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Overdue for an Overhaul: How Opioid Treatment Programs Can Learn From COVID-19

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On March 16, 2020, in the context of the spread of coronavirus disease 2019 (COVID-19) in the United States, the Substance Abuse and Mental Health Services Administration (SAMHSA) issued emergency guidance to state opioid treatment authorities permitting them to ease restrictions on take-home medication from opioid treatment programs (OTPs). Previously, decades of clinical and regulatory precedent required OTP patients to satisfy eight stringent criteria to be eligible for take-home methadone. This system was designed to prevent diversion given concerns about the safety risks and abuse potential of methadone, and to ensure that patients were deriving maximal benefit from their opioid use disorder (OUD) treatment. Although a minority of OTP patients had been able to meet the criteria and were granted the responsibility for up to 1 month of unsupervised doses, most patients were required to present at their OTP multiple days per week, during limited clinic hours, for directly observed therapy. Concerns about the safety profile of methadone compared with buprenorphine and naltrexone, compounded by persistent societal stigma about OTP-based treatment,¹ meant that the model had been remarkably impervious to experts' calls for change, other disasters, and the example of other countries where methadone dispensing is more closely akin to that of other opioids.² But now the exigencies of COVID-19 have upended this model, and SAMHSA's emergency guidance temporarily easing these restrictions allows us a brief opportunity to understand what

a less-restrictive OTP system might look like in the United States.

Methadone's benefits for individuals with OUD are unquestioned in the medical literature even as there are notes of caution regarding its potential dangers, particularly regarding overdose and in combination with other sedatives and respiratory depressants. These risks are further heightened for individuals without existing opioid tolerance, especially in the initial days of induction and following significant psychosocial changes, such as release from controlled environments. Participation in structured addiction treatment is key in preventing a devastating panoply of adverse outcomes, including death.³ However, the OTP structure can also be viewed as overly restrictive and stringent, and participants and researchers alike have eloquently described the harms of the methadone bureaucracy. One patient described it as a "system of chemical parole that endeavors to keep tens of thousands of the most vulnerable under the thumb of perverse and avaricious bureaucracy,"⁴ while a 1995 Institute of Medicine (IOM) report concluded that federal OTP regulations such as take-home restrictions put "too much emphasis on protecting society from methadone, and not enough on protecting society from the epidemics of addiction, violence, and infectious diseases that methadone can help reduce."⁵

Faced with the threat of COVID-19, SAMHSA recognized (as had OTP practitioners even before the pandemic) that requiring hundreds of thousands of methadone patients to report to their OTPs

multiple times per week was likely have adverse effects on these patients' and their communities' well-being. They allowed state opioid treatment authorities to authorize OTPs to dispense up to 28 days of take-home medication to stable patients. Patients deemed "less stable" could receive up to 14 days of medication after the initial titration phase, provided that programs found that these patients would be "clinically capable of handling the take-home medications." Given the imminent danger that COVID-19 poses to communities, individuals, and program staff — OTPs cannot run without nurses to dispense medication — most OTPs have scrambled to determine which patients could be counted on to take their methadone appropriately. At the same time, loathe to neglect patients' continuing medical and psychosocial needs, many OTPs are trying to implement new models of telecounseling and telemedicine. Unfortunately, telemedicine (largely prohibited by inflexible existing regulations) has been impractical with low-income patients; thus, scant research exists to guide these abrupt changes.

In this rapidly evolving and uncertain environment, experienced clinicians have assumed that, for example, an employed, stably housed patient with intermittent cocaine use can probably "handle" their take home methadone responsibly without harm to themselves or others. An additional assumption is that a periodic phone check-in will add some benefit in lieu of face-to-face counseling. Unfortunately, these assumptions are not empirically based, and it is far from clear whether patients attending OTPs have sufficient technological access and know-how to benefit from telemedicine interventions. Even more troubling, current evidence gives us no way to answer whether a given patient would actually benefit from less frequent clinic attendance and counseling — although one can certainly imagine benefits stemming from fewer obligations during normal work hours, less contact with other patients who might trigger addiction relapse, and more time to attend to other important responsibilities.

We encourage researchers to leverage the current natural experiment to assess rigorously the impact of relaxed regulations on methadone treatment adherence and retention, as well as on safety risks and diversion. We encourage OTPs that have granted increased take-home doses to observe carefully not only the aberrancies and harms that will undoubtedly result, but also the benefits that accrue to their patients and programs. Particularly ripe for change — and out of step with many international examples — is the time-in-treatment requirement which requires at least 9 months of OTP attendance before a patient can earn a single week of take-home methadone. Using OTP computerized dispensing records to compare treatment retention (a key quality measure) to pre-pandemic rates will allow a real-world assessment of the utility of this time-in-treatment requirement. Analysis of urine toxicology results, while limited by pandemic-induced changes in sampling frequency, may also shine light on the characteristics of patients who thrive with less intrusive oversight compared with those prone to decompensation in the absence of strict control of their methadone and mandated in-person counseling. It is crucial to capture the patient experience of these shifts, particularly for the most vulnerable and low-income individuals — from observed dosing to increased take-home doses, and from in-person to telemedicine-based counseling. There is also a need to develop adapted models of psychosocial treatments to support adherence in the context of less restrictive medication models.

We acknowledge that data collected during COVID-19 may be confounded by life changes during a respiratory pandemic — such as sheltering in place, alterations to illicit drug supply chains, and increased economic hardship — so it is vital to continue to systematically assess both qualitatively and quantitatively these behavioral changes to be able to generalize our conclusions to the post-pandemic era. Irrespective of the limitations of data collected during this time, it is important that researchers and clinicians recognize

that an unquestioning return to the status quo of reduced take-home methadone will likely cause harm to many patients, as similar policy regressions in other countries have proven to be an obstacle to retention in treatment.⁶

CONCLUSION

We now have a vital opportunity to advance the science in defining stability and success in methadone treatment, and to imagine and test ways in which telemedicine technology may facilitate OUD treatment. After the pandemic has passed we must be prepared to become thoughtful and informed advocates for systemic change that is — 25 years after the Institute of Medicine report — long overdue.

Abbreviations and Acronyms: COVID-19 = novel coronavirus disease; OTP = opioid treatment program; OUD = opioid use disorder; SAMHSA = Substance Abuse and Mental Health Services Administration

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