Expanding the Pie–Differentiated PrEP Delivery Models to Improve PrEP Uptake in the San Francisco Bay Area

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Background: Pre-exposure prophylaxis (PrEP) uptake among trans people to date has been low. Recommendations implemented in San Francisco to offer PrEP with feminizing hormones have not led to improvement of PrEP uptake in trans communities. New delivery models may be needed. The aim of this study was to examine whether a PrEP-only clinic was more likely to serve trans people at highest risk of HIV than trans-affirming primary care clinics.

Methods: Participants were recruited between 2017 and 2019 as part of a PrEP demonstration project in the San Francisco Bay Area. Survey data including sociodemographics, HIV-related risk behavior, barriers to PrEP, and self-reported PrEP adherence were collected at baseline, 3 months, and 6 months for all participants. Bivariable Poisson regression models were used to examine differences between participants in the primary care clinics and PrEP-only clinic delivered to participants.

Results: Baseline survey data were collected from 153 participants. Those with a higher number of sexual partners were significantly more likely to use the PrEP-only clinic rather than the primary care clinics. Participants with higher perceived HIV risk and those who engaged in sex work were also more likely to use the PrEP-only clinic compared with the primary care clinic. Medical mistrust was higher at baseline among participants of the PrEP-only clinic. PrEP adherence was not significantly different by delivery model. Few participants identified PrEP barriers, such as interactions with feminizing hormones, to be determinants of PrEP uptake.

Conclusions: A PrEP-only delivery model could improve PrEP uptake and may better meet the needs of trans people who could most benefit from PrEP.

Key Words: HIV prevention, transgender persons, PrEP delivery, implementation science

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INTRODUCTION

Uptake of pre-exposure prophylaxis (PrEP) among trans people is low.1 PrEP rollout began in San Francisco in 2012.2 Yet in 2013, only 14% of trans women had heard of PrEP in San Francisco.3,4 Three years later, only 15% of trans women had used PrEP, compared with almost 40% PrEP uptake among men who have sex with men in the same period.5

Low PrEP uptake among US trans communities is tied to numerous factors including social and structural barriers to information and access.1,6,7 After Food and Drug Administration approval, little marketing was tailored to trans people, and there were concerns in community that PrEP might affect the efficacy of feminizing hormones.8,9 Negative opinions of PrEP fueled by misinformation, such as side effects occurring that are not associated with PrEP, presented an additional barrier.10 PrEP was also associated with promotion of risk, HIV-related stigma, and promiscuity.11 Previous experiences of discrimination in health care is the most notable barrier to PrEP for trans communities.12,13 Furthermore, trans women of color who are most affected by HIV and face intersectional gender-based and race-based stigmas may be the least likely to seek medical care because of discrimination.14,15

Research suggests that pairing PrEP with trans-affirming care that meets needs for feminizing hormones with a trusted provider may help overcome PrEP uptake barriers in trans communities.8,16,17 Although this is most certainly true, PrEP availability in trans-affirming primary care clinics has not resulted in significant increases in PrEP starts among trans people in San Francisco. The aim of this study was to examine whether a PrEP-only clinic was more
likely to serve trans people at highest risk of HIV than trans-affirming primary care clinics. Data are from one of the first PrEP demonstration projects to increase PrEP uptake and engagement among trans people, gender nonconforming people, and nonbinary people in the United States (trans communities). The project was to increase PrEP uptake in trans-affirming primary care clinics. We also developed a PrEP-only trans-affirming clinic. In addition to assessing whether the PrEP-only clinic drew in more people who could benefit from PrEP, we also examined whether barriers to PrEP uptake identified early on in PrEP rollout are still relevant to trans people in the San Francisco Bay Area.

**METHODS**

**Study Design, Setting, and Recruitment**

Data for this analysis come from the Stay Study PrEP demonstration project conducted by researchers at the San Francisco Department of Public Health and funded by the California HIV/AIDS Research Program. The Stay Study was a collaboration between 4 trans-affirming primary care community clinics in San Francisco (3 clinics) and Fremont, California (1 clinic), where PrEP was available. We developed and implemented a social marketing campaign with trans leaders who served as ambassadors of PrEP. Participants were offered the opportunity to take a quiz to determine their risk of HIV and see the benefits of PrEP for lowering risk. We also offered peer navigation using mHealth approaches for pill-taking reminders, information about PrEP, and asynchronous text message support. Panel management was used wherein peer navigators used electronic medical record and other data to ensure optimal care of patients receiving PrEP. An important component of PrEP delivery was benefits navigation and free PrEP pills (ie, Truvada) donated by Gilead Sciences. Participants were enrolled beginning in August of 2017. By early 2019, most primary care clinic patients interested and eligible for PrEP were enrolled into the study. As a result, the team established a low-threshold PrEP-only clinic delivered at a clinical research site. PrEP care was provided by a team of nurse practitioners and a primary care model consisting of participants from 4 primary care clinics compared with those who attended our “PrEP-only” clinic. Self-reported sociodemographics were as follows: age at enrollment, gender identity (woman, trans woman, gender nonconforming or nonbinary or gender-queer people, or trans man/other identities), sexual orientation (straight, gay or lesbian or queer, bisexual, or other sexual orientation), race/ethnicity (White and non-Hispanic/Latina/o/x, Black and non-Hispanic/Latina/o/x, Hispanic/Latina/o/x, or other/multiple races/ethnicities and non-Hispanic/Latina/o/x), whether or not participants were born in the United States, current monthly income ($1000 USD or less, $1001–$1,754, or more than $1755), current housing status (unstable, including couch surfing, homeless/shelter, single room occupancy hotel, residential treatment facility, transitional/supportive housing, other or stable, own your own house, rent a house/apartment/room), and food insecurity (whether participants had cut the size of their meals or skipped meals because of lack of money/food). Gender identity categories were collapsed for trans man, and people with other identities along the transmasculine spectrum (ie, assigned female sex and identified with a masculine gender identity) were collapsed because of the small sample size and the need for model convergence. Health care access and quality characteristics were self-reported and included the following: HIV testing in the previous 6 months, previous and current PrEP use, insurance status and type, whether participants had a primary care doctor, were currently on hormones, or had completed gender-affirming surgeries, and we assessed medical mistrust using select items from a validated scale that we adapted to be relevant for people from a gender minority group.

The items we used were whether participants distrusted doctors or received unfair treatment by doctors in the past. For both these items, we collapsed “strongly disagree” or “disagree” responses into 1 category, categorized “neutral” as another category, and then collapsed “agree” or “strongly agree” into 1 category.

**Sociodemographics, Health Care Access and Quality, and Medical Mistrust**

The “primary care model” consists of participants from all 4 primary care clinics compared with those who attended our “PrEP-only” clinic. Self-reported sociodemographics were as follows: age at enrollment, gender identity (woman, trans woman, gender nonconforming or nonbinary or gender-queer people, or trans man/other identities), sexual orientation (straight, gay or lesbian or queer, bisexual, or other sexual orientation), race/ethnicity (White and non-Hispanic/Latina/o/x, Black and non-Hispanic/Latina/o/x, Hispanic/Latina/o/x, or other/multiple races/ethnicities and non-Hispanic/Latina/o/x), whether or not participants were born in the United States, current monthly income ($1000 USD or less, $1001–$1,754, or more than $1755), current housing status (unstable, including couch surfing, homeless/shelter, single room occupancy hotel, residential treatment facility, transitional/supportive housing, other or stable, own your own house, rent a house/apartment/room), and food insecurity (whether participants had cut the size of their meals or skipped meals because of lack of money/food). Gender identity categories were collapsed for trans man, and people with other identities along the transmasculine spectrum (ie, assigned female sex and identified with a masculine gender identity) were collapsed because of the small sample size and the need for model convergence. Health care access and quality characteristics were self-reported and included the following: HIV testing in the previous 6 months, previous and current PrEP use, insurance status and type, whether participants had a primary care doctor, were currently on hormones, or had completed gender-affirming surgeries, and we assessed medical mistrust using select items from a validated scale that we adapted to be relevant for people from a gender minority group.

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**HIV-Related Sexual Risk Behavior and HIV Risk Perception**

We assessed participants’ self-reported condomless anal intercourse acts and number of sexual partners in the 3 months before their baseline visit (0, 1–2, 3–4, or 5 or more). We also included a composite risk perception score (reliability coefficient = 0.75), ranging from 0 to 17, based on the following items: “What is your gut feeling about how likely
you are to get infected with HIV? [extremely unlikely/very unlikely/somewhat unlikely],” “I feel vulnerable to HIV infection [strongly disagree/disagree/somewhat disagree/somewhat agree/agree/strongly agree],” “I think my chances of getting infected with HIV are: [zero/almost zero/small/moderate/large/very large],” and “Getting HIV is something I have: [never thought about/rarely thought about/thought about some of the time/thought about often].”\(^2\)\(^2\)\(^2\) Higher scores denoted higher perceived risk. Based on previous PrEP research with trans women, we added whether participants were currently engaged in sex work.\(^4\)

**PrEP-specific Barriers and Facilitators**

PrEP-specific barriers identified in our previous formative work and the literature\(^5\) were asked of those not on PrEP at baseline and included dichotomous variables that indicated whether or not participants believed the following: fear of being seen with HIV medications, that PrEP was not for the trans community, concern about their ability to take a daily pill, concern about interactions with hormones, concern about side effects, or other fears/concerns where they could specify those concerns. PrEP-specific facilitators were dichotomous variables assessed for all participants at baseline and captured participants’ reasons for being interested in PrEP, such as protecting oneself from HIV, making sex act without condoms safer, helping the community and helping fight the HIV epidemic, wanting to avoid getting HIV from a partner with HIV, being strongly encouraged or pressured by friends/sexual partners to join the PrEP study, having a provider who recommends PrEP, finding the reimbursement money helpful, or having other reasons.

**PrEP Adherence and Missed Study Visits**

We categorized time on PrEP as (1) not being on PrEP during the study, (2) being on PrEP for 3 months, or (3) being on PrEP for 6 months. “Not being on PrEP” included participants who completed the baseline, 3-month, and 6-month visits and reported not taking PrEP, participants who completed baseline but not follow-up visits and reported no PrEP at baseline, and participants who completed baseline and the 3-month visits but not the 6-month visit and who reported not being on PrEP at these visits. Participants who were categorized as being on PrEP for 3 months included the following: those who completed all 3 visits and reported taking PrEP at the 3-month OR the 6-month but not both or those who completed baseline and 3-month visits but not the 6-month visit and reported being on PrEP at their 3-month visit. Participants on PrEP for 6 months were those who completed all 3 visits and reported taking PrEP at both their 3-month AND 6-month visits. PrEP adherence was measured at both the 3-month and 6-month visits and assessed whether participants who were on PrEP at those visits had very poor/poor/fair, very good/good, or excellent self-reported adherence to PrEP. Days of missed PrEP in the last week were also assessed at the 3-month and 6-month visits and were grouped into 0–3 days versus 4–7 days because of small cell sizes and given research suggesting protection at 4 days of use.\(^2\)\(^3\) Missed visits were recorded as yes for those who missed a 3-month and/or a 6-month visit.

**Statistical Analysis**

Our first statistical analysis examined differences in who used each delivery model by socioeconomic position and health care access/quality. We plotted the number of enrolled participants by calendar month and clinic to compare enrollment once the PrEP-only clinic was offered to see whether there were differences in volume of enrollment by delivery model. The second statistical analysis compared risk factors defined by Centers for Disease Control and Prevention PrEP guidelines for sexual risk\(^2\)\(^4\) with additions from research with trans people for participants in both delivery models. Our third analysis compared PrEP-specific barriers and facilitators for participants in each delivery model. In the fourth statistical analysis, we analyzed delivery model differences in participants’ self-reported time on PrEP, PrEP adherence, and losses to follow-up. We restricted outcomes to the baseline, 3-month, and 6-month data because of decreased follow-up at 12 months, partly due to the COVID-19 pandemic. We also included a comparison of missed visits by delivery model to examine differential losses to follow-up.
### TABLE 1. Baseline Socioeconomic Characteristics and Health Care Access/Quality, Overall and Comparing PrEP-Only Clinic Participants With Primary Care Clinic Participants, Stay Study, 2017–2019 (n = 153)

|                                | Overall | Primary Care Clinic Participants | PrEP-Only Clinic Participants | Poisson Binomial Regression Comparing Socioeconomic Characteristics and Health Care Access/Quality of PrEP-Only Clinic With Primary Care Clinic (Reference Group) Participants |
|--------------------------------|---------|---------------------------------|-------------------------------|----------------------------------------------------------------------------------------------------------------------------------|
|                                | n       | %*                             | N%*                          | n %*                                                                                                                             |
| **Total**                      | 153     | 100.0%                         | 118 77.1%§                   | 35 22.9%§                                                              |
| **Sociodemographic factors**   |         |                                 |                               |                                                                     |
| Age at interview in years, mean, and SD | 37.5 12.1 | 37.0 12.3 | 39.4 11.2 | 1.01 0.99 to 1.03 0.26 |
| Gender identity                |         |                                 |                               |                                                                     |
| Woman                          | 49      | 32.0%                          | 31 26.3%                      | 18 51.4% Ref                                                           |
| Trans woman                    | 70      | 45.8%                          | 60 50.8%                      | 10 28.6% 0.39 0.20 to 0.77 <0.01 |
| Gender nonconforming, nonbinary, or genderqueer persons | 9 | 5.9% | 6 5.1% | 3 8.6% 0.91 0.33 to 2.46 0.85 |
| Trans man and people with other identities* | 25 16.3% | 21 17.8% | 4 11.4% | 0.44 0.16 to 1.15 0.09 |
| Sexual orientation             |         |                                 |                               |                                                                     |
| Heterosexual or straight       | 75      | 49.0%                          | 64 54.2%                      | 11 31.4% Ref                                                           |
| Homosexual, gay, lesbian, or queer | 31 | 20.3% | 20 16.9% | 11 31.4% 2.42 1.17 to 5.00 0.02 |
| Bisexual                       | 23      | 15.0%                          | 14 11.9%                      | 9 25.7% 2.67 1.26 to 5.64 0.01 |
| Other                          | 24      | 15.7%                          | 20 16.9%                      | 4 11.4% 1.14 0.40 to 3.25 0.81 |
| Race/ethnicity                 |         |                                 |                               |                                                                     |
| White, non-Hispanic/Latina/o/x | 39      | 25.5%                          | 26 22.0%                      | 13 37.1% Ref                                                           |
| Black, non-Hispanic/Latina/o/x | 24      | 15.7%                          | 16 13.6%                      | 5 14.3% 0.71 0.29 to 1.73 0.46 |
| Hispanic/Latina/o/x            | 57      | 37.3%                          | 50 42.4%                      | 7 20.0% 0.37 0.16 to 0.84 0.02 |
| Other/multiple, non-Hispanic/Latina/o/x | 36 | 23.5% | 26 22.0% | 10 28.6% 0.83 0.42 to 1.66 0.61 |
| Nativity                       |         |                                 |                               |                                                                     |
| Not born in the United States  | 42      | 27.5%                          | 38 32.2%                      | 4 11.4% Ref                                                           |
| Born in the United States      | 110     | 71.9%                          | 79 66.9%                      | 31 88.6% 2.96 1.11 to 7.90 0.03 |
| Current monthly income         |         |                                 |                               |                                                                     |
| $1000 or less                  | 56      | 36.6%                          | 42 35.6%                      | 14 40.0% Ref                                                           |
| $1001–$1754                    | 20      | 13.1%                          | 12 10.2%                      | 8 22.9% 1.60 0.79 to 3.24 0.19 |
| More than $1755                | 26      | 17.0%                          | 14 11.9%                      | 12 34.3% 1.85 1.00 to 3.42 0.05 |
| Missing                        | 51      | 33.3%                          | 50 42.4%                      | 1 2.9% —                                                                |
| Current housing status         |         |                                 |                               |                                                                     |
| Unstable                       | 61      | 39.9%                          | 47 39.8%                      | 14 40.0% Ref                                                           |
| Stable                         | 92      | 60.1%                          | 71 60.2%                      | 21 60.0% 0.99 0.55 to 1.80 0.99 |
| Cut the size of meals or skipped meals because of not enough money/food | | | | |
| Never true                     | 63      | 41.2%                          | 49 41.5%                      | 14 40.0% Ref                                                           |
| Sometimes true                 | 52      | 34.0%                          | 42 35.6%                      | 10 28.6% 0.87 0.42 to 1.79 0.70 |
| Often true                     | 38      | 24.8%                          | 27 22.9%                      | 11 31.4% 1.30 0.66 to 2.58 0.45 |
| Health care access and quality |         |                                 |                               |                                                                     |
| Tested for HIV, last 6 mo      |         |                                 |                               |                                                                     |
| No                             | 24      | 15.7%                          | 15 12.7%                      | 9 25.7% Ref                                                           |
| Yes                            | 122     | 79.7%                          | 97 82.2%                      | 25 71.4% 0.55 0.29 to 1.02 0.06 |
| Ever been on PrEP              |         |                                 |                               |                                                                     |
| No                             | 87      | 56.9%                          | 66 55.9%                      | 21 60.0% Ref                                                           |
| Yes                            | 66      | 43.1%                          | 52 44.1%                      | 14 40.0% 0.88 0.48 to 1.60 0.67 |
| Currently on PrEP              |         |                                 |                               |                                                                     |
| No                             | 102     | 66.7%                          | 73 61.9%                      | 29 82.9% Ref                                                           |
| Yes                            | 51      | 33.3%                          | 45 38.1%                      | 6 17.1% 0.41 0.19 to 0.93 0.03 |
| Current insurance status       |         |                                 |                               |                                                                     |
| Uninsured                      | 12      | 7.8%                           | 9 7.6%                        | 3 8.6% Ref                                                           |
| Insured                        | 139     | 90.8%                          | 107 90.7%                     | 32 91.4% 0.92 0.33 to 2.58 0.88 |
All four statistical analyses comprised a descriptive component in which we delineated frequencies (and for continuous variables, means) of each characteristic (socioeconomic and health care access/quality, HIV prevention needs, PrEP-specific barriers and facilitators, and PrEP use/adherence/missed visits) by delivery model type (primary care or PrEP-only), and an analytic component in which we specified, bivariable Poisson regression models with robust variances were specified to directly estimate prevalence ratios of each characteristic by delivery model. All statistical analyses were conducted in Stata 16.

Ethical Considerations

All study procedures were approved by the Human Research Protection Program at the University of California, San Francisco (study ID# 16–20,339).

RESULTS

Of the 53 participants included in the analytic sample, 118 (77.1%) were enrolled at primary care clinics and 35 (22.9%) at the PrEP-only clinic. Ninety-six participants (63%) completed their 3-month visits, and 98 (64%) completed 6 months of follow-up. Figure 1 displays the number of enrolled participants by delivery model and month by delivery model type. Compared with primary care clinics, the PrEP-only clinic had the highest number of enrolled participants in each of its 4 months of enrollment.

Table 1 summarizes different sociodemographic factors and health care access and quality indicators by delivery model type.

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### Table 1. (Continued) Baseline Socioeconomic Characteristics and Health Care Access/Quality, Overall and Comparing PrEP-Only Clinic Participants With Primary Care Clinic Participants, Stay Study, 2017–2019 (n = 153)

|                        | Overall | Primary Care Clinic Participants | PrEP-Only Clinic Participants | Poisson Binomial Regression Comparing Socioeconomic Characteristics and Health Care Access/Quality of PrEP-Only Clinic With Primary Care Clinic (Reference Group) Participants |
|------------------------|---------|----------------------------------|--------------------------------|----------------------------------------------------------------------------------|
|                        | n       | %*                               | n                               | %*                                | PR†                                | 95% CI‡                           | P       |
| Insurance type         |         |                                  |                                 |                                   |                                    |                                   |         |
| Private only¶          | 16      | 10.5%                            | 8                               | 6.8%                              | 8                                  | 22.9%                             | Ref     |
| Public and private#    | 8       | 5.2%                             | 7                               | 5.9%                              | 1                                  | 2.9%                              | 0.25    | 0.04 to 1.68 | 0.15 |
| Public only**          | 122     | 79.7%                            | 99                              | 83.9%                             | 23                                 | 65.7%                             | 0.38    | 0.20 to 0.70 | <0.01|
| No insurance           | 6       | 3.9%                             | 3                               | 2.5%                              | 3                                  | 8.6%                              | 1.00    | 0.39 to 2.56 | 1.00 |
| Has a primary care doctor |      |                                  |                                 |                                   |                                    |                                   |         |
| No                     | 12      | 7.8%                             | 7                               | 5.9%                              | 5                                  | 14.3%                             | Ref     |
| Yes                    | 139     | 90.8%                            | 109                             | 92.4%                             | 30                                 | 85.7%                             | 0.52    | 0.25 to 1.09 | 0.08 |
| Currently on hormones  |         |                                  |                                 |                                   |                                    |                                   |         |
| No                     | 28      | 18.3%                            | 20                              | 16.9%                             | 8                                  | 22.9%                             | Ref     |
| Yes                    | 124     | 81.0%                            | 98                              | 83.1%                             | 26                                 | 74.3%                             | 0.73    | 0.37 to 1.45 | 0.37 |
| Surgeries completed    |         |                                  |                                 |                                   |                                    |                                   |         |
| No                     | 102     | 66.7%                            | 77                              | 65.3%                             | 25                                 | 71.4%                             | Ref     |
| Yes                    | 51      | 33.3%                            | 41                              | 34.7%                             | 10                                 | 28.6%                             | 0.80    | 0.42 to 1.54 | 0.50 |
| Unfair treatment by doctors in the past |          |                                  |                                 |                                   |                                    |                                   |         |
| (Strongly) disagree    | 87      | 56.9%                            | 71                              | 60.2%                             | 16                                 | 45.7%                             | Ref     |
| Neutral                | 21      | 13.7%                            | 17                              | 14.4%                             | 4                                  | 11.4%                             | 1.04    | 0.38 to 2.79 | 0.95 |
| (Strongly) agree       | 42      | 27.5%                            | 28                              | 23.7%                             | 14                                 | 40.0%                             | 1.81    | 0.98 to 3.36 | 0.06 |
| Distrust of doctors    |         |                                  |                                 |                                   |                                    |                                   |         |
| (Strongly) disagree    | 94      | 61.4%                            | 69                              | 58.5%                             | 15                                 | 42.9%                             | Ref     |
| Neutral                | 39      | 25.5%                            | 32                              | 27.1%                             | 7                                  | 20.0%                             | 1.01    | 0.45 to 2.27 | 0.99 |
| (Strongly) agree       | 24      | 15.7%                            | 12                              | 10.2%                             | 12                                 | 34.3%                             | 2.80    | 1.52 to 5.16 | <0.01|

*Percentages calculated out of total for that column, unless otherwise specified.
†PR, unadjusted ratio of the prevalence of being seen at PrEP-only clinic vs. primary clinics for each baseline characteristic compared with its reference group.
‡CI, confidence interval.
§Percentage calculated out of baseline sample size (n = 153).
¶Ref, reference group.
Private-only insurance includes the following: Aetna, Anthem or Anthem/Blue Cross, Blue Cross Medical for CHN, Blue Shield, Chinese Community Health Plan, Cigna, Health Net, Humana/Choice Care, Kaiser Permanente, Oscar, PacificCare Choice, PP plan with authorization, San Francisco Foundation for Medical Care, or Tri-care.
#Includes some combination of both public and private insurance.
**Public-only insurance includes the following: Healthy San Francisco, Healthy Worker, Medi-Ccal, Medicare, San Francisco Health Plan, Santa Clara County Health Plan, or other public insurance.

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All four statistical analyses comprised a descriptive component in which we delineated frequencies (and for continuous variables, means) of each characteristic (socioeconomic and health care access/quality, HIV prevention needs, PrEP-specific barriers and facilitators, and PrEP use/adherence/missed visits) by delivery model type (primary care or PrEP-only), and an analytic component in which we specified, bivariable Poisson regression models with robust variances were specified to directly estimate prevalence ratios of each characteristic by delivery model. All statistical analyses were conducted in Stata 16.
races/ethnicities and non-Hispanic/Latino/a/x. More than 1 in 4 participants were born outside of the United States. Most of them made $1000 USD or less in the last month. More than one-third of the sample was unstably housed, and almost 1 in 5 reported food insecurity. Most of the participants had tested for HIV in the 6 months before their baseline visit, almost half reported ever being on PrEP, and about a third were on PrEP at enrollment. Most of the participants were insured, had a primary care doctor, and were currently on hormones; a third had completed gender-affirming surgeries. More than 1 in 4 participants experienced unfair treatment by doctors and 15.7% distrusted doctors.

Compared with those who identified as women, trans women were less likely to be seen at the PrEP-only clinic versus the primary care clinics [28.6% vs. 50.8% of participants, respectively; prevalence ratio (PR) = 0.39, 95% confidence interval (CI) = 0.20 to 0.77, \( P < 0.01 \)]. In addition, there were more likely to be gay, lesbian, or queer (31.4% vs. 16.9%; PR = 2.42, 95% CI = 1.17 to 5.00, \( P = 0.02 \)) or bisexual (25.7% vs. 11.9%; PR = 2.67, 95% CI = 1.26 to 5.64, \( P = 0.01 \)) participants compared with heterosexual/straight participants seen at the PrEP-only clinic when compared with primary care clinics. Compared with White participants, Hispanic/Latina/o/x participants were less likely to be seen at the PrEP-only clinic versus primary care clinics (20.0% vs. 42.4%; PR = 0.37, 95% CI = 0.16 to 0.84, \( P = 0.02 \)). Those who were born in the United States (88.6% vs. 66.9%; PR = 2.96, 95% CI = 1.11 to 7.90, \( P = 0.03 \)) and those who made more than $1755 in the last month (34.3% vs. 11.9%; PR = 1.85, 95% CI = 1.00 to 3.42, \( P = 0.05 \)) were more likely to be seen at the PrEP-only versus primary clinics compared with their counterparts. Those on PrEP at their baseline visit were less likely to be seen at the PrEP-only clinic versus the primary care clinics (17.1% vs. 38.1%; PR = 0.41, 95% CI = 0.19 to 0.93, \( P = 0.03 \)). Compared with those who had only private insurance, those who had only public insurance were less likely to be seen at the PrEP-only clinic versus the primary care clinics (65.7% vs. 83.9%; PR = 0.38, 95% CI = 0.20 to 0.70, \( P < 0.01 \)). Participants who distrusted doctors were more likely to be seen at the PrEP-only clinic versus the primary care clinics (10.2% vs. 34.3%; PR = 2.80, 95% CI = 1.52 to 5.16, \( P < 0.01 \) (Table 1).

Table 2 summarizes baseline HIV prevention needs for the overall sample, with differences by PrEP delivery model. More than one-third of all participants had 3 or more sexual partners in the 3 months before their baseline visit; those with 3–4 (22.9% vs. 10.2%; PR = 5.80, 95% CI = 1.37 to 24.63, \( P = 0.02 \)) or 5 or more (31.4% vs. 20.3%; PR = 2.80, 95% CI = 1.09 to 19.03, \( P = 0.04 \)) sexual partners were more likely to be seen at the PrEP-only clinic rather than the primary care clinics. In addition, participants with higher perceived HIV risk (8.2 vs. 5.7; PR = 1.14, 95% CI = 1.07 to 1.20, \( P < 0.01 \)) and those currently engaged in sex work (40.0% vs. 24.2%; PR = 2.02, 95% CI = 1.14 to 3.59, \( P = 0.02 \)) were also more likely to be seen at the PrEP-only clinic versus primary care clinics.

### TABLE 2. Baseline HIV-Related Risk Behaviors, Overall and Comparing PrEP-Only Clinic Participants With Primary Care Clinic Participants, Stay Study, 2017–2019 (n = 153)

| HIV prevention needs | Overall | Primary Care Clinic Participants | PrEP-Only Clinic Participants | Poisson Binomial Regression Comparing HIV Prevention Needs of PrEP-Only Clinic Participants With Primary Care Clinic (Reference Group) Participants |
|----------------------|---------|----------------------------------|-------------------------------|--------------------------------------------------------------------------------|
|                      | N       | %*                              | n                             | PR† | 95% CI‡ | \( P \) |
| Total                | 153     | 100.0                           | 118                           | 35  | 22.9%§  | —       |
| HIV prevention needs |         |                                  |                               |     |         |         |
| Number of sexual partners, last 3 mo | |                                  |                               |     |         |         |
| 0                    | 29      | 19.0                            | 27                            | 2   | 5.7%    | Ref§    |
| 1–2                  | 53      | 34.6                            | 40                            | 13  | 37.1%   | 3.56    | 0.86 to 14.76 | 0.08 |
| 3–4                  | 20      | 13.1%                           | 12                            | 8   | 22.9%   | 5.80    | 1.37 to 24.63 | 0.02 |
| 5+                   | 35      | 22.9%                           | 24                            | 11  | 31.4%   | 4.56    | 1.09 to 19.03 | 0.04 |
| Missing              | 16      | 10.5%                           | 15                            | 1   | 2.9%    | —       |         |         |
| Condomless anal intercourse act, last 3 mo | |                                  |                               |     |         |         |
| No                   | 84      | 54.9%                           | 64                            | 20  | 57.1%   | Ref     |         |         |
| Yes                  | 55      | 35.9%                           | 41                            | 14  | 40.0%   | 1.07    | 0.59 to 1.94 | 0.83 |
| Missing              | 14      | 9.2%                            | 13                            | 1   | 2.9%    | —       |         |         |
| HIV risk perception (scale, 0–17) | 6.3      | 3.7%                            | 5.7                            | 8.2  | 4.0%    | 1.14    | 1.07 to 1.20 | <0.01 |
| Current sex work¶    |         |                                  |                               |     |         |         |
| No                   | 107     | 69.9%                           | 87                            | 20  | 57.1%   | Ref     |         |         |
| Yes                  | 37      | 24.2%                           | 23                            | 14  | 40.0%   | 2.02    | 1.14 to 3.59 | 0.02 |

*Percentages calculated out of total for that column, unless otherwise specified.
†PR, unadjusted ratio of the prevalence of being seen at PrEP-only clinic vs. primary clinics for each HIV prevention need compared with its reference group.
‡CI, confidence interval.
§Percentage calculated out of baseline sample size (n = 153).
¶Ref, reference group.
#Denotes a trans-specific addition to typical CDC criteria for PrEP guidelines.
TABLE 3. Baseline PrEP-specific Barriers and Facilitators to PrEP Uptake, Overall and Comparing PrEP-Only Clinic Participants With Primary Care Clinic Participants, Stay Study, 2017–2019 (n = 153)

| PrEP-specific barriers among those not on PrEP at baseline (n = 102)|| Overall | Primary Care Clinic Participants | PrEP-Only Clinic Participants | Poisson Binomial Regression Comparing PrEP-Specific Barriers and Facilitators of PrEP-Only Clinic With Primary Care Clinic (Reference Group) Participants |
|---|---|---|---|---|---|
| Total | 153 | 100.0% | 118 | 77.1%§ | 35 | 22.9%§ |
| Fear of being seen with HIV medications | 7 | 6.9% | 6 | 8.2% | 1 | 3.4% | 0.49 | 0.08 to 3.13 | 0.45 |
| Belief that PrEP is not for the trans community¶ | 3 | 2.9% | 3 | 4.1% | 0 | 0.0% | — | — | — |
| Concern about ability to take a pill daily | 14 | 13.7% | 13 | 17.8% | 1 | 3.4% | 0.23 | 0.03 to 1.56 | 0.13 |
| Concern about interaction with hormones | 13 | 12.7% | 12 | 16.4% | 1 | 3.4% | 0.25 | 0.04 to 1.69 | 0.15 |
| Concern about side effects | 22 | 21.6% | 18 | 24.7% | 4 | 13.8% | 0.59 | 0.23 to 1.53 | 0.28 |
| Other priorities | 11 | 10.8% | 8 | 11.0% | 3 | 10.3% | 0.97 | 0.35 to 2.71 | 0.96 |
| Other | 27 | 26.5% | 18 | 24.7% | 9 | 31.0% | 4.87 | 2.57 to 9.21 | <0.01 |
| PrEP-specific facilitators | | | | | | | |
| To protect oneself against HIV¶ | 139 | 90.8% | 104 | 88.1% | 35 | 100.0% | — | — | — |
| To make it safer to have sex act without condoms | 65 | 42.5% | 54 | 45.8% | 11 | 31.4% | 0.62 | 0.33 to 1.18 | 0.14 |
| To help the community/to help fight the HIV epidemic | 55 | 35.9% | 44 | 37.3% | 11 | 31.4% | 0.82 | 0.43 to 1.54 | 0.53 |
| Partner has HIV and want to avoid getting HIV¶ | 3 | 2.0% | 3 | 2.5% | 0 | 0.0% | — | — | — |
| Strongly encouraged or pressured by a friend/sexual partner to join the project¶ | 10 | 6.5% | 9 | 7.6% | 1 | 2.9% | — | — | — |
| Provider recommended PrEP | 42 | 27.5% | 37 | 31.4% | 5 | 14.3% | 0.44 | 0.18 to 1.06 | 0.07 |
| Reimbursement money is helpful | 36 | 23.5% | 29 | 24.6% | 7 | 20.0% | 0.81 | 0.39 to 1.71 | 0.58 |
| Other¶ | 5 | 3.3% | 4 | 3.4% | 1 | 3.4% | — | — | — |

Each PrEP-specific barrier and facilitator is a dichotomous variable, so reference groups are implied and are the complement of that characteristic (eg, “fear of being seen with HIV medications” has a reference group of those who responded “no” and a comparison group of those who responded “yes”).

*Percentages calculated out of total for that column, unless otherwise specified.

†PR, unadjusted ratio of the prevalence of being seen at PrEP-only clinic vs. primary clinics for each PrEP-specific barrier and facilitator compared with its reference group.

‡Confidence interval.

§Denominators are n = 102 not on PrEP at baseline overall, n = 73 not on PrEP at the primary care clinics, and n = 29 not on PrEP at the PrEP-only clinic.

¶Cell sizes too small to run bivariable comparison.

According to Table 3, few participants reported PrEP uptake barriers found in the literature, but there was some agreement with PrEP facilitators. The greatest barriers to PrEP were a concern about side effects (21.6%) and “other” concerns (eg, issues finding a provider to prescribe PrEP, cost, or insurance barriers), with participants who experienced “other” concerns being more likely to be seen at the PrEP-only clinic versus primary care clinics (31.0% vs. 24.7%; PR = 4.87, 95% CI = 2.57 to 9.21, P < 0.01). Overall, the greatest PrEP-specific facilitators were protecting oneself from HIV (90.8%), making it safer to have condomless sex act (42.5%), and helping the community or helping fight the HIV epidemic (35.9%). PrEP-specific facilitators were not statistically significantly different by delivery model.

Finally, we assessed differences in PrEP and visit adherence by delivery model (Table 4). More than a third of participants were on PrEP for 6 months, and more than half of those on PrEP reported excellent PrEP adherence at 3 and 6 months. In addition, most participants on PrEP (80%) and for whom we had data reported missing only 0–2 days of PrEP doses in the week before their 3-month and 6-month visits. Although 71.4% vs. 24.6% of participants at the PrEP-only clinic vs. primary care clinics reported being on PrEP for 6 months, along with 72.4% vs. 47.1% and 63.3% vs. 44.0% of PrEP-only vs. primary care participants reporting excellent PrEP adherence at 3-month and 6-month visits, respectively, self-reported PrEP duration and adherence at 3 months and 6 months and were not statistically significantly different by delivery model. Seventy-nine participants (51.6%) had missed their 3-month and/or 6-month study visits; of them, 71 (89.9%) were from primary care clinics.

**DISCUSSION**

We found that those who could benefit most from PrEP were more likely to use the PrEP-only clinic than those in trans-affirming primary care. PrEP-only clinic participants were significantly more likely than those who received PrEP in trans-affirming primary care to have had 3 or more sexual partners in the last 3 months, perceived that they were at high risk of HIV, and were more likely to currently be doing sex work.

The PrEP-only clinic model we provided outside business hours with low barriers to entry provided a novel model for PrEP uptake that addressed structural barriers affecting people most at risk of HIV. Establishing primary care in two of our trans-affirming primary care clinics took up...
to a 6-weeks including multiple visits, creating a high threshold to PrEP access. PrEP could be prescribed the same day at the PrEP-only clinic, which facilitated PrEP uptake. In addition, trans-affirming primary care clinics were not open past business hours, which could have reduced access for participants who worked at night or could not take off-work hours for doctor visits. A recent study in San Francisco found that the cost and time of medical visits is a major barrier to PrEP persistence and that trans women are a population most likely to discontinue PrEP. Our PrEP-only clinic was also used by significantly more people categorized as higher income and with private insurance. The PrEP-only clinic participants may have made too much income to qualify for Medi-Cal, an important pay source for PrEP, but not enough to pay for the PrEP copay, medical visits, and laboratory test costs not covered by private insurance, as has been found in research on barriers to PrEP.

We also found significant differences in medical mistrust by delivery model. Trans people in the PrEP-only clinic reported significantly more medical mistrust at baseline and most (85.7%) had a primary care physician. It is unclear why these individuals sought PrEP outside primary care, but data from trans women point to trauma from discrimination in health care settings and mistrust of providers as barriers to health care. Trans participants may not have felt safe discussing their sexual risk behaviors with their primary care doctors because of mistrust or other fears.

Few participants overall reported any of the barriers to PrEP uptake we assessed. The barrier most reported was a concern about side effects (21.6%), and only 12.7% were concerned with feminizing hormone interactions. However, a number of important facilitators did emerge in our data. The number one reason participants started PrEP was to

### TABLE 4. Differences in PrEP and Study Visit Adherence, Overall and by PrEP Delivery Model, Stay Study, 2017–2019 (n = 153)

|                          | Overall | Primary Care Clinic Participants | PrEP-Only Clinic Participants | Poisson Binomial Regression Comparing PrEP and Visit Adherence of PrEP-Only Clinic With Primary Care Clinic (Reference Group) Participants |
|--------------------------|---------|----------------------------------|-------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
|                          | n | %     | n | %     | n | %     | PR* | 95% CI† | P      |
| Time on PrEP (n = 153)‡§ | 43 28.1% | 42 35.6% | 1 2.9% | Ref||
| Not on PrEP during the study | 32 20.9% | 26 22.0% | 6 17.1% | Ref||
| 3 mo                     | 54 35.3% | 29 24.6% | 25 71.4% | 0.68 0.20 to 2.29 0.54|
| 6 mo                     | 24 15.7% | 21 17.8% | 3 8.6% | Ref||
| Missing                  | 9 11.3% | 6 11.8% | 3 10.3% | Ref||
| PrEP adherence at 3 mo among those on PrEP (n = 80)** | 22 27.5% | 17 33.3% | 5 17.2% | 0.56 0.17 to 1.84 0.34|
| (Very) poor or fair      | 45 56.3% | 24 47.1% | 21 72.4% | 1.40 0.47 to 3.23 0.67|
| (Very) good              | 8 10.0% | 5 10.0% | 3 10.0% | Ref||
| Excellent                | 24 30.0 | 19 38.0 | 5 16.7% | 0.56 0.17 to 1.84 0.34|
| PrEP adherence at 6 mo among those on PrEP (n = 80)** | 42 52.5% | 22 44.0% | 19 63.3% | 1.40 0.47 to 3.23 0.67|
| (Very) poor or fair      | 12 15.0% | 9 17.6% | 3 10.3% | 0.64 0.23 to 1.81 0.40|
| (Very) good              | 70 87.5% | 45 90.0% | 24 83.3% | Ref||
| Excellent                | 8 10.0% | 4 8.0% | 5 13.3% | 1.40 0.65 to 3.01 0.39|
| Days of missed PrEP in the last week at the 3-mo follow-up among those on PrEP (n = 80)# | 67 83.8% | 41 80.4% | 26 89.7% | Ref||
| 0–3                      | 12 15.0% | 9 17.6% | 3 10.3% | 0.64 0.23 to 1.81 0.40|
| 4–7                      | 70 87.5% | 45 90.0% | 24 83.3% | Ref||
| 6–9                      | 8 10.0% | 4 8.0% | 5 13.3% | 1.40 0.65 to 3.01 0.39|
| Days of missed PrEP in the last week at the 6-mo follow-up among those on PrEP (n = 80)** | 74 48.4% | 47 39.8% | 27 77.1% | Ref||
| 0–3                      | 79 51.6% | 71 60.2% | 8 22.9% | 0.28 0.13 to 0.57 <0.01|
| 4–7                      | 8 10.0% | 4 8.0% | 5 13.3% | 1.40 0.65 to 3.01 0.39|

*PR, unadjusted ratio of the prevalence of being seen at PrEP-only clinic vs. primary clinics for each PrEP + study visit adherence characteristic compared with reference group.
†CI, confidence interval.
‡Cell sizes too small to run bivariable comparison.
§Denominators are n = 153 participants overall, n = 118 at the primary care clinics, and n = 35 at the PrEP-only clinic.
¶Ref, reference group.
*Models did not converge because of small cell size.
#Denominator is n = 80 who reported taking PrEP since their last study visit (baseline); of them, n = 51 at the primary care clinics and n = 29 at the PrEP-only clinic.
**Denominator is n = 80 who reported taking PrEP since their last study visit (3 months); of them, n = 50 at the primary care clinics and n = 30 at the PrEP-only clinic.
protect oneself from getting HIV (90.8%). Two other facilitators, the ability to have safer sex act without condoms and to help the community fight HIV, were also frequently reported. The concern for community, self, and sex positivity may be important messaging directions for interventions hoping to increase PrEP uptake in trans communities.

Our study has limitations. Data for this project were gathered as part of a demonstration project, so there is no control group to determine the definitive impact of delivery models on PrEP uptake or adherence among participants. In addition, the data analyzed were missing 7 participants for whom baseline data in the computer-assisted survey were not captured. We used self-report adherence measures and did not include a biomarker of adherence in our analysis, which may have created bias. Imprecision in our results may be due to the small sample size. Finally, some of the factors we assessed had small sample sizes making comparison impossible or difficult for obtaining precision, as noted earlier.

Despite these limitations, our study fills an important gap in approaches for improving PrEP uptake among trans people. A recent review of delivery models for HIV prevention found only one dedicated study of PrEP delivery for trans women.30 Our study provides evidence that PrEP uptake for trans communities could be enhanced by offering low threshold PrEP-only services outside primary care, messaging building on the facilitators we identified, and attending to structural barriers to PrEP. Furthermore, the barriers to PrEP uptake identified in the literature to date are only partially relevant-based on our evidence. New research focused on structural factors may provide the insights needed to ameliorate barriers to PrEP for trans communities.

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