

Epidemic Meets Pandemic:

Treating Opioid Use Disorder in the Age of COVID-19

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Regulatory Barriers to Care for Opioid Use Disorder

Years before the COVID-19 pandemic consumed the world's attention, the opioid epidemic ravaged communities across the US. In response to the exponential rise in fatal opioid overdoses, researchers sought to develop and implement treatment strategies for individuals with opioid use disorder (OUD). Unlike COVID-19 where our treatment options are currently limited, we have evidence-based treatments for OUD that are proven to be safe and effective. Unfortunately, access to treatment for OUD remains an issue and reducing barriers to care, including current regulatory hurdles, is seen as one of the key strategies to improve health outcomes.

Two of the pharmacological therapies that have been approved by the Food and Drug Administration (FDA) for treating OUD are methadone and buprenorphine. Methadone is a synthetic opioid agonist and buprenorphine is a partial opioid agonist. Both medications can reduce withdrawal symptoms and cravings by activating the opioid receptors in the brain. However, there is some risk of diversion (illicit use of a legally prescribed controlled substance) with these two medications. Though long-acting depot injections of buprenorphine in addition to a combination buprenorphine-naloxone (also known by the brand name, Suboxone) treatment have since been created that substantially reduce diversion risk.¹ Moreover, limitations in access to treatment is actually associated with a higher likelihood of diversion.²

Methadone and buprenorphine are each classified as controlled substances and, as such, federal regulations tightly control their prescribing by providers. Methadone can only be prescribed as a daily dose that must be administered in person at a federally registered opioid treatment program facility. The Drug Addiction Treatment Act of 2000 permitted providers to treat OUD with buprenorphine in office-based settings. However, eligible providers must first complete requisite training and apply for a Drug Enforcement Administration (DEA) waiver (also known as the "X-waiver") to obtain buprenorphine prescribing privileges which are then limited to 30, 100, or 275 patients at a given time depending on the application.

These regulations not only create barriers to care in accessing methadone³ and buprenorphine,¹ but they also directly contribute to the persistent stigma associated with seeking help for addiction.⁴ While some argue that such regulations are necessary to prevent diversion of these substances and encourage providers to prescribe responsibly, it should be noted that regulations for prescribing medications used to treat opioid addiction are in fact *more* restrictive than the regulations for prescribing opioids themselves.

Changes in OUD Treatment Policy during the COVID-19 Pandemic

Though its global impact has been devastating, the COVID-19 pandemic may help us improve access to care for OUD while reducing stigma. Amid calls for social (physical) distancing to reduce disease transmission, the federal government temporarily lifted restrictions on prescribing medications to treat OUD as of March 16, 2020.⁵ Specifically, states may request blanket exemptions for practices to prescribe up to 28 doses of take-home medications for "clinically

stable patients” and up to 14 doses of take-home medication for “less stable” patients. The status of “clinically stable” is not defined and is to be left to the provider’s clinical judgment.

Additionally, temporary policies have been put in place for providers to treat existing patients with OUD through telemedicine services.⁶ This allows for providers to remotely administer and monitor their patient’s treatment with special temporary exemptions for buprenorphine prescribing (including the initiation of treatment for both new and existing patients), thereby reducing the risk of exposure to the novel coronavirus for both patients and practitioners.⁷

In their letter announcing the changes in telemedicine regulations, the DEA noted that these exemptions will only be in effect during the current COVID-19 public health emergency and may be discontinued at any point prior to the end of this pandemic. But what if we learn that the benefits of fewer regulations vastly outweigh the risks of diversion? If that proves to be the case, should we not at least consider permanently lifting these restrictions? The only way to know for sure is to systematically measure the impact of loosening these regulations on treatment access and outcomes including rates of diversion and sustained recovery. This presents a prime opportunity for scientists to play a key role in the development of data-driven policy decisions.

Opportunities to Increase Access to Care

Researchers will not be able to successfully bridge the gap between evidence and practice if they attempt to seek solutions in a vacuum. Therefore, we call on research scientists to partner with key stakeholders including policymakers, public health practitioners, health care administrators, medical and behavioral health care providers, and consumers who possess personal experience with addiction treatment. Such partnerships can help ensure that we conduct a robust evaluation of these temporary measures and that our findings are more effectively translated into policy and practice. In addition, it is imperative that a consumer-centered approach informs these efforts. By including the perspectives of individuals with lived experience with addiction treatment, we can better assure that any proposed solutions address issues and outcomes that matter most to consumers and their communities. We recommend that research evaluations explore both provider and patient experiences and outcomes with telemedicine services during the COVID-19 pandemic. Such evaluations could include:

- The impact of providing naloxone (an opioid overdose reversal agent) to all patients who receive treatment for OUD through telemedicine services;
- Educating providers and creating clinical decision support tools addressing the temporary regulations, including additional guidance on defining the “clinical stability” of their patients and evaluating how this may affect provider concerns regarding liability; and
- The impact of supplemental social support interventions including group and other talk therapy options for individuals receiving OUD treatment through telemedicine.

There are growing concerns that the COVID-19 pandemic will result in a surge in substance use including opioid use, leading to an increase in overdoses and death. While we wait and hope for the development of an effective treatment for COVID-19, let us use this time to gather the necessary data to rigorously evaluate the recent clinical and policy changes and determine if they improve access to established treatments for OUD. In doing so, we can demonstrate how policies

