Innovations in Methadone Medication for Opioid Use Disorder: A Scoping Review

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Abstract

Methadone, an opioid agonist, is an effective treatment for opioid use disorder (OUD). Methadone both lowers the likelihood of overdose and reduces illicit opioid use. However, a fairly narrow regulatory approach currently limits methadone access. Methadone currently may be dispensed for the treatment of OUD only in federally approved opioid treatment programs (OTPs).[1] This scoping review identifies and reviews the effects of different approaches to methadone medication for OUD (MOUD) aside from the most common treatment pathway used by OTPs under the current regulatory landscape. The alternatives include modifications allowed in response to the COVID-19 pandemic as well as treatment practices outside the United States. The review identifies multiple ways clinicians have tried to address barriers to access in response to the needs of rural patients or to pandemic obstacles. Early studies of the pandemic response have shown no decrease in quality of treatment or patient outcomes in response to increased take-home dosing and use of telehealth, although telehealth treatment has shown to be less accessible for patients without broadband or smartphone access. Both U.S. and international studies of office-based and pharmacy-based MOUD suggest they present opportunities to increase access to MOUD, especially for rural patients, without worsening treatment outcomes.

INTRODUCTION

Opioid use disorder (OUD) is a chronic brain disease that affects millions of Americans. Caused by misuse of prescription opioids, heroin, or other illicit opioids,[2] OUD carries with it significant mortality risks both from overdose risk and unrelated to overdose.[3] In 2021 alone, there were more than 75,000 overdose deaths attributed to opioids.[4]

Methadone, an opioid agonist, is one of the effective treatments for OUD . Methadone both lowers the likelihood of overdose and reduces illicit opioid use. However, a fairly narrow regulatory approach limits methadone access. Methadone currently may be dispensed for the treatment of OUD only in federally approved opioid treatment programs (OTPs).[1]

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In this paper, the author considers efforts to facilitate access to methadone outside the traditional OTP delivery mechanisms for medications for OUD (MOUD). To this end, the objective of this scoping review was to identify treatment pilots or programs that (1) were delivered under regulations that differ from the traditionally applicable federal regulations or (2) offer new strategies or practices to OTPs within the parameters of the traditional federal regulations and to describe what evidence exists of their efficacy to inform future clinical and policy discussions regarding MOUD in the U.S. context.

RESULTS

Pandemic Response Results

The COVID-19 pandemic stimulated a regulatory effort to ease access to MOUD in the United States. The results of this review were classified into two categories: (1) innovations specifically brought about by or in response to the COVID-19 pandemic, and (2) innovations in methadone treatment prior to or not prompted by the pandemic. The author makes this distinction because the regulatory shifts made in response to the COVID-19 pandemic have allowed for new and different approaches to methadone medication not permitted earlier. Additionally, because some of these innovations were made possible only by regulatory flexibility induced by the COVID-19 pandemic, the evidence bearing on their impact is limited by its length.

The pandemic exacerbated the difficulties faced by people who use opioids. At the same time, it resulted in significant shifts in the regulatory landscape that normally governs methadone treatment. In March 2020, the Substance Abuse and Mental Health Services Administration (SAMHSA) allowed states to request a blanket exemption allowing OTPs to issue as many as 28 days' worth of take-home methadone for patients considered "stable" and 14 days for those considered "less stable," and the Drug Enforcement Administration (DEA) granted an exemption allowing alternate delivery protocols of medication.[5,6] In June 2021, DEA issued an exemption to the rules for certifying mobile medication units to allow OTPs an additional treatment pathway to reach their patients.[7] Additionally, the Centers for Medicare & Medicaid Services issued payment and reimbursement guidelines that allowed OTP reimbursement for MOUD treatment

provided by telehealth under certain circumstances.[8] In this section, the author examines early evidence from methadone innovations introduced in response to the COVID-19 pandemic.

Telehealth and E-Health

Telehealth and e-health implemented for OUD treatment, where regulation allows, can include replacing in-person counseling for methadone or buprenorphine treatment programs with audio or audiovisual appointments, as well as prescribing MOUD electronically.[9] Data on the effects of allowing clinical oversight of telehealth patients receiving MOUD in OTPs are limited.

Programs across the country responded to this ease in regulation by implementing telemedicine at multiple points in the treatment pipeline, including the mandatory methadone counseling normally conducted in person at the OTP. Neither Chan and colleagues' recent scoping review of these changes, nor any of the studies identified in this review, demonstrated a significant difference in treatment retention or patient satisfaction, but most focused on a single clinic in their measurements.[10] Some providers have expressed concerns regarding retention and diversion when asked directly, which might demonstrate a need for better education about the merits of telehealth.[11] Provider concerns may be validated as more robust data become available, but there is not yet enough information to respond to these concerns. Chan and colleagues' review identified multiple studies where existing gaps in access to the Internet negatively impacted patient experience. In addition, this review notes that these disparities in digital access often reflect existing racial and ethnic disparities in quality of care, and may worsen them.[9]

In Rhode Island, one new telehealth MOUD counseling program demonstrated increased flexibility in provision of care by clinicians, higher patient retention rates, and more patient reports of access to care.[12] A Boston OUD center transitioned nearly all of its existing patient interactions to telehealth across multiple programs, with little to no retention issues across all programs, but their only reported MOUD program was for buprenorphine rather than methadone.[13]

At this stage, it is difficult to draw conclusions regarding tele-MOUD because of the limited data available, but the studies and case reports available suggest that telehealth may provide an opportunity for OTPs to increase access while maintaining retention.

Increased Take-Home Dosing

The effects of increased take-home dosing of methadone have become more clear as the pandemic has spread, but data are still limited because of the short period of time during which the federal changes have been in effect and the small number of studies conducted to date.

One of the first studies available on the impact of the new take-home rules on OTP behavior is a pre/post study conducted in Spokane, WA. This study demonstrated a rapid and marked uptick in take-home dosing following the regulatory easing, presumably in response to swift implementation by OTPs.[14] One concern often flagged regarding increased take-home dosing of methadone is the greater possibility of diversion, but the data thus far do not support that idea. Another Washington study, as well as studies in North Carolina and Spain, showed little to no detectable increase in diversion among their patients.[15,16,17] A qualitative assessment of the increase in take-home supply among rural methadone patients identified a sense of increased humanity (feeling "more like a regular person") and quality-of-life improvements in regaining access to time for work or with family that might have otherwise been spent at or traveling to a clinic.[18] A second concern about increased take-home dosing is greater opioid and non-opioid drug use, which was observed by Bart and colleagues. Despite that observed shift, their analysis indicated that this increase could not be attributed to the increase in take-home doses.[19]

In sum, although data are limited, studies conducted to date have not found any evidence of diversion or other adverse effects of expanding the take-home supply of methadone.

Separate from the analyses of take-home dosing, one study highlighted a potential technology-assisted intervention (an electronic pillbox) to assuage worries of diversion, finding in a small sample (25) that participants were satisfied and none of the pillbox users attempted to divert the medication.[20]

One final aspect of take-home dosing worth noting is that the shift may not have affected all patients equally. Harris and colleagues found that unhoused Boston patients reported that take-home adaptations exacerbated existing inequities for them–including limitations on take-home dosing for the unhoused and the increased social instability felt from virtual counseling–and recommended that any further take-home efforts should take into account those inequities when designing these adaptations.[21]

Innovations Unrelated to Pandemic Response

While the COVID-19 pandemic has provided a unique opportunity to observe the effects of changes to OTPs' delivery of methadone, it is not the lone source of innovations in methadone treatment. Pilot programs under the prepandemic regulatory framework and programs implemented outside the United States offer additional lessons on ways in which methods of methadone delivery affect patient outcomes.

Mobile Treatment and Outreach

Prior to a regulatory shift by DEA in 2007, mobile medication units were a permissible way to dispense methadone in rural communities and other hard-to-reach populations outside of a traditional OTP setting. In a scoping review of these programs, Chan, Hoffman and colleagues found no evidence that these programs significantly decreased treatment quality. Moreover, some evidence showed that (1) retention actually increased compared with fixed-site programs, and (2) mobile units in some cases made it easier to reach hard-to-treat populations.[22]

In addition to those mobile medication units, at least one OTP network (in Philadelphia) has established a mobile engagement unit (MEU) that provides free transportation to an OTP for intake (but not free transportation for ongoing treatment thereafter). Despite being only a one-time intervention, the study participants enrolled by the MEU showed statistically significant improvements in retention compared with other enrollees in MOUD at that OTP. The lack of randomization and limited scope of this intervention weaken the strength of these results, but this style of intervention may be worth studying at scale.[23]

Integrated Care Models

Because injection drug use is a method of transmission for HIV and the hepatitis C virus (HCV), clinicians have sought to improve MOUD retention and patient experience by integrating MOUD delivery with treatment for these viruses, as well as with syringe exchange programs (SEPs). Low and colleagues' systematic review of the literature on concurrent use of antiretroviral therapies (ARTs) and MOUD, including methadone, demonstrated significant

increases in initiation of ART and viral suppression, as well as significant reduction in attrition rates.[24] Another review of these integrated HIV care models has shown the potential for reducing HIV transmission rates, though it is difficult to determine the extent to which that reduction in use resulted from MOUD treatment itself rather than the integration of ART and other HIV care with MOUD.[25]

While there is no systematic scoping review of the HCV and MOUD literature, a study of a program in Bronx, NY, that concurrently offered HCV treatment and methadone treatment showed promising results for potential treatment retention for both disorders and suggested concurrent treatment might be particularly apt for injection drug users who have demonstrated psychosocial vulnerability.[26] A New Haven, CT, study found that a full integration of HCV and MOUD services at an existing OTP was feasible and that program support from both clinicians and administrators was important for replicability.[27] Both of these studies are limited by their geographic scope and observation of only a single OTP in each case.

This review did not identify any integration efforts between SEPs and methadone treatment at the point of syringe exchange, but multiple studies considered the efficacy of SEP *referrals* compared with other pathways. Multiple studies identified in this scoping review demonstrate successful initiation into treatment from SEP referrals, but in the United States thus far those referrals have shown higher rates of attrition from treatment than other enrollment pathways.[28] One study in Sweden showed more effective rates of retention using similar methods, but with a small sample size (71 enrollees).[29]

Interim Methadone

McCarty, Chan, and colleagues. conducted a scoping review of "interim methadone" — which refers to the provision of methadone without counseling for up to 120 days when patient circumstances require. They found that interim methadone "is associated with reductions in waitlists, less delay in receiving medication, decreased drug use, and enhanced program retention with better outcomes than no care."[30] Despite those findings, interim methadone remains in limited use because of SAMHSA's specific authorization requirement, the lack of take-home dosing, and the restriction against its use by for-profit OTPs (which account for more than half of all currently operating OTPs in the United States).

Pharmacy-Based Methadone

Some methadone delivery strategies banned in the United States are permitted abroad. Pharmacy-based methadone — widely used in Canada, the United Kingdom, and Australia — is perhaps the most prominent among them. While some differences across countries exist, they share some basic features. A patient receives an initial assessment by a licensed medical professional; after that assessment, a prescription for MOUD is issued, and the local pharmacy dispenses MOUD doses, sometimes including supervision of the dosing. The initial prescriber may still provide additional care.[31] Although pharmacists participate at quite a high rate in the United Kingdom (e.g., 88 percent participation rate in Scotland), pharmacies in Australia have shown less willingness to offer MOUD.[32] [33] Furthermore, while increased access, especially in rural areas, is a significant benefit of pharmacy-based distribution, at least one comparative study in Canada showed a more than 40 percent increase in retention for the more centralized treatment option over community pharmacy-based dispensing.[34] While such dispensing is a promising opportunity, this finding suggests that it should be implemented to take into account local context and patient needs.

The most significant potential advantage of pharmacy-based methadone in the United States is improved geographic access. A study of drive time in Appalachian areas showed that 6 percent of patients in the region faced a drive time of more than one hour to the nearest OTP, and that in rural areas, the median drive time to pharmacies was at least 30 minutes lower than the nearest OTP.[35] A recent clinical trial examined pharmacy-based methadone in the United States for both feasibility and acceptability and found pharmacy-based treatment both feasible and acceptable, with 80 percent retention at month 3 of the trial and 100 percent treatment adherence among those patients retained. That study's results are limited by the small patient count for this first trial, with only 20 patients enrolled.[36]

Office-Based Methadone

A scoping review of office-based methadone, delivering treatment in office settings like general practice or primary care, by McCarty and colleagues identified 18 studies of patients treated with office-based methadone, including observational and clinical studies. These studies

were limited to only stable methadone patients, and consistently found patient value and treatment satisfaction for office-based care and treatment outcomes, including low rates of drug use, comparable to OTP care. A primary limitation on this literature is that none of the observational or clinical studies took place after 2010, and more contemporary study of the method in the United States would speak to the continued applicability of this model.[37]

Lessons from Non-Methadone MOUD

Methadone is not the only form of MOUD administered in the United States. Buprenorphine and buprenorphine combined with naloxone (also known as Suboxone) are offered in contexts where methadone is not — in large part due to the narrower authorization of methadone administration. While studies examining these drugs are thus not directly translatable to the methadone context, they still have some common features, most notably that the participating patients all are being treated for OUD.

One advantage of buprenorphine, as compared with current U.S. methadone administration, is the ability to prescribe and manage the medication in an office-based setting as compared to an OTP. A significant advantage of office-based treatment is increased access. A travel time analysis of the distance from office-based buprenorphine treatment, as compared to an OTP, showed that the gap between the two, especially in rural areas, was significant.[38]

As noted above, community pharmacies have significant potential to increase access to MOUD, especially in rural areas in the United States. Wu and colleagues conducted a pilot physician–pharmacist collaborative to take advantage of both community proximity and the respective treatment specialties of each party to demonstrate the feasibility of a collaborative care model. That pilot (71 participants) demonstrated significant retention and adherence, a further data point for the potential of increased reliance on community pharmacies in U.S. MOUD treatment.[39]

DISCUSSION

COVID-19 has provided a unique opportunity to examine the effects of a different regulatory landscape on methadone treatment in the United States. Although the data from the

pandemic are limited, and surely will be augmented in the years ahead, early studies show a significant increase in take-home doses of methadone and suggest that increased flexibility for OTPs could yield dividends in both patient experience and treatment retention and adherence. More research is needed to increase confidence in that conclusion, especially given the lack of geographic diversity of the studies identified in this review. While telehealth undoubtedly provides certain advantages during a pandemic (e.g., decreased risk of viral transmission), its long-term impact on methadone treatment is not yet known. The regulatory flexibility that allowed these innovations is tied to the COVID-19 public health emergency declaration. For this reason, it is imperative that research be intensified to document their effects while the window remains open.

Beyond the pandemic, the literature reviewed identified challenges to MOUD access in rural areas. It highlighted the potential for leveraging existing institutions (e.g., community pharmacies) or common-sense interventions (e.g., transportation to intake) as opportunities to meet those challenges. Pharmacy-based delivery has become the norm in other countries, but multiple confounding variables prevent direct translation to the U.S. setting. The political, geographic, and cultural makeup of the United States is not that of the United Kingdom or Canada or Australia, so U.S.-centered pilot studies are needed to assess whether those findings would be replicated in the United States.

Lastly, integrated care models of methadone treatment offer opportunities to meet patients across multiple axes of care sometimes implicated by injection drug use. Integrated care has shown promise regarding the ability of MOUD to improve care for HIV or hepatitis C, as well as for the associated OUD.

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