

HIV Exposure Prophylaxis Delivery in a Low-barrier Substance Use Disorder Bridge Clinic during a Local HIV Outbreak at the Onset of the COVID-19 Pandemic

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Objectives: People who inject drugs (PWID) may experience high human immunodeficiency virus (HIV) risk and inadequate access to biomedical HIV prevention. Emerging data support integrating HIV post-exposure and pre-exposure prophylaxis (PEP, PrEP) into services already accessed by PWID. We describe PEP/PrEP eligibility and receipt in a low-barrier substance use disorder bridge clinic located in an area experiencing an HIV outbreak among PWID at the onset of the COVID-19 pandemic.

Methods: Retrospective chart review of new patients at a substance use disorder bridge clinic in Boston, MA (January 15, 2020–May 15, 2020) to determine rates of PEP/PrEP eligibility and prescribing.

Results: Among 204 unique HIV-negative patients, 85.7% were assessed for injection-related and 23.0% for sexual HIV risk behaviors. Overall, 55/204 (27.0%) met CDC criteria for HIV exposure prophylaxis, including 7/204 (3.4%) for PEP and 48/204 (23.5%) for PrEP. Four of 7 PEP-eligible patients were offered PEP and all 4 were prescribed PEP. Thirty-two of 48 PrEP eligible patients were offered PrEP, and 7/48 (14.6%) were prescribed PrEP. Additionally, 6 PWID were offered PrEP who lacked formal CDC criteria.

Conclusions: Bridge clinics patients have high rates of PEP/PrEP eligibility. The majority of patients with identified eligibility were offered PEP/PrEP, suggesting that upstream interventions that increase HIV risk assessment may support programs in initiating PEP/PrEP care. Additional work is needed to understand why patients declined PEP/PrEP.

PrEP offers to PWID who did not meet CDC criteria also suggested provider concern regarding the sensitivity of CDC criteria among PWID. Overall, bridge clinics offer a potential opportunity to increase biomedical HIV prevention service delivery.

Key Words: bridge clinic, COVID-19, HIV pre-exposure prophylaxis (PrEP), injection drug use, substance use disorder

(*J Addict Med* 2022;16: 678–683)

People who inject drugs (PWID) are disproportionately affected by human immunodeficiency virus (HIV) due to high rates of sexual and injection-related risk behaviors.^{1–3} An increasing number of HIV outbreaks in PWID across the United States and internationally,⁴ driven by the opioid use disorder and polysubstance use epidemics, have increased the urgency of HIV prevention efforts in this population.^{5–10}

HIV pre-exposure prophylaxis (PrEP) reduces HIV incidence among PWID.¹¹ PrEP with daily oral tenofovir disoproxil fumarate/emtricitabine (TDF/F) is therefore recommended for PWID with sexual and/or injection-related risk in the previous six months.¹² However, PrEP uptake in this population remains limited, due to factors that include low PrEP knowledge, structural barriers (e.g., homelessness, incarceration), competing priorities, and provider stigma.^{13–17} A 2021 systematic review of the PrEP care cascade in PWID demonstrated uptake rates of 0% to 3% and highlighted linkage to care as a priority focus to bridge “the gap between willingness to use PrEP and PrEP uptake.”¹⁸ Yet PWID are not well-engaged by traditional outpatient care settings where preventive services are typically delivered.¹⁹ A growing body of data supports the need to deliver HIV prevention in low-barrier settings where PWID already access services.^{18,20,21}

Low-barrier substance use disorder (SUD) bridge clinics offer rapid access to SUD treatment and have emerged as a model for transitional care that engages PWID including those at high risk of HIV acquisition.^{22–24} Low-barrier substance use disorder (SUD) bridge clinics offer rapid access to SUD treatment and have emerged as a model for transitional care that engages PWID, including those at high risk of HIV acquisition.^{22–25} Bridge clinics therefore offer a unique opportunity to deliver biomedical HIV prevention services, including PrEP and post-exposure prophylaxis (PEP) to PWID. However, PEP and PrEP eligibility, uptake, and utilization trends among bridge clinic patients are not adequately understood.

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Received for publication July 10, 2021; accepted February 21, 2022.

The authors report no conflicts of interest.

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ISSN: 1932-0620/22/1606-0678

DOI: 10.1097/ADM.0000000000000991

Early experience with PrEP delivery in bridge clinics has identified challenges not readily addressed by clinical guidelines, including around the initiation of PrEP in people with frequent and very high-risk HIV exposures.²⁶ Starting PEP, even if outside the recommended 72-hour eligibility period, as a bridge to PrEP is one strategy that has been proposed to mitigate concerns about starting PrEP in the setting of unrecognized acute HIV infection in this scenario.²⁶ However, little is known about how often “PEP-to-PrEP” and more standard PEP and PrEP approaches are used in the bridge clinic setting. The coronavirus disease 2019 (COVID-19) public health emergency, characterized by a substantial transition to telemedicine including for low barrier addiction services,²⁷ has added additional complexity to HIV prevention service delivery in this population.²⁴

The goal of this study is to describe PEP and PrEP eligibility and prescribing patterns in a low-barrier SUD bridge clinic in Boston, MA, an area experiencing an HIV outbreak among PWID. Bridge clinics are becoming more numerous and incorporating preventive health strategies alongside other urgent interventions requires a deliberate, program-level approach. This study will generate critical baseline data that can be used as benchmarks to inform quality improvement and programmatic interventions seeking to increase HIV exposure prophylaxis in PWID accessing bridge clinics.

METHODS

Overview

We performed a retrospective chart review of all patients who completed a new patient appointment with a licensed independent practitioner (i.e., NP or MD) at a low-barrier SUD bridge clinic in Boston, MA between January 15, 2020 and May 15, 2020 using electronic medical record (EMR) completed visit reports.

Site

Faster Paths is a low-barrier SUD bridge clinic at Boston Medical Center (BMC) in Boston, MA. Faster Paths is open Monday-Saturday and offers rapid access to medications for opioid use disorder (i.e., sublingual and injectable buprenorphine, oral and injectable naltrexone) and other SUDs, outpatient medically managed withdrawal, medical screening exams and referral to inpatient medically managed withdrawal, overdose prevention, harm reduction, and infection screening, treatment, and prevention services.^{23,28} Faster Paths sees over 600 unique patients per year, often with high acuity conditions and unmet MOUD and infection-related needs: approximately two-thirds report injection drug use, 56% are housing insecure, and over half have experienced opioid overdose.²³ The majority of Faster Paths visits are for MOUD or other medications for addiction treatment. A minority of visits (approximately 15% during the study period) are booked for medical screening exams to facilitate referral to inpatient medically managed withdrawal facilities; MOUD may or may not be addressed during medical screening exams depending on patient goals. Boston public health officials began noting clusters of new HIV infections among PWID experiencing homelessness in early 2019.¹⁰

COVID-19 Operations Impact

On March 16, 2020, Faster Paths transitioned to modified COVID operations and began to offer telemedicine visits for the first time, including impromptu telehealth visits, in line with emergency federal regulatory changes that allowed for initiation of buprenorphine without an in-person visit.²⁹ Other state changes (e.g., elimination of prior authorization requirement for injectable buprenorphine) facilitated further innovations.^{24,27,30} For the first two weeks of telemedicine availability, telemedicine visits were not reliably captured by EMR completed appointment reports. Thereafter, a programming change allowed reliable capture of telemedicine appointments, though reports were unable to distinguish an in-person from a telemedicine appointment. The clinic remained open during expanded hours to support patients in need of walk-in and in-person services.^{24,27,30} Additionally, during the first week of April 2020, the Faster Paths provider EMR note template was updated to support providers in more consistent assessment of PrEP eligibility.²⁶

Data Abstraction and Analysis

EMR completed visit reports were used to define the study population. All visits during the study period were reviewed to capture PEP and PrEP discussions occurring at initial and follow-up visits. During the study period, clinic policy was to book patients for new patient appointments if they had never been seen in the clinic previously or if they had been out of care for more than three months. Patients with multiple new appointments were linked by a unique study ID number.

EMR charts were manually reviewed to determine rates of PEP and PrEP eligibility,^{12,31} offers, and prescriptions. CDC criteria were used to define eligibility for PEP (i.e., HIV-negative person¹ within 72 hours of a possible high risk exposure) and PrEP (i.e., HIV-negative persons who: have shared injection or drug preparation equipment in the last 6 months; have condomless anal or vaginal sex; and/or have had a bacterial STD within the last 6 months). When patients meet criteria for both PEP and PrEP, guidelines recommend starting PEP and transitioning to PrEP thereafter. For the purposes of these analyses, we counted these patients as PEP eligible only and noted the frequency of which patients transitioned from PEP to PrEP. Special note was made when PEP and PrEP were discussed with patients who did not meet CDC eligibility criteria (for example, did not report an HIV-positive injecting partner or sharing injection equipment in the past 6 months). PrEP prescribing was defined as documentation of a prescription for daily oral TDF/F or tenofovir alafenamide/emtricitabine (TAF/F), another daily medication FDA-approved for PrEP in people at risk for sexually acquired HIV through anal sex only, and PEP prescribing was defined as documentation of a prescription for either formulation of tenofovir/emtricitabine plus a third antiretroviral medication. These data were then cross-checked for accuracy with a quality improvement report of all bridge clinic prescriptions to confirm capture of all PEP and PrEP prescriptions during the study period.

¹HIV status was determined based on all data available (EMR documentation, laboratory data, and patient self-report) to the provider at the time of the initial visit. The bridge clinic was additionally located next to phlebotomy services, so testing was available to the provider and patient for reassessment as needed.

TABLE 1. Patient Demographics and Characteristics

	Overall N = 207, n (%)
Age, mean (years) (SD)	40.2 (SD 10.7, range 22–79)
Sex	
Male	154 (74.4)
Female	53 (25.6)
Race	
White	109 (52.7)
Black	56 (27.1)
Asian	1 (0.5)
Other	10 (4.8)
Declined	6 (2.9)
Ethnicity	
Hispanic, Any race	40 (19.3)
Not Hispanic	164 (79.2)
Living with HIV	3* (1.4)

SD indicates standard deviation.

*Known positive HIV status at study initiation; excluded from subsequent PEP/PrEP eligibility assessments.

We used descriptive statistics to characterize the study population and describe rates of PEP and PrEP eligibility and prescribing. Fisher exact test, Freeman-Halton extension of the Fisher exact test, or *t*-test analyses assessed differences between groups offered and not offered HIV exposure prophylaxis (Vassar Stats, www.vassarstats.net).

Consent/Permissions

This study was determined to be exempt by the Boston University Medical Campus Institutional Review Board.

RESULTS

Patient Characteristics

A total of 207 unique patients (204 HIV-negative) completed 216 new visits during the study period (Table 1). Patients were 74.4% male, 52.7% white, 27.1% Black, and 19.3% Hispanic.

PEP and PrEP Eligibility

Overall, 175/204 (85.8%) were assessed for injection-related HIV risk behaviors and just 47/204 (23.0%) were assessed for sexual HIV risk behaviors conferring PrEP eligibility. Female patients were more likely than male patients to be assessed for sexual risk behaviors (20/52, 38.4% vs 24/152, 15.8%; *P* < 0.1), though not for injection risk factors (47/52, 90.4% vs 125/152, 82.2%; *P* = 0.16); otherwise, eligibility assessments for sexual or injection risk factors did not differ by age or by race/ethnicity. Rates of documented discussions on sexual and injection risk factors over time, as well as numbers of PEP or PrEP prescriptions per week, are depicted in Figure 1.

A total of 55/204 patients (27.0%) had chart documentation demonstrating HIV exposure prophylaxis eligibility by CDC criteria. Seven patients (3.4%) were eligible for PEP (1/7 due to sexual risk factors only, 4/7 due to injection risk factors only, and 2/7 due to both), and 48/204 patients (23.5%) were eligible for PrEP (6/48 due to sexual risk factors only, 32/48 due to injection risk factors only, and 10/48 due to both).

PEP and PrEP Offers and Prescriptions

Among 7 patients eligible for PEP, 4 (57.1%) had provider documentation of a PEP offer and all 4 (100.0%) were prescribed PEP. Among 48 patients eligible for PrEP, 32 (66.7%) had provider documentation of a PrEP offer and 7 patients (14.5%) were prescribed PrEP. Overall, 11/55 patients (20.0%) eligible for PEP or PrEP received prescriptions. All PEP and PrEP prescriptions used the TDF/F tenofovir formulation; to mitigate the risk of developing viral resistance if a patient with suboptimal PrEP adherence seroconverted and continued to take PrEP, patients were prescribed PrEP for short courses (7–30 days) with planned in-person follow-up.

Among PEP or PrEP eligible patients, those offered PEP or PrEP were not significantly different by age, by sex, or by race/ethnicity (Table 2) than those not offered PEP or PrEP. An additional 6 PWID were offered PrEP who did not meet CDC PrEP eligibility criteria; none of these patients were prescribed PrEP.

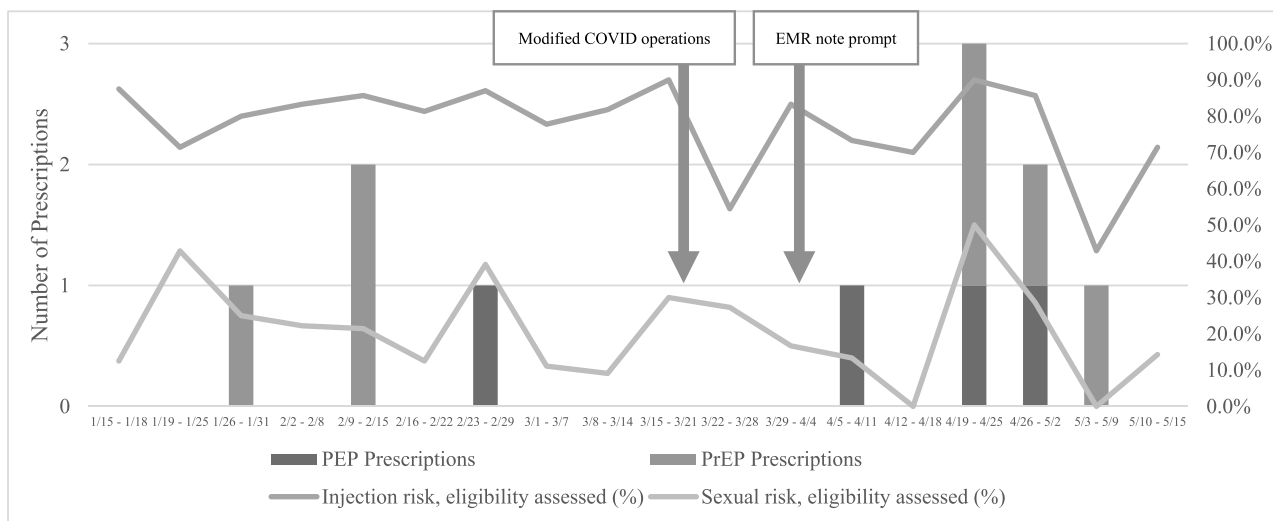


FIGURE 1. PEP and PrEP eligibility assessments and prescriptions by week.

TABLE 2. Differences by Sex and Race/Ethnicity Among HIV Exposure Prophylaxis Offers (n = 42) and Prescriptions (n = 11)

	Patients Eligible for PEP/PrEP			Patients Offered PEP/PrEP		
	Offered PEP or PrEP (n = 36)	Not Offered PEP or PrEP (n = 19)	P	Prescribed PEP or PrEP (n = 11)	Not Prescribed PEP or PrEP (n = 25)	P
Age, mean (years)	36.1	34.7	0.60*	32.9	37.5	0.22*
Sex						
Male	27	11	0.23 [†]	9	18	0.69 [†]
Female	9	8		2	7	
Race						
White	27	15	0.86 [‡]	8	19	0.71 [‡]
Black	4	3		2	2	
Asian	0	0		0	0	
Other	1	1		0	1	
Declined	0	0		0	0	
Ethnicity						
Hispanic, Any race	30	17	1.00 [†]	1	4	1.00 [†]
Not Hispanic	5	2		10	20	

*T-test.

[†]Fisher exact test.

[‡]Freeman-Halton extension of the Fisher exact test.

Although PrEP initiation after PEP prescriptions were discussed with patients, no patients prescribed PEP transitioned to PrEP (i.e., “PEP-to-PrEP”²⁶) during the study period.

The majority of PEP (3/4, 75.0%) and PrEP (4/7, 57.1%) prescriptions were sent during an initial visit. Remaining prescriptions were sent during follow-up visits. Of the 17 MD or NP bridge clinic providers during the study period, 16 performed HIV risk assessments, 14 offered PEP or PrEP, and 8

providers prescribed PEP or PrEP. Figure 2 depicts the PEP and PrEP care cascade.

COVID-19 Impact

Although this study was not designed to test the impact of COVID-19 operations changes on PEP and PrEP volume, significant differences before and after March 16th, 2020 were not

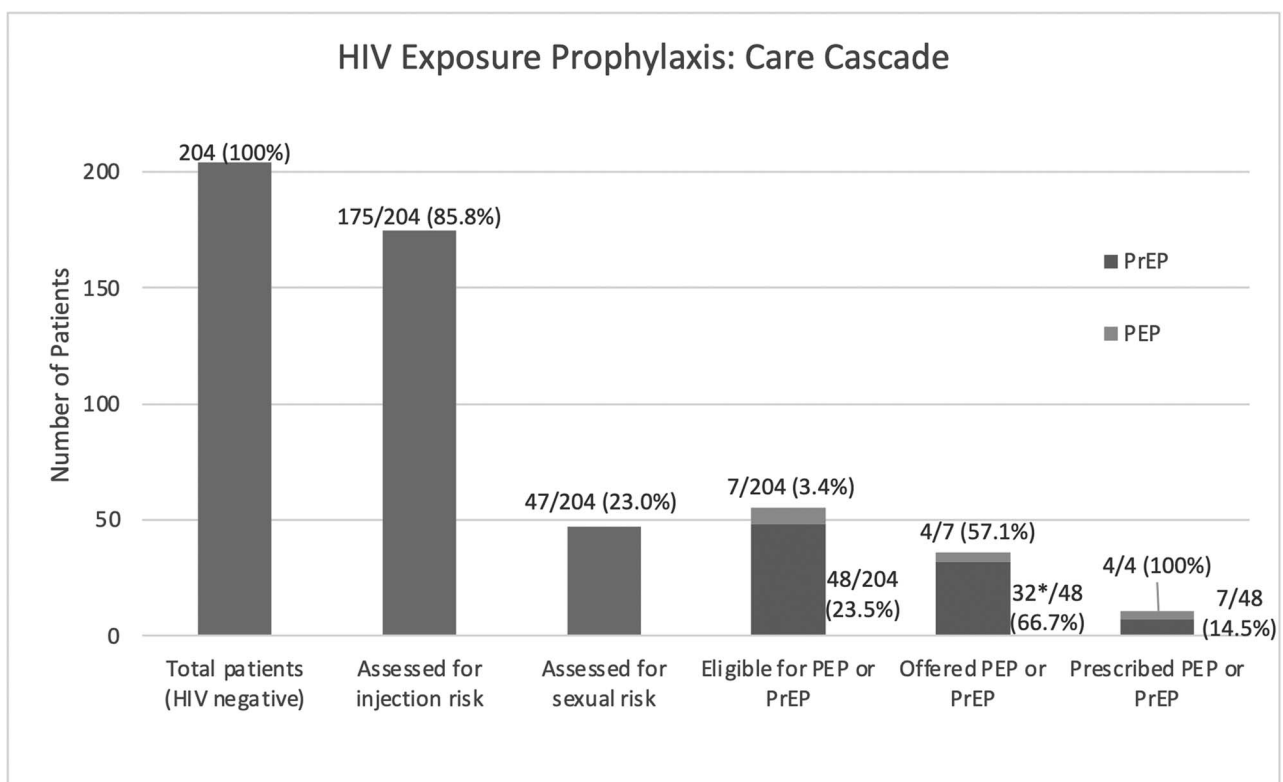


FIGURE 2. HIV exposure prophylaxis: care cascade. *Does not include the 6 patients offered PrEP who lacked formal CDC criteria.

observed, with an average of 2.0 PEP or PrEP prescriptions/month prior to operational change and 3.5 PEP or PrEP prescriptions/month after these changes (Fig. 1).

DISCUSSION

This study of PEP and PrEP eligibility and prescribing in a low-barrier SUD bridge clinic took place in the context of a local HIV outbreak¹⁰ among PWID and as programs responded to the unprecedented challenges of the COVID-19 pandemic. To our knowledge, it is the first study of PEP and PrEP in a bridge clinic setting. Results confirm high rates of HIV exposure prophylaxis eligibility in the SUD bridge clinic population. Although the PEP/PrEP uptake rate of 20% was lower than desired in the setting of high local HIV transmission, it was substantially higher than published PrEP uptake rates among PWID, suggesting that bridge clinics may have the potential to increase the delivery of biomedical HIV prevention services to PWID. Importantly, bridge clinic settings address the issue of access to and trust of a PrEP prescriber, which has been identified as a priority step in the PrEP care cascade for PWID.^{18,19,22} Further study of PEP and PrEP delivery in bridge clinic settings is warranted.

Simultaneously, results reveal missed opportunities to evaluate patients for sexual- and injection-related HIV risk behaviors and to discuss PrEP when indicated, even after the addition of an EMR note prompt, and they confirm prior work demonstrating inadequate PrEP uptake in this population. Primary care and infectious disease providers have previously identified multiple barriers to prescribing PrEP, including a lack of PrEP protocols and competing clinical demands.^{32,33} However, a majority of patients who were noted to be eligible for PrEP were offered PrEP—signaling that upstream efforts to standardize PEP and PrEP eligibility assessments may lead to increased PEP and PrEP offers. Though intake visits often have multiple competing clinical priorities, (e.g., buprenorphine initiation, overdose prevention counseling), a majority of PEP and PrEP starts occurred during an intake visit—demonstrating patient openness to PrEP starts at intake.

The COVID-19 pandemic drove rapid operations changes, with approximately half of all Faster Paths visits becoming telemedicine.²⁴ It is thus reassuring that rates of prescriptions did not decrease (and in fact increased slightly) during the onset of the COVID-19 pandemic, suggesting that PEP and PrEP can be effectively delivered to PWID even in challenging real-world circumstances.

The observation that bridge clinic providers offered PrEP to PWID who did not meet formal CDC eligibility criteria is, to our knowledge, a novel contribution to the literature, and suggests provider concern about the sensitivity of CDC criteria for HIV risk in this population. Providers, for example, judged HIV risk to be high enough to warrant biomedical HIV prevention when patients seemed to have difficulty disclosing behaviors (e.g., sharing injection equipment) that have traditionally been stigmatized by the medical system, when entering periods of potential increased risk (e.g., after incarceration or periods of forced sobriety), and due to evolving characteristics of local injection networks (e.g., increased HIV transmission). Prior work in other populations with high HIV incidence, including young Black men-who-have-sex-with-men, has demonstrated low sensitivity

of the CDC guidelines in predicting HIV seroconversion,³⁴ leading researchers to hypothesize that demographics, local HIV epidemiology, and network factors may be more relevant considerations. Future work should explore how these factors can be incorporated in PrEP eligibility determinations for PWID.

Although no significant differences in offers and prescriptions of PEP and PrEP were revealed by race and ethnicity, given the large racial and ethnic disparities in HIV incidence among PWID, a population where 1 in 7 Black women is expected to contract HIV in her lifetime compared to 1 in 49 white women and 1 in 108 white men,³ a specific focus on reducing HIV incidence among Black, Indigenous, and people of color who inject drugs is necessitated. Observed differences in sexual risk assessment by patient sex highlight the need to standardize screening.

This study has several limitations. Although SUD bridge clinic treatment models are increasingly available, study location in an urban academic safety-net hospital with significant SUD treatment infrastructure may limit generalizability to settings with fewer resources. Additionally, our retrospective chart review with a fairly small sample size ($n = 207$) relied on patient-reported data and provider documentation, which may be subject to underreporting for certain stigmatized risk behaviors, such as sharing injection equipment or condomless sex, and EMR documentation of demographics (e.g., race and ethnicity) which may be subject to misclassification. Given the likelihood of underreporting and variability in provider documentation practices, our study likely underestimates PEP and PrEP eligibility and discussions; nonetheless, the observed rates of eligibility—more than 1 in 4 new patients—are compelling. Additionally, our EMR reports were unable to capture all telemedicine encounters during the first two weeks of modified COVID operations beginning March 16, 2020 so we were unable to evaluate new telemedicine patient visits during that period. As this study was not designed to assess the impact of COVID-19's operational changes on PEP and PrEP volume, our analysis of the COVID-19 pandemic's impact on PEP and PrEP volume was limited to descriptive statistics. The low number of PEP and PrEP prescriptions as well as the complexity of identifying a proper control group limited further analysis. Finally, because our EMR does not link consistently to pharmacy prescription fill data, we were unable to assess rates of TDF/F prescription pick up, refills, and adherence; future research should assess patient uptake data (including prescription fills, adherence, and retention) for patients initiated at bridge clinics compared with more traditional settings. Additional work should also explore the challenges patients may face in transitioning their PrEP care to more traditional outpatient environments,²² and any implications for viral resistance.³⁵

Closing PEP and PrEP access gaps for PWID requires leveraging both clinical and nonclinical settings where PWID already access services. Our study demonstrates that bridge clinics, designed to serve PWID in need of low-barrier SUD treatment access, offer an important opportunity to deliver biomedical HIV prevention services in this population. Additional work is needed to understand why bridge clinic patients decline PEP/PrEP so that PEP/PrEP delivery can be tailored to their specific needs. Future work should also focus on systems interventions that support consistent HIV risk assessment and PEP/PrEP

discussions between patients and providers as well as strategies to optimize PEP/PrEP adherence in bridge clinic settings.

ACKNOWLEDGMENTS

The authors thank the staff of Faster Paths to Treatment at Boston Medical Center.

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