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Commentary

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Recent modifications to the US methadone treatment system are a Band-Aid—not a solution—to the nation's broken opioid use disorder treatment system

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Abstract

For 5 decades, US federal regulations have segregated methadone treatment for opioid use disorder from the rest of the health care system, confining its availability to specialty treatment programs that are highly regulated. These regulations have led to severe shortages in the availability of methadone and grave underutilization of this lifesaving medication despite a worsening overdose crisis. In this commentary, we discuss current barriers to methadone in the US opioid treatment system and how recent changes to federal regulations fall short of the reforms needed to significantly expand access to this treatment. Instead, we propose the urgent need to expand methadone to mainstream health care settings by allowing for office-based prescribing and pharmacy dispensing of methadone, the norm in many other developed countries.

Key words: methadone; health policy; substance use disorder; disparities; access; opioids; treatment; opioid treatment program; COVID-19.

> *Danielle always knew she hated driving 45 minutes each way across town to pick up her methadone. The unhelpful resources provided at the clinic made this time feel infinitely wasteful. When COVID changes to methadone regulations allowed her to reduce her clinic visits to once monthly, Danielle enjoyed the newfound freedom and normalcy, a reprieve from the paternalism and surveillance of the constant clinic attendance. She hadn't fully realized just how emotionally draining it was to wake up nearly every morning—for years—to stand in front of staff who looked at her with disgust and condescension as she drank her medication. Unfortunately, freedom from the specter of constant clinic attendance lasted only 6 months. When Danielle's clinic came under new management, her take-homes were rescinded and she was forced to return to a triweekly medication pick-up schedule. No longer willing to sacrifice her own freedom and dignity, Danielle quit the clinic and decided to take the risk of buying drugs on the illicit market instead.*

Sadly, the experience of Danielle—one of the authors of this commentary—is not unique. It's been 60 years since groundbreaking clinical trials showed that methadone—a synthetic opioid agonist medication—was highly effective at treating opioid use disorder (OUD). Since then, hundreds of studies worldwide have demonstrated the effectiveness of methadone in reducing illicit drug use and improving a range of health outcomes, including reducing overdose risk by half.[1,2] But the US regulatory regime that sprung up around this medical innovation could well have been locked away in a 1970's time capsule. For 5 decades, US regulations have isolated methadone treatment for OUD from the rest of the health care system by restricting its availability to specialty clinics known as opioid treatment programs (OTPs). Patients must travel to these clinics near-daily and take medication under the observation of clinic staff, a system often described by patients as "liquid handcuffs."[3] The OTP system has led to tremendous stigma and striking racial inequities in OUD treatment access[4] and has left the majority of people with OUD without access to this life-saving treatment. But despite a worsening tragedy of overdose deaths and health disparities, an entire industry of largely for-profit OTPs, represented by their trade organization the American Association for the Treatment of Opioid Dependence, continues to lobby against regulatory modernization of methadone. While other nations successfully operate more patient-centered and accessible methadone treatment systems through mainstream health care services, OTPs remain the only option for patients seeking methadone in the United States. The difficulty of accessing existing OTPs, along with the administrative burden associated with opening and maintaining new OTPs, has resulted in a disturbingly low uptake of methadone treatment in the United

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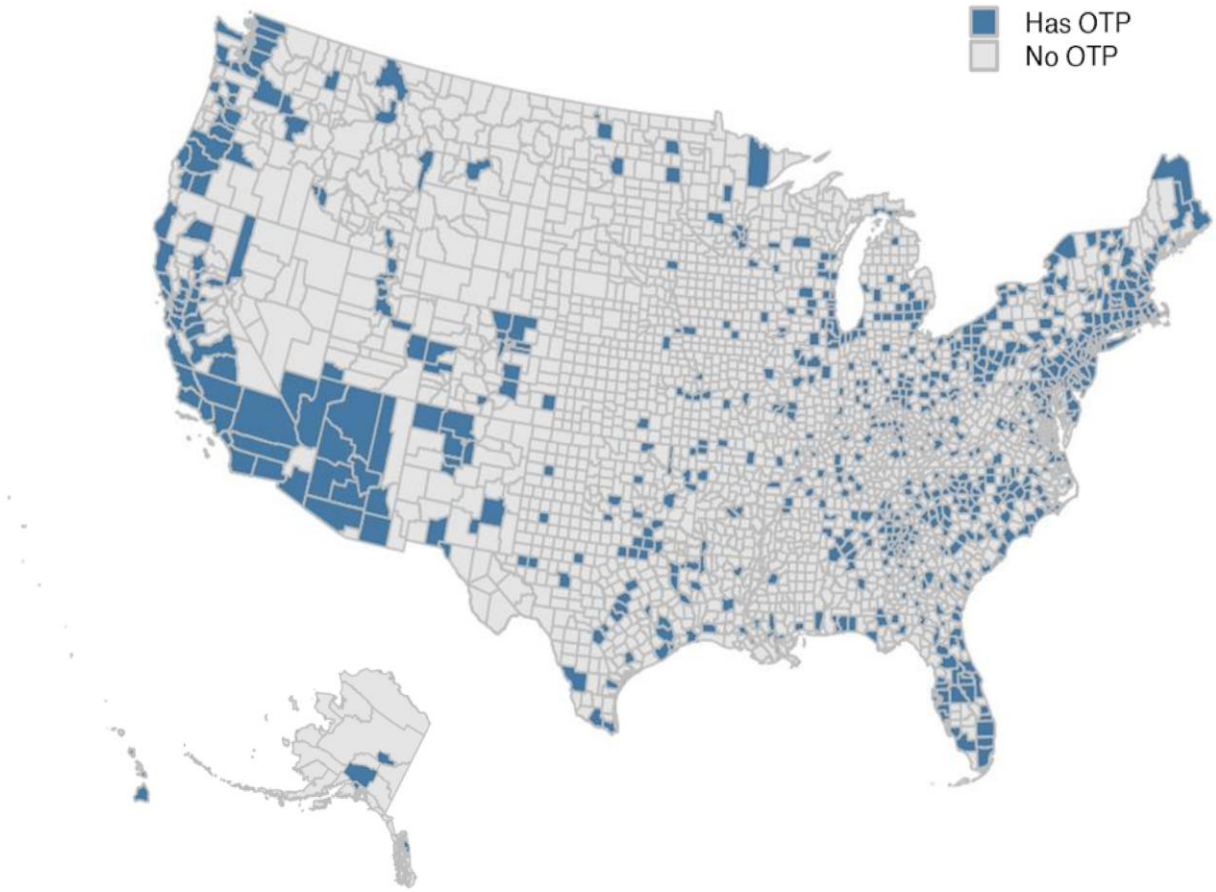

Figure 1. US counties with and without opioid treatment programs (OTPs). Data on OTP locations are derived from the Substance Abuse and Mental Health Services Administration (SAMHSA) Opioid Treatment Directory, 2022 (https://dpt2.samhsa.gov/treatment/directory.aspx; accessed December, 2022).

States: only 20% of counties even have an OTP (Figure 1), and many have patient waitlists due to the scarcity of clinics.[5,6] As a result, less than 5% of the estimated 7.6 million individuals with OUD receive any methadone treatment.[7]

But, in 2023, the US Substance Abuse and Mental Health Services Administration (SAMHSA) released a new rule for methadone treatment.[8] This rule follows changes instigated by the COVID-19 pandemic, which compelled federal regulators to loosen restrictions on methadone take-home doses. A large body of research found that pandemic flexibilities in take-home doses did not jeopardize patient safety or treatment outcomes but rather were highly beneficial for patients,[9] leading to calls to sustain these reforms in the midst of increasing fentanyl-driven overdose deaths.[10] The new rule offers long-overdue modifications, most notably to permanently loosen restrictions on when patients become eligible for take-home medications.

Unfortunately, the proposed changes—while certainly welcomed and needed to alleviate many day-to-day patient burdens within the OTP system—will not suffice to meaningfully increase access to methadone and reduce overdose deaths. This is because the single biggest hurdle to methadone treatment in the United States is the OTP system itself. The new rule does not create an option for patients to receive methadone outside of OTPs and preserves the segregation of methadone treatment for OUD from the rest of the health care system. Research and experiences, such as those of Danielle's, document that, even under loosened federal restrictions on take-home doses during the pandemic, the availability of OTPs remains limited and many continue to exert burdensome requirements.[9,10] With OTPs as the only provider of methadone for OUD, most patients—particularly those who do not respond to buprenorphine treatment that is available in other care settings—have no choice but to endure such burdens or risk their lives accessing a dangerous illicit drug supply. As OTPs were historically designed for and concentrated in racially minoritized communities,[11] already marginalized groups often bear the greatest burden of these oppressive practices.[4]

A true reformation of the US OUD treatment system to save lives will require integration of methadone into our health care system by making it available via prescribing from office-based medical settings and dispensing from pharmacies, which could significantly reduce treatment stigma and burden.[12] This is the norm in other countries, such as Canada, Australia, and the United Kingdom, which make methadone treatment available through a combination of physician prescribing, pharmacy dispensing, and specialty clinics.[13,14] There is precedent for establishing such a system in the United States, with pilot office-based methadone programs demonstrating initial success and feasibility.[15] Unfortunately, US federal regulations have prevented the wider adoption and implementation of such programs.

The potential of the option of office-based methadone treatment expanding access to care can be seen through the US experience with office-based buprenorphine, which, unlike

methadone, has seen significant growth and uptake over the past decade (222% relative to methadone 39%).[7] While the comparative effectiveness of buprenorphine and methadone remains a matter of debate, it is important to note that research suggests that patients receiving methadone have a heightened risk of mortality in the early weeks of methadone treatment.[2] Other countries have successfully mitigated such risks, particularly in the early stages of treatment, through policies that allow for a combination of supervised and take-home dosing programs from pharmacies that can be tailored to individual patient circumstances.[14,16,17]

The idea of federal policies bringing methadone into mainstream medical settings in the United States is not a new or elusive goal. In 2022, the Office of National Drug Control Policy recommended that regulators consider methadone dispensing from pharmacies, and a bipartisan bill endorsed by the American Society of Addiction Medicine (ASAM), the National Alliance for Medication Assisted (NAMA) Recovery, and many others has been introduced by Congress to do so.[18,19] Even the director of the National Institute on Drug Abuse (NIDA), Dr. Volkow, has stated that physicians should be allowed to prescribe methadone to patients.[20] In fact, expanding methadone treatment beyond OTPs in the United States does not even require immediate legislative change, as recent legal research finds that SAMHSA and the Drug Enforcement Administration have full legal authority to immediately expand methadone treatment outside the OTP system through regulation.[21]

Expanding methadone to office-based and pharmacy settings would be a game changer by making this medication more accessible for millions of individuals in a time of heightened risk of overdose from fentanyl. Indeed, patients with OUD with high tolerances due to the fentanyl drug supply have shown to continue to benefit from methadone treatment.[22] Two decades of experience with buprenorphine show us how the ability to prescribe this medication in non-specialty settings has allowed us to significantly expand its uptake across primary care practices, federally qualified health centers, specialty substance use treatment programs, emergency departments, mobile outreach, and harm-reduction programs—greatly expanding access to this life-saving treatment.[23–26]

Lowering restrictions on methadone could also transform the ability of many institutions that interact with high-risk patients—including jails and prisons, hospitals, and skilled nursing facilities—to offer methadone as an additional treatment tool. For example, current stringent restrictions on methadone create hurdles for offering these medications at skilled nursing facilities, forcing an increasingly aging population with OUD to withdraw from treatment or forego medical care.[27,28] Similarly, restrictions on methadone have led to low availability of methadone in jails and prisons, often forcing patients to withdraw from methadone while incarcerated, with detrimental and deadly consequences upon release.[29,30] Changing the way we regulate methadone would be the only way to allow for a true low-threshold and patient-centered care continuum for patients who interact with multiple systems and health care touchpoints.

Danielle and thousands of other patients not being properly served by the US methadone system deserve a more humane, effective, and accessible system of care. Just last year, the United States lost over 100,000 precious lives to overdose. Let's not wait for another round of echoing cries and worsening mortality reports to do what we know works: expand access to life-saving methadone treatment. US policymakers, the substance use treatment community, and medical field must act now to implement true and far-reaching methadone reforms to bring this treatment into mainstream health care settings. Unfortunately, just another Band-Aid will not fix a broken system.

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Supplementary material

Supplementary material is available at *Health Affairs Scholar* online.

Conflicts of interest

Please see ICMJE form(s) for author conflicts of interest. These have been provided as supplementary materials.

N.K. is involved in ongoing opioid litigation. D.R. accepts payment from Gilead. All authors participate in a grassroots community group known as the National Coalition to Liberate Methadone.

Notes

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