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Bridge clinic implementation of "72-hour rule" methadone for opioid withdrawal management: Impact on opioid treatment program linkage and retention in care

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ABSTRACT

Background: Methadone for opioid use disorder (OUD) treatment is restricted to licensed opioid treatment programs (OTPs) with substantial barriers to entry. Underutilized regulations allow non-OTP providers to administer methadone for opioid withdrawal for up to 72 h while arranging ongoing care. Our low-barrier bridge clinic implemented a new pathway to treat opioid withdrawal and facilitate OTP linkage utilizing the "72-hour rule."
Methods: Patients presenting to a hospital-based bridge clinic were evaluated for OUD, opioid withdrawal, and treatment goals. Eligible patients were offered methadone opioid withdrawal management with rapid OTP referral. OTPs accepted patients as direct admissions. We described bridge clinic patients who received at least one dose of methadone between March-August 2021 and key clinical outcomes including OTP referral completion within 72 h. For the subset of patients referred to our two primary OTP partners, we described OTP linkage (i.e., attended at least one OTP visit within one month) and OTP retention at one month.
Results: Methadone was administered during 150 episodes of care for 142 unique patients, the majority of whom were male (73%), white (67%), and used fentanyl (85%). In 92% of episodes (138/150), a plan for ongoing care was in place within 72 h. Among 121 referrals to two primary OTP partners, 87% (105/121) linked and 58% (70/121) were retained at one month.
Conclusions: Methadone administration for opioid withdrawal with direct OTP admission under the "72-hour rule" is feasible in an outpatient bridge clinic and resulted in high OTP linkage and 1-month retention rates. This model has the potential to improve methadone access.

1. Introduction

The United States (US) suffered over 76,000 deaths from opioid overdose in the year ending in April 2021, the majority of which were attributed to synthetic opioids like illicitly manufactured fentanyl (Ahmad et al., 2022; Mattson et al., 2021). Despite this surge in opioid overdose deaths, access to evidence-based treatment for opioid use disorder (OUD), including medications for OUD (MOUD), remains inadequate (Jones et al., 2015). Eliminating barriers to effective OUD treatment has never been more urgent.

Federal regulations are frequently identified by people with OUD, clinicians, and advocates as obstacles to MOUD initiation and retention (Frank et al., 2021; Joseph et al., 2021; Joudrey et al., 2020; Kleinman, 2020; McCarthy et al., 2021; Peterkin et al., 2021; Samet et al., 2018). This is particularly true for methadone, arguably the most effective medication for OUD because it improves retention in care and is associated with reduced overdose and reduced all-cause mortality (Calcaterra et al., 2019; Hser et al., 2016; Mattick et al., 2014; Santo et al.,

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2021; Srivastava et al., 2017). The use of methadone for OUD treatment is limited to opioid treatment programs (OTPs) that are licensed and certified by the Drug Enforcement Agency and the Substance Abuse and Mental Health Services Administration ("Subpart C. Certification and Treatment Standards for Opioid Treatment Programs," n.d.) and further licensed and regulated by state agencies. This has contributed to substantial deficiencies in the number, geographic location, and capacity of OTPs. Long waiting lists for treatment, limited treatment hours, inadequate insurance coverage, and stringent requirements for daily observed methadone administration further complicate access (Rosenblum et al., 2011). Patients of low socioeconomic status, those experiencing homelessness, and people from racial and ethnic minority groups are inequitably impacted by these barriers (Gryczynski et al., 2011; Lo et al., 2018; Marsh et al., 2021; Marshall et al., 2021).

One pathway to methadone administration outside of OTPs is the "72-hour rule" (21 CFR 1306.07,; Emergency Narcotic Addiction Treatment [WWW Document], n.d,) This regulation allows non-OTP providers to administer methadone for opioid withdrawal symptoms for up to 72 h while arranging referral for ongoing treatment. Medication must be directly administered (i.e. not prescribed) and provision of "take-home" doses is prohibited. Administration of methadone under the "72-hour rule" has been primarily described in Emergency Departments (EDs) to address opioid withdrawal in OTP patients unable to make it to their clinics due to an acute medical issue or weather emergency (Marshall et al., 2020; Massachusetts Health and Hospital Association, 2019; McClure et al., 2014; Su et al., 2018). However, no clinical descriptive or outcome patient data have been published in the peer-reviewed medical literature on the use of this regulation in EDs to treat withdrawal with methadone (Gupta et al., 2017; Kaczorowski et al., 2020). To our knowledge, there are also no published data from outpatient settings applying the "72-hour-rule" to treat opioid withdrawal and increase access to long-term methadone treatment.

In March 2021, Faster Paths, a low-barrier, hospital-based, outpatient substance use disorder (SUD) bridge clinic in Boston, MA, launched a quality improvement (QI) initiative to improve access to long-term methadone treatment. Patients with OUD who presented in opioid withdrawal were offered emergency opioid withdrawal management with methadone administered in the clinic for up to 72 h while addressing co-occurring medical and psychiatric conditions, providing nurse care management, and rapidly referring to local OTPs for ongoing care. Our first pilot case resulted in sustained retention at a local OTP after two days of acute withdrawal treatment and case management (Laks et al., 2021). The goal of this program description is to demonstrate the feasibility of an innovative "72-hour rule" methadone initiation pathway in a bridge clinic and describe key clinical outcomes of referral completion within 72 h, OTP linkage, and OTP retention at one month.

2. Methods

2.1. Design

Our clinical pathway was designed as a QI initiative to increase access to long-term methadone treatment by addressing opioid withdrawal symptoms and facilitating rapid OTP referral. We described the initial cohort and key clinical outcomes. This work received a determination of "not human subjects research/quality improvement" [H-41980] from the Boston University Medical Campus Institutional Review Board (IRB) and it was not formally supervised by the IRB per their policies.

2.2. Setting

Faster Paths is the low-barrier SUD bridge clinic at Boston Medical Center (BMC), an urban, safety-net hospital affiliated with Boston University School of Medicine in Boston, MA. The model, which has been described previously, centers upon same-day access to MOUD and other substance use disorders, overdose prevention, infection screening and prevention, and other harm reduction services (Harvey et al., 2021; Roy et al., 2020; Taylor et al., 2021). During the medical visit, providers with addiction medicine expertise assess for the presence and duration of OUD, discuss OUD treatment options, and determine clinical appropriateness for MOUD in interested patients. Patients are seen via scheduled and walk-in appointments; primary referral sources include word of mouth, local recovery and residential programs, the BMC ED, and the BMC inpatient addiction consult service.

Prior to March 2021, medication options for OUD included sublingual and monthly injectable buprenorphine and oral and intramuscular naltrexone. Non-controlled substance medications including clonidine, ibuprofen, and dicyclomine targeting specific symptoms of opioid withdrawal were also prescribed. Faster Paths is not licensed as an OTP, and patients interested in methadone were thus referred to local programs by calling local OTPs with the patient to schedule intake appointments, often up to 2 weeks in the future.

In March 2021, the Faster Paths team developed a clinical protocol for methadone opioid withdrawal management compliant with the provisions of the 72-hour rule in collaboration with hospital counsel, Inpatient Pharmacy, and Emergency Medicine (Supplement 1). Electronic medical record (EMR) note templates for initial and follow-up visits were also created to support compliant practice and documentation (Supplement 2). To ensure patients could be linked to an OTP within 72 h for next-day methadone dosing and to facilitate two-way collaboration and follow-up care, we signed affiliation agreements with several local OTPs who agreed to accept our patients as direct admissions. The protocol is similar to direct admissions referred from inpatient hospitalizations or acute treatment services (i.e. patients begin dosing daily at OTP immediately at their transfer dose, sometimes for two weeks or more before completion of the full OTP medical intake). Patients signed written releases of information for OTP referral. Depending on the timing of patient visit to Faster Paths (i.e. during or after OTP hours of operation), OTP referrals were initiated on day 1 or day 2 of the 72-hour protocol. OTP appointments were scheduled on days 2–4 depending on OTP availability. We treated our first patient on March 3, 2021 (Laks et al., 2021).

2.3. Participants

Participants were patients who received one or more doses of methadone in Faster Paths between March 3, 2021, and August 15, 2021, as identified on EMR administered medication reports. An "episode of care" was defined as the 72-hour period following initial methadone administration.

2.4. Data Sources

We abstracted from the EMR basic demographic and clinical data, including referral source, healthcare utilization within the BMC system, known human immunodeficiency virus (HIV) diagnosis, and urine drug test results within the previous 12 months, if available. Our clinical protocol did not require a repeat baseline UDS when confirmatory data were available in EMR including via linked EMR of other medical systems; however, we only abstracted data from the BMC EMR which thus do not represent the entirety of clinical data available to providers at the time of the visit. OTP partners provided information about linkage and retention.

2.5. Outcomes

Clinical outcomes were the following: 1) referral completion, defined as OTP appointment or inpatient care secured within 72 h of the 1st administration of methadone in Faster Paths; 2) OTP linkage, defined as attendance at an OTP appointment within 1 month of the last day in Faster Paths; and 3) retention in OTP care at one month.

2.6. Statistical Methods

To describe temporal trends in methadone dosing in our clinic, we calculated change in average dose of methadone administered on day 1 as well as the average dose administered on the last day in Faster Paths (which may have been day 1, 2, or 3 depending on timing of OTP appointment availability) per 30-day period using linear regression models with time as the main exposure. We used 2-sided t-tests to determine whether temporal trends were different from zero. We excluded patients already initiated on methadone (e.g. patients with a last dose letter from a hospitalization who missed their OTP linkage and required one or more days of emergency withdrawal management) from these analyses in order to describe prescribing trends for patients being treated "de novo" in our program.

For the subset of patients referred to our two primary OTP partners, Health Care Resource Centers Boston in Boston, MA and Addiction Treatment Centers of New England in Brighton, MA, we described the proportion of patients linked to OTP and the proportion retained in OTP care at one month. We used descriptive statistics to characterize the population and referral care cascade.

Data were collected in Microsoft Excel (version 16.43) and analyzed using R software (version 4.1.1).

3. Results

3.1. Volume

Methadone for emergency opioid withdrawal management was initiated during 150 episodes of care for 142 unique patients during the evaluation period (Fig. 1). Eight patients (5.6%) went through the pathway twice with second episodes of care occurring a mean of 44.1 days after the initial episode. In 11 episodes of care (7.3%), patients presented with a last dose letter or other reliable confirmation of recent dosing (e.g., EMR documentation) and were also in opioid withdrawal meeting criteria for emergency methadone withdrawal management.

3.2. Clinical Characteristics

Most patients treated were male (72.5%) and mean age was 40.1 years; 66.9% were white, 14.8% Black/African American, and 19.7% Hispanic or Latino (any race) (Table 1). Nearly 15% had known HIV infection. Among 73 patients with past 12-month urine drug testing on file, 62 tested positive for fentanyl (84.9%) and 48 (65.7%) tested positive for both a stimulant (i.e., amphetamines and/or cocaine) and an opioid on their most recent test. The average number of substances detected was 3.0 (SD 1.49, range 0–6).

Primary referral sources were the Boston Healthcare for the Homeless Program and the BMC ED. Patients generally had high healthcare utilization, with a mean of 4.3 (SD 5.8) BMC ED visits in the 12 months prior to day 1 methadone administration.

3.3. Referral Completion

Among 150 treatment episodes, 4 (2.7%) had a pre-existing plan for ongoing care (e.g., patient independently scheduled OTP intake up to 3 days away and presented for interim emergency withdrawal management). A new plan for ongoing care was secured within 72 h in an additional 134 episodes (89.3%) (Fig. 2). In only 12 of the 150 treatment episodes (8.0%), a plan for ongoing care was not secured because the patient did not return for day 2–3 appointment(s) to complete referrals and schedule OTP intake appointments. Overall, 138/150 (92.0%) of treated patients had a plan secured for ongoing care.

Among the 134 patients with a new plan for ongoing care, 129 (96.3%) were accepted by an OTP to start daily dosing, 4 (3.0%) were

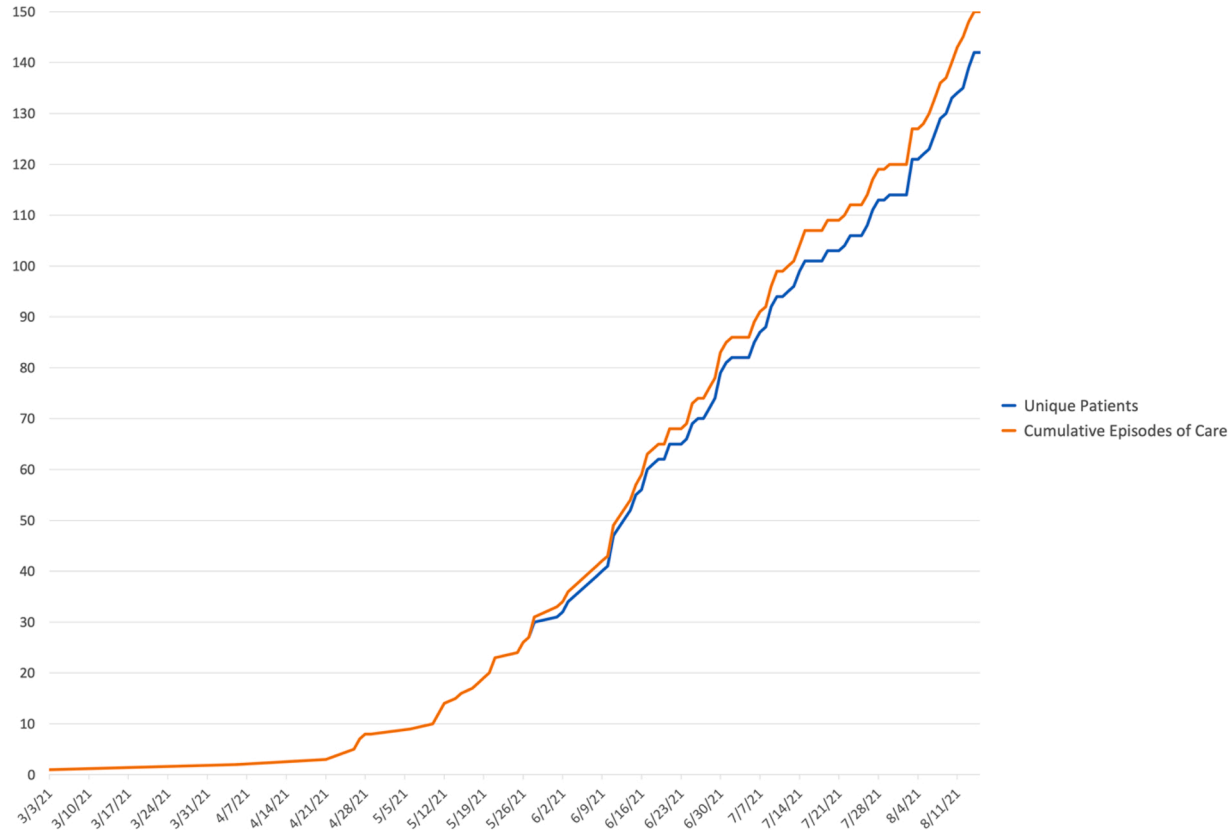

Fig. 1. Cumulative Number of Treatment Episodes and Individuals Treated for Emergency Opioid Withdrawal in a Low-Barrier Bridge Clinic in Boston, MA: March 3, 2021 - August 15, 2021.

Table 1
Characteristics of unique patients with OUD (n = 142) treated in a bridge clinic "72-hour rule" methadone administration pathway, Boston, MA, March-August 2021.

Sex, n	
Male	103 (73%)
Female	38 (27%)
Transgender female	1 (0.7%)
Age, mean (SD)	40.1 (11%)
Race, n	
White	95 (67%)
Black/African American	21 (15%)
Declined/Not Available	26 (18%)
Ethnicity, n	
Hispanic	28 (20%)
Primary Language Listed in Health Record, n	
Spanish	7 (4.9%)
English	135 (95%)
Primary Insurance Plan, n (%)	
Medicaid	132 (93%)
Medicare	6 (4.2%)
None	3 (2.1%)
Private	1 (0.7%)
Major Medical Comorbidities, n (%)	
Known HIV Infection	21 (15%)
Top Referral Sources, n (%)	
Boston Health Care for the Homeless Program	36 (25%)
Emergency Department (ED)*	25 (18%)
Self-referred	23 (16%)
Other^	23 (16%)
Not Documented	21 (15%)
Inpatient Detox and Residential	8 (5.6%)
Opioid Treatment Programs#	7 (4.9%)
Healthcare Utilization at BMC, Past 12 Months, mean (SD, range)	
ED visits	4.3 (5.8, 0–38)
Inpatient admissions	0.5 (1.1, 0–8)
Urine Drug Testing at BMC, Past 12 Months (n = 73)	
Number of substances positive, mean (SD)	3.0 (1.5)
Fentanyl positive, n	62 (86%)
Stimulant + opioid, n	48 (65%)
Benzodiazepine + opioid, n (%)	21 (29%)

* ED includes Project Assert, an ED-based program that offers screening, brief intervention, and referral to treatment

^ Other referral sources included a local drop-in center for people with SUD, primary care providers, Boston Public Health Commission staff, and local residential SUD and sober living programs

OTPs with wait times for entry began to refer patients to the SUD bridge clinic for immediate emergency opioid withdrawal management and direct admission to OTP

referred for inpatient medically managed withdrawal ("inpatient detox," "acute treatment services"), and 1 (0.70%) was referred for inpatient hospitalization due to acute medical needs. The 129 patients referred to an OTP were referred to five unique OTPs.

3.4. Opioid Withdrawal and Treatment Duration

Among patients with a recorded clinical opioid withdrawal (COWS) score, the mean score on day 1 was 10.5 (SD 4.5, range 2–27) (Table 2). Patients were treated for 1–3 days depending on the timing of OTP capacity to accept as a direct admission. Overall, patients received a mean of 2.1 days of opioid withdrawal treatment, including 39/150 (26.0%) episodes treated for one day only, 57/150 (38.0%) treated for two days, and 54/150 (36.0%) treated for three days.

3.5. Methadone Dose and Titration

For episodes of care representing de novo starts of methadone (n = 139), the mean day 1 methadone dose was 28.4 mg (Table 3). Among the subset of these patients who presented for subsequent visits on day 2 (n = 107) and day 3 (n = 52), mean methadone doses were 37.2 mg and 42.9 mg, respectively.

Day 1 and last day methadone doses both increased significantly over time. For every 30 days since the start of the protocol, the day 1 dose increased by 2.64 mg (95% CI, 1.59–3.70, $p < 0.0001$) and the last day dose increased by 2.70 mg (95% CI, 1.41–3.98, $p < 0.0001$) (Fig. 3).

3.6. OTP Linkage and One-Month Retention Rates

Referrals to our two primary OTP partners comprised 121/150 (80.7%) of overall treatment episodes for 113 unique patients. Overall, 105/121 (86.8%) of referrals resulted in successful OTP linkage, including 101 (83.5%) who attended their formal intake appointment within 48 h of its scheduled time and an additional four who attended within 30 days of the scheduled time (Fig. 4).

Among the 101 patients who attended their OTP within 48 h of the scheduled time, 94 patients (93.1%) received their methadone dose on the day of their appointment. The remaining 7 patients did not receive methadone, 6 due to sedation and one due to "aggressive behavior," resulting in denial of OTP admission. Two of the six patients who were denied dosing at their intake appointment due to sedation subsequently re-presented to the OTP for successful admission and dosing, while four were not admitted.

Overall, 57.9% of total referrals (70/121) were still retained in care at the OTP at one month (Fig. 4). Among the subset of patients who linked to OTP, 66.7% (70/105) remained in care at one month.

4. Discussion

To our knowledge, this is the first evaluation of methadone administration under the "72-hour rule" in a bridge clinic or any other setting. This QI initiative using the "72-hour rule" resulted in 150 treatment episodes for 142 unique patients in its first 24 weeks and was effective in rapidly securing plans for ongoing care (138/150, 92.0%) in line with "72-hour rule" requirements. Among the 121 patients referred to our primary OTP partners, linkage (105/121, 86.8%) and 1-month retention (70/121, 56.9%) rates were high.

These results demonstrate that offering emergency methadone withdrawal management and OTP linkage in an outpatient bridge clinic is both feasible and results in timely access to methadone treatment. Implementation of "72-hour rule" methadone through a bridge clinic is responsive to delivering the standard of care for MOUD called for by the National Academy of Sciences, Engineering and Medicine, in which all Food and Drug Administration-approved MOUD are readily accessible for patients in the same venue (National Academies of Sciences, Engineering, and Medicine Health and Medicine Division Board on Health Sciences Policy Committee on Medication-Assisted Treatment for Opioid Use Disorder, 2019). Furthermore, this protocol, implemented in a medical setting, helps close the cavernous gap between the medical and specialty addiction care systems.

Many providers are unaware that administering methadone for opioid withdrawal management is permitted under the "72-hour rule" (Joudrey et al., 2021), and those who are aware may assume that this use is limited to EDs, though the federal regulations do not limit the care setting (21 CFR 1306.07– Administering or dispensing of narcotic drugs., n.d.; Emergency Narcotic Addiction Treatment [WWW Document], n.d,) We determined that our outpatient SUD bridge clinic had the infrastructure required to comply with the provisions of "72-hour rule" regulations, including adequate visit capacity, a secure medication dispensing cabinet, EMR infrastructure for medication administration tracking, referral relationships to ensure linkage to ongoing care, and appropriate licensure. In the midst of the current opioid overdose crisis driven by illicitly manufactured fentanyl, which has rendered methadone more critical than ever due to reports of increased precipitated withdrawal with buprenorphine (Antoine et al., 2021; Silverstein et al., 2019), our results suggest there is substantial untapped potential to expand rapid methadone access by scaling up 72-hour methadone pathways to bridge clinics and other outpatient medical settings.

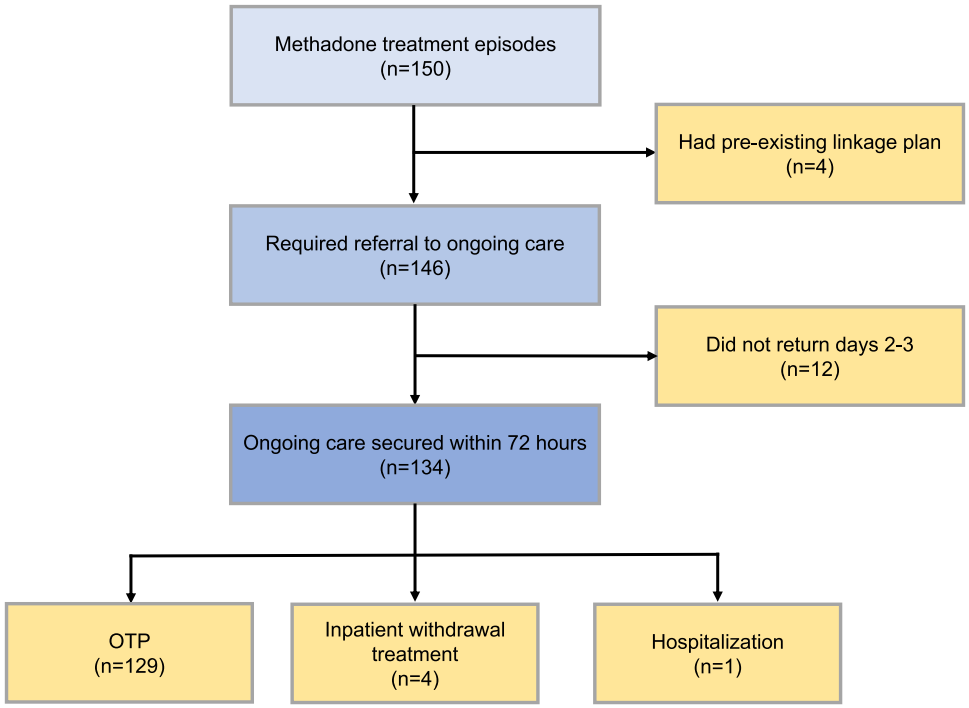

Fig. 2. Plans for Ongoing Care for Methadone Treatment Episodes in a Low-Barrier Bridge Clinic in Boston, MA: March 3, 2021 - August 15, 2021. Acronyms: OTP, opioid treatment program.

Table 2
Clinical Opioid Withdrawal (COWS) Score.

	Day 1	Day 2	Day 3
COWS recorded, n	133	88	42
Mean COWS (SD)	10.5 (4.5)	12.3 (4.8)	10.5 (3.4)
COWS range	2–27	2–25	2–17
COWS median	10	12	11

Table 3
Methadone Dose among Patients without Confirmed Recent Dosing, mg* .

	Day 1, n = 139	Day 2, n = 107	Day 3, n = 52
Mean Dose (SD)	28.4 (7.6)	37.2	42.9
Dose range	10–50	20–60	25–60
Dose median	30	40	40

* Patients already on methadone with confirmation of recent dosing (n = 11) were excluded from these analyses

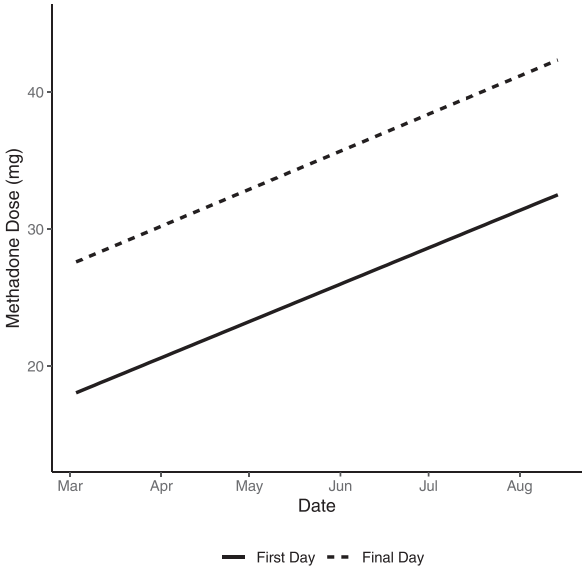

Fig. 3. Temporal trends in average methadone dosing for opioid withdrawal at the low-barrier bridge clinic.* *Average methadone dose estimates are calculated from a linear regression model with time as the predictor. Shaded areas represent 95% confidence intervals.

The observed rates of successful linkage and 1-month retention are notable considering the complexity of barriers faced by our population, and they compare favorably to linkage (76%) and 1-month retention (54%) rates for hospitalized patients initiated on methadone and buprenorphine (Roy et al., 2020; Trowbridge et al., 2017). Although we did not systematically collect housing status for this clinical QI initiative, Boston Health Care for the Homeless Program was our primary referral source. The 15% baseline HIV prevalence in this cohort, high rates of past 12-month ED utilization at our institution, and polysubstance use further support this pathway's success in reaching those with very high substance use-related risk.

Several aspects of our protocol are distinctly different from federally regulated OTP intake protocols and likely contributed to successful engagement, linkage, and retention. First, on-demand services have been described as a critical feature of bridge clinic success (Snow et al., 2019). We were able to offer same-day, walk-in methadone withdrawal management for up to 72-hours without delay. Even in a relatively resource-rich area like Boston, MA, patients can wait several weeks for OTP intake appointments. Our protocol facilitated rapid OTP enrollment and capitalized on moments of patient readiness. In addition, our patients had up to 3 days of methadone withdrawal management prior to their first OTP visit, which may have been helpful for meeting OTP requirements for care, such as arriving during specified dosing windows.

Our staffing model, which is anchored by a nurse care manager (Harvey et al., 2021) and included 8 h/day of in-person provider coverage 6 days/week during the period we describe, also offered significant flexibility compared to OTP regulations. When patients

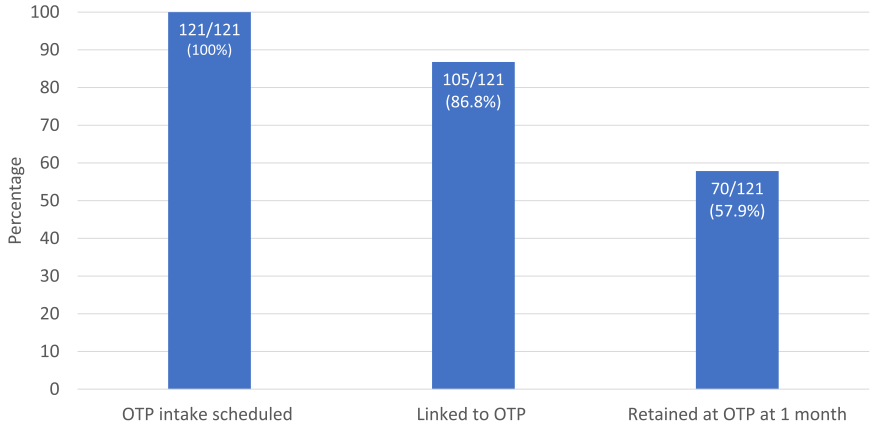

Fig. 4. Scheduled intake appointments, attendance within 1 month of scheduled intake, and 1-month retention in care at two primary collaborating OTPs. Acronyms: OTP, opioid treatment program.

presented in the morning with sedation, for example, which can occur when initial methadone dosing is inadequate and patients continue other substance use to manage withdrawal symptoms, we had the capacity to monitor throughout the day and treat withdrawal once it developed rather than denying dosing. This was important in establishing trust and maintaining engagement and progress towards linkage. Additionally, we had up to 3 high-touch days to address other common issues that present barriers to OTP linkage and retention, including transportation needs, lack of photo identification, need for information from outside providers and clinical comorbidities such as alcohol or benzodiazepine withdrawal (Laks et al., 2021).

Furthermore, under the "72-hour rule" we were not bound to OTP dose guidelines, which have not changed in response to the shift from heroin to potent synthetic opioids. Our ability to tailor patients' day 1 dose, reflected in the day 1 dose range of 10–50 mg, and to increase their dose daily based on clinical need at faster rates than those permitted at OTPs likely contributed to the high engagement in the OTP referrals process as well as to high OTP linkage and retention rates. As shown in Fig. 3, the methadone dose administered in Faster Paths increased over time. In our experience, this was due not to significant changes in the drug supply over the first 24 weeks of this protocol but rather to clinicians developing increased comfort with methadone administration. The use of higher doses was also driven by persistent opioid withdrawal symptoms observed on days 2 (mean COWS 12.3, SD 4.8) and 3 (mean COWS 10.5, SD 3.4) without reports of methadone-related sedation. Since August 2021, we most commonly treat patients with high opioid tolerance and moderate to severe withdrawal with 40 mg on day 1, 50 mg on day 2, and 60 mg on day 3. The relationship between methadone dose and linkage and retention merits future investigation.

Although we anticipated significant interest in a low-barrier, same-day pathway to methadone withdrawal management with OTP linkage, we did not expect the robust demand that followed, which further highlights the inadequacy of existing methadone entry pathways. The surge in clinic volume also created unanticipated clinical and operations challenges and prompted us to expand services from 6 to 7 days/week to accommodate need.

This evaluation is subject to several limitations. First, our program was designed as a clinical QI intervention and thus we did not collect comprehensive data on medical and psychiatric co-morbidities. Laboratory and ED utilization data were limited to those available in our own EMR and are therefore incomplete. Likewise, we relied on EMR data for race and ethnicity, which may be subject to inaccuracies (Jarrín et al., 2020). The proportion of Black and Hispanic patients treated in this pathway was similar to prior cohorts of Faster Paths patients and to patients treated in our institution's primary care office-based addiction treatment program, but a continued focus on inclusive, accessible care delivery is needed to address well-described inequities in MOUD access and opioid overdose fatalities (Cano and Sparks, 2022; Ghose et al., 2022; Goedel et al., 2020; Gryczynski et al., 2011; Harvey et al., 2021; Weinstein et al., 2017). Furthermore, we practice in a setting with a robust state Medicaid program and the institutional resources to facilitate rapid enrollment for eligible patients. Lack of and inadequate insurance coverage are well-described barriers to OTP enrollment, and the impact of this pathway may be reduced in states with insufficient Medicaid coverage of SUD services or programs with different payor mixes (Gryczynski et al., 2011; Mitchell et al., 2021).

Finally, because our program only tracks linkage and retention outcomes with our two primary OTP partners, outcomes for patients referred to other OTPs are not known. Our model depends on close collaboration with OTP partners who are willing and able to accept patients as direct admissions. Our primary OTP partners had experience accepting direct admissions from our institution's inpatient settings, and familiarity with direct admissions and our teams undoubtedly facilitated implementation. Building and maintaining a direct admission relationship between a medical program and an OTP typically follows individual-level professional relationships between medical program and OTP staff, initially established around discussing the needs of individual patients. Our protocol may be more challenging to replicate in settings with more limited OTP capacity and direct admission experience.

5. Conclusions

Overall, implementation of methadone opioid withdrawal management with rapid OTP linkage under the "72-hour rule" is feasible in outpatient medical settings and was associated with high completed referral, OTP linkage, and one-month OTP retention rates. Our findings suggest that this model of care has the potential to improve access to methadone amidst the highest rates of opioid overdose death in US history. However, the need for this pathway to access a life-saving medication highlights the fundamental flaws in current federal methadone regulations and should serve as an urgent call to action for policymakers to modernize regulations. Low-barrier access to methadone must become the rule, not the 72-hour exception.

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Analyses were conducted by Paul Christine, MD, PhD who was supported by HRSA Grant #: T25HP37593 (PI: Walley).

CRediT authorship contribution statement

J. Taylor: Designed the clinical program and quality improvement evaluation, Contributed to data collection, Contributed to data analyses, Data interpretation, Drafted the manuscript. **J. Laks:** Contributed to clinical program implementation, Contributed to evaluation design, Contributed to data collection, Contributed to data analyses, Data interpretation, Contributed to manuscript drafting, Revised the manuscript and provided critical comments. **P. Christine**: Data analyses, Data interpretation, Revised the manuscript and provided critical comments. **J. Kehoe**: Contributed to clinical program implementation, Contributed to data collection, Revised the manuscript and provided critical comments. **J. Evans**: Contributed to clinical program implementation, Contributed to data collection, Revised the manuscript and provided critical comments. **T. Kim:** Contributed to clinical program implementation, Data interpretation, Revised the manuscript and provided critical comments. **N. Farrell**: Contributed to clinical program implementation, Contributed to data collection, Revised the manuscript and provided critical comments. **C. White:** Contributed to data collection. Revised the manuscript and provided critical comments. **Z. Weinstein:** Contributed to clinical program implementation, Data interpretation, Revised the manuscript and provided critical comments. **A. Walley:** Contributed to clinical program implementation, Contributed to evaluation design, Data interpretation, Revised the manuscript and provided critical comments. All authors approved the final version of the manuscript.

Conflict of interest

The authors report no conflicts to declare.

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.drugalcdep.2022.109497.

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