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Structural Adaptations to Methadone Maintenance Treatment and Take-Home Dosing for Opioid Use Disorder in the Era of COVID-19

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Societal disruption from the COVID-19 pandemic has accelerated the opioid overdose epidemic. Given the drastic increase in opioid overdose deaths during the pandemic, particularly within Black communities,[1] it is important to reflect on the state of opioid addiction treatment in the United States. When COVID-19 was declared a public health emergency, more than 400 000 individuals were receiving methadone maintenance treatment (MMT) for opioid use disorder (OUD) across the 50 states, the District of Columbia, and US territories including Puerto Rico.[2] Individuals receiving MMT, a gold standard for OUD treatment, have lower rates of death and nonprescribed opioid use than those not receiving treatment and exhibit better treatment retention.[3]

Despite these benefits, many structural barriers exist in accessing MMT, in large part because of decades of racist policies and political scapegoating (e.g., criminalizing those with substance use disorders and being "tough on crime" through harsh drug policies for political gain).[4] Methadone dispensing is tightly regulated, and the medication can be dispensed only at opioid treatment programs (OTPs) overseen by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Drug Enforcement Administration, and state governments. When used in the treatment of OUD, no other prescription medication is as tightly regulated as methadone.

METHADONE BEFORE THE COVID-19 PANDEMIC

Before the pandemic, most patients on MMT were required to have a daily OTP visit to receive supervised dosing of methadone, usually with only one unsupervised take-home dose (THD) per week when the OTP was closed. Patients with sufficient treatment durations had to meet federal and state criteria before qualifying for additional THDs (with one additional THD allowed every 90 days), such as stable housing to allow safe methadone storage and abstinence from all illicit substances.[5] At the earliest, individuals could receive up to 14 THDs and 28 THDs after one and two years of treatment adherence, respectively. However, given the chronic, relapsing–remitting course of OUD, along with the varied individual discretion of OTP clinicians, longer periods were often required to receive higher amounts.

Individuals accessing methadone face structural and logistical challenges. Lack of treatment availability, transportation, and financial resources and inadequate insurance serve as structural barriers to care.[6] For instance, the majority of OTPs are located in urban areas, and 89% of rural counties lack sufficient OTP access.[7] The average cost of driving for individuals in rural counties is estimated to be $300 in the first month of treatment.[8] Even for insured individuals, low reimbursement and insurance

requirements are among the most common reasons OTPs do not accept new patients.[9] Individuals experiencing homelessness are excluded from receiving THDs, regardless of duration of or stability in treatment, given their lack of access to safe methadone storage.

In addition, individuals taking methadone are often drawn away from responsibilities such as child care, education, and employment, all of which promote treatment adherence and sustained recovery. Furthermore, although more than half of people who are incarcerated report a substance use disorder, only a small number of prisons provide medication treatment.[10] There is little evidence justifying guideline stringency and a growing body of evidence suggesting that decreased regulation may lead to improved treatment outcomes[11]; more research is needed.

EXEMPTIONS TO REGULATION DURING THE COVID-19 PANDEMIC

When COVID-19 reached the United States, OTPs—typically crowded, congregate settings—were identified as potential sites for severe acute respiratory syndrome coronavirus 2 (SARs-CoV-2) infection and spread. In March 2020, SAMHSA released federal guidelines allowing blanket exemptions for OTPs to dispense up to 14 THDs for "unstable" patients and up to 28 THDs for "stable" patients to reduce clinic crowding while maintaining access to the life-saving medication.[12] OTPs had discretion in defining "stable" and "unstable" patients, and the ways in which OTPs implemented these exemptions varied.[13] Public insurers including Medicaid expanded reimbursement for telemedicine, including video and telephone visits, which allowed clinicians to deliver services such as counseling remotely for the first time. Many OTPs waived urine toxicology testing, and OTPs could newly deliver medications to homes or allow trusted relatives or surrogates to pick up THDs for patients.

These broad exemptions marked the first regulatory reforms to MMT since its establishment in the 1970s, despite decades of calls to make such treatment more patient centered. Although not the stated goal, expansion of guidelines represents a giant step forward in expanding MMT access for individuals with OUD. It also establishes conditions for natural experiments to study the impact of these regulatory changes, including increased access to THDs, which was not possible prior to the pandemic. Studying the effects of these exemptions can expand our evidence base and guide future policy-making and care practice guidelines.

In early studies assessing the impact of these regulatory changes, researchers described how OTPs adapted to meet the needs of patients,[13,14] expanded telemedicine,[15] and evaluated the perspectives of both clinicians and patients.[16] These early reports indicate that OTPs nationwide have experienced few adverse events such as overdoses and diversion.[14,17] Clinicians and patients have reported improved care experiences with treatment flexibility,[16,18] although clinicians have expressed concerns about overdose risk and liability with increased take homes.[16] One OTP reported that opioid-positive drug screens increased during the pandemic, although other factors related to the pandemic (e.g., increased psychosocial stressors) may have contributed to increased drug use.[19] By expanding THD access to prioritize patient safety and protection from COVID-19, OTPs may be better able to provide patient-centered care that meets individual needs. If safety and the needs of people with OUD are prioritized and individual wellness and autonomy are promoted, THDs can be viewed as a form of harm reduction.

Few investigations have examined how structural barriers to MMT have shifted during the COVID-19 era. Elsewhere in this issue, we explore how the structural forces of financial incentives, housing, and the carceral system have played mediating roles in MMT during COVID-19 (see Wyatt et al., p. S143). We make recommendations based on this evidence to inform future methadone regulation policies.

MISALIGNED FINANCIAL INCENTIVES IN METHADONE TREATMENT

Although the pandemic has opened the door for fundamental changes to occur, it has also exacerbated the harmful and often unacknowledged ways in which existing systems disadvantage the very individuals they seek to serve. Across both for-profit and nonprofit reimbursement models, it is more financially favorable for OTPs to have patients come in multiple times per week to receive medication, regardless of clinical stability. In the for-profit model, OTPs cannot bill for the same level of in-person service they once provided if patients do not come in daily to access their medication, and some are struggling to remain financially solvent. In some states, public insurers such as Medicaid do not reimburse for patients receiving THDs.

The current billing and reimbursement model lends itself to a structure in which OTPs are incentivized to not prioritize THDs, even for patients who meet SAMHSA guidelines. Systems of

financial incentivization acting as barriers to achieving treatment stability in MMT have long warranted reevaluation, and exacerbations of these barriers during the COVID-19 pandemic further highlight the need for policy reform of incentivization structures.

COVID-19 HOUSING INTERVENTIONS AND TREATMENT PROGRESS

SAMHSA guidelines mandate that people be able to safely store medications in their home environment if they are to receive methadone THDs. This means that populations experiencing unsheltered homelessness and housing instability are excluded from consideration for THDs, posing a significant barrier for a group already facing other structural challenges. Many populations experiencing homelessness are in urban settings, and rates of homelessness have increased dramatically in the face of the significant shortages in affordable housing. More than half a million people were experiencing homelessness across the United States prior to the pandemic.

Unhoused individuals were especially vulnerable to harm during the pandemic, during which people exposed to or infected with COVID-19 or at risk for severe complications had nowhere to safely quarantine. To address this issue, California launched Project Roomkey, in which state and federal funds were used to transform hotel rooms into housing for individuals experiencing homelessness. In 2020, San Francisco used these funds to house more than 2500 individuals who met certain criteria such as needing to isolate as a result of infection with or exposure to SARs-CoV-2 or having risk factors such as older age, respiratory illnesses, compromised immunities, or severe chronic diseases.[20] Individuals isolating because of COVID-19 infection or exposure were housed at isolation and quarantine sites, whereas those vulnerable to COVID-19 were housed in shelter-in-place hotels. Individuals stably in MMT who had become housed could then safely store their methadone and were newly eligible for THDs.

The project just described is an example of how a structural intervention involving temporary housing options in response to COVID-19 intersected positively with MMT care stabilization. Despite some challenges, patients and providers have emphasized how obtaining stable housing was a vital component of successful recovery (see Wyatt et al., p. S143). Stable housing offers a pathway to receiving THDs, thereby reducing the burden of daily OTP visits and freeing up considerable time for patients to focus on other matters such as employment, education, and their health. Although unintended, these beneficial effects resulting from COVID-19 housing interventions highlight how alleviation of structural barriers can facilitate addiction recovery.

METHADONE TREATMENT IN PRISON SYSTEMS DURING COVID-19

The World Health Organization has emphasized the importance of integrating prisons into public health responses to mitigate the impact of COVID-19.[21] Prisons are fraught with barriers to social distancing, hand washing, and protection of inmates from contagion on the part of personnel, visitors, and admissions personnel. Disparities in preexisting health conditions increase the risk of severe complications and mortality from COVID-19.

Individuals with OUD are overrepresented in the carceral system. Reentering individuals with OUD are at high risk of nonfatal and fatal overdose events.[22] Despite unmet needs for care and the reductions in postrelease drug use associated with prison-based MMT, MMT is rarely provided in US correctional institutions.[10] In instances in which MMT is available, restrictions imposed to curtail COVID-19 contagion may result in treatment interruptions. A survey of OUD treatment programs in US jails revealed that half encountered challenges in maintaining adequate clinical staff and physical facilities to ensure social distancing.[23]

The SAMHSA exceptions to methadone dispensing adopted in the MMT prison we examined (see Wyatt et al., p. S143) allowed for continuity of care and a seamless transition to community treatment upon release. Our preliminary findings provide opportunities to reassess the restrictive regulations that apply to this treatment modality and to enhance its acceptability in US carceral settings.

POLICY IMPLICATIONS

Multiple structural barriers for individuals receiving MMT have shifted during the COVID-19 pandemic. The surge of opioid overdose deaths during the pandemic highlights how expanding OUD treatment is critical; evaluation of MMT structures offers one such essential avenue of addressing overdose deaths. Here we have brought together examples of methadone treatment intersecting with and being informed by financial incentive, housing, and incarceration systems. These examples highlight how substance use treatment is often

centered on the needs of institutions rather than on the needs of the individuals they serve, and they underscore the feasibility of changing previously restrictive regulations when the need to increase the availability of and access to methadone is most critical.

Several recommendations for future policy should be noted. If an individual with OUD remains in care, improves, and then stabilizes during care, then receipt of increased THDs is merited. Misaligned financial incentives should not dictate care or serve as a barrier to long-term recovery. Decreasing THDs without a clinical indication to do so (e.g., lapse in care, return to nonprescribed opioid use, co-occurring substance use) can rob individuals of their dignity and freedom to access their medication in the least restrictive manner possible. Regulatory reform is salient to ensure equitable enforcement of THD policies at OTPs that is evidence based and affirms the humanity of people with OUD.

Policy recommendations include financial restructuring to ensure that providers are reimbursed on the basis of overall provision of care as opposed to daily methadone dosing, as has already been implemented for Medicaid in New York State.[24] Furthermore, federal mandates are necessary for collection of data to better understand and address barriers to implementing the SAMHSA exemptions, including financial relief and increased reimbursement flexibility for OTPs struggling to remain financially solvent.

OTPs are witnessing how COVID-19 emergency housing interventions can interact positively with substance use treatment, adding to the evidence that housing can be a stabilizing force in addiction recovery. Emergency housing interventions during COVID-19, especially those targeting individuals with substance use disorders, have the potential to not only stabilize individuals in treatment but also reduce arrests and assaults and increase uptake of medical care. These benefits have prompted the California government to dedicate $1.3 billion to purchase hotels that will be transformed into supportive housing, and Governor Gavin Newsom has proposed an additional $1.75 billion to acquire more property for supportive housing. Yet, cities such as New York are already sundowning their COVID-19 hotel programs as they anticipate cases becoming more manageable. This approach is concerning given the incidence of more infectious COVID-19 variants.

Even more troubling is the expected nationwide increase in the number of individuals experiencing homelessness with the ending of the federal eviction moratorium. Rather than reversing early signs of progress seen during the COVID-19 pandemic, federal, state, and local governments working with populations experiencing comorbid substance use and homelessness should consider extending COVID-19 housing interventions to expand the impact and reach of these services.

Experiences to date support that uninterrupted methadone delivery in prison is possible during challenging times. Precautions instituted early by prisons can facilitate treatment stability, and we found that individuals who were provided with THDs and reentered the community transitioned seamlessly to community OTPs while adequately managing their medication (see Wyatt et al., p. S143). Such experiences suggest opportunities for research to inform models that enhance the outcomes of the treatment cascade from prison to community.

Studies of individuals receiving MMT after incarceration with longer follow-up periods are needed to identify factors contributing to community treatment retention given the variations in MMT and buprenorphine prescribing practices during COVID-19. Understanding effects on retention can inform successful implementation of MMT services for incarcerated populations during and after the pandemic to narrow the treatment gap encountered in US prisons.

As COVID-19 vaccination rates rise and the United States looks to the future in planning its recovery, it is imperative to recognize policy opportunities offered during the pandemic to reenvision methadone treatment. Centering treatment on the needs of individuals with OUD rather than on systems of surveillance, stigma, and punishment is critical. Expansion of THD exemptions during the pandemic has offered insights into MMT's potential for patient benefit, especially when structures are created to support individuals through housing, community connections, and other social elements.

US methadone policy is at a turning point. With the backdrop of surging overdose deaths, policymakers and researchers, rather than reversing progress by reverting to previous methadone policies, should continue to study and learn from the natural experiments created during the pandemic, especially as federal agencies contemplate making regulation exemptions permanent.[25] The imperative exists to develop drug treatment structures that prioritize evidence-based and patient-centered policies and clinical practices if the United States hopes to put an end to this devastating overdose crisis. AJPH

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CONFLICTS OF INTEREST

The authors report no conflicts of interest.

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