A Pharmacist-Led, Same-Day, HIV Pre-Exposure Prophylaxis Initiation Program to Increase PrEP Uptake and Decrease Time to PrEP Initiation

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Abstract

Mississippi has one of the highest rates of HIV in the United States, but has low pre-exposure prophylaxis (PrEP) uptake, particularly among black men who have sex with men (MSM) and women. From November 2018 to May 2019, patients at high risk of HIV who tested negative for HIV at a nonclinical testing center in Jackson, Mississippi, were referred to an on-site clinical pharmacist for same-day PrEP initiation. The pharmacist evaluated patients for medical contraindications to PrEP, but no baseline labs were obtained. The pharmacist provided a PrEP prescription and scheduled a clinical appointment for patients within 6 weeks, at which time they were evaluated by a clinician and completed baseline labs. The pharmacist evaluated 69 patients for PrEP; 57% were MSM, 77% were black, and 65% were uninsured. All patients received a PrEP prescription; 83% received the prescription the same day and 97% received it within 5 days. Fifty-three (77%) of 69 clients filled the prescription; 87% of whom filled it within 1 week. Only 23 (43%) of 53 clients who filled their prescription attended their initial clinical appointment within 6 weeks of obtaining PrEP. There were no differences in PrEP initiation or retention by patient sex/gender. This pilot program suggests that an on-site pharmacist working in a nonclinical testing center in the southern United States can successfully initiate PrEP among predominately low-income black MSM. Future efforts should seek to better integrate laboratory testing into this demedicalized model of PrEP and to improve retention in care.

Keywords: HIV, pre-exposure prophylaxis, pharmacist

Introduction

THE HIV EPIDEMIC in Mississippi (MS) is among the most severe in the United States (US). Relative to other US States, MS has the eighth highest rate of HIV diagnosis among all adults¹ and the second highest rate among men who have sex with men (MSM).² The prevalence of HIV among black men and women is 5 and 10 times higher, respectively, than white men and women,³ and a staggering 35% of black MSM in MS are diagnosed with HIV by age 27.⁴

Changing the course of the HIV epidemic in MS requires a fundamental shift in the delivery of HIV prevention interventions. Pre-exposure prophylaxis (PrEP) is a promising catalyst for change, but the scarce PrEP clinical capacity of MS and profound structural barriers have limited PrEP uptake in the State.^{5–8} Organizations in MS that offer HIV and sexually transmitted infection (STI) testing have developed protocols to refer clients to clinical PrEP providers, but referring entities have noted substantial drop-off—in some cases, as high as 90%—from the point of PrEP referral to PrEP initiation.⁹ Eliminating the referral period by providing

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PrEP or a PrEP prescription at the point of testing HIV negative, known as rapid initiation or same-day initiation, is a promising method for increasing PrEP uptake. Indeed, same-day PrEP programs in clinical settings in the US have been found to be safe and feasible approaches to initiating PrEP.^{10–12} However, most same-day PrEP programs are located within clinics that are able to obtain specimens for recommended laboratory tests (i.e., HIV antigen/antibody, syphilis and hepatitis B serology, other STIs, and serum creatinine) at the time of PrEP initiation.¹³ In the setting of low PrEP clinical capacity, developing models for rapid PrEP initiation that can be integrated into nonclinical settings and without direct physician involvement is paramount.

Utilizing clinical pharmacists to provide same-day PrEP is one such model. Pharmacists' accessibility provides an opportunity for ongoing adherence counseling, addressing barriers related to medication uptake and/or adherence, and linkage to additional health care services if necessary.^{14,15} Several pharmacist-managed, HIV PrEP models have demonstrated success in the US¹⁴ and may be an ideal model in a state such as MS.⁷ We implemented a pharmacist-led, same-day, PrEP pilot program in Jackson, MS, to facilitate PrEP uptake and decrease time to PrEP initiation.

Materials and Methods

Population and setting

Patients presenting to Express Personal Health (EPH) from November 2018 to May 2019 were eligible for same-day PrEP. EPH is a University of Mississippi Medical Center-affiliated, walk-in HIV/STI testing center in Jackson, MS. EPH is colocated in the same building as the Mississippi State Department of Health (MSDH) STD Clinic and routinely provides rapid HIV testing for individuals receiving MSDH partner services. EPH, which is staffed by two nurses, sees ~200 patients per month.

Staff at the clinic offered same-day PrEP to EPH patients who tested HIV negative on a rapid HIV test (Alere Determine™ HIV-1/2 Ag/Ab Combo; Alere, Inc., Waltham, MA) and explicitly recommended same-day PrEP to all men who reported sex with men, all transgender women, and cisgender women with one of the following: diagnosis with a bacterial STI, contact with a partner with HIV/STI, ongoing sexual relationship with an HIV-positive/unknown status partner, recent injection drug use, or ongoing sexual relationship with an MSM.

Rapid PrEP initiation program

Staff at EPH briefly discussed PrEP with eligible patients and escorted interested patients to a clinical pharmacist (K.V.B.) colocated in the same building. Patients who could not meet with the pharmacist that day were contacted by the pharmacist within 48 h. The pharmacist provided patients with information about PrEP effectiveness, adherence, side effects, and the schedule for ongoing clinical care. The pharmacist obtained patients' medical history (including history of kidney disease or hepatitis B infection), evaluated patients for signs and symptoms of acute HIV, and completed insurance paperwork (including Medicaid) and/or pharmaceutical company patient assistance paperwork. Patients with signs and symptoms of acute HIV or indications for postexposure pro-

phylaxis (PEP) were referred on the same day to an infectious disease specialist for evaluation. For patients without signs and symptoms of HIV, the pharmacist sent a 60-day PrEP prescription to patients' preferred pharmacy for either pick up or shipment from the pharmacy. In MS, pharmacists do not have independent prescriptive authority, but pharmacists can enter into collaborative practice agreements (CPA) with physicians, which allow pharmacists working within the context of a defined protocol to assume professional responsibility for performing patient assessments, counseling, referrals, ordering laboratory tests, administering medication, and monitoring and adjusting medication regimens.¹⁶ The CPA allowed PrEP prescriptions to be sent under the pharmacist's name, but billed under a physician's name.¹⁷

Additionally, the pharmacist scheduled patients' first clinical PrEP appointment. At the time of the clinical appointment, which was scheduled within 6 weeks, the patient received recommended baseline laboratory tests that had not yet been obtained (i.e., serum creatinine test and hepatitis B screening). The pharmacist contacted patients weekly for 1 month (or until receiving a response) if they did not pick up their prescription or if they did not attend their clinical appointment. The pharmacist did not refill the prescription if patients did not attend their clinical appointment.

Outcome monitoring and analysis

The pharmacist entered all patient information into a case management database (REDCap®)^{18,19} and verified patients' prescription pick up and attendance at the clinical appointment with the pharmacy and clinical provider, respectively. The pharmacist canceled prescriptions that were not picked up within 2 weeks.

We evaluated the number and percent of patients who were evaluated by the pharmacist, received a PrEP prescription, filled the prescription, and attended a clinical appointment within 6 weeks of filling their prescription. This pilot program and evaluation were intended to inform local implementation of same-day PrEP and were thus exempt from human subject research.

Results

Between November 1, 2018, and May 31, 2019, there were 69 patients referred to the pharmacist for same-day PrEP. Of these, 40 (58%) identified as men, the majority of whom (95%) were MSM. Twenty-nine patients (42%) were women, including two transgender women (Table 1). Approximately one-third were less than 24 years old, three-quarters were black non-Hispanic, and two-thirds did not have insurance. Nearly 20% were diagnosed with an STI or were in contact with a partner with HIV/STI.

Of 69 clients referred to the pharmacist for same-day PrEP, all received a prescription for PrEP. Two patients (2.9%) were prescribed PEP, but later transitioned to PrEP. Seventy-seven percent (53 of 69) of patients who received a prescription ultimately filled it, and 43% (23 of 53) who filled their prescription attended a clinical appointment within 6 weeks (Fig. 1). Thus, 33% (23 of 69) of patients who were referred for same-day PrEP filled a PrEP prescription and were successfully linked to ongoing PrEP care; this proportion was similar for men (42%; 14 of 40) and women (45%; 9 of 29). Of the 30 individuals who filled their PrEP prescription,

TABLE 1. CHARACTERISTICS OF PATIENTS REFERRED FOR SAME-DAY PRE-EXPOSURE PROPHYLAXIS, NOVEMBER 2018–MAY 2019 (N=69)

	Total (N=69) n (%)	Men (n=40) n (%)	Women (n=29) n (%)
Age (years)			
18–24	22 (31.9)	17 (42.5)	5 (17.2)
25–29	21 (30.4)	12 (30.0)	9 (31.0)
30–34	10 (14.5)	5 (12.5)	5 (17.2)
≥35	16 (23.2)	6 (15.0)	10 (34.5)
Race/ethnicity			
Black non-Hispanic	53 (76.8)	30 (75.0)	23 (79.3)
White non-Hispanic	14 (20.3)	8 (20.0)	6 (20.7)
Other non-Hispanic	1 (1.5)	1 (2.5)	0 (0.0)
Hispanic	1 (1.5)	1 (2.5)	0 (0.0)
Indication for PrEP ^a			
MSM	38 (55.1)	38 (95.0)	0 (0.0)
Transgender woman	2 (2.9)	0 (0.0)	2 (6.9)
Diagnosed with STD	10 (14.5)	7 (17.5)	3 (10.3)
Contact with partner with HIV/STD	3 (4.3)	2 (5.0)	1 (3.4)
Sexual partner of unknown or serodiscordant HIV status	22 (36.2)	^b	22 (75.9)
Sexual partner is MSM	1 (1.4)	^b	1 (3.4)
Insurance status ^c			
Has insurance	24 (34.8)	15 (37.5)	9 (31.0)
Does not have insurance	45 (65.2)	25 (62.5)	20 (69.0)
Payment for PrEP			
Pharmaceutical company patient assistance program	52 (75.4)	30 (75.0)	22 (75.9)
Private insurance	9 (13.0)	8 (20.0)	1 (3.5)
Medicaid	7 (10.4)	6 (20.7)	1 (2.5)
Out of pocket	1 (1.5)	1 (2.5)	0 (0.0)
PrEP prescription delivery			
Pick up in pharmacy	53 (76.8)	30 (75.0)	23 (79.3)
Shipped from pharmacy	16 (23.2)	10 (25.0)	6 (20.7)

^aNot mutually exclusive. All MSM and transgender women were eligible for same-day PrEP. Cisgender women were eligible for same-day PrEP if they were diagnosed with STI or were in contact with a partner with HIV/STI, if they reported being in an ongoing sexual relationship with a partner of unknown or serodiscordant HIV status, or if they reported being in a sexual relationship with a male sex partner who also has sex with men.

^bIndication for cisgender women only.

^cAt the time of referral to the pharmacist.

MSM, men who have sex with men; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection.

FIG. 1. Number and percentage of patients retained along steps of the same-day, pre-exposure prophylaxis program (N=69).

but did not attend their clinical appointment, 17 (57%) did not respond to subsequent contact attempts by the pharmacist, six rescheduled their appointment, five were no longer interested in taking PrEP, and two reported that inadequate access to transportation prevented them from attending their appointment. Of the 16 individuals who did not pick up their PrEP, 4 (25%) later presented to a clinic to initiate PrEP.

Nearly all patients ($n=62$; 90%) were seen by the pharmacist the same day as their rapid HIV test. Eighty-three percent of patients (57 of 69) received their PrEP prescription from the pharmacist the same day that they tested HIV negative and 97% ($n=67$) received their prescription within 5 days. Forty-one percent (22 of 53) of patients filled their PrEP prescription the same day and 87% (46 of 53) filled it within 1 week. The median number of days from filling the PrEP prescription to attendance at a clinical appointment was 20 (interquartile range: 4–35 days).

Discussion

In this pharmacist-led, same-day, PrEP pilot program in Jackson, MS, we successfully provided PrEP prescriptions to nearly 70 individuals at high risk for HIV in 7 months, with over 80% of clients receiving a PrEP prescription the same day that they tested negative for HIV. Nearly 90% of patients filled their prescription within 1 week, but only about one-third ultimately attended a clinical appointment. Our findings not only demonstrate the feasibility of integrating a same-day PrEP initiation program in a nonclinical setting in a high HIV prevalence urban area but also highlight the need for programs to enhance retention in ongoing PrEP care.

This model of same-day PrEP was conceptualized to address the high rate of drop-off noted in a PrEP referral model previously implemented in Jackson, MS.⁹ That program, integrated into the MSDH partner services program, referred individuals newly diagnosed with STD, who tested HIV negative, to a clinical PrEP provider for a PrEP initiation visit. In that model, only 11% of individuals referred for PrEP successfully linked to a clinical PrEP provider. In this study, we successfully provided a PrEP prescription to all patients ($N=69$) who were evaluated by the pharmacist, allowing patients to initiate PrEP in the time between testing HIV negative and linking to a clinical PrEP provider.

Other same-day PrEP programs in sexual health clinics in Denver, Washington D.C., and New York City have established the feasibility of the same-day model in clinical settings. In the municipal STD clinic in Denver during an 18-month period, 131 patients were referred for a same-day PrEP evaluation, of whom 100 (76%) initiated same-day PrEP.¹⁰ In a Washington D.C. 10-month pilot program in a sexual health clinic, 38 (88%) of 43 individuals received a same-day PrEP prescription, of whom 90% filled it.¹² In New York City, nearly 1400 individuals were prescribed same-day PrEP in their sexual health clinics over an 18-month period.¹¹

Comparably, we found that 77% of patients who received a PrEP prescription ultimately filled it; however, unlike these clinic-based programs, we did not obtain specimens for creatinine testing, hepatitis B screening, or laboratory-based HIV testing at the time of PrEP initiation. In our model, patients received a rapid HIV test and STI testing as per standard of care in a testing center, but all other baseline laboratory tests were to be done during the client's first

clinical appointment within 6 weeks. This model permitted us to start clients on PrEP outside of a clinical setting—unlike the aforementioned programs in Denver, Washington D.C., and New York City—but the safety of this model as it relates to kidney toxicity and bone mineral density is unknown. However, based on large cohort studies of PrEP users in the US, we did not anticipate clinically significant changes in kidney function or bone mineral density in the time between PrEP initiation and the first clinical appointment in 6 weeks.^{20–22} Importantly, although the pharmacist did collect limited past medical history at the time of the initial PrEP evaluation, we do not have information on medical contraindications to PrEP identified during patients' clinical follow-up visits. However, data from a same-day PrEP program in New York City¹¹ indicate that fewer than 1% of nearly 1400 patients initiating same-day PrEP had a medical contraindication, which suggests that the prevalence of medical contraindications in our population would likely be very low.

Although we successfully provided a PrEP prescription to all patients, only 33% of individuals who received a PrEP prescription ultimately filled it and attended a clinical appointment. This is lower than that observed in same-day PrEP programs in Denver and Washington D.C., where 78% and 56% of individuals, respectively, who received same-day PrEP linked to a clinical PrEP provider within 1 month.^{10,12} Despite weekly outreach to patients by the pharmacist after providing patients with a PrEP prescription, a substantial proportion (57%) of our same-day PrEP patients who did not attend their clinical appointment were lost to follow-up. As such, the reasons why most patients did not link to PrEP care are unclear. Some patients ($n=5$) indicated that they no longer wanted to take PrEP, highlighting the need for ongoing opportunities (e.g., frequent HIV testing) for PrEP education and initiation.

More broadly, these findings underscore the importance of implementing new methods to enhance retention in PrEP care, which are tailored to the local population. Indeed, approaches such as telemedicine for ongoing PrEP care are becoming increasingly popular^{7,23,24} and have already been deployed in some parts of MS.²⁵ Notably, manifestations of stigma within health care organizations and among PrEP providers, including pharmacists, may contribute to low PrEP uptake and retention, particularly among black men in southern US.²⁶ Efforts to reduce such stigma should be central to all models of PrEP provision.

Our same-day PrEP program was unique, in that a clinical pharmacist was responsible for completing the initial PrEP evaluation, providing clients with a PrEP prescription, and linking patients with a clinical provider. This is a different model than a pharmacy-based PrEP program, where patients receive ongoing PrEP care through pharmacies.^{7,27} Pharmacy-based PrEP programs in the Midwestern, southwestern, and western states of US have demonstrated the ability to retain individuals on PrEP at comparable levels with that seen in clinical settings^{28–30} and may be particularly well suited for areas in the US with low clinical capacity, such as the southern US.⁷ However, even in the absence of a pharmacy-based program, pharmacists may play a key role at several steps along the PrEP care continuum, including increasing PrEP awareness, uptake, adherence, and retention.¹⁴

Our findings should be interpreted in light of several limitations. First, our results are only based on outcomes of 69 patients, and it is unclear if we would see similar results in a

larger population or a population outside of Jackson. Second, we did not record the total number of patients who should have been referred to the pharmacist for PrEP initiation, so we do not know the success of our program in reaching PrEP-eligible individuals at this single testing location. Third, there was no comparison group included, so the effectiveness of this program in promoting PrEP uptake and retention is unclear. Fourth, we did not systematically collect information about why patients did not fill their PrEP prescription, and we were unsuccessful in recontacting over half of the patients who did not attend a clinical appointment. We also did not systematically collect information about patient's adherence to a standard PrEP regimen. This information would be useful to guide the development of a scaled-up, same-day PrEP model focused on retention in PrEP care.

In conclusion, this same-day, PrEP pilot program demonstrated the feasibility of a clinical pharmacist providing PrEP to a population of predominantly young black MSM and women at high risk for HIV. There is an urgent need to implement new models of PrEP delivery in areas that are heavily impacted by HIV, but do not have a large network of clinical PrEP providers. Same-day PrEP programs integrated into nonclinical settings and pharmacist-based models of PrEP initiation hold promise as mechanisms to initiate PrEP at the time of HIV testing; such programs can be deployed at locations where HIV testing is routinely provided, but there is no on-site clinical infrastructure to support laboratory testing (e.g., community-based organizations or mobile HIV testing sites). In conjunction with methods to improve retention in PrEP care, these programs have the potential to increase PrEP uptake among a population most affected by the HIV epidemic.

Acknowledgments

The authors would like to thank the nursing staff at EPH and the Disease Intervention Specialists at the MSDH for their referrals to same-day PrEP. The authors also acknowledge Courtney Gomillia at the University of Mississippi Medical Center for her assistance with REDCap.

Author Disclosure Statement

C.M.K. and M.R.G. have received donations of specimen collection kits and reagents from Hologic, Inc., unrelated to the submitted work. K.V.B. and L.M. have received honoraria as consultants to Gilead Sciences, and L.M. has received honoraria as a member of the Gilead Sciences speaker bureau. All other authors declare no conflicts of interest.

Funding Information

This work was funded by a 2018 CFAR Supplement Award from the University of Washington/Fred Hutch Center for AIDS Research, an NIH-funded program under award no. AI027757, which is supported by the following NIH Institutes and Centers: NIAID, NCI, NIMH, NIDA, NICHD, NHLBI, NIA, NIGMS, and NIDDK.

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