

**Assessment of Barriers and Facilitators to PrEP Uptake Among
Transgender Women and Non-Binary Assigned Male at Birth Persons
at Risk of Contracting HIV**

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DNP Project Report

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Abstract

Transgender women are disproportionately affected by HIV, at a rate 32 times that of the general population. In spite of high levels of efficacy, use of HIV pre-exposure prophylaxis (PrEP) – to prevent HIV infection – remains very low in transgender women at risk of HIV. The PrEP care continuum models how patients interact with PrEP at the levels of awareness, willingness, uptake, adherence, and retention. In assessing barriers and facilitators to PrEP use in transgender female and non-binary assigned male at birth (AMAB) patients, identifying the stages of disengagement in the continuum helped formulate recommendations for tailored interventions to increase PrEP use and reduce new HIV infections in this group.

To do so, a two pronged approach consisted of historical chart reviews and a Qualtrics survey of current Prism Health transfemale and non-binary AMAB patients about PrEP experience and perceptions. Both gathered sociodemographic factors, elicited sexual health related behaviors, the stage in the PrEP care continuum, and themes related to PrEP use and values. The outcomes of this study validated the adoption of gender affirming and trauma informed care models as supportive to the patient health and HIV prevention, while eliciting a few opportunities for further improvement in PrEP engagement.

Keywords: transgender; women; assigned male at birth; AMAB; non-binary; pre-exposure prophylaxis; PrEP; HIV prevention.

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Problem Description

An estimated 13.7% of transgender people in the U.S. live with HIV, human immunodeficiency virus (Becasen et al., 2019). This is 32 times higher than the reported HIV prevalence rate in the general U.S. adult and adolescent population (427.5/100,000) as of 2018 (Centers for Disease Control and Prevention, 2020b). More specifically, transgender women are disproportionately affected, with an estimated 18.8% living with HIV, and representing 90% of the new HIV diagnoses within the transgender population (Centers for Disease Control and Prevention, 2020a). Transgender women are reported to engage in HIV risk behaviors with high prevalence: an estimated 41.7% have multiple partners, 38.2% have unprotected sex, and 37.9% engage in sex work (Becasen et al., 2019). The highest risk of sexual HIV transmission is by unprotected anal receptive sex, whereas the risk via other sexual exposures declines by at least 10-fold in comparison (Patel et al., 2014). Injection drug use is involved in only about 10% of HIV transmissions (Centers for Disease Control and Prevention, 2020b), thus sexual behavior will be the primary determinant of the risk of HIV acquisition.

HIV pre-exposure prophylaxis (PrEP) combines two antiretroviral drugs in a single daily pill. It has demonstrated excellent efficacy in preventing HIV infection sexually in a variety of populations at risk (Poteat & Radix, 2020). With PrEP, one can take an active role in minimizing HIV risk, although efficacy is highly dependent on adherence. In spite of its promising efficacy, the proportion of persons with an indication for PrEP for whom it is prescribed (i.e. uptake) remains low. In the adult and adolescent population, uptake averages 18.1% nationally (Centers

for Disease Control and Prevention, 2020c), and 13.6% in Oregon as of 2018, with considerable variation between counties (NCHHSTP AtlasPlus, 2021). In transgender women, uptake is similarly low, with estimates ranging from 4% to 28% depending on the subgroup (Poteat & Radix, 2020). Increasing PrEP uptake is one of the strategies of a national effort to reduce new HIV infections, “Ending the HIV Epidemic” (Fauci et al., 2019). Assessing the specific barriers and facilitating factors to PrEP use in the transfemale and non-binary assigned male at birth (AMAB) population lays the groundwork necessary to develop effective interventions to reduce new HIV infections in this population.

Available Knowledge

A literature search was performed in May 2021 in the PubMed database using the MeSH term “Transgender Persons”, associated with the Title/Abstract terms “women” and “PrEP”. The results were narrowed down to those published in the English language, in the last 5 years (May 2016-2021). A manual assessment of the 116 results identified relevant secondary research reviews, as well as primary research articles specifically studying factors affecting PrEP uptake in the population of interest, primarily in US locales. HIV epidemiological and PrEP coverage data were obtained from the CDC, while background references and relevant frameworks and models were identified from focused PubMed searches.

PrEP is an oral daily medication indicated for adults and adolescents at risk of contracting HIV. Risk factors include sexual activity in the past 6 months with inconsistent condom use, engaging in exchange sex, HIV positive sexual partner(s), among others. Any trans person inquiring about PrEP and all trans adolescents should also be considered eligible for PrEP (Deutsch, 2018). HIV status, renal function, side effects, and adherence are assessed every 3 months. Regular HIV monitoring is important since efficacy is highly dependent on treatment

adherence, and taking PrEP after seroconversion increases the risk of developing drug resistant HIV. Although uncommon, side effects may include headache, rash, gastrointestinal symptoms, and usually resolve within a month (Centers for Disease Control and Prevention, 2018; Deutsch, 2018). Blood estrogen levels have proven unaffected by PrEP use in transgender women taking estrogen (Hiransuthikul et al., 2019). On the other hand, exogenous estrogen mildly decreases plasma levels of PrEP components, although they still remain above protective levels with daily dosing (Ackerley et al., 2019; Hiransuthikul et al., 2019). Lacking trans specific studies about event-driven PrEP (e.g. PrEP 2-1-1), only daily PrEP is recommended for persons taking exogenous estrogen. PrEP 2-1-1 is an “on demand” method of HIV chemoprophylaxis wherein one takes a loading dose of 2 PrEP pills between 2 and 24 hours before sex, and then 1 pill every 24 hours until at least 48 hours have passed after the last sexual encounter. This approach is only recommended for people having anal sex, who do not take exogenous hormones, and do not have an active hepatitis B infection.

In light of high efficacy but low uptake and adherence, many studies have identified barriers and facilitators to PrEP use in transgender women. PrEP marketing is primarily targeted to the MSM (men who have sex with men) population, and does not reach the transgender community. This results in low PrEP awareness in transgender women (Poteat, Wirtz, Malik, et al., 2019; Sevelius et al., 2016). Individual factors limiting willingness to use PrEP include heightened concerns about interactions with gender affirming hormone therapy (GAHT), side effects, PrEP/HIV stigma, and the need for frequent medical monitoring. Social rejection and transphobia are at the root of many structural barriers to PrEP uptake related to economic and insurance status, via poverty, life and housing instability, and competing priorities for basic needs such as food and shelter. This renders taking daily preventive medication and managing

recurrent medical appointments unimportant in comparison (Poteat, Wirtz, Malik, et al., 2019; Sevelius et al., 2016). Experiences of discrimination and transphobia also create barriers to healthcare, and to PrEP in particular, for transgender women who express medical mistrust, a lack of trans competent and PrEP knowledgeable providers, and of trans friendly practices. Many are uncomfortable discussing sexual risk behaviors with providers who may themselves be uncomfortable with sexual history taking, reluctant to prescribe PrEP to transgender women, or concerned about risk compensation behaviors (Koechlin et al., 2017; Nieto et al., 2021).

On the other hand, access to gender affirming care has been reported to facilitate PrEP use in transgender women. When gender affirmation needs are met, transgender women are more likely to access health promotion information, and discuss sexual risk behaviors with a provider (Nieto et al., 2021; Poteat, Wirtz, Malik, et al., 2019). HIV risk self-awareness also facilitates PrEP uptake, mediated by fear of HIV/AIDS, a high prevalence of HIV within one's sexual network, and an understanding of the efficacy of PrEP at reducing the risk of HIV (Nieto et al., 2021; Pacífico de Carvalho et al., 2019). Lastly, PrEP is seen by many transgender women as an empowering tool to control their own sexual health, as they often have low power to negotiate for condom use in the setting of a limited supply of sexual partners, whether in commercial sex work or personal relationships (Nieto et al., 2021; Sevelius et al., 2016).

Rationale

The PrEP continuum of care model seeks to understand how patients interact with PrEP at various stages of use in order to identify interventions that will support appropriate use and ultimately reduce the incidence of HIV infections (Nunn et al., 2017). In assessing barriers and facilitators to PrEP use in this project, identifying the stages of disengagement in the continuum can help formulate recommendations for tailored interventions. The continuum starts with

awareness of individual HIV risk, and of PrEP as a risk reduction method. It proceeds to PrEP uptake, then to adherence and retention. Arguably, a stage of willingness may be considered between awareness and uptake, which can be a point of disengagement with PrEP, especially if concerns with PrEP use are not addressed (Poteat, Wirtz, Malik, et al., 2019). In both the uptake and adherence/retention stages, patients often face structural and individual barriers to care which reduce PrEP use.

The model of gender affirmation is a transgender specific-framework that outlines how psychosocial factors that stem from stigma can widen the gap between the need for gender affirmation and the level of access to sources of gender affirmation (Sevelius, 2013). In turn, this imbalance threatens the identity of the individual who may seek to close this gap within high risk contexts when safer sources of gender affirmation are not accessible. High risk situations such as exchange sex, condomless sex, using sex to obtain gender affirmation from others, but also use of street hormones, fillers, and other drugs, engender poor health outcomes, including HIV infection among others. Within the context of HIV prevention, in combination with the PrEP continuum of care, this model can provide insight into psychosocial factors that influence PrEP use specifically in transgender women. This approach guided the development of chart review queries and survey design to support this assessment effort.

Specific Aims

The assessment of barriers and facilitators to PrEP use described in this report was conducted to identify the stages of disengagement in the PrEP continuum for transgender female and non-binary AMAB patients cared for in a single medical practice in the past three years. This forms a solid basis on which to design and recommend targeted interventions which will improve

PrEP uptake and adherence for those at risk of HIV, and will ultimately reduce the HIV burden in this population.

Methods

Context

The scope of this assessment includes the patient population at Prism Health, a non-profit healthcare center in the Portland metro area which provides compassionate high quality care for LGBTQ+ individuals and beyond. Founded in 2017 as a division of Cascade AIDS Project (CAP), Prism Health was designed by and for the LGBTQ+ community. Prism Health prioritizes inclusivity and a trauma informed approach, providing a safe and culturally responsive atmosphere for patient centered care.

Prism Health offers comprehensive culturally competent primary care, gender affirming care, behavioral and mental health care, Spanish speaking care, and PrEP care. Due to the current COVID19 pandemic, care is currently offered in a split model of telehealth, phone, and in clinic visits. Other services provided onsite include COVID19 vaccination, lab, pharmacy (with mail order options, free medication delivery services, and adherence programs), as well as free HIV/STI testing. Prism Health earned a federally qualified health center look-alike status, and serves all patients regardless of ability to pay, accepting Medicare, Medicaid, private insurance, provides sliding scale payment options, and navigation services to eligibility and financial assistance programs and eligibility.

Prism Health provides care to over 1500 teens and adults yearly, more than 90% endorsing a sexual orientation other than straight, and about half with a gender identity other than woman or man. Prism Health currently employs 4 primary care providers, 2 behavioral and mental health providers, 2 registered nurses, 3 medical assistants, 3 receptionists, 2 site and data

specialists, a referral specialist, and a clinic manager. Because of the connection with its parent company, CAP, patients can easily access community resources for assistance with food security, housing, transportation, communication (e.g. phones to support phone visits) among others via patient services navigators. Additionally, in keeping with their mission, CAP offers prevention and PrEP navigator services with both individual and community engagement.

Interventions

The assessment of barriers and facilitators to PrEP engagement was conducted using a two pronged approach of chart reviews and a survey of patients about PrEP experience and perceptions. Chart reviews covered a three year timeframe of medical documentation – starting on 11/29/2018 – in a population of transgender women and non-binary AMAB patients, alive at the time of writing, and seen at least once for an office, phone, or telehealth visit by a provider at Prism Health. For each patient, a qualitative review of care notes used a standardized case report form (Appendix A) to evaluate the stage of the patient in the PrEP care continuum and to extract themes related to barriers and facilitators to PrEP use. Sociodemographic factors, factors of HIV risk, and timelines of PrEP use were extracted from each patient chart as well.

A Qualtrics survey about sexual health-related behaviors was sent on November 1st, 2021 to all current patients who received care at Prism Health and had an active MyChart account. The survey started with a statement of confidentiality and a description of the end goal of the survey. Input on the survey instrument contents was solicited from clinic staff prior to approval and deployment. The survey follows a skip logic/conditional format of dichotomous questions with follow-up multiple choice questions with open ended options (Appendix B). A reminder was sent a month later, and returned surveys were accepted for 3 months after launch. Respondents who self-identified as AMAB and of gender other than male were considered in scope for this project.

This author performed chart reviews, monitored survey responses, coded, analyzed, interpreted obtained data, and reported results to clinic leadership. The project chair provided guidance for the duration of the project. The medical director and providers reviewed the survey instrument for clarity, content, and targeted patient group. The clinic site specialist assisted with EHR data access and broadcasting the survey link via MyChart.

Study of the Interventions

This dual approach related sociodemographic information and health behaviors to HIV risk and stages in the PrEP care continuum. It also elicited themes related to barriers and facilitators to progression in the PrEP care continuum, to be compared with those documented in the literature for which interventions have proven effective at increasing engagement with PrEP.

Measures

The survey gathered process measures such as socio-demographic and healthcare factors, behaviors that contribute to HIV risk, as well as self-perceived HIV risk. Subsequent questions progressed along the PrEP care continuum, starting from PrEP awareness, to uptake, adherence, and retention, adapted from Eaton et al. (2017). Answers to this section inferred the stage of the respondent along the PrEP care continuum as an outcome measure. Follow-up questions elicited barriers and facilitators specific to each stage as qualitative outcome measures. A paper version of the Qualtrics survey is included in Appendix B for more details about answer choices and definitions. The chart review approach gathered similar process measures, outcome measures, and themes. In addition, person-time of PrEP constituted a secondary outcome measure included in the standardized case report form (Appendix A). It is defined as the number of months an individual has taken PrEP accrued between initiation (or re-initiation) and discontinuation (Krakower et al., 2019).

Measures such as the number of survey requests sent via MyChart, returned, as well as the number of charts reviewed indicated response rate, degree of chart review completion, and informed statistical analyses. Survey results were reviewed monthly for response rate, completeness, to identify problems, and to perform pre-analyses. Identification of common themes indicated potential avenues to improve PrEP engagement at the population level.

Duplicate surveys were identified by extent of overlap of objective process measures, and only the initial survey was retained. Surveys with incomplete data were identified within the Qualtrics workflow and were assessed on a case by case basis for inclusion. Survey responses were checked against inclusion criteria (HIV seronegative or HIV status unknown, non-cis AMAB) before further analysis.

Analysis

Responses to open ended questions underwent a thematic analysis following an *a priori* codebook developed from existing literature on PrEP engagement in transgender women. Emerging common themes were identified during this process. A second pass was performed to revise coding as necessary prior to analysis. The top factors affecting PrEP engagement in our specific population were then identified by frequency.

Descriptive statistics of quantitative data were obtained within Excel. Significant differences to a significance level of $\alpha = .05$ were inferred via Z-test for proportions comparison, t-test for independent means comparison.

Ethical Considerations

To maintain confidentiality, data collected from surveys and chart reviews did not contain any individually identifiable information. For example, dates of PrEP initiation and discontinuation were recorded as cumulative duration of use. Survey and chart review results

were stored on OHSU's secure and HIPAA compliant cloud storage systems Box and OneDrive. Access was restricted to this author and to project team members requiring access to provide support with coding and data analysis, as well as to transfer data ownership.

To ensure ethical treatment of participants, a request for determination was filed with the OHSU Institutional Review Board (IRB). A waiver was granted on 7/14/2021 as this project was deemed to not involve human research. A statement of respondent anonymity and response confidentiality was embedded in the opening statement of the survey. Implied informed consent was thus obtained through completion and submission of the survey. The respondents were directed to the Prism Health clinic manager to address questions or concerns related to the project.

This project did not incur any additional costs. Online surveys were designed in Qualtrics, an OHSU supported platform for the creation and dissemination of secured anonymized surveys. The surveys were disseminated within Prism Health's EHR system via a URL included in a MyChart message. No competing financial interests or conflicts of interest were identified in this project.

Results

Chart Review

A report of all patients seen by a provider at Prism Health for an office, telehealth, or phone visit, between 11/29/2018 and 11/29/2021, and currently alive, returned 2267 patients. Of these, 381 AMAB patients were deemed in scope for this chart review. As shown in Appendix F, their ages averaged 31.5 years, ranging from 17 to 67 years. 98% carried healthcare insurance, 42% worked full time, while a third were unemployed. The majority had received some college education (36%), 19% obtained a Bachelor's degree, but no education level was documented for

a quarter of these patients. 9% of them had documented experiences of housing instability in the last 12 months, and 3% had documentation of injection drug use.

The W/TW group consisted of 232 patients who identified as a woman or transgender woman while the NB group was comprised of 149 patients identifying neither as a man, a woman, or a transgender person. Almost all patients in the W/TW group were on gender affirming hormone therapy (96%) while a significantly lower proportion of the NB group was (32%; $p < .00001$). HIV risk was determined from the latest documented sexual history and criteria established as in Appendix A. A significant difference in HIV risk appeared between these two populations, with 19.4% of the W/TW group and 43% of the NB group deemed at risk for HIV acquisition ($p < .00001$). In each group, the proportion of HIV positive patients was comparable, nearing 3% ($p = .653$).

Although 219 patients in our whole study sample had no documented discussion of PrEP, most of them were deemed to not be at risk of HIV. PrEP documentation established the stage in the PrEP continuum for the subset of 109 in-scope patients who were deemed at risk of HIV, with no significant differences arising between those in the W/TW and NB groups. As shown in the PrEP continuum figures in Appendix F, no documentation of PrEP discussions was available in 8% of at-risk patients (“PrEP unaware”), while 10% had declined PrEP when discussed (“PrEP aware – no uptake”). About a quarter were no longer taking PrEP either because they were no longer at risk (8%, “PrEP uptake – not retained”), but more often for other reasons (18%, “PrEP uptake – not adherent”). A large majority of at-risk patients in our sample (55%) were taking PrEP at the time of this study (“PrEP uptake – retained”).

Both patients deemed at risk of HIV and not at risk have taken PrEP. The reasons for PrEP initiation are seldom clearly documented but most often stemmed from a desire for

prevention in the setting of high risk sexual behaviors (e.g. multiple partners, partners having multiple partners, inconsistent condom use), a PCP suggestion, less frequently to provide safety in sex work, and more rarely because of a partner living with HIV or as transition from post exposure prophylaxis (PEP). Conversely, lack of risk was the overwhelming reason for declining PrEP, even though over a fifth of these patients were deemed at risk of HIV per our criteria outlined in Appendix A. Much less frequent reasons for declining PrEP included hesitation, concerns about potential side effects, deferring initiation, or simply not being interested.

In patients who have taken PrEP in the past, reasons for discontinuation mirrored those for declining PrEP with almost half of them no longer being at risk, and rare patients with intolerable side effects or starting PEP after discontinuing PrEP for an unknown reason. A gap in PrEP use due to cost / insurance concerns or pending labs accounted for about an eighth of documented discontinuations. Over a third of the patients no longer taking PrEP were lost to follow-up, either transferring care to another practice or not returning for care. On average, the cumulative duration patients used PrEP was significantly greater in the NB group than in the W/TW group (17.2 months vs. 11.7 months respectively, $p = 0.040$).

Survey

The Qualtrics survey instrument included in Appendix B was sent to all 2158 current Prism Health patients with an active MyChart account. In the three months following launch, 269 unique responses were received, representing a 12% response rate. Of these, 54 AMAB patients were deemed in scope. As shown in Appendix G, their median age bracket was 25-34 years old – representing 43% of respondents – and ranged from less than 18 to over 65 years old. All of them carried healthcare insurance, 48% worked full time, and a fifth were unemployed. The

majority had received some college education (41%) or obtained a Bachelor's degree (39%). 17% of them had experienced housing instability in the last 12 months, and half of them endorsed a yearly income below \$25,000 (~200% of the federal poverty level).

The W/TW group consisted of 29 respondents who identified as a woman or transgender woman, while the NB group was comprised of 25 respondents identifying neither as a man, a woman, or a transgender person. Almost all respondents in the W/TW group were on gender affirming hormone therapy (97%) while a significantly lower proportion of the NB group was (40%; $p < .00001$). HIV risk was determined from responses to the sexual health survey questions per criteria established in Appendix A. Although 25% of the W/TW group and 40% of the NB group were deemed at risk of HIV acquisition, this difference was not significant ($p = .1416$). Notably, 53% of the respondents endorsed a "low risk" of acquiring HIV in the next 12 months, and 42% endorsed "no risk".

None of the four respondents who had never heard about PrEP prior to this survey were deemed at risk for HIV. As shown on the PrEP continuum figures in Appendix G, only 18 in-scope respondents were deemed at risk for HIV, most of whom were currently using PrEP ("PrEP uptake – retained"). One respondent deemed at risk had heard of PrEP from friends and from their healthcare provider but had not ever taken it ("PrEP aware – no uptake"). They indicated that they would be willing to use PrEP if their risk of HIV increased. Another at-risk respondent was no longer taking PrEP because they were no longer at risk ("PrEP uptake – not retained"). A third at-risk respondent was no longer taking PrEP for reasons they could not recall ("PrEP uptake – not adherent") but indicated that it was "time to get back on it".

Among all 54 in-scope respondents, those who were aware of PrEP indicated hearing about it from their PCP, online, the community, and then from friends, in descending order of

frequency. Among those who knew about PrEP but had never taken it (“PrEP aware – no uptake”), the biggest reason for declining PrEP was lack of risk, far ahead of concerns with side effects, potential interactions, or efficacy. A smaller fraction stated a daily pill regimen as a reason to decline PrEP. However, open ended input revealed that 89% of respondents in this group indicated a willingness to use PrEP if (a) it was recommended to them by their PCP, or (b) they had new, multiple, or at-risk sexual partners, or (c) the benefits outweighed the side effects, or (d) they were more informed about the side effects of PrEP and how to manage them.

As reflected in the chart review, the reasons for respondents initiating PrEP were primarily for personal prevention, then by PCP suggestion, less so for safety in sex work, and rarely because of a partner living with HIV. They generally liked the peace of mind PrEP provided, feeling safer in their sexual encounters while being active in their prevention from HIV. The most significant burden for respondents who had used PrEP was by far the daily pill regimen as many endorsed difficulties consistently taking a daily medication. A small minority in this group mentioned side effects, cost, and lab-dependent refills as aspects of PrEP therapy they disliked. Few of the respondents actually discontinued PrEP but those who did endorsed side effects and no longer being at risk as the main causative factors.

Open ended questions revealed that, although respondents who had used PrEP were generally well informed about PrEP before initiation, some wished they had known more about side effects, long term effects, and the anticipated cost of PrEP therapy. Suggestions for improvement from respondents who had taken PrEP included lowering the cost, changing dosing frequency to a monthly pill or a vaccine, changing the formulation to a smaller pill, and studying PrEP for all genders.

Discussion

Summary

This study has demonstrated a high engagement with PrEP in the transgender female and non-binary AMAB patient population at Prism Health, with over half of at-risk patients in the desired “PrEP uptake – retained” category (i.e. currently taking PrEP). Although most patients chose to enter PrEP care for personal prevention or upon suggestion from their PCP, up to a fifth of at-risk patients were found to discontinue PrEP (“PrEP uptake – not adherent”), the majority of which were lost to follow-up. Whether these patients moved out of the area, changed medical practice, or did not present to care to continue PrEP therapy is unclear. A handful of discontinuations were related to cost / insurance issues and to pending labs prior to renewing a prescription for PrEP. Awareness of PrEP is high and perception highly positive in that population. Survey respondents who used PrEP expressed that it provided peace of mind and safety, but that the daily pill regimen was burdensome, and side effects can drive discontinuation.

The strengths of this study lay in its two pronged approach. The chart review provides a quantitative overview of the in-scope patient population distribution along the PrEP continuum, facilitating the identification of opportunities for impactful improvement. On the other hand, the survey uncovers qualitative patient perspectives not often documented or discussed during encounters. These can help direct choices of interventions to improve uptake/retention and thus patient health outcomes. This assessment validated the approach Prism Health has taken to support PrEP engagement and prevent HIV in this subset of their patient population but also identified opportunities for further improvement.

Interpretation

Although this group of transgender women and non-binary AMAB patients have a significant risk of HIV acquisition (~29% are deemed at risk), the rate of HIV infection remains very low (~3%) compared to national estimates which range above 10-15% for this population (Becasen et al., 2019). Most HIV seropositive patients in this group of patients had seroconverted prior to Prism Health's inception in 2017, indicating either a low rate of new HIV acquisition while receiving care at Prism or of new onset HIV care retention at Prism. The chart review estimated PrEP uptake in Prism's transgender women and non-binary AMAB patient population at 82%, with 55% of PrEP retention. These rates are far above national and local averages of 18 and 13.6% respectively in the general population (Centers for Disease Control and Prevention, 2020c; NCHHSTP AtlasPlus, 2021): such a high level of PrEP engagement would be protective and support a low rate of HIV acquisition in this group.

Few differences were uncovered with respect to PrEP engagement and perspectives between the transgender women and non-binary AMAB patient groups. While the risk for HIV was higher in the non-binary AMAB group, the level of engagement with PrEP showed no significant difference between groups. Interestingly, the cumulative duration of PrEP use in the non-binary AMAB group was significantly higher than in the transgender women group at 17.2 vs. 11.7 months. In this context, this may likely be more indicative of more sustained increased risk in this group than a higher engagement in PrEP.

By establishing its practice within gender affirming and trauma informed care models while actively supporting sexual health and PrEP care, Prism is successfully addressing the structural determinants of health that often lead to poor HIV related outcomes in this population (Poteat, Wirtz, & Reisner, 2019; Sevelius et al., 2016). The remaining barriers to PrEP

engagement included the daily PrEP administration regimen, experiences with side effects, and loss to follow-up, which align with published data and also represent opportunities for further improvement of PrEP retention. Interestingly, concerns with monitoring frequency or interactions with gender affirming hormone therapy appear minimal in this group. The recent approval of injectable cabotegravir for PrEP by the FDA may offer a welcome respite from daily PrEP in the form of bimonthly injections (US Food and Drug Administration, 2021).

Limitations

The limitations of this study include a lack of generalizability to other practice settings not dedicated to serving LGBTQ+ patients within a gender affirming and trauma informed care model. Because of this, our sample of patients was biased towards high engagement and access to affirming care, a known facilitator to PrEP engagement. This might have obscured the emergence of barriers that would be more prevalent in another care context. The quality of the data extracted from chart reviews was limited to the quality and accuracy of documentation and of consistent sexual health history taking. A rigorous and consistent data extraction approach via case report forms helped mitigate some of the variability, but variation between providers and encounters remain. Another source of bias in the qualitative survey data stemmed from a low response rate and a self-selection of respondents who may be more engaged in their health than the average patient within our scope, likely skewing the output towards more positive PrEP engagement. Efforts were made to avoid conclusions based on frequencies in that sample. Finally, our definition of HIV risk in a binary yes/no approach with an assessment limited to available documentation may not be aligned with patient perception of their own risk. Upon reviewing patient's self-reported risk, this study is likely overestimating HIV risk: this may

affect the distribution of patients along the PrEP continuum, specifically overemphasizing the contribution of the “PrEP aware – no uptake” category.

Conclusions

This assessment of PrEP engagement within the transgender women and non-binary AMAB patient population at Prism Health has clearly validated their adoption of gender affirming and trauma informed care models as supportive to the health of their patients and to minimize HIV acquisition in this group. Although high PrEP awareness and uptake were prevalent in this population, a few opportunities for further improvement arose. While a large contribution to PrEP discontinuation was loss to follow-up, patients currently taking PrEP endorsed a high burden from taking a daily pill. Qualitatively, PrEP side effects also contributed to discontinuation, while current users expressed they wished they had more knowledge and support to manage them. Implementation of bimonthly injectable PrEP administrations combined with lab visits, as well as further outreach and education are options that may remove some of these barriers. Expanding the approach of this study to other populations could increase engagement in other groups not typically targeted by PrEP marketing, for example in assigned female at birth patients at high risk of HIV.

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Appendices

Appendix A: Case Report Form

Sociodemographic	
Age	_____ years
Healthcare coverage	<input type="checkbox"/> Yes <input type="checkbox"/> No
Employment status	<input type="checkbox"/> Full time <input type="checkbox"/> Part time <input type="checkbox"/> Unemployed <input type="checkbox"/> Unavailable
Highest level of education	<input type="checkbox"/> Some HS <input type="checkbox"/> HS/GED <input type="checkbox"/> Some college <input type="checkbox"/> Bachelor <input type="checkbox"/> Any post graduate <input type="checkbox"/> Unavailable
Housing instability (12 mo.)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unavailable
IV drug use	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unavailable
Gender Identity	
Sex assigned at birth	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Intersex
Gender identity	<input type="checkbox"/> Woman <input type="checkbox"/> Man <input type="checkbox"/> Non-binary <input type="checkbox"/> Questioning <input type="checkbox"/> Gender non-conforming <input type="checkbox"/> Two-spirit <input type="checkbox"/> Transgender <input type="checkbox"/> Cisgender <input type="checkbox"/> Declined <input type="checkbox"/> Other: _____
Gender affirming hormone therapy	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not currently <input type="checkbox"/> Unavailable
HIV status & risk	
HIV status	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Unavailable
Estimated number of receptive / insertive sex partners in the last 12 mo.	<input type="checkbox"/> 0 <input type="checkbox"/> 1-5 <input type="checkbox"/> 5-10 <input type="checkbox"/> 10-20 <input type="checkbox"/> 20+ <input type="checkbox"/> Unavailable
↳ if >0: Condom use in past 12 mo.	<input type="checkbox"/> 1. Never <input type="checkbox"/> 2. Sometimes <input type="checkbox"/> 3. About half the time <input type="checkbox"/> 4. Most of the time <input type="checkbox"/> 5. Always <input type="checkbox"/> Unavailable
Exchanged sex (12 mo.)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unavailable
Vaginal or anal sex with someone living with HIV	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unsure/unavailable
At risk for HIV:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Undetermined
<i>Deemed at risk if (a) not always using condoms, or (b) >5 sex partners in past 12mo., or (c) exchanged sex. Edited on a case by case basis.</i>	

PrEP care continuum		
PrEP discussion mentioned in encounter notes		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unavailable
↳ If no		<input type="checkbox"/> PrEP unaware → STOP
↳ If yes: Ever taken PrEP:		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unavailable
↳ If no:	Reasons for declining PrEP	<input type="checkbox"/> Not at risk <input type="checkbox"/> Side effects concerns <input type="checkbox"/> Other/unavailable: _____
		<input type="checkbox"/> PrEP aware - no uptake → STOP
↳ If yes:	Reasons for initiation	<input type="checkbox"/> Preventive choice <input type="checkbox"/> PCP suggestion <input type="checkbox"/> Partner living with HIV <input type="checkbox"/> Sex work <input type="checkbox"/> Other/unavailable: _____
	Cumulative duration (est.)	_____ months Person-time use of PrEP
	Positives/likes	_____ Negatives/dislikes _____
	Comments	_____
Currently taking PrEP:		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unavailable/lost to follow-up
↳ If no:	Reasons for discontinuation:	<input type="checkbox"/> No longer at risk <input type="checkbox"/> Cost/insurance <input type="checkbox"/> Side effects <input type="checkbox"/> Monitor/access <input type="checkbox"/> Lost to follow-up <input type="checkbox"/> Other/unavailable: _____
		<input type="checkbox"/> PrEP uptake - not adherent (barriers, lost to f/u, etc.) <input type="checkbox"/> PrEP uptake - not retained (no longer at risk) → STOP
↳ If yes:		<input type="checkbox"/> PrEP uptake - retained → STOP

Outcome measures Open ended for thematic analysis

Appendix B: Survey Instrument (paper version)

This survey is part of a care improvement project run by your healthcare providers at Prism Health in collaboration with OHSU, with the goal of reducing the risk of HIV infections in our patients. You will be asked about sexual health related behaviors, HIV status, and prevention strategies.

Your responses will help Prism Health offer tailored services to meet our patients needs in terms of sexual health and HIV prevention. All responses you provide will be kept confidential and stored securely. They will be anonymized, which means that your responses cannot be traced back to you.

By participating, you agree to provide the most honest answers you can.

Sociodemographic	
How old are you?	<input type="checkbox"/> Under 18 <input type="checkbox"/> 18-24 <input type="checkbox"/> 25-34 <input type="checkbox"/> 35-44 <input type="checkbox"/> 45-54 <input type="checkbox"/> 55-64 <input type="checkbox"/> 65+
This survey is only available for patients 18 years or older. Thank you for your interest.	
Do you currently have healthcare coverage?	<input type="checkbox"/> Yes <input type="checkbox"/> No
What is your employment status?	<input type="checkbox"/> Full time <input type="checkbox"/> Part time <input type="checkbox"/> Unemployed <input type="checkbox"/> Other: _____
Do you make more than \$25,520 per year?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unsure <input type="checkbox"/> Decline to answer
What is your highest level of education?	<input type="checkbox"/> Grade 8 <input type="checkbox"/> Some high school <input type="checkbox"/> High school graduate or GED <input type="checkbox"/> Some college <input type="checkbox"/> Bachelor's degree <input type="checkbox"/> Any post grad education
Would you say you have a good relationship with your healthcare provider(s)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
In the past 12 months, have any of these situations applied to you?	<input type="checkbox"/> Yes <input type="checkbox"/> No
<ul style="list-style-type: none"> • I moved to escape violence • I moved because I couldn't afford my place • I became houseless • I stayed in a shelter • I have been evicted • I was denied a home, apartment, or a room • I was denied a shelter • I was forced to stay in a shelter that did not match my gender identity • I had to find different places to sleep for short periods of time (e.g. friend's couch) • I had sex with people to stay in their home • I had sex with the landlord/manager instead of paying rent 	
Gender Identity	
Sex assigned at birth	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Intersex
Gender identity	<input type="checkbox"/> Woman <input type="checkbox"/> Man <input type="checkbox"/> Non-binary <input type="checkbox"/> Gender non-conforming <input type="checkbox"/> Two-spirit <input type="checkbox"/> Cisgender <input type="checkbox"/> Transgender man <input type="checkbox"/> Transgender woman <input type="checkbox"/> Decline to answer <input type="checkbox"/> Questioning <input type="checkbox"/> Other: _____
Are you taking gender affirming hormones?	<input type="checkbox"/> Yes <input type="checkbox"/> No
In the past 12 months, have you experienced discrimination in healthcare settings?	<input type="checkbox"/> Yes <input type="checkbox"/> No

HIV status	
What is your HIV status?	<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Unknown <input type="checkbox"/> Decline to answer
Have you taken an HIV test in the past 6 months?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unsure
HIV risk	
In the past 12 months, how many anal sex partners did you have (estimated)?	<input type="checkbox"/> 0 <input type="checkbox"/> 1-5 <input type="checkbox"/> 5-10 <input type="checkbox"/> 10-20 <input type="checkbox"/> 20+
	<u>If 1 or more:</u> In the past 12 months, how often have you used condoms during anal sex? <input type="checkbox"/> Never <input type="checkbox"/> Sometimes <input type="checkbox"/> About half the time <input type="checkbox"/> Most of the time <input type="checkbox"/> Always
In the past 12 months, have you exchanged sex for something you needed?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Have you had vaginal or anal sex with someone living with HIV?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unsure
What would you say is your chance of getting HIV in the next 12 months?	<input type="checkbox"/> None <input type="checkbox"/> Low <input type="checkbox"/> Some <input type="checkbox"/> Certainly
PrEP engagement	
1. Have you ever heard of PrEP? <i>PrEP is when HIV negative people take anti-HIV medications (e.g. Truvada[®], Descovy[®]) every day to prevent HIV infection.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
↳ If no, skip to question 5	
2. Where did you hear about PrEP?	<input type="checkbox"/> Friend <input type="checkbox"/> Healthcare provider <input type="checkbox"/> Community <input type="checkbox"/> Online <input type="checkbox"/> Other: _____
3. Have you ever taken anti-HIV medication (PrEP) to prevent HIV infection?	<input type="checkbox"/> Yes <input type="checkbox"/> No
↳ If yes, skip to question 6 on page 3	
4. List some reasons for not using PrEP in the past (select all that apply):	<input type="checkbox"/> I am not at risk for HIV <input type="checkbox"/> This is not for me <input type="checkbox"/> Cost, insurance limitations <input type="checkbox"/> Stigma of HIV medications <input type="checkbox"/> Concerns about side effects, interactions, efficacy <input type="checkbox"/> Taking a daily pill <input type="checkbox"/> Other: _____ <input type="checkbox"/> Lab monitoring and clinic access challenges
5. <i>When taken as prescribed, PrEP is more than 90% effective at preventing HIV infection from sex or sharing injection equipment. It can help you protect yourself, reduce fear and worry, and focus on relationships. However PrEP does not protect against other STDs like condoms can. Side effects might include mild nausea and headache, but will disappear within a few weeks. PrEP does not affect the level of gender affirming hormones and is very effective when taken by mouth daily.</i>	
Would you be willing to take PrEP if your healthcare provider recommended it for you?	
<input type="checkbox"/> Yes → What would help you decide to use PrEP? _____	
<input type="checkbox"/> No → What are your concerns with using PrEP? _____	
You have reached the end of this survey. Consider discussing PrEP with your healthcare provider.	

Appendix D: IRB Determination



IRB MEMO

Research Integrity Office

3181 SW Sam Jackson Park Road - L106RI
Portland, OR 97239-3098
(503)494-7887 irb@ohsu.edu

NOT HUMAN RESEARCH

July 14, 2021

Dear Investigator:

On 7/14/2021, the IRB reviewed the following submission:

Title of Study:	Assessment of barriers and facilitators to PrEP uptake among transgender women and non-binary assigned male at birth persons at risk of contracting HIV.
Investigator:	Mandy McKimmy
IRB ID:	STUDY00023286
Funding:	None

The IRB determined that the proposed activity is not research involving human subjects. IRB review and approval is not required.

Certain changes to the research plan may affect this determination. Contact the IRB Office if your project changes and you have questions regarding the need for IRB oversight.

If this project involves the collection, use, or disclosure of Protected Health Information (PHI), you must comply with all applicable requirements under HIPAA. See the [HIPAA and Research website](#) and the [Information Privacy and Security website](#) for more information.

Sincerely,

The OHSU IRB Office

Appendix E: Letter of Support from Implementation Site

Letter of Support from Clinical Agency

Date: 07/08/2021

Dear Cecile Steinbeck,

This letter confirms that I, Rian Johnson, allow Cecile Steinbeck (OHSU Doctor of Nursing Practice Student) access to complete her DNP Final Project at our clinical site. The project will take place from approximately June 1st, 2021 to April 1st, 2022.

This letter summarizes the core elements of the project proposal, already reviewed by the DNP Project Preceptor and clinical liaison (if applicable):

- **Project Site(s):** Prism Health, 2236 SE Belmont, Portland OR 97214
- **Project Plan:**

Transgender women are disproportionately affected by HIV, at a rate 32 times that of the general population. In spite of high levels of efficacy, use of HIV pre-exposure prophylaxis (PrEP) therapy, to prevent HIV infection, remains very low in transgender women at risk for HIV. The PrEP care continuum models how patients interact with PrEP at the levels of awareness, willingness, uptake, adherence, and retention. In assessing barriers and facilitators to PrEP use in transgender female and non-binary AMAB patients, identifying the stages of disengagement in the continuum will help formulate recommendations for tailored interventions to increase PrEP use and reduce new HIV infections in this group.

This project aims to (1) complete an assessment of barriers and facilitators to PrEP use specific to Prism Health patients in this group by February 2022, and to (2) recommend targeted interventions to address low PrEP engagement. A two pronged approach of historical chart reviews (2 year period) and a Qualtrics survey of current patients about PrEP experience and perceptions will be adopted. Both will gather sociodemographic factors, elicit sexual health related behaviors, the stage in the PrEP care continuum, and themes related to PrEP use and values. Data will be de-identified and stored on the HIPAA compliant Qualtrics servers and OHSU's secure cloud storage Box.

The site will provide EHR and MyChart communication tools access in support to this project, the site specialist will provide support with database queries, the site medical director and providers will review and approve the survey instrument before launch, as well as facilitate the distribution of paper surveys as needed.

During the project implementation and evaluation, Cecile Steinbeck will provide regular updates and communicate any necessary changes to the DNP Project Preceptor.

Our organization looks forward to working with this student to complete their DNP project. If we have any concerns related to this project, we will contact Cecile Steinbeck and Mandy McKimmy (student's DNP Project Chairperson).

Regards,

E. Rian Johnson, FNP-C
DNP Project Preceptor

Family Nurse Practitioner
Job Title

E. Rian Johnson, FNP-C
Signature

7/8/2021
Date Signed

Appendix F: Chart review figures

Demographics:

AMAB		Employment		%	
W/TW group	232	Full time	42		
NB group	149	Part time	15		
		Unemployed	33		
		Unavailable/other	10		
Age		Education		%	
Average	31.5	Some high school	4		
Range	17-67	High school/GED	12		
		Some college	36		
		Bachelor	19		
Healthcare coverage	98%	Any post graduate	4		
Housing instability	9%	Unavailable	25		
PWID	3%				

Gender affirming hormone therapy, HIV risk/status:

AMAB	381	%GAHT	%HIV+	% at risk
W/TW group	232	96%*	2.6%	19.4%*
NB group	149	32%*	3.4%	43.0%*

Comparisons between W/TW and NB proportions:

z score	13.431	0.453	4.965
p value	<.00001	.653	<.00001

W/TW group: identifies as woman or transgender woman

NB group: does not identify as man/woman

PWID: people who inject drugs

PrEP continuum:

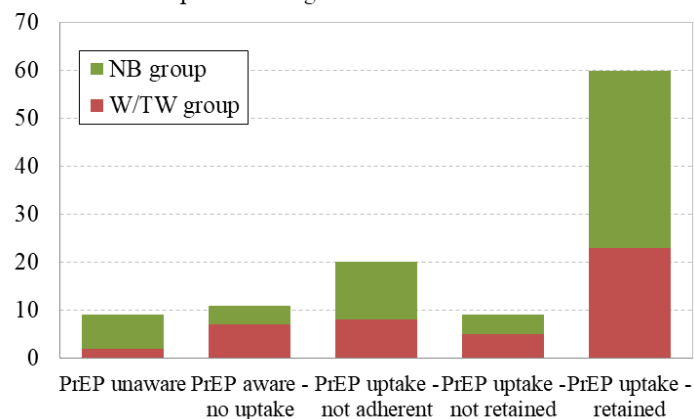
	At risk	No/unkn. risk	% at risk
PrEP unaware	9	210	4%
At risk of HIV:			
	W/TW group	NB group	% total
PrEP unaware	2	7	8%
PrEP aware - no uptake	7	4	10%
PrEP uptake - not adherent	8	12	18%
PrEP uptake - not retained	5	4	8%
PrEP uptake - retained	23	37	55%
Total at risk of HIV:	109	45	64

Cumulative duration (mo)	W/TW	NB
Average	11.7*	17.2*
Range	48	60
Stdev	12.0	15.0
N	47	64

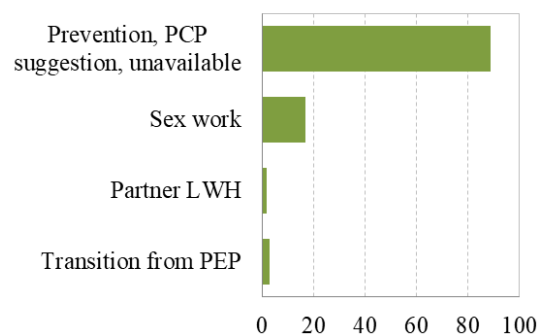
Comparisons between W/TW and NB averages:

t(109)	p
2.08	.040 (<.05)

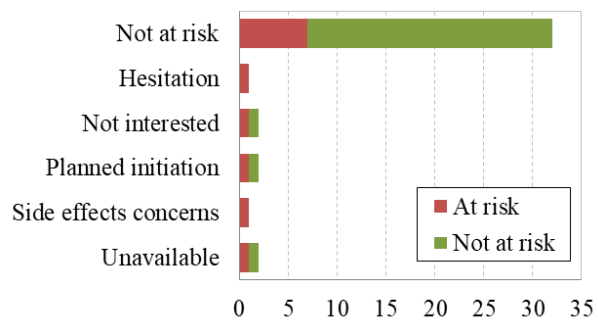
Number of at risk patients along PrEP continuum



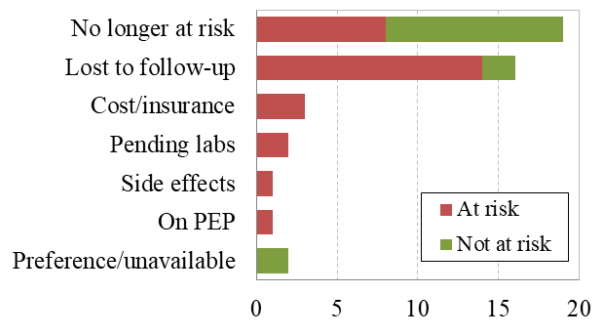
Reasons for initiating PrEP



Reasons for declining PrEP



Reasons for discontinuing PrEP



Appendix G: Survey figures

Demographics:

N		Employment	
W/TW group	29	Full time	48
NB group	25	Part time	26
		Unemployed	19
		Unavailable/other	7
Age		Education	
Median range (43%)	25-34	Grade 8	2
Range	<18-65+	Some high school	2
		High school/GED	6
		Some college	41
Healthcare coverage	100%	Bachelor	39
Housing instability	17%	Any post graduate	11
Income <\$25k	50%		

Gender affirming hormone therapy, HIV risk:

AMAB	N	%GAHT	% at risk
W/TW group	29	97%*	25.0%
NB group	25	40%*	44.0%

Comparisons between W/TW and NB proportions:

z score	4.585	1.472
p value	<.00001	0.1416

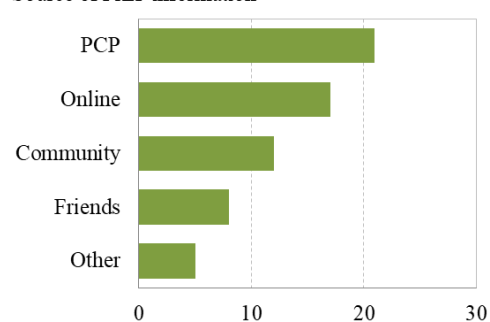
W/TW group: identifies as woman or transgender woman

NB group: does not identify as man/woman

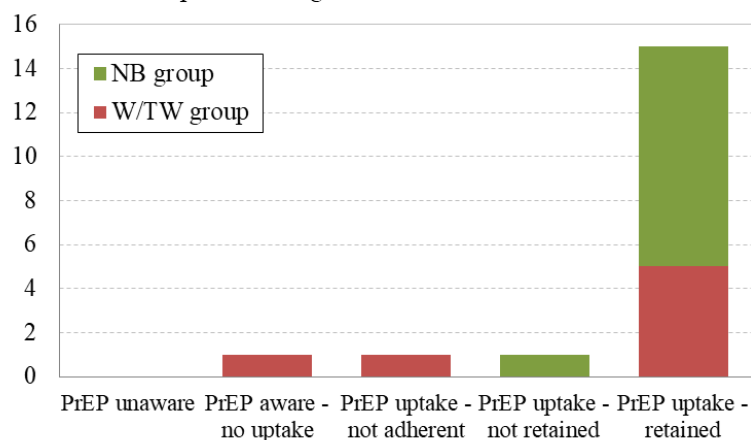
PrEP continuum:

	At risk	No/unkn. risk	% at risk
PrEP unaware	0	4	0%
At risk of HIV:			
	W/TW group	NB group	% total
PrEP unaware	0	0	0%
PrEP aware - no uptake	1	0	6%
PrEP uptake - not adherent	1	0	6%
PrEP uptake - not retained	0	1	6%
PrEP uptake - retained	5	10	83%
Total at risk of HIV:	18	7	11

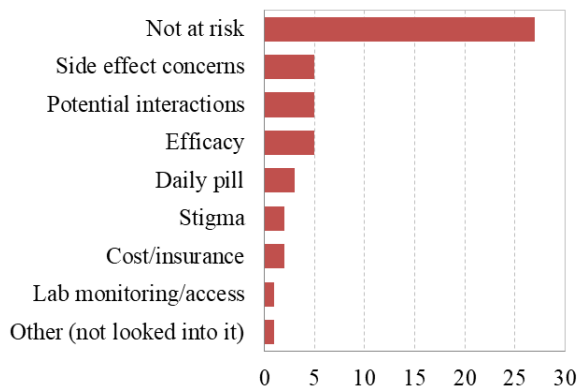
Source of PrEP information



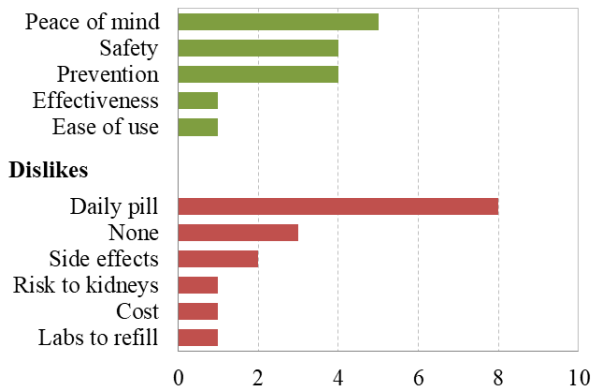
Number of at risk patients along PrEP continuum



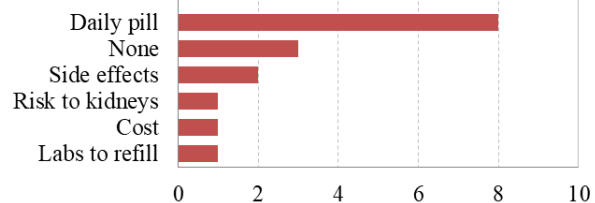
Reasons for declining PrEP



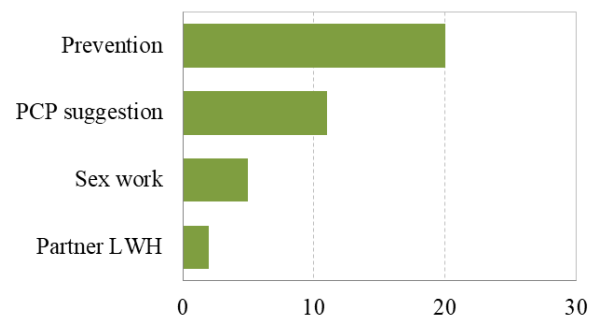
Likes



Dislikes



Reasons for initiating PrEP



Reasons for discontinuing PrEP

