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Authors

Incze, Michael A
Simon, Caty
Suen, Leslie W

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Methadone's Moment: Policies that Empower Opioid Use Disorder Treatment Are Within Reach

Authors:

Michael A. Incze, MD, MSEd

Caty Simon

Leslie W. Suen, MD, MAS

Author Affiliations: Division of General Internal Medicine, University of Utah, Salt Lake City (Incze); Program of Addiction Research, Clinical Care, Knowledge, and Advocacy (PARCKA), Division of Epidemiology, Department of Internal Medicine, University of Utah School of Medicine, Salt Lake City (Incze) National Survivors Union, Greensboro, NC, USA (Simon), Whose Corner Is It Anyway, Holyoke, MA, USA (Simon); University of California San Francisco Division of General Internal Medicine at San Francisco General Hospital, San Francisco, CA (Suen)

Corresponding Author: Michael A. Incze, MD, MSEd, Division of General Internal Medicine, University of Utah, 30 N. Mario Capecchi Dr, Salt Lake City, UT 84112 (michael.incze@hsc.utah.edu).

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In 2022, over 107,000 Americans died from drug overdose, representing a preventable death every 4.75 minutes. Over 70% of overdose deaths involve illicitly manufactured fentanyl, which has become ubiquitous in the US.[1] The need to make substance use disorder treatment broadly accessible to anyone who desires it has never been more urgent, yet only 25% of people who meet diagnostic criteria for opioid use disorder (OUD) receive life-saving medications such as buprenorphine and methadone.[2]

Expanding access to medication treatment for OUD has been a pillar of the Biden administration's plan to overcome the overdose crisis. Under Biden federal agencies, important progress has been made, including removing barriers to buprenorphine prescribing and enabling over-the-counter access to the overdose reversal medication naloxone. However, methadone - an FDA-approved treatment for OUD with over 50 years of evidence demonstrating safety and efficacy - has largely been left behind.

Methadone is one of two medications, along with buprenorphine, shown to reduce all-cause mortality among OUD patients, with a magnitude of benefit on par with prescribing aspirin after a myocardial infarction.[3] However, methadone's role in improving health and reducing overdose deaths has been hindered by decades-old policies that limit its delivery to licensed opioid treatment programs (OTP; i.e., "methadone clinics") and impose requirements such as daily observed dosing for patients to access the medication. Recently, a groundswell of advocacy among people with lived experience of OUD treatment, clinicians, regulatory bodies, and policymakers has placed needed reforms within reach.

Several recent methadone policy advances provide immediate opportunities to improve care for OUD patients, furthering alignment of federal policy with current evidence. For example, in March 2022, the DEA created an exception to 21 CFR 1306.07(b), allowing hospitals to dispense up to a 3-day supply of methadone for unsupervised use to continue treatment during care transitions. Commonly known as the "72-hour Rule", this policy empowers hospitals and emergency departments to provide more comprehensive and patient-centered methadone treatment, preserving treatment access while patients navigate the often-complex path to follow up OUD care after discharge. However, to realize the potential of this policy change, health systems must develop infrastructure (e.g., partnerships with local OTPs to strengthen care transitions), care delivery systems to enable methadone ordering and dispensing, and training to facilitate implementation. Research exploring novel ways to leverage the 72-hour rule in certain outpatient clinical environments may further amplify its potential benefit for people with OUD.[4,5]

Another contemporary policy change with immediate implications for methadone care provision is the expansion of the Americans with Disabilities Act (ADA) to cover individuals receiving treatment for substance use disorders. The ADA mandates that patients who are taking medications for OUD such as methadone must be able to continue treatment when transitioning to care settings such as hospitals, jails, and skilled nursing facilities – environments where historically patients taking methadone have faced significant discrimination.[6] While there are examples of successful litigation using this expanded definition of the ADA, only a small fraction of violations are held to account. Broader awareness, strengthened medical-legal partnerships, and systems for enforcement are needed to implement this policy.

More recently, in April 2024 the Substance Abuse and Mental Health Systems Administration (SAMHSA) made key changes to 42 CFR part 8. This final rule codified many methadone and buprenorphine delivery flexibilities granted temporarily during the COVID-19 public health emergency, including increased use of telehealth-based assessments and earlier access to OTP take-home methadone doses. These policy changes have important clinical implications for patients who face barriers to attending daily in-person appointments at OTPs, including individuals living in rural areas for whom methadone access has historically been all but non-existent.[7] In order to actualize the benefits of this policy change, states must ensure that their laws are not more restrictive than current federal regulations and incentivize OTPs to fully implement these new patient-centered flexibilities. Quality improvement initiatives and strengthened accountability infrastructure for OTPs at the state level may help to expedite broad adoption of these important advances in methadone care delivery.

At the forefront of continuing policy advances related to methadone care delivery is the Modernizing Opioid Treatment Access Act (M-OTAA), a bicameral, bipartisan bill awaiting Congressional approval ahead of the presidential election. The bill's aim is to create new avenues for patients to access methadone treatment. It includes a provision that would allow methadone prescription by board-certified addiction specialists and dispensing at commercial pharmacies outside the OTP system for the first time within the US in the history of the modern opioid crisis. M-OTAA is supported by the American Medical Association, the American Society of Addiction Medicine, and many other experts and interprofessional organizations. However, its enactment remains uncertain amid policymaker apprehension and fierce opposition from OTP trade groups and private equity firms who have invested in OTPs.

Some critics of M-OTAA cite safety concerns around unsupervised methadone use and diversion risk as reasons to keep methadone delivery confined to OTPs. Data collected during the COVID-19 public health emergency provide useful insight into the magnitude of these risks. During this period, the federal government temporarily relaxed restrictions on observed methadone dosing requirements to enable people to shelter-in-place. Studies found that policies enabling increased

take-home doses were associated with improved retention and fewer treatment interruptions without a corresponding increase in methadone overdose.[8] Concurrent qualitative research highlighted improved care experiences and enhanced relationships for both patients and clinicians.[9]

Critics also state that OTP wrap-around services, such as mandatory counseling, are integral to methadone's efficacy. However, expanding methadone to community settings like primary care where many addiction specialists work may enhance the availability of wrap-around services such as interdisciplinary, team-based clinical models; strengthened care coordination; and full-spectrum medical care. In contrast, OTPs are often siloed from the rest of medical care, limiting care integration opportunities for patients with complex needs. Finally, some believe that M-OTAA does not go far enough, and that all licensed clinicians must be able to prescribe methadone for OUD to meaningfully expand treatment access – mirroring policy in Canada, England, France, and other comparator countries. It is true that limiting prescribing to board-certified specialists will be insufficient to fully meet treatment needs, and further expansion of methadone treatment in general medical settings should be a long-term policy goal. Still, M-OTAA represents a significant step toward broader methadone access, allowing states and health systems to develop infrastructure and implementation strategies to facilitate methadone’s expansion.

Taken together, recent federal methadone policy advances and M-OTAA could catalyze a sea change in OUD care delivery, matching the unprecedented health crisis that our nation faces. However, their success hinges on action and investment by states and health systems. Currently many states have methadone policies that are more restrictive than federal law. For OUD care to progress, states must revise their policies to ensure that they do not impede implementation of new federal regulations. States must also invest in infrastructure supporting pharmacies, clinicians, and patients to expand methadone access broadly and equitably in concordance with federal guidance.

As clinicians, researchers, and advocates for patients with OUD, it is hard to overstate the importance of this moment for methadone. Without broad and convenient access to evidence-based OUD treatments, we are combating a deadly public health crisis with one hand tied behind our backs. While OTPs play an important role in delivering methadone treatment - a role that would continue under M-OTAA - operating alone they are simply not a scalable solution to a public health crisis that affects over 2 million people nationally. Furthermore, the concentration of OTPs around urban centers reinforces geographic and racial disparities in OUD care, which is anathema to the Biden administration’s drug policy objective of advancing equity in OUD treatment. Only 20% of U.S. counties have access to OTPs, rendering methadone inaccessible for thousands of people in need of help.[7] By enabling

patients to pick-up methadone at their local pharmacies, M-OTAA is a crucial step toward expanding equitable treatment access.

As the 2024 election approaches, and our political leaders reflect on their priorities and promises to the American people, we urge them to think boldly about solutions to overcome a relentless and indiscriminate overdose crisis which has outpaced current interventions. Unfettering methadone from outdated regulations represents a crucial step forward in empowering patients, clinicians, health systems, and states to expand access to evidence-based and patient-centered care. Methadone's moment is here.

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