HHS Public Access

Author manuscript

AIDS Behav. Author manuscript; available in PMC 2023 July 27.

Published in final edited form as:

AIDS Behav. 2023 March ; 27(3): 901–908. doi:10.1007/s10461-022-03826-y.

PrEP Use and Adherence among Transgender Persons in Chicago, IL (SHIPP Study, 2014–2018, USA)

Ashley Townes[1,2], **Maria Pyra**[3,4], **Dawn K. Smith**[2], **Aruna Surendera Babu**[5], **Tiffany Williams**[6], **Jeffrey Wiener**[2], **Kirk D. Henny**[2], **John Schneider**[3]

[1] Oak Ridge Institute for Science and Education, Oak Ridge, TN, USA

[2] Division of HIV Prevention, Centers for Disease Control and Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, 1600 Clifton Road, NE, Mailstop 8-4, 30329 Atlanta, GA, USA

[3] Howard Brown Health, Chicago, IL, USA

[4] University of Chicago, Chicago, IL, USA

[5] ICF International Inc, Atlanta, GA, USA

[6] Social & Scientific Systems, Silver Spring, MD, USA

Abstract

Few studies investigating daily oral preexposure prophylaxis (PrEP) focus on transgender persons. The Sustainable Health Center Implementation PrEP Pilot (SHIPP) Study included a large observational cohort of transgender persons with implications for PrEP in the United States. We examined data from SHIPP's observational cohort and its Medication Adherence Substudy (MAS) to understand adherence among transgender participants in Chicago, IL. We assessed adherence by the proportion of days covered (PDC) for PrEP medication prescriptions, self-reported interview

✉ Ashley Townes atownes@cdc.gov.

Authors' Contributions Study conceptualization and design were performed by Ashley Townes and Dawn K. Smith. Data analyses were performed by Aruna Surendera Babu, Tiffany Williams, and Jeffrey Wiener. The first draft of the manuscript was written by Ashley Townes, Maria Pyra, and Dawn K. Smith. All authors commented on subsequent versions of the manuscript. All authors read and approved the final manuscript.

Conflict of Interest The authors declare that they have no relevant financial or nonfinancial conflicts of interest to disclose.

Financial Disclosure No financial relationships relevant to this article to disclose.

Code Availability Not applicable.

CDC Disclaimer The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention. This analysis was supported in part by an appointment to the Research Participation Program at the Centers for Disease Control and Prevention administered by the Oak Ridge Institute for Science and Education through an interagency agreement between the U.S. Department of Energy and the Centers for Disease Control and Prevention.

Ethics Approval The SHIPP Study received human subjects research review and approval by the CDC IRB and the IRB of the City of Philadelphia IRB and was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Consent to Participate All participants in the SHIPP medication adherence substudy (MAS) provided written informed consent for data and specimen collection and for publication of anonymized data.

Consent for Publication Not applicable.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s10461-022-03826-y.

data, and concentrations of intracellular tenofovir diphosphate (TFV-DP) in dried blood spot (DBS) samples. Between 2014 and 2018, there were 510 transgender participants, 349 (68.4%) transgender women and 152 (29.8%) transgender men. Forty-five of these participants were enrolled in the MAS, 31 (68.9%) transgender women and 9 (20.0%) transgender men. By the 3-month follow up, 100% of MAS participants who completed an interview reported taking 4 or more doses of PrEP in the previous week. At 6, 9, and 12 months, taking 4 or more doses in the past week was reported by 81.0%, 94.1%, and 83.3% of participants, respectively. Results from TFV-DP DBS indicated that fewer participants reached the same level of adherence (4 or more doses/week) at clinical visits compared to self-report and even fewer participants reached this level of adherence based on the calculated PDC. Among participants who remained on PrEP throughout the study, DBS adherence levels declined after the first three months. There remains a critical need to develop strategies to address barriers and interventions that support PrEP adherence among transgender people.

Keywords

Transgender persons; PrEP use; PrEP adherence; HIV prevention

Introduction

Transgender persons continue to experience disproportionately high rates of HIV infection in the United States despite efforts to address their HIV prevention and care needs [1]. According to the Centers for Disease Control and Prevention (CDC), approximately one million Americans identify as transgender and the number of diagnoses for HIV infection among transgender persons increased between 2015 and 2019 [1, 2].Within the larger transgender population, additional disparities exists between groups. A recent study reported higher HIV prevalence estimates among transgender women (TGW) compared to transgender men (TGM) [3]. In 2019, Black/African American and Hispanic/Latino transgender persons accounted for 2% of new HIV diagnoses; 93% of these diagnoses were among TGW [2]. The uptake of daily oral preexposure prophylaxis (PrEP) is a potent biomedical prevention tool that reduces overall HIV infections [4].

A persistent challenge for conducting scientific investigations involving PrEP among transgender persons is that most clinical trials and demonstration projects combine TGW participants with men who have sex with men (MSM) participants [5, 6]. Further, the sample sizes of TGW in these studies have been small relative to the number of MSM included. Qualitative research has indicated that TGW, specifically, do not feel included in the promotion of PrEP and that there is limited PrEP research specifically for transgender persons [7]. To date, the largest samples of TGW participants have been enrolled in the HPTN (HIV Prevention Trials Network) 083 study (N = 570) and iPrEx trial (N = 339) [8, 9]. Additional PrEP studies for transgender persons include HPTN 085 and HPTN 091 [10]. The inclusion of transgender populations (both TGW and TGM) is important to understanding specific PrEP implementation strategies and interventions for them [11].

A recent review of the literature found low to moderate awareness of PrEP and high willingness to use PrEP among TGW [12]. Common barriers to accepting or initiating PrEP among TGW included potential side effects, anticipated associated costs, possible interactions with hormone therapy, adherence concerns, and PrEP-related stigma [12]. To address gaps in knowledge around PrEP needs for this population, the current analysis used data collected from one participating site of the Sustainable Health Center Implementation PrEP Pilot (SHIPP) Study, which included a large observational sample of transgender participants. Briefly, the SHIPP study collected information related to the delivery and clinical outcomes of persons prescribed daily oral PrEP in community health centers The specific objectives of this analysis were: (1) to describe the characteristics of PrEP use and adherence among transgender persons in the observational health services research cohort (OC) and medication adherence substudy (MAS) cohorts and (2) to report common PrEP barriers to adherence (e.g., out-of-pocket costs, PrEP disclosure, and attitudes towards PrEP) among transgender persons interviewed in the medication adherence substudy.

Methods

The SHIPP Study received human subjects research review and approval by the CDC and the City of Philadelphia IRB and was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments of comparable ethical standards. There were two study components: (1) for the OC, only medical record data (including laboratory evaluations) were collected from the initial PrEP assessment and subsequent visits from clinic patients while on PrEP medication and (2) for the MAS, in addition to medical record data, information was collected from persons who provided written informed consent to interviews and blood measurements of PrEP medication at quarterly visits while PrEP was prescribed. An incentive of $25 was provided to the substudy participants for each completed interview and blood sample collection at subsequent clinic visits.

All transgender persons who participated in the SHIPP Study at the Howard Brown Health study site in Chicago, IL were included in the descriptive analysis. Data were collected between October 2014 – November 2018, including those from 510 transgender participants in the OC and among those, 45 participants were recruited into the MAS. We used electronic medical record (EMR) data and baseline interview data for demographic and clinical measures of interest. Measures pulled from EMR included age, sex, gender, and race/ethnicity. Demographic data collected among enrolled MAS participants during the initial interview included: sex at birth (male/female), gender (male/female/transgender), sexual orientation (heterosexual or “straight”/homosexual, gay, or lesbian/bisexual), employment status(full-time/part-time/homemaker/full-time student/retired/unable to work/unemployed), marital status (single-never married/legally married/living together as married/separated/widowed/divorced), insurance status (yes/no and type: Private/Medicaid/Medicare/Military or VA coverage), and homeless status (yes/no). Clinical outcome data consisted of laboratory diagnoses of sexually transmitted infections (i.e., syphilis, gonorrhea, chlamydia, and HIV) and prescription records of receiving gender affirming therapy (i.e., antiandrogens, estrogen, progestin, and testosterone) documented in EMR at one or more follow-up visits

during the study. For sexually transmitted infections (STIs), a positive result may include multiple positive tests per participant.

Additional measures of interest from interviews in the MAS cohort included self-reported number of partners, out-of-pocket costs associated with PrEP (medication and clinic visits), PrEP disclosure, and attitudes toward PrEP at semiannual visits. PrEP disclosure was assessed based on those self-reported to main partner (yes/no). PrEP attitudinal measures included self-reported comfort level discussing PrEP with medical provider (agree, undecided, and disagree) and discomfort with talking to medical provider about missed doses of PrEP due to fear of disappointing them (agree/undecided/disagree). PrEP adherence was assessed using EMR prescription refill data for all participants. Quarterly interview data and blood collected by fingerstick was used to assess levels of PrEP adherence among participants in the MAS cohort.

Analysis

We report descriptive statistics for demographic characteristics, clinical outcomes, and for all PrEP measures of interest at baseline and follow-up semiannual visits in the MAS cohort (e.g., self-reported number sexual partners, disclosure of PrEP, attitudes towards PrEP, and out-of-pockets costs associated with PrEP). For all transgender persons who participated in the SHIPP study, we relied on EMR data to abstract the prescription date and the number of pills prescribed. PrEP supply was calculated using the total number of pills prescribed at each prescription. PrEP time was calculated as the number of months, based on 30-day intervals, from the date of the first prescription. PDC was calculated for each month with a method excluding gaps in PrEP use, rolling over excess pills to subsequent month, and moving overlapping prescriptions to the end of the previous prescription [13, 14]. We used a 90-day measurement period based on the clinical PrEP guidelines for follow-up and monitoring [4]. While PDC > 80% is often used as the threshold for determining high levels of adherence [13], for this analysis we chose to divide PDC into four categories: non-adherent (< 28.6% of days covered or < 2 doses/week), minimally adherent (28.6–57.0% of days covered or approximately 2–3 doses/week), modestly adherent (57.1–99.9% days covered or approximately 4–6 doses/week), and fully adherent (100% days covered or 7 doses/week).

MAS participants completed interviews and had blood collected at quarterly follow-up visits. Data from the interviews were used to measure self-reported adherence and concentrations of intraerythrocyte tenofovir diphosphate (TFV-DP) in dried blood spot (DBS) samples were used to objectively measure PrEP adherence. Self-reported PrEP adherence was measured by the number of doses taken in the previous 7 days collected via tablet during clinical visits. For these two measures, adherence was defined as: non-adherent (0–1 doses/week or TFV-DP DBS concentrations < 350 fmol/punch), minimally adherent (2–3 doses/week or TFV-DP DBS concentrations 350–699 fmol/punch), modestly adherent (4–6 doses/week or TFV-DP DBS concentrations 700–1249 fmol/punch), and fully adherent (7 doses/week or TFV-DP DBS concentrations ≥ 1250 fmol/punch fmol/punch). The correlation between self-reported adherence and TFV-DP concentrations was estimated by calculating Spearman’s rank correlation coefficients at each follow-up visit.

Results

Cohort Demographic Characteristics

Between October 2014 and November 2018, there were a total of 510 transgender participants in the SHIPP study at the Howard Brown Health study site in Chicago, IL (see Table1). Among these participants, there were 349 (68.4%) TGW and 152 (29.8%) TGM in the OC (median age: 25, interquartile range [IQR] 21 to 30). By race/ethnicity, there were 169 (33.1%) White, 119 (23.3%) Black, 135 (26.5%) Hispanic participants. Among the 45 participants who were enrolled in the MAS, 31 (68.9%) were TGW and 9 (20.0%) were TGM (median age: 27, IQR 24 to 34). Race/ethnicity proportions of participants were evenly distributed; 14 (31.1%) for White, Black, and Hispanic, respectively. Data from baseline interviews, used to assess PrEP indications in the MAS, revealed that more than half (51.1%) of transgender MAS participants identified as homosexual, gay, or lesbian. The majority of MAS participants (86.7%) were single, not married. Almost half of MAS participants (40%) reported being employed and 71.9% had health insurance (29.7% Private, 42.2% Medicaid/Medicare). Homelessness was reported by 13.3% of MAS participants.

Clinical Findings

Table1 also includes data about findings from one or more clinical visits. During the study, the median number of PrEP visits attended was 4 (IQR 2–8) in the observational cohort. During these visits, there was a total of 40 (7.8%) participants who screened positive for syphilis, 129 (25.2%) screened positive for gonorrhea, and 154 (30.2%) screened positive for chlamydia. There was a higher number of PrEP visits attended by MAS participants, the median was 8 (IQR 4–12). There was also a higher proportion of MAS participants who screened positive for gonorrhea and syphilis, 44.4% (n = 20) and 42.2% (n = 19), respectively. There were no HIV seroconversions among transgender participants at this SHPP study site during the study. Gender affirming therapy was reported by 73% of all participants in the study (n = 372). Approximately the same proportion was reported among participants in the MAS (73.3%, n = 33). The majority of participants (> 58%) reported gender affirming therapy containing estrogen.

MAS Baseline and Semiannual Interview Data

At baseline, 45 transgender MAS participants completed an interview and reported a median of 5 (IQR 1–10) sexual partners in the past 6 months. Only 5 participants reported having HIV + partners and 1 participant reported injection drug use, see Table2. There was approximately a 50% drop-off of participants at each 6-month follow-up visit and though the duration of the SHIPP study was 36 months, participation in the substudy did not exceed 18 months. Among participants who attended 6-, 12-, and 18-month follow-up visits, the median number of partners (in the past 3 months) was 2 (IQR 1–3), 3 (IQR 1–5), and 3 (IQR 1–3), respectively. Approximately half of participants disclosed PrEP use to their main partner at follow-up visits. Majority of MAS participants (> 80%) reported being comfortable talking to a medical provider about PrEP, their sexual behaviors, and sexual relationships. Few participants reported out-of-pocket expenses for PrEP with average amounts less than $10 for PrEP medication and approximately $30 for clinic visits.

PrEP Adherence

Figure1 shows the levels of PrEP adherence for all transgender participants with EMR data, using a calculated proportion of days covered (PDC), see supplemental Fig.2. At 3 months, 42.4% of transgender participants (N = 216) were covered for at least 57.1% of days in the 90-day period (estimated at taking 4 or more doses/week). Similar levels of adherence were found among 13.6% of TG participants at 6 months, 11.5% at 9 months, and 10.0% at 12 months, respectively.

Table3 shows the levels of PrEP adherence among MAS participants, using self-reported interview data and dried blood spot (DBS) samples collected at quarterly follow-up visits. Among MAS participants who completed interviews or had DBS measures at follow-up visits, the proportion of participants who self-reported taking 4 or more doses in the previous week was consistently higher at all follow-up visits compared to TFV-DP DBS levels. At the 3-month follow-up visit, 100% of participants who completed an interview reported taking 4 or more doses of PrEP medication in the previous week while results from the TFV-DP DBS estimated 4 or more doses for 73.7% of participants. At 6, 9, and 12 months, taking 4 or more doses in the past week was reported by 81.0%, 94.1%, and 83.3% of participants compared to TFV-DP DBS estimating 4 or more doses for 70.0%, 46.7%, and 75.0% of participants, respectively. Among TGW participants who used estrogen, we found lower concentrations of TFV-DP in DBS compared with those who were not, however, the sample size was too small to perform an inferential analysis.

Discussion

We assessed PrEP adherence in one of the largest US cohorts of transgender participants using self-report, PDC and TFV-DP DBS data. Our analysis revealed that PrEP adherence among TG persons was at its highest level in the first 3 months and decreased over time, with low adherence overall. Similar to findings in TGW in the iPrEx study [8], we found high positivity rates for syphilis, gonorrhea, and chlamydia at one or more clinical visits. Low medication adherence and high STI positivity could be an indication that TGW are at substantial ongoing risk for HIV infection [4].

In the MAS, we assessed previously identified barriers to adherent PrEP use, including nondisclosure of PrEP use to others, attitudes towards PrEP, and out-of-pocket costs associated with PrEP [12]. We found high levels of positive attitudes towards discussing sexual behaviors, sexual relationships, and PrEP with medical providers at this SHIPP clinic site. Previous studies indicate that co-location of healthcare services (including gender affirming care) and the cost of PrEP are ongoing challenges to PrEP care and adherence [15–18]. The SHIPP Study provided the opportunity to examine PrEP use and adherence in a clinical setting where gender affirming therapy was available, costs were minimal, and where providers were trained to work with the transgender population. Though our study did not examine TGW and TGM separately, our findings are consistent with qualitative research among young TGW who reported positive attitudes towards PrEP use [16].

The MAS aimed to assess adherence among participants who were provided adherence support. Our descriptive analysis showed lower levels of adherence measured by TFV-DP in

DBS (at least 4 doses/week) than participants' self-reported adherence and even lower levels based on a calculated PDC. It is important to note that less than half of MAS participants completed follow-up interviews or received DBS collection throughout the study, and therefore adherence data was limited in this population. Among those who remained on PrEP, adherence declined after the first three months. The self-report data, while useful as a measure accessible to providers in real time, was less accurate than TFV-DP measurements. These findings are consistent with those among all MAS participants in the SHIPP study, (both cisgender and transgender) across five study sites [19]. In our sub-analysis, we found lower concentrations of TFV-DP in DBS among TGW participants compared with those who were not, however, the sample size was too small to perform an inferential analysis. While this finding is similar to evidence from other pharmacokinetic and drug level studies, there has not been substantial evidence to suggest a change to the current recommendations for PrEP regimens that contain tenofovir disoproxil fumarate (TDF) [20–23]. Though TFV-DP in DBS concentrations may be affected by the use of gender affirming therapy, the size of the observed effects in studies so far are not expected to lower the efficacy of PrEP medication [23]. Messaging about PrEP efficacy remains an essential component to improve adherence among this population.

Our study has some limitations. The analysis focused only on TG participants in one study site participating in the SHIPP study, as opposed to combining all TG participants across sites. This selection was done with the intent of analyzing PrEP use and adherence data in a particular clinical setting where barriers to working with the TG population were minimal. Our selection poses a limitation in understanding how various factors such as participant demographics or lifestyle behaviors impact adherence. The study sample in the Medication Adherence Substudy was too small to conduct additional analyses. This poses a limitation to the generalizability of our findings among TG persons using PrEP in the Chicago area and elsewhere in the United States, however, the implications suggest a need for future studies investigating PrEP specifically among this population. Using EMR data to calculate PDC is likely to overestimate true adherence [13, 14]. Further, not all PrEP prescriptions are filled and not all individuals take their PrEP medication daily.

While there are efforts to improve PrEP uptake among sexual and gender minority groups, there remains a critical need to develop strategies and interventions that address barriers and support PrEP adherence among transgender persons. There is growing literature about the specific HIV prevention and care needs among transgender persons. However, there are limited data to show what interventions work well among TG persons, especially among Black/African American and Hispanic/Latino persons who are disproportionately affected by HIV. Careful considerations are needed when designing and implementing demonstration projects and observational studies to improve recruitment and retention of transgender persons [24]. The implementation of PrEP care among transgender persons must consider strategies that address the barriers to and facilitators of uptake and adherence, including co-location of gender-affirming healthcare, offering trainings to providers and frontline staff, and providing culturally appropriate information [25–27]. To improve the use of PrEP and realize its potential to reduce HIV incidence in the US [28], it is essential to consider the unique needs of this important group.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Funding

The SHIPP study was funded by the National Center for HIV, STD, Viral Hepatitis and TB Prevention at the Centers for Disease Control and Prevention and by donations to the CDC Foundation.

Data Availability

The data that support the findings of this study are not openly available due to the sensitivity of the clinical data.

References

1. Centers for Disease Control and Prevention. HIV and transgender people. https://www.cdc.gov/hiv/pdf/group/gender/transgender/cdc-hiv-transgender-factsheet.pdf. Published April 2021. [Accessed July 6, 2021].
2. Centers for Disease Control and Prevention. Surveillance Report HIV. 2019; vol.32. http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html. Published May 2021. [Accessed July 6, 2021].
3. Becasen JS, Denard CL, Mullins MM, Higa DH, Sipe TA. Estimating the prevalence of HIV and sexual behaviors among the US transgender population: A systematic review and meta-analysis, 2006–2017. AJPH. 2019;109:e1–8.
4. Centers for Disease Control and Prevention. US Public Health Service: preexposure prophylaxis for the prevention of HIV infection in the United States—2017 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf. Published March 2018. [Accessed July 6, 2021].
5. Escudero DJ, Kerr T, Operario D, Socias ME, Sued O, Marshall BD. Inclusion of trans women in pre-exposure prophylaxis trials: a review. AIDS Care. 2015;27(5):637–41. [PubMed: 25430940]
6. Liu A, Cohen S, Follansbee S, Cohan D, Weber S, Sachdev D, et al. Early experiences implementing pre-exposure prophylaxis (PrEP) for HIV prevention in San Francisco. PLoS Med. 2014;11(3):e1001613. [PubMed: 24595035]
7. Rael CT, Martinez M, Giguere R, Bockting W, MacCrate C, Mellman W, et al. Barriers and facilitators to oral PrEP use among transgender women in New York City. AIDS Behav. 2018;22(11):3627–36. [PubMed: 29589137]
8. Landovitz RJ, Donnell D, Clement ME, Hanscom B, Cottle L, Coelho L. et al. Cabotegravir for HIV prevention in cisgender men and transgender women. N Engl J Med. 2021;385(7):595–608. [PubMed: 34379922]
9. Deutsch MB, Glidden DV, Sevelius J, Keatley J, McMahan V, Guanira J, et al. HIV pre-exposure prophylaxis in transgender women: a subgroup analysis of the iPrEx trial. Lancet HIV. 2015;2:e512–9. [PubMed: 26614965]
10. HIV Prevention Trials Network. https://www.hptn.org/research/studies. Published June 2021. [Accessed July 6, 2021].
11. Grant RM, Sevelius JM, Guanire JV, Aguilar JV, Chariyalertsak S, Deutsch MB. Transgender women in clinical trials of pre-exposure prophylaxis. J Acquir Immune Defic Syndr. 2016;72(Suppl 3):226–9.
12. Pacífico de Carvalho N, Mendicino CCP, Cândido RCF, Alecrim DJD, Menezes de Pádua CA. HIV pre-exposure prophylaxis (PrEP) awareness and acceptability among trans women: a review. AIDS Care. 2019;31(10):1234–40. [PubMed: 31043069]
13. Nau DP. Proportion of days covered (PDC) as a preferred method of measuring medication adherence. Pharmacy Quality Alliance; 2012.

14. Pyra M, Rusie L, Castro M, Keglovitz Baker K, McNulty M, Bohm N, et al. A taxonomy of pragmatic measures of HIV preexposure prophylaxis use. AIDS. 2020;34(13):1951–7. [PubMed: 33009011]
15. Sevelius JM, Keatley J, Calma N, Arnold E. 'I am not a man': trans-specific barriers and facilitators to PrEP acceptability among transgender women. Glob Public Health. 2016:1–16.
16. Wood SM, Lee S, Barg FK, Castillo M, Dowshen N. Young transgender women's attitudes toward HIV pre-exposure prophylaxis. J Adolesc Health. 2017;60(5):549–55. [PubMed: 28132744]
17. Reisner SL, Radix A, Deutsch MB. Integrated and gender-affirming transgender clinical care and research. J Acquir Immune Defic Syndr. 2016;72(Suppl 3):235–42.
18. Mayer KH, Grinsztejn B, El-Sadr WM. Transgender people and HIV prevention: what we know and what we need to know, a call to action. J Acquir Immune Defic Syndr. 2016;72(Suppl 3):207–9.
19. Smith DK, Rawlings MK, Glick N, Mena L, Coleman M, Houlberg M, et al. Adherence to daily oral TDF/FTC for prep in community health center populations: the sustainable health center implementation prep pilot (SHIPP) study. AIDS Behav. 10.1007/s10461-021-03388-5. Published online August 2021.
20. Hiransuthikul A, Janamnuaysook R, Himmad K, Kerr SJ, Thammajaruk N, Pankam T, et al. Drug-drug interactions between feminizing hormone therapy and pre-exposure prophylaxis among transgender women: the iFACT study. J Int AIDS Soc. 2019;22(7):e25338. [PubMed: 31298497]
21. Shieh E, Marzinke MA, Fuchs EJ, Hamlin A, Bakshi R, Aung W, et al. Transgender women on oral HIV pre-exposure prophylaxis have significantly lower tenofovir and emtricitabine concentrations when also taking estrogen when compared to cisgender men. J Int AIDS Soc. 2019;22(11):e25405. [PubMed: 31692269]
22. Yager JL, Anderson PL. Pharmacology and drug interactions with HIV prep in transgender persons receiving affirming hormone therapy. Expert Opin Drug Metab Toxicol. 2020;16(6):463–74. [PubMed: 32250177]
23. Grant RM, Pellegrini M, Defechereuz PA, Anderson PL, Yu M, Glidden DV. et al. Sex hormone therapy and tenofovir diphosphate concentration in dried blood spots: primary results of the iBrEATHe study. Clin Infect Dis. 2020; n. pag.
24. Sevelius JM, Deutsch MB, Grant R. The future of PrEP among transgender women; the critical role of gender affirmation in research and clinical practices. J Int AIDS Soc. 2016;19(Suppl 6):21105. [PubMed: 27760683]
25. Marcus JL, Buisker T, Horvath T, Amico KR, Fuchs JD, Buchbinder SP, et al. Helping our patients take HIV pre-exposure prophylaxis (PrEP): a systematic review of adherence interventions. HIV Med. 2014;15(7):385–95. [PubMed: 24580813]
26. Radix AE, Lelutiu-Weinberger C, Gamarel KE. Satisfaction and healthcare utilization of transgender and gender non-conforming individuals in NYC: a community-based participatory study. LGBT Health. 2014;1(4):302–8. [PubMed: 26789858]
27. Haberer JE. Current concepts for PrEP adherence in the PrEP revolution: from clinical trials to routine practice. Curr Opin HIV AIDS. 2016;11(1):10–7. [PubMed: 26633638]
28. Fauci AS, Redfield RR, Sigounas G. et al. Ending the HIV epidemic: a plan for the United States. JAMA. 2019;321:844–5. [PubMed: 30730529]

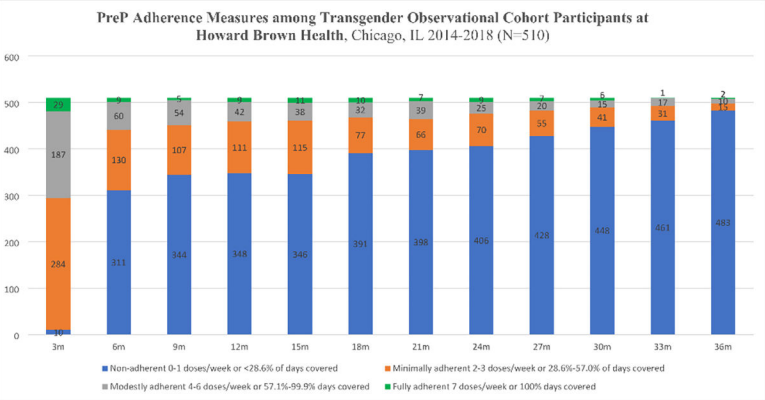

Fig. 1.

PrEP Adherence Measures among Transgender Observational Cohort Participants at Howard Brown Health, Chicago, IL, 2014–2018, (N = 510). (*percentages reported are based on the estimated number of days covered over a 90-day time period, PDC = proportion of days covered = number of pills dispensed/90-day interval) *100)

Table 1

Characteristics of Transgender Participants at Howard Brown Health, Chicago, IL, 2014–2018 (SHIPP Study)

	Medication Adherence Substudy* (N = 45)	Observational Cohort** (N=510)
Demographic Characteristics		
Age in Years (median, IQR)	27 years, IQR (24–34)	25 years, IQR (21–30)
Sex at Birth	n (%)	n (%)
Male	36 (80.0)	356 (69.8)
Female	9 (20.0)	153 (30.0)
Gender		
Transgender Female	31 (68.9)	349 (68.4)
Transgender Male	9 (20.0)	152 (29.8)
Unknown/Missing	5(11.1)	9 (1.8)
Race/Ethnicity		
White, Non-Hispanic	14 (31.1)	169 (33.1)
Black, Non-Hispanic	14 (31.1)	119 (23.3)
Hispanic	14 (31.1)	135 (26.5)
Other	3 (6.6)	80 (15.7)
Clinical Findings (from one or more visits)		
# of PrEP Clinic Visits (median, IQR)	8, IQR (4–12)	4, IQR (2–8)
STI Positive Laboratory Findings	n (%)	n (%)
Syphilis	2 (4.4)	40 (7.8)
Gonorrhea	20 (44.4)	129 (25.2)
Chlamydia	19 (42.2)	154 (30.2)
Gender Affirming Therapy		
Antiandrogens	2 (4.3)	37 (7.3)
Estrogen	27 (58.7)	305 (59.8)
Progestin	-	1 (0.2)
Testosterone	4 (8.7)	29 (5.7)

*due to missing values, some categories do not equal 100%

**represents the total number of transgender participants in the SHIPP study

PrEP = pre-exposure prophylaxis;

STI = sexually transmitted infection; IQR = interquartile range

Table 2

Baseline and Semiannual Measures among Transgender Medication Adherence Substudy Participants at Howard Brown Health, Chicago, IL, SHIPP Study, 2014–2018, (N = 45)

	Baseline	6-month	12-month	18-month
Interviews Completed [a] **(%)**	45 (100.0)	22 (48.9)	13 (28.9)	7(15.6)
# of partners, past 3 months (median, IQR)	5, IQR 1–10	2, IQR 1–3	3, IQR 1–5	3, IQR 1–3
PrEP disclosure to main partner [b] **(n (%)) Perception statements (n (%))**	-	11 (50.0)	7 (53.9)	4(57.1)
I feel comfortable talking to my medical provider about PrEP	40 (88.9)	22 (100.0)	12 (92.3)	7 (100.0)
I avoid telling my medical provider about how often I miss doses of my PrEP medication because I would not want him/her to be disappointed in me	7 (15.6)	1 (4.5)	1 (7.7)	2 (28.6)
I feel comfortable talking to my medical provider about my sexual behaviors and sexual relationships	36 (80.0)	20 (90.9)	11 (84.6)	7 (100.0)
I worry that my medial provider will make judgements about me for my sexual behavior	7 (15.6)	2 (9.1)	-	1 (14.3)

[a] percentages reported are based on the number of participants who completed an interview for each time period

[b] the number of partners at baseline were based on the past 6 months

Table 3

PrEP Adherence Measures among Transgender Participants in the Medication Adherence Substudy at Howard Brown Health, Chicago, IL, SHIPP Study, 2014–2018, (N = 45)

	3-month	6-month	9-month	12-month
Interviews Completed (%)	18 (40.0)	21 (46.7)	17 (37.8)	12 (26.7)
Self-Reported Number of Doses Taken in Prior 7 Days (n (%)) *				
0–1 (Non-adherent)	-	4 (19.0)	1 (5.9)	2 (16.7)
2–3 (Minimally adherent)	-	-	-	-
4–6 (Modestly adherent)	2 (11.1)	6 (28.6)	6 (35.3)	3 (25.0)
7 (Fully adherent)	16 (88.9)	11 (52.4)	10 (58.8)	7 (58.3)
DBS Samples Collected (%)	19 (42.2)	20 (44.4)	15 (33.3)	8 (17.8)
TFV-DP – Estimated Doses Taken in Prior 7 Days (n (%) *				
0–1 (< 350 fmol per punch)	4 (21.0)	3 (15.0)	4 (26.7)	2 (25.0)
2–3 (350–699 fmol per punch)	1 (5.3)	3 (15.0)	1 (6.6)	-
4–6 (700–1249 fmol per punch)	3 (15.8)	8 (40.0)	3 (20.0)	-
7 (≥ 1250 fmol per punch)	11 (57.9)	6 (30.0)	7 (26.7)	6 (75.0)
Correlation Coefficient (95% CI) **				
TFV-DP vs. Doses Taken (continuous)	0.25 (−0.27–0.65)	0.65 (0.27–0.85)	0.39 (−0.19–0.36)	0.53 (−0.40–0.91)
TFV-DP – Esti-mated Doses Taken vs. Doses Taken (ordinal)	0.34 (−0.18–0.70)	0.59 (0.17–0.82)	0.22 (−0.36–0.67)	0.76 (−0.04–0.96)

* percentages reported are based on the number of participants who provided self-report data and/or DBS data for each time period

** Spearman's Rank Correlation Coefficient (All Visits Combined):

TFV-DP vs. Doses Taken (continuous): 0.43 (0.20–0.61)

TFV-DP – Estimated Doses Taken vs. Doses Taken (ordinal): 0.40 (0.16–0.58)

DBS = dried blood spot; CI = confidence interval; Non-adherent (0–1 doses/week or TFV-DP DBS concentrations < 350 fmol/punch), minimally adherent (2–3 doses/week or TFV-DP DBS concentrations 350–699 fmol/punch), modestly adherent (4–6 doses/week or TFV-DP DBS concentrations 700–1249 fmol/punch), and fully adherent (7 doses/week or TFV-DP DBS concentrations ≥ 1250 fmol/punch