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Transgender Women and PrEP Care: High PrEP Adherence in a Real-World Health Care Setting in New York City

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Abstract

Background: Transgender women and trans feminine individuals (TGW/TFI) are a high priority population for the provision of HIV pre-exposure prophylaxis (PrEP) care within the United States, but there is limited research that focuses specifically on PrEP adherence within this population.

Setting: Observational study of patients prescribed PrEP at a community-based health center.

Methods: We enrolled 100 TGW/TFI PrEP patients at a community health center during clinic visits. Adherence data were collected at three time points, using self-report surveys, patient interviews, and urine assays measuring tenofovir. Data were summarized descriptively.

Results: The sample was diverse in age, race/ethnicity, and socioeconomic characteristics. Participants demonstrated strong PrEP adherence; at least 80% of the sample reported 90% or greater adherence at each time point. Concordance between self-report and urine assay was high. Among patients who reported taking PrEP within the last 48 hours, 82%-92% had detectable urine tenofovir. However, many patients reported PrEP stop periods of 4 or more days (28%-39% per time point).

Conclusions: Our data highlight TGW/TFI's capacity to adhere to daily PrEP and sustain PrEP use over time. The concordance between patient self-report and urine TFV levels suggest that providers can trust patient reports of PrEP adherence behavior, and support the use of adherence conversations in clinical settings, without the need for point of care biological monitoring. Findings also underscore the importance of continued attention to drivers of PrEP stops at the

patient, clinic, and systems levels and the development of strategies that support sustained PrEP use.

Keywords: HIV, pre-exposure prophylaxis (PrEP), implementation science, transgender women, transgender, medication adherence

Introduction

In the United States (US), transgender women and transfeminine individuals (TGW/TFI) experience disproportionate rates of HIV infection.[1–3] HIV prevalence among TGW/TFI is estimated at 14.1% for laboratory confirmed tests, and 21% for self-reported HIV status, with the highest prevalence found among African American TGW.[2] HIV pre-exposure prophylaxis (PrEP) presents an opportunity to address this disparity, however, there is a considerable lack of research on PrEP with this population.[4–8] Existing research has predominantly focused on documenting facilitators and barriers to PrEP uptake among TGW/TFI, including PrEP awareness, attitudes, acceptability and eligibility.[9–24] Few studies in the US have included a substantial sample of TGW/TFI on PrEP,[8,10] and none have closely examined dynamics over time of real-world PrEP use (i.e., in absence of research incentive or intervention). As such, there has been little investigation of PrEP adherence patterns among TGW/TFI in the US.[6,7,25–28] There is an urgent need to understand patterns of PrEP adherence among TGW/TFI in real world clinical settings. These data would contribute to our ability to ensure that this high-priority population receives access both to PrEP medication and to the necessary supports to promote PrEP efficacy.

In this brief report, we present data on PrEP adherence among a cohort of TGW/TFI receiving PrEP as part of their comprehensive health care at a Federally Qualified Health Center. We compared biological and self-report adherence measures and examined patterns of continuous or interrupted PrEP adherence over time.

Methods

Participants and Procedures

Data originate from *FIRED UP*, an observational cohort study of TGW/TFI patients at a Federally Qualified Health Center (FQHC) serving lesbian, gay, bisexual, transgender, and queer (LGBTQ) communities in New York City. The study was designed to understand and improve PrEP implementation efforts with TGW/TFI in a real-world setting. Data were collected from November 2018 to May 2020. Study staff embedded within the health center identified eligible patients with upcoming healthcare appointments, and conducted screening, informed consent, and enrollment procedures at appointments. Eligibility criteria included 18 years of age or older, negative HIV status, sex recorded at birth of 'male,' and gender identity of woman, transgender woman, trans feminine, non-binary, two-spirit, or gender non-conforming.

The present analysis includes 100 TGW/TFI who were PrEP patients at the clinic and had been prescribed once daily tenofovir disoproxil fumarate/emtricitabine. The majority of the sample (54%) were under 30 years of age, 50% reported a Hispanic/Latinx ethnicity, 22% were White non-Hispanic, 20% were Black non-Hispanic, and 8% reported other race and non-Hispanic. Most participants identified as women or transgender women (88%). More than half reported having less than a 4-year college degree (56%), 72% reported earning < $25,000 a year,

89% reported having health insurance (67% Medicaid/Medicare; 22% private insurance), and 18% reported current unstable housing or homelessness.

Measures and Data Analysis

Study data were collected at three time points, T1 (enrollment), T2 (approximately 3 months after enrollment), and T3 (approximately 6 months after enrollment), with date-range flexibility to accommodate patient availability and scheduled clinic visits.

Online surveys were completed prior to or at each study visit. These included two questions from a self-report measure of medication adherence[29]: "In the last 30 days, on how many days did you miss your PrEP pill?" and "In the last 30 days, how often did you take your PrEP medication exactly as prescribed by your doctor?" (6-point Likert-type scale, ranging from "Never" to "Always"). In these analyses, the second item was dichotomized into Always/Almost Always versus Usually/Sometimes/Rarely/Never.

Patient interviews occurred immediately before or after patients' clinic visits, and mirrored standard clinical PrEP adherence conversations. Research staff asked participants when they had taken their most recent PrEP pill and whether or not they had stopped taking PrEP for four or more consecutive days in the past three months. Those who reported four or more consecutive days of missed pills were defined as having a "PrEP stop," based on data suggesting that HIV protection is reduced once pill-taking drops below four pills in a given 7-day period.[30,31] Those who did not were defined as having "continuous PrEP adherence" during that three-month period. This question was also asked on the online survey. Participants who reported a PrEP stop were asked whether or not they had resumed taking PrEP (coded as a "restart").

Urine samples were collected from participants who reported having taken PrEP within the 7 days preceding their follow up study visit. Samples were analyzed using a liquid chromatography-tandem mass spectrometry (LC-MS/MS) urine assay with high sensitivity and specificity for tenofovir, performed by a third-party laboratory.[32] This assay has been validated, demonstrating high sensitivity and positive predictive value when compared to dried blood spots (DBS), as well as greater sensitivity than plasma-based measures.[33–35] It differentiates between high levels of urine TFV (>1000 ng/mL), lower levels of urine TFV (10-1000 ng/mL), and the absence of detectable levels (<10 ng/mL). High levels indicate having taken a pill in the last 7 days, and are a probable indicator for last pill within the last 2-3 days.[33,36] Urine specimen collection is more commonplace than DBS in clinical care, and also tends to be more widely acceptable to patients.[40] These factors increase study procedure generalizability to other community-based settings.

Urine TFV results are presented for participants who reported being on PrEP at the study visit and provided a urine sample with valid assay results (T2, n = 64; T3, n = 55). Additional participants had follow up visits at these time points, but their urine TFV data are not included in the analysis, either because they reported being off PrEP at the time of their visit (T2, n = 14 ; T3, n = 13), or due to specimen processing issues (T2, n = 2; T3, n = 5).

Participants received $40 for T1 and T2 surveys, each, and $60 for the T3 survey, in cash or online gift card, based on participant preference. Participants did not receive compensation for clinic visits and were not incentivized to use PrEP. Follow up visit data were entered into a secure HIPAA-compliant online REDCap (Research Electronic Data Capture) database hosted by the City University of New York (CUNY).[41,42] Ethical approval was obtained from the CUNY Institutional Review Board.

Results

Although all participants in the sample were receiving PrEP prescriptions from the health center at enrollment, only 87% reported being on PrEP at the time of their T1 survey. The remaining 13% had temporarily stopped PrEP for a variety of reasons (e.g., unstable housing, insurance gap, missed their most recent refill appointment), and planned to restart PrEP. Table 1 presents self-reported adherence data from surveys and patient interviews. Between 78% and 82% reported taking PrEP "always/almost always" as prescribed at each time point, and between 80% and 82% reported missing three or fewer pills (90% or greater adherence) in the past 30 days. Regarding most recent dosage, 77% of patients reported taking a PrEP pill in the last 48 hours at T2, and 73% of participants reported this at T3.

At T2 patient interviews, 72% of patients reported continuous adherence in the prior three months, and 61% reported continuous adherence at T3. Of those who reported a PrEP stop at the T2 assessment (n = 21, 28% of the sample), 57% restarted and stayed on PrEP, 29% did not restart, and 14% reported multiple PrEP stops. At T3, 39% of the sample reported a stop (n = 28), of whom 54% restarted PrEP, 43% did not, and 4% reported multiple PrEP stops. We examined overall 9-month PrEP coverage, limiting the analysis to participants with survey data at all 3 time points (n = 77). Forty-four percent of participants reported continuous PrEP adherence over all three 3-month periods.

In Table 2, we report urine TFV concentrations overall and stratified by self-reported adherence. TFV was detected among 86% of valid samples at T2 and among 76% at T3, with 78% and 73% of samples indicating >1000 ng/ml, respectively. The results display a high degree of concordance between self-report and urine TFV detection level. Among participants who said

they had taken PrEP within the last 48 hours during their patient interview, 92% and 82% (at T2 and T3, respectively) had TFV detected in their urine, and the majority (83% at T2 and 80% at T3) had a high concentration of TFV detected (>1000 ng/mL). Among participants who said that they "always or almost always" took PrEP as prescribed on their self-report survey, 78% and 83% had a high concentration of TFV detected, at T2 and T3 respectively.

DISCUSSION

In our study of 100 TGW/TFI receiving PrEP in a real-world clinic, the vast majority had good PrEP adherence. Patients' self-report was consistent with TFV levels detected in urine, with TFV >1000 ng/mL detected in 83% of samples at T2 and 80% of samples at T3. The majority of patients (56%) reported at least one PrEP "stop" during the nine-month study period. Most restarted PrEP, with between 16% and 21% stopping and restarting PrEP during each three-month period.

Our data highlight TGW/TFI's capacity to adhere to daily PrEP and sustain PrEP use over time. Past studies have suggested that that healthcare providers may be less willing to prescribe PrEP to patients who they believe will not adhere.[43–47] Given research documenting evidence of bias toward TGW/TFI within U.S. healthcare,[48–53] it is important to underscore data that demonstrate high rates of adherence in this population. It is also important to note the concordance between patient self-report and urine TFV levels. These data suggest that providers can – and should – trust patient reports of PrEP adherence behavior, and support the use of adherence conversations in clinical settings. While there have been calls for increased use of point-of-care (POC) biological adherence monitoring for PrEP users,[54,55] this approach raises several concerns. In addition to the logistical and cost barriers for community health centers,

evidence suggests that this type of "monitoring" might be triggering for patients, or make them feel like they are not being trusted.[56] This issue might be even more salient for TGW/TFI; the largest study of using biomarker testing to prompt increased PrEP adherence support was only able to enroll one TGW.[57] Our data suggest that training providers to have more effective and open conversations with their patients about adherence may be an optimal strategy for ongoing clinical care.[58]

Our data have important implications for understanding and supporting patients who may experience periodic breaks in their daily PrEP use. While a complete analysis is beyond the scope of this brief report, the majority of reasons for PrEP "stops" focused on insurance/pharmacy issues, missed visits/missed refills or lost pills, or changes in sexual behavior that made PrEP less relevant. Most patients who stopped reported restarting PrEP, but we do not know whether they had an exposure in the interim. Additional research should focus on drivers of PrEP stops at the patient, clinic, and systems levels, and develop strategies that facilitate "prevention effective adherence."[59]

Our study is limited by a sample collected in a real-world clinical setting, in which we prioritized the needs of our sample as patients, rather than as research participants. This method caused variability in sample size across time points, but may increase the generalizability of our findings and the validity of our data, as participants were not concerned about "pleasing" our research team in order to receive medication or compensation. Participants were patients of an LGBTQ-focused health center with specialization in PrEP and gender-affirming trans healthcare, as well as with integrated insurance and PrEP payment navigation services. This may constrain immediate generalizability of our findings for healthcare contexts without such program components in place.

In conclusion, among this sample of TGW/TFI receiving PrEP in an LGBTQ-focused community health center, we found strong PrEP adherence and high concordance between self-report and biological measures. The need for more data on real-world PrEP use among TGW/TFI continues to be critical, as is the development of comprehensive, patient-focused strategies for supporting PrEP adherence and sustained prevention-effective use.

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Table 1. Self-Reported PrEP Adherence Measures									
		N	*%*		*N*	*%*		*N*	*%*
PrEP Use in the Last 30 Days [1]		T1			T2			T3	
Total with data, per time point		100	-		89	-		81	-
On PrEP at Survey Date		87	87%		76	85%		68	84%
Takes PrEP as prescribed during past 30 days									
Always or almost always		68	78%		62	82%		56	82%
Usually or less often		19	22%		14	18%		12	18%
Number of missed pills in past 30 days									
0 missed pills (100% adherence)		38	44%		27	36%		23	34%
1-3 missed pills (90-99% adherence)		32	37%		35	46%		29	43%
4-6 missed pills (80-89% adherence)		9	10%		9	12%		5	7%
7 or more missed pills (<80% adherence)		8	9%		5	7%		11	16%
Most Recent Pill Taken [2]									
Total with data, per time point		-	-		81	-		73	-
Took pill within last 48 hours		-	-		62	77%		53	73%
PrEP Stop and Restart Patterns, Last 3 Months [2]									
Total with data, per time point		-	-		72	-		72	-
Continuous PrEP adherence, no stops		-	-		53	72%		44	61%
Stopped/off PrEP and restarted		-	-		12	16%		15	21%
Stopped/off PrEP, no restart		-	-		6	8%		12	17%
Multiple PrEP stops		-	-		3	4%		1	1%
Continuous PrEP Adherence, Entire Study [1]		T1 through T3							
Total with data at all three time points		77	-						
Continuous adherence over all 3 three-month periods		34	44%						
Continuous adherence for 2 periods only		23	30%						
Continuous adherence 1 period only		12	16%						
PrEP stops in all 3 periods		8	10%						
[1] Survey data, [2] Patient interview data									

Table 2. Urine TFV Concentration Among Patients On PrEP [1]					
	T2			T3	
	N	*%*		*N*	*%*
Total Sample	64	-		55	-
TFV Detected	55	86%		42	76%
>1000 ng/mL	50	78%		40	73%
10-1000 ng/nL	5	8%		2	4%
TFV Not Detected (<10 ng/mL)	9	14%		13	24%
Patient Interview: Self-Reported Last Pill [2]					
Took pill within last 48 hours	59	-		49	-
TFV Detected	54	92%		40	82%
>1000 ng/mL	49	83%		39	80%
10-1000 ng/nL	5	8%		1	2%
TFV Not Detected (<10 ng/mL)	5	8%		9	18%
Online Survey: Takes PrEP As Prescribed (past 30 days) [3]					
Always or Almost Always	55	-		41	-
TFV Detected	46	84%		34	83%
>1000 ng/mL	43	78%		34	83%
10-1000 ng/nL	3	5%		0	0%
TFV Not Detected (<10 ng/mL)	9	16%		7	17%
Usually or less often	9	-		12	-
TFV Detected	9	100%		7	58%
>1000 ng/mL	7	78%		5	42%
10-1000 ng/nL	2	22%		2	17%
TFV Not Detected (<10 ng/mL)	0	0%		5	42%

[1] Table includes patients with a valid urine specimen who self-reported recent PrEP use on their specimen date, defined as last pill within 7 days of specimen collection.
[2] Based on self-reported last pill data on date of specimen collection
[3] Based on survey data, which may fall on a different date from the urine specimen collection