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Shoshana V. Aronowitz
University of Pennsylvania

Czarina Navos Behrends

Margaret Lowenstein
University of Pennsylvania

Bruce Schackman

Janet Weiner
University of Pennsylvania

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Abstract

Overdose deaths have reached unprecedented levels in the U.S., despite effective medications to treat opioid use disorders (OUDs). Because the regulatory and administrative barriers to treatment are high, only about 11% of people with OUD receive effective medications, which include buprenorphine, methadone, and naltrexone. In response, clinicians and advocates have looked to a “low-threshold” approach that reduces the stigma surrounding effective medications and facilitates their use. This brief summarizes the barriers to treatment, the evidence on the low-threshold approach, and areas for future research. The evidence suggests that low-threshold approaches can increase access to treatment, with outcomes comparable to high-barrier, standard care. Policymakers, providers, and payers should lower the barriers to medication treatment through regulatory flexibility (including telehealth prescribing), and harm reduction strategies that de-emphasize abstinence and place a priority on initiating or re-initiating treatment whenever and wherever individuals are ready to do so.

Keywords

overdose, opioid, opioid epidemic, substance use

Disciplines

Health Law and Policy | Health Services Research

Comments

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ISSUE BRIEF

Lowering the Barriers to Medication Treatment for People with Opioid Use Disorder

Evidence for a Low-Threshold Approach

Shoshana V. Aronowitz, PhD, MSHP, FNP-BC, Czarina Navos Behrends, PhD, MPH, Margaret Lowenstein, MD, MPhil, MSHP, Bruce R. Schackman, PhD, MBA, and Janet Weiner, PhD, MPH

Overdose deaths have reached unprecedented levels in the U.S., despite effective medications to treat opioid use disorders (OUDs). Because the regulatory and administrative barriers to treatment are high, only about 11% of people with OUD receive effective medications, which include buprenorphine, methadone, and naltrexone. In response, clinicians and advocates have looked to a “low-threshold” approach that reduces the stigma surrounding effective medications and facilitates their use. This brief summarizes the barriers to treatment, the evidence on the low-threshold approach, and areas for future research. The evidence suggests that low-threshold approaches can increase access to treatment, with outcomes comparable to high-barrier, standard care. Policymakers, providers, and payers should lower the barriers to medication treatment through regulatory flexibility (including telehealth prescribing), and harm reduction strategies that de-emphasize abstinence and place a priority on initiating or re-initiating treatment whenever and wherever individuals are ready to do so.

INTRODUCTION

With overdose deaths in the U.S. reaching unprecedented levels in 2021, it becomes increasingly urgent to find new ways to deliver effective treatments for opioid use disorders (OUDs). We have effective medications¹ to treat OUD, including buprenorphine, methadone, and naltrexone, but in 2020, only about 11%² of people with opioid use disorder received one of them. In addition, there are significant racial disparities³ with Black patients less likely than white patients to receive medication treatment across multiple settings. The barriers to treatment are high, and they include philosophical, regulatory, administrative, and clinical

constraints. In response, clinicians and advocates have looked to a “low threshold” approach that reduces the stigma surrounding effective medications and facilitates their use.

Methadone and buprenorphine are both opioids, and their use for OUD treatment is often portrayed in a stigmatizing light as “trading one addiction for another.” But this ignores the clear and convincing evidence that treatment with methadone or buprenorphine substantially reduces the risk of an opioid overdose. In a comparative effectiveness study, Wakeman et al.⁴ (2020) estimated that these medications are associated with a 76% decrease in the risk of overdose at three months and a 59% decrease at 12 months.

Buprenorphine stands out as the front-line treatment most amenable to a low-threshold approach. Methadone is a highly regulated medication that, by law, must be dispensed by a certified treatment program with frequent, often daily, in-person dosing when used to treat OUD; in contrast, in contrast, buprenorphine can be prescribed by office-based clinicians with a specialized federal waiver after an in-person examination. They must obtain additional training in order to obtain a federal waiver to treat more than 30 patients at a time. Naltrexone is an opioid antagonist (meaning it blocks the effects of opioids) and can be administered as a monthly injection by clinicians without special training or permission. However, naltrexone requires that patients be opioid-free for 7-10 days, making it difficult for many patients to initiate treatment. Because of problems in induction and retention in treatment, questions remain⁵ about the real-world effectiveness of long-acting injectable naltrexone.

During the COVID-19 pandemic, federal agencies relaxed certain restrictions surrounding methadone and buprenorphine. For methadone, they allowed telemedicine appointments and additional take-home doses for established patients; for buprenorphine, they allowed clinicians to prescribe buprenorphine with no specialized training for up to 30 patients and allowed prescribers to initiate buprenorphine over the phone.

In this brief, we discuss barriers to treatment, the low-threshold approach, the evidence of its effectiveness, and areas for future research.

BARRIERS TO MEDICATIONS FOR OUD TREATMENT

In a recent review, Mackey et al.⁶ (2020) synthesized the evidence on barriers and facilitators of medications for OUD. They identified four types of barriers: stigma related to OUD medications, treatment experiences and beliefs, logistical issues (time and costs as well as insurance and regulatory requirements), and knowledge of OUD and the role of medications. Stigma was the most common barrier among patients, while logistical issues were the most common barrier among providers and administrators.

In assessing the current research, we note that many of the existing barriers and regulatory hurdles are themselves not evidence-based, and have historical roots in misperceptions and stigma around substance use. Because methadone and buprenorphine are opioids, does the potential for diversion and misuse warrant regulatory restrictions and in-person, observed induction? Currently no evidence exists that

in-person visits are more effective than telemedicine visits in improving treatment outcomes or minimizing diversion. In a recent study, Han et al.⁷ (2021) found that although the use of buprenorphine increased in the U.S. between 2015 and 2019, misuse and diversion decreased slightly. In fact, the opioids hydrocodone and oxycodone were much more commonly misused than buprenorphine, and are not subject to the same kind of regulatory requirements. A National Institute on Drug Abuse report⁸ notes that most of the diverted use of buprenorphine and methadone is for the purpose of controlling withdrawal and cravings for other opioids and not to get high. As such, diversion may reflect the need to increase, rather than restrict, access to prescribed buprenorphine.

DEFINITION OF LOW-THRESHOLD APPROACH

Jakubowski and Fox⁹ (2020) recently described four guiding principles of low-threshold approaches to OUD treatment. Together they help define the parameters of a medication-first, low-barrier approach. The principles include:

- 1. Same-day treatment entry and medication access.** Given the ongoing risk of overdose, any treatment delay, whether due to waiting lists, prior authorizations, or clinical protocols, can be deadly.
- 2. Harm reduction approach.** This principle acknowledges the primacy and urgency of the goal of reducing the harm from substance use, rather than achieving abstinence.
- 3. Flexibility.** Rigid protocols for in-person appointments, psychosocial counseling, meeting attendance, or drug testing all serve to reduce the likelihood that a person can successfully initiate and maintain medication therapy.
- 4. Wide availability in places where people with opioid use disorder go.** This includes non-traditional settings, such as emergency departments, syringe services programs and mobile treatment sites.

THE EVIDENCE

A low-threshold approach holds great appeal for its potential to increase rates of medication initiation and retention in treatment and to reach people underserved by the standard, high-barrier care. Below we review the evidence around each of the principles guiding a low-threshold approach.

1. Same-day treatment initiation can overcome delays in initiating buprenorphine without any negative effect on treatment retention. One concern is that initiating medication at the first visit might worsen retention rates, because patients would not have already successfully completed follow-up visits that engage them in care. But in a recent retrospective study at an urban health center, Jakubowski et al.¹⁰ (2020) found that 30-day retention in treatment was high (80%) with no difference observed for patients receiving prescriptions at their initial encounter. Given the lack of evidence that delaying prescribing has benefits for the patient and the overwhelming evidence for the benefits of MOUDs overall, the authors suggest that same-day treatment with medication should become the standard of care.

2. Harm reduction can reduce the negative consequences of drug use, including overdoses and transmission of HIV, HCV, and other infectious diseases. The salient feature of harm reduction is the elimination of abstinence requirements to start or continue treatment for OUD. There is no evidence that abstinence requirements are effective in retaining patients in medication treatment or in improving outcomes of care. A number of studies suggest that people with OUD who continue to use a variety of substances, including cocaine,¹¹ methamphetamines, and benzodiazepines, can be successfully retained in medication treatment¹² for their OUD and achieve similar outcomes as people who do not use these substances.

In a qualitative study, Kapadia et al.¹³ (2021) described the attributes of a nurse-led, primary care model for buprenorphine treatment that emphasizes a broad harm reduction approach. They identified three important aspects of implementation: an organizational mission to provide equitable and low-stigma health care; providing low-threshold buprenorphine and other clinical and social services; and creating and retaining health care workers in the harm reduction culture and mindset. In another study, Kapadia et al.¹⁴ (2021) identified some of the challenges that independent medical practices might face in delivering low-threshold buprenorphine treatment, including funding shortfalls and building relationships across treatment programs, community organizations, the legal system, and government agencies.

3. Flexibility in the regulations and the requirements around prescribing medication for OUDs increased access during a global pandemic. As described by Aronowitz et al.¹⁵ (2021), this included expanded use of telehealth for buprenorphine prescribing, and increasing leniency by methadone programs in their take-home dose scheduling. Anecdotally, Wang et al.¹⁶ (2021) report that telemedicine increased access to buprenorphine during the pandemic and is eliminating many traditional barriers to treatment, particularly for individuals leaving incarceration, and people who use syringe services programs. Harris et al.¹⁷ (2022) report an 80% retention rate in buprenorphine treatment for patients transitioned from a street medicine program to telemedicine in Baltimore during the pandemic. Also in Baltimore, Nordeck et al.¹⁸ (2021) report that a buprenorphine program consisting of pop-up clinics and van service to vulnerable populations shifted to telehealth during the pandemic and had 30-day retention rates of 63%, similar to its in-person rates.

These findings are consistent with longer-term studies of loosening the requirements around medication prescribing. In a rural treatment setting, Weintraub et al.¹⁹ (2021) reported that, over 3.5 years, a program prescribing medication treatment by videoconferencing achieved retention rates and toxicology results comparable to face-to-face treatment. In New York City, a 7-year longitudinal study²⁰ of "low threshold" treatment in a public hospital clinic (including unobserved home induction of buprenorphine and no psychosocial counseling requirement) found the practice to be safe and feasible, with retention rates comparable to other centers.

Low-barrier approaches are justified based on mixed evidence²¹ about the effectiveness of requiring counseling and other behavioral interventions, with multiple high-quality studies showing no added benefit of counseling compared to buprenorphine maintenance alone. These findings have led expert groups like the National Academy of Sciences, Engineering and Medicine¹ to recommend that "lack of availability or utilization of behavioral interventions is not a sufficient justification to withhold MOUDs."

4. Making medications widely available in non-traditional settings can increase access for marginalized populations, such as homeless individuals and people who inject drugs. The idea is to meet people where they are, both in terms of location and their receptivity to starting medication treatment. These settings include:

a. Emergency departments (EDs). There is strong evidence that initiating buprenorphine in EDs improves engagement in treatment and is cost effective. In a randomized trial, D'Onofrio et al.²² (2015) found that ED-initiated buprenorphine treatment, compared to a brief intervention and referral, significantly increased treatment engagement and reduced self-reported illicit opioid use at 30 days. Further, the intervention was cost-effective and high-value,²³ with continued effectiveness at 2 months²⁴ when buprenorphine was continued in primary care. Despite this strong evidence, a new national study²⁵ indicates that buprenorphine was prescribed after just 1 in 12 ED visits for opioid overdose. In a recent study, Lowenstein et al.²⁶ (2021) implemented and evaluated a multicomponent strategy designed to increase ED buprenorphine prescribing in an urban, academic health system. The strategy, which included provider training, electronic health record decision support, integration of peer recovery specialists into clinical teams, and the use of automated prompts, was associated with sustained increases in ED initiation of treatment.

b. Syringe services programs (SSPs). Now legal in 33 states, SSPs are an important setting for reaching people who inject drugs. A number of programs now initiate buprenorphine onsite. In one study, Bachhuber et al.²⁷ (2018) found that retention rates for buprenorphine treatment in a Philadelphia SSP were comparable to rates achieved in more traditional settings. In Seattle, Hood et al.²⁸ (2020) found that an SSP was an effective point of entry for a co-located buprenorphine treatment program, with sustained retention and reductions in opioid use, despite patients who had housing instability and polysubstance use. Recently, Jakubowski et al.²⁹ (2021) described the implementation of buprenorphine services in eight SSPs in New York City, and recommended ways to facilitate treatment through infrastructural support, training, and staffing. Despite these successes, only 11% of SSPs³⁰ in 2014

reported offering on-site methadone or buprenorphine treatment.

c. Mobile treatment sites. In June 2021, the Drug Enforcement Administration³¹ allowed certified opioid treatment programs (that dispense methadone) to add a "mobile component" without separate registration for those services. The new policy is designed to encourage expansion of these programs into communities that lack access. Weintraub et al.³² (2021) described a mobile buprenorphine program in which staff traveled to rural areas in a modified recreational vehicle equipped with medical, videoconferencing, and data collection devices. Three-month treatment retention and opioid use outcomes were similar to those achieved in office-based settings. Mobile outreach and buprenorphine treatment have also been successful in engaging hard to reach populations, such as justice-involved individuals³³ (with a mobile van parked outside of Baltimore City jail) and those experiencing homelessness³⁴ (at local shelters and homeless encampment sites).

RESEARCH QUESTIONS

While existing research on low-threshold medication treatments, including same-day treatment, generally shows that outcomes are not worse than traditional care, most studies are small, short-term, and lack appropriate controls. More rigorous comparative effectiveness and cost effectiveness studies are needed to fully evaluate the effects on a broad range of outcomes including retention in treatment and overdose rates, as well as quality of life, housing, employment, criminal justice involvement, and family considerations. Studies should avoid a sole focus on abstinence outcomes, which is inconsistent with the harm reduction principle of low-threshold treatment, and may not reflect patients' own goals for their treatment.

As Nunes et al.³⁵ (2021) notes, the abrupt relaxation of regulations around medications for OUD represents a large natural experiment, one that could yield valuable information on the need for in-person visits, urine toxicology, and psychosocial counseling. Do initial and recurrent in-person visits increase patient engagement, motivation, and retention? When and for whom does psychosocial counseling serve to improve outcomes with medication treatment, and when does it function as a barrier? These are empirical questions that warrant further study. Moreover,

policy changes during the pandemic, such as allowing take-home doses of methadone, are designed to increase access to treatment. Understanding the actual effects of these changes on access, outcomes and costs, both intended and unintended, will be critical as policymakers debate making them permanent.

In addition, the impact on access to care for different populations needs to be considered. There are longstanding equity concerns in access to different treatments for racial and ethnic minorities; for example, white patients are far more likely to receive buprenorphine in office-based settings, while Black patients are more likely to receive treatment in highly-regulated methadone clinics with long waiting lists and burdensome demands on patients. Research is needed to analyze the effects of low-barrier care on addressing these known disparities.

In addition to further studies of treatment in EDs, SSPs, and mobile settings, there are many unanswered questions about the optimal use of telemedicine to make medication treatment of OUD more widely available. Providers need evidence to inform clinical protocols about how often to interact with patients, how best to monitor use and retention in care, and when to see patients in person. Insurers also need evidence to design and implement appropriate reimbursement. Are there characteristics or patient factors that can distinguish patients that would benefit from one approach or another? How and where do people who use drugs want to receive medication treatment, and what would encourage them to do so?

POLICY AND PRACTICE IMPLICATIONS

Out of necessity during the pandemic, policymakers lowered barriers to medication treatment for OUD. With more than 100,000 people dying of an overdose in the past year, the urgent question is whether to keep them lowered permanently, or even to further relax regulations. The evidence suggests that expanding telehealth options for buprenorphine and increasing flexibility for methadone prescribing and dispensing have expanded access to medication treatment, and warrant continuation. Given the effectiveness of medications and the depth and breadth of the treatment gap, federal and state policymakers should cast a critical eye on the rules and regulations that reduce access, and promote a low-threshold approach that could facilitate treatment for the vast majority of people at high risk for overdose or death.

While regulatory changes are consistent with some of the principles of low-threshold treatment, they are only a part of a broader approach that seeks to directly address stigma as well as logistical barriers. Implementing low-threshold treatment more broadly will require providers and payers to embrace clinical paradigms that de-emphasize abstinence and place a priority on initiating or re-initiating treatment whenever and wherever individuals are ready to do so.

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Since 1967, the University of Pennsylvania's Leonard Davis Institute of Health Economics (Penn LDI) has been the leading university institute dedicated to data-driven, policy-focused research that improves our nation's health and health care. Penn LDI's priority areas include (1) health care access and coverage; (2) health equity; (3) improving care for older adults; (4) opioid epidemic; and (5) population health. Penn LDI connects all twelve of Penn's schools, the University of Pennsylvania Health System, and the Children's Hospital of Philadelphia through its more than 300 Senior Fellows.

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The Center for Health Economics of Treatment Interventions for Substance Use Disorder, HCV, and HIV (CHERISH) is a multi-institutional Center of Excellence, funded by the National Institute on Drug Abuse. The Center's mission is to develop and disseminate health economic research on healthcare utilization, health outcomes, and health-related behaviors that informs substance use disorder treatment policy and HCV and HIV care of people who use substances. To increase the impact of this research, CHERISH supports research conducted at the individual, system, and community levels. The Center is a collaboration among Weill Cornell Medicine, Boston Medical Center, Boston University School of Public Health, the University of Pennsylvania, and the University of Miami Miller School of Medicine.

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