioid-related mortality.[38] In order to foster true broad access, naloxone should be moved to nonprescription status.[39] Furthermore, recognizing that fatal overdose is not the only consequence of increased illegal drug use and that COVID-19–related quarantines may also lead to increasing reuse of syringes by people who inject drugs, pharmacists should seek to increase access to sterile injection equipment and education. Unfortunately, inconsistent state laws and pharmacy policies also represent barriers to nonprescription syringe sales, which can be resolved by advocating for state-level legalization and expansion of syringe services programs as well as liberalization of pharmacy policies related to nonprescription syringe sales. As stigma is a critical barrier to access to sterile syringes from pharmacies, an internal assessment of pharmacy professionals' inherent bias towards nonprescription syringe sales should also be performed in each pharmacy. Stigma reduction education should be implemented when it is found to be indicated.

Conclusion

The COVID-19 pandemic has fostered a collaborative spirit amongst healthcare professionals to overcome counterproductive laws and implement evidence-based medicine. The tragedies of the opioid crisis may be exacerbated by the COVID-19 crisis, but these risks may be mitigated by creative use of available resources for increased and expeditious access to MOUD to improve patient outcomes and reduce harm. Leveraging of pharmacists to extend access to MOUD, particularly buprenorphine, remains an underutilized strategy that should be implemented, particularly during the concurrent COVID-19 global pandemic.

Disclosures

The authors have declared no potential conflicts of interest.

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