JIAS
JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

Improving the HIV response for transgender populations: evidence to inform action

Guest Editors: Tonia Poteat, Nittaya Phanuphak, Beatriz Grinsztejn, Sari L. Reisner
Supplement Editors: Marlène Bras, Karoline Soerensen

Volume 25, Supplement 5, October 2022

WILEY

Acknowledgements

The Guest Editors – Tonia Poteat, Nittaya Phanuphak, Beatriz Grinsztejn, and Sari L. Reisner - would like to thank all of the authors who submitted abstracts and full manuscripts, and worked so hard throughout the rigorous selection process. We wish that many more studies could have been included and hope there will be future opportunities to disseminate important research on transgender health and HIV. We are hopeful that data presented in this Supplement will propel us towards improved engagement of transgender and gender diverse individuals in the HIV response. We also thank the editors and staff of the *Journal of the International AIDS Society* for thoughtful guidance, rigorous support, and encouragement throughout the process.

Support

This supplement was funded with support from Gilead Sciences, Merck & Co, and the National Institutes of Health via the HIV Prevention Trials Network. The authors alone are responsible for the views expressed in this Supplement and they do not necessarily represent the views, decisions, or policies of the institutions with which they are affiliated nor any of the funding agencies.

Improving the HIV response for transgender populations: evidence to inform action

Guest Editors: Tonia Poteat, Nittaya Phanuphak, Beatriz Grinsztejn, Sari L. Reisner
Supplement Editors: Marlène Bras, Karoline Soerensen

Contents

Volume 25, Supplement 5
October 2022

JIAS
JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

Poteat T et al. *Journal of the International AIDS Society* 2022, **25**(S5):e25993
http://onlinelibrary.wiley.com/doi/10.1002/jia2.25993/full | https://doi.org/10.1002/jia2.25993

JIAS JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

EDITORIAL

Improving the HIV response for transgender populations: evidence to inform action

Tonia Poteat[1,§], Nittaya Phanuphak[2], Beatriz Grinsztejn[3] and Sari L. Reisner[4,5,6]

[§]**Corresponding author**: Tonia Poteat, Department of Social Medicine, University of North Carolina School of Medicine, 333 S. Columbia Street, CB7240, Chapel Hill, NC 27599, USA. (tonia_poteat@med.unc.edu)

Keywords: HIV testing; HIV prevention; HIV treatment; HIV continuum; differentiated service delivery; HIV pre-exposure prophylaxis

Received 10 July 2022; **Accepted** 2 August 2022

Our knowledge about HIV among transgender populations has substantially improved since the *Journal of the International AIDS Society* (JIAS) published its first special issue about HIV in transgender populations in 2016 [1]. A PubMed search indicates that more than 1000 peer-reviewed manuscripts focused on HIV among transgender people have been published in the past 5 years. While this increased volume of research is heartening, the findings indicate transgender people remain disproportionately burdened by HIV globally. A recent meta-analysis of studies published between 2000 and 2019 found an overall HIV prevalence of 19.9% for trans feminine individuals and 2.6% for trans masculine individuals with odds ratios of 66 and 7, respectively, compared to all individuals ages 15 years and older [2]. While data on the HIV prevention and care continuum among transgender people are limited, existing studies indicate lower engagement in HIV testing, pre-exposure prophylaxis (PrEP) uptake, persistence and adherence, as well as antiretroviral therapy (ART) uptake and adherence [3]. These appalling inequities in HIV prevalence, prevention and care are driven by socio-structural factors rooted in stigma and discrimination [4].

In keeping with the most recent World AIDS Day call to "end inequalities" as well as the AIDS 2022, the 24th International AIDS Conference theme, "re-engage and follow the science," we dedicated this special issue to research that fills important gaps in science and provides data that can be used to end inequities in HIV prevention and care for transgender people. We called for abstracts that fill gaps in knowledge about trans masculine people, gender non-binary people, transgender people in sub-Saharan Africa, as well as data on community-based and clinical interventions. Manuscripts by transgender authors were encouraged. We were excited to receive more than 70 abstracts. Through a careful process of editorial and peer review, we selected 13 quality manuscripts that contribute to the evidence base for advancing equity for transgender people in the HIV response. This issue includes research from countries across the globe, including rare data focused on transgender people in sub-Saharan Africa; studies inclusive of and/or focused specifically on transgender men; and programmatic data that provide practical insights into potentially effective strategies to engage transgender people in HIV prevention and care. We are delighted that more than half of the manuscripts in this special issue are led or co-authored by transgender and nonbinary people.

We include two manuscripts that address some of the extensive gaps in HIV research focused specifically on the experiences and needs of transgender men. Radix et al. provide one of the largest clinical data sets on HIV prevalence and sexual risk among transgender men in the United States. Data from this relatively diverse sample of 577 transgender men found that White participants were less likely to be tested for HIV, Black participants were more likely to be living with laboratory-confirmed HIV and HIV prevalence was highest for transgender men who reported having only cisgender male partners [5]. In multivariable analyses, race was no longer significantly associated with HIV status; however, participants with only cisgender male partners had a statistical odds of living with HIV that was 10-fold higher than those without a cisgender male partner. The authors underscore the need to collect better data on sexual practices among transgender men, particularly those who have sex with cisgender men, in order to include them in HIV prevention efforts for men who have sex with men (MSM) and to develop culturally and anatomically appropriate educational materials for them.

Appenroth and colleagues directly compare self-reported sexual health outcomes of 122 transgender MSM with more than 22,000 cisgender MSM in Germany [6]. In their study, transgender MSM were less likely to self-report living with HIV but were also less likely to report receiving an HIV test result, suggesting that some transgender MSM may be living with HIV but are unaware because they have not been tested. Transgender MSM were less likely than cisgender MSM to

have ever talked to a provider about PrEP, representing a missed opportunity for HIV prevention education for this group. Compared with cisgender MSM, transgender MSM had a higher odds of reporting sexual unhappiness, having sex that was less safe than they wanted, having an income too low to live comfortably and having negative mental health symptoms. These psychosocial and structural differences may play a role in HIV vulnerability for transgender men, deserving further exploration in future research. Taken together, the Radix and Appenroth studies begin to paint a picture in which transgender MSM may face elevated HIV vulnerability compared to heterosexual transgender men yet face higher barriers to HIV testing and PrEP uptake than cisgender MSM. More research, as well as interventions tailored to the specific needs of transgender MSM, are clearly needed.

Four manuscripts expand the evidence base on the uptake of HIV testing and prevention among transgender populations. Lacombe-Duncan et al. examine the prevalence and associated factors for HIV testing among 539 transgender and gender non-binary people in the Midwestern United States [7]. More than a quarter (26.2%) of participants had never been tested for HIV. The highest proportion to never have an HIV test were non-binary people assigned female at birth (AFAB) and trans masculine people at 32% and 30%, respectively—likely reflecting the invisibility of these groups in the HIV response. Importantly, the study found that having a transgender-inclusive primary care provider was associated with lower odds of never having an HIV test—supporting the premise that training providers to be more culturally responsive and medically competent in the care of transgender patients may improve HIV outcomes in this population.

Research from multiple countries provides insights on HIV prevention strategies used by transgender people. Byrne et al. analysed data from 704 sexually active transgender and non-binary people in Aotearoa/New Zealand [8]. Most study participants felt able to successfully negotiate the use of a protective barrier with a sexual partner. However, among participants attracted to men, self-efficacy scores were lower for transgender men and non-binary AFAB people than transgender women. Overall awareness of PrEP was high; however, knowledge about PrEP was higher among transgender men attracted to men than transgender women attracted to men. PrEP uptake was quite low overall at only 1%.

Aguayo-Romero and colleagues used innovative latent class analyses to examine data from 958 transgender women across the Eastern and Southern United States [9]. They identified four latent classes of HIV awareness and prevention strategies used by site-based and online participants: (1) "limited strategies—less sexually active" (15% and 9%, in site-based and online, respectively), (2) "limited strategies—insertive sex" (16%/36%), (3) "limited strategies—receptive sex" (33%/37%) and (4) "multiple strategies—insertive and receptive sex" (36%/18%). The probability of reporting condomless sex was high in all classes. Membership in class 4 was characterized by PrEP use and may indicate the use of adaptive strategies in response to known HIV risk, while membership in class 3 indicated the use of a limited number of HIV prevention strategies in the face of heightened HIV vulnerability. Overall findings suggest prioritizing combination strategies, with a particular focus on HIV testing and PrEP, and indicate that future interventions may benefit from acknowledging the HIV prevention steps transgender women are already taking and offering tailored support to meet their goals.

A multicentre study (n=28 sites) assessing same-day daily oral PrEP in Brazil, Mexico and Peru provided baseline data for Konda et al.'s study of factors associated with long-term PrEP engagement and adherence among transgender women (N=494) [10]. Over 274.5 person-years of follow-up, 48% of transgender women demonstrated long-term PrEP engagement, that is attendance at the 4-week visit and two or more quarterly visits within a 52-week period. PrEP adherence increased over follow-up from 38% at the first visit to 53% at the final visit. In multivariable models, adherence was lower among participants who reported PrEP-associated gastrointestinal symptoms, and PrEP engagement was higher among transgender women with 100% adherence at 4 weeks on PrEP. These findings highlight the importance of early adherence and addressing PrEP side effects to promote adherence and long-term PrEP engagement.

We included four manuscripts describing innovative, transgender-inclusive approaches to HIV service delivery. Two describe differentiated service delivery models in sub-Saharan Africa [11, 12]. Mwango and colleagues describe a service-delivery model in Zambia in which community health workers use a peer-to-peer community-based approach in partnership with local transgender civil society organizations to reach transgender people for HIV testing, counselling and linkage to biomedical prevention or treatment [11]. This model reached more than 1800 transgender people over 8 months. Of the 424 transgender people who received HIV testing, 78% of those who were HIV negative (n=268) were initiated on PrEP and 97% of those who tested positive for HIV (n=78) were started on ART.

Bothma and colleagues provide programmatic data from dedicated differentiated healthcare centres for transgender people in four South African districts [12]. Unlike other sites in the country, these centres provide gender-affirming hormone therapy and HIV services at a primary healthcare level. Over 18 months, they reached over 5000 transgender people via peer outreach and linked 62% of them to clinical services. Fourteen percent (n=687) of the 4829 who tested for HIV had a positive result and 91% of them initiated ART. However, only 28% (n=1165) of those who tested HIV negative accepted PrEP. The success of community-based peer outreach for PrEP engagement in Zambia and South Africa provides evidence to support this strategy. The differences in PrEP uptake in the two programmes suggest the need for more data to understand what factors influence the success of community outreach for the engagement of transgender people in PrEP.

Doan et al. describe the implementation of participatory continuous quality improvement and Plan-Do-Study Act methods to increase PrEP uptake among transgender women in Vietnam [13]. This approach identified five key barriers and implemented corresponding solutions that included offering gender-affirming care training, integrating gender-affirming medical services (e.g. hormone therapy), implementing a transgender women-led campaign addressing concerns about PrEP and hormone drug interactions, and the development of national HIV and transgender health guidelines. These initia-

tives significantly increased new PrEP enrolment and continuation among transgender women.

Rebchook et al. describe a variety of innovative interventions implemented to increase engagement in HIV care among transgender women of colour in nine sites across the United States, including housing linkages, legal services and peer support [14]. Heterogeneous, tailored, combination interventions were offered across the sites. Compared to baseline, each site significantly increased ART prescriptions and viral suppression over 12 and 24 months of follow-up. Taken together, studies across southern Africa, Vietnam and the United States demonstrate that tailored interventions that address the specific needs of transgender people can be successful in increasing HIV prevention and care engagement.

The final three articles highlight the history of guideline development and emphasize the importance of best practices for engaging transgender people in HIV research. Given the significant geographic variability in the provision of care and treatment for transgender people across the globe, the World Health Organization (WHO) has a critical role to play in setting the fundamental standards of transgender-inclusive HIV services. Macdonald and colleagues lay out the history of WHO's evolving role in facilitating quality, gender-affirming, culturally responsive care for transgender people across the globe [15]. Articles led by Allison [16] and Klein [17] provide important insights on best practices for conducting research with transgender people. Allison and colleagues outline the importance of trauma-informed approaches, given the well-documented structural and interpersonal violence experienced by transgender people [16]. Klein and Golub lay out ethical challenges observed in research with transgender people and provide practical recommendations for the conduct of research that addresses these challenges [17].

While more data are clearly needed, especially among non-binary people and transgender men, existing research provides an important road map for action. The articles in this supplement outline the unmet needs of transgender men, describe intervenable barriers and facilitators to HIV engagement and provide evidence of effective programmatic interventions across multiple continents. We hope the manuscripts in this supplement also make clear that the way forward must be led by and meaningfully engage transgender people. If we follow the science and engage communities, we have the necessary tools to end HIV inequities and advance the health and wellbeing of transgender people.

AUTHORS' AFFILIATIONS

[1]Department of Social Medicine, University of North Carolina School of Medicine, Chapel Hill, North Carolina, USA; [2]Institute of HIV Research and Innovation, Bangkok, Thailand; [3]Evandro Chagas National institute of Infectious Diseases-Fundação Oswaldo Cruz (FIOCRUZ), Rio de Janeiro, Brazil; [4]The Fenway Institute, Fenway Health, Boston, Massachusetts, USA; [5]Division of Endocrinology, Diabetes and Hypertension, Brigham and Women's Hospital, Boston, Massachusetts, USA; [6]Department of Epidemiology, Harvard T.H. Chan School of Public Health, Boston, Massachusetts, USA

COMPETING INTERESTS

The authors declare no competing interests.

AUTHORS' CONTRIBUTIONS

TP conceived and wrote the initial draft of the manuscript. SLR, NP and BG provided feedback, reviewed and edited the initial draft and approved the final version prior to submission.

ACKNOWLEDGEMENTS

The Guest Editors - Tonia Poteat, Nittaya Phanuphak, Beatriz Grinsztejn, and Sari Reisner - would like to thank all of the authors who submitted abstracts and full manuscripts and who worked so hard throughout the rigorous review and selection process. We wish that many more studies could have been included and anticipate there will be future opportunities to disseminate important research on transgender health and HIV. We are hopeful that data presented in this special issue will propel us towards improved engagement of transgender people and gender diverse individuals in the HIV response. We also thank the editors and staff of the journal for thoughtful guidance, rigorous support, and encouragement throughout the process.

FUNDING

Publication of this open access special issue was supported by funding from Gilead Sciences, Merck & Co., Inc., and the National Institutes of Health via the HIV Prevention Trials Network. The authors alone are responsible for the views expressed in this issue. They do not necessarily represent the views, decisions or policies of the institutions with which they are affiliated nor any of the funding agencies.

REFERENCES

1. Poteat TC, Keatley J, Wilcher R, Schwenke C. Evidence for action: a call for the global HIV response to address the needs of transgender populations. J Int AIDS Soc. 2016;19(3):21193.
2. Stutterheim SE, van Dijk M, Wang H, Jonas KJ. The worldwide burden of HIV in transgender individuals: an updated systematic review and meta-analysis. PLoS One. 2021;16(12):e0260063.
3. Vaitses Fontanari AM, Zanella GI, Feijó M, Churchill S, Rodrigues Lobato MI, Costa AB. HIV-related care for transgender people: a systematic review of studies from around the world. Soc Sci Med. 2019;230:280–94.
4. Magno L, Silva LAVD, Veras MA, Pereira-Santos M, Dourado I. Stigma and discrimination related to gender identity and vulnerability to HIV/AIDS among transgender women: a systematic review. Cad Saude Publica. 2019;35(4):e0112718.
5. Radix AE, Larson EL, Harris AB, Chiasson MA. HIV prevalence among transmasculine individuals at a New York City Community Health Center: a cross-sectional study. J Int AIDS Soc. 2022;25(S5):e25981.
6. Appenroth MN, Koppe U, Hickson F, Schink S, Hahne A, Schmidt AJ, et al. Sexual happiness and satisfaction with sexual safety among German trans men who have sex with men: results from EMIS-2017. J Int AIDS Soc. 2022;25(S5):e25992.
7. Lacombe-Duncan A, Kattari L, Kattari SK, Scheim AI, Alexander F, Yonce S, et al. HIV testing among transgender and nonbinary persons in Michigan, United States: results of a community-based survey. J Int AIDS Soc. 2022;25(S5):e25972.
8. Byrne JL, Tan KKH, Saxton PJ, Bentham RM, Veale JF. PrEP awareness and protective barrier negotiation among transgender people attracted to men in Aotearoa New Zealand. J Int AIDS Soc. 2022;25(S5):e25980.
9. Aguayo-Romero RA, Cannon CM, Wirtz AL, Cooney EE, Mayer KH, Reisner SL, et al. HIV awareness and prevention strategies among transgender women in the Eastern and Southern United States: findings from the LITE cohort. J Int AIDS Soc. 2022;25(S5):e25999.
10. Konda KA, Torres TS, Mariño G, Ramos A, Moreira RI, Leite IC, et al. Factors associated with long-term pre-exposure prophylaxis engagement and adherence among transgender women in Brazil, Mexico and Peru: results from the ImPrEP study. J Int AIDS Soc. 2022;25(S5):e25974.
11. Mwango L, Toeque MG, Lindsay B, Tembo K, Sakala H, Reggee S, et al. Reaching transgender populations in Zambia for HIV prevention and linkage to treatment using community-based service delivery. J Int AIDS Soc. 2022;25(S5):e25995.
12. Bothma R, Segale J, Nkusi J, Shiba V, O'Connor C, Lawrence JJ, et al. Differentiated HIV services for transgender individuals in four South African districts: population characteristics and HIV care cascade. J Int AIDS Soc. 2022;25(S5):e25987.
13. Doan AH, Vu CMH, Nguyen TT, Green KE, Phan HTT, Janamnuaysook R, et al. Caring for the whole person: transgender-competent HIV pre-exposure prophylaxis as part of integrated primary health care services in Vietnam. J Int AIDS Soc. 2022;25(S5):e25996.

14. Rebchook GM, Chakravarty D, Xavier J, Keatley JA, Maiorana A, Shade SB, et al. An evaluation of nine interventions designed to enhance engagement in HIV care among transgender women of colour in the United States. J Int AIDS Soc. 2022;25(S5):e25991.
15. Macdonald V, Verster A, Mello MB, Blondeel K, Amin A, Luhmann N, et al. The World Health Organization's work and recommendations for improving the health of trans and gender diverse people. J Int AIDS Soc. 2022;25(S5):e26004.
16. Allison SM, Parker KL, Senn TE. Incorporating a trauma-informed perspective in HIV-related research with transgender and gender diverse individuals. J Int AIDS Soc. 2022;25(S5):e25976.
17. Klein A, Golub SA. Ethical HIV research with transgender and non-binary communities in the United States. J Int AIDS Soc. 2022;25(S5):e25971.

Radix AE et al. *Journal of the International AIDS Society* 2022, **25**(S5):e25981
http://onlinelibrary.wiley.com/doi/10.1002/jia2.25981/full | https://doi.org/10.1002/jia2.25981

SHORT REPORT

HIV prevalence among transmasculine individuals at a New York City Community Health Centre: a cross-sectional study

Asa E. Radix[1,2,§], Elaine L. Larson[2], Alexander B. Harris[1] and Mary Ann Chiasson[2,3]

[§]**Corresponding author:** Asa E. Radix, Department of Medicine, Callen-Lorde Community Health Center, 356 West 18th Street, New York, NY 10011, USA. Tel: +1 212-271-7275. (aradix@callen-lorde.org)

Abstract

Introduction: Multiple studies have demonstrated elevated incidence and prevalence of HIV among transgender women; however, few studies have been conducted among transmasculine individuals. HIV prevalence among transgender men in the United States is estimated to be 0–4%; however, there have not been any US studies examining HIV prevalence that stratify by the gender of sexual partners. The aim of this research was to examine HIV prevalence and its association with socio-demographic and other factors, including the gender of sexual partners and receipt of gender-affirming care (hormones/surgery), among transmasculine individuals at the Callen-Lorde Community Health Center in New York City.

Methods: The Transgender Data Project was an Institutional Review Board-approved retrospective chart review of all transgender and gender diverse clients at the clinic, ages 18+, between 1 January 2009 and 12 December 2010. Charts were reviewed manually. Data included birth sex, gender, race/ethnicity, education, employment, housing, insurance status, gender of sexual partners, HIV screening and status, and receipt of gender-affirming care. Bivariate and multivariable logistic regression models were used to assess the association between HIV status and other variables.

Results and discussion: Five hundred and seventy-seven transmasculine individuals, mean age 32.1 years (18.3–70.5), were included in this analysis. A small majority were White (55% White, 13.9% Black and 11.7% Hispanic). The majority, 78.9%, had received hormones (testosterone) and 41.6% had received at least one gender-affirming surgery. The HIV screening rate was 43.4%. HIV prevalence was 2.8%, (95% CI: 1.13%, 5.68%) among those screened, notably higher than the US population prevalence. HIV prevalence was highest among transmasculine individuals who had sex exclusively with cisgender men (11.1%). In the multivariable model (age, education and gender of sexual partners), the adjusted odds ratio of HIV for those who had sex exclusively with cisgender male partners compared to no cisgender male partners was 10.58 (95% CI: 1.33, 84.17).

Conclusions: Although HIV prevalence has been estimated to be low among transgender men, the analysis found heterogeneous results when stratified by gender of sexual partners. The results underscore the need to understand sexual risk among transmasculine individuals and to disaggregate HIV data for those having sex with cisgender men, thus also allowing for better inclusion in HIV prevention efforts.

Keywords: transgender; HIV; transgender men; transmasculine; HIV risk; gender diverse

Received 14 January 2022; **Accepted** 30 July 2022

1 | INTRODUCTION

There are an estimated 1 million transgender adults in the United States [1] who are heterogeneous in terms of age, race, ethnicity, socio-economic status, gender and sexual orientation identities [2, 3]. Over the last decade, there has been a heightened awareness of the many health disparities faced by transgender people, including the high prevalence of HIV, sexually transmitted infections (STIs), substance use and mental health conditions that are mainly driven by a complex array of individual, interpersonal and structural factors [4–6]. Despite rapid growth in transgender health research, especially HIV-related research, much of this has been conducted in populations of transgender women with very few studies examining HIV prevalence, risk and prevention among transgender men [5, 7, 8]. Multiple studies have demonstrated elevated HIV incidence and prevalence among transgender women, including an often-cited estimated global prevalence of 19% [9–12]. In the United States, a systematic review estimated a prevalence of 14% among transgender women, with rates two- to three-fold higher among Hispanic and Black transgender women [13]. HIV prevalence among transgender men in the same study was estimated to be 3.2% (95% CI: 1.4%, 7.1%); however, insufficient data

did not allow stratification by risk factor, that is transgender men who have sex with men (TMSM) versus transgender men who have sex with cisgender women, or race/ethnicity [13]. Despite these limited data, it is evident that TMSM, similar to cisgender MSM, may engage in sexual behaviours that are associated with increased risk of HIV acquisition, such as condomless anal receptive sex, sex with partners who are HIV positive or of unknown status and substance use during sex (chem sex), placing them at heightened risk for HIV and STI acquisition [13–18]. Understanding factors related to HIV acquisition among transgender men is important and can lay the foundation for appropriate and targeted prevention interventions. This remains an important gap in the literature. This study describes the prevalence of HIV among transmasculine clients at the Callen-Lorde Community Health Center, a healthcare clinic in New York City that predominately serves the lesbian, gay, bisexual, transgender and queer communities. The objective of this study was to investigate HIV prevalence among transmasculine individuals and its association with socio-demographic factors and receipt of gender-affirming medical interventions.

2 | METHODS

This study was an observational retrospective chart review. Data were extracted from the electronic health record (EHR) at Callen-Lorde. The inclusion criteria were (1) registered clients with medical visits between 1 January 2009 and 12 December 2010, (2) transgender identity and (3) age ≥18 years. The analysis in this manuscript only includes transgender individuals assigned female at birth. The Clinical Directors Network, Inc's Institutional Review Board approved study activities and granted a waiver of informed consent (004-11E).

2.1 | Measures

Gender identity was ascertained with an algorithm using (1) ICD-9 codes 302.85 (gender identity disorder) or 259.9 (unspecified endocrine disorder), (2) mismatch between legal gender and assigned birth sex, (3) self-reported transgender status, (4) discordant legal name and preferred name, and (5) designated female receiving testosterone treatment. All charts with at least one of these underwent chart review by two reviewers to verify gender identity and birth sex. Race, ethnicity, income, insurance status, education and housing status were obtained from designated demographic fields in the EHR. Receipts of gender-affirming hormone therapy and surgery (GAHT and GAS) were obtained from the medical and surgical history and prescription records. The genders of sexual partners were identified from a sexual health template that was used for those undergoing HIV screening. This included data on substance use and whether sexual partners were cisgender men, cisgender women, transgender men or transgender women. There was no option for non-binary sexual partners in the EHR template, as this identity and term were less recognized at the time. Additionally, there were no recorded data on the number of sexual partners, or sexual behaviours (whether engaging in vaginal/anal/oral sex). Receipt of HIV/STI screening and results were obtained from HIV testing fields and laboratory orders and results. The variables were dichotomized for the analysis as follows: gender-affirming hormones—receipt of GAHT ever (yes/no); gender-affirming surgeries—receipt of any GAS (including phalloplasty, metoidioplasty, chest reconstruction or top surgery and hysterectomy/oophorectomy) (yes/no); education—less than high school diploma or ≥ high school diploma; substance use—a record of a diagnosis of substance use ever in EHR (yes/no); and employment—current employment status documented in the medical record (employed/unemployed). Transmasculine individuals who have sex with cisgender men belong to a heterogeneous group, including those who predominately partner with cisgender women, and others who predominately partner with cisgender men. To minimize uncertainty in the assessment of risk, the variable "sex with cisgender men only" (yes/no) was created that compared those with cisgender male partners only to those without a history of cisgender male partners.

2.2 | Statistical analysis

Chi-square tests were used to examine differences in expected and observed proportions by HIV screening status. Crude odds ratios (ORs) were estimated for associations between HIV status and socio-demographic, behavioural and health variables among those who had been screened for HIV (n = 250). We used multivariable logistic regression to estimate the adjusted odds of an HIV diagnosis by age and the variables that were significant at $p<0.1$ in the bivariate analyses. This model included 220 complete cases. The Hosmer–Lemeshow goodness of fit test was performed for model fitness ($p>0.05$). All p-values are two-tailed at a significance level of 5%. Analyses were performed using IBM SPSS Statistics for Windows, Version 26.0.

3 | RESULTS AND DISCUSSION

A total of 3197 records were retrieved and reviewed, of these 1670 of records were verified as being transgender clients. This analysis is restricted to the 577 transgender individuals assigned female at birth, whose identities included transgender men, FTM (female-to-male), transsexual men, gender non-conforming and genderqueer. In view of these diverse identities, the term "transmasculine" will be used in this analysis.

3.1 | Patient characteristics

Table 1 presents frequencies of socio-demographic characteristics and utilization of gender-affirming care for the 577 transmasculine individuals in the sample. The mean age was 32.15 years, (SD 9.31, range 18.3–70.5). A small majority were White (55.0%); 95.1% had attained at least a high school diploma, 33.1% 4-year college degree and 18.7% held a graduate degree. Over one quarter was unemployed (28.7%) and 12.2% were uninsured. Most were stably housed (96.6%) versus unstable/homeless. The low rates of housing instability and high proportion with health insurance in this group differed from Callen-Lorde's usual patient demographics. In 2012, approximately 47% of Callen-Lorde's patient population was uninsured. Due to a dearth of gender-affirming care

Table 1. Demographic and other socio-economic variables among transmasculine clients

Variable	All patients *N* = 577 *N* (%) or mean (SD)	No HIV screen *N* = 327 *N* (%) or mean (SD)	HIV screened *N* = 250 *N* (%) or mean (SD)	*p*-value
Mean age in years (SD)	32.2 (9.31)	31.4 (9.76)	33.2 (8.58)	0.017
Range	(18.3–70.5)	(18.3–70.5)	(18.8–58.9)	
Race/Ethnicity	*n* = 496	*n* = 274	*n* = 222	0.000
Hispanic	58 (11.7)	27 (9.9)	31 (14.0)	
White	273 (55.0)	173 (63.1)	100 (45)	
Black	69 (13.9)	25 (9.1)	44 (19.8)	
Asian/Pacific Islander	29 (5.8)	17 (6.2)	12 (5.4)	
Other/multiracial	67 (13.5)	32 (11.7)	35 (15.8)	
Education (highest level)	*n* = 493	*n* = 273	*n* = 220	0.831
Less than high school	24 (4.9)	12 (4.4)	12 (5.5)	
High school diploma	58 (11.8)	30 (11.0)	28 (12.7)	
Some college	156 (31.6)	86 (31.5)	70 (31.8)	
Bachelors' degree	163 (33.1)	97 (35.5)	66 (30.0)	
Graduate degree	92 (18.7)	48 (17.6)	44 (20.0)	
History of substance use	18 (3.9)	3 (0.9)	15 (6.0)	0.001
Employment	(*n* = 540)	(*n* = 302)	(*n* = 238)	0.251
Employed	385 (71.3)	209 (69.2)	176 (73.9)	
Unemployed	155 (28.7	93 (30.8)	62 (26.1)	
Housing	(*n* = 526)	(*n* = 292)	(*n* = 234)	0.639
Stable	508 (96.6)	283 (96.9)	225 (96.2)	
Unstable	18 (3.4)	9 (3.1)	9 (3.8)	
Insurance	(*n* = 499)	(*n* = 270)	(*n* = 229)	0.002
Uninsured	61 (12.2)	42 (15.6)	19 (8.3)	
Private	302 (60.5)	169 (62.6)	133 (53.2)	
Public	136 (27.5)	59 (21.9)	77 (33.6)	
Reported sexual partners	(*n* = 494)	(*n* = 281)	(*n* = 213)	
Cisgender men	185 (32.1)	99 (30.3)	86 (34.4)	0.293
Cisgender men only	46 (9.3)	28 (9.96)	18 (8.45)	0.566
Cisgender women	367 (63.6)	204 (62.4)	163 (65.2)	0.486
Transgender men	18 (3.1)	15 (4.6)	3 (1.2)	0.027
Transgender women	8 (1.4)	2 (0.6)	6 (2.4)	0.083
None	52 (10.7)	29 (8.9)	23 (9.2)	0.890
Gender-affirming interventions	(*n* = 577)	(*n* = 327)	(*n* = 250)	
Hormones (testosterone)	455 (78.9)	243 (74.3)	212 (84.8)	0.002
Mastectomy	227 (39.3)	114 (34.9)	113 (45.2)	0.012
Metoidioplasty	6 (1.0)	3 (0.9)	3 (1.2)	0.525
Phalloplasty	4 (0.7)	1 (0.3)	3 (1.2)	0.321
Hysterectomy	53 (9.2)	27 (8.3)	26 (10.4)	0.230
Oophorectomy	45 (7.8)	21 (6.4)	24 (9.6)	0.158
Any of the above surgeries	240 (41.6)	121 (37.0)	119 (47.6)	0.010
HIV screening	250 (43.3)	–	–	
HIV positive	7 (1.21)	–	7 (2.8)	

Abbreviation: SD, standard deviation.

available in the city, many transgender and gender diverse individuals seek care in this "safety net" health centre, and demographic factors, such as housing and insurance, may not be typical of the traditional populations served by US community health centres.

The majority of transmasculine individuals had used GAHT (455, 78.9%) and fewer had undergone surgical interventions (240, 41.6%). The most frequent GAS was mastectomy (227, 39.3%). Less than 2% had phalloplasty or metoidioplasty.

Table 2. HIV prevalence and gender identity of sexual partners[a]

Gender of sex partners	*n*	HIV positive	%	(95% CI)
Cisgender men only	18	2	11.1	(1.37, 34.71)
Cisgender men	86 (34.4)	3	3.49	(0.73, 9.86)
Cisgender women	163 (65.2)	3	1.84	(0.38, 5.28)
Transgender men	3 (1.2)	1	33.3	(0.84, 90.57)
Transgender women	6 (2.4)	0	–	–
No sexual partner	23 (9.2)	0	–	–
Declined to state	37	1	2.7	(0.07, 14.16)
Total screened for HIV	250	7	2.8	(1.13, 5.68)

[a]Clients who were ever screened for HIV. Sexual partners listed are not mutually exclusive except where stated.
Abbreviation: CI, confidence interval.

Transmasculine individuals had diverse sexual partnerships. The majority reported having at least one cisgender female sex partner (63.6%), while 32.1% reported at least one cisgender male partner. Forty-six (9.3%) reported having cisgender male partners only.

3.2 | HIV screening and prevalence

Less than half of transmasculine individuals in the sample had ever had an HIV screen (250, 43.3%). The Centers for Disease Control and Prevention and the United States Prevention Services Task Force recommend that clinicians screen patients at least once for HIV [19, 20]; therefore, HIV screening was suboptimal. This has been seen in previous research with transgender populations [21]; however, it was unexpected that this occurred in a health centre with a robust HIV programme and where all individuals presumably had good access to HIV and STI screening services.

Of screened individuals, 7/250 had a positive HIV test (2.8%; 95% CI 1.13%, 5.68%) (Table 1). HIV prevalence among screened individuals did not significantly differ by race/ethnicity, was likely due to the small sample size: Black individuals 3/44 (6.8%; 95% CI: 0.84%, 90.57%), Hispanic 1/31 (3.2%; 95% CI: 0.08%, 16.7%); other/multiracial 1/36 (2.8%; 95% CI: 0.07%, 14.53%) and White 2/96 (2.1%; 95% CI: 0.25%, 7.32%) (Table 1). HIV prevalence was highest for those with cisgender male partners only 2/18 (11.1%; 95% CI: 1.37%, 34.71%) (Table 2).

In the bivariate analysis, living with HIV was associated with having a cisgender male partner only compared to those without cisgender male sexual partners (OR = 5.68, 95% CI 1.02, 31.58). Individuals with at least a high school diploma had reduced odds of HIV (OR = 0.07, 95% CI = 0.01, 0.49). Age, education and sex partner were placed into the multivariate model and both cisgender male partner only (OR = 10.58, 95% CI 1.33, 84.17) and high school diploma (OR 0.08, 95% CI 0.01, 0.72) remained significant predictors of HIV status (Table 3).

The HIV prevalence found in this study is in line with a recent systematic review and meta-analysis that estimated HIV prevalence among transgender men to be 1.2% by self-report and 3.2% laboratory confirmed [13]. Although Becasen's review was unable to provide estimates by race or ethnicity for transgender men, data from the US National HIV Surveillance System reported that in 2019, 41% and 26% of newly diagnosed transgender men, and 45% and 22% of 461 transgender men living with HIV were Black and Hispanic, respectively [22].

These data revealed an HIV prevalence among transmasculine individuals who have sex with cisgender men that is substantially higher than the US population prevalence (0.41%) [23]. Previous research evaluating HIV prevalence among transgender men has not stratified results by the gender of sexual partners despite a wide range of reported sexual orientation identity [24] as well as sexual practices in this group [25], including higher rates of condomless sex, and numbers of sex partners among TMSM compared to those who do not [14, 15]. These findings have important implications for clinicians, researchers and policymakers, since transgender men are often not included in HIV prevention research and are not prioritized for HIV prevention intervention efforts [15, 26], which may contribute to their suboptimal utilization of HIV pre-exposure prophylaxis (PrEP) [15, 27].

Our study had some important limitations. There have been important shifts over the last decade in the landscape of transgender health in the United States that limit the generalizability of these data. Public and commercial insurance coverage of gender-affirming care has improved, in part, due to federal and state anti-discrimination laws. There is greater visibility of transgender individuals, and those who identify as nonbinary, an identity not captured in these data. Other relevant changes include the routinization of HIV screening instead of risk-based screening, as well as the implementation and scale-up of HIV PrEP. The distribution of gender identities, prevalence of HIV screening and receipt of gender-affirming care, therefore, reflect the period that these data were collected.

Additional limitations to this study include that clients were engaged in care at a single community health centre recognized for their transgender health programme and likely not representative of the US transgender male population.

EHR data on sexual practices beyond the genders of sexual partners were limited. Nonbinary identities for sexual partners were not recorded. These data did not capture sexual behaviours (i.e. receptive vaginal/receptive anal/receptive oral sex, etc.). Because of incomplete records, some data regarding HIV risk factors were missing, and it was also not possible

Table 3. HIV prevalence: bivariate and multivariable logistic regression models

Variables	Bivariate		Multivariate	
	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value
Age in years	1.00 (0.92, 1.09)	0.977	1.04 (0.93, 1.15)	0.522
Race/Ethnicity				
White, non-Hispanic	1.00	0.602	–	
Hispanic	1.63 (0.14, 18.65)		–	
Black, non-Hispanic	3.56 (0.58, 22.26)		–	
Asian	–		–	
Other/multiracial	1.44 (0.127, 16.40)		–	
Employment status				
Employed	1.00	0.315	–	
Unemployed	2.19 (0.48, 10.06)		–	
Education				**0.009**
No high school diploma	**1.00**	0.007	**1.00**	
High school diploma	**0.07 (0.01, 0.49)**		**0.08 (0.01, 0.72)**	
Sexual partner(s)				**0.026**
No cisgender male sex partner	**1.00**	0.047	–	
Cisgender male sex partner only	**5.68 (1.02, 31.58)**		**10.58 (1.33, 84.17)**	
Gender-affirming care				
No gender-affirming care	1.00	0.583	–	
Gender-affirming care	0.78 (0.09, 6.73)		–	
Gender-affirming hormone therapy				
No hormones	1.00	0.946	–	
Hormones	1.08 (0.13, 9.21)		–	
Gender-affirming surgery				
No gender-affirming surgery	1.00	0.111	–	
Gender-affirming surgery	0.18 (0.02, 1.49)		–	
Substance use				
No substance use	1.00	0.368	–	
Substance use	2.73 (0.31, 24.23)		–	

Note: Bolded ORs are statistically significant ($p < 0.05$).
Abbreviations: CI, confidence interval; OR, odds ratio.

to confirm whether data were current, for example for insurance data, housing status, and so on. It is possible that individuals may have been tested for HIV at other facilities and have not disclosed this fact to providers. The small number of individuals living with HIV, especially when categorized by race/ethnicity or gender of sexual partners, limited the ability to see significant/strong(er) associations.

4 | CONCLUSIONS

This study of HIV prevalence among transmasculine individuals is the largest to date conducted at a community clinic in the United States. By stratifying HIV prevalence by the gender of sexual partners, this study adds important new information about HIV vulnerability among transmasculine individuals. These findings also underscore the need for improved inclusion of TMSM in HIV prevention research, which they have often been excluded from, and their recognition as a priority population for HIV prevention interventions.

AUTHORS' AFFILIATIONS

[1]Department of Medicine, Callen-Lorde Community Health Center, New York City, New York, USA; [2]Department of Epidemiology, Columbia University Mailman School of Public Health, New York City, New York, USA; [3]Division of Infectious Diseases, Department of Medicine, Columbia University Irving Medical Center, New York City, New York, USA

COMPETING INTERESTS

The authors declare no competing interests.

AUTHORS' CONTRIBUTIONS

AER performed the research. AER, ELL and MAC conceptualized the manuscript. AER analysed the data. AER wrote the first draft with assistance from ELL, MAC and ABH. All authors read and approved the final version.

ACKNOWLEDGEMENTS

None.

FUNDING

Research reported in this publication was supported by the National Institute of Mental Health under award number R25MH087217.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

REFERENCES

1. Meerwijk EL, Sevelius JM. Transgender population size in the United States: a meta-regression of population-based probability samples. Am J Public Health. 2017;107(2):216.
2. Feldman JL, Luhur WE, Herman JL, Poteat T, Meyer IH. Health and health care access in the US transgender population health (TransPop) survey. Andrology. 2021;9(6):1707–18.
3. James SE, Herman JL, Rankin S, Keisling M, Mottet L, Anafi M. The Report of the 2015 U.S.Transgender Survey. Washington, DC: National Center for Transgender Equality; 2016.
4. White Hughto JM, Reisner SL, Pachankis JE. Transgender stigma and health: a critical review of stigma determinants, mechanisms, and interventions. Soc Sci Med. 2015;147:222–31.
5. Reisner SL, Poteat T, Keatley J, Cabral M, Mothopeng T, Dunham E, et al. Global health burden and needs of transgender populations: a review. Lancet. 2016;388(10042):412–36.
6. Institute of Medicine. Committee on Lesbian Gay Bisexual Transgender Health Issues and Research Gaps and Opportunities. The health of lesbian, gay, bisexual, and transgender people: building a foundation for better understanding. National Academies Press; 2011.
7. Reisner S. Integrated and gender-affirming transgender clinical care and research. AMA J Ethics. 2016;72(Suppl 3):S235–42.
8. Del Río-González AM, Lameiras-Fernández M, Modrakovic D, Aguayo-Romero R, Glickman C, Bowleg L, et al. Global scoping review of HIV prevention research with transgender people: transcending from trans-subsumed to trans-centred research. J Int AIDS Soc. 2021;24(9):e25786.
9. Baral SD, Poteat T, Stromdahl S, Wirtz AL, Guadamuz TE, Beyrer C. Worldwide burden of HIV in transgender women: a systematic review and meta-analysis. Lancet Infect Dis. 2012;3(3):214–22.
10. Castillo R, Konda KA, Leon SR, Silva-Santisteban A, Salazar X, Klausner JD, et al. HIV and sexually transmitted infection incidence and associated risk factors among high-risk MSM and male-to-female transgender women in Lima, Peru. J Acquir Immune Defic Syndr. 2015;69(5):567–75.
11. Kimani M, van der Elst EM, Chiro O, Oduor C, Wahome E, Kazungu W, et al. PrEP interest and HIV-1 incidence among MSM and transgender women in coastal Kenya. J Int AIDS Soc. 2019;22(6):e25323.
12. Buchbinder SP, Glidden DV, Liu AY, McMahan V, Guanira JV, Mayer KH, et al. HIV pre-exposure prophylaxis in men who have sex with men and transgender women: a secondary analysis of a phase 3 randomised controlled efficacy trial. Lancet Infect Dis. 2014;14(6):468–75.
13. Becasen JS, Denard CL, Mullins MM, Higa DH, Sipe TA. Estimating the prevalence of HIV and sexual behaviors among the US transgender population: a systematic review and meta-analysis, 2006–2017. Am J Public Health. 2019;109(1):e1–8.
14. Reisner SL, Perkovich B, Mimiaga MJ. A mixed methods study of the sexual health needs of New England transmen who have sex with nontransgender men. AIDS Patient Care STDs. 2010;24(8):501–13.
15. Reisner SL, Moore CS, Asquith A, Pardee DJ, Sarvet A, Mayer G, et al. High risk and low uptake of pre-exposure prophylaxis to prevent HIV acquisition in a national online sample of transgender men who have sex with men in the United States. J Int AIDS Soc. 2019;22(9):e25391.
16. Pitasi MA, Kerani RP, Kohn R, Murphy RD, Pathela P, Schumacher CM, et al. Chlamydia, gonorrhea, and human immunodeficiency virus infection among transgender women and transgender men attending clinics that provide sexually transmitted disease services in six US cities: results from the Sexually Transmitted Disease Surveillance Network. Sex Transm Dis. 2019;46(2):112–7.
17. Chen S, McFarland W, Thompson HM, Raymond HF. Transmen in San Francisco: what do we know from HIV test site data? AIDS Behav. 2011;15(3):659–62.
18. Reisner SL, Moore CS, Asquith A, Pardee DJ, Mayer KH. The pre-exposure prophylaxis cascade in at-risk transgender men who have sex with men in the United States. LGBT Health. 2021;8(2):116–24.
19. USPSTF Task Force. Screening for HIV infection: US Preventive Services Task Force Recommendation statement. JAMA. 2019;321(23):2326–36.
20. Branson BM, Handsfield HH, Lampe MA, Janssen RS, Taylor AW, Lyss SB, et al. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. MMWR Recomm Rep. 2006;55(Rr-14):1–17; quiz CE1-4.
21. Pitasi MA, Oraka E, Clark H, Town M, DiNenno EA. HIV testing among transgender women and men - 27 states and guam, 2014–2015. MMWR Morb Mortal Wkly Rep. 2017;66(33):883–7.
22. Centers for Disease Control and Prevention. HIV Surveillance Report, 2019. Atlanta, GA: CDC; 2021.
23. McQuillan GM, Kruszon-Moran D, Masciotra S, Gu Q, Storandt R. Prevalence and trends in HIV infection and testing among adults in the United States: the National Health and Nutrition Examination Surveys, 1999–2018. J Acquir Immune Defic Syndr. 2021;86(5):523–9.
24. Kuper LE, Nussbaum R, Mustanski B. Exploring the diversity of gender and sexual orientation identities in an online sample of transgender individuals. J Sex Res. 2012;49(2–3):244–54.
25. Feldman J, Romine RS, Bockting WO. HIV risk behaviors in the U.S. transgender population: prevalence and predictors in a large internet sample. J Homosex. 2014;61(11):1558–88.
26. del Río-González AM, Lameiras-Fernández M, Modrakovic D, Aguayo-Romero R, Glickman C, Bowleg L, et al. Global scoping review of HIV prevention research with transgender people: transcending from trans-subsumed to trans-centred research. J Int AIDS Soc. 2021;24(9):e25786.
27. Golub SA, Fikslin RA, Starbuck L, Klein A. High rates of PrEP eligibility but low rates of PrEP access among a national sample of transmasculine individuals. J Acquir Immune Defic Syndr. 2019;82(1):e1–7.

Appenroth MN et al. *Journal of the International AIDS Society* 2022, **25**(S5):e25992
http://onlinelibrary.wiley.com/doi/10.1002/jia2.25992/full | https://doi.org/10.1002/jia2.25992

JIAS JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

RESEARCH ARTICLE

Sexual happiness and satisfaction with sexual safety among German trans men who have sex with men: results from EMIS-2017

Max Nicolai Appenroth[1,2,§], Uwe Koppe[1], Ford Hickson[3], Susanne Schink[1], Alexander Hahne[4], Axel J. Schmidt[3], Peter Weatherburn[3] and Ulrich Marcus[1]

[§]**Corresponding author**: Max Nicolai Appenroth, Institute of Public Health, Charité Universitätsmedizin Berlin, Charitéplatz 1, 10117 Berlin, Germany. (max.appenroth@charite.de)

Abstract

Introduction: The population of men-who-have-sex-with-men (MSM) includes people who are on the masculine spectrum but were assigned female at birth (AFAB), that is trans MSM. This study aims to identify current circumstances regarding sexual happiness and safety among German trans MSM. To date, there is no health information about trans MSM in Germany, limiting the ability of MSM sexual health programmes to meet their needs.

Methods: Data were used from the European MSM Internet Survey (EMIS-2017), where people identifying as men and/or trans men were recruited through dating apps for MSM, community websites and social media to participate in an online survey. We analysed parameters on sexual happiness and satisfaction with sexual safety among Germany-based trans MSM and compared those to outcomes of MSM assigned male at birth (cis MSM) living in Germany using descriptive methods and logistic regression models adjusting for age.

Results: In total, 23,001 participants from Germany were included, of which 122 (0.5%) indicated to be AFAB (i.e. trans MSM). Trans MSM were markedly younger than cis participants (median age: 28.5 vs. 39 years).

Trans MSM more often reported being unhappy with their current sex life (adjusted odds ratio [aOR] = 1.82, 95% CI 1.24–2.67), had higher odds of disagreeing with the statements "the sex I have is always as safe as I want" ([aOR] = 1.82, 95% CI 1.24–2.67) and "I find it easy to say no to sex that I don't want" ([aOR] = 1.80, 95% CI 1.18–2.77).

Trans MSM were more likely to not be living comfortably financially ([aOR] = 2.43, 95% CI 1.60–3.67) and to be living with severe anxiety and/or depression ([aOR] = 3.90, 95% CI 2.22–6.83). Trans MSM were less likely to have ever tested for HIV ([aOR] = 0.63, 95% CI 0.43–0.93).

Conclusions: Sexual happiness, control of sexual boundaries, satisfaction with sexual safety, financial security, mental wellbeing and HIV testing were all lower in German trans MSM compared with cis MSM. Tailored sexual health interventions, contextualized with regard to needs and vulnerabilities, could address this inequality.

Keywords: trans MSM; trans men; gender diversity; HIV prevention; sexual happiness; MSM

Received 3 January 2022; **Accepted** 30 July 2022

1 | INTRODUCTION

In the past 5 years, human immunodeficiency virus (HIV) prevention and research among men-who-have-sex-with-men (MSM) has increasingly included transmasculine people. Yet, little is known about individuals who are on the masculine spectrum and whose gender is different from their sex assigned at birth. HIV prevention and other sexual health data about trans MSM are scarce.

The World Health Organization has declared trans people as a key population in regard to HIV exposure [1] and this community, especially trans women of colour, is disproportionately affected by HIV and other sexually transmitted infections (STIs) [2–4]. However, little is known about trans community members who were assigned female at birth (AFAB; i.e. trans men, transmasculine individuals and AFAB men) [2]. A U.S.-based analysis of trans-inclusive research found laboratory-confirmed HIV infections in 3.2% of transmasculine participants [3]. Estimations suggest that currently, 1.2 million people are living with HIV in the United States [5], which represents about 0.36% of the U.S. population. Accordingly, transmasculine people appear to be more likely living with HIV than the general population. Due to a lack of research, estimations about HIV prevalence in transmasculine

communities in other global regions are not possible at this point.

Although experiencing a possible elevated risk for HIV, testing rates among transmasculine people appear lower compared to cis gay and bisexual men [6]. Additionally, access and uptake of HIV pre-exposure prophylaxis (PrEP) have been limited in this group [7, 8]. Both issues were associated with poor knowledge of healthcare providers about the specific HIV risks and vulnerabilities of transmasculine individuals [6]. Many transmasculine people engage sexually with cis men [9–12]. Physical changes accompanying gender-affirming hormones (i.e. vaginal/front hole tissue changes and a greater need for using lubricants, when engaging in vaginal/front hole sex) [13] and difficulties navigating safer sex discussions [14–16] put transmasculine people at risk for STI/HIV infections. This risk comes alongside a lack of knowledge about trans-lived realities among healthcare providers. In healthcare settings, trans people are often confronted with gendered body stereotypes (e.g. norms like "all men have a penis"), heteronormative expectations (e.g. "trans men sexually engage only with cis women"), lack of trans-competent treatment knowledge by healthcare providers [17], alongside experiences of discrimination [18–21].

Overall sexual satisfaction in trans communities is understudied. Barriers to sexual satisfaction among trans individuals are difficulties creating sexual encounters and being afraid of sexual contact in general [22]. A study sample (n = 518) collected at three gender clinics in Belgium, the Netherlands and Germany included results of 307 trans women and 211 trans men. The results showed that 26% of trans women and 32% of trans men who indicated sexual problems found it difficult to initiate sexual contact. Additionally, 21% of trans women and 22% of trans men reported being afraid of sexual contact. Another study with cis and trans participants from Canada and the United States, regardless of their sexual orientation, found that 87.5% would not date a trans person [23]. Heterosexual cis men (96.7%) and cis women (98.2%) were most likely not to be interested in dating a trans person. Respondents identifying as bisexual, queer or non-binary (48.3%) were more likely to consider trans individuals as potential dating partners. An Australian-based study among trans people showed that 42.2% of trans men were anxious when thinking about their sex life [24].

When discussing a fulfilling sexual life in trans communities, it is crucial to acknowledge the importance of gender affirmation (e.g. being gendered correctly by others). Gender affirmation is directly linked to improved mental health [25], and although not all trans people undergo physical changes to align their bodies with their gender identity, access to such gender-affirming treatment minimizes negative body images [26]. Gender-confirming treatment has a positive influence on sexual feeling in trans women, but a greater impact is attributed to bodily satisfaction (e.g. feeling comfortable in a person's own body) [27]. Sexual confidence significantly improved in AFAB trans people who underwent masculinizing chest surgery [27, 28]. Besides multiple barriers to healthcare, the research found that sexual body image worries in trans populations are linked with poor sexual health outcomes. Higher self-esteem and sexual satisfaction were associated with stronger condom negotiation skills [29].

Currently, information on sexual happiness and sexual safety among trans MSM in Germany is lacking. The data about this group in Germany, collected through the European MSM Internet Survey 2017 (EMIS-2017) and presented in this article, is the first of its kind, and it will depict risks and vulnerabilities in regard to HIV/STIs faced by this community.

2 | METHODS

The data used for this analysis come from the European MSM Internet Survey 2017, a community-recruited online survey (EMIS-2017; www.emis2017.eu). Fieldwork occurred from 9 October 2017 to 31 January 2018 for self-completion of the questionnaire. Community-based recruitment occurred on targeted websites, apps and social media. Responses were included if individuals: identified as MSM, were legally old enough (in their country) to have sex with men, understood the purpose of the study and gave their consent to participate. A more detailed description of the methods has been published previously [30].

Based on the German EMIS sub-sample, we compared demographics, sexual behaviour, sexual happiness and satisfaction with sexual safety among German trans MSM with outcomes of German cis MSM using descriptive methods and logistic regression models adjusting for age.

2.1 | Participants

The analytic sub-sample for this paper was EMIS respondents living in Germany who provided valid responses about their sex assigned at birth and current gender identity.

In this report, we define trans MSM as people who are "men" or "trans men" (by self-identification) and female assigned at birth, and who are sexually attracted to and/or have sex with men. "Men" assigned male at birth (AMAB) are referred to as "cis" in this analysis. "Trans men" AMAB were excluded from this study.

2.2 | Outcome variables

The study asked for a number of demographic and sexual health information. The way in which questions were asked in detail with answer options has been described elsewhere [14].

Age was recorded in years and collapsed into five categories (14–17; 18–29; 30–39; 40–49; 50 and older). Financial coping was categorized into "living comfortably" and "not living comfortably" on current income. The sexual identity included the answers "gay/homosexual," "straight/heterosexual," "bisexual," "any other term" and "I don't usually use a term." Partnership status was dichotomized as "single or unsure" and "steady partner," and HIV diagnosis was captured through a "yes" or "no" answer to the question of whether participants ever received a positive HIV test result.

As for mental health, EMIS-2017 used the PHQ-4 to provide a combined indicator for anxiety and depression. Answers were measured with a standardized system of "normal," "mild," "moderate" and "severe." The question about feeling suicidal was categorized into "yes, at least some days" or "never."

A numerical scale from 1 to 10 was offered to gather data about sexual happiness, and participants were asked "On a scale of 1 to 10 (where 1 is the most unhappy and 10 is the most happy), how happy are you with your sex life?" Answers were dichotomized into "unhappy" (1–4) and "happy" (5–10).

The answer regarding the number of steady male sexual partners in the past 12 months was categorized as "0," "1," "2," or "3 or more," and the answer to the question about the number of non-steady male sexual partners in the past 12 months was grouped into four categories (0, 1–3, 4–10 and 11 or more).

Participants were asked whether they "agree" or "disagree" with the statements "the sex I have is always as safe as I want to be" and "I find it easy to say 'no' to sex I don't want" to assess their safer sex self-efficacy [14].

Questions regarding HIV testing and prevention (ever having received an HIV test result; ever had an STI test other than HIV; ever heard of PrEP; ever used PrEP; ever talked to a healthcare provider about PrEP) were dichotomized to "yes" or "no."

2.3 | Ethical approval

The study received approval from the Observational & Interventions Research Ethics Committee of the London School of Hygiene & Tropical Medicine (14 September 2017; LSHTM ethics ref: 14421) [14].

3 | RESULTS

We included 23,001 individuals living in Germany participating in EMIS-2017 who either reported that they were AMAB and identified as men (n = 22,879; 99.5%) or who indicated having been AFAB but who identified as trans men (n = 95; 0.4%) or men (n = 27; 0.1%). AFAB trans men and men were grouped into the category of trans MSM (n = 122) for this analysis. The 56 respondents who indicated being AMAB and who identified as a "trans man" were excluded from this analysis.

3.1 | Demographics

Participating trans MSM were considerably younger (median age 28.5 years [IQR 23–37]) compared to cis MSM (39 years [IQR 29–49]). Over half (52.5%) of trans MSM were aged 18–29 compared to about a quarter (26.4%) of cis MSM.

Trans MSM were much more likely to not be living comfortably on their current income (74.6% vs. 49.9%, age-adjusted odds ratio [aOR] = 2.43, 95% CI = 1.60–3.67) compared to cis MSM (Table 1).

3.2 | Sexuality and relationship status

While similar proportions of trans and cis MSM identified as "bisexual" (17.2% and 16.7%), trans MSM were less likely to identify as "gay" or "homosexual" (48.4% vs. 78.3%; [aOR] = 0.56, 95% CI = 0.34–0.93) and were more likely to use other terms (18.9% vs. 0.8%; [aOR] = 16.49, 95% CI = 8.87–30.66) or no term (13.9% vs. 3.6%; [aOR] = 3.24, 95% CI = 1.70–6.20). Trans MSM (65.6%) were numerically more likely to report being single or of unsure relationship status (vs. 53.6% in cis MSM; [aOR] = 1.23, 95% CI = 0.84–1.81) (Table 1).

3.3 | Mental health

14.8% of trans MSM had a PHQ-4 score suggesting they are living with depression and/or anxiety compared to 5.0% of cis MSM ([aOR] = 3.90, 95% CI 2.22–6.83).

Trans MSM were more likely than cis respondents to feeling suicidal on some days ([aOR] = 3.27, 95% CI 2.27–4.72) (Table 1).

3.4 | Sexual happiness and satisfaction with sexual safety

Trans MSM were more likely than cis MSM to report being unhappy with their current sexual life (33.6% vs. 22.3%; [aOR] = 1.82, 95% CI 1.24–2.67). Additionally, they were more likely to disagree with the statements "The sex I have is always as safe as I want to be" ([aOR] = 1.77, 95% CI 1.11–2.82) and "I find it easy to say 'no' to sex I don't want" ([aOR] = 1.80, 95% CI 1.18–2.77) (Table 2).

3.5 | Sexual behaviour

About three quarters (75.4%) of trans participants reported having no steady sexual partner (vs. 58.4% of cis MSM) and trans MSM were less likely to have multiple non-steady sexual partners (1–3 non-steady sexual partners [aOR] = 0.54, 95% CI 0.35–0.84; 4–10 non-steady sexual partners [aOR] = 0.36, 95% CI 0.20–0.64; 11 or more non-steady sexual partners [aOR] = 0.26, 95% CI 0.12–0.57) compared to the cis sample. Engagement in stimulant drug use for sex (chemsex) in the past 12 months prior to the study was comparable between the study groups ([aOR] = 0.89, 95% CI 0.46–1.70) (Table 2).

3.6 | HIV and HIV prevention

Trans MSM were less likely to have ever received an HIV test result (58.2% vs. 76.1%; [aOR] = 0.63, 95% CI 0.43–0.93) and were less likely to have been diagnosed with HIV (2.5% vs. 10.7%; [aOR] = 0.33, 95% CI 0.10–1.04) compared to cis MSM.

Ever having been tested for (non-HIV) STIs was less common than HIV testing among both study groups. Even though the proportion of trans MSM that tested for other STIs was numerically smaller than for cis MSM, the confidence interval overlaps the null value, and this difference might have arisen by chance (reported 45.1% vs. 54.3%; [aOR] = 0.84, 95% CI 0.58–1.21).

Trans MSM were numerically less likely to have heard of PrEP (45.1% vs. 59.3%; [aOR] = 0.81, 95% CI 0.57–1.16) and were also less likely to have talked to a healthcare provider about PrEP (1.6% vs. 7.2%; [aOR] = 0.22, 95% CI 0.06–0.91). Subsequently, while PrEP use was uncommon overall, it was numerically even less likely to have ever been used by trans MSM (0.8% vs. 2.8%; [aOR] = 0.40, 95% CI 0.06–2.88) (Table 2).

Table 1. Demographic and mental health data of trans MSM and cis MSM EMIS participants (*N* = 23,001)

Variable	Trans MSM	Cis MSM	Univariable regression[a]	Regression adjusted for age[b]	*p*-value[c]
Overall	122 (0.5%)	22,879 (99.5%)	–	–	
Age (years)					
Median (IQR)	28.5 (23–37)	39 (29–49)	–	–	
14–17	4 (3.3%)	197 (0.9%)	1.92 (0.69–5.32)	–	0.211
18–29	64 (52.5%)	6043 (26.4%)	1	–	–
30–39	27 (22.1%)	5681 (24.8%)	0.45 (0.29–0.70)	–	**0.001**
40–49	19 (15.6%)	5382 (23.5%)	0.33 (0.20–0.56)	–	**<0.001**
50 and older	8 (6.5%)	5576 (24.4%)	0.14 (0.06–0.28)	–	**<0.001**
Income					
Living comfortably	31 (25.4%)	11,466 (50.1%)	1	1	
Not living comfortably	91 (74.6%)	11,413 (49.9%)	2.98 (1.98–4.48)	2.43 (1.60–3.67)	**<0.001**
Sexual identity					
Gay or homosexual	59 (48.4%)	17,918 (78.3%)	0.60 (0.36–0.99)	0.56 (0.34–0.93)	**0.024**
Bisexual	21 (17.2%)	3818 (16.7%)	1	1	
Straight or heterosexual	2 (1.6%)	125 (0.6%)	2.91 (0.67–12.54)	2.63 (0.61–11.37)	0.196
Any other term	23 (18.9%)	175 (0.8%)	23.89 (12.97–44.01)	16.49 (8.87–30.66)	**<0.001**
I don't usually use a term	17 (13.9%)	824 (3.6%)	3.75 (1.97–7.14)	3.24 (1.70–6.20)	**<0.001**
Missing	–	19 (0.1%)	–	–	
Partnership status					
Single or unsure	80 (65.6%)	12,257 (53.6%)	1.65 (1.13–2.40)	1.23 (0.84–1.81)	0.284
Steady partner	42 (34.4%)	10,599 (46.3%)	1	1	
Living with depression/anxiety					
Normal	42 (34.4%)	13,463 (58.8%)	1	1	
Mild	44 (36.1%)	6190 (27.1%)	2.28 (1.49–3.48)	1.97 (1.29–3.02)	**0.002**
Moderate	15 (12.3%)	1729 (7.6%)	2.78 (1.54–5.03)	2.14 (1.18–3.88)	**0.012**
Severe	18 (14.8%)	1133 (5%)	5.09 (2.92–8.88)	3.90 (2.22–6.83)	**<0.001**
Missing	3 (2.5)	364 (1.6%)			
Suicidal ideation					
Yes, at least some days	50 (41%)	3523 (15.5%)	3.79 (2.64–5.44)	3.27 (2.27–4.72)	**<0.001**
Never	72 (59%)	19,211 (84.5%)	1	1	
Missing	–	–			

[a]Univariable logistic regression model with 122 trans and 22,879 cis EMIS-2017 participants.
[b]Multivariable logistic regression model with 122 trans and 22,879 cis EMIS-2017 participants adjusting for age.
[c]*p*-values of age-adjusted regression. Statistically significant *p*-values ($p < 0.05$) are shown in bold.
Abbreviations: EMIS, European MSM Internet Survey; IQR, interquartile range; MSM, men who have sex with men.

4 | DISCUSSION

The data analysis from the European MSM Internet Survey 2017 (EMIS-2017) demonstrates differences in a range of sexual health indicators between trans and cis MSM in Germany. Trans MSM were less likely to access sexual health services (spoken to about PrEP and received HIV/STI test results) and were less likely to have their sexual health needs met (being aware of PrEP, being able to say "no" and only doing things I don't regret). They were also less likely to engage in sexual risk behaviours (multiple partners) and less likely to engage in precautionary behaviour (taking PrEP). They were both less likely to be living with diagnosed HIV and less likely to be happy with their sex life.

These differences were large enough to be detected despite a relatively small number of trans MSM in the sample. The findings present a first outline of the sexual health profile of trans MSM in Germany.

Looking at the results of this study, trans MSM were more likely to not live comfortable financially. Socio-economic disadvantages in trans MSM found here align with previous findings [18, 31, 32]. This may be attributed to the relatively younger age of trans participants, but also to discriminatory experiences in education and work settings [18, 21].

The high levels of mental health problems and suicidality among trans MSM participants of the EMIS-2017 align with previous research showing that trans individuals are disproportionately affected by mental health-related issues and

Table 2. Sexual behaviour and HIV/STI prevention data of trans MSM and cis MSM EMIS-2017 participants (*N* = 23,001)

	Trans MSM	Cis MSM	Univariable regression[a]	Regression adjusted for age[b]	*p*-value[c]
Overall	122 (0.5%)	22,879 (99.5%)			
Sexual happiness					
Unhappy (1–4)	41 (33.6%)	5106 (22.3%)	1.89 (1.29–2.77)	1.82 (1.24–2.67)	0.002
Happy (5–10)	73 (59.8%)	17,182 (75.1%)	1	1	–
Missing	8 (6.6%)	591 (2.6%)	–	–	–
Sex is always as safe as I want					
Agree	100 (82%)	20,386 (89.1%)	1	1	–
Disagree	22 (18%)	2394 (10.5%)	1.87 (1.18–2.98)	1.77 (1.11–2.82)	**0.016**
Missing	–	99 (0.4%)	–	–	–
I find it easy to say no to sex I don't want					
Agree	94 (77.1%)	19,952 (87.2%)	1	1	–
Disagree	28 (23%)	2767 (12.1%)	2.15 (1.41–3.28)	1.80 (1.18–2.77)	**<0.001**
Missing	–	160 (0.7%)	–	–	–
Number of steady sexual partners in the past 12 months					
0	92 (75.4%)	13,350 (58.4%)	1	1	–
1	27 (22.1%)	6940 (30.3%)	0.56 (0.37–0.87)	0.51 (0.33–0.79)	**0.002**
2	3 (2.5%)	1074 (4.6%)	0.42 (0.31–1.32)	0.40 (0.13–1.28)	0.123
3 or more	0 (0%)	1348 (5.9%)	–	–	–
Missing	–	194 (0.9%)	–	–	–
Number of non-steady sexual partners in the past 12 months					
0	74 (60.7%)	8531 (37.3%)	1	1	–
1–3	28 (22%)	6129 (26.8%)	0.53 (0.34–0.81)	0.54 (0.35–0.84)	**0.006**
4–10	13 (10.7%)	4373 (19.1%)	0.34 (0.19–0.62)	0.36 (0.20–0.64)	**0.001**
11 or more	7 (5.7%)	3518 (15.4%)	0.23 (0.11–0.50)	0.26 (0.12–0.57)	**0.001**
Missing	–	328 (1.4)	–	–	
Chemsex in the past 12 months					
Yes	10 (8.2%)	2145 (9.4%)	0.86 (0.45–1.64)	0.89 (0.46–1.70)	0.715
No	111 (91%)	20,420 (89.3%)	1	1	–
Missing	1 (0.8%)	314 (1.4%)	–	–	–
Received HIV-positive diagnosis					
Yes	3 (2.5%)	2448 (10.7%)	0.21 (0.07–0.66)	0.33 (0.10–1.04)	0.059
No	118 (96.7%)	20,242 (88.5%)	1	1	–
Missing	1 (0.8%)	189 (0.8%)	–	–	–
Ever received an HIV test result					
Yes	71 (58.2%)	17,411 (76.1%)	0.44 (0.31–0.63)	0.63 (0.43–0.93)	**0.018**
No	50 (41%)	5390 (23.6%)	1	1	–
Missing	1 (0.8%)	78 (0.3%)	–	–	–
Ever tested for STIs					
Yes	55 (45.1%)	12,427 (54.3%)	0.67 (0.47–0.96)	0.84 (0.58–1.21)	0.358
No	67 (54.9%)	10,215 (44.7%)	1	1	–
Missing	–	237 (1%)	–	–	–

(*Continued*)

Table 2. (Continued)

	Trans MSM	Cis MSM	Univariable regression[a]	Regression adjusted for age[b]	*p*-value[c]
Ever heard of PrEP					
Yes	55 (45.1%)	13,567 (59.3%)	0.78 (0.55–1.12)	0.81 (0.57–1.16)	0.256
No	66 (54.1%)	8872 (38.8%)	1	1	–
Missing	1 (0.8%)	440 (1.9%)	–	–	–
Ever talked to healthcare provider about PrEP					
Yes	2 (1.6%)	1644 (7.2%)	0.22 (0.05–0.87)	0.22 (0.06–0.91)	**0.036**
No	119 (97.5%)	21,121 (92.3%)	1	1	–
Missing	1 (0.8%)	114 (0.5%)	–	–	–
Ever used PrEP					
Yes	1 (0.8%)	491 (2.2%)	1	1	–
No	121 (99.2%)	22,234 (97.2%)	0.37 (0.05–2.68)	0.40 (0.06–2.88)	0.363
Missing	–	154 (0.7%)	–	–	–

[a]Univariable logistic regression model with 122 trans and 22,879 cis EMIS-2017 participants.
[b]Multivariable logistic regression model with 122 trans and 22,879 cis EMIS-2017 participants adjusting for age.
[c]*p*-values of adjusted regression. Statistically significant *p*-values ($p < 0.05$) are shown in bold.
Abbreviations: EMIS-2017, European MSM Internet Survey 2017; MSM, men who have sex with men; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infections.

suicidal ideation [18]. Although studies have found higher HIV testing rates among people living with mental health problems, HIV prevalence is higher among people affected by poor mental health [33]. It is unclear if higher testing rates can be found among transmasculine individuals living with mental health-related problems, as testing rates are comparably low in this group [6]. Trans MSM could specifically benefit from combined and integrated mental and sexual health services.

Sexual risk behaviour measured by the number of sexual partners differed within both study groups. Cis participants were more likely to engage more with steady and non-steady sexual partners compared to trans participants. This finding may reflect results from other studies where trans participants reported difficulties initiating sex and fear of sexual activity [22, 24]. Barriers of finding sexual contacts and that trans people are not considered as dating partners may account for lower numbers of sexual partners found in this analysis.

Additionally, sexual unhappiness in trans MSM may be directly linked to difficulties in finding sexual partners. This study showed that cis participants were more likely to be satisfied with their current sexual life, and more trans MSM indicated not being satisfied with their sex life. Sexual (dis-) satisfaction in trans MSM may be directly linked to gender dis-affirmation by cis MSM, leading to higher levels of psychological distress and anxiety in trans MSM [34].

This data analysis suggests lower levels of HIV testing among trans MSM and even lower frequencies for other STI testing. This finding aligns with other research reporting low testing frequencies in trans populations [6, 35]. A cross-sectional online study in the United States found high rates of trans MSM who have never tested for HIV or bacterial and viral STIs, especially among younger participants [36]. Trans MSM receiving positive gender affirmation by cis MSM had higher HIV testing frequency [34].

Lower testing rates might be associated with negative experiences of trans people in healthcare settings. An analysis based on the 2015 U.S. Transgender Survey showed that specifically transmasculine participants postponed or even avoided seeking healthcare due to anticipated discrimination in healthcare settings [32]. A European-wide study among Lesbian, Gay, Bisexual, Trans and Inter people found that 34% of the trans respondents experienced discrimination in healthcare or social service settings, with disproportionately higher rates in Germany (40%) [21]. A previous study among trans people in Europe showed that trans men were especially vulnerable to discrimination by healthcare providers [37]. Besides the experiences of discrimination, stereotypical assumptions about the sexuality and sexual practices of trans MSM may lead to inadequate service provision [38]. A poor risk assessment by healthcare providers, specifically in the field of sexual health, may cause a lack of appropriate testing and prevention opportunities.

The analysed data were collected in 2017 before the formal rollout of PrEP in Germany. Lacking knowledge on the side of healthcare providers about lived realities of trans MSM may contribute to the fact that trans MSM in this sample were less likely to have heard about PrEP, talked to a healthcare provider about PrEP or ever used PrEP. These findings align with previous studies that showed low PrEP uptake in transmasculine individuals and a lack of conversations with healthcare providers about this drug [7] and country-specific barriers to PrEP uptake in trans individuals in Germany have been described previously [39]. That 2.5% of the trans MSM in this sample are living with diagnosed HIV illustrates the large benefit gap when only 0.8% of those who are not positive are using PrEP. While trans MSM group risk may be lower than

that of cis MSM, it is higher than that of the general population (see Introduction). PrEP services and promotions for MSM should be trans inclusive, and trans MSM-specific programmes should be considered.

In 2020, the Deutsche Aidshilfe (German AIDS Service Organization) published a brochure developed by and targeted to transmasculine individuals who have sex with men [40]. This brochure is the only published sexual health information inclusive of the target population in German. Regarding service provision, for example, CliniQ in London/UK is a sexual health clinic operated by and for trans people (https://cliniq.org.uk/). Given the shared experience of discrimination in healthcare settings by trans people and the reduced risk for HIV acquisition through peer-led education [41], peer-led sexual health services are a very much-needed intervention for the trans community. However, such services are only offered periodically in two cities in Germany. The Checkpoint BLN (Berlin) offers peer-testing and counselling for trans, non-binary and inter individuals once a month [42]. The Münchner Aids-Hilfe (Munich AIDS Service Organization) runs a counselling service for trans and inter people. Every 3 months for 3 hours, HIV/STI-testing is offered on a peer basis [43]. Both opportunities are for the wider trans and inter community, and sexual health services specifically targeted at transmasculine identities are missing.

The study has a few limitations. The small sample size of German trans MSM in this study only allows a small insight into the lived experiences of this community, and further research is needed. MSM recruited online differ from the general MSM population by over-representing MSM identifying as gay and reporting more sexual risk behaviours [44]. In all self-selection surveys, participants with lower education levels are underrepresented.

We are aware that grouping together "trans men" and people AFAB who refer to themselves simply as "men" is not ideal, as the latter group might reject an identification as trans. However, for more appropriate analysis, this seemed like the best choice, but we wish to highlight that the matter of self-identification of trans people is a sensitive topic.

However, this analysis opens a path for a better understanding of the needs of trans MSM and the possibility to target their sexual health needs in a more appropriate way. Trans community members were consulted to review measures on gender identity and sex assigned at birth, and the analysis, as well as drafting of the manuscript, have been conducted by a transmasculine researcher from Germany.

5 | CONCLUSIONS

This research presents the first data about trans men and AFAB men who have sex with men (trans MSM) living in Germany and shows their comparative disadvantage. The outcomes demonstrate complex aspects of sexual happiness of trans MSM, negotiating safer sex and sexual boundaries. Lower uptake of HIV and STI testing and talking to healthcare providers about HIV prevention methods, such as PrEP, may be connected to potential experiences of discrimination in healthcare settings faced by many trans people.

Sexual health services need to expand their efforts to include this population in their prevention strategies, outreach and care. For example, community-informed safer sex negotiation and sexual boundary trainings or peer-led sexual health interventions may reduce the overall risk of HIV/STI exposure, improve the uptake of sexual health services and enhance satisfaction with sexual life in trans MSM. Taking these outcomes and other existing data into account, sexual health interventions need to be tailored to meet the needs and vulnerabilities of trans MSM in the German context and beyond.

AUTHORS' AFFILIATIONS

[1]Department of Infectious Disease Epidemiology, Robert Koch-Institute, Berlin, Germany; [2]Institute of Public Health, Charité Universitätsmedizin Berlin, Berlin, Germany; [3]Department of Public Health, Environments & Society, Faculty of Public Health & Policy, London School of Hygiene & Tropical Medicine, London, UK; [4]Freelance Sex Educator and Bodyworker, Hamburg, Germany

COMPETING INTERESTS

The authors declare no competing interests.

The funder defined the primary population (men who have sex with men) and morbidities (sexually transmitted infections) of concern. The funder had no role in the collection, analyses or interpretation of data, in the writing of the manuscript, or in the decision to publish the results.

AUTHORS' CONTRIBUTIONS

AJS, FH, PW and UM designed the study. SS and UM prepared the German subdata set for pre-analysis. MNA, UK and UM performed the analysis presented in this manuscript. MNA wrote the first original draft. All authors reviewed and edited the manuscript.

ACKNOWLEDGEMENTS

Thanks to Michelle Ross and Aedan Woolton (ClinicQ, London) for comments on the gender identity and sex assigned at birth measures. We thank all EMIS-2017 participants and collaborators: PlanetRomeo, European AIDS Treatment Group (EATG), Eurasian Coalition on Male Health (ECOM), European Centre for Disease Prevention and Control (ECDC), European Monitoring Centre for Drugs & Drug Addiction (EMCDDA), European Commission (DG SANTE), Deutsche AIDS-Hilfe, Robert Koch Institute, BZgA, Michael Bochow and Richard Lemke.

FUNDING

This research was funded by the European Union in the framework of the Third EU Health Programme (2014–2020).

DATA AVAILABILITY STATEMENT

The EMIS-2017 dataset used for this analysis has been obtained from the London School of Hygiene and Tropical Medicine under a data transfer agreement that prohibits sharing the dataset publicly. Although we cannot make study data publicly accessible at the time of publication, all authors commit to make the data underlying the findings of the study available in compliance with the JIAS Data Availability Policy.

Data requests should be addressed to the London School of Hygiene and Tropical Medicine Research Operations Office Data Management Lead (alex.hollander@lshtm.ac.uk), the first author (Max.appenroth@charite.de) and the Principal Investigator of EMIS-2017 (Peter.Weatherburn@lshtm.ac.uk). Individuals requesting data should present their research objective(s) and enclose a list of requested variables. To protect the confidentiality of participants, data sharing is contingent upon appropriate data handling and good scientific practice by the person requesting the data and should furthermore be in accordance with all applicable local requirements.

The London School of Hygiene and Tropical Medicine administrative offices are located at Keppel Street, London WC1E 7HT, United Kingdom.

REFERENCES

1. World Health Organization. Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations. 2016 [cited 2022 July 12]. Available from: http://apps.who.int/iris/bitstream/handle/10665/246200/9789241511124-annexes-eng.pdf?sequence=5.
2. Van Gerwen OT, Jani A, Long DM, Austin EL, Musgrove K, Muzny CA. Prevalence of sexually transmitted infections and human immunodeficiency virus in transgender persons: a systematic review. Transgend Health. 2020;5(2):90–103.
3. Becasen JS, Denard CL, Mullins MM, Higa DH, Sipe TA. Estimating the prevalence of HIV and sexual behaviors among the US transgender population: a systematic review and meta-analysis, 2006–2017. Am J Public Health. 2019;109(1):e1–8.
4. Poteat T, Scheim A, Xavier J, Reisner S, Baral S. Global epidemiology of HIV infection and related syndemics affecting transgender people. J Acquir Immune Defic Syndr. 2016;72(Suppl 3):S210–9.
5. U.S. Department of Health. U.S. Statistics, Fast Facts. 2021 [cited 2022 July 12]. Available from: https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics.
6. Pitasi MA, Oraka E, Clark H, Town M, DiNenno EA. HIV testing among transgender women and men - 27 states and guam, 2014–2015. MMWR Morb Mortal Wkly Rep. 2017;66(33):883–7.
7. Golub SA, Fikslin RA, Starbuck L, Klein A. High rates of PrEP eligibility but low rates of PrEP access among a national sample of transmasculine individuals. J Acquir Immune Defic Syndr. 2019;82(1):e1–7.
8. Reisner SL, Moore CS, Asquith A, Pardee DJ, Sarvet A, Mayer G, et al. High risk and low uptake of pre-exposure prophylaxis to prevent HIV acquisition in a national online sample of transgender men who have sex with men in the United States. J Int AIDS Soc. 2019;22(9):e25391.
9. Rowniak S, Chesla C. Coming out for a third time: transmen, sexual orientation, and identity. Arch Sex Behav. 2013;42(3):449–61.
10. Bauer GR, Redman N, Bradley K, Scheim AI. Sexual health of trans men who are gay, bisexual, or who have sex with men: results from Ontario, Canada. Int J Transgend. 2013;14(2):66–74.
11. Scheim AI, Adam BD, Marshall Z. Gay, bisexual, and queer trans men navigating sexual fields. Sexualities. 2019;22(4):566–86.
12. Grov C, Westmoreland DA, Carrico AW, Nash D. Are we on the precipice of a new epidemic? Risk for hepatitis C among HIV-negative men-, trans women-, and trans men- who have sex with men in the United States. AIDS Care. 2020;32(sup2):74–82.
13. Scheim AI, Santos GM, Arreola S, Makofane K, Do TD, Hebert P, et al. Inequities in access to HIV prevention services for transgender men: results of a global survey of men who have sex with men. J Int AIDS Soc. 2016;19(3 Suppl 2):20779.
14. Hickson F, Appenroth M, Koppe U, Schmidt AJ, Reid D, Weatherburn P. Sexual and mental health inequalities across gender identity and sex-assigned-at-birth among men-who-have-sex-with-men in Europe: findings from EMIS-2017. Int J Environ Res Public Health. 2020;17(20):7379.
15. Rowniak S, Chesla C, Rose CD, Holzemer WL. Transmen: the HIV risk of gay identity. AIDS Educ Prev. 2011;23(6):508–20.
16. Sevelius J. "There's no pamphlet for the kind of sex I have": HIV-related risk factors and protective behaviors among transgender men who have sex with nontransgender men. J Assoc Nurses AIDS Care. 2009;20(5):398–410.
17. McPhail D, Rountree-James M, Whetter I. Addressing gaps in physician knowledge regarding transgender health and healthcare through medical education. Can Med Educ J. 2016;7(2):e70–8.
18. James SE, Herman JL, Rankin S, Keisling M, Mottet L, Anafi M. The report of the 2015 U.S. Transgender Survey. Washington, DC; 2016.
19. Jaffee KD, Shires DA, Stroumsa D. Discrimination and delayed health care among transgender women and men: implications for improving medical education and health care delivery. Med Care. 2016;54(11):1010–6.
20. Safer JD, Coleman E, Feldman J, Garofalo R, Hembree W, Radix A, et al. Barriers to healthcare for transgender individuals. Curr Opin Endocrinol Diabetes Obes. 2016;23(2):168–71.
21. European Agency of Fundamental Rights. LGBTI Survey Data Explorer. 2020 [cited 2022 July 12]. Available from: https://fra.europa.eu/en/data-and-maps/2020/lgbti-survey-data-explorer.
22. Kerckhof ME, Kreukels BPC, Nieder TO, Becker-Hebly I, van de Grift TC, Staphorsius AS, et al. Prevalence of sexual dysfunctions in transgender persons: results from the ENIGI follow-up study. J Sex Med. 2019;16(12):2018–29.
23. Karen L, Blair RAH. Transgender exclusion from the world of dating: patterns of acceptance and rejection of hypothetical trans dating partners as a function of sexual and gender identity. J Soc Pers Rel. 2019;36(7):2074–95.
24. Holt M, Broady T, Callander D, Pony M, Duck-Chong L, Cook T, et al. Sexual experience, relationships, and factors associated with sexual and romantic satisfaction in the first Australian Trans & Gender Diverse Sexual Health Survey. Int J Transgend Health. 2022.
25. Bauer GR, Scheim AI, Pyne J, Travers R, Hammond R. Intervenable factors associated with suicide risk in transgender persons: a respondent driven sampling study in Ontario, Canada. BMC Public Health. 2015;15:525.
26. Coleman E, Bockting W, Botzer M, Cohen-Kettenis P, DeCuypere G, Feldman J, et al. Standards of care for the health of transsexual, transgender, and gender-nonconforming people, version 7. Int J Transgend. 2012;13(4):165–232.
27. Nikkelen SWC, Kreukels BPC. Sexual experiences in transgender people: the role of desire for gender-confirming interventions, psychological well-being, and body satisfaction. J Sex Marital Ther. 2018;44(4):370–81.
28. Poudrier G, Nolan IT, Cook TE, Saia W, Motosko CC, Stranix JT, et al. Assessing quality of life and patient-reported satisfaction with masculinizing top surgery: a mixed-methods descriptive survey study. Plast Reconstr Surg. 2019;143(1):272–9.
29. Dharma C, Scheim AI, Bauer GR. Exploratory factor analysis of two sexual health scales for transgender people: trans-specific condom/barrier negotiation self-efficacy (T-Barrier) and trans-specific sexual body image worries (T-Worries). Arch Sex Behav. 2019;48(5):1563–72.
30. Weatherburn P, Hickson F, Reid DS, Marcus U, Schmidt AJ. European men-who-have-sex-with-men internet survey (EMIS-2017): design and methods. Sex Res Soc Policy. 2020;17(4):543–57.
31. Crissman HP, Berger MB, Graham LF, Dalton VK. Transgender demographics: a household probability sample of US adults, 2014. Am J Public Health. 2017;107(2):213–5.
32. Kcomt L, Gorey KM, Barrett BJ, McCabe SE. Healthcare avoidance due to anticipated discrimination among transgender people: a call to create trans-affirmative environments. SSM Popul Health. 2020;11:100608.
33. Hobkirk AL, Towe SL, Lion R, Meade CS. Primary and secondary HIV prevention among persons with severe mental illness: recent findings. Curr HIV/AIDS Rep. 2015;12(4):406–12.
34. Reisner SL, Moore CS, Asquith A, Pardee DJ, Mayer KH. Gender non-affirmation from cisgender male partners: development and validation of a brief stigma scale for HIV research with transgender men who have sex with men (trans MSM). AIDS Behav. 2020;24(1):331–43.
35. Bauer GR, Travers R, Scanlon K, Coleman TA. High heterogeneity of HIV-related sexual risk among transgender people in Ontario, Canada: a province-wide respondent-driven sampling survey. BMC Public Health. 2012;12:292.
36. Antebi-Gruszka N, Talan AJ, Reisner SL, Rendina HJ. Sociodemographic and behavioural factors associated with testing for HIV and STIs in a US nationwide sample of transgender men who have sex with men. Sex Transm Infect. 2020;96(6):422–7.
37. European Agency of Fundamental Rights. Being trans in the European Union: comparative analysis of LGBT Survey Data. 2014 [cited 2022 July 12]. Available from: https://fra.europa.eu/sites/default/files/fra-2014-being-trans-eu-comparative-0_en.pdf.
38. Scheim AI, Travers R. Barriers and facilitators to HIV and sexually transmitted infections testing for gay, bisexual, and other transgender men who have sex with men. AIDS Care. 2017;29(8):990–5.
39. Appenroth MN, Marcus U, Albrecht S, Jansen K, Gunsenheimer-Bartmeyer B, Bremer V, et al. Similar sexual behaviour yet different outcomes: comparing trans and gender diverse and cis PrEP users in Germany based on the outcomes of the PrApp study. Sexes. 2022;3(1):178–88.
40. Deutsche Aidshilfe EV. Schwul. Trans*. Teil der Szene. 2020 [cited 2022 July 12]. Available from: https://www.aidshilfe.de/shop/pdf/11314.
41. He J, Wang Y, Du Z, Liao J, He N, Hao Y. Peer education for HIV prevention among high-risk groups: a systematic review and meta-analysis. BMC Infect Dis. 2020;20:1–20.
42. Checkpoint BLN. Trans Inter Non-Binary Day. [cited 2022 July 12]. Available from: https://checkpoint-bln.de/trans-inter-nonbinary/.
43. Münchner Aids-Hilfe EV. CheckpoinT*I*N - Beratung und Tests für trans*, inter* und nicht-binäre Personen. [cited 2022 July 12]. Available from: https://www.trans-inter-beratungsstelle.de/de/CheckpoinT-I-N.html.
44. Prah P, Hickson F, Bonell C, McDaid LM, Johnson AM, Wayal S, et al. Men who have sex with men in Great Britain: comparing methods and estimates from probability and convenience sample surveys. Sex Transm Infect. 2016;92(6):455–63.

Lacombe-Duncan A et al. *Journal of the International AIDS Society* 2022, **25**(S5):e25972
http://onlinelibrary.wiley.com/doi/10.1002/jia2.25972/full | https://doi.org/10.1002/jia2.25972

SHORT REPORT

HIV testing among transgender and nonbinary persons in Michigan, United States: results of a community-based survey

Ashley Lacombe-Duncan[1,§], Leonardo Kattari[2], Shanna K. Kattari[1,3], Ayden I. Scheim[4], Flyn Alexander[1], Sophie Yonce[5] and Brayden A. Misiolek[6]

[§]**Corresponding author**: Ashley Lacombe-Duncan, School of Social Work, University of Michigan, 1080 South University Avenue, Ann Arbor, MI 48109-1106, USA. (lacombed@umich.edu)

Abstract

Introduction: Transgender (trans) and nonbinary people (TNB) are disproportionately impacted by HIV. HIV testing is critical to engage TNB people in HIV prevention and care. Yet, scant literature has examined social and structural factors associated with HIV testing among TNB people of diverse genders and in geographies with potentially lower trans acceptance. We: (1) characterized the prevalence of never having been tested for HIV; and (2) identified associated factors, among TNB people in Michigan, United States.

Methods: Data were from a community-based participatory cross-sectional survey (n = 539 sexually experienced TNB people). The prevalence of never having had an HIV test was reported overall and compared across socio-demographic, clinical, social and structural factors using bivariable and multivariable logistic regression analyses.

Results and discussion: Approximately one-quarter (26.2%) of participants had never had an HIV test (20.8% transfeminine; 30.0% transmasculine; 17.8% nonbinary assigned male at-birth; and 32.0% nonbinary assigned female at-birth). In a multivariable socio-demographic model, older age (adjusted odds ratio [aOR] for 1-year increase: 0.93, 95% CI: 0.90, 0.96, p<0.001) and Black/African American race (vs. White) (aOR: 0.28, 95% CI: 0.09, 0.86, p<0.05) were associated with increased odds of HIV testing (aORs for never testing). In separate multivariable models controlling for socio-demographics, ever experiencing sexual violence (aOR: 0.38, 95% CI: 0.21, 0.67, p<0.001), not accessed sexual/reproductive healthcare in the past 12 months (aOR: 4.46, 95% CI: 2.68, 7.43, p<0.001) and reporting a very/somewhat inclusive primary care provider (PCP) (aOR: 0.29, 95% CI: 0.17, 0.49, p<0.001) were associated with HIV testing (aORs for never testing).

Conclusions: Findings contribute to scant literature about gender-based differences in HIV testing inclusive of transmasculine and nonbinary people. Lack of statistically significant gender differences suggests that broad TNB interventions may be warranted. These could include training healthcare providers in trans-inclusive practices with sexual violence survivors and PCPs in trans-inclusive HIV prevention and care. Findings showing Black participants were less likely to have never had an HIV test suggest the promise of culturally tailored services, though further investigation is needed. Findings identify social and structural factors associated with HIV testing and can inform multi-level interventions to increase TNB person's HIV testing.

Keywords: HIV care cascade; transmasculine; transfeminine; gender diverse; stigma; gender affirmation

Received 7 January 2022; **Accepted** 19 July 2022

1 | INTRODUCTION

Transgender (trans) and nonbinary (TNB) people are disproportionately impacted by HIV [1, 2]. HIV testing is a critical first step to engage TNB people in HIV prevention and care. Yet, research has identified HIV care disparities among trans women compared to cisgender (cis) persons [3–10], including lower HIV testing rates [11]. Findings from a national probability sample of sexually active trans people in the United States reported that while nearly half of respondents (46.4%) met Centers for Disease Control and Prevention (CDC) recommendations for HIV testing, almost one-quarter (22.8%) had never tested for HIV, identifying no significant differences between trans women and trans men [12]. A paucity of literature has examined within-TNB community differences or HIV testing among nonbinary persons, who comprise one-third of U.S. trans people [13].

There are also gaps in understanding multi-level factors associated with HIV testing among TNB persons, particularly anti-trans stigma and gender affirmation. Quantitative studies have shown negative associations between anti-trans stigma and HIV care access [14], whereas qualitative studies have identified how intersecting anti-trans and HIV stigma limit trans women's access to HIV prevention/care [15].

Conversely, gender affirmation, the process of recognizing and supporting a TNB person's gender, is associated with engagement in HIV care and viral suppression [16] and uptake of biomedical HIV prevention [12, 17].

Finally, much U.S. TNB-focused HIV testing research has been conducted in large urban centres with higher trans acceptance (e.g. New York City [18, 19]), limiting our understanding of HIV testing among TNB persons in other, potentially more stigmatizing, areas of the United States, such as Michigan, part of the U.S. Midwest [20]. Michigan's population is just under 10 million [21] with 18,970 persons living with HIV [22]. New diagnoses are primarily concentrated in Detroit, among the most racially segregated U.S. regions [23, 24]. Michigan has limited protections for lesbian, gay, bisexual, trans and queer (LGBTQ+) people [25], with lower LGBTQ+ equality than several states [26]. For example, both a national LGBTQ+ youth survey (23.1% Midwest) [27] and a qualitative study with Midwestern TNB youth [28, 29] identified pervasive interpersonal and structural sexual and anti-trans stigma and negative impacts on participants' wellbeing.

The aims of this study were to: (1) characterize the prevalence of never testing for HIV, and (2) identify associated socio-demographic, clinical, social and structural factors, among trans and nonbinary people in Michigan, United States.

2 | METHODS

2.1 | Study design

This study utilized secondary data from the Michigan Trans Health Survey (MTHS) [30], an online survey with 659 TNB people (2018). Survey items were collected from study investigators, a TNB advocacy group and TNB people [30]. Eligible participants were those 18 years of age or older, living in Michigan and identifying as transgender, trans, nonbinary, genderqueer, agender, genderfluid, two-spirit, transsexual or another non-cisgender identity. The sample for this paper was limited to those self-reporting having ever been sexually active (yes/no). As described elsewhere [30, 31], participants were recruited using convenience methods both online (e.g. Facebook) and in-person (e.g. Pride events) as well as snowball sampling. The survey was determined exempt by the University of Michigan Institutional Review Board (HUM00143266). All participants clicked a box to indicate informed consent prior to beginning the survey. Participants were provided a $10 USD gift card upon completion of the survey.

2.2 | Measures

The primary outcome of lifetime HIV testing history was assessed by asking "When was the last time you took an HIV test" with response options: "within the last year," "more than 1 year ago but less than three years ago," "three to five years ago" and "more than five years ago" (categorized as ever) versus "I have never taken an HIV test" categorized as never.

Socio-demographic factors included age, gender identity (transfeminine; transmasculine; nonbinary assigned male at-birth [AMAB]; nonbinary assigned female at-birth [AFAB]); sexual orientation (monosexual [i.e. attracted to one gender]; heterosexual; monosexual sexual minority; asexual/demisexual [i.e. primarily nonsexual attraction]; polysexual [i.e. attracted to multiple genders]), race/ethnicity (Black/African American; Latinx/Chicanx/Hispanic; multiracial/biracial; additional races; White), one or more disabilities (yes; no), geographic locality (small city [10,000 to <100,000 people]/rural [<10,000 people]/frontier [< 6 people/square mile]; urban [cities ≥ 100,000 people]/suburban [neighbourhoods on outskirts/near cities ≥100,000 people]), education (high school/GED or less; some college; trade school/associates degree; bachelors degree; graduate degree) and relationship status (single/divorced; casually dating; multiple committed partners; one committed partner). Clinical factors included self-reported current use of gender-affirming hormones via any source (e.g. prescription/non-prescription) (yes/no) and illicit substance use (yes/no). Social/structural factors included lifetime sexual violence (yes/no), past 12-month experience of discrimination based on gender identity when accessing sexual or reproductive healthcare (yes/no/did not access this care in the past 12 months), trans inclusivity of ones' primary care provider (PCP) (does not have a PCP/neutral or not inclusive/very or somewhat inclusive) and health insurance type (private [self/partner], private [parent(s)], public).

2.3 | Analyses

Descriptive statistics were analysed for all variables overall and by HIV testing history (ever vs. never). Then, we estimated unadjusted associations between socio-demographic, clinical, social and structural factors, and never-testing for HIV using bivariable logistic regression. Next, we fit a multivariable logistic regression model, including all socio-demographic variables, to identify those independently associated with never-testing. Finally, we conducted multivariable analyses whereby each clinical, social and structural factor was examined adjusting for socio-demographic factors associated with never-testing at $p<0.2$ (age, gender identity, race, sexual orientation, geographic location and education). All analyses were conducted on cases with complete data as little data were missing (7/14 variables missing no data; range of missing data from 0.4% to 11.5%).

3 | RESULTS AND DISCUSSION

Among 539 eligible participants, approximately one-quarter (26.5%, $n = 143$) had never had an HIV test. Among those for whom gender identity data were categorizable ($n = 521$), 21.0% ($n = 22$) of transfeminine participants; 30.7% ($n = 47$) of transmasculine participants; 17.8% ($n = 16$) of nonbinary AMAB participants; and 32.4% ($n = 56$) of nonbinary AFAB participants had never had an HIV test. Almost half of participants (46.2%) had tested < 1 year ago, 13.4% had tested 1 year to < 3 years ago, 6.4% had tested 3 years to < 5 years ago and 7.1% 5 or more years ago (Table 1).

The following socio-demographic factors were associated with never having had an HIV test in bivariable analyses: age (odds ratio [OR] for 1-year increase: 0.93, 95% CI: 0.90, 0.95, $p<0.001$), nonbinary AFAB gender (vs. transfeminine) (OR: 1.81, 95% CI: 1.02, 3.19, $p<0.05$), Black/African American race (vs. White) (OR: 0.30, 95% CI: 0.10, 0.87, $p<0.05$)

Table 1. Socio-demographic, clinical, social and structural factors by HIV testing history among sexually active trans and nonbinary people in the Midwestern United States (*n* = 539)

Variable	Total sample (*N* = 539) *n* (%) or mean (SD)	HIV tested ever (*n* = 396) *n* (%) or mean (SD)	HIV tested never (*n* = 143) *n* (%) or mean (SD)
Socio-demographic factors			
Age***	28.8 (9.7)	30.1 (9.9)	25.1 (8.2)
Gender identity (*n* = 521)*			
Transfeminine	105 (20.2)	83 (79.0)	22 (21.0)
Transmasculine	153 (29.4)	106 (69.3)	47 (30.7)
Nonbinary AMAB	90 (17.3)	74 (82.2)	16 (17.8)
Nonbinary AFAB	175 (33.2)	117 (67.6)	56 (32.4)
Sexual orientation (*n* = 514)			
Monosexual (heterosexual)	64 (12.5)	43 (67.2)	21 (32.8)
Monosexual (sexual minority)	112 (21.8)	90 (80.4)	22 (19.6)
Asexual/demisexual	19 (3.7)	12 (63.2)	7 (36.8)
Polysexual	319 (62.1)	228 (71.7)	91 (28.5)
Race (*n* = 515)			
Black/African American	37 (7.2)	33 (89.2)	4 (10.8)
Latinx/Chicanx/Hispanic	23 (4.5)	16 (69.6)	7 (30.4)
Multiracial/biracial	30 (5.8)	23 (76.7)	7 (23.3)
Additional races	18 (3.5)	11 (61.1)	7 (38.9)
White	407 (79.0)	290 (71.3)	142 (28.7)
One or more disabilities			
Yes	239 (43.8)	168 (71.5)	67 (28.5)
No	307 (56.2)	228 (75.0)	76 (25.0)
Geographic locality			
Small city/rural/frontier	164 (30.0)	110 (67.9)	52 (32.1)
Urban/suburban	382 (70.0)	286 (75.9)	91 (24.1)
Education			
High school/GED or less	83 (15.2)	52 (62.7)	31 (37.3)
Some college	189 (34.6)	134 (72.4)	51 (27.6)
Trade school/associates degree	87 (15.9)	69 (79.3)	18 (20.7)
Bachelors degree	122 (22.3)	86 (71.1)	35 (28.9)
Graduate degree	65 (11.9)	55 (87.3)	8 (12.7)
Relationship status			
Single/divorced	150 (27.5)	104 (70.3)	44 (29.7)
Casually dating	47 (8.6)	35 (76.1)	11 (23.9)
Multiple committed partners	44 (8.1)	34 (77.3)	10 (22.7)
One committed partner	305 (55.9)	223 (74.1)	301 (25.9)
Clinical, social and structural factors			
Current hormone use (*n* = 537)			
Yes	271 (50.5)	208 (76.8)	63 (23.2)
No	266 (49.5)	187 (70.3)	79 (29.7)
Current illicit drug use (*n* = 523)			
Yes	62 (11.9)	47 (75.8)	15 (24.2)
No	461 (88.1)	340 (73.8)	121 (26.2)
Sexual violence (*n* = 515)***			
Ever	155 (30.1)	132 (85.2)	23 (14.8)
Never	360 (69.9)	249 (69.2)	111 (30.8)

(*Continued*)

Table 1. Continued

Variable	Total sample (*N* = 539) *n* (%) or mean (SD)	HIV tested ever (*n* = 396) *n* (%) or mean (SD)	HIV tested never (*n* = 143) *n* (%) or mean (SD)
Discrimination in sexual health or reproductive care in the past 12 months (*n* = 528)***			
Yes	86 (16.3)	76 (88.4)	10 (11.6)
No	216 (40.9)	181 (83.8)	35 (16.2)
I did not access this care past 12 months	226 (42.8)	131 (58.0)	95 (42.0)
Trans inclusivity of primary care provider (PCP) (*n* = 537)***			
Does not have PCP	142 (26.4)	85 (59.9)	57 (40.1)
Neutral or not inclusive	112 (20.9)	75 (67.0)	37 (33.0)
Very or somewhat inclusive	283 (52.7)	234 (82.7)	49 (17.3)
Health insurance type (*n* = 477)***			
Private (self/partner)	165 (34.6)	128 (79.5)	33 (20.5)
Private (parent[s])	154 (32.3)	94 (61.0)	60 (39.0)
Public[a]	158 (33.1)	126 (80.3)	31 (19.7)

Note: *n* = 539 unless otherwise specified.
Abbreviations: AFAB, assigned female at birth; AMAB, assigned male at birth; SD, standard deviation.
[a]Monosexual (i.e. attracted to one gender); asexual/demisexual (i.e. primarily non-sexual attraction); and polysexual (i.e. attracted to multiple genders).
*$p<0.05$; ***$p<0.001$; analyses conducted using *t*-test for age and chi-square for all other variables.

and high school/GED or less, some college, or bachelor's (vs. graduate degree) (OR: 4.10, 95% CI: 1.73, 9.93, $p<0.01$; OR: 2.62, 95% CI: 1.17, 5.59, $p<0.05$; OR: 2.80, 95% CI: 1.21, 6.48, $p<0.05$, respectively) (Table 2). In multivariable analyses, age (adjusted odds ratio [aOR]: 0.93, 95% CI: 0.90, 0.96) and Black/African American race (vs. White) (aOR: 0.28, 95% CI: 0.09, 0.86, $p<0.05$) maintained significance.

The following were also statistically significantly associated with never having had an HIV test: ever experienced sexual violence (vs. never) (OR: 0.39, 95% CI: 0.24, 0.64, $p<0.001$), not having accessed sexual or reproductive healthcare in the past 12 months (vs. no discrimination in sexual healthcare or reproductive healthcare in the past 12 months) (OR: 3.76, 95% CI: 2.40, 5.87, $p<0.001$), reporting a very/somewhat inclusive PCP (vs. no PCP) (OR: 0.31, 95% CI: 0.20, 0.49, $p<0.001$) and private insurance, parents (vs. public) (OR: 2.59, 95% CI: 1.56, 4.32, $p<0.001$) (Table 3).

In multivariable analyses adjusting for socio-demographic characteristics (age, gender identity, race, sexual orientation, geographic location and education), ever experiencing sexual violence (aOR: 0.38, 95% CI: 0.21, 0.67, $p<0.001$), not having accessed sexual or reproductive healthcare in the past 12 months (aOR: 4.46, 95% CI: 2.68, 7.43, $p<0.001$) and reporting a very/somewhat inclusive PCP (aOR: 0.29, 95% CI: 0.17, 0.49, $p<0.001$) were significantly associated.

While our findings are not contextualized with details regarding sexual or other risks, that almost one-quarter of sexually active TNB participants had never been tested for HIV warrants further attention given the U.S. CDC recommendation that everyone ages 13–64 be tested for HIV once in their lifetime. However, high HIV testing rates are promising. It could be that national attention to HIV disparities among TNB communities has led to increased awareness of HIV testing needs among this group or that Michigan is more trans-accepting than hypothesized [32]. We contribute to scant literature about gender-based differences in HIV testing within TNB communities, finding no statistically significant differences across genders.

Black participants were more likely to have been tested for HIV than their White peers, corroborating other research [12]. Michigan is among the most racially segregated U.S. states, contributing to both health inequities [23] and access to culturally tailored programming (e.g. Trans Sistas of Color Project) [33–35]. More HIV testing among Black participants may be due to tailored programming or because these participants are more likely to live in Detroit with better access to services. Given racial HIV-related disparities in the United States [36], these findings suggest that at-risk populations may be being appropriately tested.

Prior literature found that in addition to disclosure concerns related to being on a parent's insurance posing a barrier to TNB young adults' access to gender-affirming healthcare [28], so too is this a barrier to accessing HIV prevention and testing [37, 38]. Options such as free and confidential testing through HIV community-based organizations (e.g. Unified HIV Health and Beyond [39]) should be discussed with young adults.

Our finding that having a very or somewhat inclusive PCP was associated with increased odds of having ever had an HIV test adds to a growing body of literature about the importance of trans-inclusive PCPs [40], including qualitative findings with TNB youth from the U.S. Midwest [29]. These findings demonstrate training PCPs to be more trans-affirming and intersectionally inclusive utilizing evidence-informed interventions is essential (e.g. [15, 41, 42]). Moreover, findings suggest the need for trans-affirming support for TNB survivors of

Table 2. Logistic regression results for socio-demographic factors in association with never having had an HIV test among trans and nonbinary persons in the Midwestern United States (n = 504 adjusted model)

Variables	Unadjusted odds ratio (OR)	95% CI	Adjusted odds ratio (aOR)	95% CI
Socio-demographic factors				
Age	0.93	0.90, 0.95***	0.93	0.90, 0.96***
Gender identity				
Transfeminine (ref)				
Transmasculine	1.67	0.94, 2.99	1.10	0.56, 2.19
Nonbinary AMAB	0.82	0.40, 1.67	0.73	0.32, 1.63
Nonbinary AFAB	1.81	1.02, 3.19*	1.36	0.69, 2.67
Sexual orientation				
Polysexual (ref)				
Monosexual (sexual minority)	0.61	0.36, 1.04	0.80	0.44, 1.45
Monosexual (heterosexual)	1.22	0.69, 2.18	1.54	0.76, 3.14
Asexual/demisexual	1.46	0.40, 3.83	1.63	0.56, 4.74
Race				
White (ref)				
Black/African American	0.30	0.10, 0.87*	0.28	0.09, 0.86*
Latinx/Chicanx/Hispanic	1.08	0.44, 2.70	1.04	0.39, 2.79
Multiracial/biracial	0.75	0.32, 1.81	0.68	0.27, 1.73
Additional races	1.58	0.60, 4.17	1.20	0.41, 3.56
One or more disabilities				
No (ref)				
Yes	1.20	0.82, 1.76	1.02	0.65, 1.61
Geographic locality				
Urban/suburban (ref)				
Small city/rural/frontier	1.49	0.99, 2.23	1.24	0.78, 1.97
Education				
High school/GED or less	4.10	1.73, 9.73**	2.15	0.79, 5.87
Some college	2.62	1.17, 5.59*	1.40	0.55, 3.54
Trade school/associates degree	1.79	0.73, 4.43	1.42	0.53, 3.81
Bachelors degree	2.80	1.21, 6.48*	1.83	0.73, 4.59
Graduate degree (ref)				
Relationship status				
Single/divorced (ref)				
Casually dating	0.74	0.35, 1.59	0.60	0.26, 1.38
One committed partner	0.83	0.53, 1.28	0.75	0.46, 1.25
Multiple committed partners[a]	0.70	0.32, 1.53	0.60	0.25, 1.46

Abbreviations: AFAB, assigned female at birth; AMAB, assigned male at birth; CI, confidence interval.
[a]Monosexual (i.e. attracted to one gender); asexual/demisexual (i.e. primarily non-sexual attraction); and polysexual (i.e. attracted to multiple genders).
*p<0.05; **p<0.01; ***p<0.001.

sexual violence, potentially fostered through integrating components of promising provider-level interventions [43, 44] into training more broadly focused on HIV prevention and care for TNB persons, with the potential benefit of increasing access to HIV care [45].

These study results must be interpreted with caution. Cross-sectional studies do not show causality. Our sample was close to four-fifths (79%) White, and while representative of Michigan (78% White) [46], a larger sample size of various racial groups would allow us to draw conclusions more relevant to those most affected by HIV in the United States [47] and Michigan [24]. Future studies should track how participants were recruited, as each of recruitment strategy may differentially introduce biases (e.g. online venues may contribute to oversampling of higher socioeconomic status participants) [48]. Our recruitment through TNB-specific Facebook groups and Pride events may have limited access to those less connected to TNB communities with hypothetically more barriers. As the MTHS, to our knowledge, was the first statewide survey conducted with TNB people, we are unable to conclusively determine the extent to which our sample represents the broader TNB population. However, drawing on the

Table 3. Logistic regression for clinical, social and structural factors associated with never having had an HIV test among trans and nonbinary persons in the Midwestern United States

Variable	Unadjusted OR	95% CI	Adjusted OR[a]	95% CI
Current hormone use				
No (ref)				
Yes	0.72	0.49, 1.05	0.69	0.41, 1.15
Current illicit drug use				
No (ref)				
Yes	0.73	0.90, 1.66	1.22	0.58, 2.55
Sexual violence				
Never (ref)				
Ever	0.39	0.24, 0.64***	0.38	0.21, 0.67***
Discrimination in sexual health or reproductive care in the past 12 months				
No (ref)				
Yes	0.68	0.32, 1.44	088	0.38, 2.02
Did not access past 12 months	3.76	2.40, 5.87***	4.46	2.68, 7.43***
Trans inclusivity of primary care provider (PCP)				
Does not have PCP (ref)				
Neutral or not inclusive	0.74	0.44, 1.23	0.62	0.34, 1.10
Very or somewhat inclusive	0.31	0.20, 0.49***	0.29	0.17, 0.49***
Health insurance				
Public (ref)				
Private (self/partner)	1.05	0.61, 1.81	0.90	0.48, 1.71
Private (parent[s])	2.59	1.56, 4.32***	1.75	0.95, 3.20

[a]Adjusting for statistically significant ($p<0.2$) socio-demographic factors (age, gender identity, race, sexual orientation, geographic location and education).
***$p<0.001$.
Abbreviations: CI, confidence interval; OR, odds ratio.

data reported in the state-specific U.S. Transgender Survey (USTS) report (N = 894 Michigan participants) [49], metrics such as lifetime homelessness (34% USTS; 39% MTHS) and past-year anti-trans discrimination in healthcare (38% USTS; 28% MTHS) [49] were similar. These comparisons lend confidence to the representativeness of our sample.

While we cannot say for certain participant's sexual and other risk practices (e.g. illicit substance use) warranted ongoing or recent HIV testing, given the CDC recommendation, the expectation is that all participants should have been tested for HIV at least once in their lifetime. TNB community partners explicitly requested the removal of a standardized question about sexual risk practices on the MTHS, which they saw as problematic (e.g. assuming condomless anal sex is a risk of sexually transmitted infections even when with a monogamous partner). Future researchers could work with communities to identify appropriate sexual and substance use, including injection drug use, questions, to further contextualize HIV testing findings.

4 | CONCLUSIONS

In conclusion, our study identified important socio-demographic, social and structural factors associated with HIV testing among a gender-diverse sample of TNB people. Findings suggest a need for trans-inclusive HIV testing practices, including at the point of sexual violence intervention, and training PCPs in trans-inclusion and gender affirmation. Ultimately, these interventions may increase the uptake of HIV testing among TNB people of diverse genders.

AUTHORS' AFFILIATIONS

[1]School of Social Work, University of Michigan, Ann Arbor, Michigan, USA; [2]School of Social Work, Michigan State University, East Lansing, Michigan, USA;

[3]Department of Women's and Gender Studies, University of Michigan, Ann Arbor, Michigan, USA; [4]Dornsife School of Public Health, Drexel University, Philadelphia, Pennsylvania, USA; [5]Lyman Briggs College, Michigan State University, East Lansing, Michigan, USA; [6]Transcend the Binary, Ferndale, Michigan, USA

ACKNOWLEDGEMENTS

We extend our sincerest thank you to all the Michigan Trans Health Survey (MTHS) study participants for generously donating their time and expertise in completing this survey, as well as to the Michigan Trans Health Research Advisory Board (MITHRAB) for their guidance throughout the research process.

COMPETING INTERESTS

The authors have no competing interests to disclose.

AUTHORS' CONTRIBUTIONS

ALD, SKK and AIS conceived of the study. LK and ALD completed data analyses, with consultation from AIS. ALD, SKK, FA and SY completed a first draft of the manuscript. All authors (ALD, LK, SKK, AIS, FA, SY and BAM) contributed to a second draft of the manuscript and approved the final version.

FUNDING

The original MTHS study received no external funding. These analyses were partially supported by the National Institutes of Allergy and Infectious Diseases (NIAID) grant #1R03AI159298-01.

DATA AVAILABILITY STATEMENT

Data are available upon request to the University of Michigan Health Sciences and Behavioral Sciences Institutional Review Board (irbhsbs@umich.edu).

REFERENCES

1. Becasen JS, Denard CL, Mullins MM, Higa DH, Sipe TA. Estimating the prevalence of HIV and sexual behaviors among the US transgender population: a systematic review and meta-analysis, 2006–2017. Am J Public Health. 2019;109(1):e1–8.
2. Baral SD, Poteat T, Stromdahl S, Wirtz AL, Guadamuz TE, Beyrer C. Worldwide burden of HIV in transgender women: a systematic review and meta-analysis. Lancet Infect Dis. 2013;13(3):214–22.
3. Yehia BR, Fleishman JA, Moore RD, Gebo KA. Retention in care and health outcomes of transgender persons living with HIV. Clin Infect Dis. 2013;57(5):774–6.
4. Klein PW, Psihopaidas D, Xavier J, Cohen SM. HIV-related outcome disparities between transgender women living with HIV and cisgender people living with HIV served by the Health Resources and Services Administration's Ryan White HIV/AIDS Program: a retrospective study. PLoS Med. 2020;17(5):e1003125.
5. Kalichman SC, Hernandez D, Finneran S, Price D, Driver R. Transgender women and HIV-related health disparities: falling off the HIV treatment cascade. Sex Health. 2017;14(5):469–76.
6. Baguso GN, Gay CL, Lee KA. Medication adherence among transgender women living with HIV. AIDS Care. 2016;28(8):976–81.
7. Dowshen N, Matone M, Luan X, Lee S, Belzer M, Fernandez MI, et al. Behavioral and health outcomes for HIV+ young transgender women (YTW) linked to and engaged in medical care. LGBT Health. 2016;3(2):162–7.
8. Sevelius JM, Carrico A, Johnson MO. Antiretroviral therapy adherence among transgender women living with HIV. J Assoc Nurses AIDS Care. 2010;21(3):256–64.
9. Mizuno Y, Frazier EL, Huang P, Skarbinski J. Characteristics of transgender women living with HIV receiving medical care in the United States. LGBT Health. 2015;2(3):228–3.
10. Wiewel EW, Torian LV, Merchant P, Braunstein SL, Shepard CW. HIV diagnoses and care among transgender persons and comparison with men who have sex with men: New York City, 2006–2011. Am J Public Health. 2016;106(3):497–502.
11. Pitasi MA, Oraka E, Clark H, Town M, DiNenno EA. HIV testing among transgender women and men — 27 states and Guam, 2014–2015. MMWR Morb Mortal Wkly Rep. 2017;66(33):883–7.
12. Sevelius JM, Poteat T, Luhur WE, Reisner SL, Meyer IH. HIV testing and PrEP use in a national probability sample of sexually active transgender people in the United States. J Acquir Immune Defic Syndr. 2020;84(5):437.
13. James SE, Herman JL, Rankin S, Keisling M, Mottet L, Anafi M. The Report of the 2015 U.S. Transgender Survey. Washington, DC: National Center for Transgender Equality; 2016.
14. Lacombe-Duncan A, Bauer GR, Logie CH, Newman PA, Shokoohi M, Kay ES, et al. The HIV care cascade among transgender women with HIV in Canada: a mixed-methods study. AIDS Patient Care STDs. 2019;33(7):308–22.
15. Lacombe-Duncan A, Kia H, Logie CH, Todd KP, Persad Y, Leblanc G, et al. A qualitative exploration of barriers to HIV prevention, treatment and support: perspectives of transgender women and service providers. Health Soc Care Community. 2020;29(5):e33–46.
16. Sevelius JM. Gender affirmation: a framework for conceptualizing risk behavior among transgender women of color. Sex Roles. 2013;68(11–12):675–89.
17. Sevelius JM, Glidden DV, Deutsch M, Welborn L, Contreras A, Salinas A, et al. Uptake, retention, and adherence to pre-exposure prophylaxis (PrEP) in TRIUMPH: a peer-led PrEP demonstration project for transgender communities in Oakland and Sacramento, California. J Acquir Immune Defic Syndr. 2021;88(1):S27.
18. Lelutiu-Weinberger C, Wilton L, Koblin BA, Hoover DR, Hirshfield S, Chiasson MA, et al. The role of social support in HIV testing and PrEP awareness among young black men and transgender women who have sex with men or transgender women. J Urban Health. 2020;97(5):715–27.
19. Golub SA, Gamarel KE. The impact of anticipated HIV stigma on delays in HIV testing behaviors: findings from a community-based sample of men who have sex with men and transgender women in New York City. AIDS Patient Care STDs. 2013;27(11):621–7.
20. Goldenberg T, Reisner SL, Harper GW, Gamarel KE, Stephenson R. State policies and healthcare use among transgender people in the US. Am J Prev Med. 2020;59(2):247–59.
21. U.S. Census Bureau. QuickFacts: Michigan 2021. Available from: https://www.census.gov/quickfacts/fact/table/MI/PST045219. Accessed October 18, 2021.
22. Michigan Department of Health and Human Services (MDHHS). Michigan statewide HIV surveillance report new diagnoses and prevalence tables 2020. Available from: https://www.michigan.gov/documents/mdhhs/Michigan_Statewide_HIV_Surveillance_Report-July_2019_660527_7.pdf. Accessed October 18, 2021.
23. Schulz AJ, Mentz GB, Sampson N, Ward M, Anderson R, De Majo R, et al. Race and the distribution of social and physical environmental risk: a case example from the Detroit Metropolitan Area. Du Bois Rev. 2016;13(2):285–304.
24. Michigan Department of Health and Human Services (MDHHS). HIV & STD's in Michigan — an overview 2019. Available from: https://www.michigan.gov/documents/mdhhs/HIV_in_Michigan_an_overview_July_2019_660525_7.pdf. Accessed October 18, 2021.
25. Movement Advancement Project (MAP). Michigan's Equality Profile. 2019. Available from: http://www.lgbtmap.org/equality-maps/profile_state/MI. Accessed October 18, 2021.
26. Movement Advancement Project (MAP). Snapshot: LGBTQ Equality by State. 2021. Available from: https://www.lgbtmap.org/equality-maps. Accessed October 18, 2021.
27. Kosciw JG, Clark CM, Truong NL, Zongrone AD. The 2019 National School Climate Survey: the experiences of lesbian, gay, bisexual, transgender, and queer youth in our nation's schools. A Report from GLSEN: ERIC; 2020.
28. Goffnett J, Paceley MS, Fish JN, Saban P. Between cornfields and Kinfolk: identity management among transgender youth in Midwestern families and communities. Fam Process. 2022. https://onlinelibrary.wiley.com/doi/abs/10.1111/famp.12759
29. Paceley MS, Sattler P, Goffnett J, Jen S. "It feels like home": transgender youth in the Midwest and conceptualizations of community climate. J Community Psychol. 2020;48(6):1863–81.
30. Kattari SK, Curley KM, Bakko M, Misiolek BA. Development and validation of the Trans-Inclusive Provider Scale. Am J Prev Med. 2020;58(5):707–14.
31. Kattari SK, Kattari L, Johnson I, Lacombe-Duncan A, Misiolek BA. Differential experiences of mental health among trans/gender diverse adults in Michigan. Int J Environ Res Public Health. 2020;17(18):6805.
32. White Hughto JM, Murchison GR, Clark K, Pachankis JE, Reisner SL. Geographic and individual differences in healthcare access for U.S. transgender adults: a multilevel analysis. LGBT Health. 2016;3(6):424–33.
33. Trans Sistas of Color Project - Detroit. About. Available from: https://www.facebook.com/TSCOPD/about/. Accessed March 18, 2022.
34. Ruth Ellis Center. Who we are. Available from: https://www.ruthelliscenter.org. Accessed March 18, 2022.
35. LGBT Detroit. About us. Available from: https://www.lgbtdetroit.org. Accessed March 18, 2022.

36. Centers for Disease Control and Prevention. HIV in the United States: at a glance. 2021. Available from: https://www.cdc.gov/hiv/statistics/overview/ataglance.html. Accessed March 18, 2022.
37. Doll M, Fortenberry JD, Roseland D, McAuliff K, Wilson CM, Boyer CB. Linking HIV-negative youth to prevention services in 12 US cities: barriers and facilitators to implementing the HIV prevention continuum. J Adolescent Health. 2018;62(4):424–33.
38. Nelson KM, Underhill K, Carey MP. Consent for HIV testing among adolescent sexual minority males: legal status, youth perceptions, and associations with actual testing and sexual risk behavior. AIDS Behav. 2020;24(2):373–8.
39. Unified: HIV Health and Beyond. Sexual Health Screenings. 2022. Available from: https://miunified.org/Services/Prevention/SexualHealthScreenings. Accessed March 18, 2022.
40. Kattari SK, Atteberry-Ash B, Kinney MK, Walls NE, Kattari L. One size does not fit all: differential transgender health experiences. Soc Work Health Care. 2019;58(9):899–917.
41. Lacombe-Duncan A, Logie CH, Persad Y, Leblanc G, Nation K, Kia H, et al. 'Transgender Education for Affirmative and Competent HIV and Healthcare (TEACHH)': protocol of community-based intervention development and a non-randomised multisite pilot study with pre–post test design in Canada. BMJ Open. 2020;10(7):e034144.
42. Lacombe-Duncan A, Logie CH, Persad Y, Leblanc G, Nation K, Kia H, et al. Implementation and evaluation of the 'Transgender Education for Affirmative and Competent HIV and Healthcare (TEACHH)' Provider Education Pilot. BMC Med Educ. 2021;21(1):561.
43. Du Mont J, Kosa SD, Abavi R, Kia H, Macdonald S. Toward affirming care: an initial evaluation of a sexual violence treatment network's capacity for addressing the needs of trans sexual assault survivors. J Interpers Violence. 2021;36(21–22):NP12436–55.
44. Du Mont J, Saad M, Kosa SD, Kia H, Macdonald S. Providing trans-affirming care for sexual assault survivors: an evaluation of a novel curriculum for forensic nurses. Nurse Educ Today. 2020;93:104541.
45. Goldhammer H, Marc LG, Psihopaidas D, Chavis NS, Massaquoi M, Cahill S, et al. HIV care continuum interventions for transgender women: a topical review. Public Health Rep. 2022. https://pubmed.ncbi.nlm.nih.gov/35060802/
46. World Population Review. Michigan Population 2021. 2021. Available from: https://worldpopulationreview.com/states/michigan-population. Accessed October 18, 2021.
47. Centers for Disease Control and Prevention. Diagnoses of HIV infection in the United States and dependent areas. 2019. Available from: http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html. Accessed October 18, 2021.
48. Owens C, Stall R, Dodge B. Sampling considerations for LGBTQ health research. In: Stall R, Dodge B, Bauermeister JA, Poteat T, Beyrer C, editors. LGBTQ health research: theory, methods, practice. 2020. p. 99–103. https://www.amazon.com/LGBTQ-Health-Research-Methods-Practice/dp/142143878X
49. The National Center for Transgender Equality. 2015 U.S. Transgender Survey: Michigan State Report. Washington, DC: National Center for Transgender Equality; 2017.

Byrne JL et al. *Journal of the International AIDS Society* 2022, **25**(S5):e25980
http://onlinelibrary.wiley.com/doi/10.1002/jia2.25980/full | https://doi.org/10.1002/jia2.25980

JIAS JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

RESEARCH ARTICLE

PrEP awareness and protective barrier negotiation among transgender people attracted to men in Aotearoa New Zealand

Jack L. Byrne[1,#], Kyle K. H. Tan[1,2,§,#], Peter J. Saxton[3,4], Ryan M. Bentham[1] and Jaimie F. Veale[1]

[§]**Corresponding author**: Kyle K. H. Tan, Trans Health Research Lab, School of Psychology, University of Waikato, Ground Floor J Block, Gate 1 Knighton Road, Private Bag 3105, Hamilton 3240, New Zealand. Tel: +64275791459. (k.tan@waikato.ac.nz)
[#]These authors have contributed equally to the work.

Abstract

Introduction: Internationally, trans women are disproportionately impacted by HIV, encounter specific barriers navigating safer sex and face inequities accessing HIV prevention, including pre-exposure prophylaxis (PrEP). Aotearoa/New Zealand (hereafter Aotearoa) was one of the first countries internationally to publicly fund PrEP in 2018, including for trans people. However, few data exist on PrEP awareness or sexual negotiation among trans populations to guide implementation. We present the first Aotearoa data on trans people's ability to negotiate barrier protection and awareness of PrEP efficacy and availability.

Methods: We used data from a large, diverse community-based nationwide survey of trans (including non-binary) people in Aotearoa: Counting Ourselves (N = 1178) conducted from 21 June to 30 September 2018. Generalized regression analyses were carried out among participants who have had sex (n = 704; M_{age} = 32.5) to identify associations between demographic factors (age, gender and sexual attraction, ethnicity, income, education qualification and current sex work involvement) and the Trans-Specific Barrier Negotiation Self-Efficacy (T-Barrier) Scale and PrEP awareness.

Results: The mean value of a 40-point T-Barrier Scale was 33.45 (SD: 6.89), suggesting a relatively high perceived ability among our participants to negotiate protective barrier usages in different situations. Asian participants scored 3.46 points lower compared to Pākehā (White) participants, and trans women attracted to men (cisgender and/or trans men) scored 2.40 points higher than trans women not attracted to men. Three-fifths (59.7%) were aware that PrEP reduced HIV risks and did not prevent sexually transmitted infections (STI) transmission, and only two-fifths (40.2%) knew PrEP was publicly funded for trans people. In multivariate models, we found participants who were older, trans women or those with lower education qualifications were less likely to have increased levels of PrEP awareness.

Conclusions: Participants attracted to men have a higher potential need for PrEP and were more likely to report PrEP awareness and that they could negotiate protective barrier usage. However, trans women and those with lower educational qualifications reported lower levels of PrEP awareness. More trans-competent sexual health education, drawing on the newly released PrEP guidelines, is needed to promote the benefits of PrEP in the Aotearoa HIV epidemic context, particularly for trans women.

Keywords: transgender; sexuality; condom; pre-exposure prophylaxis; HIV; New Zealand

Additional information may be found under the Supporting Information tab of this article.

Received 6 January 2022; **Accepted** 30 July 2022

1 | INTRODUCTION

Initial international data specific to transgender (trans) people demonstrate a heavy burden of HIV among trans women, specifically trans women who have sex with men [1]. HIV inequities persist for trans women, with some limited data now available about the specific vulnerabilities of non-binary people and trans men. The first US national probability survey of trans people (TransPoP), conducted between 2016 and 2018, found HIV infection was highest among trans women (6.5%), followed by 5.1% for non-binary people and 0.8% for trans men [2]. Overall, the US trans population had more than three times the odds of self-reporting HIV infection compared to their cisgender counterparts (7.1% vs. 2.1%; odds ratio = 3.56) [2].

Trans people in Aotearoa/New Zealand (hereafter, Aotearoa) include trans women, trans men, people with non-binary genders and those who identify with non-Western

gender diverse identities, including indigenous Māori terms whakawahine or tangata ira tāne, and the Samoan term fa'afafine [3]. In this article, we use the term "trans" to refer to people who identify their gender as different from their sex assigned at birth. The only population-based study that has collected data on the size of the trans adult population in Aotearoa, the Household Economic Survey, found that 0.8% were trans [4].

Aotearoa has had a successful record controlling HIV, being one of the first countries to record a decline in AIDS diagnoses in the 1990s [5]. Annual per-capita HIV diagnosis rates have remained low [6] and in 2019 were 2.4/100,000 adults [7]. The epidemic is concentrated in men who have sex with men (MSM) who comprised over three-quarters of all locally acquired HIV diagnoses in 2019 [7]. HIV transmission among other key populations has been effectively contained, including sex workers [8] and people who inject drugs [9]. Internationally, Aotearoa has among the lowest HIV prevalence and incidence in these groups. This outcome is mainly due to progressive public health and human rights law reform, such as public funding of needle exchange programmes in 1988 and decriminalization of sex work in 2003. Since the initiation of enhanced epidemiological surveillance in 1996, few trans individuals have been recorded with an HIV diagnosis in Aotearoa (0.5%), with only 23 of 4323 recorded diagnoses between 1996 and 2020 [10]. Further, no evidence of hidden undiagnosed infection among trans people has been identified by sentinel surveillance at sexual health clinics [11]. However, this picture is likely to underestimate incidence due to incomplete reporting, misclassification or small sample sizes. For example, 1.7% of those identified with HIV in 2018 in Aotearoa were trans women [12], indicating transmission among trans people may be more common than previously thought. There is currently no population-based estimate of HIV infection among trans people in Aotearoa.

Trans people in Aotearoa experience discrimination and a lack of relevant and culturally competent health services [3], resulting in high unmet health needs. Transpeople have tended to be excluded from HIV prevention research that has focused on cis MSM [8]. For example, behavioural surveillance has historically presented identity options for fa'afafine but no explicit option for trans men, trans women or non-binary people [13]. Similarly, HIV prevention organizations have been funded to prioritize cis MSM with an unclear remit regarding trans communities. These practices contribute to invisibility surrounding trans people's experience of HIV prevention specifically and safe sex and sexual health more broadly. Our nationwide community survey found only 9% of trans people in Aotearoa have ever received any information about sexually transmitted infections (STI) prevention or safer sex that was specific to trans people [3].

Aotearoa was also one of the first countries to publicly fund pre-exposure prophylaxis (PrEP) in March 2018 on a targeted basis [14]. Eligible individuals had to be male or trans and to have had sex with a male, as well as fulfilling other criteria, such as having engaged in receptive anal intercourse with casual partners, having been recently diagnosed with rectal gonorrhoea, rectal chlamydia or infectious syphilis, or having recently used methamphetamine. Based on these eligibility criteria [14], researchers estimated that 5847 individuals would be eligible for PrEP, noting that the lack of official statistics on trans adults precluded a reliable estimate [15]. Our study took place in June 2018 and provides baseline data on PrEP awareness. Further waves of the Counting Ourselves survey will explore links between awareness and the use of PrEP. Calls for greater flexibility in PrEP provision resulted in Aotearoa's first formal PrEP prescribing guidelines in 2021 [12] that included specific sections on trans individuals, to help physicians and trans individuals decide whether PrEP would be beneficial.

Aotearoa's epidemiological, policy and healthcare context presents a unique setting for examining the experiences of trans people concerning HIV. This is because while there are data showing some key populations (notably sex workers and people who inject drugs) have low rates of HIV infection in Aotearoa, trans people remain invisible in research and surveillance data here. We present the first Aotearoa data on trans people's ability to negotiate barrier protection and awareness of PrEP efficacy and availability.

2 | METHODS

2.1 | Procedure

We performed data analyses on the 2018 Counting Ourselves: Aotearoa New Zealand Trans and Non-Binary Health Survey. As a trans-led community-based survey, Counting Ourselves aimed to counter the long-held invisibility of trans people in national statistics by asking participants questions from national population-based surveys (e.g. the New Zealand Health Survey [16]), overseas trans surveys (e.g. the US Trans Survey [17] and Trans PULSE Ontario [18, 19]), and questions designed in collaboration with the survey's community advisory group. Eligible participants met the following criteria: (1) aged 14 or above; (2) identified as trans or non-binary; and (3) residing in Aotearoa. Participants were recruited through community networks and organizations, with community leaders fronting social media posts to harder-to-reach trans communities (including indigenous Māori, Pasifika, Asian and older people). In addition, we promoted the survey through networks of health professionals and academic researchers working in trans health.

The New Zealand Health and Disability Ethics Committee approved the study procedure (18/NTB/66/AM01). Participants were allowed sufficient time to read through the information sheet that outlined their rights and information on accessing support if the survey topics raised concerns or were stressful. Participants gave their consent by completing the survey. The survey was available to self-complete online with the option of requesting a paper copy and pre-paid envelope to return it. More details about the survey methods can be read in the published community report [3].

2.2 | Measures

2.2.1 | *Gender*

Participants were categorized into four gender groups based on responses to two questions on sex assigned at birth and current gender identification. Trans men were those assigned

female at birth (AFAB) who identified as a man, trans man, transsexual and/or as the indigenous Māori identity tangata ira tāne. Trans women were those assigned male at birth (AMAB) who identified as a woman, trans woman, transsexual, or as the indigenous Māori identities tangata ira wahine, and/or whakawahine, or using other culturally specific identities, such as the Samoan term fa'afafine. Participants who did not meet these criteria were classified either as nonbinary AFAB or nonbinary AMAB.

2.2.2 | *Sexual attraction*

Using the question from Trans PULSE Ontario [18, 19], participants were asked "Who are you sexually attracted to? Mark all that apply." Response options included "trans men," "cis men," "trans women," "cis women," "genderqueer or nonbinary people," "none of the above" and "others." As HIV prevalence in Aoteaora is concentrated among MSM [7], we created a nominal variable "gender and sexual attraction" that differentiated between participants who are sexually attracted to men—either trans or cis men—and those who are not (Table 1). We chose trans women who are sexually attracted to men as the reference group given previous literature has identified this group as vulnerable to HIV risk [2, 7].

2.2.3 | *Ethnicity*

Participants were asked the New Zealand Health Survey's ethnicity question which permits multiple responses. Using the Ministry of Health's ethnicity prioritization protocol [20], we classified participants into one of the four ethnic groups in the priority order of Māori, Pasifika, Asian and New Zealand European/Pākehā (approximately equivalent to White in other contexts) or other.

2.2.4 | *T-Barrier Scale*

The T-Barrier 8-item Scale was adopted from Trans PULSE Ontario to assess participants' perceived ability to negotiate protective barrier use in different situations with a sexual partner [18]. For example, participants were asked to rate their level of certainty on an ordinal scale from "not at all certain (1)" to "completely certain (5)" about using protection when meeting a new partner, a cisgender partner and a trans or non-binary partner. Total scores of the T-Barrier Scale range from 8 to 40. All eight items demonstrated high factor loading in a one-factor construct which explained 65% of the variance in the Ontario sample [18]. Similar to previous studies [18, 21], the internal consistency of the T-Barrier Scale in the current dataset was high (Cronbach's $\alpha = 0.92$).

2.2.5 | *PrEP awareness*

Our research team created three questions about awareness of PrEP provision in Aotearoa (Table 2). Participants who responded "I wasn't sure" were treated as missing in the regression models.

2.3 | Data analysis

All statistical analyses were conducted in IBM SPSS Statistics version 27. Missing data for education qualification (2.6%)

Table 1. Demographic details of Counting Ourselves participants who have ever had sex ($N = 704$)

	n (%)
Age groups	
14–18	51 (7.2)
19–24	192 (27.3)
25–39	283 (40.2)
40–54	111 (15.8)
55+	67 (9.5)
Gender groups	
Trans women	227 (32.3)
Trans men	185 (26.4)
Non-binary people AFAB	218 (31.1)
Non-binary people AMAB	72 (10.3)
Prioritized ethnicity groups	
Māori	90 (12.8)
Pasifika	20 (2.8)
Asian	25 (3.6)
Pākehā/New Zealand European (White)	549 (78.0)
Others including MELAA	20 (2.8)
Regions	
Auckland	217 (31.4)
Wellington	206 (29.8)
Other north island	116 (16.8)
Other north island	76 (11.0)
Other south island	76 (11.0)
Personal income in the last 12 months	
Loss and zero	42 (6.4)
1–15,000	202 (30.7)
15,001–50,000	257 (39.1)
50,001 and more	156 (23.7)
Education qualification	
None	30 (4.6)
Levels 1–5 (certificate)	293 (44.6)
Levels 6 and 7 (diploma and bachelor)	177 (26.9)
Level 8 and above (postgraduate)	157 (23.9)
Gender and sexual attraction[a]	
Trans women attracted to men	113 (16.2)
Trans women not attracted to men	112 (16.1)
Trans men attracted to men	145 (20.8)
Trans men not attracted to men	39 (5.6)
Non-binary AFAB attracted to men	164 (23.3)
Non-binary AFAB not attracted to men	52 (7.5)
Non-binary AMAB attracted to men	53 (7.6)
Non-binary AMAB not attracted to men	19 (2.7)
Ever engaged in sex work	135 (19.7)
Engaged in sex work in the past year	49 (7.2)

Abbreviations: AFAB, assigned female at birth; AMAB, assigned male at birth; MELAA, Middle Eastern/Latin/African.
[a]There were two non-binary participants who did not report sex assigned at birth.

Table 2. Percentage of participants who were aware of the following PrEP information (*N* = 685)

	I knew that *n* (%)	I wasn't sure *n* (%)	I didn't know that *n* (%)
1. PrEP (pre-exposure prophylaxis) is a pill that, if taken every day by someone who is HIV negative, significantly decreases their risk of acquiring HIV	409 (59.7)	58 (8.5)	218 (31.8)
2. If taken correctly, PrEP significantly reduces the risk of acquiring HIV but it does not prevent the transmission of other STIs like gonorrhoea and syphilis[a]	407 (59.7)	48 (7.0)	227 (33.3)
3. PrEP is now publicly funded in New Zealand, if you are "male or transgender" and meet other eligibility criteria[a]	274 (40.2)	86 (12.6)	322 (47.2)

[a]Compared to the first statement, there were three participants who did not respond to these statements out of participants who have ever had sex.

Table 3. Individual items within the imputed Trans-Specific Condom/Barrier Negotiation Self-Efficacy (T-Barrier) Scale (*N* = 618)

	Mean (SD)	Participants who responded "somewhat certain" and "completely certain" (*n*, %)
I could ask a new sexual partner to use a protective barrier	4.50 (0.94)	551 (89.2)
I could ask a sexual partner I haven't been using protective barriers with to start using them	4.32 (1.02)	519 (84.0)
I could refuse sex when I don't have a protective barrier available	4.32 (1.07)	511 (82.7)
I could get a sexual partner to use a protective barrier, even if I'm drunk or high	3.60 (1.29)	359 (58.1)
I could get a sexual partner to use a protective barrier, even if they don't want to	3.52 (1.31)	342 (55.3)
If a sexual partner truly sees my gender identity, I could ask them to use a protective barrier	4.28 (1.04)	489 (79.1)
I could ask a sexual partner who is cisgender (not trans or non-binary) to use a protective barrier	4.39 (1.03)	528 (85.4)
I could ask a trans or non-binary sexual partner to use a protective barrier	4.51 (0.90)	547 (88.5)
T-Barrier Scale [8–40] (Mean/SD)		33.45 (6.89)

Abbreviation: SD, standard deviation.

and income (13.1%) were imputed using the expectation maximization (EM) method based on means and covariances of related socio-economic status measures, such as employment status and deprivation. We also imputed the missing data for participants who had responded to at least two items on the T-Barrier Scale (ranging from 10.7% to 22.5%) using the EM method. The high percentage of missing values for T-Barrier items included "this does not apply" responses (see Appendix S1).

Next, using Chi-square goodness of fit tests, we determined whether the proportion of participants reported being somewhat or completely certain varied across gender and sexual attraction groups. Next, we undertook generalized linear regression analyses to examine characteristics associated with the T-Barrier Scale, and logistic regressions for each of the three PrEP awareness statements. Variables that displayed statistically significant differences in bivariate models were treated as covariates in multivariate models. In all analyses, an alpha level of $p < 0.05$ was utilized to determine statistical significance.

3 | RESULTS

There were 1178 valid responses. For this analysis, we included only participants who completed the sexual health section (894; 74.9% completion rate). We also excluded participants who have never had sex ($n = 190$).

In the analytic sample ($n = 704$; mean [SD; range] age, 32.5 [13.63; 14–82] years), about one-third identified as trans women or nonbinary people AFAB. Approximately four-fifths identified as Pākehā/New Zealand European. Table 1 presents additional demographic characteristics. Appendix S2 presents the genders that our participants were sexually attracted to. Approximately three-fifths were sexually attracted to trans men (57.2%) or cis men (59.5%) and these

Table 4. Linear regression of T-Barrier Scale across demographic groups

	Bivariate b [95% CI]	Multivariate b [95% CI]
Age	−0.00 [−0.05 to 0.04]	–
Gender and sexual attraction		
Trans women attracted to men	Ref	Ref
Trans women not attracted to men	−2.28 [−4.26 to −0.31]*	−2.40 [−4.37 to −0.43]*
Trans men attracted to men	−2.26 [−4.00 to −0.52]*	−2.18 [−3.93 to −0.43]*
Trans men not attracted to men	−2.22 [−5.08 to 0.63]	−2.10 [−4.95 to 0.74]
Non-binary AFAB attracted to men	−2.37 [−4.07 to 3–0.68]**	−2.30 [−4.00 to −0.59]**
Non-binary AFAB not attracted to men	−1.35 [−3.85 to 1.14]	−1.47 [−3.96 to 1.02]
Non-binary AMAB attracted to men	−0.84 [−3.15 to 1.47]	−1.03 [−3.34 to 1.28]
Non-binary AMAB not attracted to men	−1.88 [−5.48 to 1.71]	−2.08 [−5.66 to 1.50]
Prioritized ethnicity groups		
Others including Pākehā/New Zealand European (White)	Ref	Ref
Māori	−0.38 [−1.98 to 1.23]	−0.31 [−1.91 to 1.30]
Pasifika	−1.70 [−4.92 to 1.51]	−2.16 [−5.39 to 1.07]
Asian	−3.84 [−6.70 to −0.98]**	−3.46 [−6.32 to −0.58]*
Income	0.14 [−0.48 to 0.77]	–
Education qualification	0.01 [−0.61 to 0.63]	–
Sex work in the last 12 months	−0.07 [−2.03 to 2.01]	–

Note: *b* refers to the differences in the predicted scores from the respective category to the reference category.
Abbreviations: AFAB, assigned female at birth; AMAB, assigned male at birth; CI, confidence interval.
*$p < 0.05$; **$p < 0.01$.

participants were grouped together as sexually attracted to men. The largest gender group among our survey participants was non-binary, and more than one-fifth were trans men attracted to men or non-binary AFAB attracted to men.

On average, our participants were at least somewhat certain that they could negotiate protective barrier use with a sexual partner in all situations. Table 3 shows the proportion of participants who were somewhat or completely certain about protective barrier use in each situation. Approximately nine-tenths were certain that they would use a protective barrier with a new sexual partner, or one who was trans or non-binary. This was followed by about four-fifths who felt certain they would refuse sex when a protective barrier was not available or would ask other sexual partners to use one (including someone who truly saw their gender identity, a cisgender partner or when their previous sex together had not involved using a protective barrier). Protective barrier use was lower when participants were drunk or high or when their partner refused to use such protection, with less than three-fifths reported feeling certain they would use a protective barrier in these circumstances.

Findings of linear regressions examining factors associated with the T-Barrier Scale are displayed in Table 4. Differences in the proportion of participants able to negotiate barrier use across gender and sexual attraction groups are outlined in Appendices S3 and S4, respectively. In the multivariate model that adjusted for covariates, trans women not attracted to men (b = −2.40), trans men attracted to men (b = −2.18) and non-binary AFAB people attracted to men (b = −2.30) had lower average points than trans women attracted to men, of reporting being able to negotiate protective barrier use. Compared to Pākehā/White participants, Asian participants scored 3.46 lower average points in certainty about being able to ask a sexual partner to use protective barriers. See Appendix S5 for the marginal mean of each gender and sexual attraction group.

Table 2 presents the proportion of participants who were aware of the efficacy and public funding of PrEP in Aotearoa. About three-fifths responded that they knew PrEP can reduce the risk of acquiring HIV or that PrEP does not protect against transmission of other STIs. Two-fifths were aware of the funding of PrEP for males or transpeople who meet other eligibility criteria. A very low proportion of our participants (1.0%) were currently taking PrEP or had previously taken it in the last 6 months. All of these participants responded "I knew that" to each of the three questions about the efficacy of PrEP and its availability for trans people.

We report the differences in proportion across gender and sexual attraction groups for PrEP awareness in Appendices S6 and S7, respectively. Findings of logistic regressions on socio-demographic characteristics across three variables on PrEP awareness are reported in Table 5. Multivariate models showed trans men attracted to men were significantly more likely than trans women attracted to men to know about PrEP's function in reducing HIV acquisition risk (OR = 2.99), to be aware of PrEP's inability to prevent other STIs (OR = 2.56) and to know about eligibility for publicly funded PrEP in Aotearoa (OR = 2.80). In all multivariate models, participants with higher education qualifications had higher knowledge of PrEP's efficacy and availability.

Table 5. Logistic regression of PrEP awareness across demographic groups

	First statement		Second statement		Third statement	
	Bivariate OR [95% CI]	Multivariate OR [95% CI]	Bivariate OR [95% CI]	Multivariate OR [95% CI]	Bivariate OR [95% CI]	Multivariate OR [95% CI]
Age	0.99 [0.97–1.00]**	0.99 [0.98–1.00]	0.98 [0.97–0.99]**	0.99 [0.97–1.00]	0.99 [0.98–1.00]	–
Gender and sexual attraction						
Trans women attracted to men	Ref		Ref		Ref	Ref
Trans women not attracted to men	0.65 [0.37–1.16]	0.70 [0.39–1.26]	0.51 [0.29–0.92]*	0.53 [0.29–0.98]*	0.59 [0.32–1.09]	0.58 [0.31–1.08]
Trans men attracted to men	3.07 [1.68–5.61]**	2.99 [1.61–5.54]**	2.94 [1.61–5.37]**	2.56 [1.35–4.84]**	2.66 [1.51–4.70]**	2.80 [1.58–4.96]**
Trans men not attracted to men	1.75 [0.75–4.07]	1.76 [0.75–4.14]	1.37 [0.61–3.06]	1.22 [0.53–2.78]	1.62 [0.71–3.72]	1.73 [0.75–4.00]
Non-binary AFAB attracted to men	1.78 [1.04–3.06]*	1.67 [0.96–2.91]	1.48 [0.86–2.53]	1.26 [0.72–2.23]	0.97 [0.57–1.67]	0.96 [0.55–1.65]
Non-binary AFAB not attracted to men	2.09 [0.95–4.53]	2.08 [0.95–4.56]	1.37 [0.65–2.87]	1.28 [0.59–2.75]	1.29 [0.62–2.69]	1.31 [0.63–2.75]
Non-binary AMAB attracted to men	2.03 [0.93–4.41]	1.88 [0.86–4.14]	1.56 [0.74–3.31]	1.34 [0.62–2.90]	1.78 [0.87–3.65]	1.66 [0.80–3.43]
Non-binary AMAB not attracted to men	0.57 [0.18–1.75]	0.64 [0.20–2.02]	0.51 [0.17–1.60]	0.58 [0.18–1.85]	0.79 [0.25–2.54]	0.83 [0.25–2.70]
Prioritized ethnicity groups			–			
Others including Pākehā/New Zealand European (White)	Ref		Ref		Ref	–
Māori	1.77 [1.00–3.15]	–	1.79 [1.01–3.18]*	1.56 [0.85–2.84]*	1.43 [0.85–2.41]	–
Pasifika	0.69 [0.27–1.77]	–	0.56 [0.22–1.44]	0.55 [0.21–1.48]	0.78 [0.30–2.05]	–
Asian	1.54 [0.54–4.34]	–	0.96 [0.37–2.49]	0.60 [0.22–1.60]	1.63 [0.68–3.95]	–
Income	1.09 [0.90–1.33]	–	1.05 [0.87–1.27]	–	1.19 [0.99–1.44]	–
Education qualification	1.33 [1.09–1.63]**	1.41 [1.14–1.75]**	1.39 [1.14–1.69]**	1.50 [1.21–1.86]**	1.36 [1.12–1.65]**	1.41 [1.16–1.73]**
Sex work in the last 12 months	1.44 [0.70–2.93]	–	1.86 [0.87–4.00]		1.46 [0.77–2.79]	–

Note. First—PrEP (pre-exposure prophylaxis) is a pill that, if taken every day by someone who is HIV negative, significantly decreases their risk of acquiring HIV.
Second—If taken correctly, PrEP significantly reduces the risk of acquiring HIV but it does not prevent the transmission of other STIs like gonorrhoea and syphilis.
Third—PrEP is now publicly funded in New Zealand, if you are "male or transgender" and meet other eligibility criteria.
Abbreviations: AFAB, assigned female at birth; AMAB, assigned male at birth; CI, confidence interval; OR, odds ration; PrEP, pre-exposure prophylaxis.
*$p < 0.05$; **$p < 0.01$.

4 | DISCUSSION

These data are the first from Aotearoa measuring the ability of a diverse range of trans people to access two important HIV prevention strategies, through negotiating barrier protection and building awareness of PrEP's efficacy and availability. Current research on HIV prevention among trans people has primarily focused on trans women [22]. Any automatic generalization of findings from these studies to the larger population of trans people should be made with caution as studies have documented variability in health experiences for trans women, trans men and non-binary people [2, 17, 23].

In our study, trans women who were attracted to men were more likely to report certainty about using protective barriers compared to trans women not attracted to men. Previous studies on the T-Barrier Scale have produced mixed findings on gendered differences. For instance, Trans PULSE did not detect significant gendered differences between AFAB and AMAB groups [18] and a Brazilian study reported a higher perceived ability to negotiate protective barriers (e.g. condoms) among trans men than trans women [21]. Our study asserted the importance of examining the intersection of gender and sexual attraction, as we only found significant gendered differences among those attracted to men: trans women had higher certainty around negotiating protective barrier use than trans men and non-binary AFAB people. Future research is required to examine correlates of T-Barrier Scale (e.g. self-esteem, experiences of stigma and discrimination, and the types of protective barrier used) for trans women, trans men and nonbinary people disaggregated by sexual attraction.

In this study, Asian trans participants had a lower ability to negotiate protective barrier use. Earlier published Counting Ourselves data also showed they were more likely to have been rejected by a family member because they were trans or non-binary [3, 24]. In contrast, a previous US study found young trans women who reported having parental support consistently practiced safe sex [25]. Other Aotearoa research has identified difficulties negotiating protective barrier use with a sexual partner can also be due to power asymmetry (including interpersonal differences in language, age, sexual experience or openness about one's sexuality) [14]. Our study points towards a need to facilitate sexual health equity for Asian trans people. Sexual health services can play an important role by providing language support, promoting culturally safe care and addressing institutional racism [26, 27].

PrEP should benefit those most at risk, not just those most able to navigate healthcare systems [15]. In line with previous studies [28, 29], our trans participants with a higher level of education qualification had higher awareness of PrEP. Previous studies comparing trans people's PrEP awareness based on sexual attraction have mostly focused on trans women and non-binary people AMAB [29, 30]. Our study provided more nuanced findings by exploring the differences in PrEP awareness for trans women, trans men and non-binary people who are sexually attracted to men. Among those sexually attracted to men, we found lower levels of PrEP awareness among trans women compared to trans men. Our finding on gender differences is similar to the US TransPoP survey that found a lower level of PrEP familiarity among trans people AMAB than those AFAB [31].

Trans and non-binary people in Aotearoa commonly access gender-affirming healthcare through doctors working as general practitioners (GPs) in primary care settings [3]. This reflects GPs' role in prescribing subsidized hormones and referring trans people to the limited number and range of surgeries available through public hospitals. Yet, earlier Counting Ourselves findings revealed that almost half of our participants (48%) were uncomfortable or very uncomfortable discussing being trans or non-binary with their GP, rising to over two-thirds (68%) with a new GP [3]. Increasing PrEP uptake among trans people in Aotearoa is likely to require upskilling GPs about the newly released PrEP guidelines [12], alongside an already identified need to improve primary healthcare providers' competency in delivering general and gender-affirming care to trans people [32].

There are several limitations to consider in this study. Counting Ourselves utilized convenience sampling which led to over-recruitment of participants, who were younger, from urban regions and more connected to trans community organizations. However, this method resulted in a sample size that was many times larger than other national trans surveys relative to the overall population [17]. Similar to overseas nationwide community-based studies [17], our non-binary sample contained a smaller proportion of AMAB participants (24.8%). Only 2.7% (n = 19) of our overall sample were non-binary AMAB attracted to men. Considering our novel finding on the variability in protective barrier use and PrEP awareness across gender and sexual attraction groups, we recommend future studies recruit a large representative sample of trans people to better understand these nuances.

We used the sexual attraction question from Counting Ourselves, as this measured participants' current sexual attraction to one or more gender groups. The survey also asked participants "who they had ever sex with," with the same range of response options. As the sexual behaviour question encompasses lifetime sexual experiences, some of these would have been when participants identified as cisgender. Our survey questionnaire did not include a sexual identity question. There is a need for more detailed survey questions that enable trans people to describe the diverse complexity of sexual orientation, attraction and behaviour across time and gender transitions.

5 | CONCLUSIONS

Participants attracted to men have a higher potential need for PrEP. This group was more likely to report PrEP awareness and that they could negotiate protective barrier usage. However, among participants attracted to men, we found trans women had less PrEP awareness than trans men, and awareness was lower for those with a lower educational qualification. Asian participants were less certain they could negotiate the use of protective barriers. More trans-competent, accessible sexual health education, drawing on the newly released PrEP guidelines, is needed to promote the benefits of PrEP in the Aotearoa HIV epidemic context,

particularly for trans women. Improving the use of PrEP is likely to require upskilling primary healthcare providers to improve their knowledge and cultural competency around supporting all trans people.

AUTHORS' AFFILIATIONS

[1]Trans Health Research Lab, School of Psychology, University of Waikato, Hamilton, New Zealand; [2]Faculty of Māori and Indigenous Studies, University of Waikato, Hamilton, New Zealand; [3]School of Population Health, Faculty of Medical and Health Sciences, University of Auckland, Auckland, New Zealand; [4]AIDS Epidemiology Group, Department of Preventive and Social Medicine, University of Otago, Dunedin, New Zealand

COMPETING INTERESTS

The authors declare that they have no competing interests.

AUTHORS' CONTRIBUTIONS

All authors were involved in the development of the study and JLB, KKHT and PJS wrote the manuscript. KKHT and RMB analysed the data. JFV provided essential input on the analysis and manuscript. All authors critically reviewed and edited the manuscript.

ACKNOWLEDGEMENTS

We would like to acknowledge the work of Counting Ourselves research team, and give special thanks to the community advisory group members and to the survey participants.

FUNDING

This work was supported by the Health Research Council of New Zealand [JFV, 17/587], the Rule Foundation and the University of Waikato. PS's involvement was supported by the NZ AIDS Foundation Fellowship at the University of Auckland.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

REFERENCES

1. Baral SD, Poteat T, Strömdahl S, Wirtz AL, Guadamuz TE, Beyrer C. Worldwide burden of HIV in transgender women: a systematic review and meta-analysis. Lancet Infect Dis. 2013;13(3):214–22.
2. Feldman JL, Luhur WE, Herman JL, Poteat T, Meyer IH. Health and health care access in the US transgender population health (TransPop) survey. Andrology. 2021;9(6):1707–18.
3. Veale JF, Byrne JL, Tan KKH, Guy S, Yee A, Nopera T, et al. Counting ourselves: the health and wellbeing of trans and non-binary people in Aotearoa New Zealand. New Zealand: Trans Health Research Lab, University of Waikato; 2019.
4. Stats NZ. LGBT+ population of Aotearoa: year ended June 2020. New Zealand: Stats NZ; 2021.
5. Sharples KJ, Dickson NP, Paul C, Skegg DC. HIV/AIDS in New Zealand: an epidemic in decline? AIDS. 1996;10(11):1273–8.
6. Saxton PJ, Dickson NP, McAllister SM, Sharples K, Hughes AJ. Increase in HIV diagnoses among men who have sex with men in New Zealand from a stable low period. Sex Health. 2011;8(3):311–8.
7. Saxton PJ, McAllister SM, Thirkell CE, Ludlam AH, Bateman JP, Anglemyer AT, et al. Population rates of HIV, gonorrhoea and syphilis diagnoses by sexual orientation in New Zealand. Sex Transm Infect. 2022;98:376–9.
8. Dickson N, Lee B, Foster T, Saxton P. The first 30 years of HIV in New Zealand: review of the epidemiology. N Z Med J. 2015;128(1426):31–48.
9. Saxton PJ, McAllister SM, Noller GE, Newcombe DA, Leafe KA. Injecting drug use among gay and bisexual men in New Zealand: findings from national human immunodeficiency virus epidemiological and behavioural surveillance. Drug Alcohol Rev. 2020;39(4):365–74.
10. AIDS Epidemiology Group. AIDS-New Zealand (Issue 80-May 2021). New Zealand: Department of Preventive and Social Medicine, University of Otago; 2021.
11. McAllister SM, Dickson NP, Sharples K, Reid MR, Morgan JM, MacDonald EJ, et al. Unlinked anonymous HIV prevalence among New Zealand sexual health clinic attenders: 2005–2006. Int J STD AIDS. 2008;19(11):752–7.
12. The Australasian Society of HIV, Viral Hepatitis and Sexual Health Medicine (ASHM). PrEP guidelines update for New Zealand. Prevent HIV by prescribing PrEP. New Zealand: New Zealand AIDS Foundation; 2021.
13. Saxton PJ, Dickson NP, Hughes AJ. Location-based HIV behavioural surveillance among MSM in Auckland, New Zealand 2002–2011: condom use stable and more HIV testing. Sex Transm Infect. 2014;90(2):133–8.
14. Saxton PJ, Giola M, Coughlan EP, Rich JG, Azariah S, Ludlam AH, et al. Implementing HIV pre-exposure prophylaxis (PrEP): let's not get caught with our pants down. N Z Med J. 2018;131(1481):64–73.
15. Saxton PJ, McAllister SM. Enumerating the population eligible for funded HIV pre-exposure prophylaxis (PrEP) in New Zealand. Sex Health. 2019;16(1):63–9.
16. Ministry of Health. Methodology report 2018/19: New Zealand Health Survey. New Zealand: Ministry of Health; 2019.
17. James SE, Herman JL, Rankin S, Keisling M, Mottet L, Anafi M. The report of the 2015 U.S. Transgender Survey. Washington, DC: National Center for Transgender Equality; 2016.
18. Dharma C, Scheim AI, Bauer GR. Exploratory factor analysis of two sexual health scales for transgender people: Trans-specific Condom/Barrier Negotiation Self-Efficacy (T-Barrier) and Trans-specific Sexual Body Image Worries (T-Worries). Arch Sex Behav. 2019;48(5):1563–72.
19. Bauer GR, Redman N, Bradley K, Scheim AI. Sexual health of trans men who are gay, bisexual, or who have sex with men: results from Ontario, Canada. Int J Transgend. 2013;14(2):66–74.
20. Ministry of Health. Ethnicity data protocols. New Zealand: Ministry of Health; 2017.
21. Catelan RF, Saadeh A, Lobato MI, Gagliotti DA, Costa AB. Condom-protected sex and minority stress: associations with condom negotiation self-efficacy, "passing" concerns, and experiences with misgendering among transgender men and women in Brazil. Int J Environ Res Public Health. 2021;18(9):4850.
22. Poteat T, Scheim A, Xavier J, Reisner S, Baral S. Global epidemiology of HIV infection and related syndemics affecting transgender people. J Acquir Immune Defic Syndr. 2016;72(suppl 3):S210–9.
23. Veale JF, Watson RJ, Peter T, Saewyc EM. Mental health disparities among Canadian transgender youth. J Adolesc Health. 2017;60(1):44–9.
24. Tan KK, Yee A, Veale JF. "Being trans intersects with my cultural identity": social determinants of mental health among Asian transgender people. Transgend Health. 2022;7(4):329-39.
25. Wilson EC, Iverson E, Garofalo R, Belzer M. Parental support and condom use among transgender female youth. J Assoc Nurses AIDS Care. 2012;23(4):306-17.
26. Wong, SF. Asian public health in Aotearoa New Zealand [Internet]. New Zealand: The Asian Network Inc; 2021 [cited 2021 Dec 21]. Available from: https://www.asiannetwork.org.nz/resources/asian-health/
27. Mukerjee R, Wesp L, Singer R. Clinician's guide to LGBTQIA+ care: Cultural safety and social justice in primary, sexual, and reproductive healthcare. 2022, Springer Publishing Company: New York.
28. Yan L, Yan Z, Wilson E, Arayasirikul S, Lin J, Yan H, et al. Awareness and willingness to use HIV Pre-exposure Prophylaxis (PrEP) among trans women in China: a community-based survey. AIDS Behav. 2021;25(3):866-74.
29. Restar AJ, Adia A, Cu-Uvin S, Operario D. Characterizing PrEP awareness and interest among Filipina transgender women. AIDS Educ Prev. 2020;32(3):212-28.
30. Macapagal K, Kraus A, Korpak AK, Jozsa K, Moskowitz DA. PrEP awareness, uptake, barriers, and correlates among adolescents assigned male at birth who have sex with males in the U.S. Arch Sex Behav. 2020;49(1):113-24.
31. Sevelius JM, Poteat T, Luhur WE, Reisner SL, Meyer IH. HIV testing and PrEP use in a national probability sample of sexually active transgender people in the United States. J Acquir Immune Defic Syndr. 2020;84(5):437-42.
32. Oliphant J, Veale JF, Macdonald J, Carroll R, Johnson R, Harte M, et al. Guidelines for gender affirming healthcare for gender diverse and transgender children, young people and adults in Aotearoa, New Zealand [Internet]. New Zealand: Trans Health Research Lab, University of Waikato; 2018 [cited 2021 Oct 15]. Available from: https://hdl.handle.net/10289/12160

SUPPORTING INFORMATION

Additional information may be found under the Supporting Information tab for this article:
Appendix 1. Missing Value Analysis of T-Barrier Scale.

Appendix 2. Sexual Attraction towards Gender Groups ($n = 699$).
Appendix 3. Proportions of Participants who were "Somewhat certain" and "Completely certain" for the Imputed T-Barrier Scale across Gender Groups.
Appendix 4. Proportions of Participants who were "Somewhat certain" and "Completely certain" for the 8-item T-Barrier Scale across Sexual Attraction Groups.
Appendix 5. Estimated Marginal Mean for T-Barrier Scale for each Gender and Sexual Attraction Group.
Appendix 6. Proportions of Participants who Responded "I knew that" about PrEP Information across Gender Groups.
Appendix 7. Proportions of Participants who Responded "I knew that" about PrEP Information across Sexual Attraction Groups.

Aguayo-Romero RA et al. *Journal of the International AIDS Society* 2022, **25**(S5):e25999
http://onlinelibrary.wiley.com/doi/10.1002/jia2.25999/full | https://doi.org/10.1002/jia2.25999

JIAS JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

RESEARCH ARTICLE

HIV awareness and prevention strategies among transgender women in the Eastern and Southern United States: findings from the LITE Study

Rodrigo A. Aguayo-Romero[1,2,3,§,#], Christopher M. Cannon[4,#], Andrea L. Wirtz[5], Erin E. Cooney[6], Kenneth H. Mayer[2,3,7], Sari L. Reisner[1,2,3,7] and the American Cohort to Study HIV Acquisition among Transgender Women (LITE) Study Group[1]

[§]**Corresponding author**: Rodrigo A. Aguayo-Romero, Division of Endocrinology, Diabetes, and Hypertension, Brigham and Women's Hospital, 221 Longwood Ave., 5th Floor, Boston, MA 02115, USA. Tel: 001 202 681 7789. (raguayoromero@bwh.harvard.edu)
[#]These authors have contributed equally to the work.

Abstract

Introduction: Transgender women (TW) experience an increased risk of human immunodeficiency virus (HIV) acquisition. This study identified patterns of HIV awareness and prevention strategies used by TW who were not living with HIV.

Methods: Data were drawn from a baseline survey of the LITE Study, a multi-site cohort of TW in Eastern and Southern United States (March 2018–August 2020). We conducted a latent class analysis to identify classes of HIV awareness and prevention strategies among TW who reported past 12-month sexual activity (N = 958) using 10 variables spanning HIV knowledge, receipt and use of HIV prevention strategies, and sexual practices. Due to differences across the cohort arms, classes were estimated separately for TW enrolled in site-based versus online study arms. We identified demographic characteristics, gender-affirming indicators and HIV vulnerabilities associated with class membership.

Results: Four parallel classes emerged: class 1 "limited strategies—less sexually active" (15% and 9%, site-based and online, respectively), class 2 "limited strategies—insertive sex" (16%/36%), class 3 "limited strategies—receptive sex" (33%/37%) and class 4 "multiple strategies—insertive and receptive sex" (36%/18%). Across all classes, condomless sex, pre-exposure prophylaxis (PrEP)/post-exposure prophylaxis (PEP) prevention knowledge and awareness were high but reported PrEP/PEP use was low. Compared with class 1, membership in class 4 was associated with being a person of colour (site-based OR = 2.15, 95% CI = 1.15–4.00, online OR = 4.54, 95% CI = 1.09–18.81) increased odds of self-perceived medium-to-high HIV risk (site-based OR = 4.12, 95% CI = 2.17–7.80, online OR = 11.73, 95% CI = 2.98–46.13), sexually transmitted infections (STI) diagnosis (site-based OR = 6.69, 95% CI = 3.42–13.10, online OR = 8.46, 95% CI = 1.71–41.78), current sex work (site-based OR = 6.49, 95% CI = 2.61–16.11, online OR = 10.25, 95% CI = 1.16–90.60) and 2–4 sexual partners in the last 3 months (site-based OR = 2.61, 95% CI = 1.33–5.13). Class 3, compared with class 1, had increased odds of current sex work partners (site-based OR = 3.09, 95% CI = 1.19–8.07) and of having 2–4 sexual partners in the last 3 months (site-based OR = 3.69, 95% CI = 1.85–7.39).

Conclusions: TW have varied HIV awareness and prevention strategy utilization, with clear gaps in the uptake of prevention strategies. Algorithms derived from latent class membership may be used to tailor HIV prevention interventions for different subgroups and those reached through facility-based or digital methods.

Keywords: transgender women; gender diverse; HIV prevention strategies; latent class analysis; PrEP; PEP

Additional information may be found under the Supporting Information tab of this article.

Received 7 January 2022; **Accepted** 30 July 2022

1 | INTRODUCTION

Human immunodeficiency virus (HIV) disproportionately impacts transgender women (TW). Previous meta-analyses reflected HIV prevalence estimates ranging from 7% (2012) to 19% (2018) in the United States [1, 2]. The Centers for Disease Control and Prevention (CDC) Report on HIV among TW estimated an HIV prevalence of 42% in seven US cities

in 2019–2020 [3]. The CDC report also showed that TW of colour have higher rates of HIV as compared to previous meta-analyses; 44–62% for Black/African American TW, 26–35% for Hispanic/Latina TW and 7–17% for White TW [2, 3]. Reported behavioural risks underscore HIV prevalence estimates; for example, 38% of TW reported sex work and condomless sex (independently), and 42% reported multiple partnerships [2], as well as dense sexual networks, which facilitate more rapid transmission across networks [4, 5].

Extant literature has documented TW's prevention knowledge and strategies to prevent HIV. Data from a cross-sectional study in Baltimore and Washington DC demonstrated that TW of colour had high scores of HIV knowledge and HIV risk perceptions [6]. Studies from 2012 to 2020 revealed that three out of four TW got HIV tested within a 12-month period [2, 3, 6, 7]. A survey among TW in New York City found that TW reported condoms as their first choice (59%), followed by abstinence (14%), pre-exposure prophylaxis (PrEP) (12%) and limiting the number of partners (9%) [8]. Surveys estimate that 57–63% of TW reported post-exposure prophylaxis (PEP) knowledge [6, 8], of which 9–13% reported ever using this prevention modality in the past [6, 8]. PrEP use among TW is also limited. This may be due to limited numbers of TW who participated in PrEP clinical trials, concerns of interactions with hormones, side effects and pill burden, and no specific guidelines for PrEP use tailored to the unique experiences of the trans community [9–11]. Recent research has demonstrated that 87% of TW had PrEP knowledge, and 81% knew how to get it if desired [6]. The CDC report revealed an increase in PrEP awareness (92%); however, PrEP use among TW was limited, with only 32% of HIV uninfected TW reporting PrEP use [3]. HIV prevention requires effective combination strategies to mitigate HIV acquisition risk [12–15]. Yet, the combinations of HIV prevention strategies TW use to reduce HIV risk and how these may differ for subgroups are unknown.

There is limited research on combination HIV prevention strategies among TW. One review on sex work in TW estimated that the implementation of tailored interventions could decrease the incidence of HIV by 50% in 10 years [15]. More combination prevention strategies for TW are needed [4], but there is no evidence-based research examining combination HIV prevention strategies utilized individually by TW. This study aimed to fill this gap through latent class analysis (LCA) to explore distinct patterns of HIV prevention strategies among TW in Eastern and Southern United States. These regions have the highest HIV rates across the United States [16]. We sought to determine the association of class membership with demographics, gender-affirming indicators and HIV vulnerabilities to inform future interventions. This is the first use of LCA among HIV-negative TW to model combination HIV prevention strategies in the United States.

2 | METHODS

2.1 | Data

This study used baseline data from the American Cohort to Study HIV Acquisition among Transgender Women—LITE Study. The LITE cohort included two arms: a technology-enhanced, site-based arm (N = 732) in six cities in the Eastern and Southern United States (Atlanta, Baltimore, Boston, Miami, New York City and Washington, DC) and an auxiliary online arm that enrolled participants in 72 cities matched on population size and demographics to the cities above (N = 582). Participants were enrolled and completed baseline surveys between March 2018 and August 2020. 98.12% (N = 940) of participants completed the baseline visit prior to the beginning of the lockdown in the United States on 15 March 2020. TW were recruited via technology-based (social media and dating apps) and non-technology-based (clinical-based referrals, peer referrals and gender-affirming events) recruitment methods. Protocols for the LITE Study have been published [17, 18].

Eligibility criteria for participation in the baseline survey included being ≥ age 18 years, reporting a trans feminine identity based on a two-step measure (being assigned male sex at birth, identifying as woman, female or along the trans-feminine spectrum), speaking English or Spanish, a negative HIV test and providing consent to participate in at least the baseline study visit. We restricted this analysis to participants who reported being sexually active (anal or vaginal sex) in the last 12 months regardless of condom use practices (n = 577 site-based arm; n = 381 online arm). We were interested in HIV prevention strategies among TW who may be exposed to HIV through condomless sex since this represents a primary mode of HIV acquisition for TW [1]. Study protocols were approved by the Johns Hopkins School of Medicine single institutional review board for all study sites.

2.2 | Measures

2.2.1 | *Manifest variables: HIV awareness and prevention strategies*

We conceptualized HIV awareness and prevention strategies as a combination of 10 psychoeducational, biomedical use (PEP [19, 20] and PrEP [21–23]), and behavioural interventions and strategies carrying varying degrees of HIV risk and protective levels. For instance, we included oral sex as a strategic behaviour with a significantly lower risk of HIV acquisition than engaging in anal and/or vaginal sex. Table 1 contains a detailed description of the manifest variables.

2.2.2 | *Covariates*

Demographics, gender-affirming variables and HIV vulnerabilities were used as covariates and were selected based on documented relationships with HIV prevention strategies in the transgender HIV literature. Table S1 includes detailed covariate descriptions.

2.3 | Statistical analysis

LCA was selected to empirically identify distinct classes of HIV awareness and prevention strategies. LCA is a person-centred statistical approach of identifying underlying patterns or subgroups—also known as latent classes—sharing similar characteristics based on the interconnectedness of multiple observed categorical variables [24, 25]. Previous LCA research has focused on TW living with HIV and

Table 1. Measures for manifest variables included in latent class analysis models in the LITE Study of transgender women in the United States (*N* = 958)

Variable	Measure description
HIV information from organizations	Based on answering "Yes" to any of the three following responses to the question "In the last 3 months, have you received any of the following services from a clinic, community organization or health facility (other than in this study)?": "One-on-one conversation with an outreach worker, counsellor or prevention programme worker;" "Participated in an organized group session to discuss ways to prevent HIV infections;" or "Received HIV/STI prevention information (e.g. a flyer or info sheet)"
HIV knowledge	Based on answering the following two questions correctly: "What type of sex puts someone most at risk for HIV infection?" (answer = anal) and "Can someone get HIV from sharing a needle to inject hormones or silicone?" (answer = yes)
PrEP/PEP awareness	Based on answering "Yes" to either of the following questions: "Have you ever heard about PrEP (pre-exposure prophylaxis) for the prevention of HIV infection in people who are HIV-negative?" or "Have you heard of PEP for preventing HIV after someone has had possible contact with HIV (e.g. after unsafe sex or rape)?"
HIV test last year	Based on selecting any of the three response options to the question: "When was your most recent HIV test? If you're not sure, please give your best guess. If you are living with HIV, this refers to when you were first told that you have HIV." Responses: "Less than 3 months ago," "3–6 months ago," or "7–11 months ago."
PrEP use ever	Based on answering "Yes" to the question: "Have you ever taken PrEP (pre-exposure prophylaxis) for the prevention of HIV infection?"
PEP use ever	Based on answering "Yes" to the question: "Have you ever taken PEP?"
Condomless sex	Based on answering "Yes" to the question: "In the last 12 months, have you ever had sex (anal or vaginal) without a condom?"
Receptive anal/vaginal sex	Based on answering "Yes" to any of the two sexual behaviours on the question: "Which type(s) of sex did you have with (casual partners, regular partners or sex work clients) in the last 3 months?" Behaviours: "Receptive anal sex (a partner put their penis in your anus or butt)" or "Receptive vaginal sex (a partner put their penis into your vagina)."
Insertive anal/vaginal sex	Based on answering "Yes" to any of the two sexual behaviours on the question: "Which type(s) of sex did you have with (casual partners, regular partners or sex work clients) in the last 3 months?" Behaviours: "Insertive anal sex (you put your penis in a partner's anus or butt)" or "Insertive vaginal sex (you put your penis in a partner's vagina.)."
Oral sex	Based on answering "Yes" to any of the four sexual behaviours on the question: "Which type(s) of sex did you have with (casual partners, regular partners or sex work clients) in the last 3 months?" Behaviours: "Receptive penile oral sex (a partner put their penis in your mouth)," "Insertive penile oral sex (you put your penis in a partner's mouth)," "Received oral-vaginal sex (a partner put their mouth on your vagina)," or "Performed oral-vaginal sex (you put your mouth on a partner's vagina)."

Note. All manifest variables were recoded as binary (yes vs. no).
Abbreviations: PEP, post-exposure prophylaxis; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection.

HIV-related health outcomes but not on their prevention strategies [26–28].

All analyses were conducted using SAS 9.4. Data were analysed using complete cases since missing data was 0.10% and only for HIV risk and social support. Where data were missing due to skip patterns, we specified that participants did not receive the question(s). For instance, HIV risk includes a category for those who noted they never received an HIV test and, therefore, did not receive the subsequent question about HIV risk. We tested measurement invariance between site-based and online arms. We used PROC LCA 1.3.2 macro [29, 30] to identify the LCA baseline model, which refers to the base model that does not include grouping variables or covariates. The determination of the base models for each arm was based on multiple indicators, including maximum likelihood solution percentage, Akaike's information criterion, Bayesian information criterion, a bootstrap likelihood ratio test and entropy (Table S2) [29]. Lastly, we used a three-step covariates macro in SAS to estimate the odds ratios statistically predicting class membership from the covariates [31, 32].

3 | RESULTS

3.1 | Study population

Half of TW in both arms were 18–29 years old (58%), had some college education or higher (70%), had incomes above the federal poverty line (FPL) (54%) and lived in the North (51%; Table 2).

Table 2. Social demographics of sexually active transgender women in the LITE Study, Eastern and Southern United States (*N* = 958)

Characteristics		Site-based (*n* = 577) *n* (%)	Online (*n* = 381) *n* (%)	Total (*N* = 958) *n* (%)
Age in years	18–29	320 (56)	231 (61)	551 (58)
	30–39	147 (25)	106 (28)	253 (26)
	40+	110 (19)	44 (11)	154 (16)
Race/ethnicity	Non-Hispanic White	186 (32)	287 (75)	473 (49)
	Non-Hispanic Black	122 (21)	17 (4)	139 (15)
	Hispanic White	58 (10)	12 (3)	70 (7)
	Hispanic Black	21 (4)	1 (0.3)	22 (2)
	Non-Hispanic and more than one race or other	83 (14)	47 (12)	130 (14)
	Hispanic and more than one race or other	98 (17)	15 (4)	113 (12)
	Unknown	9 (2)	2 (0.5)	11 (1)
Education	<HS Diploma/GED	212 (37)	70 (18)	282 (29)
	≥ Some college	360 (62)	309 (81)	669 (70)
	Unknown	5 (0.9)	2 (0.5)	7 (0.7)
Income	Above FPL	263 (46)	255 (67)	518 (54)
	Below FPL	223 (39)	87 (23)	310 (32)
	Unknown	91 (16)	39 (10)	130 (14)
Employment	Full-time	174 (30)	181 (48)	355 (37)
	Part-time	139 (24)	80 (21)	219 (23)
	Not employed	250 (43)	108 (28)	358 (37)
	Unknown	14 (2)	12 (3)	26 (3)
Insurance	Uninsured	63 (11)	37 (10)	100 (10)
	Public	279 (48)	90 (24)	369 (39)
	Private	192 (33)	234 (61)	426 (45)
	Unknown	43 (7)	20 (5)	63 (7)
Region	North	296 (51)	189 (50)	485 (51)
	Mid-Atlantic	151 (26)	64 (17)	215 (22)
	South	130 (23)	128 (33)	258 (27)

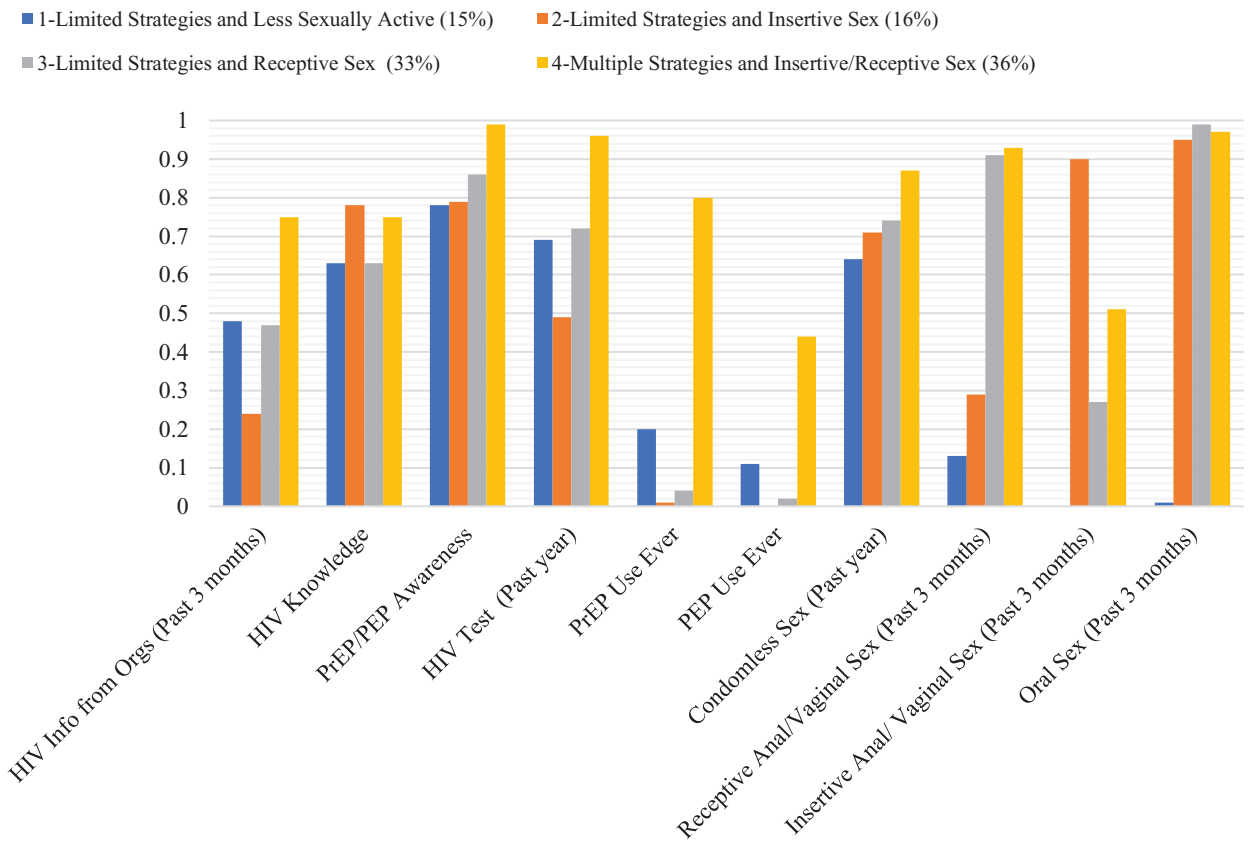
Abbreviations: FPL, federal poverty line; GED, general educational development; HS, high school.

Half of the participants identified as trans woman/trans female (51%), though gender identities varied (Table S3). Nearly, half (47%) had at least one gender-affirming procedure and a majority of TW in both arms reported being on hormone therapy. Nearly, three-quarters of the sample said they had not received HIV prevention education or trans-specific materials in the last 3 months (72%). More than half of TW reported low social support in the past 6 months.

Among all participants, vulnerabilities included never testing for STI (22%), lifetime involvement in sex work (42%), two or more sexual partners in the past 12 months (56%) and 27% medium to high perceived risk for HIV acquisition (Table S4). Sixty-four percent reported partnerships with cisgender men, though the genders of sexual partners were diverse.

3.2 | Four class model

The G^2 difference test (G^2 = 718.08, *df* = 44, $p<0.001$) was statistically significant, suggesting that measurement invariance did not hold across site-based and online arms. Therefore, we conducted separate analyses for the two arms. Five competing models containing 10 manifest variables were compared to determine a well-identified LCA baseline model in both arms. The model with four classes for the site-based arm (G^2 of 416.52 with 980 degrees of freedom) and the online arm (G^2 of 302.78 with 980 degrees of freedom) were selected as final models because these provided an optimal balance between statistical criteria and interpretability. Classes in both models had similar characteristics but differed in class prevalence and probability of particular strategies. Given both models' parallel nature, we used the same class names for both arms. The four classes in each arm were labelled as: class 1—limited strategies and less sexually active, class 2—limited strategies and insertive sex, class 3—limited strategies and receptive sex and class 4—multiple strategies and insertive/receptive sex. The composition of classes in site-based and online arms can be seen in Figures 1 and 2 (see Tables S5 and S6 for item-response probabilities and prevalence of awareness and prevention strategies). Analysis was restricted to those who were sexually active in the last 12



Note. Classes are characterized by the HIV awareness and prevention item-response probabilities > .50.

Figure 1. Probability of endorsing each HIV awareness and prevention item among transgender women in the LITE Study, Eastern and Southern United States—site-based (*N* = 577). Abbreviations: Orgs, organizations; PEP, post-exposure prophylaxis; PrEP, pre-exposure prophylaxis.

months. Yet, class 1 emerged to represent TW who had a very low probability of having had sex in the previous 3 months before the survey. Class 4 was the largest group (36%) in the site-based arm, characterized by high probabilities of 9 out of the 10 HIV awareness and prevention strategies (all except for prior PEP use). Class 3 was the largest (37%) in the online arm, characterized by high probabilities of HIV knowledge, PrEP/PEP awareness, condomless sex, receptive anal/vaginal sex and oral sex.

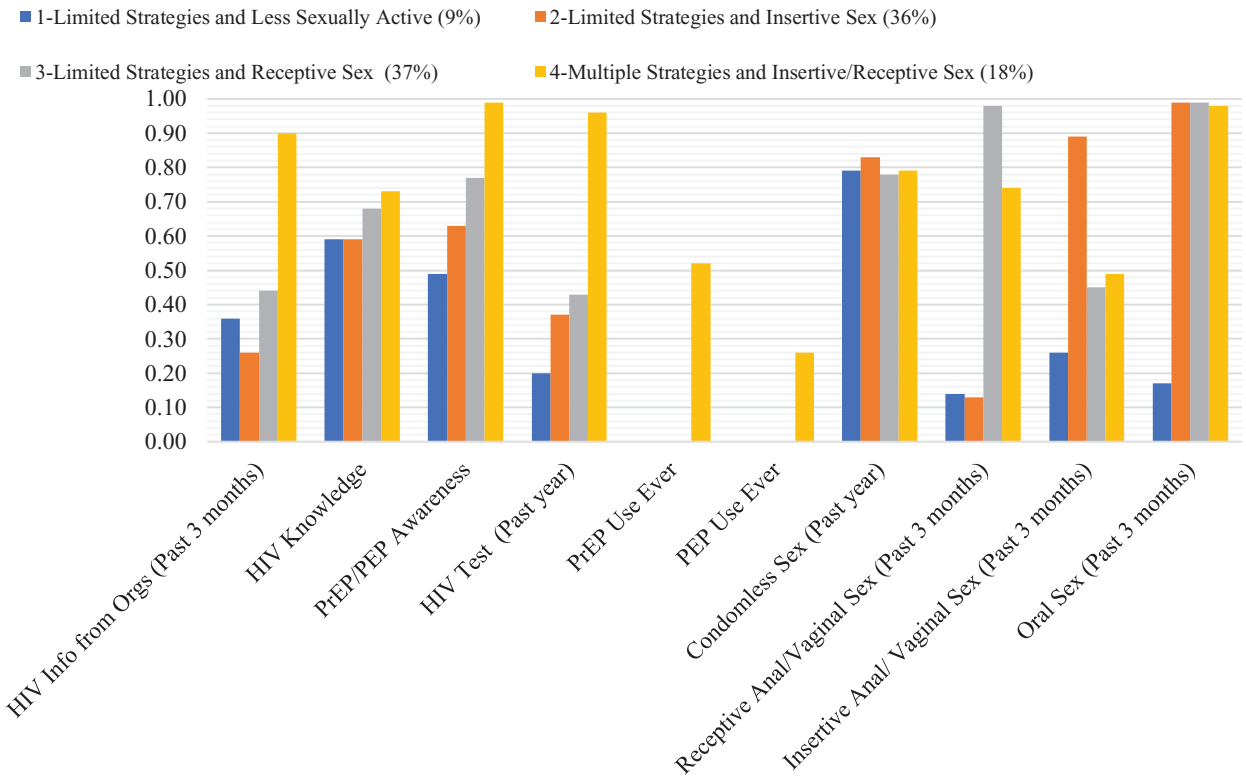
The classes in both arms were differentiated by self-reported behaviours. All site-based classes had a high probability of HIV testing (range 0.49–0.96), while it was only a characteristic of class 4 in the online cohort. Participants in both arms and across all classes exhibited high probabilities of being knowledgeable about HIV, PrEP, and PEP and engaging in condomless sex in the past year. The probability of PrEP/PEP awareness was just below the 0.50 threshold in the online class 1. All site-based and online classes were characterized by a low probability of lifetime PEP use (18% site-based arm; 5% online arm; see Tables S5 and S6). PrEP use was only a characteristic of class 4 in both arms.

3.2.1 | *Demographic covariates*

As seen in Table 3, people of colour had higher odds of belonging to class 4 in both arms. Similarly, TW with ≥ some college education were more likely to be in class 2 in both arms. In the site-based cohort, TW with private insurance had higher odds of belonging to class 2. In the online cohort, TW living below the FPL and with public insurance had higher odds of belonging to class 4.

3.2.2 | *Gender-affirming covariates*

TW receiving trans-specific HIV prevention information in the past 3 months had higher odds of being in class 4 and TW who had high social support had higher odds of being in class 2 in both arms (Table 4). The remaining covariates were only associated with membership in class 2. TW who identified as non-binary (NB) or another gender diverse identity and who were currently taking hormones had higher odds of belonging to class 2. While those TW who identified as woman/female had lower odds of belonging to class 2 than those in class 1.



Note. Classes are characterized by the HIV awareness and prevention item-response probabilities > .50.

Figure 2. Probability of endorsing each HIV awareness and prevention item among transgender women in the LITE Study, Eastern and Southern United States—online (*N* = 381). Abbreviations: Orgs, organizations; PEP, post-exposure prophylaxis; PrEP, pre-exposure prophylaxis.

3.2.3 HIV vulnerabilities covariates

Participants in both arms self-reporting a positive sexually transmitted infection (STI) test, sex work and medium-to-high HIV risk level had higher odds of being in class 4 (Table 5). Current sex work was also associated with membership in class 3 for the site-based arm. Significant associations between the number of partners and class membership emerged for the site-based arm. TW who reported one partner in the last 3 months had higher odds of belonging to class 2, while those with 2–4 partners had higher odds of being in classes 3 and 4. TW in the site-based arm who reported partnerships with cisgender women (CW), transgender men (TM) and non-binary (female at birth—NB FAB) partners had higher odds of belonging to class 2. Participants who reported cisgender men (CM) as partners had higher odds of being in site-based classes 3 and 4, and those who reported TW and NB (male at birth—MAB) partners had higher odds of being in class 3 for both arms and in the online class 4.

4 | DISCUSSION

We identified four classes of combination HIV awareness and prevention strategies being used by TW and evaluated characteristics associated with using these strategies. We identified gaps where increased HIV prevention efforts should be allocated. Consistent with the literature on HIV vulnerabilities [1, 2, 4, 6, 7], TW in classes 3—limited strategies and receptive sex and 4—multiple strategies and insertive/receptive sex in both arms were at increased HIV risk due to engaging in condomless sex and receptive sex, which was associated with higher odds of STI diagnosis, sex work and multiple partners within a 3-month period. TW of colour in class 4—multiple strategies and insertive/receptive sex were at heightened risk for HIV at the intersection of gender and race/ethnicity. The association of self-assessed medium-to-high HIV risk perception, STI history and sex work with class 4—multiple strategies and insertive/receptive sex membership could indicate that the multiple strategies utilized are an adaptive response to previous experiences, indicating greater resilience when facing high HIV vulnerability. In contrast, class 3—limited strategies and receptive sex was also at heightened risk but only utilizes a limited number of strategies.

Meanwhile, classes 1—limited strategies and less sexually active and 2—limited strategies and insertive sex in both arms had profiles indicating lower HIV risk attributed to either low probabilities of sexual activity in the last 3 months or a high probability of insertive sexual positioning. Covariates associated with class 2—limited strategies and insertive sex included having ≥ some college education, private insurance, lower odds of income below the FPL, increased social support and a lower number of partners who were predominantly CW, TM

Table 3. Covariates table: demographics associated with class membership in site-based and online cohorts among transgender women in the LITE Study, Eastern and Southern United States (March 2018–August 2020)

Class	Site-based arm (*N* = 577)			Online arm (*N* = 381)		
	2 Limited strategies and insertive sex	3 Limited strategies and receptive sex	4 Multiple strategies and insertive/ receptive sex	2 Limited strategies and insertive sex	3 Limited strategies and receptive sex	4 Multiple strategies and insertive/ receptive sex
Age in years (continuous)	1.32 (0.90–1.93)	1.36 (0.99–1.87)	1.24 (0.93–1.66)	**0.55 (0.37–0.82)**	**0.62 (0.44–0.88)**	0.73 (0.52–1.02)
POC (reference: White)[a]	**0.11 (0.04–0.26)**	1.11 (0.59–2.08)	**2.15 (1.15–4.00)**	2.11 (0.52–8.50)	3.79 (1.00–14.35)	**4.54 (1.09–18.81)**
≥ Some college (reference: HS Diploma GED)	**8.85 (2.73–28.68)**	1.16 (0.66–2.05)	1.23 (0.72–2.10)	**3.96 (1.20–13.11)**	1.49 (0.57–3.90)	0.76 (0.26–2.17)
Income below federal poverty level (reference: above)	**0.44 (0.21–0.89)**	**0.43 (0.24–0.78)**	0.80 (0.47–1.37)	1.12 (0.31–4.03)	2.16 (0.66–7.08)	**4.38 (1.24–15.44)**
Employment						
Employed part-time	1.94 (0.86–4.38)	1.76 (0.87–3.59)	1.38 (0.69–2.75)	1.68 (0.49–5.78)	2.46 (0.76–7.99)	1.06 (0.26–4.37)
Employed full-time	1.41 (0.69–2.90)	1.09 (0.58–2.02)	0.91 (0.50–1.64)	**0.29 (0.11–0.80)**	**0.23 (0.09–0.60)**	**0.15 (0.05–0.46)**
Insurance						
Uninsured	0.85 (0.26–2.77)	1.65 (0.70–3.87)	0.66 (0.26–1.69)	0.63 (0.17–2.41)	0.69 (0.20–2.45)	0.66 (0.15–2.99)
Public	**0.41 (0.20–0.85)**	0.69 (0.39–1.22)	1.50 (0.87–2.57)	1.02 (0.32–3.29)	1.39 (0.46–4.22)	**4.07 (1.26–13.14)**
Private	**3.00 (1.48–6.10)**	1.06 (0.57–1.95)	0.68 (0.37–1.23)	1.16 (0.44–3.01)	0.59 (0.24–1.45)	**0.30 (0.11–0.84)**
Region						
North	1.71 (0.85–3.44)	0.79 (0.45–1.40)	0.99 (0.58–1.69)	1.27 (0.53–3.02)	1.11 (0.48–2.57)	1.00 (0.38–2.61)
Mid-Atlantic	0.49 (0.20–1.17)	0.91 (0.48–1.72)	1.11 (0.62–2.00)	0.72 (0.22–2.42)	0.82 (0.26–2.59)	2.19 (0.67–7.22)
South	0.95 (0.40–2.22)	1.51 (0.78–2.93)	0.89 (0.45–1.72)	0.92 (0.37–2.26)	1.00 (0.42–2.38)	0.51 (0.18–1.48)

Note. Limited strategies and less sexually active is the reference group. Odds ratios are unadjusted. Boldface indicates statistically significant association—CI does not contain 1.0. Unknown responses were included in the modelling.
[a]People of Colour (POC) include every race/ethnicity other than non-Hispanic White versus non-Hispanic White. Recoded because of the low prevalence of some racial groups. Unemployed did not yield robust estimates and was not included in this table.

or NB (FAB) individuals, which have all been identified as protective or mitigating factors in the literature [4, 33–36]. These findings demonstrate that partnerships are diverse among TW and not universally with CM. This suggests that tailored HIV prevention programming is needed to recognize and discuss appropriate strategies across various partnerships and sexual practices.

PrEP and PEP awareness was high in almost all classes for both arms, consistent with previous studies [9, 11, 37]. But awareness did not appear to reflect PrEP or PEP uptake overall. This could be due to limited points of access to biomedical interventions, especially outside of larger urban centres. Class 4—multiple strategies and insertive/receptive sex in both arms was characterized by PrEP use and information from organizations, while no classes were characterized by PEP use. The larger size of the site-based class 4—multiple strategies and insertive/receptive sex and higher probability of PrEP use compared to the online equivalent may be due to the availability of medical care and services that TW in the site-based arm have access to. Low PEP uptake is likely due to limited access and the 72-hour time window needed to start treatment. Meanwhile, HIV testing was a prevention strategy underutilized in the online arm. Online classes 1–3 showed that TW are not regularly tested. High HIV testing utilization in the four site-based classes (77%) compared to the online arm (48%) might be attributed to their direct linkage and engagement with health or social services organizations. Overall, TW face an array of barriers that hinder their access and uptake of prevention strategies that include but are not limited to insurance coverage, education, transportation, education, stigma, discrimination and low HIV perception risk [37, 38].

4.1 | Implications

A common pattern across all classes was the high probability of having engaged in condomless sex in the past 12 months, indicating that efforts should be redirected towards other prevention strategies. Therefore, current educational outreach efforts, which have led TW to be knowledgeable about HIV,

Table 4. Covariates table: gender-affirming variables associated with class membership in site-based and online arms among transgender women in the LITE Study, Eastern and Southern United States (March 2018–August 2020)

	Site-based arm (*N* = 577)			Online arm (*N* = 381)		
	2	3	4	2	3	4
Class	Limited strategies and insertive sex	Limited strategies and receptive sex	Multiple strategies and insertive/receptive sex	Limited strategies and insertive sex	Limited strategies and receptive sex	Multiple strategies and insertive/receptive sex
Gender identity						
Woman/female	**0.44**	0.99	0.85	1.22	1.58	0.65
	(0.20–0.96)	(0.56–1.76)	(0.49–1.46)	(0.39–3.82)	(0.53–4.69)	(0.16–2.61)
Transwoman/transfemale	1.20	0.85	0.85	1.16	0.71	1.11
	(0.60–2.38)	(0.48–1.50)	(0.50–1.46)	(0.45–2.99)	(0.29–1.73)	(0.39–3.21)
Non-binary or other gender diverse[a]	**3.81**	1.86	2.64	0.53	1.04	1.26
	(1.18–12.29)	(0.58–5.98)	(0.90–7.70)	(0.13–2.12)	(0.31–3.50)	(0.32–4.91)
Hormone therapy (past 3 months)	**3.55**	1.10	1.35	1.27	0.89	2.26
	(1.02–12.28)	(0.55–2.18)	(0.69–2.66)	(0.49–3.30)	(0.36–2.20)	(0.70–7.26)
Any gender-affirming procedure	1.44	1.02	1.54	0.65	0.67	2.25
	(0.73–2.84)	(0.58–1.80)	(0.90–2.63)	(0.27–1.57)	(0.28–1.57)	(0.84–6.01)
Trans-specific HIV prevention info	0.09	1.20	**1.95**	0.49	0.97	**4.78**
	(0.01–1.03)	(0.63–2.29)	**(1.07–3.55)**	(0.11–2.09)	(0.28–3.43)	**(1.37–16.64)**
Social support (high vs. low)	**3.17**	1.75	1.42	**2.47**	1.20	1.53
	(1.56–6.45)	(0.97–3.16)	(0.81–2.49)	**(1.01–6.05)**	(0.50–2.88)	(0.57–4.12)

Note. Limited strategies and less sexually active is the reference group. Odds ratios are unadjusted. Boldface indicates significant association—CI does not contain 1.0. "Prefer not to answer" and "Don't know" responses were included in the modelling.
[a]Includes non-binary, woman of trans experience, person of trans experience, two-spirit and other identities.

PrEP and PEP, should expand their reach to the greater TW community and need improved efforts to link TW with these prevention strategies. Health educators may need to look for newer methods and/or novel media tools to better reach the population. The private sector, such as television and film, could help reach more people by getting more HIV storylines into mainstream media.

Class 4—multiple strategies and insertive/receptive sex demonstrated that using multiple prevention strategies is possible, but many of these require access to structural supports for their uptake. Structural supports, like health and social services organizations, need to explore alternative schedules, telehealth, mobile healthcare and/or mail delivery services. TW communities are often unable to and/or uncomfortable accessing physical facilities. Providers need to make their facilities more trans-inclusive to ensure patients are respected, affirmed and welcomed. Online arm findings highlight the need for public health departments and providers to increase engagement with online promotion methods and outreach to increase PrEP and PEP uptake. Online medical services may increase access for many TW across the country [38, 39]. Providers need to do more in-person education during all medical appointments; however, increasing accurate and easy-to-understand educational opportunities online about biomedical prevention options may be necessary to reach TW who are in increased need and not affiliated with a medical clinic. Given the significant differences found among TW in online versus site-based arms, different intervention models may be required to fill prevention gaps among TW. Overall, increasing telehealth options may fill some of those gaps, but it will be important to be thoughtful about TW who may not be reached due to lack of technology access or other barriers.

Except for online class 4—multiple strategies and insertive/receptive sex, TW in the other online classes did not get HIV tested the year before the study. Given that HIV self-testing has gained acceptability among TW in the United States [40], TW in online classes 2—limited strategies and insertive sex and 3—limited strategies and receptive sex may benefit from free or low-cost home self-testing HIV kits and more mobile testing clinics or events. Meanwhile, online class 1—limited strategies and less sexually active may not need to participate in HIV testing as frequently. PrEP and PEP awareness was high among all classes except online class 1. However, class 4—multiple strategies and insertive/receptive sex was characterized by PrEP use. Although all PrEP indicated participants could benefit from PrEP programmes that include in-person and telehealth options, TW in class 3—limited strategies and receptive sex for both arms would benefit from PrEP referrals by healthcare providers. Further, TW in online class 3 may be more likely to uptake PrEP through programmes focused on individual needs or preferences, such as telehealth services and home delivery to maximize accessibility. In contrast, TW in site-based class 3 should be linked to local PrEP services, particularly if already receiving care from local health centres. Participants across classes may benefit from the availability

Table 5. Covariates table: HIV vulnerabilities associated with class membership in site-based and online arms among transgender women in the LITE Study, Eastern and Southern United States (March 2018–August 2020)

Class	Site-based arm (*N* = 577)			Online arm (*N* = 381)		
	2	**3**	**4**	**2**	**3**	**4**
	Limited strategies and insertive sex	**Limited strategies and receptive sex**	**Multiple strategies and insertive/ receptive sex**	**Limited strategies and insertive sex**	**Limited strategies and receptive sex**	**Multiple strategies and insertive/ receptive sex**
Positive STI test result (vs. negative-lifetime)	0.37 (0.10–1.42)	1.70 (0.82–3.52)	**6.69 (3.42–13.10)**	0.12 (0.00–11.33)	1.34 (0.25–7.13)	**8.46 (1.71–41.78)**
Sex work (lifetime)	0.47 (0.22–1.02)	1.18 (0.67–2.10)	**3.37 (1.93–5.89)**	0.72 (0.23–2.22)	2.10 (0.77–5.78)	**4.29 (1.42–13.02)**
Sex work (current)	0.29 (0.02–3.97)	**3.09 (1.19–8.07)**	**6.49 (2.61–16.11)**	0.46 (0.02–11.04)	4.21 (0.49–36.18)	**10.25**[a] **(1.16–90.60)**
HIV risk						
Med to high risk	0.52 (0.18–1.51)	1.67 (0.84–3.32)	**4.12 (2.17–7.80)**	0.10 (0.00–6.77)	2.39 (0.64–8.96)	**11.73 (2.98–46.13)**
Low risk	0.80 (0.40–1.59)	1.05 (0.59–1.85)	0.64 0.37–1.10)	1.66 (0.61–4.52)	1.68 (0.64–4.45)	1.61 (0.54–4.84)
No risk	0.84 (0.34–2.09)	0.65 (0.29–1.45)	0.66 (0.31–1.37)	0.88 (0.32–2.46)	0.39 (0.13–1.17)	0.42 (0.11–1.56)
No. of sex partners						
One partner	**7.75 (3.52–17.07)**	1.95 (0.98–3.85)	0.88 (0.44–1.76)	5.22 (2.00–13.61)	0.55 (0.23–1.31)	0.29 (0.10–0.88)
2–4 partners	2.04 (0.89–4.66)	**3.69 (1.85–7.39)**	**2.61 (1.33–5.13)**	–	–	–
Gender of sex partners (12 months)						
Cisgender men	**0.05 (0.02–0.15)**	**3.55 (1.23–10.22)**	**6.34 (2.59–15.50)**	–	–	–
Cisgender women	**18.45 (7.29–46.71)**	0.73 (0.29–1.83)	0.91 (0.44–1.92)	1.75 (0.70–4.35)	**0.24 (0.10–0.58)**	0.53 (0.20–1.40)
TW/NB (MAB)	2.22 (0.97–5.08)	**2.27 (1.11–4.66)**	1.50 (0.74–3.05)	3.31 (0.61–17.91)	**18.99**[a] **(3.76–95.84)**	**13.23**[a] **(2.45–71.43)**
TM/NB (FAB)	**5.68 (2.45–13.17)**	0.98 (0.40–2.42)	0.91 (0.40–2.06)	1.83 (0.64–5.26)	0.87 (0.29–2.58)	2.20 (0.71–6.86)

Note. Limited strategies and less sexually active is the reference group. Odds ratios are unadjusted. Boldface indicates significant association—CI does not contain 1.0. Positive STI test—last 3 months, zero partners, 2–4 partners (online arm only), 5+ partners and cisgender men (online arm only) did not yield robust estimates and were not included in this table. "Prefer not to answer" responses and never tested category were also included in the model when applicable. HIV risk is missing data from one participant.

[a]Unstable confidence intervals should be interpreted with caution.

Abbreviations: FAB, female assigned at birth; MAB, male assigned at birth; NB, non-binary; STI, sexually transmitted infection; TM, transgender men; TW, transgender women.

of long-acting injectable PrEP, approved by the United States Food and Drug Administration (FDA) in 2021 [41], which has the potential to address some of the barriers associated with oral PrEP, such as adherence. The probability of PEP use was low among all classes in both arms. More research is needed to understand PEP uptake/decision-making when indicated, given that increasing PEP access could increase opportunities to link and engage TW in PrEP care. Moreover, our results highlight that LCA is a tool that can inform providers and public health departments in HIV prevention efforts with TW. These findings can guide where they allocate prevention resources based on the set of manifest variables that we used to conduct the analysis. Primarily, we have identified that the manifest variables endorsed by TW in classes 3—limited strategies and receptive sex and 4—multiple strategies and insertive/receptive sex make them more vulnerable to HIV infection and should be prioritized.

One major study limitation is that the three-step covariates macro produced robust estimates when including one covariate at a time, which could be attributed to our sample size and multiple manifest variables. Adding multiple covariates of the same category as in the case of employment and region

did not converge. The inability to estimate multivariable models could have led to confounding effects. Studies with larger samples, particularly with online arms, are needed to estimate adjusted multivariable models. Although multi-site studies have greater generalizability than single-site studies, data of this subsample are not representative since we restricted inclusion to sexually active TW.

5 | CONCLUSIONS

Our findings demonstrate that sexually active TW in the Eastern and Southern United States are characterized by four distinct classes of HIV awareness and prevention strategies associated with different levels of vulnerability to HIV. Findings indicated that prevention efforts should prioritize combination strategies among TW, with a particular focus on HIV testing and PrEP. Future interventions may use algorithms derived from latent classes to target TW reached in-person or online. Honouring and acknowledging the steps TW currently take to prevent HIV and offering tailored support and services to meet HIV prevention goals will be important moving forward.

AUTHORS' AFFILIATIONS

[1]Division of Endocrinology, Diabetes, and Hypertension, Brigham and Women's Hospital, Boston, Massachusetts, USA; [2]The Fenway Institute, Fenway Health, Boston, Massachusetts, USA; [3]Harvard Medical School, Boston, Massachusetts, USA; [4]Research Department, Whitman-Walker Institute, Washington, DC, USA; [5]Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, USA; [6]Department of International Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, USA; [7]Harvard T.H. Chan School of Public Health, Boston, Massachusetts, USA

COMPETING INTERESTS

The authors report no competing interests.

AUTHORS' CONTRIBUTIONS

The following are members of the collaborative author, American Cohort to Study HIV Acquisition Among TW (LITE): Sari L. Reisner (multiple PI, Harvard University, BWH); Andrea L. Wirtz (multiple PI; JHU); Keri Althoff (JHU); Chris Beyer (JHU); James Case (JHU); Erin E. Cooney (JHU); Oliver Laeyendecker (JHU); Dee Adams (JHU); Megan Stevenson (JHU); Tonia Poteat (University of North Carolina); Kenneth H. Mayer (Fenway Health); Asa Radix (Callen-Lorde Community Health Center); Christopher M. Cannon (Whitman-Walker Institute); Jason Schneider (Emory University and Grady Hospital); J. Sonya Haw (Emory University and Grady Hospital); Allan Rodriguez (University of Miami); Andrew Wawrzyniak (University of Miami); and the LITE Community Advisory Board, including the following individuals: Flora Marques, Sherri Meeks, Sydney Shackelford, Nala Toussaint, SaVanna Wanzer, and, as well as those who have remained anonymous. ALW and SLR conceptualized and oversaw the LITE site-based and online arms; RAAR and CMC conceptualized this analysis and wrote the first draft of the manuscript; RAAR analyzed the data. RAAR, CMC, EEE, ALW, KHM, and SLR reviewed, edited, and approved the final manuscript.

ACKNOWLEDGEMENTS

The authors would like to express their gratitude to the TW who took part in this study. This study would not be possible without their participation and input. The LITE Study is also appreciative of the support from the CFAR at partner institutions, including JHU (P30AI094189), Emory University (P30AI050409), Harvard University (P30AI060354), DC CFAR (AI117970) and the University of Miami (P30AI073961).

FUNDING

Research reported in this publication was jointly supported by the National Institute of Allergy and Infectious Diseases, the National Institute of Mental Health and the National Institute of Child Health and Human Development of the National Institutes of Health under Award Number UG3/UH3AI133669 (ALW and SLR). Research reported in this publication was also supported by HIV/AIDS, Hepatitis, STD and TB Administration (HAHSTA), Washington, DC, Department of Health. A diversity supplement supports RAAR from the National Institute of Allergy and Infectious Diseases of the National Institutes of Health under Award Number (UH3AI133669-S2). EEC is supported by a predoctoral fellowship from the National Institute of Mental Health (F31MH124582).

DISCLAIMER

The content is solely the authors' responsibility and does not necessarily represent the official views of the National Institutes of Health or HAHSTA.

DATA AVAILABILITY STATEMENT

The authors confirm that all data underlying the findings are fully available upon request. Requests should be sent to the PIs, sreisner@bwh.harvard.edu and awirtz1@jhu.edu.

REFERENCES

1. Baral SD, Poteat T, Strömdahl S, Wirtz AL, Guadamuz TE, Beyrer C. Worldwide burden of HIV in transgender women: a systematic review and meta-analysis. Lancet Infect Dis. 2013;13:214–22.
2. Becasen JS, Denard CL, Mullins MM, Higa DH, Sipe TA. Estimating the prevalence of HIV and sexual behaviors among the US transgender population: a systematic review and meta-analysis, 2006–2017. Am J Public Health. 2019;109:e1-8.
3. CDC. HIV risk, prevention, and testing behaviors among transgender women—National HIV Behavioral Surveillance, 7 U.S. Cities, 2019–2020. HIV Surveillance Special Report 27. 2021. http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html. (cited 2021 September 1).
4. Neumann MS, Finlayson TJ, Pitts NL, Keatley J. Comprehensive HIV prevention for transgender persons. Am J Public Health. 2017;107:207–12.
5. Poteat T, Malik M, Scheim A, Elliott A. HIV prevention among transgender populations: knowledge gaps and evidence for action. Curr HIV/AIDS Rep. 2017;14:141–52.
6. Poteat T, Wirtz A, Malik M, Cooney E, Cannon C, Hardy WD, et al. A gap between willingness and uptake: findings from mixed methods research on HIV prevention among Black and Latina transgender women. J Acquir Immune Defic Syndr. 2019;82:131–40.
7. Schulden JD, Song B, Barros A, Mares-Delgrasso A, Martin CW, Ramirez R, et al. Rapid HIV testing in transgender communities by community-based organizations in three cities. Public Health Rep. 2008;123:101–14.
8. Koblin BA, Usher D, Nandi V, Tieu H-V, Bravo E, Lucy D, et al. Post-exposure prophylaxis awareness, knowledge, access and use among three populations in New York City, 2016–17. AIDS Behav. 2018;22:2718–32.
9. Rael CT, Martinez M, Giguere R, Bockting W, Maccrate C, Mellman W, et al. Barriers and facilitators to oral PrEP use among transgender women in New York City. AIDS Behav. 2018;22:3627–36.
10. Chandler CJ, Creasy SL, Adams BJ, Eaton LA, Bukowski LA, Egan JE, et al. Characterizing biomedical HIV prevention awareness and use among Black transgender women in the United States. AIDS Behav. 2021;25(9):2929–40.
11. Ogunbajo A, Storholm ED, Ober AJ, Bogart LM, Reback CJ, Flynn R, et al. Multilevel barriers to HIV PrEP uptake and adherence among Black and Hispanic/Latinx transgender women in Southern California. AIDS Behav. 2021;25:2301–15.
12. Doyle CM, Maheu-Giroux M, Lambert G, Mishra S, Apelian H, Messier-Peet M, et al. Combination HIV prevention strategies among Montreal gay, bisexual and other men who have sex with men in the PrEP era : a latent class analysis. AIDS Behav. 2020;25(1):269–83.
13. Hankins CA, De Zalduondo BO. Combination prevention: a deeper understanding of effective HIV prevention. AIDS. 2010;24:S70–80.
14. Joint United Nations Programme on HIV/AIDS (UNAIDS). Fast-tracking combination prevention. 2015.
15. Poteat T, Wirtz AL, Radix A, Borquez A, Silva-Santisteban A, Deutsch MB, et al. HIV risk and preventive interventions in transgender women sex workers. Lancet. 2015;385:274.

16. U.S. Statistics. HIV.gov. https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics (cited 2021 December 21).
17. Wirtz AL, Poteat T, Radix A, Althoff KN, Cannon CM, Wawrzyniak AJ, et al. American cohort to study HIV acquisition among transgender women in high-risk areas (the LITE study): protocol for a multisite prospective cohort study in the eastern and southern United States. J Med Internet Res. 2019;21:e14704.
18. Wirtz AL, Cooney EE, Stevenson M, Radix A, Poteat T, Wawrzyniak AJ, et al. Digital epidemiologic research on multilevel risks for HIV acquisition and other health outcomes among transgender women in eastern and southern United States: protocol for an online cohort. JMIR Res Protoc. 2021;10:e29152.
19. Barber TJ, Benn PD. Postexposure prophylaxis for HIV following sexual exposure. Curr Opin HIV AIDS. 2010;5:322–6.
20. Sultan B, Benn P, Waters L. Current perspectives in HIV post-exposure prophylaxis. HIV/AIDS. 2014;6:147–58.
21. Grant RM, Lama JR, Anderson PL, Mcmahan V, Liu AY, Vargas L, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. N Engl J Med. 2010;363:2587–99.
22. Grant RM, Anderson PL, Mcmahan V, Liu A, Amico KR, Mehrotra M, et al. Uptake of pre-exposure prophylaxis, sexual practices, and HIV incidence in men and transgender women who have sex with men: a cohort study. Lancet Infect Dis. 2014;14:820–9.
23. Buchbinder SP, Glidden DV, Liu AY, Mcmahan V, Guanira JV, Mayer KH, et al. HIV pre-exposure prophylaxis in men who have sex with men and transgender women: a secondary analysis of a phase 3 randomized controlled efficacy trial. Lancet Infect Dis. 2014;14:468–75.
24. Lanza S, Rhoades B. Latent class analysis: an alternative perspective on subgroup analysis in prevention and treatment. Prev Sci. 2013;14:157–68.
25. Collins L, Lanza S. Latent class and latent transition analysis; with applications in the social, behavioral, and health sciences. New York: Wiley; 2010.
26. Dawit R, Sheehan DM, Gbadamosi SO, Fennie KP, Li T, Curatolo D, et al. Identifying patterns of retention in care and viral suppression using latent class analysis among women living with HIV in Florida 2015–2017. AIDS Care - Psychol Socio-Med Asp AIDS/HIV. 2021;22:131–5.
27. Hotton AL, Perloff J, Paul J, Parker C, Ducheny K, Holloway T, et al. Patterns of Exposure to Socio-structural Stressors and HIV Care Engagement Among Transgender Women of Color. AIDS Behav. 2020;24:3155–63.
28. Swartz JA, Ducheny K, Holloway T, Stokes L, Willis S, Kuhns LM, et al. A latent class analysis of chronic health conditions among HIV-positive transgender women of color. AIDS Behav. Epub ahead of print 2021;25:52–63.
29. Lanza S, Collins L, Lemmon D, Schafer JL. PROC LCA: a SAS procedure for latent class analysis. Struct Equ Model. 2007;14:671–94.
30. SAS PROC LCA & PROC LTA - latent class analysis knowledge base. https://www.latentclassanalysis.com/software/proc-lca-proc-lta/ (cited 2021 Oct 16).
31. LCA covariates SAS macro - latent class analysis knowledge base. https://www.latentclassanalysis.com/software/lca-covariates-3-step-macro/. (cited 2021 Oct 16).
32. Dziak JJ, Bray BC, Wagner AT. %LCA_Covariates_3Step SAS Macro Users' Guide (Version 1.0). http://methodology.psu.edu. 2020. (cited 2021 Oct 16).
33. Reback CJ, Clark KA, Rünger D, Fehrenbacher AE. A promising PrEP navigation intervention for transgender women and men who have sex with men experiencing multiple syndemic health disparities. J Community Health. 2019;44:1193–203.
34. Crosby R, Salazar L, Hill B. Gender affirmation and resiliency among Black transgender women with and without HIV infection. Transgend Health. 2016;1:86–93.
35. Ramirez-Valles. The protective effects of community involvement for HIV risk behavior: a conceptual framework. Health Educ Res. 2002;17:389–403.
36. Wood SM, Ratcliffe S, Gowda C, Lee S, Dowshen NL, Gross R. Impact of insurance coverage on HIV transmission potential among antiretroviral therapy-treated youth living with HIV. AIDS. 2018;32:895.
37. Malone J, Reisner SL, Cooney EE, Poteat T, Cannon CM, Schneider JS, et al. Perceived HIV acquisition risk and low uptake of PrEP among a cohort of transgender women with PrEP indication in the eastern and southern United States. J Acquir Immune Defic Syndr. 2021;88:8–10.
38. Hamnvik O-PR, Agarwal S, AhnAllen CG, Goldman AL, Reisner SL. Telemedicine and inequities in health care access: the example of transgender health. Transgend Health. 2022;7(2):113–68.
39. Stewar MK, Allison MK, Grant Hunthrop MS, Marshall SA, Cornell CE. Outcomes research on telemedicine-delivered gender-affirming health care for transgender youth is needed now: a call to action. Transgend Health. Epub ahead of print. 2021;1–5.
40. Lippman SA, Moran L, Sevelius J, Castillo LS, Ventura A, Treves-Kagan S, et al. Acceptability and feasibility of HIV self-testing among transgender women in San Francisco: a mixed methods pilot study. AIDS Behav. 2016;20:928–38.
41. FDA. FDA approves first injectable treatment for HIV pre-exposure prevention. https://www.fda.gov/news-events/press-announcements/fda-approves-first-injectable-treatment-hiv-pre-exposure-prevention (cited 2021 December 28).

SUPPORTING INFORMATION

Additional information may be found under the Supporting Information tab for this article:

Table S1. Measures for covariates included in latent class analysis models in the LITE Study of transgender women in the Eastern and Southern United States (*N* = 958).

Table S2. Goodness-of-fit criteria for competing latent class models among transgender women in the LITE Study, Eastern and Southern United States (*N* = 958).

Table S3. Gender-affirming characteristics of sexually active transgender women in the LITE Study, Eastern and Southern United States (*N* = 958).

Table S4. HIV vulnerabilities of sexually active transgender women in the LITE Study, Eastern and Southern United States (*N* = 958).

Table S5. Item-response probabilities for four-class model: the probability of endorsing each HIV awareness and prevention item-site based among transgender women in the LITE Study, Eastern and Southern United States (*N* = 577).

Table S6. Item-response probabilities for four-class model: the probability of endorsing each HIV awareness and prevention item online among transgender women in the LITE Study, Eastern and Southern United States (*N* = 381).

JIAS JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

RESEARCH ARTICLE

Factors associated with long-term HIV pre-exposure prophylaxis engagement and adherence among transgender women in Brazil, Mexico and Peru: results from the ImPrEP study

Kelika A. Konda[1,§,§], Thiago S. Torres[2,§], Gabriela Mariño[1], Alessandra Ramos[2,¥], Ronaldo I. Moreira[2], Iuri C. Leite[3], Marcelo Cunha[3], Emilia M. Jalil[2], Brenda Hoagland[2], Juan V. Guanira[1], Marcos Benedetti[2], Cristina Pimenta[4], Heleen Vermandere[5], Sergio Bautista-Arredondo[5], Hamid Vega-Ramirez[6], Valdilea G. Veloso[2], Carlos F. Caceres[1], Beatriz Grinsztejn[2] and for the ImPrEP Study Group

[§]**Corresponding author**: Kelika A. Konda, Universidad Peruana Cayetano Heredia, Centro de Investigaciones Interdisciplinaria en Salud, Sexualidad, y SIDA, Av. Armendariz 445, Lima 15047, Peru. (kelika.konda@upch.pe)
[§]Contributed equally and joint first authors.
[¥]*In memoriam*.

Abstract

Introduction: The HIV epidemic continues to disproportionately impact Latin-American transgender women (TGW). We assessed factors associated with long-term pre-exposure prophylaxis (PrEP) engagement and adherence among TGW enrolled in the Implementation of PrEP (ImPrEP) study, the largest PrEP demonstration study in Latin America.

Methods: HIV-negative TGW aged ≥18 years reporting 1+eligibility criteria in the 6 months prior to enrolment (e.g. sex partner known to be living with HIV, condomless anal sex [CAS], transactional sex or having a sexually transmitted infection [STI]) who could safely take PrEP were enrolled. Follow-up visits were conducted at 4 weeks and then quarterly. We conducted logistic regression to identify factors associated with long-term PrEP engagement (3+ follow-up visits in 52 weeks) and complete self-reported adherence (no missed pills in the past 30 days) during follow-up. For both outcomes, we constructed multivariable models controlling for country, socio-demographics, sexual behaviour, substance use, STIs and self-reported adherence at 4 weeks (long-term engagement outcome only).

Results: From March 2018 to June 2021, ImPrEP screened 519 TGW, enrolled 494 (Brazil: 190, Mexico: 66 and Peru: 238) and followed them for 52 weeks. At baseline, 27.5% of TGW were aged 18–24 years, 67.8% were mixed-race and 31.6% had >secondary education. Most, 89.9% reported CAS, 61.9% had >10 sex partners and 71.9% reported transactional sex. HIV incidence was 1.82 cases per 100 person-years (95% confidence interval [CI]: 0.76–4.38). Almost half of TGW (48.6%) had long-term PrEP engagement, which was positively associated with reporting complete adherence at week 4 (aOR:2.94 [95%CI:1.88–4.63]) and was inversely associated with reporting CAS with unknown-HIV partner (aOR:0.52 [95%CI:0.34–0.81]), migration (aOR:0.54 [95%CI:0.34–0.84]), and being from Mexico (aOR:0.28 [95%CI:0.14–0.53]). Self-reported adherence was associated with TGW aged >34 (aOR:1.61 [95%CI:1.10–2.34]) compared to those aged 25–34 and those with >secondary education (aOR:1.55 [95%CI:1.10–2.19]) and was lower among TGW from Peru (aOR:0.29 [95%CI:0.21–0.41]) or reporting PrEP-related adverse effects (aOR:0.63 [95%CI:0.42–0.92]).

Conclusions: Although TGW were willing to enrol in ImPrEP, long-term PrEP engagement and complete self-reported adherence were limited, and HIV incidence remained relatively high. A successful HIV prevention agenda should include trans-specific interventions supporting oral PrEP and exploring long-acting PrEP strategies for TGW.

Keywords: pre-exposure prophylaxis; transgender persons; HIV; Latin America; medication adherence; public health

Received 8 January 2022; **Accepted** 19 July 2022

1 | INTRODUCTION

HIV infection disproportionately impacts transgender women (TGW) worldwide, with HIV prevalence being 50 times greater than adults of reproductive age in low- and middle-income countries (LMICs), such as those in Latin America [1–3]. The HIV prevalence among TGW in Latin America was estimated at 25.9% [4], 32–49% in Brazil [5], 20–64% in Mexico [6] and 30% in Peru [7]. This increased vulnerability is caused by substantial social marginalization and isolation

experienced by TGW, leading to poverty, lower education and exclusion from the formal labour market [8], leading to high rates of sex work [6, 9–11]. In Brazil, Mexico and Peru, TGW also experience substantial violence [11–14], internalized stigma and fear of discrimination [15, 16] and increased burdens of mental health and substance abuse [17]. These vulnerabilities can also influence their health-seeking behaviour and engagement in HIV prevention services. Moreover, these services often do not have the resources to truly address the needs of this population [18].

Daily oral pre-exposure prophylaxis (PrEP) with tenofovir disoproxil fumarate 300 mg (TDF) combined with emtricitabine 200 mg (FTC) has been demonstrated to prevent HIV infection [19]. Still, it is highly dependent on pill adherence and engagement in prevention services [20, 21]. A sub-analysis of TGW included in the iPrEx study yielded no difference in HIV acquisition between study arms (PrEP vs. placebo); however, PrEP was efficacious in preventing HIV among TGW who were adherent to daily oral PrEP as measured by drug levels [22]. Questions remain on the interactions between feminizing hormone therapy (FHT) and PrEP among TGW, with studies showing decreased levels of TDF/FTC among FHT users [23–25], or lack of interaction [26]. The vulnerability of TGW to HIV makes their use of PrEP of vital importance [27–29]. However, few TGW have been engaged in HIV prevention services [5, 30] or PrEP studies [31], hindering the possibility of meaningful analysis [32], despite high willingness to use PrEP [33–35]. In addition, PrEP studies have shown low PrEP continuation among TGW [36]. Research has highlighted the need for PrEP programmes to specifically address the needs of trans populations, including TGW [31, 37–39]. However, efforts towards this end have been limited [3].

Although daily oral PrEP was recommended in 2014 by the World Health Organization, PrEP availability has been limited in Latin America [29, 40]. PrEP has been available within Brazil's Public Health System (SUS) since 2017, Mexico since 2021 [41], but remains accessible only via purchase or through limited demonstration studies in Peru. The Implementation of PrEP (ImPrEP) study is the largest PrEP demonstration study in Latin America and aims to evaluate the feasibility of PrEP implementation among gay, bisexual and other cisgender men who have sex with men (MSM) and TGW in the context of the Public Health Systems of Brazil, Mexico and Peru. This analysis aims to assess the factors associated with long-term PrEP engagement and self-reported adherence among TGW enrolled in the ImPrEP study.

2 | METHODS

2.1 | Study design and participants

ImPrEP was a prospective, single arm, open-label, multicentre study that assessed same-day oral PrEP implementation in Brazil (14 sites in 12 cities), Mexico (4 sites in 3 cities) and Peru (10 sites in 6 cities). Inclusion criteria were HIV-negative MSM and TGW, aged ≥18 years and at least one of the following in the prior 6 months: condomless anal sex (CAS), anal sex with partner(s) known to be living with HIV, sexual transmitted infections (STIs) signs/symptoms or diagnosis, or transactional sex. Participants were enrolled from March 2018 to December 2020. This analysis only includes participants self-identified as women, *travestis* [12, 33, 42] or TGW who had time to complete 52 weeks of follow-up by 30th June 2021 (data extraction).

Institutional review board (IRB) in each country approved the study: in Brazil, INI Evandro Chagas-FIOCRUZ IRB (#CAAE:79259517.5.1001.5262) and local IRB at each Brazilian site; in Mexico, National Institute of Public Health IRB (#CI-1515); and in Peru, Universidad Peruana Cayetano Heredia IRB (#100740). All study participants provided written informed consent before initiating any study procedure. The study was registered at the Brazilian Registry of Clinical Trials (ReBEC:20-Aug-2018, ID RBR-4x3cnp, UTN code: U1111-1217-6021).

2.2 | Study procedures

Participants were recruited through social media advertisements, peer/healthcare provider referrals and through MSM/TGW peer-educators at each site. We also offered enrolment to individuals seeking PrEP or HIV/STI testing. Potentially eligible individuals were screened using laboratory, clinical and risk criteria and enrolled to receive same-day oral PrEP [43]. HIV viral load and serum creatinine clearance (CrCl) were evaluated at enrolment. Participants were contacted to discontinue PrEP and return to the site in case of acute HIV infection (detectable HIV viral load) or CrCl<60 ml/minute [44]. Follow-up visits were scheduled at week 4 and quarterly thereafter, for a total of five planned follow-up visits in 52 weeks. Given restrictions due to the COVID-19 pandemic during 2020 and 2021 [45–47], the total number of visits and the visit intervals were impacted. At each visit, participants received TDF/FTC refills according to the next scheduled visit interval. Individuals who returned more than 24 weeks after any visit were required to re-enrol in the study.

Data on demographics, prior post-exposure prophylaxis (PEP) use (past 12 months), indication for PEP and the main reason for attending the service were assessed at enrolment. Participants also reported information on sexual behaviour and substance use at enrolment and quarterly visits. Self-reported adherence and symptoms related to PrEP use were assessed at follow-up visits. HIV rapid tests were performed every visit; HIV confirmatory testing was conducted as needed.

2.3 | Study definitions

Age was described as median and interquartile range (IQR) and in categorical ranges of 18–24, 25–34 and >34 years. We categorized self-reported race/skin colour as White, Black, Indigenous, Asian and Mixed-race (*Pardo* or *Mestizo*); however, as these categories are distinct by country, they were dichotomized into white versus any other race. We used the following education categories: primary or less (complete or incomplete), secondary (complete or incomplete) and more than secondary. Individuals born in a state or country different from the implementation site were considered as migrants. Main reason to attend the service was stratified as

seeking PrEP and other (seeking an HIV test, other health service or PEP).

Sexual behaviour was assessed with the questions: number of cisgender men or/and TGW sexual partners (described with median and IQR, categorized into <5, 5–10 and >10 for analyses), any CAS (yes/no), receptive CAS (yes/no), CAS with partner(s) known to be living with HIV (yes, no or I don't know) and transactional sex (sex in exchange for money, drugs, gifts or favours; yes/no). Binge drinking was assessed with the question: "Did you have five or more drinks within a two-hour period?" (yes/no) [48]. Stimulant use was considered use of any of the following: club drugs (e.g. ecstasy, LSD and GHB), cocaine (powder, crack or base). PrEP-related gastrointestinal symptoms were defined as any of the following: diarrhoea, flatulence, nausea, vomit, abdominal pain or other. At enrolment, questions on sexual behaviour referred to the previous 6 months, while number of sex partners in Brazil and Mexico and substance use referred to the previous 3 months. At quarterly visits, all questions referred to the previous 3 months. At the 4-week visit, any PrEP-related symptom(s) referred to the previous 30 days; at other visits, this information dated back to the period since the last visit.

2.4 | Outcomes

We evaluated two main outcomes: long-term PrEP engagement and complete self-reported adherence. Long-term PrEP engagement was defined as attendance at the 4-week visit and two or more quarterly visits within a 52-week period. As most participants attending these three visits would have received 210 PrEP pills (30 pills at enrolment and 90 pills at each follow-up visit), this would be enough for achieving highly protective levels of tenofovir diphosphate (4 pills per week for 52 weeks) [20]. Participants' self-reported adherence was assessed at every follow-up visit with the question: "In the previous 30 days, approximately how many pills did you NOT take?" Those who answered zero were considered as having complete self-reported adherence, as a previous analysis estimated "zero" as the self-reported PrEP adherence cut-off equivalent to highly protective levels of tenofovir diphosphate [49, 50]. Individuals who re-enrolled in the study completed the initial study assessment, which did not include an adherence question. Re-enrolled individuals were classified as non-adherent as the quantity of pills received in their prior visit (30 or 90) would have been insufficient to cover the period that they were absent from the study.

2.5 | Statistical analysis

We described TGW's characteristics at enrolment, long-term PrEP engagement and self-reported adherence overall and according to country. We censored participants at study withdrawal or on 30th June 2021. HIV incidence was calculated based on the number of new HIV cases detected during the follow-up overall and stratified by country and age.

We used logistic regression to identify initial enrolment factors associated with long-term PrEP engagement. Potential predictors included baseline socio-demographic and behavioural characteristics, such as country, age group, race, education, main reason to attend the service, migration, number of sex partners, any CAS, receptive CAS, CAS with partner known to be living with HIV, transactional sex, binge drinking, stimulant use and self-reported adherence at week 4. Individuals who did not return to follow-up visits were considered non-adherent. We evaluated PrEP-related gastrointestinal symptoms in bivariate analysis, but not in the multivariable model as this variable is only available for individuals returning to a week 4 visit, which would modify the analytic sample. In the initial model, the effect of each variable was controlled by country and all statistically significant variables at a p-value ≤0.1 were included in the final adjusted model.

To account for correlated measures within participants, we used logistic generalized estimating equation models to identify factors associated with complete self-reported adherence at each post-enrolment visit completed by the study participants over the 52 weeks. We used the same potential predictors considered in the long-term PrEP engagement analysis allowing behavioural characteristics and symptoms related to PrEP to be included as time-varying variables. In the initial models, the effect of each variable was controlled by country and study visit. All variables statistically significant at p-value ≤0.1 were included in the final adjusted model. All analyses were conducted in R version 4.1.1 [51].

3 | RESULTS

A total of 9979 individuals were screened, 559 (5.6%) TGW. Of these, 543 were enrolled and 494 were followed for at least 52 weeks and included in this analysis (Brazil: 190, Mexico: 66 and Peru: 238) (Figure 1). Reasons for ineligibility included HIV infection at screening/enrolment (one acute and 16 chronic HIV infections), referral for PEP, adherence concerns (clinician thought the person would not be adherent to PrEP) and clinical concerns (other clinical condition, such as untreated tuberculosis or diabetes) (Figure 1). During follow-up, 32 individuals were re-enrolled, their additional visits were included in our analysis.

Among the 494 TGW included in this analysis, median age was 29 years (IQR: 24, 36); 27.5% aged 18–24 years. Most were mixed race (67.8%), had secondary education (58.7%), had not migrated (70.2%), attended the service seeking PrEP (65.4%) and most (71.9%) reported transactional sex. Median number of sex partners was 25 (IQR: 5, 100), and 61.9% reported >10 partners. The majority reported CAS (89.9%) and CAS with partner with unknown HIV status (64.8%), while 4.0% reported CAS with partner known to be living with HIV. Binge drinking and stimulant use were reported by 67.8% and 20.2%, respectively (Table 1).

Overall, TGW were followed-up for 274.5 person-years and five HIV seroconversions occurred resulting in an overall HIV incidence rate of 1.82 (95% CI: 0.76–4.38) per 100 person-years. The HIV incidence rate was 3.80 (95% CI: 1.58–9.13) in Peru, while no HIV cases were observed in Brazil or Mexico. Incidence rate among TGW aged 18–24 and 25–34 years was twice as high compared to TGW aged >34 years (Table 2).

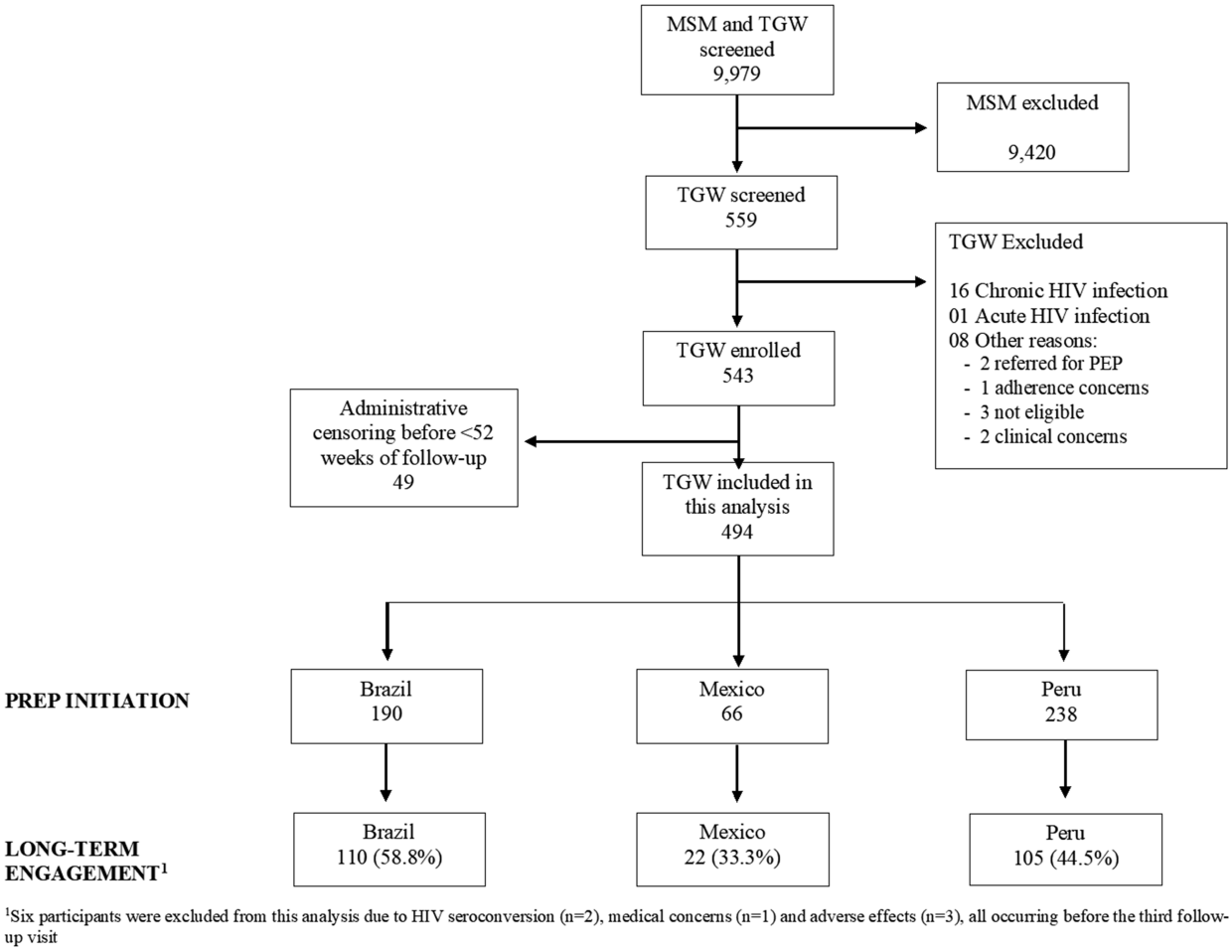


Figure 1. Study flow chart. Abbreviations: MSM, men who have sex with men; PrEP, pre-exposure prophylaxis: TGW, transgender women.

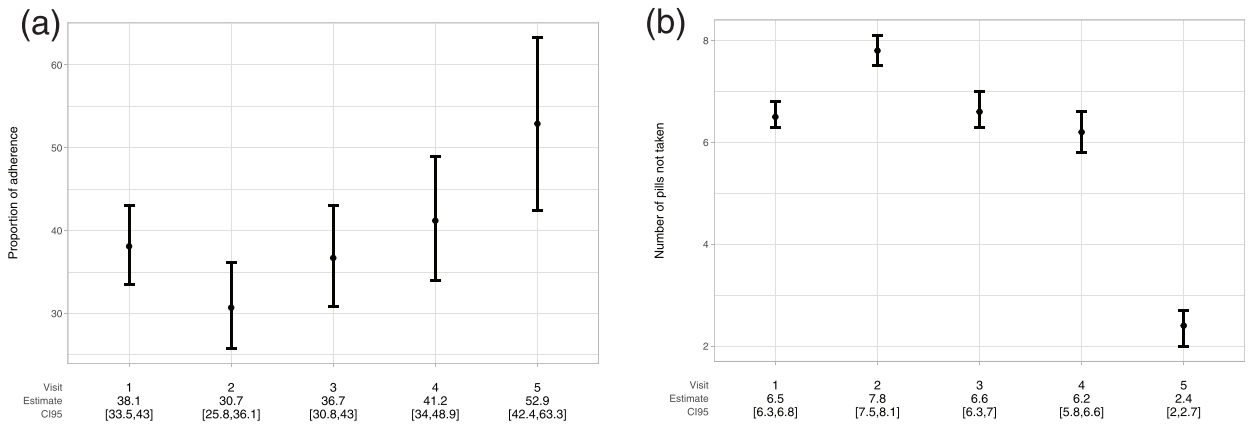


Figure 2. (a) Proportion of complete self-reported adherence. (b) Number of PrEP pills not taken by visit.

Overall, 101 (20.5%) TGW attended one follow-up visit, 66 (13.4%) two, 72 (14.6%) three, 80 (16.2%) four, while only 85 (17.2%) completed all five visits. A total of 237 (48.6%) had long-term PrEP engagement, higher in Brazil (58.8%) than Peru (44.7%) and Mexico (33.3%). Complete self-reported PrEP adherence increased over time among TGW who attended follow-up visits (38.1% [95% CI: 33.5–43.0] at visit 1 (4 weeks) vs. 52.9% [95% CI: 42.4–63.3] at visit 5 (~52 weeks); Figure 2a). Similarly, the number of pills not taken decreased during follow-up (6.5 [95% CI: 6.3–6.8]

Table 1. Characteristics at enrolment, long-term PrEP engagement and complete self-reported adherence at week 4 among TGW according to country

	Total *N* = 494 (%)	Brazil *N* = 190 (%)	Mexico *N* = 66 (%)	Peru *N* = 238 (%)	*p* Value[h]
Age (Years)					0.013
Median (IQR)	29 (24, 36)	28 (23, 34)	28 (24, 34)	31 (25, 38)	
18–24	136 (27.5)	62 (32.6)	19 (28.8)	55 (23.1)	
25–34	208 (42.1)	84 (44.2)	31 (47.0)	93 (39.1)	
>34	150 (30.4)	44 (23.2)	16 (24.2)	90 (37.8)	
Race or skin colour					<0.001
White	106 (21.5)	70 (36.8)	6 (9.1)	30 (12.6)	
Black	42 (8.5)	21 (11.1)	2 (3.0)	19 (8.0)	
Mixed-race (*Pardo* or *Mestizo*)	335 (67.8)	95 (50.0)	58 (87.9)	182 (76.5)	
Asian	2 (0.4)	2 (1.1)	0 (0.0)	0 (0.0)	
Indigenous	9 (1.8)	2 (1.1)	0 (0.0)	7 (2.9)	
Education					
Primary (complete or incomplete)	48 (9.7)	20 (10.5)	7 (10.6)	21 (8.8)	<0.001
Secondary (complete or incomplete)	290 (58.7)	106 (55.8)	22 (33.3)	162 (68.1)	
More than secondary	156 (31.6)	64 (33.7)	37 (56.1)	55 (23.1)	
Gender identity					<0.001
Transgender woman	377 (76.3)	130 (68.4)	64 (97.0)	183 (76.9)	
Travesti	66 (13.4)	34 (17.9)	1 (1.5)	31 (13.0)	
Woman	51 (10.3)	26 (13.7)	1 (1.5)	24 (10.1)	
Migration					0.010
Yes	141 (29.8)	51 (29.1)	10 (15.4)	80 (34.3)	
No	332 (70.2)	124 (70.9)	55 (84.6)	153 (65.7)	
Main reason to attend the service					<0.001
Seeking PrEP	323 (65.4)	177 (93.2)	61 (92.4)	85 (35.7)	
Other	171 (34.6)	13 (6.8)	5 (7.6)	153 (64.3)	
PEP use[a]					<0.001
Yes	64 (13.0)	55 (28.9)	8 (12.1)	1 (0.4)	
No	430 (87.0)	135 (71.1)	58 (87.9)	237 (99.6)	
Number of cisgender men or/and TGW sex partners[b]					0.026
Median (IQR)	25 (5, 100)	33 (5, 158)	20 (9, 60)	20 (5, 60)	
<5	104 (21.1)	39 (20.5)	7 (10.6)	58 (24.4)	
5–10	84 (17.0)	26 (13.7)	18 (27.3)	40 (16.8)	
>10	306 (61.9)	125 (65.8)	41 (62.1)	140 (58.8)	
CAS[c]					
Yes	444 (89.9)	168 (88.4)	53 (80.3)	223 (93.7)	0.006
No	50 (10.1)	22 (11.6)	13 (19.7)	15 (6.3)	
Receptive CAS[c]					
Yes	424 (85.8)	160 (84.2)	50 (75.8)	214 (89.9)	0.011
No	70 (14.2)	30 (15.8)	16 (24.2)	24 (10.1)	
CAS with partner known to be living with HIV[c]					0.400
Yes	20 (4.0)	11 (5.8)	3 (4.5)	6 (2.5)	
No	154 (31.2)	54 (28.4)	21 (31.8)	79 (33.2)	
I don't know	320 (64.8)	125 (65.8)	42 (63.6)	153 (64.3)	
Transactional sex[c]					0.200
Yes	355 (71.9)	133 (70.0)	54 (81.8)	168 (70.6)	
No	139 (28.1)	57 (30.0)	12 (18.2)	70 (29.4)	

(*Continued*)

Table 1. (Continued)

	Total N = 494 (%)	Brazil N = 190 (%)	Mexico N = 66 (%)	Peru N = 238 (%)	p Value[h]
Binge drinking[d]					<0.001
Yes	333 (67.7)	114 (60.6)	34 (51.5)	185 (77.7)	
No	159 (32.3)	74 (39.4)	32 (48.5)	53 (22.3)	
Stimulant use[d,e]					0.002
Yes	100 (20.2)	48 (25.3)	19 (28.8)	33 (13.9)	
No	394 (79.8)	142 (74.7)	47 (71.2)	205 (86.1)	
Long-term PrEP engagement[f]					<0.001
Yes	237 (48.6)	110 (58.8)	22 (33.3)	105 (44.5)	
No	251 (51.4)	77 (41.2)	44 (66.7)	131 (55.5)	
Early continuation (attending 4-week visit within the initial 60 days of follow-up)					0.001
Yes	341 (69.0)	149 (78.4)	46 (69.7)	146 (61.3)	
No	153 (31.0)	41 (21.6)	20 (30.3)	92 (38.7)	
Complete self-reported PrEP adherence (week 4)[g]					<0.001
Yes	154 (31.2)	79 (41.6)	24 (36.4)	51 (21.4)	
No	340 (68.8)	111 (58.4)	42 (63.6)	187 (78.6)	
Any PrEP-related gastrointestinal symptoms (week 4)[h]					0.036
Yes	170 (43.1)	80 (50.3)	16 (32.0)	74 (40.0)	
No	224 (56.9)	79 (49.7)	34 (68.0)	111 (60.0)	

[a]Last 12 months.
[b]For Brazil and Mexico: last 6 months, for Peru: last 3 months.
[c]Last 6 months.
[d]Last 3 months.
[e]Stimulant use was defined as use of any: club drugs (e.g. ecstasy, LSD and GHB), cocaine (powder, crack or paste).
[f]Attending the 4-week visit and two or more visits in 52 weeks of follow-up.
[g]Report of missing any pill in the previous 30 days.
[h]Measured among the *n* = 395 (80.0%) of individuals who returned for a 4-week visit.
[i]Fisher's exact test for count data with simulated *p*-value.
Source: ImPrEP Study (2018–2021).
Abbreviations: CAS, condomless anal sex; IQR, interquartile range; PrEP, pre-exposure prophylaxis; TGW, transgender women.

Table 2. PrEP use and HIV incidence overall and stratified per country and age

	HIV infection, *n*	Person-years of follow-up	Incidence rate per 100 person-years (95% CI)
Overall	5	274.5	1.82 (0.59–4.25)
Country			
Brazil	0	116.4	0.00 (0.00–3.17)
Mexico	0	26.5	0.00 (0.00–13.92)
Peru	5	131.6	3.80 (1.23–8.87)
Age (years)			
18–24	2	72.3	2.77 (0.34–9.99)
25–34	3	110.3	2.72 (0.56–7.95)
>34	0	91.9	0.00 (0.00–4.01)

Abbreviations: CI, confidence interval; PrEP, pre-exposure prophylaxis.

pills at visit 1 vs. 2.4 [95% CI: 2.0–2.7] at visit 5; Figure 2b). PrEP-related gastrointestinal symptoms at week 4 were reported by 43.1%, with higher proportion among Brazilian TGW (50.3%).

In the final multivariate model, long-term PrEP engagement was higher among TGW who had complete self-reported PrEP adherence at week 4 (aOR: 2.94 [95% CI: 1.88–4.63]) (Table 3). Long-term engagement was lower among TGW reporting CAS with partner(s) of unknown HIV status (aOR: 0.52 [95% CI: 0.34–0.81]), who had migrated (aOR: 0.54 [95% CI: 0.34–0.84]) and were from Mexico (aOR: 0.28 [95% CI: 0.14–0.53]). After adjustment, more than secondary education and seeking PrEP as the main reason to attend the service were no long significant. However, the direction of the association remained the same and both had borderline p-values and confidence intervals.

In the final multivariate model, complete self-reported PrEP adherence was lower among Mexican (aOR: 0.48 [95% CI: 0.28–0.82]) and Peruvian TGW (aOR: 0.29 [95% CI: 0.21–0.41]) compared to those from Brazil. TGW reporting PrEP-related symptoms also had lower self-reported adherence (aOR: 0.63 [95% CI: 0.42–0.92]). TGW aged

Table 3. Factors associated with long-term PrEP engagement

	Long-term PrEP engagement[a]		Bivariate analyses		Multivariate analysis	
	Yes *N* = 237 (%)	No *N* = 251 (%)	OR (95% CI)	*p*-value	aOR (95% CI)	*p*-value
Country						
Brazil	110 (58.8)	77 (41.2)	Ref.	Ref.		
Mexico	22 (33.3)	44 (66.7)	**0.35 (0.19, 0.62)**	**<0.001**	**0.28 (0.14, 0.53)**	**<0.001**
Peru	105 (44.5)	130 (55.5)	**0.57 (0.38, 0.83)**	**0.004**	0.91 (0.54, 1.56)	0.740
Age (years)						
18–24	58 (43.3)	76 (56.7)	0.81 (0.52, 1.27)	0.360	0.89 (0.55, 1.46)	0.650
25–34	97 (47.1)	109 (52.9)	Ref.	Ref.	Ref.	
>34	82 (55.8)	66 (44.6)	1.49 (0.97, 2.31)	0.070	1.22 (0.75, 1.97)	0.430
Race or skin colour						
Other race	179 (46.6)	205 (53.4)	0.87 (0.55, 1.39)	0.560	NA	NA
White	58 (55.8)	46 (44.2)	Ref.	Ref.	NA	NA
Education						
Primary (complete or incomplete)	17 (37.0)	29 (63.0)	0.73 (0.37, 1.39)	0.340	0.93 (0.44, 1.92)	0.850
Secondary (complete or incomplete)	128 (44.6)	159 (55.4)	Ref.	Ref.	Ref.	Ref.
More than secondary	92 (59.4)	63 (40.6)	**2.05 (1.35, 3.14)**	**<0.001**	1.55 (0.98, 2.46)	0.063
Migration						
Yes	53 (38.7)	84 (61.3)	**0.55 (0.36, 0.83)**	**0.005**	**0.54 (0.34, 0.84)**	**0.007**
No	171 (51.8)	159 (48.2)	Ref.	Ref.	Ref.	Ref.
Main reason to attend the service						
Searching for PrEP	171 (53.4)	149 (46.6)	**1.82 (1.13, 2.95)**	**0.014**	1.59 (0.95, 2.67)	0.081
Other	66 (39.3)	102 (60.7)	Ref.	Ref.	Ref.	Ref.
Number of cisgender man or/and TGW sex partners[b]						
<5	54 (52.9)	48 (47.1)	Ref.	Ref.	NA	NA
5–10	46 (55.4)	37 (44.6)	1.24 (0.68, 2.26)	0.480	NA	NA
>10	137 (45.2)	166 (54.8)	0.73 (0.46, 1.16)	0.190	NA	NA
CAS[c]						
Yes	217 (49.3)	223 (50.7)	1.34 (0.72, 2.53)	0.360	NA	NA
No	20 (41.7)	28 (58.3)	Ref.	Ref.	NA	NA
Receptive CAS[c]						
Yes	208 (49.4)	213 (50.6)	1.26 (0.74, 2.16)	0.400	NA	NA
No	29 (43.3)	38 (56.7)	Ref.	Ref.	NA	NA
CAS with partner(s) known to be living with HIV[c]						
Yes	13 (65.0)	7 (35.0)	1.22 (0.46, 3.47)	0.700	0.98 (0.33, 3.08)	0.970
No	87 (58.0)	63 (42.0)	Ref.	Ref.	Ref.	Ref.
I don't know	137 (43.1)	181 (56.9)	**0.52 (0.35, 0.78)**	**0.002**	**0.52 (0.34, 0.81)**	**0.004**
Transactional sex[c]						
Yes	158 (45.3)	191 (54.7)	**0.65 (0.43, 0.97)**	**0.038**	0.96 (0.60, 1.52)	0.85
No	79 (56.8)	60 (43.2)	Ref.	Ref.	Ref.	Ref.
Binge drinking[d]						
Yes	158 (47.7)	173 (52.3)	0.92 (0.62, 1.36)	0.660	NA	NA
No	79 (50.3)	78 (49.7)	Ref.	Ref.	NA	NA
Stimulant use[d,e]						
Yes	49 (49.0)	51 (51.0)	0.98 (0.62, 1.55)	0.940	NA	NA
No	188 (48.5)	200 (51.5)	Ref.	Ref.	NA	NA

(*Continued*)

Table 3. (Continued)

	Long-term PrEP engagement[a]		Bivariate analyses		Multivariate analysis	
	Yes N = 237 (%)	No N = 251 (%)	OR (95% CI)	*p*-value	aOR (95% CI)	*p*-value
Complete self-reported PrEP adherence at week 4[f]						
Yes	104 (67.5)	50 (32.5)	**3.09 (2.05, 4.72)**	**<0.001**	**2.94 (1.88, 4.63)**	**<0.001**
No	133 (39.8)	201 (60.2)	Ref.	Ref.	Ref.	Ref.

Bold indicates $p < 0.05$.
Abbreviations: CAS, condomless anal sex; CI, confidence interval; OR, odds ratio; PrEP, pre-exposure prophylaxis; TGW, transgender women.
[a]Attending the 4-week visit and two or more visits in 52 weeks of follow-up. Six participants were excluded from this analysis due to HIV seroconversion ($n = 2$), medical concerns ($n = 1$) and adverse effects ($n = 3$), all occurring before the third follow-up visit.
[b]For Brazil and Mexico: last 3 months, for Peru: last 6 months.
[c]Last 6 months.
[d]Last 3 months.
[e]Stimulant use was defined as use of any: club drugs (e.g. ecstasy, LSD and GHB), cocaine (powder, crack or paste).
[f]Report of any missing pill in the previous 30 days.

>34 years (aOR: 1.61 [95% CI: 1.10–2.34]) compared to those aged 25–34 years; TGW reporting CAS with a partner of unknown HIV status also had higher self-reported adherence (aOR: 1.47 [95% CI: 1.01–2.12]; and those who completed more than secondary education (aOR: 1.55 [95% CI: 1.10–2.19]) compared to secondary education had higher odds of complete self-reported PrEP adherence (Table 4).

4 | DISCUSSION

TGW enrolled in the ImPrEP study were able to safely initiate same-day oral PrEP. The ImPrEP study is the first to evaluate PrEP implementation among Latin-American TGW and includes a large cohort of TGW, the largest in LMICs with results reported separately from MSM to our knowledge. Long-term PrEP engagement and self-reported adherence were low and associated with underlying socio-demographic characteristics, such as age and education. Our data corroborate the finding that early adherence as measured by self-report at week 4 is associated with higher likelihood of long-term PrEP engagement [31]. Although HIV prevalence among TGW is high in Latin America, no HIV incident cases were observed in Brazil and Mexico in a context with PrEP availability at no cost to the user. Conversely, HIV incidence in Peru was high, especially among younger TGW.

In our analysis, less than half of TGW (47.6%) remained engaged in PrEP over the year of follow-up, lower than observed for MSM included in the ImPrEP study ($p<0.001$) [52] and reflecting long-term PrEP engagement among TGW in past studies [31, 36]. Long-term PrEP engagement was lower in Mexico, while complete self-reported PrEP adherence was lower in Peru, indicating gaps in PrEP services in these settings. Peru and Mexico have adopted trans-specific guidelines for care [37, 53], but the promises of services tailored to the needs of TGW remain a goal rather than a reality. More than half of TGW (49/89, 55%) enrolled in a Peruvian study to provide support for PrEP users were lost to follow-up in a short period (3 months) [36]. In Brazil, high retention (111/130, 85%) was observed in the PrEParadas study, a PrEP demonstration study designed for TGW, including gender-affirming care environment implemented at the study site and TGW peer-educators [39]; nonetheless, PrEP adherence decreased over time, especially among TGW with lower education [39]. TGW consistently have more difficulties in engaging in prevention and treatment services, reflecting their underlying vulnerabilities and the poor adaptation of services to their needs. Novel HIV prevention strategies will only succeed if health services are acceptable and accessible to TGW [3].

Although long-term PrEP engagement and self-reported PrEP adherence are related outcomes, the variables associated with each were distinct. Self-reported PrEP adherence was higher among TGW with post-secondary education. Lower education was previously associated with low PrEP adherence among Brazilian TGW [39]. Education level is also an important aspect related to HIV outcomes among people living with HIV [54, 55]. Notably, long-term PrEP engagement was lower among TGW who had migrated. Internal and external migration seeking better opportunities is common in LMICs. TGW usually migrate to larger cities probably aiming for less stigma and more life opportunities [56]. In a Brazilian study that enrolled 345 TGW, 40% were internal migrants [30]. Although we have not measured income in this study, these results suggest that additional social and financial support might increase PrEP adherence and engagement among TGW with high socio-economic vulnerability.

Interest in PrEP, based on complete adherence at the week 4 visit was associated with long-term PrEP engagement. Additionally, PrEP as the main reason for attending the service was borderline significant. In South Africa, PrEP education emerged as an urgent matter for TGW [57]. Expanding PrEP literacy among TGW communities, including knowledge about PrEP benefits, duration of side effects and importance of adherence, is essential for achieving better PrEP outcomes. Targeted adherence-supporting interventions and peer support activities may be especially important [36] for TGW who are offered PrEP but were not looking for PrEP, those who are younger and with lower education levels, helping

Table 4. Factors associated with complete self-reported adherence during the study

	Bivariate analyses		Multivariate analysis	
	OR (95% CI)	*p*-value	aOR (95% CI)	*p*-value
Country[a]				
Brazil	Ref.	Ref.	Ref.	Ref.
Mexico	**0.52 (0.31, 0.86)**	**0.011**	**0.48 (0.28, 0.82)**	**0.007**
Peru	**0.32 (0.23, 0.44)**	**<0.001**	**0.29 (0.21, 0.41)**	**<0.001**
Age (years)[a]				
18–24	0.73 (0.49, 1.10)	0.12	0.76 (0.51, 1.14)	0.160
25–34	Ref.	Ref.	Ref.	Ref.
>34	**1.69 (1.16, 2.45)**	**0.006**	**1.61 (1.10, 2.34)**	**0.014**
Race or skin color[a]				
Other race	0.97 (0.66, 1.44)	0.88	NA	NA
White	Ref.	Ref.	NA	NA
Education[a]				
Primary (complete or incomplete)	0.82 (0.43, 1.57)	0.55	0.85 (0.45, 1.61)	0.620
Secondary (complete or incomplete)	Ref.	Ref.	Ref.	Ref.
More than secondary	**1.60 (1.15, 2.23)**	**0.005**	**1.55 (1.10, 2.19)**	**0.013**
Migration[a]				
Yes	1.08 (0.75, 1.55)	0.67	NA	NA
No	Ref.	Ref.	NA	NA
Main reason to attend the service[a]				
Seeking PrEP	1.11 (0.73, 1.69)	0.62	NA	NA
Other	Ref.	Ref.	NA	NA
Number of cisgender man or/and TGW sex partners[b]				
<5	Ref.	Ref.	NA	NA
5–10	1.35 (0.87, 2.09)	0.18	NA	NA
>10	1.29 (0.89, 1.88)	0.19	NA	NA
Condomless anal sex[c]				
Yes	0.89 (0.61, 1.31)	0.55	NA	NA
No	Ref.	Ref.	NA	NA
Condomless receptive anal sex[c]				
Yes	0.96 (0.68, 1.37)	0.83	NA	NA
No	Ref.	Ref.	NA	NA
Condomless sex with partner(s) known to be living with HIV[c]				
Yes	1.07 (0.48, 2.39)	0.87	1.03 (0.45, 2.38)	0.940
No	Ref.	Ref.	Ref.	Ref.
I don't know	1.39 (0.97, 1.98)	0.072	**1.47 (1.01, 2.12)**	**0.047**
Transactional sex[a]				
Yes	0.80 (0.57, 1.13)	0.21	NA	NA
No	Ref.	Ref.	NA	NA
Binge drinking[c]				
Yes	0.84 (0.60, 1.31)	0.30	NA	NA
No	Ref.	Ref.	NA	NA
Stimulant use[c,d]				
Yes	0.90 (0.61, 1.31)	0.57	NA	NA
No	Ref.	Ref.	NA	NA

(*Continued*)

Table 4. (Continued)

	Bivariate analyses		Multivariate analysis	
	OR (95% CI)	***p*-value**	**aOR (95% CI)**	***p*-value**
Any symptom related to PrEP[e]				
Yes	**0.61 (0.41, 0.90)**	**0.012**	**0.63 (0.42, 0.92)**	**0.019**
No	Ref.	Ref.	Ref.	Ref.

Bold indicates $p < 0.05$.
Abbreviations: aOR, adjusted OR; 95% CI, 95% confidence interval; NA, not applicable; OR, odds ratio.
[a]Data collected at enrolment.
[b]Collected every visit (except at week 4) and referred to the previous 3 months. For week 4, we considered information collected at enrolment (for Brazil and Mexico: previous 3 months, for Peru: previous 6 months).
[c]Collected every visit (except at week 4) and referred to the previous 3 months. For week 4, we considered information collected at enrolment (previous 6 months for all variables, except number of sex partners in Brazil and Mexico and substance use [previous 3 months]).
[d]Stimulant use was defined as use of any: club drugs (e.g. ecstasy, LSD and GHB), cocaine (powder, crack or paste).
[e]Any of the following: diarrhoea, flatulence, nausea, vomit, abdominal pain or other. Collected every visit since week 4 and referred to any symptom related to PrEP since the previous visit.

to improve PrEP engagement and adherence. TGW remain highly vulnerable to HIV and public health programmes offering PrEP should include tailored support for this population to bolster adherence and engagement to services.

The country-level differences observed for long-term PrEP engagement and self-reported adherence likely reflect underlying distinct public health systems and TGW populations included in each setting. Lower long-term PrEP engagement in Mexico may reflect the fact that most study sites had stronger connections with MSM, which might made TGW feel less included and hence less informed. In Peru, TGW reported consistently lower adherence compared to the other countries. Compared to Brazil and Mexico, TGW from Peru had lower educational levels and were the least likely to have enrolled seeking PrEP, suggesting lower PrEP awareness, and ultimately impacting their PrEP adherence. Differences in the characteristics of the enrolled TGW may have contributed to their lower adherence and consequently higher HIV incidence, even though not all evaluated variables were significant on their own.

Our findings on long-term PrEP engagement reflect the difficulties that TGW face to remain engaged in services. Efforts should be taken to retain TGW, including support to their existing social networks [36, 58, 59] and building on the experience of TGW who do return for follow-up visits. TGW remain highly marginalized, as evidenced by the rates of transphobia in Latin America. Out of the 375 murders of trans people reported between October 2020 and September 2021 worldwide, the great majority (83%) occurred in Latin America; and Brazil and Mexico are in the top of the list [60]. Intersecting social vulnerabilities must be acknowledged when planning PrEP services for TGW.

Our study has limitations. First, ImPrEP was not designed to specifically assess outcomes among TGW, and, therefore, measures of key importance for this population were not evaluated. Data on FHT use are not available for most of TGW participants, so we could not include this information in this analysis. Additional qualitative studies to assure understanding of the factors influencing PrEP adherence and engagement among TGW may be needed. Our results are not informative of PrEP uptake, given the study design, study screening only occurred among TGW who expressed an interest in participating. The study inclusion criteria focused on enrolling individuals who could benefit from PrEP, but not all potentially eligible individuals wanted to be screened. Data on PrEP refusal were not collected. Inclusion of fewer TGW from Mexico and data from various sites within a relatively small sample may limit cross country comparisons.

Although self-reported adherence can be limited by different biases, such as recall, response or social desirability bias, which may overestimate adherence [61], neutral assessment (assessment conducted by non-clinical/non-counselling staff trained to collect adherence information without judgement or negative consequences) [62] can minimize these biases and is recommended to ensure the quality of self-report [49]. Previous analyses from a Brazilian PrEP study have shown that, self-reported adherence can discriminate participants with and without protective TDF-FTC levels [49, 50]. In a recent study from New York (USA), self-reported PrEP adherence has shown to be accurate and a valid indicator of PrEP uptake [63]. Our analysis of self-reported PrEP adherence used a very stringent definition, requiring only individuals who reported taking all pills in 30 days to be categorized as adherent. However, the number of missing pills reported by visit (Figure 2a) led to sufficient number of pills required for protection (i.e. 4 pills per week, which would provide sufficient protection) [20]. Additionally, the average number of missing pills (Figure 2b) ranged from 2 to 8 within the past 30 days and decreased over time. Importantly, self-reported adherence is based on TGW who attended the service and, therefore, does not include those who missed visits.

5 | CONCLUSIONS

Although TGW ere willing to be enrolled in ImPrEP and remained on oral PrEP during short-term follow-up, long-term PrEP engagement and PrEP adherence were limited. HIV incidence remained high in Peru despite the availability of PrEP free of charge throughout the study. A successful HIV prevention agenda among TGW considering country or region particularities will need to address social and financial barriers

and include trans-tailored interventions supporting PrEP education, engagement and adherence. Long-acting PrEP may be particularly useful for this population.

AUTHORS' AFFILIATIONS

[1]Universidad Peruana Cayetano Heredia, Centro de Investigaciones Interdisciplinaria en Salud, Sexualidad, y SIDA, Lima, Peru; [2]Instituto Nacional de Infectologia Evandro Chagas, Fundação Oswaldo Cruz (INI-Fiocruz), Rio de Janeiro, Brazil; [3]Escola Nacional de Saúde Pública, Fundação Oswaldo Cruz (ENSP-Fiocruz), Rio de Janeiro, Brazil; [4]Ministério da Saúde, Brasília, Brazil; [5]Instituto Nacional de Salud Pública (INSP), Cuernavaca, Mexico; [6]Instituto Nacional de Psiquiatria Ramon de la Fuente Muñiz, Mexico City, Mexico

COMPETING INTERESTS

KAK reports employment at Universidad Peruana Cayetano Heredia and University of California, Los Angeles. All other authors report no potential competing interests.

AUTHORS' CONTRIBUTIONS

VGV, CFC, BG and HV-R conceived and designed the ImPrEP study. BG conceived and supervised the current analysis and manuscript preparation. KAK and TST interpreted the findings and drafted the manuscript. RIM, ICL and MC did the statistical analyses. EMJ, BH, JVG, MB, CP, SB-A and HV helped with data acquisition, interpretation of the findings and drafting the manuscript. GM and AR were involved in revising the manuscript for important intellectual content. All authors read and approved the final manuscript.

ImPrEP Study Group

Brazil

Marcus V. de Lacerda, Alessandro Farias, J. David Urbaez-Brito, Polyana d'Albuquerque, Claudio Palombo, Lilian Lauria, Josué Lima, Paulo Ricardo de Alencastro, Ronaldo Zonta, Raquel Keiko de Luca Ito, José Valdez Madruga, João L. de Benedetti, Fabio V. Maria, Paula M. Luz, Lucilene Freitas, Kim Geraldo, Monica Derrico, Sandro Nazer, Tania Kristic, Renato Girade (*in memoriam*), Renato Lima, Antônio R. de Carvalho, Julio Moreira, Carla Rocha, Pedro Leite, Marcio Lessa, Marilia Santini, Daniel R. B. Bezerra, Cleo de Oliveira Souza, Jacinto Corrêa, Marcelo Alves, Carolina Souza, Camilla Portugal, Mônica dos Santos Valões, Gabriel Lima Mota, Joyce Alves Gomes, Cynthia Ferreira Lima Falcão, Fernanda Falcão Riberson, Luciano Melo, Talita Andrade Oliva, Agnaldo Moreira de Oliveira Júnior, Bruna Fonseca, Leonor Henriette de Lannoy, Ludymilla Anderson Santiago Carlos, João Paulo da Cunha, Sonia Maria de Alencastro Coracini, Thiago Oliveira Rodrigues, Emília Regina Scharf Mettrau, Kelly Vieira Meira; Heder Tavares, Ana Paula Nunes Viveiros Valeiras, Taiane Miyake Alves de Carvalho Rocha, Alex Amorim, Patrícia Sabadini, Luiz Gustavo Córdoba, Caio Gusmão, Erika Faustino, Julia Soares da Silva Hansen, Agatha Mirian Cunha, Neuza Uchiyama Nishimura, Jaime Eduardo Flygare Razo Prereira dos Santos, Aline Barnabé Cano, Willyam Magnum Telles Dias, Magô Tonhon, Tania Regina Rezende, Alex Gomes, Eloá dos Santos Rodrigues, Maria das Dores Aires Carneiro, Alexandre Castilho, Mariana Carvalho.

Mexico

Steven Díaz, Centli Guillén, Lorena Hernández, Rebeca Robles, María Elena Medina-Mora, Marcela González, Ivonne Huerta Icelo, Araczy Martinez Davalos, Diego Cerecero Garcia, José Gomez Castro, Santiago Aguilera Mijares, Luis Obed Ocampo Valdez, Alma Cruz, Arantxa Colchero Aragones.

Peru

Gino Calvo, Silver Vargas, Oliver Elorreaga, Ximena Gutierrez, Fernando Olivos, Damaris Caviedes, Daniela Oquendo, Eduardo Juárez, Jazmin Qquellon, Francesca Vasquez, Jean Pierre Jiron, Sonia Flores, Karen Campos

ImPrEP Programme Officers

Heather L. Ingold, Anna Hellstrom

ImPrEP Study Sites

Brazil

Fundação de Medicina Tropical (Manaus, Amazonas), Hospital Universitário Oswaldo Cruz (Recife, Pernambuco), CEDAP – Centro Estadual Especializado em Diagnóstico, Assistência e Pesquisa (Salvador, Bahia), Hospital Dia Asa Sul (Brasília, Distrito Federal), Instituto Nacional de Infectologia Evandro Chagas, Fundação Oswaldo Cruz INI-Fiocruz (Rio de Janeiro), Hospital Municipal Rocha Maia (Rio de Janeiro), Hospital Municipal Carlos Tortelly (Niterói, Rio de Janeiro), Centro de Referência em DST/AIDS- AMDA (Campinas, São Paulo), Centro de Referência e Treinamento em DST/AIDS – CRT-SP (São Paulo), SAE DST/AIDS – CECI (São Paulo), SAE DST/AIDS – Fidélis Ribeiro (São Paulo), SAE Adulto (Santos, São Paulo), Poli Centro (Florianópolis, Santa Catarina), SAT – Sanatório Partenon (Porto Alegre, Rio Grande do Sul).

Mexico

Clínica Especializada Condesa (Cuauhtémoc, Mexico City), Fundación Unidos por un México Vivo A.C. (Cuauhtémoc, Mexico City), Comité Humanitario de Esfuerzo Compartido Contra El Sida A.C. (Guadalajara, Jalisco), Solidaridad Ed Thomas A.C. (Puerto Vallarta, Jalisco).

Peru

Centro de Referencia de Infecciones de Transmisión Sexual del Centro Materno Infantil San José (Lima), Centro de Referencia de Infecciones de Transmisión Sexual del Centro Materno Infantil Tahuantinsuyo Bajo (Lima), Centro de Referencia de Infecciones de Transmisión Sexual del Centro de Salud Alberto Barton (Callao), Centro de Referencia de Infecciones de Transmisión Sexual de Caja de Agua (Lima), Centro de Referencia de Infecciones de Transmisión Sexual del Hospital Amazónico Pucallpa (Ucayali), Centro de Referencia de Infecciones de Transmisión Sexual del Hospital La Caleta Chimbote (Ancash), Centro de Referencia de Infecciones de Transmisión Sexual del Hospital Regional Ica (Ica), Centro de Referencia de Infecciones de Transmisión Sexual del Hospital Regional Trujillo (La Libertad), Investigaciones Médicas en Salud, INMENSA (Lima), Centro de Referencia de Infecciones de Transmisión Sexual del Hospital San Juan De Dios, Pisco (Ica).

ACKNOWLEDGEMENTS

We would like to thank all study participants. This project was made possible thanks to Unitaid's funding and support. Unitaid accelerates access to innovative health products and lays the foundations for their scale-up by countries and partners. Unitaid is a hosted partnership of WHO. We would like to thank the support of the Ministries of Health of Brazil, Mexico and Peru. The funding bodies had no role in the design of the study and collection, analysis and interpretation of data and in writing the manuscript.

FUNDING

BG and TST are funded by the National Council of Technological and Scientific Development (CNPq) and Carlos Chagas Filho Foundation for Research Support in the State of Rio de Janeiro (FAPERJ).

DATA AVAILABILITY STATEMENT

Data will be available upon reasonable request and will be approved by ImPrEP coordination team.

REFERENCES

1. Reisner SL, Poteat T, Keatley J, Cabral M, Mothopeng T, Dunham E, et al. Global health burden and needs of transgender populations: a review. Lancet. 2016;388(10042):412–36.
2. Baral SD, Poteat T, Stromdahl S, Wirtz AL, Guadamuz TE, Beyrer C. Worldwide burden of HIV in transgender women: a systematic review and meta-analysis. Lancet Infect Dis. 2013;13(3):214–22.
3. Poteat T, Scheim A, Xavier J, Reisner S, Baral S. Global epidemiology of HIV infection and related syndemics affecting transgender people. J Acquir Immune Defic Syndr. 2016;72(Suppl 3):S210–9.
4. Stutterheim SE, van Dijk M, Wang H, Jonas KJ. The worldwide burden of HIV in transgender individuals: an updated systematic review and meta-analysis. PLoS One. 2021;16(12):e0260063.

5. Bastos FI, Bastos LS, Coutinho C, Toledo L, Mota JC, Velasco-de-Castro CA, et al. HIV, HCV, HBV, and syphilis among transgender women from Brazil: assessing different methods to adjust infection rates of a hard-to-reach, sparse population. Medicine (Baltimore). 2018;97(1S Suppl 1):S16–24.
6. Colchero MA, Cortes-Ortiz MA, Romero-Martinez M, Vega H, Gonzalez A, Roman R, et al. HIV prevalence, sociodemographic characteristics, and sexual behaviors among transwomen in Mexico City. Salud Pública Méx. 2015;57(Suppl 2):s99–106.
7. Silva-Santisteban A, Raymond HF, Salazar X, Villayzan J, Leon S, McFarland W, et al. Understanding the HIV/AIDS epidemic in transgender women of Lima, Peru: results from a sero-epidemiologic study using respondent driven sampling. AIDS Behav. 2012;16(4):872–81.
8. Badgett MVL, Nezhad S, Waaldijk K, Rodgers YM. The relationship between LGBT inclusion and economic development: an analysis of emerging economies. 2014. https://www.usaid.gov/sites/default/files/documents/15396/lgbt-inclusion-and-development-november-2014.pdf. Accessed 15 July 2022.
9. Silva MAD, Luppi CG, Veras M. Work and health issues of the transgender population: factors associated with entering the labor market in the state of Sao Paulo, Brazil. Cien Saude Colet. 2020;25(5):1723–34.
10. Silva-Santisteban A, Raymond HF, Salazar X, Villayzan J, Leon S, McFarland W, et al. Understanding the HIV/AIDS epidemic in transgender women of Lima, Peru: results from a sero-epidemiologic study using respondent driven sampling. AIDS Behav. 2012;16(4):872–81.
11. Cheney MK, Gowin MJ, Taylor EL, Frey M, Dunnington J, Alshuwaiyer G, et al. Living outside the gender box in Mexico: testimony of transgender Mexican asylum seekers. Am J Public Health. 2017;107(10):1646–52.
12. Mendes WG, Silva C. Homicide of lesbians, gays, bisexuals, travestis, transexuals, and transgender people (LGBT) in Brazil: a spatial analysis. Cien Saude Colet. 2020;25(5):1709–22.
13. Suarez EB, Logie C, Arocha JF, Sanchez H, Shokirova T. Contesting everyday violence: resilience pathways of gay and transgender youth in Peru. Glob Public Health. 2021;16(5):706–28.
14. Murphy EC, Segura ER, Lake JE, Huerta L, Perez-Brumer AG, Mayer KH, et al. Intimate partner violence against transgender women: prevalence and correlates in Lima, Peru (2016–2018). AIDS Behav. 2020;24(6):1743–51.
15. Leite BO, de Medeiros DS, Magno L, Bastos FI, Coutinho C, de Brito AM, et al. Association between gender-based discrimination and medical visits and HIV testing in a large sample of transgender women in northeast Brazil. Int J Equity Health. 2021;20(1):199.
16. Sevelius J, Murray LR, Martinez Fernandes N, Veras MA, Grinsztejn B, Lippman SA. Optimising HIV programming for transgender women in Brazil. Cult Health Sex. 2019;21(5):543–58.
17. Passaro RC, Segura ER, Lama JR, Sanchez J, Lake JE, Shoptaw S, et al. High-risk, but hidden: binge drinking among men who have sex with men and transgender women in Lima, Peru, 2012–2014. Subst Use Misuse. 2020;55(3):399–404.
18. Wylie K, Knudson G, Khan SI, Bonierbale M, Watanyusakul S, Baral S. Serving transgender people: clinical care considerations and service delivery models in transgender health. Lancet. 2016;388(10042):401-11.
19. Grant RM, Lama JR, Anderson PL, McMahan V, Liu AY, Vargas L, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. N Engl J Med. 2010;363(27):2587–99.
20. Anderson PL, Glidden DV, Liu A, Buchbinder S, Lama JR, Guanira JV, et al. Emtricitabine-tenofovir concentrations and pre-exposure prophylaxis efficacy in men who have sex with men. Sci Transl Med. 2012;4(151):151ra25.
21. Coelho LE, Torres TS, Veloso VG, Landovitz RJ, Grinsztejn B. Pre-exposure prophylaxis 2.0: new drugs and technologies in the pipeline. Lancet HIV. 2019;6(11):e788–99.
22. Deutsch MB, Glidden DV, Sevelius J, Keatley J, McMahan V, Guanira J, et al. HIV pre-exposure prophylaxis in transgender women: a subgroup analysis of the iPrEx trial. Lancet HIV. 2015;2(12):e512–9.
23. Cottrell ML, Prince HMA, Schauer AP, Sykes C, Maffuid K, Poliseno A, et al. Decreased tenofovir diphosphate concentrations in a transgender female cohort: implications for human immunodeficiency virus preexposure prophylaxis. Clin Infect Dis. 2019;69(12):2201–4.
24. Hiransuthikul A, Janamnuaysook R, Himmad K, Kerr SJ, Thammajaruk N, Pankam T, et al. Drug–drug interactions between feminizing hormone therapy and pre-exposure prophylaxis among transgender women: the iFACT study. J Int AIDS Soc. 2019;22(7):e25338.
25. Shieh E, Marzinke MA, Fuchs EJ, Hamlin A, Bakshi R, Aung W, et al. Transgender women on oral HIV pre-exposure prophylaxis have significantly lower tenofovir and emtricitabine concentrations when also taking oestrogen when compared to cisgender men. J Int AIDS Soc. 2019;22(11):e25405.
26. Cattani VB, Jalil EM, Eksterman LF, Torres T, Cardoso SW, Castro CRV, et al. Impact of feminizing hormone therapy on tenofovir and emtricitabine plasma pharmacokinetics: a nested drug–drug interaction study in a cohort of Brazilian transgender women using HIV pre-exposure prophylaxis. J Antimicrob Chemother. 2022;dkac229.
27. Gomez GB, Borquez A, Caceres CF, Segura ER, Grant RM, Garnett GP, et al. The potential impact of pre-exposure prophylaxis for HIV prevention among men who have sex with men and transwomen in Lima, Peru: a mathematical modelling study. PLoS Med. 2012;9(10):e1001323.
28. Ferreira ACG, Coelho LE, Jalil EM, Luz PM, Friedman RK, Guimaraes MRC, et al. Transcendendo: a cohort study of HIV-infected and uninfected transgender women in Rio de Janeiro, Brazil. Transgend Health. 2019;4(1):107–17.
29. Luz PM, Veloso VG, Grinsztejn B. The HIV epidemic in Latin America: accomplishments and challenges on treatment and prevention. Curr Opin HIV AIDS. 2019;14(5):366–73.
30. Grinsztejn B, Jalil EM, Monteiro L, Velasque L, Moreira RI, Garcia ACF, et al. Unveiling of HIV dynamics among transgender women: a respondent-driven sampling study in Rio de Janeiro, Brazil. Lancet HIV. 2017;4(4):e169–76.
31. Grinsztejn B, Hoagland B, Moreira RI, Kallas EG, Madruga JV, Goulart S, et al. Retention, engagement, and adherence to pre-exposure prophylaxis for men who have sex with men and transgender women in PrEP Brasil: 48 week results of a demonstration study. Lancet HIV. 2018;5(3):e136–45.
32. Del Rio-Gonzalez AM, Lameiras-Fernandez M, Modrakovic D, Aguayo-Romero R, Glickman C, Bowleg L, et al. Global scoping review of HIV prevention research with transgender people: transcending from trans-subsumed to trans-centred research. J Int AIDS Soc. 2021;24(9):e25786.
33. Zucchi EM, Couto MT, Castellanos M, Dumont-Pena E, Ferraz D, Felix Pinheiro T, et al. Acceptability of daily pre-exposure prophylaxis among adolescent men who have sex with men, travestis and transgender women in Brazil: a qualitative study. PLoS One. 2021;16(5):e0249293.
34. Perez-Brumer A, Naz-McLean S, Huerta L, Salazar X, Lama JR, Sanchez J, et al. The wisdom of mistrust: qualitative insights from transgender women who participated in PrEP research in Lima, Peru. J Int AIDS Soc. 2021;24(9):e25769.
35. Jalil EM, Grinsztejn B, Velasque L, Ramos Makkeda A, Luz PM, Moreira RI, et al. Awareness, willingness, and PrEP eligibility among transgender women in Rio de Janeiro, Brazil. J Acquir Immune Defic Syndr. 2018;79(4):445–52.
36. Clark J, Reisner S, Perez-Brumer A, Huerta L, Sanchez H, Moriarty K, et al. TransPrEP: results from the pilot study of a social network-based intervention to support PrEP adherence among transgender women in Lima, Peru. AIDS Behav. 2021;25(6):1873–83.
37. Salazar X, Nunez-Curto A, Villayzan J, Castillo R, Benites C, Caballero P, et al. How Peru introduced a plan for comprehensive HIV prevention and care for transwomen. J Int AIDS Soc. 2016;19(3 Suppl 2):20790.
38. Salazar X, Nunez-Curto A, Villayzan Aguilar J, Lusquinos M, Motta Ochoa A, Caceres CF. Confluent paths: research and community participation to protect the right to health among transgender women in Peru. Glob Public Health. 2019;14(6–7):954–62.
39. Jalil EM, Torres TS, Luz PM, Monteiro L, Moreira RI, de Castro CRV, et al. Low PrEP adherence despite high retention among transgender women in Brazil: the PrEParadas study. J Int AIDS Soc. 2022;25(3):e25896.
40. PPAH Organization. HIV epidemic and response in Latin America and the Caribbean. 2021. https://www.paho.org/en/documents/hiv-epidemic-and-response-latin-america-and-caribbean. Accessed 15 July 2022.
41. Gobierno de Mexico CNplPyCdVyes. Campaña de la Profilaxis pre exposición (PrEP) ąPara prevenir, éntrale con todo! 2021. https://www.gob.mx/censida/articulos/campana-de-la-profilaxis-pre-exposicion-prep-para-prevenir-entrale-con-todo?idiom=es. Accessed 15 July 2022.
42. Infante C, Sosa-Rubi SG, Cuadra SM. Sex work in Mexico: vulnerability of male, travesti, transgender and transsexual sex workers. Cult Health Sex. 2009;11(2):125–37.
43. Rowan SE, Patel RR, Schneider JA, Smith DK. Same-day prescribing of daily oral pre-exposure prophylaxis for HIV prevention. Lancet HIV. 2021;8(2):e114–20.
44. Solomon MM, Lama JR, Glidden DV, Mulligan K, McMahan V, Liu AY, et al. Changes in renal function associated with oral emtricitabine/tenofovir disoproxil fumarate use for HIV pre-exposure prophylaxis. AIDS. 2014;28(6):851–9.
45. Torres TS, Hoagland B, Konda K, Vega-Ramirez EH, Guanira JV, Vermandere H, et al. Impact of COVID-19 pandemic and pandemic response on cisgender men who have sex with men (MSM) and transwomen in a PrEP cohort from Brazil, Peru and Mexico - ImPrEP study. IAS Conference on HIV Science; 2021.
46. Hoagland B, Torres TS, Bezerra DRB, Geraldo K, Pimenta C, Veloso VG, et al. Telemedicine as a tool for PrEP delivery during the COVID-19 pandemic

in a large HIV prevention service in Rio de Janeiro-Brazil. Brazil J Infect Dis. 2020;24(4):360–4.
47. Hoagland B, Torres TS, Bezerra DRB, Benedetti M, Pimenta C, Veloso VG, et al. High acceptability of PrEP teleconsultation and HIV self-testing among PrEP users during the COVID-19 pandemic in Brazil. Brazil J Infect Dis. 2021;25(1):101037.
48. (NIAAA) NIoAAaA. Drinking levels defined. 2021. https://www.niaaa.nih.gov/alcohol-health/overview-alcohol-consumption/moderate-binge-drinking. Accessed 15 July 2022.
49. Monteiro Spindola Marins L, Silva Torres T, Luz PM, Moreira RI, Leite IC, Hoagland B, et al. Factors associated with self-reported adherence to daily oral pre-exposure prophylaxis among men who have sex with man and transgender women: PrEP Brasil study. Int J STD AIDS. 2021;32(13):1231–41.
50. Marins LMS, Torres TS, Leite IDC, Moreira RI, Luz PM, Hoagland B, et al. Performance of HIV pre-exposure prophylaxis indirect adherence measures among men who have sex with men and transgender women: results from the PrEP Brasil study. PLoS One. 2019;14(8):e0221281.
51. RC Team. R: a language and environment for statistical computing. 2020. www.R-project.org. Accessed 15 July 2022.
52. Veloso V, Moreira RI, Konda KA, Hoagland B, Vega-Ramirez H, Leite IC, et al. PrEP long-term engagement among MSM and TGW in Latin America - the ImPrEP study. Conference on Retroviruses and Opportunistic Infections; 2022.
53. Mexico Gd. Protocolo para el acceso sin discriminación a la prestación de servicios de atención médica de las personas lésbico, gay, bisexual, transexual, travesti, transgénero e intersexual y guías de atención específicas. 2020. https://www.gob.mx/cms/uploads/attachment/file/558167/Versi_n_15_DE_JUNIO_2020_Protocolo_Comunidad_LGBTTI_DT_Versi_n_V_20.pdf. Accessed 15 July 2022.
54. Rodrigues A, Struchiner CJ, Coelho LE, Veloso VG, Grinsztejn B, Luz PM. Late initiation of antiretroviral therapy: inequalities by educational level despite universal access to care and treatment. BMC Public Health. 2021;21(1):389.
55. Pascom ARP, Meireles MV, Benzaken AS. Sociodemographic determinants of attrition in the HIV continuum of care in Brazil, in 2016. Medicine (Baltimore). 2018;97(1S Suppl 1):S69–74.
56. Gamarel KE, King WM, Mouzoon R, Xie H, Stanislaus V, Iwamoto M, et al. A "tax" on gender affirmation and safety: costs and benefits of intranational migration for transgender young adults in the San Francisco Bay area. Cult Health Sex. 2020;23(12):1763–78.
57. Poteat T, Malik M, van der Merwe LLA, Cloete A, Adams D, Nonyane BAS, et al. PrEP awareness and engagement among transgender women in South Africa: a cross-sectional, mixed methods study. Lancet HIV. 2020;7(12):e825–34.
58. Perez-Brumer AG, Reisner SL, McLean SA, Silva-Santisteban A, Huerta L, Mayer KH, et al. Leveraging social capital: multilevel stigma, associated HIV vulnerabilities, and social resilience strategies among transgender women in Lima, Peru. J Int AIDS Soc. 2017;20(1):21462.
59. Bezerra DRB, Jalil CM, Jalil EM, Coelho LE, Carvalheira E, Freitas J, et al. Complementary recruitment strategies to reach men who have sex with men and transgender women: the experience of a large Brazilian HIV prevention service. AIDS Behav. 2022;26(8):2643–52.
60. (TGEU) TE. TVT TMM update trans day of remembrance. 2021. https://transrespect.org/en/tmm-update-tdor-2021/. Accessed 15 July 2022.
61. Haberer JE. Current concepts for PrEP adherence in the PrEP revolution: from clinical trials to routine practice. Curr Opin HIV AIDS. 2016;11(1):10–7.
62. MacQueen KM, Tolley EE, Owen DH, Amico KR, Morrow KM, Moench T, et al. An interdisciplinary framework for measuring and supporting adherence in HIV prevention trials of ARV-based vaginal rings. J Int AIDS Soc. 2014;17(3 Suppl 2):19158.
63. Qasmieh S, Nash D, Gandhi M, Rozen E, Okochi H, Goldstein H, et al. Self-reported use of HIV pre-exposure prophylaxis is highly accurate among sexual health clinic patients in New York City. Sex Transm Dis. 2022.

Mwango L et al. *Journal of the International AIDS Society* 2022, **25**(S5):e25995
http://onlinelibrary.wiley.com/doi/10.1002/jia2.25995/full | https://doi.org/10.1002/jia2.25995

RESEARCH ARTICLE

Reaching transgender populations in Zambia for HIV prevention and linkage to treatment using community-based service delivery

Linah Mwango[1,#], Mona-Gekanju Toeque[2,3,#], Brianna Lindsay[2,3], Kalima Tembo[2], Henry Sakala[2], Sean Reggee[4], Sibusiso Mimi Malunga[5], McLean Kabwe[5], Ina Kafunda[2], Adebayo Olufunso[2], Annie Mwila[6], Jackson Okuku[6], Nzali Kancheya[6], Kennedy Nkwemu[6], Daliso Mumba[7], Lottie Hachaambwa[1,3], Robb Sheneberger[2,3], Natalia Blanco[3], Marie-Claude Lavoie[3], Kristen A. Stafford[3] and Cassidy W. Claassen[2,3,§]

[§]**Corresponding author**: Cassidy W. Claassen, Maryland Global Initiatives Corporation Zambia, 31C Bishops Rd, Lusaka 10101, Zambia. (cclaassen@ihv.umaryland.edu)
[#]These authors contributed equally.

Abstract

Introduction: Transgender and gender-diverse communities in Zambia are highly vulnerable and experience healthcare differently than cisgender persons. The University of Maryland, Baltimore (UMB) supports projects in Zambia to improve HIV case-finding, linkage and antiretroviral treatment (ART) for Zambia's transgender community. We describe programme strategies and outcomes for HIV prevention, testing and ART linkage among transgender communities.

Methods: UMB utilizes a differentiated service delivery model whereby community health workers (CHWs) recruited from key populations (KPs) reach community members through a peer-to-peer approach, with the support of local transgender civil society organizations (CSOs) and community gatekeepers. Peer CHWs are trained and certified as HIV testers and psychosocial counsellors to offer counselling with HIV testing and prevention services in identified safe spaces. HIV-negative people at risk of HIV infection are offered pre-exposure prophylaxis (PrEP), while those who test positive for HIV are linked to ART services. CHWs collect data using the standardized facility and community tools and a dedicated DHIS2 database system. We conducted a descriptive analysis examining HIV testing and prevention outcomes using proportions and comparisons by time period and geographic strata.

Results: From October 2020 to June 2021, across Eastern, Lusaka, Western and Southern Provinces, 1860 transgender persons were reached with HIV prevention messages and services. Of these, 424 (23%) were tested for HIV and 78 (18%) tested positive. Of the 346 HIV-negative persons, 268 (78%) eligible transgender individuals were initiated on PrEP. ART linkage was 97%, with 76 out of the 78 transgender individuals living with HIV initiating treatment. Programme strategies that supported testing and linkage included peer CHWs, social network strategy testing, same-day ART initiation and local KP CSO support. Challenges included non-transgender-friendly environments, stigma and discrimination, the high transiency of the transgender community and the non-availability of transgender-specific health services, such as hormonal therapy.

Conclusions: Peer KP CHWs were able to reach many members of the transgender community, providing safe HIV testing, PrEP services and linkage to care. Focusing on community gatekeepers and CSOs to disburse health messages and employ welcoming strategies supported high linkage to both PrEP and ART for transgender people in Zambia.

Keywords: transgender people; HIV care continuum; Africa; HIV prevention; community; differentiated care

Received 11 January 2022; **Accepted** 30 July 2022

1 | INTRODUCTION

Transgender denotes a diverse population of people whose birth sex does not correspond to their gender identity [1]. Globally, an estimated 25 million people identify as transgender and have some of the highest risks for HIV acquisition [1]. UNAIDS data estimate HIV risk is 13 times higher among transgender people, while studies have reported estimates of up to 50 times higher compared to the general adult population. Transgender people also have lower access to HIV services compared to other target populations [2–4]. Most research to date has focused on transgender women due to their disproportionate rates of HIV infection; transgender women who are sex workers are more likely to have HIV than cisgender female or male sex workers, with an estimated worldwide HIV prevalence of 27.3% [5]. A meta-analysis found that laboratory-confirmed HIV infection was significantly higher in transgender women (14.1%) compared to transgender men (3.2%) [6].

Factors associated with high HIV prevalence result from complex determinants of transmission risk, such as structural (e.g. violence, discrimination, stigma and social exclusion) and individual factors (e.g. drug dependence and anal sex without condoms) [1, 7, 8]. These interlocking factors impede progress at each stage of the HIV care continuum and prevent transgender populations from accessing services. HIV disease burden among transgender women and men is likely underestimated due to HIV programmes' infrequent reporting on transgender persons, or from limited self-identification in healthcare settings [1, 9]. These barriers impact opportunities for positive health outcomes, which could be improved through provisioning community-friendly HIV treatment and prevention services [10]. HIV outcomes among transgender people are consistently poorer compared to cisgender populations, including lower rates of antiretroviral treatment (ART) adherence, retention in care, and viral suppression [11–14].

Information on HIV's impact on transgender persons in sub-Saharan Africa (SSA) is scant, as are acceptable, feasible and effective strategies to reach this population. In Zambia, HIV prevalence is estimated to be 11.1% among adults 15–49 [15]. Data on transgender populations are largely unavailable; however, UNAIDS estimates approximately 4000 transgender persons live in Zambia, of whom an estimated 38.6% have not yet been reached with HIV testing services (HTS) [16]. Despite transgender persons being disproportionally impacted by HIV, evidence-informed strategies to optimize HIV care continuity remain scarce [17, 18]. In addition, transgender populations frequently relocate due to stigma and risks of criminalization, as Zambian law prohibits rights to exercise their sexuality and express their gender identity. Zambian laws criminalize same-sex sexual acts for both men and women, which may be used to persecute transgender people. While sex work is not criminalized and Zambian law does not explicitly mention transgender persons, transgender people are often arrested on charges of loitering or vagrancy when practicing sex work [19–21].

The Community Impact to Reach Key and Underserved Individuals for Treatment and Support (CIRKUITS) and Zambia Community HIV Epidemic Control for Key Populations (Z-CHECK) projects, implemented by the Center for International Health, Education, and Biosecurity (Ciheb) at the University of Maryland, Baltimore (UMB), and in collaboration with the Zambia Ministry of Health (MOH) and respective provincial health authorities, aimed to improve HIV case-finding and linkage to care and treatment for key populations (KPs), including transgender people, at the community level in Zambia. The objectives of this paper are to present the CIRKUITS and Z-CHECK approaches among transgender people in Zambia to HIV testing, treatment, and prevention services and to examine HIV positivity yield and ART linkage, with sub-analyses by time period and province.

2 | METHODS

2.1 | Study design and setting

We conducted a retrospective analysis of aggregate programmatic data collected as part of routine CIRKUITS and Z-CHECK service delivery from 1 October 2020 to 30 June 2021. Data included four of Zambia's 10 provinces—Lusaka, Southern, Western and Eastern—with estimated HIV prevalence of 15.1%, 12.4%, 10.6% and 7.4%, respectively [22]. Clients from all communities within catchment areas of 129 participating facilities were included.

2.2 | CIRKUITS and Z-CHECK interventions

CIRKUITS and Z-CHECK are community HIV prevention and treatment programmes targeting key and priority populations. HIV services are delivered to residents of facility catchment areas by community health workers (CHWs) supervised by community liaison officers (CLOs) working with MOH healthcare workers (HCWs) in corresponding health facilities. CHWs must have completed secondary education; they are trained in HTS and psychosocial counselling. Following training, CHWs are assessed and certified as competent counsellors and HIV testers using MOH mentorship tools which are administered quarterly; they are recertified for HIV testing every 2 years. CLOs and CHWs are supervised by the public health facility staff in their catchment areas and report all community activities to the facility. Index testing, mobile testing, voluntary community testing and other HTS modalities, such as ad hoc and social network strategy (SNS) testing, were employed [23].

CHWs provided combination HIV preventive services, including social behavioural communication change, referral for voluntary medical male circumcision (VMMC), HIV pre-exposure prophylaxis (PrEP), family planning (FP), and condom and lubricants distribution. Using a bidirectional referral system, HCWs, CLOs and CHWs direct clients to services based on medical conditions and preferences. Ninety-four mobilizers, 287 CHWs and 55 CLOs were trained, mentored and deployed to conduct community mobilization and community-based testing modalities, including index testing services and SNS (Table 1). Staffing included one technical lead, five CLOs and 53 CHWs who identified as KPs, including female sex workers (FSWs), men who have sex with men (MSM) and transgender persons.

2.3 | Approach to HIV case finding

Working with local KP-led civil society organizations (CSOs), including TransBantu Association Zambia and The Lotus Identity, we focused on communities where most transgender people are found and tailored our approach to include all gender-diverse people, that is transgender men, transgender women, and non-binary and gender-non-conforming individuals. Health facility staff, CLOs and CHWs used community hotspot mapping to identify locations where KPs gather, such as social events, guesthouses, nightclubs, brothels and lodges. The identified KP members could then access health services at community safe spaces. We established three community safe spaces in Lusaka and five in Southern Province. We trained HCWs in KP sensitivity, safety and security, PrEP and ART; HCWs then provided comprehensive healthcare services at safe spaces. Additionally, we trained transgender community members as community mobilizers; KP

Table 1. CIRKUITS and Z-CHECK staffing across supported provinces and districts

Province	Estimated provincial HIV prevalence[a]	Provincial nurses	District	District CLOs	CIRKUITS/Z-CHECK supported facilities	CHWs in district
Eastern	7.4%	1	Chipata	3	18	20
			Lundazi	3	8	10
			Petauke	3	7	10
Western	10.6%	1	Mongu	2	7	18
			Senanga	2	4	6
			Kaoma	2	3	6
			Kalabo	2	4	6
			Limulunga	0	1	2
Lusaka	15.1%	0	Lusaka Urban	16	17	45
			Chilanga	1	2	0
Southern	12.4%	1	Livingstone	4	13	41
			Kalomo	4	12	26
			Choma	4	12	31
			Monze	4	9	31
			Mazabuka	5	12	45
Total	Country: 11.1%	3		55	129	297

Abbreviations: CHW, community health worker; CLO, community liaison officer.
[a]Prevalence data from ZDHS 2018 [22].

CHWs and mobilizers established networks with individuals belonging to KPs by sub-type. Following prevention messaging services, CHWs offered HTS; persons interested in testing were screened with the MOH HIV risk screening tool and those with substantial risk (i.e. engaging in risk behaviours and have not tested for HIV within the past 3 months) were tested. Individuals who needed treatment or prevention services were linked to appropriate services at safe spaces or referred to health facilities for further management (Figure 1).

We employed safe and ethical index testing to identify people who did not know their HIV status [23]. Individuals who tested HIV positive were offered index testing services; all who accepted were screened for intimate partner violence (IPV) with the World Health Organization (WHO) IPV screening questionnaire prior to contact tracing. If individuals indicated a risk for IPV, this was documented and contact tracing was deferred. Persons at-risk for IPV were referred to the "Gender-Based Violence One-Stop Center," a structured system in Zambia where clinical, paralegal and psychosocial counsellors provide comprehensive care to IPV clients. For clients with a low risk of IPV who consented to partner notification services, the health provider and client agreed on a referral process [24]. Three WHO-recommended approaches for index client partner notification were offered: (1) client referral: index client chooses to disclose their HIV status to sexual partners and suggest HTS; (2) provider referral: CHWs obtained consent from index client to contact sexual partners or biological children to offer HTS; and (3) dual referral: CHWs accompanied index client to assist with disclosure of HIV status and offer HTS to partner(s) and/or biological children.

2.4 | Targeted community-based testing modalities and linkage strategies

We provided community-based HTS approaches, including SNS which provides HIV testing and counselling by using social network connections to locate individuals at the highest risk for HIV (Figure 2). SNS relies on the underlying assumption that people in the same social network share similar HIV-risk behaviours [25]. Transgender people at risk of HIV acquisition received coupons to invite their networks to safe spaces or health facilities for the prevention or HTS. HIV-negative persons were offered combination HIV prevention services consisting of condoms, FP, VMMC and PrEP. People who screened at substantial risk of HIV and tested HIV negative were offered and initiated on PrEP if eligible. HIV-positive persons were offered same-day ART by a clinical team of HIV nurse prescribers, pharmacists and psychosocial counsellors in the community or safe space. If facility HCWs were unavailable to join the clinical team, clients were escorted to the facilities by a CLO or CHW for ART initiation, and provided peer health navigation and adherence support to encourage sustained ART.

To optimize uptake and coverage of HIV testing, we provided tailored HIV/AIDS messaging for transgender men and women on HIV risks and benefits of early HTS. Working closely with the National AIDS/TB/STI Council, educational messages were developed and distributed in safe spaces; in addition, CLOs and CHWs offered pre- and post-counselling for the transgender community. Using the peer-to-peer model and working with the transgender-focused CSOs and community-based mobilizers, we offered HIV prevention and HTS in hot spots predominantly frequented by

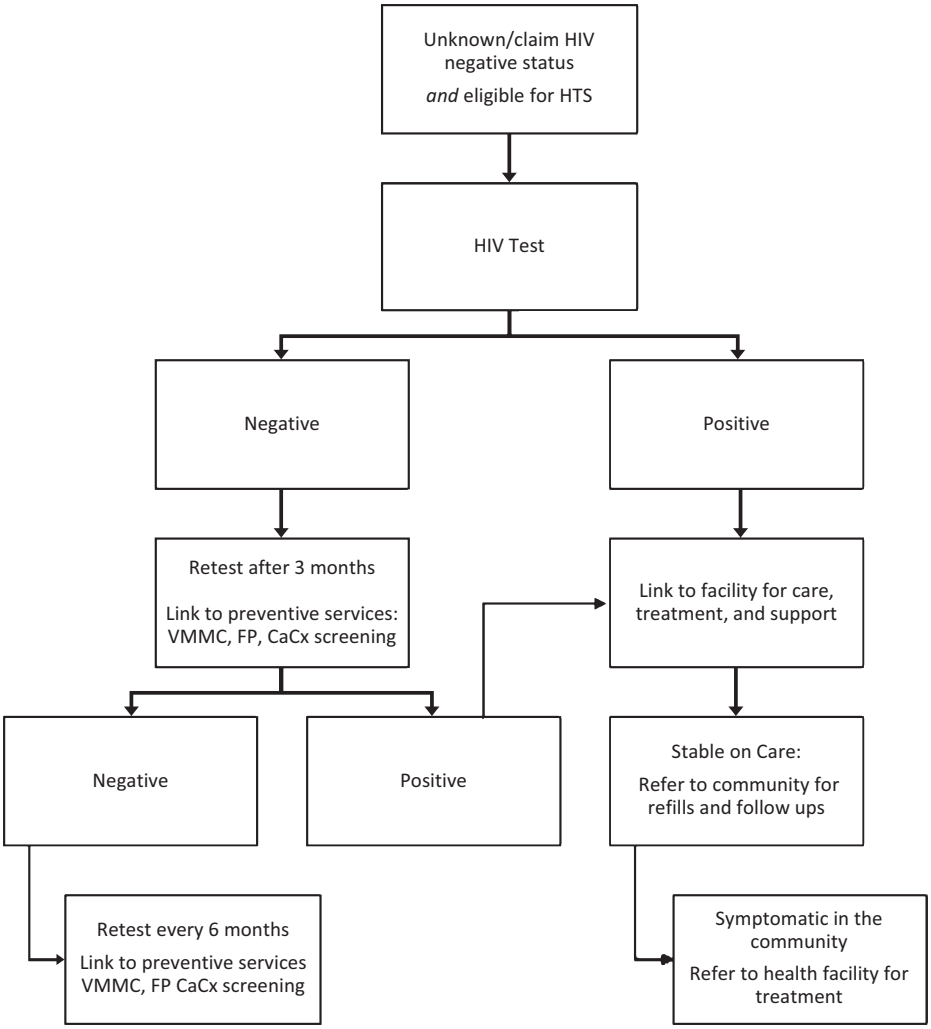


Figure 1. Community HIV testing services and ART linkage flow chart. Abbreviations: CaCx, cervical cancer; FP, family planning; HTS, HIV testing services; VMMC, voluntary male medical circumcision.

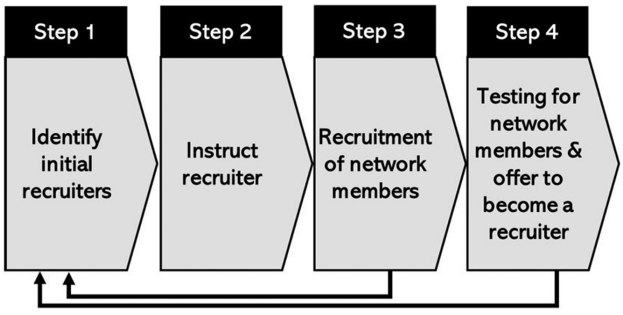


Figure 2. Diagram showing social network strategy recruitment strategy.

transgender community members. Owners and managers of hotpots were oriented on the benefits of HIV prevention and HTS. All HTS was conducted confidentially according to national guidelines [26].

2.5 | HIV testing and prevention outcomes

Outcomes of interest included: (1) the number of transgender persons reached with individual and/or small group-level HIV prevention interventions; (2) the number of transgender individuals who accepted HTS; (3) the proportion of individuals tested; (4) the number of transgender persons identified HIV positive; (5) positivity yield, defined as the number of individuals newly diagnosed as HIV positive divided by the total number of individuals who received HTS and test results; (6) the number of transgender clients linked to ART among newly and previously identified HIV-positive persons; (7) the proportion of individuals linked to treatment, defined as the total number of individuals newly enrolled and dispensed ART divided by the number of individuals newly diagnosed as HIV positive; and (8) PrEP uptake, the proportion of transgender individuals who were newly enrolled on oral PrEP among those who previously tested negative for HIV infection. For outcomes, we used definitions and guidance from the PEPFAR Monitoring, Evaluation and Reporting Indicator Reference Sheet

Table 2. Prevention and treatment outcomes by province and quarter, Oct 2020–June 2021

	Reached *n*	Tested *n*	Testing rate (%)	HIV positive *n*	Yield (%)	Linked	Linkage (%)	HIV negative *n*	PrEP *n*	PrEP (%)
Province										
Eastern	32	22	68.8	10	45.5	10	100.0	12	12	100.0
Lusaka	1505	316	21.0	55	17.4	55	100.0	261	209	80.1
Southern	304	81	26.6	13	16.0	11	84.6	68	42	61.8
Western	19	5	26.3	0		0		5	5	100.0
Quarter										
Oct to Dec 2020	866	214	24.7	46	21.5	44	95.7	168	122	72.6
Jan to Mar 2021	557	105	18.9	16	15.2	16	100.0	89	78	87.6
Apr to Jun 2021	437	105	24.0	16	15.2	16	100.0	89	68	76.4
Overall	1860	424	22.8	78	18.4	76	97.4	346	268	77.5

Abbreviation: PrEP, pre-exposure prophylaxis.

(MER) version 2.3 [27]. We present results disaggregated by province and time period.

2.6 | Data sources and collection

Aggregate data were abstracted from routine Zambian MOH HTS, PrEP and ART linkage registers. At the community level, each CHW collected patient-level information onto individual community HTS and referral forms. At the facility level, CLOs then merged these data and entered them into facility registers. Aggregate data were manually entered into a customized District Health Information Software 2 data platform with internal data quality checks and validation rules.

2.7 | Statistical analysis

Proportions were calculated for outcomes of interest, and the HIV care cascade analysed using descriptive statistics. Chi-square tests were used to compare overall positivity yield and ART linkage by time period and province strata. All analyses were performed using *R* version 4.0.3.

2.8 | Ethical approval

Ethical approval for this analysis was approved under the Z-CHECK and CIRKUITS protocols by the ERES Converge Zambian Institutional Review Board (IRB) (2020-Mar-015, 2021-Jan-010), the Zambian National Health Research Authority (NHRA29/4/2020, NHRA0008/15/03/2021) and the UMB IRB (HP-00086064, HP-00096480). This project was reviewed in accordance with Centers for Disease Control and Prevention (CDC) human research protection procedures and was determined to be non-research by the CDC. Informed consent was waived by the IRBs as this study was a retrospective review of aggregate programme data.

3 | RESULTS

From October 2020 to June 2021, across 13 districts in Eastern, Lusaka, Western and Southern Provinces, 1860 transgender persons were reached with HIV prevention messages and services. The majority of transgender persons reached were in Lusaka Province, 81% (1505/1860), then Southern Province, 16% (304/1860) and only 3% (51/1860) in Eastern and Western Provinces combined.

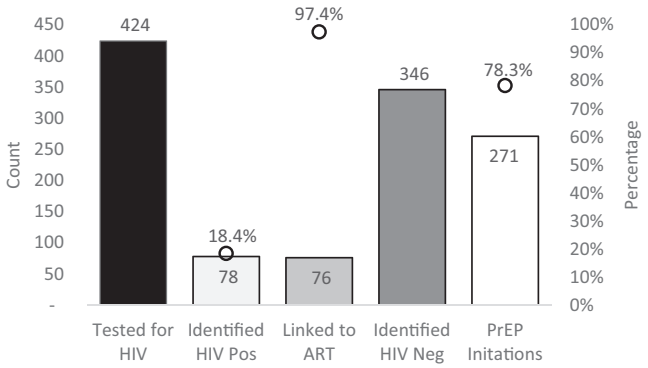


Figure 3. Transgender client prevention and treatment outcomes, Oct 2020–June 2021. Circles indicate HIV testing yield, linkage to treatment and PrEP uptake. Abbreviations: ART, antiretroviral therapy; HIV Neg, HIV negative; HIV Pos, HIV positive; PrEP, pre-exposure prophylaxis.

Of transgender individuals who reached with HIV prevention messages, 424 (22.8%) were tested for HIV and 78 (18.4%) tested positive. Testing proportions ranged from 18.9% to 24.7% by quarter and were the highest in Eastern Province (68.8%). ART linkage was high overall with 76 (97.4%) initiating treatment (Figure 3). Positivity yield did not vary significantly by province ($p = 0.21$); however, there were low numbers tested in Eastern and Western Provinces (Table 2). In Lusaka Province, yield was 17.4% (95% CI 13.6–22.0%) compared to 16.0% (95% CI 9.6–25.5%) in Southern Province. Of the 346 HIV-negative transgender persons, 268 (77.5%) initiated PrEP. PrEP uptake did not vary significantly by province, but was 80.1% (95% CI 74.8–84.5%) in Lusaka (209/261) and 61.8% (95% CI 49.9–72.4%) in Southern (42/68) (Table 2).

October to December 2020 demonstrated the highest number of transgender individuals reached with HIV prevention messages and the highest percentage of HIV testing yield (21.5%). ART linkage was consistently high over all three quarters (Table 2). The absolute number of PrEP initiations was highest from October to December 2020; however, PrEP uptake was highest between January and March 2021.

4 | DISCUSSION

We report programmatic achievements across the CIRKUITS and Z-CHECK projects in Zambia, which used community mobilizers and peer navigators, including transgender CHWs and CLOs, to reach transgender individuals with HIV services. Although uptake of HTS was modest (22.8%), overall HIV positivity yield was 18%, with 97% linkage to ART. Linkage to PrEP among transgender individuals who tested negative for HIV was 78%.

HIV positivity yield among transgender clients in this study was above the national adult prevalence of 11–12%. However, this yield was relatively low compared to other effective general population testing strategies, such as index testing (45%) [23] and HIV prevalence among other KP in Zambia, for example 21.1% among MSM, 42.2% among FSW and 28.0% among incarcerated persons [23, 28]. Regional data on transgender HIV positivity rates are scarce; however, our finding of 18.4% HIV positivity among all transgender people was consistent with the global HIV prevalence of 19% among transgender women [4] but lower than the estimated prevalence among transgender women in SSA, which may range from 25% to 43%, with an incidence rate from 4.7 to 20.6 infections per person-years [4, 29].

Our HIV yield data are limited by low uptake of HTS, meaning that most transgender persons declined HIV testing. Low testing may have been due to ineligibility: per MOH guidelines, people being tested for HIV must be deemed at substantial risk using the MOH HIV risk screening tool. Thus, not everyone who is offered HTS is tested. It remains unclear whether HIV prevalence among transgender-identifying individuals is lower in Zambia, or if we are missing a critical portion of the HIV-positive transgender population, especially if those declining to be tested are likely to be HIV positive, or if some KP clients were not correctly classified as transgender.

We employed several key strategies to reach transgender persons, including partnering with local transgender CSOs, TransBantu Association Zambia and The Lotus Identity. These CSOs provided introductions to local KP networks and helped access members of the transgender community. They also trained our staff and HCW in KP sensitivity, safety and security, especially around the unique concerns and health needs of transgender persons. Second, we employed peer navigators to help reach the transgender community. Local KP CSO involvement was critical to success as it ensured a trusted member of the community was bringing services. Other studies using similar peer navigation networks to reach the community have also demonstrated success [30, 31].

Data showed an initial push of increased volume during the first quarter of implementation with lower volume but sustained testing yield and linkage, perhaps owing to an outlet for unmet need. Of note, this time period also overlaps with the second significant wave of COVID-19 in Zambia, potentially impacting service delivery.

We used targeted HTS strategies and while we were unable to disaggregate data by modality, our programmatic implementation focused on SNS and index testing. SNS has been an effective strategy in reaching the transgender community, as social network members know best where to find other community members. Other studies using SNS testing in SSA have proven cost-effective and increased the identification of hard-to-reach undiagnosed HIV-positive KPs [32–34].

ART linkage was moderate; however, it compares favourably to other rates of linkage among KPs in the region. For example, a study from Tanzania found linkage rates of 78% [35], and other studies reported rates as low as 55% [36–40]. We attribute this programmatic achievement to several key strategies. First, we provided high-quality training in KP and transgender-specific health needs and sensitivity to key healthcare personnel, who then worked with our programmes and transgender community members. These HCWs provided care in a non-stigmatizing or non-discriminatory manner and came to be trusted by the transgender community. Second, we provided same-day initiation of ART to people who tested positive in the community, which helped to ensure high linkage. Finally, we provided ART refills at healthcare centres, community safe spaces and via home delivery by the CHWs. HCWs would visit offsite locations and provide refills, which also served as a reminder for medication adherence.

Our programme demonstrated remarkable achievements in PrEP, with 78% uptake of PrEP among transgender clients. This constitutes one of the first estimates of PrEP linkage for transgender persons in SSA. Other studies in the region have shown PrEP uptake of 81% in Kenya; lower rates have been reported in South Africa with uptake at 16% which underscores the existing challenges [41, 42]. Livingstone and Lusaka were the first areas to begin PrEP implementation, enabling a robust healthcare infrastructure to support PrEP to specifically engage the transgender community. Transgender peer navigators provided counselling about the benefits of PrEP and shared their personal experiences on PrEP. Being able to obtain refills via the community safe spaces likely improved PrEP uptake and persistence [43].

We faced several challenges to programme implementation. Although reasons for not testing were not routinely collected, counsellors reported anecdotally that KP members, including gender-diverse individuals, are exhausted from being tested for HIV. They are tested often and feel like the international donor community is not addressing their other health concerns, particularly around the unavailability of transgender-affirmative health services, such as hormonal therapy or counselling. This may have led to the relatively low uptake of HTS among those who were provided HIV prevention messages. Future efforts should include transgender-related healthcare, such as hormonal therapy and mental health services.

Second, the transgender population is highly mobile as they continue to face criminalization, which creates challenges to viral load coverage, ART adherence and PrEP persistence. Highly unfriendly environments exist for transgender people, leading to stigma and discrimination.

Finally, most of our success in reaching transgender men and women was limited to the urban areas of Lusaka and Livingstone. This geographic concentration may be for several reasons: (1) members of the transgender community willing to identify as transgender may be more likely to reside in and identify as transgender at a greater frequency in urban areas compared to rural areas; (2) limited transgender friendly service opportunities exist in rural versus urban areas; (3) rural parts of Zambia may be more influenced by local tradition, norms and culture, with less awareness of transgender identities; and/or (4) our transgender peer navigators were based in Lusaka, and thus we had the greatest success in Lusaka compared to non-transgender peer navigators located outside of Lusaka.

The primary limitation of this study is that clients had to identify as transgender for inclusion in our analysis. Due to stigma, we may have underestimated the number of transgender-identifying individuals reached with prevention and treatment services. We were unable to disaggregate the study population by identification as transgender men, transgender women, non-binary or gender-non-conforming, which would help to shed more light on populations being reached under these projects. Similarly, our HIV testing proportion includes all individuals who were reached with prevention messages in the denominator; data were not available on reasons for declining HTS. Therefore, the tested proportion is best interpreted with caution as we are not able to ascertain if individuals were not tested because they had been tested within the previous 3 months or declined for other reasons. These results also do not include HIV self-testing, so reach with HTS is likely higher. We also note the lack of both ART and PrEP persistence data, so we cannot gauge how many people remained on PrEP and ART after initial uptake.

Finally, episodic COVID-19 waves during programme implementation potentially affected both project achievement and client uptake of services. During periods of increased COVID cases, there were restrictions on the number of people at health facilities, causing some clients to miss lab, pharmacy or clinical appointments. Furthermore, global logistics challenges resulted in shortages of PrEP drugs. The programme was adapted by having CHWs deliver services and commodities to clients in the community as much as possible.

5 | CONCLUSIONS

The UMB peer navigation model was able to reach many transgender community members with HIV services in Zambia. Engaging local transgender CSOs is critical to establishing trust and reaching community members. Index testing and SNS are effective high-yield testing strategies for reaching transgender persons. Using sensitized HCWs and community safe spaces enhanced ART linkage and PrEP uptake among the transgender population. Moving forward, the inclusion of transgender-specific health services can be considered a best practice for programmes supporting the transgender community.

AUTHORS' AFFILIATIONS

[1]Ciheb Zambia, Lusaka, Zambia; [2]Maryland Global Initiatives Corporation Zambia, Lusaka, Zambia; [3]Center for International Health, Education, and Biosecurity, University of Maryland School of Medicine, Baltimore, Maryland, USA; [4]TransBantu Association Zambia, Lusaka, Zambia; [5]The Lotus Identity, Lusaka, Zambia; [6]Division of Global HIV and Tuberculosis, U.S. Centers for Disease Control and Prevention, Lusaka, Zambia; [7]National AIDS/TB/STI Council, Lusaka, Zambia

COMPETING INTERESTS

The authors declare that they have no competing interests.

AUTHORS' CONTRIBUTIONS

All authors contributed to writing, reviewing and editing the manuscript. All authors have read and approved the final manuscript.

ACKNOWLEDGEMENTS

We gratefully acknowledge the community and facility health workers who made this work possible, as well as the clients served through their efforts.

FUNDING

The CIRKUITS and Z-CHECK projects and this publication are supported by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) through the U.S. Centers for Disease Control and Prevention (CDC), Division of Global HIV and Tuberculosis (DGHT), and in collaboration with the Ministry of Health of Zambia, under the terms of NU2GGH002123-01-02 and U2GGH001913. CDC investigators did not interact with human participants or have access to identifiable data or specimens for research purposes.

DISCLAIMER

The views expressed in the manuscript do not necessarily represent the views of CDC. The findings and conclusions in this manuscript are those of the authors and do not necessarily represent the official position of the funding agencies.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available upon reasonable request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

REFERENCES

1. Poteat T, Wirtz AL, Radix A, Borquez A, Silva-Santisteban A, Deutsch MB, et al. HIV risk and preventive interventions in transgender women sex workers. Lancet. 2015;385(9964):274–86.
2. UNAIDS. HIV and transgender and other gender-diverse people — Human rights fact sheet series 2021. 2021. Available from: https://www.unaids.org/sites/default/files/media_asset/04-hiv-human-rights-factsheet-transgender-gender-diverse_en.pdf. Accessed June 14, 2022.
3. Winter S, Diamond M, Green J, Karasic D, Reed T, Whittle S, et al. Transgender people: health at the margins of society. Lancet. 2016;388(10042):390–400.
4. Baral SD, Poteat T, Strömdahl S, Wirtz AL, Guadamuz TE, Beyrer C. Worldwide burden of HIV in transgender women: a systematic review and meta-analysis. Lancet Infect Dis. 2013;13(3):214–22.
5. Operario D, Soma T, Underhill K. Sex work and HIV status among transgender women: systematic review and meta-analysis. J Acquir Immune Defic Syndr. 2008;48(1):97–103.
6. Becasen JS, Denard CL, Mullins MM, Higa DH, Sipe TA. Estimating the prevalence of HIV and sexual behaviors among the US transgender population: a systematic review and meta-analysis, 2006–2017. Am J Public Health. 2019;109(1):e1–8.
7. Silva-Santisteban A, Raymond HF, Salazar X, Villayzan J, Leon S, McFarland W, et al. Understanding the HIV/AIDS epidemic in transgender women of Lima, Peru: results from a sero-epidemiologic study using respondent driven sampling. AIDS Behav. 2012;16(4):872–81.
8. Nemoto T, Operario D, Keatley J, Villegas D. Social context of HIV risk behaviours among male-to-female transgenders of colour. AIDS Care. 2004;16(6):724–35.
9. Jobson GA, Theron LB, Kaggwa JK, Kim H-J. Transgender in Africa: invisible, inaccessible, or ignored? SAHARA J. 2012;9(3):160–3.

10. World Health Organization. *Serving the needs of key populations: case examples of innovation and good practice on HIV prevention, diagnosis, treatment and care*. World Health Organization; 2017.
11. Baguso GN, Gay CL, Lee KA. Medication adherence among transgender women living with HIV. AIDS Care. 2016;28(8):976–81.
12. Kalichman SC, Hernandez D, Finneran S, Price D, Driver R. Transgender women and HIV-related health disparities: falling off the HIV treatment cascade. Sex Health. 2017;14(5):469–76.
13. Mizuno Y, Frazier EL, Huang P, Skarbinski J. Characteristics of transgender women living with HIV receiving medical care in the United States. LGBT Health. 2015;2(3):228–34.
14. Wiewel EW, Torian LV, Merchant P, Braunstein SL, Shepard CW. HIV diagnoses and care among transgender persons and comparison with men who have sex with men: New York City, 2006–2011. Am J Public Health. 2016;106(3):497–502.
15. Floyd S, Ayles H, Schaap A, Kwame S, David M, Mwelwa P, et al. Towards 90-90: findings after two years of the HPTN 071 (PopART) cluster-randomized trial of a universal testing-and-treatment intervention in Zambia. PLoS One. 2018;13(8):e0197904.
16. UNAIDS. Global HIV & AIDS statistics — Fact sheet. UNAIDS. The Joint United Nations Programme on HIV/AIDS. [Cited 2021 June 20]. Available from: https://www.unaids.org/en/resources/fact-sheet
17. Gardner EM, McLees MP, Steiner JF, del Rio C, Burman WJ. The spectrum of engagement in HIV care and its relevance to test-and-treat strategies for prevention of HIV infection. Clin Infect Dis. 2011;52(6):793–800.
18. Kay ES, Batey DS, Mugavero MJ. The HIV treatment cascade and care continuum: updates, goals, and recommendations for the future. AIDS Res Ther. 2016;13(1):35.
19. Ministry of Legal Affairs, Government of the Republic of Zambia. The Penal Code Act - Chapter 87 of the Laws of Zambia. Ministry of Legal Affairs, Government of the Republic of Zambia. 2007. Available from: https://www.parliament.gov.zm/sites/default/files/documents/acts/Penal%20Code%20Act.pdf. Accessed June 14, 2022.
20. Maguire S. The human rights of sexual minorities in Africa. Calif West Int Law J. 2004;35(1):52.
21. Yelverton V, Qiao S, Menon JA, Ngosa L, Kabwe M, Harrison S, et al. Criminalization of sexual and gender minorities and its consequences for the HIV epidemic in Zambia: a critical review and recommendations. J Assoc Nurses AIDS Care. 2021;32(4):423–41.
22. Zambia Statistics Agency, Ministry of Health (MOH). Zambia Demographic and Health Survey 2018. 2018. Available from: https://dhsprogram.com/pubs/pdf/FR361/FR361.pdf. Accessed June 14, 2022.
23. Mwango LK, Stafford KA, Blanco NC, Lavoie M-C, Mujansi M, Nyirongo N, et al. Index and targeted community-based testing to optimize HIV case finding and ART linkage among men in Zambia. J Int AIDS Soc. 2020;23(Suppl 2):e25520.
24. World Health Organization. Consolidated guidelines on HIV testing services. 2019 [cited 2021 December 6]. Available from: https://www.who.int/publications-detail-redirect/978-92-4-155058-1
25. Social Network Strategy for HIV Testing Recruitment. Diagnose | Effective Interventions | HIV/AIDS | CDC. 2021 [cited 2021 November 22]. Available from: https://www.cdc.gov/hiv/effective-interventions/diagnose/social-network-strategy/index.html
26. Ministry of Health. Zambia consolidated guidelines for treatment and prevention of HIV infection. 2020. Available from: https://differentiatedservicedelivery.org/Portals/0/adam/Content/1n5xWfh8dk2-rs95a9-rbA/File/Zambia_Consolidated%20Guidelines%202020.pdf. Accessed June 14, 2022.
27. PEPFAR USPEP for AR (Version 2. 3). Monitoring, evaluation, and reporting indicator reference guide. 2018. Available from: https://Users/monatoeque/Downloads/MER%20Indicator%20Reference%20Guide%20(Version%202.3%20FY19).pdf. Accessed June 14, 2022.
28. 2020 Global AIDS Update. Seizing the moment—tackling entrenched inequalities to end epidemics. 2020.
29. Jin H, Restar A, Beyrer C. Overview of the epidemiological conditions of HIV among key populations in Africa. J Int AIDS Soc. 2021;24(S3):e25716.
30. Dijkstra M, Mohamed K, Kigoro A, Mumba T, Mahmoud S, Wesonga A, et al. Peer mobilization and human immunodeficiency virus (HIV) partner notification services among gay, bisexual, and other men who have sex with men and transgender women in coastal Kenya identified a high number of undiagnosed HIV infections. Open Forum Infect Dis. 2021;8(6):ofab219.
31. Kimani M, van der Elst EM, Chiro O, Oduor C, Wahome E, Kazungu W, et al. PrEP interest and HIV-1 incidence among MSM and transgender women in coastal Kenya. J Int AIDS Soc. 2019;22(6):e25323.
32. Njagi M, Chandler CJ, Coulter RWS, Siconolfi DE, Stall RD, Egan JE. Approaches to identify unknown HIV-positive men who have sex with men in Nairobi, Kenya. AIDS Behav. 2019;23(6):1580–5.
33. Girault P, Green K, Clement NF, Rahman YAA, Adams B, Wambugu S. Piloting a social networks strategy to increase HIV testing and counseling among men who have sex with men in Greater Accra and Ashanti Region, Ghana. AIDS Behav. 2015;19(11):1990–2000.
34. Nowak RG, Mitchell A, Crowell TA, Liu H, Ketende S, Ramadhani HO, et al. Individual and sexual network predictors of HIV incidence among men who have sex with men in Nigeria. J Acquir Immune Defic Syndr. 2019;80(4):444–53.
35. Sanga ES, Lerebo W, Mushi AK, Clowes P, Olomi W, Maboko L, et al. Linkage into care among newly diagnosed HIV-positive individuals tested through outreach and facility-based HIV testing models in Mbeya, Tanzania: a prospective mixed-method cohort study. BMJ Open. 2017;7(4):e013733.
36. Genberg BL, Naanyu V, Wachira J, Hogan JW, Sang E, Nyambura M, et al. Linkage to and engagement in HIV care in western Kenya: an observational study using population-based estimates from home-based counseling and testing. Lancet HIV. 2015;2(1):e20–6.
37. Labhardt ND, Ringera I, Lejone TI, Klimkait T, Muhairwe J, Amstutz A, et al. Effect of offering same-day ART vs usual health facility referral during home-based HIV testing on linkage to care and viral suppression among adults with HIV in Lesotho: the CASCADE Randomized Clinical Trial. JAMA. 2018;319(11):1103–12.
38. Muhula S, Memiah P, Mbau L, Oruko H, Baker B, Ikiara G, et al. Uptake and linkage into care over one year of providing HIV testing and counselling through community and health facility testing modalities in urban informal settlement of Kibera, Nairobi Kenya. BMC Public Health. 2016;16(1):373.
39. Hatcher AM, Turan JM, Leslie HH, Kanya LW, Kwena Z, Johnson MO, et al. Predictors of linkage to care following community-based HIV counseling and testing in rural Kenya. AIDS Behav. 2012;16(5):1295–307.
40. Sharma M, Ying R, Tarr G, Barnabas R. A systematic review and meta-analysis of community and facility-based approaches to address gaps in HIV testing and linkage in sub-Saharan Africa. Nature. 2015;528(7580):S77–85.
41. Wahome EW, Graham SM, Thiong'o AN, Mohamed K, Oduor T, Gichuru E, et al. PrEP uptake and adherence in relation to HIV-1 incidence among Kenyan men who have sex with men. EClinicalMedicine. 2020;26:100541.
42. Pillay D, Stankevitz K, Lanham M, Ridgeway K, Murire M, Briedenhann E, et al. Factors influencing uptake, continuation, and discontinuation of oral PrEP among clients at sex worker and MSM facilities in South Africa. PLoS One. 2020;15(4):e0228620.
43. Mwango L, Kafunda I, Lubinda R, Kabombo H, Fundulu E, Chipukuma J, et al. PrEP initiation in community safe spaces increases PrEP access among key and priority populations in Zambia. International AIDS Society (IAS); 2021.

Bothma R et al. *Journal of the International AIDS Society* 2022, **25**(S5):e25987
http://onlinelibrary.wiley.com/doi/10.1002/jia2.25987/full | https://doi.org/10.1002/jia2.25987

JIAS JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

RESEARCH ARTICLE

Differentiated HIV services for transgender people in four South African districts: population characteristics and HIV care cascade

Rutendo Bothma[1,§], Cara O'Connor[1], Jolie Nkusi[1], Vusi Shiba[1], Jacob Segale[1], Luyanda Matsebula[1], J. Joseph Lawrence[2], L. Leigh-Ann van der Merwe[3], Matthew Chersich[1] and Naomi Hill[1]

[§]**Corresponding author**: Rutendo Bothma, Wits Reproductive Health and HIV Institute (Wits RHI), University of the Witwatersrand, Hillbrow Health Precinct, 22 Esselen Street, Hillbrow, Johannesburg 2000, South Africa. (rbothma@wrhi.ac.za)

Abstract

Introduction: Transgender people in South Africa are disproportionately affected by HIV, discrimination and stigma. Access to healthcare and health outcomes are poor. Although integrating gender-affirming healthcare with differentiated HIV prevention, care and treatment services has shown improvement in HIV service uptake and health outcomes among transgender people, evidence is lacking on the implementation of differentiated service delivery models in southern Africa. This article describes a differentiated service delivery model across four South African sites and transgender individuals who access these services. We assess whether hormone therapy (HT) is associated with continued use of pre-exposure prophylaxis (PrEP) and viral load suppression.

Methods: In 2019, differentiated healthcare centres for transgender individuals opened in four South African districts, providing gender-affirming healthcare and HIV services at a primary healthcare level. Routine programme data were collected between October 2019 and June 2021. Descriptive statistics summarized patient characteristics and engagement with HIV prevention and treatment services. We conducted a multivariate logistic regression analysis to determine whether HT was associated with viral load suppression and PrEP continued use.

Results: In the review period, we reached 5636 transgender individuals through peer outreach services; 86% (4829/5636) of them accepted an HIV test and 62% (3535/5636) were linked to clinical services. Among these, 89% (3130/3535) were transgender women, 5% (192/3535) were transgender men and 6% (213/3535) were gender non-conforming individuals. Of those who received an HIV test, 14% (687/4829) tested positive and 91% of those initiated antiretroviral treatment. Viral load suppression was 75% in this cohort. PrEP was accepted by 28% (1165/4142) of those who tested negative. Five percent (161/3535) reported ever receiving HT through the public healthcare system. Service users who received HT were three-fold more likely to achieve viral load suppression. We did not find any association between HT and continued use of PrEP.

Conclusions: A differentiated HIV and gender-affirming service delivery model at a primary healthcare level is feasible and can enhance service access in South Africa. HT can improve HIV clinical outcomes for transgender people. As trust is established between the providers and population, uptake of HIV testing and related services may increase further.

Keywords: differentiated service delivery models; gender-affirming; HIV services; hormone therapy; South Africa; transgender

Received 11 January 2022; **Accepted** 30 July 2022

1 | INTRODUCTION

South Africa bears 19% of the global HIV burden, with over 7.7 million people living with HIV [1]. The risk for HIV varies considerably between population groups, and globally transgender people—those whose gender identity differs from their birth-assigned sex [2]—are among those at highest risk [3, 4]. The increased burden of HIV is largely due to economic and social marginalization and structural factors that affect transgender people, such as poor access to services, experience of discrimination, violence and human rights violations, as well as the prevalence of risk behaviours [5].

In 2017, the South African National AIDS Council developed the South African National Lesbian, Gay, Bisexual, Transgender and Intersex (LGBTI) HIV Plan 2017–2022 in response to the global call to reach key and vulnerable populations with targeted interventions [6], recognizing transgender people as a key population in South Africa's HIV response for the first time. Modelling data suggest that for HIV incidence to fall below the AIDS elimination threshold, that is incidence of less than 0.1%, South Africa needs to markedly scale up HIV prevention among key populations, including transgender people [7].

HIV prevalence among the South African general population aged 15–49 is 19.1% [8], while prevalence among transgender women (TGW) is much higher: 63% in Johannesburg and approximately 50% in Cape Town and Buffalo City [9]. Globally HIV prevalence among transgender men is 10 times that of the general population [10, 11]; however, the prevalence in transgender men in South Africa is unknown. In South Africa, there are an estimated 87,214 TGW, 28,065 transgender men and 66,076 gender non-conforming individuals, about 0.3% of the total population [12].

The Joint United Nations Programme on HIV/AIDS (UNAIDS) has recognized that comprehensive, people-centred services are pivotal to ending AIDS by 2030 [13]. Reaching this global goal will require 90% of transgender people to have access to *"HIV services differentiated with or linked to sexually transmitted infections (STIs), mental health, gender-affirming therapy, IPV [intimate partner violence] programmes, and SGBV [sexual- and gender-based violence] programmes that include PEP, emergency contraception and psychological first aid"* by 2025. Similarly, the World Health Organization and the International AIDS Society have called for a differentiated service delivery model with a people-centred approach to engage transgender people in health services and decrease treatment interruption [14, 15].

Global studies have shown that when HIV services are provided within a gender-affirming healthcare approach, including hormone therapy (HT), pre-exposure prophylaxis (PrEP) acceptability among TGW increases [16, 17] and continuity of treatment and viral suppression rates for transgender people on antiretroviral therapy (ART) strengthens [18–20]. In South Africa, access to gender-affirming healthcare in the public sector is limited, with HT provision limited to a handful of tertiary hospitals.

Our study describes a gender-affirming healthcare intervention in which HIV prevention and treatment services and HT were delivered in a differentiated HIV service delivery model at a primary healthcare level. Differentiated service delivery offers stigma-free services adapted to the needs of transgender people who may require specialized services, such as community ART and PrEP refills, one-stop services which address HIV and other health issues, involvement of transgender peers for service delivery and flexible clinic hours [14]. The study describes the characteristics of the TGW, transgender men and gender non-conforming people who received services from the programme. These services were gender-affirming, where service delivery integrates transgender individuals' mental, physical, social and health needs, while respecting their self-identified gender [21]. We report on the services they received through the programme and their clinical outcomes and assess whether the provision of HT was associated with continued use of PrEP or viral load suppression.

2 | METHODS

2.1 | Study setting and programmatic model

The Wits Health and HIV Research Institute (Wits RHI) is a multi-disciplinary research institute of the University of the Witwatersrand, Johannesburg. In 2019, the Wits RHI key populations programme opened healthcare centres for transgender people in four South African districts—Cape Town, Johannesburg, Buffalo City and Nelson Mandela Bay. The first two are stand-alone sites in large urban centres, and the last two are co-located within public health facilities in smaller towns which serve remote rural areas (Figure 1). These centres, funded by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) through the U.S. Agency for International Development (USAID) Southern Africa, are the first U.S. Government-funded centres addressing the specific needs of transgender people in sub-Saharan Africa and build on global lessons in gender-affirming healthcare [22–24].

Our differentiated service delivery model included multidisciplinary teams who provided gender-affirming healthcare, including HT for adult transgender and gender non-conforming people. Individuals younger than 18 years were referred to public and private health services. Services were provided on site or through mobile clinics equipped with gazebos, which enabled service provision on streets, in informal settlements and in the *veld* (open fields). Transgender peer outreach workers (who were trained to provide outreach services) recruited and retained service users in care. The clinical team initiated ART for HIV-positive individuals, usually on the same day of HIV diagnosis. Viral load testing was conducted after 6 months of ART initiation, at 12 months and annually thereafter for virally suppressed clients. Clients who were not virally suppressed had viral load testing more frequently according to the South African guidelines [25]. Nurses offered PrEP to anyone who tested HIV negative, empowering service users with the choice to take PrEP based on their own assessment of their HIV risk.

Our programme is unable to fulfil the demand for HT, with over 200 transgender individuals on a waiting list to receive this service. HT was added to the South African Department of Health Essential Medicines List in December 2019, with the indication that it should be prescribed by doctors in tertiary settings. Therefore, there is a limited stock made available in district pharmacies to provide for clients referred by doctors for maintenance of care in primary healthcare facilities, as in our sites.

2.2 | Data collection

Peer educators, social workers and clinicians collected data at service delivery points using standardized forms for outreach, behavioural risk assessment, demographic and clinical services information. Information on sexual and behavioural risk was collected during peer outreach activities. Demographic data were collected only when clients were enrolled in clinical services and included information about HIV status and past experiences utilizing gender-affirming healthcare. Paper-based data were captured into a Research Electronic Data Capture (REDCap) database [26, 27]. Our programme ensured that data collection and management complied with the provision of the South African Protection of Personal Information Act (4 of 2013) [28].

2.3 | Study design and measures

This retrospective record review utilized routine programme data collected between October 2019 and June 2021 at the

Site	Johannesburg	Cape Town	Buffalo City	Nelson Mandela Bay
Location	Stand-alone/verticalised service		Co-located within Department of Health community health centre	
Catchment area	Urban		Peri-urban and rural	
Gender-affirming healthcare	Informed consent support, HT initiation and monitoring, referrals for sex reassignment surgery.			
Community Engagement and Outreach	Outreach Strategies: Area mapping, door-to-door recruitment, incentivised peer recruitment, social network mapping, online mobilisation.			
Community-based services	HIV testing; distribution of condoms and lubricants; health information materials and talks; tracking and tracing individuals back to care.			
Clinical services	HIV prevention, testing, and treatment; a range of sexual and reproductive health services, including treatment of sexually transmitted infections, contraceptives, and pap smears; tuberculosis screening and referral provided onsite or in the community.			
Complimentary services	Psychosocial support; referral to post-violence care, legal support, and harm reduction services; referrals for name and gender marker changes with the Department of Home Affairs.			
Service providers	Full time: Professional nurse (2), community health worker (2), peer educator (4-8, dependent on site volume), social worker (1). Sessional: Medical doctor (1), psychologist (1).			

Figure 1. Wits RHI differentiated transgender healthcare model. Abbreviations: HT, hormone therapy; Wits RHI, the Wits Health and HIV Research Institute.

four transgender healthcare centres. We describe the number of community outreach contacts, sexual and behavioural risks of HIV infection and socio-demographic characteristics. We present the HIV prevention and treatment cascade, HT initiations and examine associations between HT and HIV clinical outcomes.

2.4 | Data analysis

Using STATA 15, we conducted a descriptive data analysis of the characteristics of the study population. All transgender people who received services at the four programme sites between the specified dates were included. Categorical variables were described with proportions and continuous variables were presented as means with standard deviations. In instances of incomplete or missing data, all available data points were included. The denominator for each proportion is the total number of respondents for whom the relevant data collection tool was completed, with non-response included as a category for each variable. We examined whether HT was associated with key HIV clinical outcomes: continuous use of PrEP for 10 months among PrEP users and viral load suppression among clients on ART for 6 months or more. Crude odds ratios (ORs) were calculated with logistic regression. Then, factors significant at p-value <0.1 on univariate analysis were included in a multivariate logistic regression analysis. Variables were excluded from the multivariate if there was collinearity or reverse causality.

2.5 | Ethical considerations

Ethical clearance for the use of routine programmatic data for research purposes was obtained from the University of the Witwatersrand Human Research Ethics Committee (protocol number M190428). Individual consent was waivered for this record review as data were presented at an aggregate level.

3 | RESULTS

3.1 | Characteristics of service users

3.1.1 | Socio-demographic characteristics

The programme reached 5636 transgender individuals through peer outreach. Of the 5636 individuals, 62% (3535/5636) were linked to a professional nurse for further on-site clinical services (Table 1). The majority, 89% (3130/3535) of the service users were TGW; 5% (192/3535) were transgender men and 6% (213/3535) were gender non-conforming individuals. The mean age of our service users was 26 years with a standard deviation of 7.8. Fewer than half had completed high school (45%) and only 29% (1011/3535) were formally employed. Of those who reported earning an income (through employment, sex work, stipend or government social grants), 70% (1733/2487) earned less than R1000 (USD70) per month. Only 22% (761/3535) reported renting or owning their residence and 3.3% were homeless.

3.1.2 | Sexual and behavioural risk

Information on sexual and behavioural risk was collected for 78% (4417/5636) of the transgender individuals reached through outreach services (Table 2). Over a third (1517/4417) reported having condomless receptive anal sex in the last 12 months. Our service users reported low levels of violence, with 11% (483/4417) disclosing experiences of violence in the last 3 months. Most violence was experienced from current romantic partners, family members and neighbours. Close to

Table 1. Socio-demographic characteristics of service-users

	Frequency (*N* = 3535)	Percentage (%)
Gender		
Transgender woman	3130	88.5%
Transgender man	192	5.4%
Gender non-conforming	213	6.0%
Sex assigned at birth		
Female	215	6.1%
Male	3320	93.9%
Age (years)		
<25	1714	48.5%
25–30	914	25.9%
31–35	466	13.2%
≥ 36	441	12.5%
Education		
No schooling	353	10.0%
Primary	34	1.0%
Grade 8–10	615	17.4%
Grade 11–12	1576	44.6%
Tertiary	913	25.8%
Unknown/refused	44	1.2%
Living situation		
Staying with family/friends	2497	70.6%
Rent or own house/apartment	761	21.5%
Streets/no place to live	115	3.3%
Unknown/refused	162	4.6%
Employed		
No	2362	66.8%
Yes	1011	28.6%
Unknown/refused	162	4.6%
Current monthly income *n* = 2487		
<R1000	1733	69.7%
R1000–R2999	253	10.2%
R3000–R4999	237	9.5%
R5000–R10,000	174	7.0%
>R10,000	90	3.6%

Table 2. Sexual and behavioural risk factors

	Frequency (*N* = 4417)	Percentage (%)
Condomless receptive anal sex in the last 12 months		
No	2829	64.0%
Yes	1517	34.3%
Unknown/refused	71	1.6%
Experience of sexual, psychological, physical violence		
No	3872	87.7%
Yes	483	10.9%
Unknown/refused	62	1.4%
Violence perpetrators *n* = 528[a]		
Current romantic partner	121	22.9%
Ex-romantic partner	25	4.7%
Sex partner	63	11.9%
Sex work service user	41	7.8%
Family	97	18.4%
Employer/co-worker	18	3.4%
Fellow transgender community member	16	3.0%
Neighbours	98	18.6%
Police/law enforcement	11	2.1%
Other	38	7.2%
Sad, depressed, anxious, worried much of the time in the last 12 months		
No	3107	70.3%
Yes	1226	27.8%
Unknown/refused	84	1.9%
Substance use in the last 30 days[a] *n* = 4664		
Alcohol use (>4 drinks in a day)	3303	70.8%
Dagga (cannabis)	1219	26.1%
Nyaope (street drug blending heroin and other agents)	18	0.4%
Tik (methamphetamine)	85	1.8%
Heroin	39	0.8%
HIV risk perception		
No risk	487	11.0%
Some risk	1771	40.1%
Great risk	851	19.3%
Don't know	804	18.2%
N/A (known HIV-positive status)	436	9.9%
Refused	68	1.5%

[a]Multiple-response question.

a third (1226/4417) reported feeling sad, anxious and worried most of the time in the preceding 12 months. Most of our service users, 71% (3303/4664) had consumed more than four alcoholic drinks per day in the last month. When asked about their HIV risk perception, 59% (2622/4417) of the respondents reported to be at some risk/great risk of contracting HIV.

3.1.3 | HIV status and utilization of gender-affirming healthcare at enrolment

Before accessing services through our programme, 69% (2437/3535) of our clients did not know their HIV status. Of the service users who were previously diagnosed with HIV, 73% (241/329) were taking ART (Table 3). Among the respondents who had recently tested negative in the last 12 weeks, 8% (57/706) were taking PrEP. Of note, only 190 (5%) of service users reported any prior utilization of gender-affirming healthcare services through the formal healthcare sector, with HT being the most utilized service.

Table 3. HIV status and utilization of gender-affirming healthcare services at enrolment

	Frequency (*N* = 3535)	Percentage (%)
HIV status		
Unknown	2437	68.9%
Known negative (tested last 12 weeks)	706	20.0%
Known positive	329	9.3%
Refused	63	1.8%
HIV positive *n* = 329		
On ART	241	73.3%
If HIV negative *n* = 706		
On PrEP	57	8.1%
Prior utilization of gender-affirming healthcare services		
No	3168	89.6%
Yes	161	4.6%
Unknown/refused	206	5.8%
Type of gender-affirming healthcare received *n* = 190[a]		
Counselling/therapy	49	25.8%
Puberty blockers	8	4.2%
HT	65	34.2%
Surgery	2	1.1%
Birth control	44	23.2%
Other	22	11.6%

[a]Multiple-response question as some transgender people utilized more than one service.
Abbreviations: ART, antiretroviral therapy; HT, hormone therapy; PrEP, pre-exposure prophylaxis.

3.1.4 | *HIV prevention cascade*

The HIV prevention cascade showed that 86% (4829/5636) of transgender people who were reached by peer educators through outreach accepted an HIV test (Figure 2). Of the 4142 (86%) who tested negative, 28% (1165/4142) accepted PrEP, this is 44% (1165/2662) of those who had indicated either some risk or great risk perception of contracting HIV. Most of the PrEP initiations occurred in the community, that is at the mobile clinic or gazebo (86%; 1001/1165).

There was no difference in the continued use of PrEP for 10 months or more between PrEP patients who were also taking HT and those not taking HT (OR = 1.04, p = 0.885) (Table 4). There was no evidence detected of association between age (p = 0.627) or gender identity (p = 0.753) and continued use of PrEP for 10 months or more, therefore, these variables were not included in a multivariate model.

3.2 | HIV treatment cascade

Among service users who tested for HIV, 14% (687/4829) were HIV positive, and 91% of those (625/687) received ART (Figure 3). Our programme retained 609 HIV-positive people in care (97% of 625 initiated on ART), and 77% (467/609) of those were on ART for 6 months or more at the time of review, and therefore, eligible for a viral load test. The nurses collected blood samples for viral load testing from 89% (416/467) of those who were eligible for a viral load. The viral load suppression rate among service users who had a viral load test done was 75% (314/416) (HIV RNA <50 copies/ml).

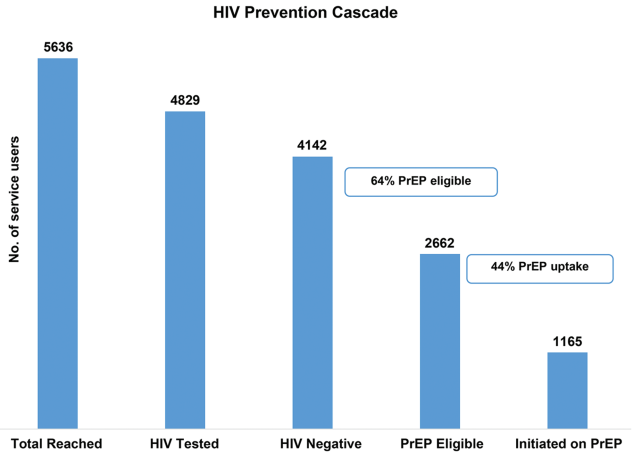


Figure 2. The HIV prevention cascade. Total number of people tested for HIV who received PrEP. Abbreviation: PrEP, pre-exposure prophylaxis.

3.3 | HT and HIV services

We initiated 10% (365/3535) of service users on HT (Figure 4). HT provision was limited by the supply of pharmacy stock, and more than 200 people were on a waiting list at the time of review. Of those on HT, 35% (126/365) were linked to PrEP and 40% (145/365) were linked to ART. Viral load suppression among those on ART and taking HT was 90% (83/92), higher than the viral load recorded with the overall cohort.

ART clients who were receiving HT were three times more likely to have suppressed viral load (OR = 3.01, p<0.001) compared to those who were not receiving HT (Table 5). There was no difference detected in coverage of viral load test done between those receiving HT and those not receiving HT (OR = 1.76, p = 0.306). There was no detected evidence of an association between age (p = 0.407) or gender identity (p = 0.445) and viral load suppression, therefore, these variables were not included in the multivariate model. Geographic location was excluded from the model due to collinearity with the variable HT.

4 | DISCUSSION

In this analysis of data from four transgender healthcare centres across South Africa, 88% of service users identified as TGW, higher than what has been reported in the South African transgender population size estimates, where 48% of transgender people identified as TGW [12]. The remainder of the participants identified as transgender men or gender non-conforming. The high number of TGW in our programme compared to transgender men and gender non-conforming individuals in our study is likely due to our programme's focus on TGW, identified as the priority population by the funder,

Table 4. Hormone therapy and continued use of PrEP

	Total (*N* = 287)		Continued use of PrEP for 10 months or more (*n* = 95)		Discontinued PrEP before 10 months (*n* = 192)			
	n	(%)	*n*	(%)	*n*	(%)	Crude OR (95% CI)	*p*-value
Hormone therapy	80	27.87	27	33.75	53	66.3	1.04 (0.60–1.80)	0.885
No hormone therapy	207	72.13	68	32.85	139	67.2	1	

Abbreviations: CI, confidence interval; OR, odds ratio; PrEP, pre-exposure prophylaxis.

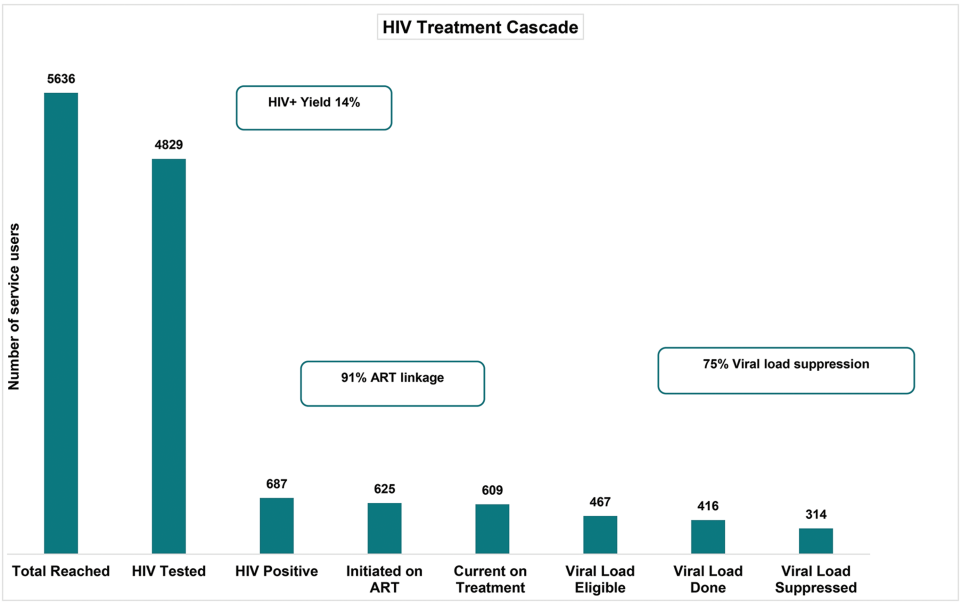


Figure 3. The HIV treatment cascade. Total number of people tested for HIV who received ART. Abbreviation: ART, antiretroviral therapy.

PEPFAR through USAID. The low levels of high school completion (45% reported completing high school) echo previous studies which have shown that transgender people are often excluded from the education system [29, 30]. Participants reported a monthly income of less than R1000 (USD70), which is considerably below the minimum wage in South Africa of R20/hour [31] (approximately R3600 per month), and only one in five participants had their own place to live. These low levels are consistent with global findings regarding the barriers transgender people experience in accessing health-determining resources, such as education, employment and housing, in addition to the stigma and discrimination they experience when accessing healthcare [29].

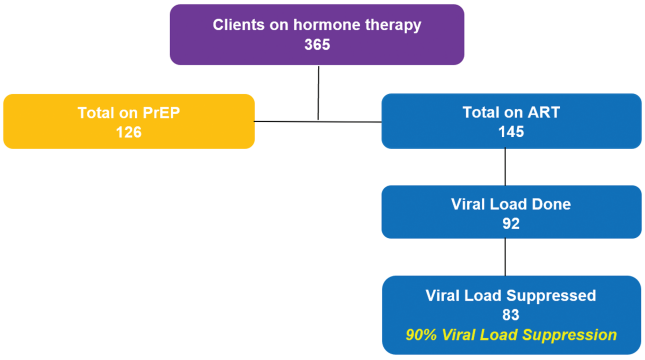


Figure 4. HIV services for transgender individuals on hormone therapy. Abbreviations: ART, antiretroviral therapy; PrEP, pre-exposure prophylaxis.

In our study, 36% of the service users reported condomless receptive anal sex in the last 12 months, consistent with what has been reported among transgender people in other countries [32]. A systematic review estimating per-act HIV transmission reported that the risk of HIV transmission through condomless receptive anal sex was 138 infections per 10,000 exposures [33]. Full viral suppression with ART, known as U = U (Undetectable = Untransmittable), means that the risk of HIV transmission is very low, even without condom use [33]. Securing access to ART and promoting condom use is key. Fewer service users in our study reported experiences of violence compared to prior research in South Africa [34, 35] potentially due to social desirability bias in the data collection process. The high prevalence of violence experienced by transgender people has been well documented and UNAIDS has set targets to address the deeply entrenched stigma and

Table 5. Hormone therapy and viral load suppression

	Total (*N* = 472)		Viral load suppressed (≤50 copies/ml) (*n* = 303)		Viral load unsuppressed (>50 copies/ml) (*n* = 169)			
	n	(%)	*n*	(%)	*n*	(%)	Crude OR (95% CI)	*p*-value
Hormone therapy	98	20.76	80	81.63	18	18.4	3.01 (1.73–5.22)	<0.001
No hormone therapy	374	79.24	223	59.63	151	40.4	1	

Abbreviation: OR, odds ratio.

discrimination which perpetuate violence against transgender people [32].

In South Africa, over 90% of the population know their HIV status and 75% of these are on HIV treatment [8]. Contrary to the general population, only a third of transgender individuals knew their HIV status in our study, of those who knew they were HIV positive, 73% were on HIV treatment, at the time they began accessing our services. These data are important in understanding the effectiveness of the HIV response for transgender people. It supports the need for innovative strategies, such as differentiated service delivery, to reach individuals at the highest risk of HIV infection [36].

Despite the progressive constitution in South Africa which prohibits discrimination based on sex, gender or sexual orientation [37], transgender people continue to face numerous social and structural barriers that hinder their access to quality healthcare services [38, 39]. Our study showed that one in 20 individuals had utilized gender-affirming healthcare services. This low utilization could be a result of being denied healthcare, fear of stigma and discrimination from healthcare providers, which has been documented in previous studies and reports [5, 35, 40]. Among people who had received gender-affirming services before utilizing our services, HT was the most sought-after service. In the absence of gender-affirming HT, it is common for TGW to use off-label contraceptives, herbal medicines and other pills/substances without medical supervision [41]. The prevalence of unsupervised hormone use among transgender people ranged between 29% and 63% in New York City and Ontario, and was associated with health risks, such as hypercoagulability and decreased insulin sensitivity [41, 42]. Although there may be a considerable geographic variation of unsupervised hormone use, providing gender-affirming healthcare in routine HIV programming could reduce these health risks among transgender people in South Africa.

Our study showed that PrEP was generally acceptable among service users who perceived themselves at risk of contracting HIV. The differentiated gender-affirming healthcare services offered by our programme created trusting relationships between the clinical team and service users which may have enabled PrEP uptake, as was shown in San Francisco where gender-affirming providers were described as facilitators for PrEP acceptability [17]. Most research has focused on the role of HT on PrEP uptake, without long-term follow-up, our study showed no significant association between HT and PrEP continued use for 10 months or more. Unlike ART, clients can cycle on and off PrEP. Barriers to the continued use of PrEP have been documented in several literatures [43–45]. Our clients reported the following barriers to continuation: pill fatigue, the stigma associated with HIV infection when PrEP is misidentified as ART and fear of disclosing PrEP use to partners. As HT becomes more readily available, there is a need to implement innovations to support the continued use of PrEP among transgender people.

Overall, 14% of all transgender individuals who received an HIV test tested positive, this HIV positive yield among our service users is lower than the HIV prevalence reported in previous studies [9]. The relatively low HIV-positive yield in our study may be due to people who already knew their HIV status and declined testing without disclosing their status, or our programme reached relatively lower-risk transgender people. Using the UNAIDS goal to reach 95-95-95 by 2030 as a benchmark, our programme achieved an 86-91-75 treatment cascade, linking a greater proportion of service users to ART and PrEP compared to the general population in South Africa [8]. These HIV prevention and treatment data are important in understanding the HIV epidemic among transgender people in South Africa, where data are still very sparse.

Our study findings are consistent with previous research, which suggests that gender-affirming HT may improve engagement in the HIV care continuum among TGW [21, 46]. We found that service users who were on HT were three times more likely to be virally suppressed compared to those who did not have access to HT. Studies have reported improved quality of life and social functioning when HT [47, 48], which may enable individuals on ART to adhere to treatment with minimal interruption of treatment.

Our study is limited by the use of routine programme data, which is potentially of lower quality and completeness than data collected in a research project. To improve data reliability and validity, the programme provides in-depth training to peer educators and clinical staff, many of whom are highly experienced in programme implementation. The data on demographics, sexual and behavioural risks were based on self-report and may be skewed by recall or social desirability bias, poor understanding of the questions or reluctance to divulge sensitive personal information. One example of this is that contrary to expectations and reports from other studies, very few transgender people reported experiencing violence during the reporting period. As our programme matures, continuous staff training to improve screening and referrals for interpersonal violence is indicated. Incomplete data due

to omission or respondents' refusal to answer may have introduced bias. However, missing data were infrequent (<5% of records) and are unlikely to affect the interpretation of findings. Lastly, while the findings presented in this paper reflect the largest group of transgender service users in the country, they are not generalizable to different service delivery models in the country or region.

5 | CONCLUSIONS

Our study addresses knowledge gaps in evidence-based programming for transgender people in South Africa by providing data on a differentiated HIV and gender-affirming healthcare service delivery model. We have shown that transgender people have low utilization of gender-affirming healthcare in the public sector, leaving a high unmet demand for differentiated care. Overall, our findings indicate that differentiated gender-affirming healthcare and HIV service delivery at a primary healthcare level is feasible in South Africa. The service user numbers reached and the high referral rate from outreach services into the clinics suggest high acceptability and a high potential for this programme model to engage the transgender population in HIV services. We have shown that providing gender-affirming healthcare services, including HT, as a primary healthcare intervention significantly increases viral load suppression. Future reports from these transgender centres will provide critical information on the impact of differentiated services on retention in care and clinical outcomes. Studies to elucidate how the HIV treatment and prevention cascades differ for transgender people on HT at each point of the cascade are needed. Additional studies exploring the costing implications of integrating differentiated services into public sector primary healthcare would be beneficial.

AUTHORS' AFFILIATIONS

[1]Wits Reproductive Health and HIV Institute (Wits RHI), University of the Witwatersrand, Johannesburg, South Africa; [2]United States Agency for International Development/Southern Africa, City of Tshwane, South Africa; [3]Social, Health & Empowerment Feminist Collective of Transgender Women of Africa, East London, South Africa

COMPETING INTERESTS

LLvdM: Community Global Advisory Committee for the Gilead Len4PrEP Study.

AUTHORS' CONTRIBUTIONS

RB conceptualized the study and drafted the initial version of the manuscript. CO, JN, VS, JS and LM contributed to data collection tool design, data collection and analysis. CO, MC and NH contributed to scientific aspects of the review, interpretation of results and revision of the paper. JJL and LLvdM provided editorial input to the manuscript. All authors reviewed and approved the manuscript for submission.

ACKNOWLEDGEMENTS

This review would not have been possible without the attendance of the transgender community at our healthcare centres. Many thanks to our community collaborators—Social, Health & Empowerment Feminist Collective of Transgender Women of Africa (S.H.E) and Gender Dynamix (GDX), in South Africa, which continue to advocate for the human rights of transgender people. The South African National Department of Health has been instrumental in supporting the four transgender sites with drugs, commodities and capacity development when required. We would like to acknowledge the support from the district departments of health in Johannesburg Health District and the metropolitan municipalities of Cape Town, Buffalo City and Nelson Mandela Bay. We would like to thank Willem Daniel Francois Venter who was instrumental in the inception and early stages of our programme and provided thoughtful input and editorial advice on this manuscript.

FUNDING

The Wits RHI key populations programme is funded through the support of the American People through the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) as implemented by the United States Agency for International Development 72067418CA00027 (USAID)/Southern Africa.

DISCLAIMER

The contents of this review do not necessarily reflect the views of USAID or the United States Government.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

REFERENCES

1. Avert. HIV and AIDS in South Africa. 2020. Available from: https://www.avert.org/professionals/hiv-around-world/sub-saharan-africa/south-africa#footnote7_teuqm4x. Accessed October 20, 2021.
2. Reisner SL, Poteat T, Keatley J, Cabral M, Mothopeng T, Dunham E, et al. Global health burden and needs of transgender populations: a review. Lancet North Am Ed. 2016;388(10042):412–36.
3. Baral SD, Poteat T, Strömdahl S, Wirtz AL, Guadamuz TE, Beyrer C. Worldwide burden of HIV in transgender women: a systematic review and meta-analysis. Lancet Infect Dis. 2013;13(3):214–22.
4. The Joint United Nations Programme on HIV/AIDS (UNAIDS). Seizing the moment: tackling entrenched inequalities to end epidemics. Geneva: UNAIDS; 2020.
5. Luvuno ZP, Ncama B, Mchunu G. Transgender population's experiences with regard to accessing reproductive health care in Kwazulu-Natal, South Africa: a qualitative study. Afr J Prim Health Care Fam Med. 2019;11(1):1–9.
6. South African National AIDS Council. The South African National LGBTI HIV Plan, 2017–2022. Pretoria; 2017.
7. Dimitrov DMJ, Donnell DJ, Boily M-C. Achieving 95-95-95 may not be enough to end AIDS epidemic in South Africa. 2020 Conference on Retroviruses and Opportunistic Infections; Boston, MA; 2020.
8. The Joint United Nations Programme on HIV/AIDS (UNAIDS). Country factsheets: South Africa 2020. 2020. Available from: https://www.unaids.org/en/regionscountries/countries/southafrica. Accessed June 27, 2022.
9. Cloete A, Wabiri N, Savva H, Van der Merwe L, Simbayi L. The Botshelo Ba Trans study: results of the first HIV prevalence survey conducted amongst transgender women (TGW) in South Africa. 2019.
10. Scheim A, Kacholia V, Logie C, Chakrapani V, Ranade K, Gupta S. Health of transgender men in low-income and middle-income countries: a scoping review. BMJ Glob Health. 2020;5(11):e003471.
11. Scheim AI, Santos GM, Arreola S, Makofane K, Do TD, Hebert P, et al. Inequities in access to HIV prevention services for transgender men: results of a global survey of men who have sex with men. J Int AIDS Soc. 2016;19:20779.
12. Tshuma N, Mtapuri O, Ndagurwa P, Nyengerai T, Maphosa T, Mushavhanamadi K, et al. Population size estimates among transgender people in South Africa. 2021.
13. The Joint United Nations Programme on HIV/AIDS (UNAIDS). Prevailing against pandemics by putting people at the centre. 2020.
14. World Health Organization. Key considerations for differentiated antiretroviral therapy delivery for specific populations: children, adolescents, pregnant and breastfeeding women and key populations. Geneva: World Health Organization; 2017.
15. International AIDS Society. Differentiated service delivery for HIV: a decision framework for differentiated antiretroviral therapy delivery for key populations. Amsterdam; 2018.

16. Sevelius JM, Deutsch MB, Grant R. The future of PrEP among transgender women: the critical role of gender affirmation in research and clinical practices. J Int AIDS Soc. 2016;19:21105.
17. Sevelius JM, Keatley J, Calma N, Arnold E. 'I am not a man': trans-specific barriers and facilitators to PrEP acceptability among transgender women. Glob Public Health. 2016;11(7–8):1060–75.
18. Summers NA, Huynh TT, Dunn RC, Cross SL, Fuchs CJ. Effects of gender-affirming hormone therapy on progression along the HIV care continuum in transgender women. Open Forum Infect Dis. 2021;8(9).
19. Rosen JG, Malik M, Cooney EE, Wirtz AL, Yamanis T, Lujan M, et al. Antiretroviral treatment interruptions among Black and Latina transgender women living with HIV: characterizing co-occurring, multilevel factors using the gender affirmation framework. AIDS Behav. 2019;23(9):2588–99.
20. Baguso GN, Turner CM, Santos GM, Raymond HF, Dawson-Rose C, Lin J, et al. Successes and final challenges along the HIV care continuum with transwomen in San Francisco. J Int AIDS Soc. 2019;22(4):e25270.
21. Reisner SL, Radix A, Deutsch MB. Integrated and gender-affirming transgender clinical care and research. J Acquir Immune Defic Syndr. 2016;72:S235–42.
22. WPATH. World Professional Association for Transgender Health Standards of Care. 7th Edition. 2011.
23. Callen Lorde. Protocol for the Provision of Hormone Therapy. 2018.
24. Center of Excellence in Transgender Health. The Thai Handbook of Transgender Healthcare Services. 2021. Available from: https://ihri.org/wp-content/uploads/2021/09/The-Thai-Handbook-of-Transgender-Heatlhcare-Services.pdf. Accessed October 20, 2021.
25. National Department of Health. ART clinical guidelines for the management of HIV in adults, pregnancy, adolescents, children, infants and neonates. Pretoria; 2020.
26. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform. 2009;42(2):377–81.
27. Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O'Neal L, et al. The REDCap consortium: building an international community of software platform partners. J Biomed Inform. 2019;95:103208.
28. The Presidency. Protection of Personal Information Act 4 of 2013. South African Government. Pretoria, RSA: Government Printers; 2013.
29. Thomas R, Pega F, Khosla R, Verster A, Hana T, Say L. Ensuring an inclusive global health agenda for transgender people. Bull World Health Organ. 2017;95(2):154.
30. Blondeel K, Say L, Chou D, Toskin I, Khosla R, Scolaro E, et al. Evidence and knowledge gaps on the disease burden in sexual and gender minorities: a review of systematic reviews. Int J Equity Health. 2016;15(1):1–9.
31. Department of Labour and Employment. Employment and Labour Minister TW Nxesi announces minimum wage increases. Department of Employment and Labour; 2021.
32. The Joint United Nations Programme on HIV/AIDS (UNAIDS). Confronting inequalities: lessons for pandemic responses from 40 years of AIDS. UNAIDS Global AIDS Update. 2021. Available from: https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2021/july/20210714_global-aids-update. Accessed June 27, 2022.
33. Patel P, Borkowf CB, Brooks JT, Lasry A, Lansky A, Mermin J. Estimating per-act HIV transmission risk: a systematic review. AIDS. 2014;28(10):1509–19.
34. Poteat T, Ackerman B, Diouf D, Ceesay N, Mothopeng T, Odette K-Z, et al. HIV prevalence and behavioral and psychosocial factors among transgender women and cisgender men who have sex with men in 8 African countries: a cross-sectional analysis. PLoS Med. 2017;14(11):e1002422.
35. Müller A, Daskilewicz K. Are we doing alright? Realities of violence, mental health, and access to healthcare related to sexual orientation and gender identity and expression in East and Southern Africa: research report based on a community-led study in nine countries. 2019.
36. Grubb IR, Beckham SW, Kazatchkine M, Thomas RM, Albers ER, Cabral M, et al. Maximizing the benefits of antiretroviral therapy for key affected populations. J Int AIDS Soc. 2014;17(1):19320.
37. The Republic of South Africa. The Constitution of the Republic of South Africa, 1996. Pretoria, RSA: https://www.gov.za/documents/constitution-republic-south-africa-1996. Accessed August 18, 2022.
38. Grant JM, Mottet L, Tanis JE, Herman J, Harrison J, Keisling M. National transgender discrimination survey report on health and health care: findings of a study by the National Center for Transgender Equality and the National Gay and Lesbian Task Force. National Center for Transgender Equality; 2010.
39. Leigh Ann Van der Merwe L, Nikodem C, Ewing D. The socio-economic determinants of health for transgender women in South Africa: findings from a mixed-methods study. Agenda. 2020;34(2):41–55.
40. Ritshidze. State of healthcare for key populations. 2022.
41. Rotondi NK, Bauer GR, Scanlon K, Kaay M, Travers R, Travers A. Non-prescribed hormone use and self-performed surgeries: "do-it-yourself" transitions in transgender communities in Ontario, Canada. Am J Public Health. 2013;103(10):1830–6.
42. Sanchez NF, Sanchez JP, Danoff A. Health care utilization, barriers to care, and hormone usage among male-to-female transgender persons in New York City. Am J Public Health. 2009;99(4):713–9.
43. Dollah A, Ongolly F, Ngure K, Odoyo J, Irungu E, Mugwanya K, et al. " I just decided to stop:" understanding PrEP discontinuation among individuals initiating PrEP in HIV care centers in Kenya and its implications for a public health approach to prevention. J Int AIDS Soc. 2021;24(S1):19–20.
44. Pillay D, Stankevitz K, Lanham M, Ridgeway K, Murire M, Briedenhann E, et al. Factors influencing uptake, continuation, and discontinuation of oral PrEP among clients at sex worker and MSM facilities in South Africa. PLoS One. 2020;15(4):e0228620.
45. Makhakhe NF, Sliep Y, Meyer-Weitz A. "Whatever is in the ARVs, is also in the PrEP" challenges associated with oral pre-exposure prophylaxis use among female sex workers in South Africa. Front Public Health. 2022;10.
46. Grant RM, Sevelius JM, Guanira JV, Aguilar JV, Chariyalertsak S, Deutsch MB. Transgender women in clinical trials of pre-exposure prophylaxis. J Acquir Immune Defic Syndr. 2016;72:S226–9.
47. Gorin-Lazard A, Baumstarck K, Boyer L, Maquigneau A, Gebleux S, Penochet JC, et al. Is hormonal therapy associated with better quality of life in transsexuals? A cross-sectional study. J Sex Med. 2012;9(2):531–41.
48. Gómez-Gil E, Zubiaurre-Elorza L, Esteva I, Guillamon A, Godás T, Almaraz MC, et al. Hormone-treated transsexuals report less social distress, anxiety and depression. Psychoneuroendocrinology. 2012;37(5):662–70.

JIAS JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

RESEARCH ARTICLE

Caring for the whole person: transgender-competent HIV pre-exposure prophylaxis as part of integrated primary healthcare services in Vietnam

Anh H. Doan[1,#], Chau M. H. Vu[2], Thu T. Nguyen[3], Kimberly E. Green[1,§,#], Huong T. T. Phan[4], Rena Janamnuaysook[5], Bao N. Vu[1], Thanh M. Le[6], Khang Q. Do[7], Tham T. Tran[1], Trang M. Ngo[8], Lopa Basu[8], Long K. Tran[1] and Zoe Humeau[1]

[§]**Corresponding author**: Kimberly Elizabeth Green, PATH, #1101, 11th Floor, Hanoi Towers, 49 Hai Ba Trung Street, Hanoi 10,000, Vietnam. (kgreen@path.org)
[#]These authors have contributed equally to the work.

Abstract

Introduction: Although HIV prevalence among transgender women who have sex with men in Vietnam is high (16–18%), uptake of pre-exposure prophylaxis (PrEP) is low compared to other populations. When PrEP was initiated in 2017, gender-affirming healthcare was largely unavailable. Lack of access to competent, stigma-free healthcare is a well-documented barrier to transgender women's uptake of PrEP and primary healthcare (PHC). We aimed to demonstrate the utility of a PrEP quality improvement intervention in pinpointing and addressing barriers to PrEP use among transgender women in Vietnam.

Methods: We applied a real-world participatory continuous quality improvement (CQI) and Plan-Do-Study-Act (PDSA) methodology to ascertain barriers to PrEP uptake among transgender women and determine priority actions for quality improvement. A CQI team representing transgender women leaders, key population (KP)-clinic staff, public-sector HIV managers and project staff applied PDSA to test solutions to identified barriers that addressed the primary quality improvement outcome of the monthly change in PrEP uptake among transgender women and secondary outcomes, including month-3 PrEP continuation, the impact of offering PHC on PrEP uptake and unmet PrEP need. We utilized routine programmatic data and a descriptive cross-sectional study enrolling 124 transgender women to measure these outcomes from October 2018 to September 2021.

Results: Five key barriers to PrEP uptake among transgender women were identified and corresponding solutions were put in place: (1) offering gender-affirming care training to KP-clinics and community-based organizations; (2) integrating gender-affirming services into 10 KP-clinics; (3) offering PHC through five one-stop shop (OSS) clinics; (4) implementing a campaign addressing concerns related to hormone use and PrEP interactions; and (5) developing national HIV and transgender healthcare guidelines. New PrEP enrolment and month-3 PrEP continuation increased significantly among transgender women. Of 235 transgender women who initially sought healthcare other than PrEP at OSS clinics, 26.4% subsequently enrolled in PrEP. About one-third of transgender women reported unmet PrEP need, while two-thirds indicated an interest in long-acting cabotegravir.

Conclusions: Offering gender-competent, integrated PHC can increase PrEP enrolment and continuation, and can be an entry-point for PrEP among those seeking care within PHC clinics. More work is needed to expand access to transgender women-led and -competent healthcare in Vietnam.

Keywords: transgender women; gender-affirming care; HIV; PrEP; primary healthcare; Vietnam

Received 10 January 2022; **Accepted** 19 July 2022

1 | INTRODUCTION

While no HIV prevalence or incidence estimates exist for transgender women who have sex with men in Vietnam, small urban samples have measured HIV prevalence from 16.0% to 18.0% [1, 2]. These rates are higher than sentinel HIV prevalence rates measured among men who have sex with men (13.4%), people who inject drugs (12.7%) and female sex workers (3.1%) in Vietnam within the same time period [3]. As in other countries, studies in Vietnam have found that transgender women who have sex with men may experience intersectional and reinforcing factors that increase the risk of HIV

acquisition, including frequency of condomless receptive anal sex, sex work, poverty, violence, stigma, discrimination and social exclusion [4–6].

The Vietnam Ministry of Health (MOH) has developed and led a robust national HIV programme focused on reaching people who inject drugs, female sex workers and, since 2015, men who have sex with men [2]. Since 2020, the programme has recognized transgender women as distinct from men who have sex with men and has made HIV services designed to meet the specific needs of transgender women available in some localities [7].

Oral pre-exposure prophylaxis (PrEP) services have been available in Vietnam since 2017 and can be accessed in 29 of Vietnam's 63 provinces, with 32,000 people using PrEP in 2021 [8]. PrEP services are delivered through a combination of public- and private-sector clinics, including those owned and operated by key population (KP)-led social enterprises. Efforts have been made to differentiate, demedicalize and simplify oral PrEP in Vietnam by making it available through mobile services ("PrEP Bus"), via telehealth and home-delivery, and integrated into primary healthcare (PHC).

When PrEP was first initiated in Vietnam, gender-affirming healthcare for transgender women was largely unavailable. During the first PrEP pilot in Vietnam, "Prepped for PrEP," we found that while PrEP uptake increased five-fold among men who have sex with men from the start to the end of the pilot (reaching 1069 PrEP users), there was no increase in monthly enrolment among transgender women, with only 62 enrolling over the 18 months of implementation [9]. The main reasons transgender women cited for not accessing PrEP were fear that PrEP antiretrovirals would interfere with or reduce the impact of feminizing hormones or would otherwise result in unwelcome side effects [9].

To better respond to transgender women's PrEP and healthcare needs, the US Agency for International Development (USAID)/PATH Healthy Markets project implemented a rapid needs assessment recruiting 409 transgender women in December 2018 from Hanoi and Ho Chi Minh City (HCMC) [10]. The median age of survey respondents was 23. The assessment found that while most (68.6%) transgender women participants knew about PrEP, only 7.6% had ever used or reported currently using PrEP. However, more than half (59.8%) of those not on PrEP stated that they wanted to use it, indicating a significant unmet need. The assessment also found that most (60.5%) transgender women wanted gender-affirming care to be a part of their routine healthcare services. Overall, fear of mistreatment by staff and/or other patients for being transgender and feeling that healthcare providers are not comfortable or knowledgeable in providing care for transgender individuals were cited as major reasons for not seeking healthcare [10].

These findings led to an initiative by Healthy Markets to improve the quality of PrEP services reaching transgender women as part of integrative PHC in Vietnam through a continuous quality improvement (CQI) intervention utilizing the Plan-Do-Study-Act (PDSA) methodology. This paper describes the actions taken and the key results and implications of that work. It aims to demonstrate the utility of a PrEP quality improvement intervention in pinpointing and addressing key barriers to PrEP use among transgender women in Vietnam.

2 | METHODS

2.1 | Application of a participatory quality improvement intervention

In response to the low monthly uptake of PrEP among transgender women noted by 2017–2018 Prepped for PrEP pilot and findings from the Healthy Markets project's 2018 transgender healthcare rapid needs assessment, this paper's authors applied a CQI approach to better understand and address barriers to care among transgender women. CQI best practice involves applying a participatory team approach to assessing and responding to quality challenges and utilizing complimentary data sources to inform the state of healthcare quality being measured, including perspectives from the people who use the services, routine programme data, service provision observation, medical record audits and in some cases, survey data [11]. PDSA can be used in CQI to systematically and iteratively assess the quality of care (often against standards), identify problem areas, generate possible solutions, test those solutions and adjust them over time through ongoing PDSA cycles [12]. PDSA, therefore, provides a framework for continued learning and measurement of change in healthcare quality through practical, real-world experiments.

In 2017, we incrementally developed and adapted a tailored CQI approach for PrEP services. This work evolved into forming CQI teams around each clinic (n = 29) that included clinic health workers and managers, community PrEP users, local government HIV focal points and Healthy Markets staff. Of the 29 clinics, 10 were private clinics led and owned by KPs and primarily served men who have sex with men and transgender women. Their CQI efforts are described in this paper. Of these 10 clinics, two are located in Hanoi, the capital city of Vietnam; six in HCMC, the largest city in the country; and two in Dong Nai, a peri-urban province adjacent to HCMC. These CQI efforts were ultimately encoded in a toolkit that has helped to systematize CQI-PDSA approaches for all key HIV and PHC services [13].

To address the key challenge of low PrEP uptake among transgender women, we formed a specific group comprised of transgender women community leaders and organizations, 10 private KP-led clinics and Healthy Markets staff (known from here on as the transgender women CQI healthcare team) to pinpoint key quality-of-care challenges (using a baseline quality assessment that reviews indicators from six data sources), determine how to address these challenges, put in place strategies and then track quantitative and qualitative data at designated time points to determine if the action or course correction was effective. From mid- to late-2018, this involved organizing feedback sessions with transgender women PrEP users, assessing KP-clinic standard operating procedures and staff capacity to offer gender-affirming care, reviewing clinic data and assessing national guidance.

2.1.1 | Outcomes of interest

Our *primary* outcome of interest was the monthly change in PrEP uptake among transgender women over time (calculated as a monthly variation in new PrEP enrolment among transgender women). We defined our *secondary* CQI-PDSA

Table 1. Data methods

No.	Method	Description	Linked outcomes and results
1	Continuous quality improvement (CQI)—Plan-Do-Study-Act (PDSA) cycles	CQI teams applied PDSA to test solutions to identified barriers in pre-exposure prophylaxis (PrEP) uptake among transgender women. This process includes an iterative cycle of assessment, action planning and testing actions to address quality challenges: (1) gathering data from six information sources at each clinic (i.e. a clinic self-assessment, observation of service delivery and clinic practices, file audit, routine performance data, infrastructure check and direct client feedback); (2) developing action plans for addressing these challenges; and (3) tracking quantitative and qualitative data at designated time points to determine if the action or course correction was effective.	Key barriers to PrEP uptake and quality improvement actions needed
2	Routine programmatic data analysis	HIV service data from 10 KP-led PrEP clinics were reported by clinics monthly through a secure online system and assessed by the study team to explore transgender women's use of PrEP and other services from October 2020 to September 2021.	Cumulative and monthly changes in PrEP enrolment over time, month-3 PrEP continuation, one-stop shop service utilization and secondary PrEP enrolment
3	Descriptive cross-sectional study	Data were collected through individual interviews and tablet recordings using CSPro software and descriptive statistics were used to calculate the main and secondary outcomes of interest for CQI-PDSA efforts.	PrEP use and unmet PrEP need; preferences for use of long-acting injectable cabotegravir

Abbreviations: CQI, continuous quality improvement; KP, key population; PDSA, Plan-Do-Study-Act; PrEP, pre-exposure prophylaxis.

outcomes of interest as: (1) month-3 PrEP continuation over time among transgender women (measured as a successful 3-month refill after the first 3 months on PrEP); (2) whether offering integrated services might lead to secondary PrEP enrolment for transgender women accessing non-PrEP services when first seeking care (measured through five KP-led one-stop shop [OSS] clinics' service use data); (3) degree of unmet PrEP need among transgender women and the role a new PrEP product, namely long-acting cabotegravir (CAB-LA), might play in influencing PrEP use decision-making.

Related to measuring unmet PrEP need, we utilized data from a February 2021 cross-sectional survey on KP preferences, use of, and willingness to pay for HIV and PHC services. The study enrolled 124 transgender women in Hanoi, HCMC, Can Tho and Dong Nai Provinces. An ethics review was provided by the Institute of Social and Medical Studies Institutional Review Board in Hanoi. Oral informed consent was obtained from all participants. Preliminary PrEP-focused results from this study have been published in brief elsewhere [14].

2.2 | Data capture and analysis

To assess changes in PrEP uptake among transgender women following implementation of the above change strategies, we utilized programmatic HIV service data from 10 KP-led PrEP clinics (including five designated as integrated PHC OSS clinics—see below) supported through Healthy Markets. These data are reported by clinics monthly through a secure online system. Specific programmatic data from the five OSS clinics were assessed to explore transgender women's use of PrEP and other services from October 2020 to September 2021. We were interested in whether offering integrated person-centred care services might lead to secondary PrEP enrolment for transgender women.

Programmatic PrEP and OSS services data (including HIV testing; sexually transmitted infection, hepatitis B and C, and hormone testing/services; and mental healthcare) were cleaned and analysed monthly based on Healthy Markets project monitoring protocols. Data quality was verified based on routine project data quality assurance procedures. The data were used to calculate transgender women's cumulative and monthly changes in PrEP enrolment over time, month-3 PrEP continuation, OSS service utilization and secondary PrEP enrolment.

For the cross-sectional survey, data were collected through individual interviews and tablet recordings (CAPI) using CSPro software. Data were transferred to Stata v14.0 for cleaning and analysis. The data collectors synthesized the data daily, after which the data management team conducted a data quality assessment. If data were unavailable, missing or unusual (based on the general local trends), the data management team contacted the clinics providing the data the same day to determine the reasons behind data gaps or inconsistencies and then correct them. Descriptive statistics were used to calculate PrEP use and unmet need. See Table 1 for a

description of these methods.

3 | RESULTS

3.1 | Key barriers identified through CQI

Through the baseline quality assessment, the transgender women CQI healthcare team identified five fundamental barriers to PrEP uptake among transgender women to address through PDSA: (1) limited knowledge of transgender-competent healthcare among healthcare providers; (2) limited roles of transgender women in health service provision within private- and KP-clinics; (3) lack of gender-affirming care integrated into PHC services in PrEP clinics and related, absence of guidelines to inform *how* to integrate gender-affirming care; (4) limited information on transgender women community norms around drug–drug interaction between PrEP and gender-affirming hormones; and (5) lack of national guidelines on gender-affirming care as part of HIV services (Table 2).

3.2 | Quality improvement actions

Below (and in Table 2), we describe the quality improvement actions taken to address these barriers.

3.2.1 | Training

In August 2018, the Tangerine Academy, a training branch of the Institute of HIV Research and Innovation in Bangkok, Thailand, provided in-person trainings on transgender-competent care to 20 healthcare providers from KP-clinics in Hanoi and HCMC, representatives from transgender women-led community-based organizations (Ruby, Strong Lady and Venus), and members of the HCMC and Hanoi Provincial AIDS Committees. The training oriented healthcare providers and local health leaders on gender-sensitive and -affirming care, management of gender-affirming hormone treatment and service provision, and strategies to integrate gender-affirming care into HIV services.

The Tangerine Academy then provided on-site technical assistance, followed by remote mentoring for clinic staff on interpretation of laboratory results and management of hormone treatment with PrEP. A second on-site visit was conducted in late 2019 to mentor clinics in Hanoi. The Tangerine Academy also participated in a meeting with the MOH to inform the development of national HIV guidelines focused on the needs of transgender individuals. Subsequent online training was held in August 2021 for more than 90 people, including 40 healthcare providers from 14 clinics, 30 staff from transgender women-led community-based organizations and participants from the MOH.

3.2.2 | Staffing

Although clinics led and staffed by KPs in HCMC and Hanoi existed in 2018, they had no adequately defined and dedicated roles specifically for transgender women providers. The transgender women CQI healthcare team supported the placement of transgender women healthcare providers in the participating KP-led PHC clinics.

Table 2. Key barriers to care and Plan-Do-Study-Act steps taken to enable greater access and uptake

No.	Major barriers to PrEP/PHC	Quality improvement actions to enable greater PrEP/PHC access
1	Limited knowledge of transgender-sensitive and transgender-competent healthcare among healthcare providers.	**Training**. Improved PrEP clinic healthcare provider competencies in gender-affirming care through training and mentoring by Tangerine Academy and reinforced through local learning.
2	Limited roles of transgender women in care delivery within private and KP clinics.	**Staffing**. Transgender women lay healthcare workers were employed by clinics and trained to provide dedicated counselling and support to clients.
3	Lack of gender-affirming or adequately integrated primary healthcare services in clinics offering PrEP.	**Service**. Offered gender-affirming hormone-level testing, counselling and referrals for feminizing procedures, and additional integrative primary healthcare services through private clinics.
4	Limited information on transgender women's community norming around drug–drug interaction between PrEP and gender-affirming hormones.	**Outreach**. Implemented a transgender women-led communications campaign on PrEP use and hormones to address concerns expressed by the community.
5	No national guidelines on gender-affirming care as part of HIV services.	**Guidelines**. Assisted the Vietnam Ministry of Health in developing first-ever transgender HIV and healthcare guidelines as a result of actions 1–4.

Abbreviations: KP, key population; PHC, primary healthcare; PrEP, pre-exposure prophylaxis.

3.2.3 | Service

In October 2018, five KP-led PHC PrEP clinics (Alocare, Bien Viet, Galant, Glink and My Home) began offering estradiol and testosterone hormone-level testing, and counselling and referrals for feminizing procedures (of which there are limited options in Vietnam). The KP-led clinics then further expanded their service offerings by adding sexually transmitted infection testing and treatment, viral hepatitis services, and mental health assessments and counselling, alongside the existing HIV services (i.e. testing, antiretroviral therapy, care for coinfections, and PrEP and non-occupational post-exposure prophylaxis). These clinics were designated as OSS clinics in 2020 and received additional financing through USAID/US President's Emergency Plan for AIDS Relief to offer an expanded service package to clients. Five additional KP-clinics were opened from late 2018 to 2021 and provided with training and standard operating procedures on gender-affirming PrEP service delivery.

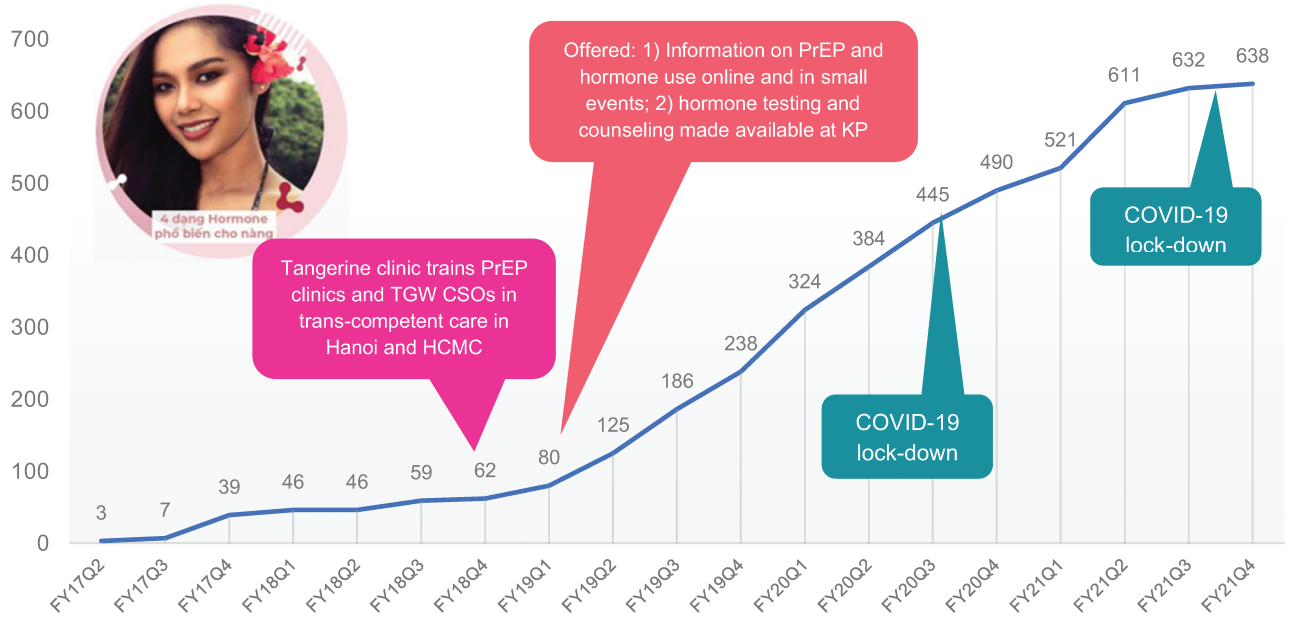


Figure 1. Transgender women's pre-exposure prophylaxis uptake before and after the introduction of gender-affirming services and impact of COVID-19 on enrolment. Abbreviations: CSO, civil society organization; HCMC, Ho Chi Minh City; KP, key population; PrEP, pre-exposure prophylaxis; TGW, transgender women.

3.2.4 | *Outreach*

The Healthy Markets project assisted the Vietnam Network of Transgender People, transgender women influencers and KP-led private clinics to launch a dedicated campaign known as "Be Me, Be Happy" that focused on creating an inclusive online and offline community for information and support on healthcare and wellbeing among transgender women. Through this campaign, transgender women leaders (including the co-authors of this paper) aimed to directly address hormone–PrEP drug interaction concerns through specific online content on the "Be Me, Be Sexy" Facebook page (with 21,000 followers), video clips, a TikTok PrEP ambassador championship and small-scale engagements that enable transgender women considering PrEP to ask questions to peer transgender women PrEP experts and healthcare workers.

3.2.5 | *Guidelines*

As a result of the described quality improvement efforts undertaken, the Vietnam Administration for HIV/AIDS Control (VAAC) expressed interest in developing national guidelines on transgender healthcare as part of HIV services. Healthy Markets, with technical engagement from Tangerine Academy, and transgender leaders (including the co-authors of this paper) partnered with the VAAC to develop and publish these guidelines in 2020.

3.3 | Key outcomes

3.3.1 | *PrEP uptake*

The cumulative number of transgender women ever enrolled in PrEP increased from 46 in 2018 to 638 in 2021, with 485 using PrEP from October 2020 to September 2021. Cumulative transgender women's PrEP uptake increased from 3.4 new enrolments per month on average from 2017 through 2018 to 20 per month on average from 2019 through 2020, during the implementation of the five described CQI interventions (Figure 1). New enrolment rates declined substantially from April through September 2021 as strict COVID-19 lock-down orders were enforced [15, 16].

3.3.2 | *Month-3 PrEP continuation*

Overall, month-3 PrEP continuation among transgender women increased from 87% during October 2018 through September 2019 to 98% during October 2019 through September 2020 to 99% during October 2020 through September 2021 (Figure 2). These represented the highest continuation rates among all other KP groups using PrEP.

3.3.3 | *Impact of integrated PHC services on PrEP uptake*

From October 2020 through September 2021, 416 transgender women sought healthcare at one of the five OSS clinics, representing 637 total visits. The median age among transgender women seeking OSS healthcare services was 29 (range 15–49). The majority of transgender women (96.6%, n = 402) sought services in HCMC, while 14 did so in Hanoi. The most frequent services transgender women used at the OSS clinics were HIV testing (97.6%) and PrEP services (62.8%), followed by sexually transmitted infection testing (23.1%), hepatitis C testing (21.0%) and hepatitis B testing (14.1%). Mental health counselling and hormone testing were accessed less frequently (Figure 3).

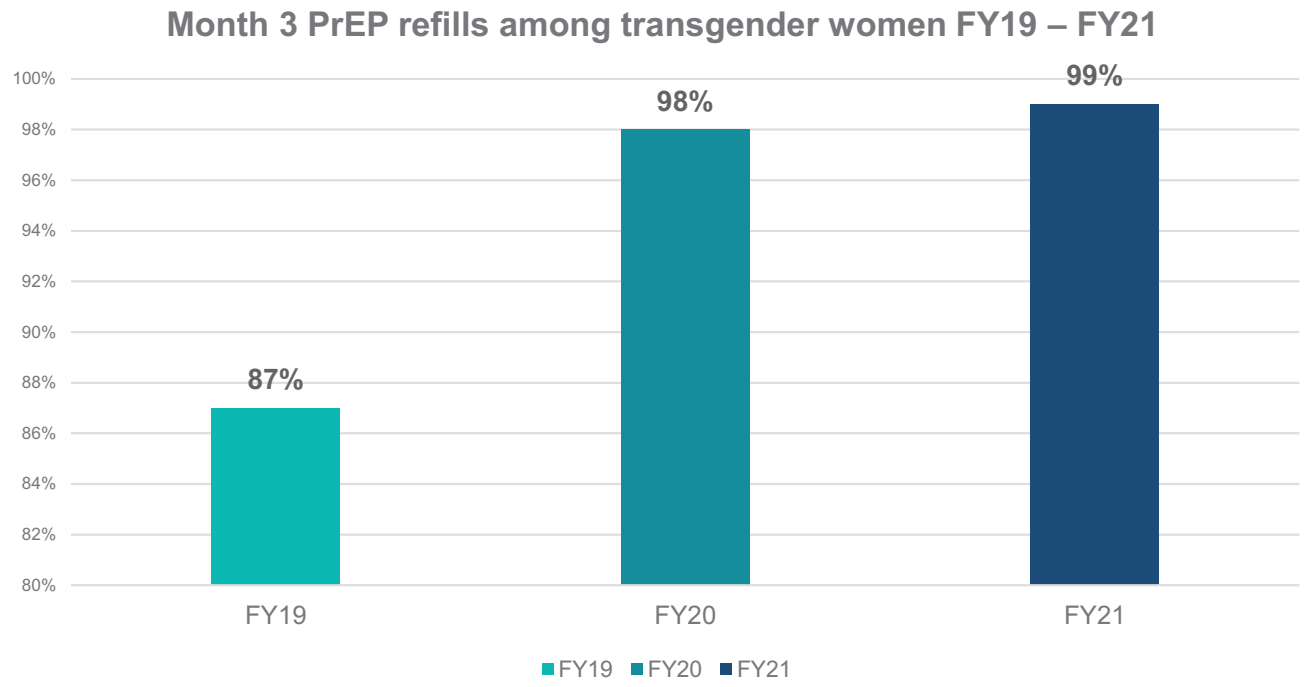


Figure 2. Month-3 pre-exposure prophylaxis continuation among transgender women in the fiscal year 2019 (October 2019–September 2020), the fiscal year 2020 (October 2020–September 2021) and the fiscal year 2021 (October 2020–September 2021). Abbreviation: FY, fiscal year.

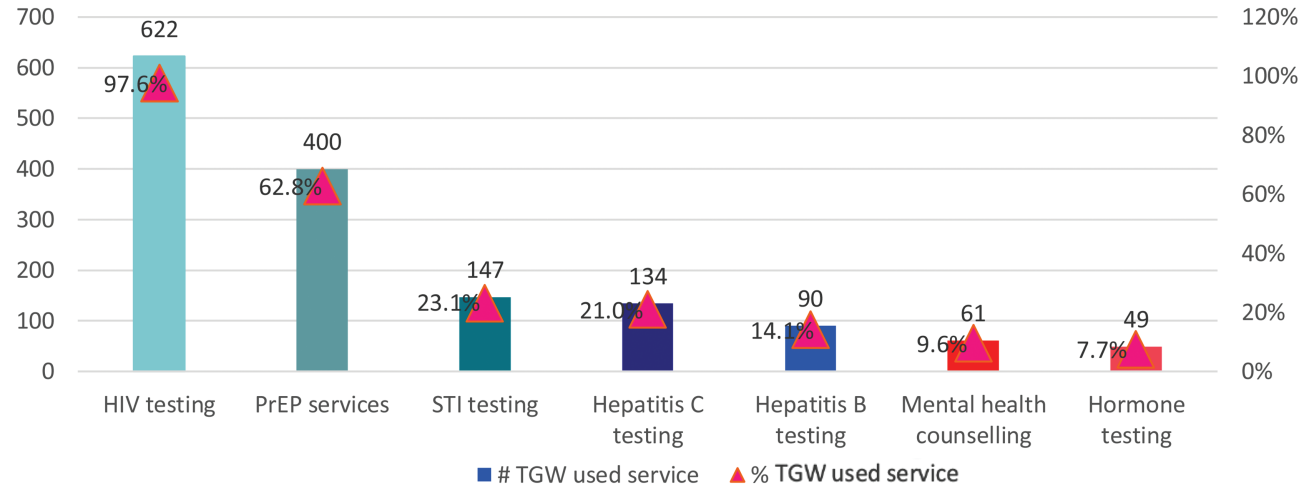


Figure 3. Services used by transgender women at five key population-led one-stop shop primary healthcare clinics, October 2020–September 2021 (number of clinic visits). Abbreviations: PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection; TGW, transgender women.

offset="-5pt"Among the 235 transgender women who sought healthcare other than PrEP at the OSS clinics, 62 (26.4%) subsequently enrolled in PrEP services. Transgender women who were of older age (OR = 5.21, 95% CI 2.05–13.39, p <0.001) and who sought PrEP offline (through word-of-mouth, direct peer referrals or attending an event) (OR = 2.29; 95% CI 1.20–4.44, p = 0.007) had greater odds of PrEP services being the initial/primary reason they attended an OSS clinic (Table 3). Among this population, 41% subsequently used other OSS health services.

3.3.4 | *Unmet PrEP need*

Thirty-one percent (n = 39) of transgender women reported being on PrEP, 28.2% (n = 35) wanted to take PrEP but not having done so yet, 26.2% had heard of CAB-LA and 63.4% indicated an interest in using CAB-LA over oral PrEP. The primary reason stated for wanting CAB-LA over oral PrEP was not needing to remember to take pills (66.9%); conversely, the primary reason for opting for oral PrEP over CAB-LA was not liking injections (61.8%).

Table 3. Unadjusted factors associated with secondary pre-exposure prophylaxis enrolment at one-stop shop clinics

		Transgender women who sought PrEP first	Transgender women who sought PrEP only after receiving other services	Univariate logistic regression
Age group	25–49	168 (79.3%)	44 (20.7%)	OR = 0.19, 95% CI 0.07–0.49, p <0.001
	15–24	11 (42.3%)	15 (57.7%)	
Sources	Offline only	100 (82.6%)	21 (17.4%)	OR = 2.29, 95% CI 1.20–4.44, p = 0.007
	Both offline and online	79 (67.5%)	38 (32.5%)	

Abbreviations: CI, confidence interval; OR, odds ratio. PrEP, pre-exposure prophylaxis.

4 | DISCUSSION

We found that by applying collaborative CQI-PDSA approaches, we were able to pinpoint five primary barriers to transgender women's PrEP uptake and put in place actions to address them. After applying these programmatic change actions, we saw an overall 17-fold monthly increase in PrEP uptake among transgender women from the initial Prepped for PrEP pilot and measured a 12% increase in month-3 PrEP continuation among transgender women from the end of 2018 to September 2021.

The participants described in this paper represent the majority of transgender women on PrEP in Vietnam. The national PrEP programme reported a total of 32,000 people on PrEP from October 2020 to September 2021; of these, 574 (2%) identify as transgender women. The 10 KP-clinics described in this paper enrolled 485 transgender women on PrEP during the same time period, representing 84.5% of the national total [15].

Offering integrated gender-affirming PHC may have supported the increase in PrEP continuation. van Griensven et al. reported that offering transgender-specific integrated PHC services resulted in increased PrEP enrolment and retention [16]. Additionally, we found that offering integrated services led to secondary PrEP enrolment of just over one-quarter of the transgender women seeking other healthcare services at OSS clinics. We also found that about one-quarter of transgender women first seeking PrEP at OSS clinics subsequently utilized other PHC services at the clinics. However, we noted lower than anticipated utilization in mental health, sexually transmitted infection and hormone testing services at these clinics. These services were intended to be offered on a greater scale starting from late 2019 but with COVID-19 surges, training, clinical mentoring and in-clinic care seeking were curtailed. With the adult COVID-19 vaccination rate near 96% and the country has opened up from May 2022, training and support to OSS clinics to intensify and strengthen these services has begun. Importantly, the OSS model is delivered by KP-owned and -led private clinics that have diversified their income streams and are able to sustain these services.

While CQI-PDSA efforts described in this paper equipped KP-led clinics to offer transgender-sensitive and -competent care, a critical next step will be the establishment of transgender-led and -owned clinics providing differentiated care [17, 18]. The 2020 MOH transgender HIV services guidelines will be vital in enabling comprehensive gender-affirming services to be available on a larger scale.

Though the described improvements in the quality of gender-affirming care have been important, there is still an unmet PrEP need among transgender women in the country. Nearly, a third of individuals in the cross-sectional study reported wanting PrEP but not yet seeking it. While this is lower than the reported unmet PrEP need (56%) reported in the December 2018 needs assessment, it is still significant [10]. It will be very important to understand the underlying root causes of this unmet need. Moreover, given about two-thirds of transgender women indicated an interest in taking CAB-LA over oral PrEP, it will be essential to understand potential challenges and opportunities in the use of CAB-LA among transgender women and ensure its integration into gender-affirming services.

COVID-19 has had a profound impact on the overall well-being of transgender women in Vietnam [19, 20]. During the worst part of the lockdown (April–September 2021), 46.2% of transgender women stopped using PrEP at Healthy Markets-supported clinic sites [21]. Efforts are underway by community organizations and clinics to offer economic relief and re-engage transgender women in PHC services, including PrEP.

There are several limitations associated with the data presented in this paper. First, our CQI-PDSA methodology was not able to directly isolate the linear impact of the CQI-PDSA interventions on the increased PrEP uptake we observed. Second, the sample size and very limited number of programmatic socio-demographic factors routinely collected (age and online or offline PrEP enrolment) limited robust multivariable analysis for exploring factors associated with PrEP uptake. Third, our work was not based on a probability sample nor necessarily representative of transgender women in HCMC, Hanoi and Dong Nai so cannot be interpreted as such. Last, with limited resources, we were not able to address the needs of transgender men and gender-nonbinary individuals who might be interested in PrEP. This will be an important area of focus in Vietnam's next phase of PrEP scale-up.

Despite these limitations, the increase in transgender women enrolling in PrEP after the five primary quality improvement actions were put in place is encouraging. The improvements in month-3 PrEP continuation are equally

reassuring. Further, our paper included data from 85% of transgender women using PrEP in Vietnam, allowing for confidence in interpreting results.

5 | CONCLUSIONS

Using a participatory CQI-PDSA approach was critical to identifying underlying barriers to transgender women's uptake of PrEP services and significantly increasing new PrEP uptake, month-3 continuation and secondary PrEP enrolment through other PHC services. Our findings suggest that more investment and resources are needed to increase transgender-sensitive and -competent care in Vietnam, including through transgender-led and -owned clinics, and to support the implementation at scale of the 2020 MOH transgender HIV services guidelines. Another vital next step will be to expand PHC services to include a wider array of gender-affirming care and address the needs of transgender men and gender-nonbinary individuals. Intensive work will also be needed to enable transgender communities to recover from COVID-19 impacts. By taking these actions, the Vietnam MOH will be better placed to meet its goals for HIV epidemic control and universal health coverage by 2030.

AUTHORS' AFFILIATIONS

[1]PATH, Hanoi, Vietnam; [2]Vietnam Network of Transgender People, Hanoi, Vietnam; [3]My Home, Ho Chi Minh City, Vietnam; [4]Vietnam Administration for HIV/AIDS Control, Ministry of Health, Hanoi, Vietnam; [5]Institute of HIV Research and Innovation, Bangkok, Thailand; [6]Glink, Ho Chi Minh City, Vietnam; [7]Galant, Ho Chi Minh City, Vietnam; [8]US Agency for International Development, Hanoi, Vietnam

COMPETING INTERESTS

The authors have no competing interests to declare.

AUTHORS' CONTRIBUTIONS

AHD and KEG conceived the paper and wrote the manuscript in equal parts. CMHV and TTN provided leadership in all CQI-PDSA efforts. HTTP provided national leadership for CQI-PDSA and the development of the national guidelines. RJ led training and mentoring described in the manuscript and contributed to the writing of the paper. AHD, KEG, BNV and TTT guided CQI-PDSA efforts on behalf of USAID/PATH Healthy Markets. CMHV, TTN, TML and KQD oversaw the delivery of transgender-affirming care in KP-clinics. TMN and LB provided technical input and strong commitment to the improvement of PrEP services for transgender women. LKT led programmatic and descriptive study data analytics and contributed to the writing of the paper. ZH provided copy editing and coordination.

ACKNOWLEDGEMENTS

The authors would like to acknowledge the significant contributions of participating transgender and gender-nonbinary-led community-based organizations (Ruby, Strong Lady and Venus), and the Ho Chi Minh City and Hanoi Provincial AIDS Centers that pioneered PrEP delivery among transgender women in Vietnam. We thank the US Agency for International Development and the US President's Emergency Plan for AIDS Relief for their support and funds for PrEP scale-up and integrative person-centred PHC services among transgender women and other key populations, and the USAID-funded LINKAGES project implemented by FHI 360 through which IHRI provided technical assistance.

FUNDING

Financing for the work described in this article was made possible by the US Agency for International Development, through the US President's Emergency Plan for AIDS Relief.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

REFERENCES

1. Bao A, Colby DJ, Trang T, Le BQ, Dinh TD, Nguyen QH, et al. Correlates of HIV testing among transgender women in Ho Chi Minh, Vietnam. AIDS Behav. 2016;20(3):371–8.
2. Pham QD, Wilson DP, Kerr CC, Shattock AJ, Do HM, Duong AT, et al. Estimating the cost-effectiveness of HIV prevention programmes in Vietnam, 2006–2010: a modelling study. PLoS One. 2015;10(7):e0133171.
3. Vietnam Ministry of Health (MOH). HIV sentinel surveillance report. Hanoi: Vietnam MOH; 2020.
4. Poteat T, Wirtz AL, Reisner S. Strategies for engaging transgender populations in HIV prevention and care. Curr Opin HIV AIDS. 2019;14(5):393–400.
5. Vu BN, Mulvey KP, Baldwin S, Nguyen ST. HIV risk among drug-using men who have sex with men, men selling sex, and transgender individuals in Vietnam. Cult Health Sex. 2012;14(2):167–80.
6. Baral SD, Poteat T, Strömdahl S, Wirtz AL, Guadamuz TE, Beyrer C. Worldwide burden of HIV in transgender women: a systematic review and meta-analysis. Lancet Infect Dis. 2013;13(3):214–22.
7. Vietnam Ministry of Health (MOH). Guidelines on HIV/AIDS prevention interventions for transgender people. Hanoi: Vietnam MOH; 2020.
8. Vietnam Administration for HIV/AIDS Control, Ministry of Health (MOH). PrEP data. Hanoi: Vietnam MOH; 2021.
9. Green KE, Nguyen LH, Phan HTT, Vu BN, Tran MH, Ngo HV, et al. Prepped for PrEP? Acceptability, continuation and adherence among men who have sex with men and transgender women enrolled as part of Vietnam's first pre-exposure prophylaxis program. Sex Health. 2021;18(1):104–15.
10. Tran MH. A needs assessment of health care and social services among transgender women in Hanoi and Ho Chi Minh City. Hanoi: PATH and CCIHP; 2019.
11. Reed JE, Davey N, Woodcock T. The foundations of quality improvement science. Future Hosp J. 2016;3:199–202.
12. Taylor MJ, McNicholas C, Nicolay C, Darzi A , Bell D , Reed JE , et al. Systematic review of the application of the Plan-Do-Study-Act method to improve quality in healthcare. BMJ Qual Saf. 2014;23:290–8.
13. USAID/PATH Healthy Markets Project. Continuous quality improvement toolkit. Hanoi: PATH; 2020.
14. Green KE, Phan HTT, Vu BN, Nguyen NT, Le TM, Vu YN. Acceptability of and willingness to pay for long-acting injectable pre-exposure prophylaxis among men who have sex with men, transgender women, female sex workers and people who inject drugs in Vietnam. IAS 2021: Proceedings of the 11th IAS International AIDS Society Conference on HIV Science. Berlin; 2021.
15. Data from the national MOH PrEP database. Cited 2021 November 3.
16. van Griensven F, Janamnuaysook R, Nampaisan O, Peelay J, Samitpol K, Mills S, et al. Uptake of primary care services and HIV and syphilis infection among transgender women attending the Tangerine Community Health Clinic, Bangkok, Thailand, 2016–2019. J Int AIDS Soc. 2021;24(6):e25683.
17. Janamnuaysook R, Green KE, Seekaew P, Vu BN, Van Ngo H, Doan HA, et al. Demedicalisation of HIV interventions to end HIV in the Asia–Pacific. Sex Health. 2021;18(1):13–20.
18. Phanuphak N, Sungsing T, Jantarapakde J, Pengnonyang S, Trachunthong D, Mingkwanrungruang P, et al. Princess PrEP program: the first key population-led model to deliver pre-exposure prophylaxis to key populations by key populations in Thailand. Sex Health. 2018;15(6):542–55.
19. Phan A. A Covid year to remember (and forget) for Vietnam. Vietnam Express International; 2021. https://e.vnexpress.net/news/news/a-covid-year-to-remember-and-forget-for-vietnam-4406392.html. January 15, 2022
20. United Nations in Viet Nam. UN analysis on social impacts of COVID-19 and strategic policy recommendations for Viet Nam. [Cited 2021 November 3]. https://www.unicef.org/vietnam/media/5996/file/UN%20analysis%20on%20social%20impacts%20of%20COVID-19%20and%20strategic%20policy%20recommendations%20for%20Viet%20Nam.pdf
21. USAID/PATH Healthy Markets. Annal Progress Report Fiscal Year 2021. Hanoi: PATH; 2021.

Rebchook GM et al. *Journal of the International AIDS Society* 2022, **25**(S5):e25991
http://onlinelibrary.wiley.com/doi/10.1002/jia2.25991/full | https://doi.org/10.1002/jia2.25991

JIAS JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

RESEARCH ARTICLE

An evaluation of nine culturally tailored interventions designed to enhance engagement in HIV care among transgender women of colour in the United States

Gregory M. Rebchook[1,§], Deepalika Chakravarty[1], Jessica M. Xavier[2], JoAnne G. Keatley[1,3], Andres Maiorana[1], Jae Sevelius[1], Starley B. Shade[1,4] and the SPNS Transgender Women of Color Study Group[1]

[§]**Corresponding author**: Gregory M. Rebchook, Division of Prevention Science, Department of Medicine, University of California, San Francisco, Center for AIDS Prevention Studies (CAPS) & UCSF Prevention Research Center, UCSF Box 0886, 550 16th Street, 3rd Floor, San Francisco, CA 94143, USA. Tel: 1-415-502-1000 x 14621. (greg.rebchook@ucsf.edu)

Abstract

Introduction: Transgender women (TW) worldwide have a high prevalence of HIV, and TW with HIV encounter numerous healthcare barriers. It is critical to develop evidence-informed interventions to improve their engagement in healthcare to achieve durable viral suppression (VS). We evaluated whether participation in one of nine interventions designed specifically for TW was associated with improved engagement in HIV care among transgender women of colour (TWC).

Methods: Between 2013 and 2017, nine US organizations implemented nine distinct and innovative HIV care engagement interventions with diverse strategies, including: individual and group sessions, case management and navigation, outreach, drop-in spaces, peer support and/or incentives to engage TWC with HIV in care. The organizations enrolled 858 TWC, conducted surveys, captured intervention exposure data and extracted medical record data. Our evaluation of the interventions employed a pre-post design and examined four outcomes—any HIV care visit, antiretroviral therapy (ART) prescription, retention in HIV care and VS (both overall and among those with a clinic visit and viral load test), at baseline and every 6 months for 24 months. We employed logistic generalized estimating equations to assess the relative odds of each outcome at 12 and 24 months compared to baseline.

Results: Overall, 79% of participants were exposed to at least one intervention activity. Over 24 months of follow-up, participants received services for a median of over 6 hours (range: 3–69 hours/participant). Compared to baseline, significantly ($p<0.05$) greater odds were demonstrated at both 12 and 24 months for three outcomes: prescription of ART (ORs: 1.42 at 12 months, 1.49 at 24 months), VS among all participants (ORs: 1.49, 1.54) and VS among those with a clinic visit and viral load test (ORs: 1.53, 1.98). The outcomes of any HIV care visit and retention in HIV care had significantly greater odds (ORs: 1.38 and 1.58, respectively) only at 12 months compared to baseline.

Conclusions: These evaluation results illustrate promising approaches to improve engagement in HIV care and VS among TWC with HIV. Continued development, adaptation and scale-up of culturally tailored HIV care interventions for this key population are necessary to meet the UNAIDS 95-95-95 goals.

Keywords: transgender persons; HIV infections; delivery of healthcare; acquired immunodeficiency syndrome; continuity of patient care; evidence-informed interventions

Additional information may be found under the Supporting Information tab of this article.

Received 11 January 2022; **Accepted** 2 August 2022

1 | INTRODUCTION

Transgender women (TW) are highly impacted by HIV worldwide and in the United States. Global HIV prevalence estimates among TW range from 19.9% to 40% [1, 2]. In the United States, HIV prevalence estimates among TW range from 14% to 42% [3, 4]. Transgender women of colour (TWC) have the highest prevalence of HIV in the United States, with 44.2% among African American TW and 25.8% among Latina TW [3].

Despite this disproportionate HIV burden, TW overall and TWC specifically have been overlooked in HIV surveillance,

prevention, and treatment efforts. Until 2020, HIV surveillance in the United States did not separately monitor HIV incidence, prevalence, and mortality among TW [5]. Only a small number of prevention interventions, most developed in the past decade, have specifically addressed TWC [6–12]. In the absence of systematic national surveillance, the lack of a coordinated response to HIV disparities among TWC, and the ongoing epidemic of anti-transgender violence [13–15], the devastating impact of HIV among TWC became a silent tragedy [16].

TWC with HIV face many barriers to engagement in HIV care and treatment. Intersectional stigmas [17], including transphobia, racism, discrimination, hostility, and provider bias, produce systemic barriers to care, such as poverty, homelessness, unemployment, and lack of insurance [18–21]. The Ryan White HIV/AIDS Program (RWHAP), administered by the US Health Resources and Services Administration (HRSA), funds HIV care and treatment for low-income persons. In 2020, about 1.8% of all RWHAP clients were TW [22]. Compared to their cisgender peers, TW RWHAP clients are more likely to be of colour, be younger, have unstable housing, and have incomes at or below the federal poverty level [22, 23]. They are also more likely to report unmet needs for food and nutrition, harm reduction, mental health, and housing services at entry into HIV care compared with cisgender women and men [24]. From 2016 to 2020, TW demonstrated retention in HIV care (range: 77.3–79.8%) close to the average for all RWHAP clients (79.4–81.7%), but they have notably lower than average viral suppression (VS; 79.0–84.2% vs. 84.9–89.4%) [22].

To address these disparities, the RWHAP funded a Special Program of National Significance (SPNS), *Enhancing Engagement and Retention in Quality HIV Care for Transgender Women of Color* in 2012. The RWHAP's SPNS Program has funded demonstration projects to improve HIV care engagement since 1991 [25]. SPNS interventions have pioneered behavioural and treatment approaches to improve access to and engagement in care and HIV service delivery for diverse populations [26–33]. Until HRSA funded this initiative, there were no interventions focused upon improving TW's access to HIV primary care [34]. Nine demonstration projects were funded to develop and implement culturally tailored interventions to enhance engagement in HIV care among TWC with HIV. In this paper, we present the findings from the evaluation of health outcomes associated with these nine interventions.

2 | METHODS

2.1 | Settings and populations

The nine demonstration sites were located in four US urban centres: New York City, New York (Community Health Network in Queens and the State University of New York [SUNY]—Downstate in Brooklyn), Chicago, Illinois (Chicago House and Howard Brown Health Center), Los Angeles, California (Bienestar Human Services and Friends Research Institute) and California's San Francisco Bay area (Tri City Health Center in Fremont, Public Health Institute in Oakland and a partnership between the San Francisco Department of Health and the Asian/Pacific Islander Wellness Center in San Francisco). Additionally, HRSA funded the University of California, San Francisco to provide technical assistance and perform a multisite evaluation of the nine interventions.

2.2 | Recruitment and eligibility

The sites used multiple recruitment and intervention strategies [35], including community outreach, social network recruitment, printed materials and referrals from clinics and other service providers to recruit participants into their interventions. To be eligible, participants had to be assigned male sex at birth; identify as transgender or female; and be at least 18 years old, living with HIV, and fluent in English or Spanish. Participants provided informed consent at enrolment. The study was approved annually by the Institutional Review Boards of each site and the evaluation centre.

2.3 | Interventions

Intervention manuals are available that describe each of these nine interventions [36], and Table 1 provides an overview of the underlying theories and central components of each intervention. The interventions dynamically evolved over time—starting and stopping group sessions, adding new incentives, modifying modes of outreach, varying drop-in hours, locations and policies—to meet participants' needs.

2.4 | Evaluation

Data were collected from December 2013 to August 2017 from three sources.

2.4.1 | Participant survey

Prior to their first interaction with the intervention, participants were interviewed by non-intervention staff or completed a self-administered baseline survey in REDCap [37, 38] in the language of their choosing (English or Spanish). The survey included questions about demographic and psychosocial characteristics, as well as gender-affirming and HIV care. Participants were paid $25–$40 for baseline survey completion.

2.4.2 | Medical chart data from electronic health systems

Sites that provided HIV care extracted medical chart data from all visits for all participants within each reporting period. Sites that did not provide HIV care obtained signed medical release forms from each participant and obtained medical record data from their HIV care providers. The 6 months prior to enrolment was treated as the baseline period. Data were also extracted for every succeeding 6-month period through the end of the study.

2.4.3 | Intervention exposure data

Participants' exposure to the intervention was recorded in real-time by research staff at each site. Here, we use data from the first 24 months following enrolment.

Table 1. Intervention core elements and theories

Intervention name	TWEET [54][a]	INFINI-T [55]	Howard Brown[b] [56]	Trans Life Care [57]	Brandy Martell Project [58]	Trans-Access [58]	Princess Project [59]	Transactivate [60]	Alexis Project [61]
Organization (sub-population)	Community Health Network	SUNY Downstate (adolescents and young adult TW)	Howard Brown Health Center	Chicago House	Tri City Health Center[c]	San Francisco Department of Public Health/Asian Pacific Islander Wellness Center[d]	Public Health Institute (Black/African American TW)	Bienestar Health Services (Latina TW)	Friends Research Institute
Foundation for the intervention									
	Social Cognitive Theory, Trans Theoretical Model	Singer's Syndemic Theory	Community-tailored health intervention programmes that create safe spaces for transgender women	Trauma-informed, Client centred, Strengths-based, Systems theory, Harm reduction	Critical Race Theory	Trans-affirming care, self-actualizing services, mindful medicine, care coordination and continuity, harm reduction, community centred, radical healthcare	Motivational Enhancement Therapy, Motivational interviewing	Trans Theoretical Model, Strengths-based perspective	Social Network Engagement, Social Cognitive Theory, Contingency Management/behavioural economics
Intervention activities									
Individual-level services	Navigation by patient services specialist and retention specialist Assistance with benefits, name change, gender marker, referrals for trans-affirming surgeries, referral to comprehensive legal services and trans-sensitive shelters and housing specialists	Transgender peer youth advocates facilitated linkage and retention in HIV care Social work sessions—screening, referrals for mental health and substance use services. Case management	[e]	HIV care coordination/peer resource navigation On-site medical services provided by a local clinic. Assistance with housing, legal and employment issues	Peer advocates and health educators provided navigation services Counselling and case management Direct legal counsel	Individualized, hands-on support to clients to improve follow-through on care plans Supplemental mental health support services Case manager to provide consistent support	Six Motivational Enhancement Intervention (MEI) sessions In-hand referrals to needed services at partner agencies	Peer navigation to guide clients through Los Angeles's complex medical system and ensure engagement, re-engagement and retention in HIV care. Motivational interviewing-based linkage	Peer navigator to develop client-centred treatment plans and link participants to healthcare and/or other services
Small group sessions	Series of five peer-facilitated "teach back" groups focused on HIV/AIDS/STDs, sexual health, transitioning, wellness and mental health	One session of psychoeducational group	Weekly youth group and biweekly adult group	NA	16-session workshop with five tracks	The first hour of weekly drop-in clinic was devoted to a trans-led support group	Weekly support group	NA	NA

(*Continued*)

Table 1. (Continued)

Intervention name	TWEET [54][a]	INFINI-T [55]	Howard Brown[b] [56]	Trans Life Care [57]	Brandy Martell Project [58]	Trans-Access [58]	Princess Project [59]	Transactivate [60]	Alexis Project [61]
Outreach (OR)	Weekly non-traditional outreach and hosted social events	Worked with a community partner to provide outreach and engagement	Community outreach at trans events and venues	Event and street-based OR	Social network recruitment; street, online and venue-based OR; OR to referral agencies	OR to clients out of care or needing additional support (e.g. home visits)	Community, social network and online outreach and referral coupons	Social network testing, mobile testing, social network engagement, promotional materials to medical providers	Community-wide social network recruitment, venue and street-based OR, publicity materials, in-reach and work with community partners to increase referrals
Drop-in centre	NA	NA	A biweekly evening trans-only drop in called "After Hours" that provided medical, pharmacy, needle exchange and behavioural healthcare, staff and community-led programming, insurance counselling and dinner	Weekly Trans Safe resource drop-in centre and on-site medical services	NA	A weekly "Trans-Access" clinic that provided comprehensive care and support services in a safe, welcoming and respectful setting	Butterfly nest: a safe space where participants and community members came to relax, take workshops and participate in support groups	NA	NA
Incentives offered to promote engagement in care, participation in activities or engaging peers in the intervention	Participants received small incentives for bringing in peers to the intervention	NA	NA	NA	Participants received a $50 gift card for each peer brought into the intervention. Participants received a $100 gift card.	NA	Participants received a $20 gift card for each successful referral (up to 3/participant) Participants received a $20 gift card for each MEI session Participants received a $50 gift card for completing clinic visits	Participants received a $50 gift card after their referred client was active in the programme for 6 months. Participants received a $10 gift card for enrolment	Escalating valued gift cards to incentivize both clinic attendance and achieving HIV milestones ($500 maximum for reaching all targeted HIV health-promoting goals)

Note: Behind the scenes components (e.g. community trainings and community advisory boards) are not included as intervention components in this table.

[a]References after each intervention name are their peer-reviewed published results.

[b]The intervention implemented by the Howard Brown Community Health Center did not have a stand-alone identity. It was a combination of the After Hours Clinic and the TYRA and T-Time support groups.

[c]The Tri City Health Center is now called Bay Area Community Health.

[d]The Asian Pacific Islander Wellness Center is now called the San Francisco Community Health Center.

[e]Behavioural health, linkage to care, retention in care and case management services were all available on site at Howard Brown as part of its regular suite of services.

Abbreviations: MEI, Motivational Enhancement Intervention; NA, not applicable; OR, outreach; STDs, sexually transmitted diseases; TW, transgender women.

2.5 | Measures

Participant survey measures have been previously described [39]. In brief, demographic data included age, race/ethnicity, education, and financial insecurity in the past 6 months. Other baseline information categorized in a binary format (0 = No or missing, 1 = Yes) included homelessness in the past 6 months, exchange of sex to pay for necessities in the past 6 months, incarceration in the past 6 months, lack of transportation leading to a missed medical appointment in the past 12 months, presence of significant depression [40–42], gender-based discrimination experienced in the past 6 months in employment and housing [43], ever experiencing transphobia [44], disclosure of transgender identity, disclosure of HIV status, and hormone use in the past 6 months. A healthcare empowerment score was also calculated (range: 1–5) [45].

Intervention exposure data included the date of exposure, length of exposure in minutes, and type(s) of contact (community outreach, individual face-to-face session, small group session, drop-in centre or other individual virtual contact [e.g. telephone call, text message, email, social network site or postal mail]).

Medical chart data from electronic health record systems were used to create the following binary outcome variables (0 = No or missing, 1 = Yes):

- Any HIV care visit: The participant had an HIV outpatient ambulatory health services (OAHS) visit in the past 6 months.
- Antiretroviral therapy (ART) prescription: The participant had been prescribed ART in the past 6 months.
- Retention in HIV care: In the past 12 months, the participant had at least one OAHS visit in each 6-month period with a minimum of 60 days between the first visit in the first 6-month period and the last visit in the subsequent 6-month period [46]. These calculated values were unavailable at baseline as we only recorded medical chart data during the 6-month period preceding enrolment.
- VS: The participant had at least one HIV viral load test in the past 6 months and had a suppressed viral load (<200 copies/ml) at their last test in that period.
- VS among those with an OAHS visit and viral load test: Among participants who had both an OAHS visit and a viral load test in the past 6 months, the participants had a suppressed HIV viral load (<200 copies/ml) at their last test in the period. This variable represents the HRSA indicator for VS among RWHAP participants [46].

2.6 | Analysis

Using information from baseline participant surveys, we computed descriptive statistics for the overall sample and by the site.

Using intervention exposure data, we assessed the proportion of participants who received any component of the intervention, the median and inter-quartile range of the overall duration of interaction with the intervention, the proportion of participants who had each type of interaction (outreach, individual, group, drop-in and virtual), and the median number of interactions of each type.

Using medical chart data, we computed the proportion of patients who had any HIV care visit, had an ART prescription, were retained in HIV care and had verification of VS (both overall and among those with an OAHS visit and viral load test) at baseline and each 6-month period through 24 months of follow-up. Using data from each site, we employed logistic generalized estimating equations (GEE) to assess the odds of each outcome at the 12- and 24-month follow-up intervals compared to baseline. These models included a linear variable for months-since-baseline ("period") as well as a quadratic variable ("period"*"period") for months-since-baseline-squared to represent the curvilinear relationship between follow-up time and the primary outcomes. We present unadjusted odds ratios and their 95% confidence intervals (CI). Next, we employed inverse probability of treatment weighting to assess whether the observed results were due to differences in participant characteristics at baseline. We employed logistic GEE models to estimate the probability of each participant being from their observed site given the observed distribution of participant characteristics across all sites. In these models, the sample for each site is compared to the total sample across all sites. These models included participant characteristics previously found to be associated with engagement in HIV care in our sample [39]. These control characteristics are listed in Table 2. We employed multiple imputation for missing data. Next, we used the results from each model (the predicted probability of being from each site among individuals from that site) to compute the weight for each individual from each site (weight = 1/predicted probability). This weight was then applied in a weighted GEE model as defined above. The result of these models is to create pseudo-populations where the distribution of participant characteristics is similar across each site. These models have wider confidence limits compared to unweighted models as they employ re-sampling (n = 100 iterations) to impute missing data and estimate weights. We present the adjusted odds ratios and their 95% CIs from these models in the Supplementary Materials. All analyses were performed in SAS 9.4 [47].

3 | RESULTS

3.1 | Participant characteristics

At baseline, the 858 participants' median age was 36 years (Table 2). Almost half of the participants identified as Hispanic, Latina or of Spanish origin, and 42% identified as Black, non-Hispanic. Two of every five participants reported having less than a 12th-grade education. Additional participant characteristics are discussed in the Supplementary Materials.

3.2 | Intervention exposure

During the first 24 months of follow-up, 79% of participants had at least one interaction with intervention staff (Table 3). Most sites had over 90% participation in intervention components. Interventions that had lower-than-average participation included Trans Life Care, Howard Brown, and Trans Access, which implemented system-level interventions that provided

Table 2. Sample characteristics—overall and by demonstration site

	Overall *n* (%)	TWEET *n* (%)	INFINI-T *n* (%)	Howard Brown *n* (%)	Trans Life Care *n* (%)	Trans Access *n* (%)	Brandy Martell Project *n* (%)	Princess Project *n* (%)	Transactivate *n* (%)	Alexis Project *n* (%)
Race-ethnicity										
Hispanic, Latina or of Spanish origin	417 (48.6%)	144 (88.9%)	11 (47.8%)	20 (19.2%)	6 (5.0%)	12 (22.2%)	14 (30.4%)	8 (13.3%)	150 (100%)	52 (37.4%)
Black, non-Hispanic	364 (42.4%)	7 (4.3%)	11 (47.8%)	73 (70.2%)	113 (94.2%)	28 (51.9%)	32 (69.6%)	48 (80.0%)		52 (37.4%)
American Indian or Alaska Native, non-Hispanic	9 (1.0%)									9 (6.5%)
Asian or Pacific Islander, non-Hispanic	14 (1.6%)			2 (1.9%).		8 (14.8%)		1 (1.7%)		3 (2.2%)
Additional, non-Hispanic	11 (1.3%)	3 (1.9%)								8 (5.8%)
Multiracial, non-Hispanic	28 (3.3%)	1 (0.6%)		7 (6.7%)	1 (0.8%)	4 (7.4%)		3 (5.0%)		12 (8.6%)
No response	15 (1.7%)	7 (4.3%)	1 (4.3%)	2 (1.9%)		2 (3.7%)				3 (2.2%)
Education										
Less than grade 12	346 (40.3%)	79 (48.8%)	8 (34.8%)	22 (21.2%)	29 (24.2%)	14 (25.9%)	19 (41.3%)	23 (38.3%)	99 (66.0%)	53 (38.1%)
Completed grade 12	291 (33.9%)	39 (24.1%)	9 (39.1%)	34 (32.7%)	73 (60.8%)	24 (44.4%)	17 (37.0%)	17 (28.3%)	33 (22.0%)	45 (32.4%)
At least some college	195 (22.7%)	29 (17.9%)	6 (26.1%)	45 (43.3%)	18 (15.0%)	16 (29.6%)	9 (19.6%)	19 (31.7%)	14 (9.3%)	39 (28.1%)
No response	26 (3.0%)	15 (9.3%)		3 (2.9%)			1 (2.2%)	1 (1.7%)	4 (2.7%)	2 (1.4%)
Ran out of money for basics (past 6 months)?										
Yes	560 (65.3%)	100 (61.7%)	17 (73.9%)	72 (69.2%)	67 (55.8%)	33 (61.1%)	32 (69.6%)	38 (63.3%)	93 (62.0%)	108 (77.7%)
No	180 (21.0%)	44 (27.2%)	4 (17.4%)	16 (15.4%)	37 (30.8%)	11 (20.4%)	7 (15.2%)	2 (3.3%)	47 (31.3%)	12 (8.6%)
No response	118 (13.8%)	18 (11.1%)	2 (8.7%)	16 (15.4%)	16 (13.3%)	10 (18.5%)	7 (15.2%)	20 (33.3%)	10 (6.7%)	19 (13.7%)
Ever homeless (past 6 months)?										
Yes	352 (41.0%)	66 (40.7%)	8 (34.8%)	28 (26.9%)	69 (57.5%)	24 (44.4%)	19 (41.3%)	26 (43.3%)	39 (26.0%)	73 (52.5%)
No	381 (44.4%)	68 (42.0%)	13 (56.5%)	49 (47.1%)	35 (29.2%)	23 (42.6%)	24 (52.2%)	17 (28.3%)	104 (69.3%)	48 (34.5%)
No response	125 (14.6%)	28 (17.3%)	2 (8.7%)	27 (26.0%)	16 (13.3%)	7 (13.0%)	3 (6.5%)	17 (28.3%)	7 (4.7%)	18 (12.9%)

(*Continued*)

Table 2. (Continued)

	Overall *n* (%)	TWEET *n* (%)	INFINI-T *n* (%)	Howard Brown *n* (%)	Trans Life Care *n* (%)	Trans Access *n* (%)	Brandy Martell Project *n* (%)	Princess Project *n* (%)	Transactivate *n* (%)	Alexis Project *n* (%)
Exchanged sex to pay for necessities (past 6 months)?										
Yes	330 (38.5%)	59 (36.4%)	7 (30.4%)	23 (22.1%)	68 (56.7%)	25 (46.3%)	20 (43.5%)	29 (48.3%)	45 (30.0%)	54 (38.8%)
No	400 (46.6%)	75 (46.3%)	13 (56.5%)	53 (51.0%)	35 (29.2%)	24 (44.4%)	22 (47.8%)	17 (28.3%)	98 (65.3%)	63 (45.3%)
No response	128 (14.9%)	28 (17.3%)	3 (13.0%)	28 (26.9%)	17 (14.2%)	5 (9.3%)	4 (8.7%)	14 (23.3%)	7 (4.7%)	22 (15.8%)
Incarcerated (past 6 months)?										
Yes	83 (9.7%)	12 (7.4%)	2 (8.7%)	2 (1.9%)	10 (8.3%)	13 (24.1%)	6 (13.0%)	6 (10.0%)	13 (8.7%)	19 (13.7%)
No	665 (77.5%)	126 (77.8%)	18 (78.3%)	80 (76.9%)	94 (78.3%)	35 (64.8%)	39 (84.8%)	42 (70.0%)	134 (89.3%)	97 (69.8%)
No response	110 (12.8%)	24 (14.8%)	3 (13.0%)	22 (21.2%)	16 (13.3%)	6 (11.1%)	1 (2.2%)	12 (20.0%)	3 (2.0%)	23 (16.5%)
Missed medical visit due to lack of transportation (past 12 months)?										
Yes	202 (23.5%)	32 (19.8%)	2 (8.7%)	23 (22.1%)	17 (14.2%)	16 (29.6%)	15 (32.6%)	14 (23.3%)	33 (22.0%)	50 (36.0%)
Never/rarely	515 (60.0%)	104 (64.2%)	18 (78.3%)	60 (57.7%)	82 (68.3%)	31 (57.4%)	27 (58.7%)	24 (40.0%)	105 (70.0%)	64 (46.0%)
No response	141 (16.4%)	26 (16.0%)	3 (13.0%)	21 (20.2%)	21 (17.5%)	7 (13.0%)	4 (8.7%)	22 (36.7%)	12 (8.0%)	25 (18.0%)
Significant depression?										
Yes	449 (52.3%)	83 (51.2%)	7 (30.4%)	43 (41.3%)	68 (56.7%)	30 (55.6%)	25 (54.3%)	23 (38.3%)	82 (54.7%)	88 (63.3%)
No	309 (36.0%)	61 (37.7%)	14 (60.9%)	38 (36.5%)	39 (32.5%)	17 (31.5%)	19 (41.3%)	20 (33.3%)	64 (42.7%)	37 (26.6%)
No response	100 (11.7%)	18 (11.1%)	2 (8.7%)	23 (22.1%)	13 (10.8%)	7 (13.0%)	2 (4.3%)	17 (28.3%)	4 (2.7%)	14 (10.1%)
Disclosed transgender identity?										
Yes	576 (67.1%)	104 (64.2%)	18 (78.3%)	53 (51.0%)	87 (72.5%)	34 (63.0%)	35 (76.1%)	45 (75.0%)	122 (81.3%)	78 (56.1%)
No	131 (15.3%)	29 (17.9%)	1 (4.3%)	20 (19.2%)	15 (12.5%)	7 (13.0%)	4 (8.7%)	5 (8.3%)	13 (8.7%)	37 (26.6%)
No response	151 (17.6%)	29 (17.9%)	4 (17.4%)	31 (29.8%)	18 (15.0%)	13 (24.1%)	7 (15.2%)	10 (16.7%)	15 (10.0%)	24 (17.3%)
Disclosed HIV status?										
Yes	536 (62.5%)	95 (58.6%)	13 (56.5%)	55 (52.9%)	78 (65.0%)	34 (63.0%)	27 (58.7%)	41 (68.3%)	112 (74.7%)	81 (58.3%)
No	183 (21.3%)	39 (24.1%)	5 (21.7%)	22 (21.2%)	23 (19.2%)	9 (16.7%)	12 (26.1%)	7 (11.7%)	31 (20.7%)	35 (25.2%)
No response	139 (16.2%)	28 (17.3%)	5 (21.7%)	27 (26.0%)	19 (15.8%)	11 (20.4%)	7 (15.2%)	12 (20.0%)	7 (4.7%)	23 (16.5%)

(*Continued*)

Table 2. (Continued)

	Overall *n* (%)	TWEET *n* (%)	INFINI-T *n* (%)	Howard Brown *n* (%)	Trans Life Care *n* (%)	Trans Access *n* (%)	Brandy Martell Project *n* (%)	Princess Project *n* (%)	Transactivate *n* (%)	Alexis Project *n* (%)
Taken hormones (past 6 months)?										
Yes	397 (46.3%)	63 (38.9%)	16 (69.6%)	58 (55.8%)	49 (40.8%)	30 (55.6%)	25 (54.3%)	27 (45.0%)	78 (52.0%)	51 (36.7%)
No	383 (44.6%)	91 (56.2%)	7 (30.4%)	32 (30.8%)	59 (49.2%)	18 (33.3%)	18 (39.1%)	15 (25.0%)	67 (44.7%)	76 (54.7%)
No response	78 (9.1%)	8 (4.9%)		14 (13.5%)	12 (10.0%)	6 (11.1%)	3 (6.5%)	18 (30.0%)	5 (3.3%)	12 (8.6%)
Employment discrimination (past 6 months)?										
Yes	302 (35.2%)	80 (49.4%)	9 (39.1%)	24 (23.1%)	36 (30.0%)	14 (25.9%)	10 (21.7%)	16 (26.7%)	75 (50.0%)	38 (27.3%)
No	394 (45.9%)	52 (32.1%)	12 (52.2%)	48 (46.2%)	63 (52.5%)	28 (51.9%)	30 (65.2%)	21 (35.0%)	65 (43.3%)	75 (54.0%)
No response	162 (18.9%)	30 (18.5%)	2 (8.7%)	32 (30.8%)	21 (17.5%)	12 (22.2%)	6 (13.0%)	23 (38.3%)	10 (6.7%)	26 (18.7%)
Shelter discrimination (past 6 months)?										
Yes	283 (33.0%)	72 (44.4%)	6 (26.1%)	20 (19.2%)	38 (31.7%)	21 (38.9%)	10 (21.7%)	24 (40.0%)	41 (27.3%)	51 (36.7%)
No	418 (48.7%)	60 (37.0%)	16 (69.6%)	56 (53.8%)	64 (53.3%)	24 (44.4%)	31 (67.4%)	16 (26.7%)	85 (56.7%)	66 (47.5%)
No response	157 (18.3%)	30 (18.5%)	1 (4.3%)	28 (26.9%)	18 (15.0%)	9 (16.7%)	5 (10.9%)	20 (33.3%)	24 (16.0%)	22 (15.8%)
Ever experienced transphobia?										
Yes	745 (86.8%)	150 (92.6%)	18 (78.3%)	84 (80.8%)	100 (83.3%)	47 (87.0%)	41 (89.1%)	45 (75.0%)	145 (96.7%)	115 (82.7%)
No	50 (5.8%)	3 (1.9%)	4 (17.4%)	7 (6.7%)	11 (9.2%)	4 (7.4%)	3 (6.5%)		4 (2.7%)	14 (10.1%)
No response	63 (7.3%)	9 (5.6%)	1 (4.3%)	13 (12.5%)	9 (7.5%)	3 (5.6%)	2 (4.3%)	15 (25.0%)	1 (0.7%)	10 (7.2%)
	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)
Age	36 (28–46)	36.5 (30–47)	24 (22–26)	31 (26.5–42.5)	27.5 (23–35)	41.5 (31–51)	36.5 (29–44)	41 (32.5–50)	44 (38–50)	35 (28–44)
Healthcare empowerment	4 (3.75–4.75)	4 (4–5)	4.25 (3.75–4.75)	4 (3.63–5)	4 (3.75–4.38)	4.13 (3–5)	4.25 (3.25–5)	3.88 (3.25–4.25)	4 (4–4.5)	4 (2.75–5)

Table 3. Summary of intervention exposure

	Overall	TWEET	INFINI-T	Howard Brown	Trans Life Care	Trans Access	Brandy Martell	Princess Project	Transactivate	Alexis Project
Total participants enrolled	858	162	23	104	120	54	46	60	150	139
Participants exposed to intervention	676	152	19	20	58	39	44	57	150	137
% Exposed to intervention	79%	94%	83%	19%	48%	72%	96%	95%	100%	99%
Duration of intervention exposure (in hours)—median (IQR)	6.2 (3–12)	5.17 (1.67–11.13)	68.75 (35.53–210.72)	3 (2–7)	9 (3–15.83)	17 (9.25–45)	10.83 (6.25–32.08)	4.58 (2.75–7.08)	7.33 (4.5–11.33)	3.93 (2.07–6.87)
% Exposed to each type of contact:										
Outreach	2.66					35.90				2.92
Individual session	79.88	80.92	100		1.72	94.87	36.36	100	100	100
Group session	26.33	65.13	100	70		41.03	65.91	1.75		
Drop-in session	13.17			40	98.28	48.72		8.77		
Virtual[a]	60.36	79.61	68.42		1.72	84.62	93.18	40.35	91.33	28.47
Median number of contacts (among participants with each type of contact):										
Outreach	1					1				1
Individual session	4	7	7		1	9	2	4	4	4
Group session	5.5	5	31	1		2.5	12	2		
Drop-in session	3			2	3	6		1		
Virtual interaction[a]	3	1	10		16	5	34	1	7	2

[a]Telephone call, text message, email, social media and postal mail.
Abbreviation: IQR, interquartile range.

Rebchook GM et al. *Journal of the International AIDS Society* 2022, **25**(S5):e25991
http://onlinelibrary.wiley.com/doi/10.1002/jia2.25991/full | https://doi.org/10.1002/jia2.25991

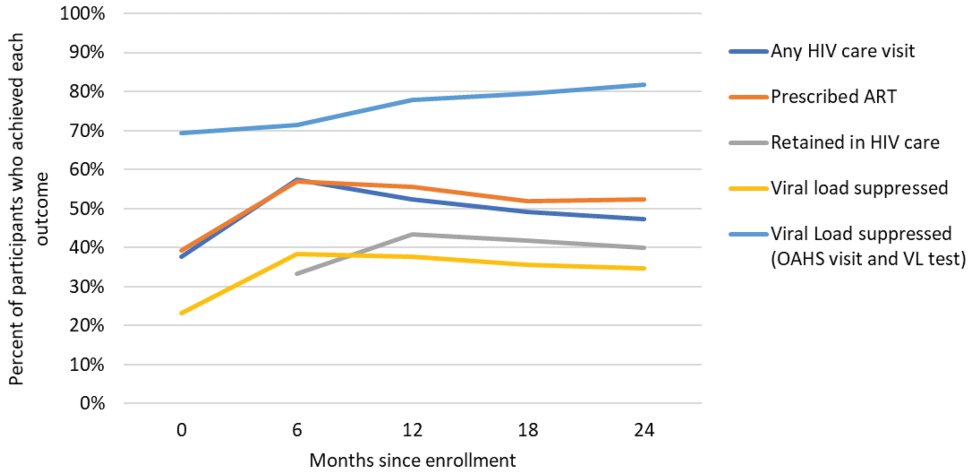


Figure 1. Changes in outcomes over time. Abbreviations: ART, antiretroviral therapy; OAHS, outpatient ambulatory health services; VL, viral load.

comprehensive trans-competent services. Thus, their participants often interacted with the existing care system to receive routine services (not recorded as intervention exposure), in addition to specified intervention activities (recorded as intervention exposure).

The interventions provided substantial support to participants. Participants received services for a median of over 6 hours (interquartile range = 3–12 hours) over 24 months. Median time receiving services ranged from 3 hours at Howard Brown to 69 hours (almost 3 hours per month) in INFINI-T. The majority of participants had in-person individual sessions (80%; median = 4 sessions) and/or virtual sessions (60%; median = 3 sessions), including reminder phone calls. Fewer participants were reached through group sessions (26%; median = 5.5 sessions), drop-in settings (13%; median = 3 visits) and outreach (3%; median = 1 contact).

3.3 | Overall outcomes

Figure 1 displays outcomes across all sites by follow-up period. The proportion of participants who had a suppressed viral load increased from 22% at baseline to 38% at 6 months and decreased to 35% at 24 months. Trends were similar for any HIV care visit (38% at study entry, 58% at 6 months and 47% at 24 months), prescription of ART (39% at study entry, 57% at 6 months and 53% at 24 months) and retention in HIV care (33% at 6 months, 44% at 12 months and 40% at 24 months). In contrast, among participants who had an OAHS visit in addition to a viral load test during a study period, the proportion with suppressed viral load increased during each study period from 69% at study entry to 82% at 24 months.

The GEE models revealed that these increases for the overall sample were statistically significant at 12 months for all outcomes (unadjusted odds ratio [OR] = 1.38, 95% CI = 1.10–1.74 for any HIV care visit; OR = 1.42, 95% CI = 1.07–1.89 for prescription of ART; OR = 1.58, 95% CI = 1.03–2.42 for retention in HIV care; OR = 1.49, 95% CI = 1.23–1.81 for VS among all participants; and OR = 1.53, 95% CI = 1.23–1.89 for VS among those with an OAHS visit and viral load test) (Table 4). At 24 months, the increases remained significant for prescription of ART (OR = 1.49, 95% CI = 1.02–2.18), VS among all participants (OR = 1.54, 95% CI = 1.24–1.93); and VS among those with an OAHS visit and viral load test (OR = 1.98, 95% CI = 1.61–2.43).

3.4 | Outcomes by site

Table 4 also includes results from the unadjusted models for each site. We observed statistically significant ($p < 0.05$) increases in the odds of suppressed viral load at six of the nine sites at 12 months (Transactivate, TWEET, Alexis Project, INFINI-T, Howard Brown and Trans Access) and at four sites at 24 months (Transactivate, TWEET, Howard Brown and Trans Access). Sites where the odds of any HIV primary care visit, prescription of ART or retention in HIV primary care were significantly higher at 12 months relative to baseline, also demonstrated increased odds of VS at 12 months. Multiple sites had higher odds of any HIV visit, prescription of ART or retention in HIV care at 24 months. Of the six sites where the odds of ART prescription at 24 months were significantly higher compared to baseline, five also had significantly higher odds of VS at 24 months.

Next, we employed inverse probability weighting to examine the effect of each site's intervention on HIV care continuum outcomes, while accounting for differences in client characteristics at baseline (see Supplementary Materials). While these models had larger confidence intervals than our unadjusted model due to increased variance associated with the estimation of weights and missing data, the estimates of effect (odds ratios) were similar or larger for five of the six sites where the odds of VS increased significantly between baseline and 12 months. The odds ratio for TWEET declined 15% (from 2.67 to 2.32), but this estimate of effect remained larger than that of any other site. We observed substantially more variability in the estimates of effect for odds of VS at 24 months, likely due to differential loss-to-follow-up among clients who were less likely to remain engaged in HIV care.

Table 4. Unadjusted primary outcomes

	At 12 months follow-up					At 24 months follow-up				
	Any visit	Prescribed ART	Retained in HIV care	Suppressed viral load	Suppressed viral load (among those with OAHS visit)	Any visit	Prescribed ART	Retained in HIV care	Suppressed viral load	Suppressed viral load (among those with OAHS visit)
Overall sample	**1.38 (1.10, 1.74)**	**1.42 (1.07, 1.89)**	**1.58 (1.03, 2.42)**	**1.49 (1.23, 1.81)**	**1.53 (1.23, 1.89)**	1.34 (0.93, 1.92)	**1.49 (1.02, 2.18)**	1.73 (0.91, 3.32)	**1.54 (1.24, 1.93)**	**1.98 (1.61, 2.43)**
TWEET	**3.62 (1.54, 8.50)**	**3.02 (2.11, 4.31)**	**5.42 (2.78, 10.57)**	**2.67 (1.90, 3.75)**	2.03 (0.29, 14.05)	**3.85 (1.30, 11.40)**	**3.91 (2.49, 6.13)**	**11.28 (4.78, 26.65)**	**2.51 (1.64, 3.85)**	4.47 (0.53, 37.60)
INFINI-T	**1.49 (1.15, 1.93)**	1.53 (0.65, 3.57)	**11.93 (2.58, 55.20)**	**2.39 (1.03, 5.51)**	1.00 (0.53, 1.89)	**1.52 (1.08, 2.13)**	1.28 (0.40, 4.10)	**24.98 (3.22, 193.47)**	2.38 (0.77, 7.34)	1.46 (0.63, 3.39)
Howard Brown	**1.81 (1.12, 2.96)**	1.30 (0.78, 2.18)	1.15 (0.58, 2.26)	**1.76 (1.24, 2.50)**	**2.09 (1.00, 4.34)**	1.87 (0.96, 3.65)	**2.57 (1.34, 4.93)**	1.06 (0.41, 2.71)	**2.01 (1.21, 3.35)**	**2.90 (1.11, 7.58)**
Trans Life Care	1.23 (0.83, 1.83)	1.07 (0.80, 1.40)	0.85 (0.49, 1.48)	0.96 (0.71, 1.28)	**1.93 (1.09, 3.41)**	1.12 (0.64, 1.94)	1.15 (0.82, 1.61)	0.76 (0.37, 1.57)	1.12 (0.75, 1.68)	**2.41 (1.16, 5.00)**
Trans Access	1.03 (0.69, 1.54)	**2.52 (1.50, 4.23)**	1.73 (0.80, 3.74)	**1.87 (1.11, 3.16)**	**0.50 (0.17, 1.50)**	0.71 (0.39, 1.30)	**2.87 (1.49, 5.53)**	2.05 (0.72, 5.85)	**2.16 (1.12, 4.19)**	0.42 (0.13, 1.43)
Brandy Martell	1.28 (0.98, 1.68)	1.20 (0.82, 1.74)	1.07 (0.54, 2.12)	1.23 (0.81, 1.87)	1.87 (0.98, 3.54)	1.08 (0.76, 1.53)	**1.59 (1.02, 2.47)**	1.03 (0.39, 2.69)	1.32 (0.73, 2.40)	2.19 (0.95, 5.08)
Princess Project	1.02 (0.66, 1.59)	0.98 (0.69, 1.41)	1.16 (0.54, 2.50)	1.03 (0.62, 1.73)	1.82 (0.76, 4.35)	0.87 (0.47, 1.60)	0.73 (0.41, 1.30)	0.86 (0.29, 2.57)	0.70 (0.34, 1.45)	**3.10 (1.19, 8.07)**
Transactivate	**2.31 (1.64, 3.24)**	**1.60 (1.22, 2.10)**	**1.70 (1.08, 2.68)**	**1.43 (1.09, 1.87)**	2.27 (0.89, 5.83)	**3.23 (2.06, 5.04)**	**1.48 (1.05, 2.09)**	**2.07 (1.14, 3.77)**	**1.56 (1.07, 2.26)**	2.87 (0.85, 9.66)
Alexis Project	0.90 (0.66, 1.24)	**1.33 (1.00, 1.77)**	1.23 (0.74, 2.04)	**1.61 (1.09, 2.39)**	1.01 (0.53, 1.95)	0.82 (0.54, 1.24)	1.15 (0.80, 1.64)	1.09 (0.58, 2.02)	1.43 (0.87, 2.45)	1.58 (0.69, 3.63)

Note: Bold indicates statistically significant result ($p<0.05$).

Abbreviation: ART, antiretroviral therapy; OAHS, outpatient ambulatory health services.

4 | DISCUSSION

TWC with HIV experience many direct and indirect barriers to care. The nine US-based community service providers participating in this initiative developed strategies to help TWC overcome these barriers and engage in HIV-related healthcare. Together, these clinics and community-based organizations enrolled 858 TWC with HIV, of whom over three-quarters received intervention services. Despite TWC often being reluctant to engage in health-related programmes due to prior negative experiences with healthcare agencies, these organizations had great success recruiting participants and partnering with their local communities. Engaging trans women in leadership, staffing, and other meaningful roles has consistently been found to positively impact enrolment and retention in trans-specific programming [48]. These strategies were successfully employed by most of these interventions to leverage social networks, increase trust, and provide peer navigation services that maximized participants' safety and support.

Overall, the interventions achieved improvements in engagement in HIV care and VS at 12 and 24 months. Specifically, the odds of being virally suppressed at 12 and 24 months were significantly higher compared to baseline among all enrolled participants, among participants with an OAHS visit in the previous 6 months, and among participants in multiple sites (i.e. for six sites at 12 months and four sites at 24 months for VS among enrolled participants regardless of OAHS visit, and three sites each at 12 and 24 months for VS among those with an OAHS visit in the previous 6 months). This is an important success of the initiative. Of note, this improvement in VS was not always accompanied by a statistically significant improvement in retention in care suggesting that some intervention participants continued to take ART and achieved or maintained VS even if they did not always have the number and timing of appointments necessary to meet HRSA's definition of retention in care [46].

It is not surprising that sustaining engagement and retention in HIV care over 24 months was challenging since TWC with HIV experience intersectional oppression in the forms of racism and transphobia, community and institutional violence, stigma, discrimination, and marginalization from mainstream economic opportunities, which combine to adversely impact their access to healthcare and health outcomes [49]. Additional implementation research is necessary to study how interventions can be integrated into practice and maintained at the level of intensity necessary to result in sustained improvement in healthcare engagement and health outcomes over longer periods of time.

Given the challenges faced by TWC with HIV, the successes of these programmes demonstrate how well tailored they were to meet the specific needs of their communities. They are also a testament to the dedication of the intervention staff (many of whom were TWC), and the trusting relationships that developed between staff and participants [50]. While these programmes were heterogeneous in many ways, many shared important common elements. Recruiting, supporting, and retaining peer staff in HIV programming has consistently been found to contribute to positive outcomes [48]. In addition, many of these programmes aimed to address TWC's social determinants of health and intersecting vulnerabilities, including structural barriers, such as assistance with housing, legal concerns, and employment issues, and they provided trans-affirming HIV care either on site or by referral. Indeed, the literature around health disparities increasingly acknowledges that it is critical that interventions to improve HIV-related health outcomes among marginalized populations address social and structural factors that contribute to HIV-related health disparities, rather than simply focus on individual-level behaviour change [51, 52].

Due to the variations in the design and implementation of the individual interventions, we cannot pinpoint with certainty the intervention components that contributed to improvements in HIV care. However, we believe that keys to improving VS at 24 months included having structured activities clearly defined in written intervention curricula (e.g. TWEET), creating systemic change at the organizational level to make the entire system of care responsive to the needs of TWC with HIV (e.g. Howard Brown) and offering ongoing peer navigation/case management services to facilitate linkage to and retention in care (e.g. Trans Access and Transactivate). Some interventions did not last for 24 months (e.g. the Alexis Project); thus, VS not always being sustained beyond 12 months is not surprising.

4.1 | Limitations

These findings should be interpreted in the context of certain limitations. First, the interventions were implemented in urban settings in the United States with participants whose median age was 36 years. Results may differ in programmes operating in dissimilar settings or with younger or older populations. Second, there were inconsistencies in how demonstration sites recorded various intervention activities (e.g. not all sites recorded short, virtual interactions). Therefore, we are limited in our ability to compare the effect of intervention exposure across interventions. Third, there was variability in the completeness of medical record data submitted for analysis. Thus, these results may underestimate the effect of some interventions. Fourth, one site enrolled few participants (INFINI-T). This limited our ability to evaluate the effect of this intervention in larger settings. Fifth, these interventions were designed to "float above" the existing RWHAP services that the organizations already provided. A new activity that was integral to intervention at one site might have been routinely provided at another site. In the latter instance, these existing services were not recorded as exposure to the intervention being studied, thus making direct comparisons between the interventions difficult. Sixth, the structure of the HRSA SPNS Initiative prevented a randomized controlled trial design, which is used to develop evidence-based interventions (EBIs). In addition, because of this community's great need for support, it was not viable to allocate some TWC to wait to receive these interventions. Thus, we are not able to determine whether broader changes in practice patterns or interventions external to this initiative contributed to the observed changes in engagement in HIV care. However, given the consistency of the results observed across the interventions, we are confident that these interventions enhanced engagement in HIV care among the TWC that they served.

5 | CONCLUSIONS

Based on these findings, all the evaluated interventions meet HRSA's criteria for evidence-informed interventions since they were based on theory and demonstrated improvement in at least one aspect of HIV care and treatment [35]. The evaluation results from this "real world" initiative are very promising since they documented significant improvements in engagement and retention in HIV care, ART prescriptions, and VS. Scientifically rigorous studies, such as adaptive trials or hybrid implementation science designs, could be conducted in the future on these or similar intervention models to help increase the number of EBIs that can further reduce HIV-related health disparities. This HRSA SPNS initiative presents an alternative and complementary approach to the randomized-controlled trial model to help ameliorate the research-to-practice gap and reduce health disparities among TWC with HIV. This approach is vital to eliminate inequalities that fuel the HIV/AIDS epidemic and ultimately achieve the UNAIDS 95-95-95 targets [53].

AUTHORS' AFFILIATIONS

[1]Division of Prevention Science, Department of Medicine, University of California, San Francisco, California, USA; [2]Independent Consultant, Silver Spring, Maryland, USA; [3]Innovative Response Globally for Transgender Women and HIV (IRGT), San Francisco, California, USA; [4]Department of Epidemiology and Biostatistics, University of California, San Francisco, California, USA

COMPETING INTERESTS

The authors declare that they have no competing interests.

AUTHORS' CONTRIBUTIONS

All authors have read and approved the final manuscript. GMR, SBS, AM, JS and JGK made substantial contributions to conceptualizing and designing the national evaluation protocol. JMX conceptualized and designed the multisite initiative. SBS and DC analysed the data. GMR, DC, JMX, JS, AM and SBS wrote the paper.

ACKNOWLEDGEMENTS

Thank you to the 858 transgender women of colour who participated in this Initiative and to the dedicated principal investigators (Robert Contreras, Judith Perloff, Luis Freddy Molano, Cathy J. Reback, Kelly Ducheny, Tooru Nemoto, Royce Lin, Jeffrey Birnbaum and Tiffany Woods), researchers and staff at each of the nine community demonstration sites.

FUNDING

This project was supported by the Health Resources and Services Administration (HRSA) of the US Department of Health and Human Services (HHS) under grant number U90HA24973 in the amount of $536,244 awarded to the University of California at San Francisco.

DISCLAIMER

The views expressed in this publication are solely the opinions of the authors and do not necessarily reflect the official policies of the US Department of Health and Human Services or the Health Resources and Services Administration, nor does mention of the department or agency names imply endorsement by the US Government. This publication was also made possible with help from the UCSF-Center for AIDS Prevention Studies (P30 MH062246) and the UCSF-Gladstone Center for AIDS Research (CFAR), an NIH-funded programme (P30 AI027763).

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on reasonable request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

REFERENCES

1. Poteat T, Scheim A, Xavier J, Reisner S, Baral S. Global epidemiology of HIV infection and related syndemics affecting transgender people. J Acquir Immune Defic Syndr. 2016;72(3):S210–9
2. Stutterheim SE, van Dijk M, Wang H, Jonas KJ. The worldwide burden of HIV in transgender individuals: an updated systematic review and meta-analysis. PLoS One. 2021;16(12):e0260063.
3. Becasen JS, Denard CL, Mullins MM, Higa DH, Sipe TA. Estimating the prevalence of HIV and sexual behaviors among the US transgender population: a systematic review and meta-analysis, 2006–2017. Am J Public Health. 2019;109(1):e1–8.
4. Centers for Disease Control and Prevention. HIV infection, risk, prevention, and testing behaviors among transgender women. National HIV behavioral surveillance 7 U.S. cities, 2019–2020. HIV Surveillance Special Report 27. 2021.
5. Centers for Disease Control and Prevention. HIV surveillance report. 2018 (Updated). 2020 [cited 2020 May 8]. Available from: https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2018-updated-vol-31.pdf
6. Centers for Disease Control and Prevention. Transgender women involved in strategies for transformation (TWIST). 2021 [cited 2021 October 10]. Available from: https://www.cdc.gov/hiv/effective-interventions/treat/twist/index.html.
7. Collier KL, Colarossi LG, Hazel DS, Watson K, Wyatt GE. Healing our women for transgender women: adaptation, acceptability, and pilot testing. AIDS Educ Prev. 2015;27(5):418–31.
8. Garofalo R, Kuhns LM, Reisner SL, Mimiaga MJ. Behavioral interventions to prevent HIV transmission and acquisition for transgender women: a critical review. J Acquir Immune Defic Syndr. 2016;72(3):S220–5.
9. Martinez O, Lopez N, Woodard T, Rodriguez-Madera S, Icard L. Transhealth Information Project: a peer-led HIV prevention intervention to promote HIV protection for individuals of transgender experience. Health Soc Work. 2019;44(2):104–12.
10. Reback CJ, Clark K, Fletcher JB. TransAction: a homegrown, theory-based, HIV risk reduction intervention for transgender women experiencing multiple health disparities. Sex Res Social Policy. 2019;16(4):408–18.
11. Sevelius JM, Neilands TB, Dilworth S, Castro D, Johnson MO. Sheroes: feasibility and acceptability of a community-driven, group-level HIV intervention program for transgender women. AIDS Behav. 2020;24(5):1551–9.
12. Skeen SJ, Cain D, Gamarel KE, Hightow-Weidman L, Reback CJ. mHealth for transgender and gender-expansive youth: harnessing gender-affirmative cross-disciplinary innovations to advance HIV prevention and care interventions. Mhealth. 2021;7:37.
13. Dinno A. Homicide rates of transgender individuals in the United States: 2010–2014. Am J Public Health. 2017;107(9):1441–7.
14. Human Rights Campaign. An epidemic of violence: fatal violence against transgender and gender non-conforming people in the U.S. in 2020. [Cited 2021 October 19]. Available from: https://reports.hrc.org/an-epidemic-of-violence-fatal-violence-against-transgender-and-gender-non-confirming-people-in-the-united-states-in-2020
15. Wirtz AL, Poteat TC, Malik M, Glass N. Gender-based violence against transgender people in the United States: a call for research and programming. Trauma Violence Abuse. 2020;21(2):227–41.
16. Xavier J. The orphans of the epidemic: transgender women of color. AIDS Behav. 2021;25(Suppl 1):1–2.
17. Berger MT. Coining intersectional stigma: historical erasures and the future. Am J Public Health. 2022;112(S4):S338–9.
18. Xavier J, Honnold JA, Bradford J. The health, health-related needs, and lifecourse experiences of transgender Virginians. Richmond, VA: Virginia HIV Community Planning Committee and Virginia Department of Health; 2007.
19. Reback C, Simon P, Bemis C, Gatson B. The Los Angeles Transgender Health Study: community report. Los Angeles, CA: University of California at Los Angeles; 2001.
20. Kenagy GP, Bostwick WB. Health and social service needs of transgender people in Chicago. Int J Transgend. 2005;8(2/3):57–66.
21. Kenagy GP. The health and social service needs of transgender people in Philadelphia. Int J Transgend. 2005;8(2/3):49–56.
22. Health Resources and Services Administration. Ryan White HIV/AIDS Program annual client-level data report 2020. 2021. Accessed December 20, 2021.

Available from: https://hab.hrsa.gov/sites/default/files/hab/data/datareports/RWHAP-annual-client-level-data-report-2020.pdf
23. Klein PW, Psihopaidas D, Xavier J, Cohen SM. HIV-related outcome disparities between transgender women living with HIV and cisgender people living with HIV served by the Health Resources and Services Administration's Ryan White HIV/AIDS Program: a retrospective study. PLoS Med. 2020;17(5):e1003125.
24. Thomas JA, Irvine MK, Xia Q, Harriman GA. Service utilization and HIV outcomes among transgender women receiving Ryan White Part A services in New York City. PLoS One. 2021;16(7):e0253444.
25. Brady RE, Singer B, Marconi KM. Special Projects of National Significance Program: ten models of adolescent HIV care. J Adolesc Health. 1998;23(2 Suppl):1–4.
26. Health Resources and Services Administration. Part F: Special Projects of National Significance (SPNS) Program. Accessed October 19, 2021. Available from: https://hab.hrsa.gov/about-ryan-white-hivaids-program/part-f-special-projects-national-significance-spns-program.
27. Herwehe J, Wilbright W, Abrams A, Bergson S, Foxhood J, Kaiser M, et al. Implementation of an innovative, integrated electronic medical record (EMR) and public health information exchange for HIV/AIDS. J Am Med Inform Assoc. 2012;19(3):448–52.
28. Weiss L, Egan JE, Botsko M, Netherland J, Fiellin DA, Finkelstein R. The BHIVES collaborative: organization and evaluation of a multisite demonstration of integrated buprenorphine/naloxone and HIV treatment. Acquir Immune Defic Syndr. 2011;56(1):S7–13.
29. Blank AE, Ryerson Espino SL, Eastwood B, Matoff-Stepp S, Xavier J; Women of Color Initiative. The HIV/AIDS women of color initiative improving access to and quality of care for women of color. J Health Care Poor Underserved. 2013;24(1):15–26.
30. Bradford JB, Coleman S, Cunningham W. HIV system navigation: an emerging model to improve HIV care access. AIDS Patient Care STDs. 2007;21(1):S49–58.
31. Jordan AO, Cohen LR, Harriman G, Teixeira PA, Cruzado-Quinones J, Venters H. Transitional care coordination in New York City jails: facilitating linkages to care for people with HIV returning home from Rikers Island. AIDS Behav. 2013;17(2):S212–9.
32. Sauceda JA, Brooks RA, Xavier J, Maiorana A, Georgetti Gomez L, Zamudio-Haas S, et al. From theory to application: a description of transnationalism in culturally-appropriate HIV interventions of outreach, access, and retention among Latino/a populations. J Immigr Minor Health. 2019;21(2):332–45.
33. Koester KA, Fuller SM, Maiorana A, Steward WT, Zamudio-Haas S, Xavier J, et al. Implementing multi-level interventions to improve HIV testing, linkage-to- and retention-in-care interventions. J Health Care Poor Underserved. 2016;27(3):1234–51.
34. Rebchook G, Keatley J, Contreras R, Perloff J, Molano LF, Reback CJ, et al. The Transgender Women of Color Initiative: implementing and evaluating innovative interventions to enhance engagement and retention in HIV care. Am J Public Health. 2017;107(2):224–9.
35. Psihopaidas D, Cohen SM, West T, Avery L, Dempsey A, Brown K, et al. Implementation science and the Health Resources and Services Administration's Ryan White HIV/AIDS Program's work towards ending the HIV epidemic in the United States. PLoS Med. 2020;17(11):e1003128.
36. Health Resources and Services Administration. SPNS Transgender Women of Color Initiative: Project Interventions Manuals, November 14, 2018. Accessed November 19, 2018. Available from: https://targethiv.org/library/spns-transgender-women-color-initiative-manual.
37. Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O'Neal , et al. The REDCap consortium: building an international community of software platform partners. J Biomed Inform. 2019;95:103208.
38. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)–a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform. 2009;42(2):377–81.
39. Sevelius JM, Xavier J, Chakravarty D, Keatley J, Shade S, Rebchook G, et al. Correlates of engagement in HIV care among transgender women of color in the United States of America. AIDS Behav. 2021;25(1):3–12.
40. Andresen EM, Malmgren JA, Carter WB, Patrick DL. Screening for depression in well older adults: evaluation of a short form of the CES-D (Center for Epidemiologic Studies Depression Scale). Am J Prev Med. 1994;10(2):77–84.
41. Kohout FJ, Berkman LF, Evans DA, Cornoni-Huntley J. Two shorter forms of the CES-D (Center for Epidemiological Studies Depression) depression symptoms index. J Aging Health. 1993;5(2):179–93.
42. Zhang W, O'Brien N, Forrest JI, Salters KA, Patterson TL, Montaner JS, et al. Validating a shortened depression scale (10 item CES-D) among HIV-positive people in British Columbia, Canada. PLoS One. 2012;7(7):e40793.
43. Bradford J, Reisner SL, Honnold JA, Xavier J. Experiences of transgender-related discrimination and implications for health: results from the Virginia Transgender Health Initiative Study. Am J Public Health. 2013;103(10):1820–9.
44. Jefferson K, Neilands T, Sevelius J. Transgender women of color: discrimination and depression symptoms. Ethn Inequal Health Soc Care. 2013;6(4):121–36.
45. Johnson MO, Rose CD, Dilworth SE, Neilands TB. Advances in the conceptualization and measurement of Health Care Empowerment: development and validation of the Health Care Empowerment inventory. PLoS One. 2012;7(9):e45692.
46. Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2014. 2015. Accessed February 12, 2016. Available from: http://hab.hrsa.gov/data/servicesdelivered/2014RWHAPDataReport.pdf.
47. SAS Institute Inc. SAS OnlineDoc® 9.4. Cary, NC: SAS Institute Inc.; 2013.
48. Reback CJ, Ferlito D, Kisler KA, Fletcher JB. Recruiting, linking, and retaining high-risk transgender women into HIV prevention and care services: an overview of barriers, strategies, and lessons learned. Int J Transgend. 2015;16(4):209–21.
49. Lacombe-Duncan A. An intersectional perspective on access to HIV-related healthcare for transgender women. Transgend Health. 2016;1(1):137–41
50. Maiorana A, Sevelius J, Keatley J, Rebchook G. "She is like a sister to me." Gender-affirming services and relationships are key to the implementation of HIV care engagement interventions with transgender women of color. AIDS Behav. 2021;25(1):72–83.
51. Poteat T, Wirtz AL, Reisner S. Strategies for engaging transgender populations in HIV prevention and care. Curr Opin HIV AIDS. 2019;14(5):393–400.
52. Sievwright KM, Stangl AL, Nyblade L, Lippman SA, Logie CH, Veras M, et al. An expanded definition of intersectional stigma for public health research and praxis. Am J Public Health. 2022;112(S4):S356–61.
53. UNAIDS. Global AIDS Strategy 2021–2026. End inequalities. End AIDS. 2021. Accessed January 6, 2022. Available from: https://www.unaids.org/sites/default/files/media_asset/global-AIDS-strategy-2021-2026_en.pdf.
54. Hirshfield S, Contreras J, Luebe RQ, Swartz JA, Scheinmann R, Reback CJ, et al. Engagement in HIV care among New York City transgender women of color: findings from the peer-led, TWEET intervention, a SPNS Trans Women of Color Initiative. AIDS Behav. 2021;25(1):20–30.
55. Eastwood EA, Nace AJ, Hirshfield S, Birnbaum JM. Young transgender women of color: homelessness, poverty, childhood sexual abuse and implications for HIV care. AIDS Behav. 2021;25(1):96–106.
56. Swartz JA, Ducheny K, Holloway T, Stokes L, Willis S, Kuhns LM. A latent class analysis of chronic health conditions among HIV-positive transgender women of color. AIDS Behav. 2021;25(1):52–63.
57. Kuhns LM, Hotton AL, Perloff J, Paul J, Parker C, Muldoon AL, et al. Evaluation of Translife Care: an intervention to address social determinants of engagement in HIV care among transgender women of color. AIDS Behav. 2021;25(1):13–9.
58. Wilson EC, Turner C, Arayasirikul S, Woods T, Tryon J, Franza K, et al. HIV care engagement among trans women of color in San Francisco Bay Area demonstration projects: findings from the Brandy Martell Project and TransAccess. AIDS Behav. 2021;25(1):31–9.
59. Nemoto T, Iwamoto M, Suico S, Stanislaus V, Piroth K. Sociocultural contexts of access to HIV primary care and participant experience with an intervention project: African American transgender women living with HIV in Alameda County, California. AIDS Behav. 2021;25(1):84–95.
60. Galvan FH, Chen YT, Contreras R, O'Connell B. Violence inflicted on Latina transgender women living with HIV: rates and associated factors by perpetrator type. AIDS Behav. 2021;25(1):116–26.
61. Reback CJ, Kisler KA, Fletcher JB. A novel adaptation of peer health navigation and contingency management for advancement along the HIV care continuum among transgender women of color. AIDS Behav. 2021;25(1):40–51.

SUPPORTING INFORMATION

Additional information may be found under the Supporting Information tab for this article:
Supplemental Table 1. Adjusted Primary Outcomes.

Macdonald V et al. *Journal of the International AIDS Society* 2022, **25**(S5):e26004
http://onlinelibrary.wiley.com/doi/10.1002/jia2.26004/full | https://doi.org/10.1002/jia2.26004

COMMENTARY

The World Health Organization's work and recommendations for improving the health of trans and gender diverse people

Virginia Macdonald[1,#], Annette Verster[1,§,#], Maeve B. Mello[1], Karel Blondeel[2], Avni Amin[2], Niklas Luhmann[1], Rachel Baggaley[1] and Meg Doherty[1]

[§]**Corresponding author**: Annette Verster, Global Programme for HIV, Hepatitis and STIs, World Health Organization, 20 Avenue Appia, Geneva 1211, Switzerland. (versteran@who.int)

Abstract

Introduction: The World Health Organization (WHO) is guided by its global programme of work and the goal that a billion more people have universal health coverage (UHC). To achieve UHC, access for those most vulnerable must be guaranteed and prioritized. WHO is committed to developing evidence-based guidance to work towards UHC for trans and gender diverse (TGD) people. This commentary describes WHO's work related to TGD people over the last decade.

Discussion: In 2011, WHO developed guidelines for the prevention and treatment of HIV and sexually transmitted infections (STIs) in men who have sex with men and TGD people. In 2013, the "HIV civil society reference group" called on WHO to provide specific guidance for TGD people. Values and preferences of TGD people were considered by WHO for the first time, which informed the development of the 2014 WHO Consolidated Guidelines on HIV Prevention, Diagnosis, Treatment and Care for Key Populations. The 2014 Guidelines included a comprehensive package of HIV-related health and enabling interventions with specific considerations for TGD people, as well as a specific policy brief in 2015. Regional WHO offices developed and/or supported the development of blueprints on transgender health and HIV in 2014 and 2016. A 2015 WHO report on sexual health, human rights and the law elucidated the harmful impacts of discriminatory laws on the basis of sexual orientation and gender identity. In 2019, the 11th edition of the international classification of diseases saw the removal of "transsexualism" as a mental and behavioural disorder. WHO's first guideline on self-care interventions, updated in 2021, included key considerations concerning TGD people. In 2022, WHO's updated key populations guidelines include a prioritized package of not just HIV, but also viral hepatitis and STI health interventions for TGD people. Still, a broader and more specific health approach and a greater focus on social issues are needed to better serve the health needs of TGD people.

Conclusions: WHO's understanding and commitment to TGD people's health has evolved and improved over the past decade. Together with professional and community trans health organizations, WHO should now start developing evidence-informed global guidance on TGD health as part of its remit to support UHC to all.

Keywords: transgender; HIV; World Health Organization; policy; guideline; key populations

Received 27 December 2021; **Accepted** 30 July 2022

1 | INTRODUCTION

The Thirteenth General Programme of Work defines the World Health Organization's (WHO's) strategy for 2019–2023. It focuses on triple billion targets to achieve measurable impacts on people's health at the country level. The triple billion targets are to ensure by 2023 that 1 billion more people are better protected from health emergencies; 1 billion more people are enjoying better health and well-being and 1 billion more people are benefiting from universal health coverage (UHC) (1). UHC means that all people can use the promotive, preventive, curative, rehabilitative and palliative health services and commodities they need, of sufficient quality to be effective, while also ensuring that the use of these services does not expose the user to financial hardship (2).

For trans and gender diverse (TGD) people, as well as other key populations for the HIV epidemic, there are additional barriers to reaching UHC. Structural barriers which limit access to health services for TGD people include stigma, discrimination, violence, criminalization and lack of legal gender recognition. These can be compounded by other vulnerabilities, such as disability, ethnicity, migrant status, sexual orientation and poverty. In countries where TGD people are officially recognized, health insurance schemes rarely cover specialized care for this community, including gender-affirming care. Further, the absence of trans knowledgeable and trained clinicians who can provide quality, specialized care can deter

TGD people from accessing health services (3). But the concept of UHC, in which "no one is left behind" and the most vulnerable should be prioritized (progressive universalism), provides opportunities for TGD people to advocate for the inclusion of their specific health needs in national health packages (4). As WHO supports countries to realize UHC, some countries are also working towards better representation of TGD people in policy and planning and a better understanding of and guidance on how to address their specific health needs (5). In this commentary, we look back at WHO's development of norms and standards for TGD people's health and wellbeing.

2 | DISCUSSION

Historically, within WHO, there has been limited focus on the healthcare needs of TGD people. Only in 2008, WHO held a global consultation on "Prevention and treatment of HIV and other sexually transmitted infections (STI) for men who have sex with men and transgender populations," and highlighted for the first time that "[…] many transgender people object to being labelled as men who have sex with men, since they do not identify themselves as men." (6). This statement considered only transgender women, excluding transgender men who have sex with men. Recommendations from the 2008 global consultation called for WHO to develop guidance for delivering an evidence-informed package of interventions to prevent and treat HIV and STIs among transgender women and men who have sex with men. It is important to note that the term "men who have sex with men" was adopted by epidemiologists, focusing exclusively on sexual behaviours which lead to HIV acquisition and transmission rather than cultures, communities and identities, considerably overlooking gender diversity and population-specific health needs. Further, the focus at this stage was only on transgender women due to their high burden of HIV infection with insufficient evidence on the burden of HIV infection in transgender men. In 2011, the WHO HIV department developed such guidelines and, while recognizing that transgender women were a separate population from men who have sex with men, no transgender-specific recommendations were made (7). Rather, all recommendations concerning men who have sex with men were indirectly applied to transgender women.

In 2013, the HIV civil society reference group, an advisory group to the WHO, called on WHO to provide specific recommendations for TGD people, recognizing that this was a continuing major gap in WHO guidance. In response, a qualitative assessment of TGD people's values and preferences related to HIV was commissioned by WHO, the first global WHO study that explicitly included trans men. Results showed that there was poor availability of trans-specific health information and persistent barriers to access and utilization of health services, including stigma, discrimination, legal constraints related to gender recognition, criminalization and violence. Results also showed a lack of understanding and training among health workers to provide gender-sensitive and gender-affirming care and particularly that TGD people prioritized gender-affirming care over other health interventions, including those related to STIs and HIV (8).

The Pan American Health Office, WHO regional office for the Americas (PAHO/WHO), had also flagged TGD health as an issue to which WHO headquarters needed to provide better global guidance. Aware of the need to bring visibility to the trans community in the English-speaking Caribbean, PAHO/WHO published the "Blueprint for the Provision of Comprehensive Care for Trans Persons and their Communities in the Caribbean and other Anglophone Countries" in 2014 (9). The "Blueprint" was published after PAHO/WHO's Member States approved a resolution for countries to address the causes of disparities in health service access and utilization for lesbian, gay, bisexual and trans (LGBT) persons (10), which was followed, in 2018, by a report analysing their situation in the Americas (11). The report overtly recommended countries to "cease to regard transgender identities as pathology," "post visible non-discrimination statements that explicitly refer to sexual orientation and gender identity/expression, and visitation rights for same-sex/-gender partners in cases of hospitalization," "collect qualitative and quantitative data on sexual orientation and gender identity to monitor any obstacles that LGBT people face when accessing health services and barriers," among others. In 2015, following a similar format, the Asia Pacific region released the "Blueprint for the Provision of Comprehensive Care for Trans People and Trans Communities" led by the United Nations Development Programme (UNDP) in close partnership with WHO and others (12).

The regional Blueprints provide a practical guide to help countries implement health services for TGD people. Both include how to conduct respectful reception and registration of TGD people and physical exam describing in detail the steps to providing TGD-sensitive care. Furthermore, they provided guidance on specific healthcare related to body modification, including hormone therapy and surgery for gender affirmation. Additionally, in 2016, WHO worked with other United Nations (UN) partners, technical agencies and networks of TGD people to develop the TRANSIT, an implementing tool for comprehensive HIV and STI Programmes with Transgender People, which focused on supporting and empowering TGD communities (13).

WHO headquarters' role within WHO is to set norms and standards. In 2014, the WHO published the "Consolidated Guidelines on HIV Prevention, Diagnosis, Treatment and Care for Key Populations" promoting a comprehensive package for HIV-related interventions for key populations. This guidance and related policy brief included specific recommendations for TGD people, such as those related to access to sterile needles and syringes for injecting hormones, cervical cancer screening for transgender men, use of oral contraceptives and interactions between hormones for gender affirmation and antiretroviral drugs. The guideline also included language for better quality and sensitive healthcare provision for TGD people recommending that healthcare providers should be sensitive to and knowledgeable about the specific health needs of TGD people, in particular during the genital examination and specimen collection. This was the first time that TGD-specific health interventions were included in a WHO guideline (8, 14).

The 2014 Consolidated Guidelines were also the first global guidance to include enabling interventions as part of a

suggested comprehensive package of interventions for HIV in response to the impact that structural barriers have on TGD people and other key populations' access and utilization of health services (8, 14).

One year later, the specific needs of young people who are TGD were addressed in a WHO technical brief, which highlighted the complexities of addressing HIV while recognizing and realizing different gender identities among youth, the possible accompanying mental health issues, potential stigma and isolation from families and communities (15). Additionally, in 2016, the WHO recommended pre-exposure prophylaxis for all people at substantial risk of HIV, including transgender women (16).

In 2015, WHO was a signatory to a joint statement with other UN agencies calling for an end to discrimination and violence against gender and sexual minorities, including in healthcare settings (17). Also, in 2015, WHO published a report on sexual health, human rights and the law, elucidating the harmful impacts of discriminatory laws on the basis of sexual orientation and gender identity and recommending ways to improve services, including information on gender-affirming care, gender-sensitive healthcare services and addressing violence against TGD people (18). In 2016, the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the WHO Global Health Workforce Alliance jointly launched the Agenda for Zero Discrimination in Health Care (19). The agenda set out a seven-piece action plan, all relevant for eliminating stigma against TGD people, which included removing legal and policy barriers, setting standards for discrimination-free healthcare, community empowerment, and mechanisms and frameworks for monitoring, evaluation and accountability.

Ongoing analysis of the adoption of the recommendations included in the 2016 HIV key populations consolidated guidelines in the WHO African region show consistently low uptake of those specific to TGD people, with only 10 out of 49 (20%) National HIV Strategic Plans (NSP) from the region including this population in 2020. A similar analysis in the Americas region demonstrated a greater uptake, but still with less than half (6 out of 14) of the Caribbean countries having referred to trans or gender diverse people in their NSPs. On the other hand, 100% (19) of Latin American countries cited trans or gender diverse people in their NSP and 58% of them included language on the need to review national laws, policies or practices that criminalize trans or gender diverse people. Additionally, 42% of NSPs from Latin American countries recommended the training of health providers to be sensitive to this population.

As part of its normative role, WHO is also responsible for the International Classification of Diseases (ICD) and works on its development with several stakeholders, including communities. The ICD is used to define eligibility and access to health services and health insurance and can facilitate the collection of data that guides policy and programme decisions. From 1992 to 2019, the ICD classified variations of the binomial male-female as "transsexualism" as a mental and behavioural disorder (20). This classification reinforced stigma and barriers to care for TGD people. For example, under the ICD-10 classification, many TGD people required a diagnosis from a psychiatrist before they were able to access gender-affirming care where available. Further, the previous classification created an environment where mental health issues, such as depression and anxiety, were misdiagnosed and poorly managed in TGD people. The TGD communities advocated to remove "transsexualism" from the ICD and after an extensive review of the evidence, in 2019 the ICD-11 replaced the prior classification with the concept of "gender incongruence" and defined it as a condition within the sexual health chapter rather than as a mental and behavioural disorder (21). Some advocates called for the removal of gender identity from the ICD-11 altogether, given its classification as an issue of sexual health is also inaccurate (22). However, inclusion in the ICD helps to ensure TGD people's access to gender-affirming healthcare as well as health insurance coverage. This change should reduce barriers and move TGD people one step closer to equity in health coverage, in countries where they are recognized.

Given the paucity of evidence about trans health beyond HIV (23) and in diverse geographies and legal contexts, evidence-informed recommendations for TGD people using WHO standards (24) can be difficult to make. The gaps in evidence and knowledge of the health needs of TGD populations call for specific research with attention to safe and ethical methods to include them in research and develop inclusive data collection systems (25). In 2019, WHO developed Consolidated Guidelines on Self-care Interventions for Health: Sexual and Reproductive Health and Rights, which were updated in 2021 (26). For the first time, these guidelines contain key considerations related to the self-administration of gender-affirming hormones for TGD people. The guidelines development group urgently called for more research to support further evidence-informed guidance for TGD people in order to support a WHO recommendation.

In 2022, the 2016 WHO Consolidated Key Population Guidelines have been updated and include recommendations related to viral hepatitis and STI prevention, diagnosis, treatment and care for TGD and other key populations alongside HIV-related recommendations (27). For this update, WHO commissioned values and preferences research through the TGD people's global network GATE (Global Action for Trans Equality) to inform the development of the guidelines. The guidelines also include prioritized packages of health interventions for each key population group, highlighting, in the case of the TGD people, the importance of national programmes establishing and providing gender-affirming care or effective linkage and referral to services which can provide such care. As in prior editions, the Consolidated Guidelines make the case for recognition of TGD peoples' gender identity in official documents to improve access to healthcare.

3 | CONCLUSIONS

WHO's role, to promote health for all, means it is committed to inclusive healthcare and equitable access for trans, gender diverse and all other people. In December 2020, Dr Tedros Adhamon Ghebreyesus, Director-General of WHO tweeted "Ultimately, our fight is not against a single disease. Our fight is against a world in which people get sick and die simply because they are poor, or female, or young, gay, transgender, sex workers, use drugs or are in prison. Our fight is for

#HealthForAll" (28), demonstrating WHO's highest level commitment to support countries to attend to the health needs of TGD people. While commitment from WHO and other global partners, including donors is crucial, ultimately it is for countries to make the necessary changes, to recognize gender diversity and remove structural barriers to ensure UHC which also includes TGD people. WHO's understanding and commitment to TGD people's health and wellbeing has evolved and improved, but there is still further to go. While WHO has demonstrated increasing commitment to engaging meaningfully, and on an equal basis with TGD communities, this partnership should be further strengthened. Together with professional and community trans health organizations, such as GATE, WPATH and other UN cosponsors, WHO should facilitate more research and start developing evidence-informed global guidance to improve TGD people's health beyond HIV, viral hepatitis and STIs as part of its remit to support UHC to all.

AUTHORS' AFFILIATIONS

[1]Global Programme for HIV, Hepatitis and STIs, World Health Organization, Geneva, Switzerland; [2]UNDP-UNFPA-UNICEF-WHO-World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP), Department of Sexual and Reproductive Health and Research, World Health Organization, Geneva, Switzerland

COMPETING INTERESTS

No competing interests exist.

AUTHORS' CONTRIBUTIONS

AV and VM wrote the main text and coordinated input. KB contributed considerable text as well. MBM, RB, NL, AA and MD reviewed the text and provided additional text.

ACKNOWLEDGEMENTS

No additional acknowledgements.

FUNDING

This work received funding from the UNDP-UNFPA-UNICEF-WHO-World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP), a cosponsored programme executed by the World Health Organization (WHO) and the Bill and Melinda Gates Foundation.

DISCLAIMER

Authors alone are responsible for the views expressed in this publication and do not necessarily represent the decisions or the policies of the UNDP-UNFPA-UNICEF-WHO-World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP) or the World Health Organization (WHO).

REFERENCES

1. World Health Organization. The thirteenth general programme of work, 2019–2023. Geneva: WHO; 2019.
2. World Health Organization. Health in 2015 from millenium development goals to sustainable development goals. Geneva: WHO; 2015.
3. Safer JD, Coleman E, Feldman J, Garofalo R, Hembree W, Radix A, et al. Barriers to healthcare for transgender individuals. Curr Opin Endocrinol Diabetes Obes. 2016;23(2):168–71.
4. Macdonald V, Verster A, Seale A, Baggaley R, Ball A. Universal health coverage and key populations. Curr Opin HIV AIDS. 2019;14(5):433–8.
5. Chiam Z, Duffy S, Gil MG, Goodwin L, Patel NTM. Trans legal mapping report 2019: recognition before the law. Geneva: ILGA World; 2020.
6. World Health Organization. Prevention and treatment of HIV and other sexually transmitted infections among men who have sex with men and transgender populations. Report of a technical consultation. Geneva: WHO; 2009.
7. World Health Organization. Guidelines: prevention and treatment of HIV and other sexually transmitted infections among men who have sex with men and transgender people: recommendations for a public health approach. Geneva: WHO; 2011.
8. World Health Organization. Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations. World Health Organization; 2016.
9. Pan American Health Organization, John Snow Inc, Health WPAfT. Blueprint for the provision of comprehensive care for trans persons and their communities in the Caribbean and other anglophone countries. Arlington, VA: John Snow Inc; 2014.
10. Resolution CD52.R6 Addressing the causes of disparities in health service access and utilization for lesbian, gay, bosexual and trans (LGBT) persons. 2013.
11. Report of the director on addressing the causes of disparities in health servcies access and utlization for lesbian, gay, bisexual and trans (LGBT) persons. 2018.
12. Health Policy Project, Asia Pacific Transgender Network, United Nations Development Programme. Blueprint for the provision of comprehensive care for trans people and trans communities. Washington, DC: Futures Group, Health Policy Project; 2015.
13. United Nations Development Programme, IRGT: A Global Network of Transgender Women and HIV, United Nations Population Fund, UCSF Center of Excellence for Transgender Health, Johns Hopkins Bloomberg School of Public Health, World Health Organization, et al. Implementing comprehensive HIV and STI programmes with transgender people: practical guidance for collaborative interventions. New York: United Nations Development Programme; 2016.
14. World Health Organization. HIV and transgender people. Geneva: WHO; 2015.
15. World Health Organization. HIV and young transgender people: a technical brief. Geneva: WHO; 2015.
16. World Health Organization. Guidelines: updated recommendations on HIV prevention, infant diagnosis, antiretroviral initiation and monitoring. Geneva: WHO; 2016.
17. Office of the High Commissioner for Human Rights. Joint statement on ending violence and discrimination against lesbian, gay, bisexual, transgender and intersex people. Geneva: OHCHR; 2015.
18. World Health Organization. Sexual health, human rights and the law. Geneva: WHO; 2015.
19. Joint United Nations Programme on HIV/AIDS. Agenda for zero discrimination in health-care settings. Geneva: UNAIDS; 2016.
20. World Health Organization. ICD-10: International Statistical Classification of Diseases and Related Health Problems. 2nd ed. Geneva: WHO; 2004.
21. World Health Organization. International Statistical Classification of Diseases and Related Health Problems (ICD-11). Geneva: WHO; 2019.
22. Thomas R, Pega F, Khosla R, Verster A, Hana T, Say L. Ensuring an inclusive global health agenda for transgender people. Bull World Health Organ. 2017;95(2):154–6.
23. Blondeel K, Say L, Chou D, Toskin I, Khosla R, Scolaro E, et al. Evidence and knowledge gaps on the disease burden in sexual and gender minorities: a review of systematic reviews. Int J Equity Health. 2016;15:1–9. Published online 2016 january 22. https://doi.org/10.1186/s12939-016-0304-1
24. World Health Organization. Handbook for guideline development. 2nd ed. Geneva: World Health Organization; 2014.
25. Reisner SL, Poteat T, Keatley J, Cabral M, Mothopeng T, Dunham E, et al. Global health burden and needs of transgender populations: a review. Lancet. 2016;388(10042):412–36.
26. World Health Organization. WHO guideline on self-care interventions for health and well-being. Geneva: WHO; 2021.
27. World Health Organization. Consoldiated guidelines on HIV, viral hepatitis and STI prevention, diagnosis, treatment and care for key populations. Geneva: WHO; 2022.
28. Ghebreyesus TA. Ultimately, our fight is not against a single disease. Our fight is against a world in which people get sick and die simply because they are poor, or female, or young, gay, transgender, sex workers, use drugs or are in prison. Our fight is for #HealthForAll. Twitter; 2020.

Allison SM et al. *Journal of the International AIDS Society* 2022, **25**(S5):e25976
http://onlinelibrary.wiley.com/doi/10.1002/jia2.25976/full | https://doi.org/10.1002/jia2.25976

VIEWPOINT

Incorporating a trauma-informed perspective in HIV-related research with transgender and gender diverse individuals

Susannah M. Allison[1,#], Karen L. Parker[2,#] and Theresa E. Senn[1,§,#]

[§]**Corresponding author**: Theresa E. Senn, National Institute of Mental Health, National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20852, USA. (teri.senn@nih.gov)

[#]These authors have contributed equally to the work.

Keywords: transgender; gender diverse; HIV; trauma; violence; health behaviour

Received 6 January 2022; **Accepted** 30 July 2022

Transgender and gender diverse (TGD) individuals experience high rates of trauma and violence, including physical, sexual and psychological violence, as well as stigma and discrimination as a result of being a sexual and gender minority. These experiences may be exacerbated when intersecting, stigmatized identities such as some racial or ethnic identities are also present [1–3]. Thus, it is essential that HIV researchers understand how TGD participants' experience of trauma impacts their research participation. A trauma-informed lens, where everyone on the research team understands and recognizes potential signs and impact of trauma, where interactions are shaped by this recognition of trauma and where policies are developed to minimize trauma-related distress [4], should be utilized throughout the HIV research process, including: developing research aims; staff training; study procedures; intervention development; and interpretation of findings (Figure 1). Utilizing a trauma-informed lens in HIV research is critical regardless of the country or setting, given the universally high rates of transphobia and potential for related traumatic experiences. This article presents a set of suggestions for the field to consider when conducting HIV research with TGD individuals; these recommendations are not intended to set research or funding priorities.

Engagement with TGD community members should begin well in advance of any formal research development. Given the discrimination and trauma experienced by many TGD individuals, communities may not want to collaborate with researchers; establishing trust is critical, particularly when researchers are not from the TGD community. It is important to recognize that not all TGD individuals are active in TGD-related organizations; additional outreach beyond these organizations is needed to incorporate a diversity of perspectives. Researchers engaging with TGD individuals should meet them in the communities where they live. TGD individuals who are advising the research team should be provided with the opportunity to talk about their and their community's health concerns and inform a collaborative approach to outlining the research goals. In addition, when developing research aims and questions, researchers should consider that trauma may influence the health outcomes of interest.

A trauma-informed, trans-sensitive environment is essential for staff and participants in any TGD-related study. All staff should be trained in understanding trauma and its impacts [5]. It is important that staff avoid stigmatizing language [6] and use gender-affirming language and materials during interactions with participants. While a research staff that reflects the study participants may increase participant comfort and trust and has been identified as important by TGD individuals [7], having a TGD research staff does not replace the need to incorporate a trauma-informed perspective by everyone who interacts with study participants. Given that TGD individuals working on the study may themselves have histories of trauma, the research environment needs to support and empower all staff to address trauma and cope with secondary traumatic stress. Standard operating procedures, including appropriate referrals, need to be in place to address staff distress, re-traumatization and potential burnout.

The potential impact of trauma should be considered throughout all study procedures. Many TGD individuals have experienced discrimination in healthcare or research settings; these prior experiences may be barriers to study participation. During the consent process, it is important to recognize the power differential between research staff and potential participants. Researchers should consider whether trauma assessments should be included in the assessment battery, as trauma may be an important predictor or moderator of outcomes. If traumatic experiences will be assessed, participants should be prepared for these questions through the informed consent process. In addition, researchers should recognize that trauma may take different forms depending on the participant population and should use appropriate measures to assess trauma. For example, measures of partner violence developed based on cisgender, heterosexual relationships may not adequately capture the range of partner violence experienced by TGD individuals (e.g. a partner threatening to "out" someone as transgender) [8]. Finally,

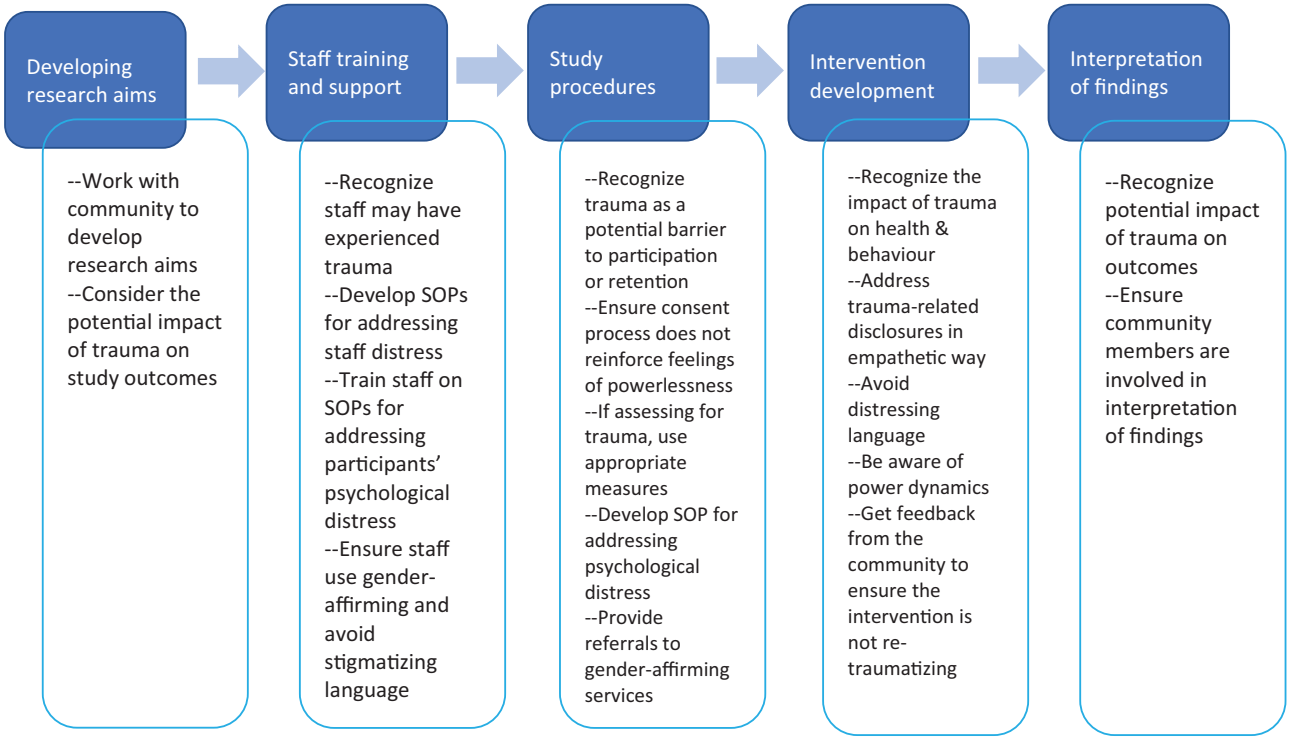


Figure 1. Incorporating a trauma-informed perspective at each stage of the research process. Abbreviation: SPO, standard operating procedure.

researchers should develop standard operating procedures so that staff are consistently monitoring participants' emotional reactions and are trained to handle psychological distress at any point. Specific plans should be developed to respond to instances of severe distress immediately by study staff, and referrals to gender-affirming, accessible mental health services should be provided when needed. This may be a challenge in settings where there are few mental health and/or culturally competent providers; strategies used to deliver mental health services in low- and middle-income countries, such as task sharing (i.e. when non-specialists are trained and carefully supervised in the delivery of services) [9] and digital or mHealth interventions [10], may be useful tools in these settings.

In intervention-focused HIV research, the potential impact of trauma on participation in and response to the intervention should be recognized. Researchers should understand that while behaviours addressed in the intervention may be harmful or unhealthy, they may also be an understandable reaction to the trauma participants have experienced [11]. Individuals may have experienced different types of traumas across social and structural levels and may cope in different ways [12]; interventions should acknowledge these different traumas and the multiple intersectional identities that may influence an individual's current behaviour and response to an intervention. Researchers should engage with the TGD community to ensure that the language and content of the intervention minimize distress. Those delivering the intervention should be aware of power differences due to roles and social identities and should empower participants to make informed decisions about their behaviours; telling participants what to do may reinforce participants' feelings of powerlessness. If appropriate for the context and with trained facilitators, the intervention may directly address trauma. Even if the intervention does not directly address trauma, facilitators should be prepared for trauma-related issues to arise and should respond in a non-judgemental and empathetic way. If the intervention is delivered in a group format, hearing about others' experiences may be upsetting for group members. Facilitators should be trained in how to balance sensitively acknowledging someone's experiences with the need to be sensitive to the potential distress of other participants. Discussing with the group up front how these situations will be handled may help to alleviate unnecessary challenges.

Finally, it is important to consider trauma when interpreting findings. Researchers should ensure that TGD community members are meaningfully involved in the interpretation and reporting of findings. Findings should not be overpathologized but should be interpreted through the lens that thoughts or behaviours may be an understandable response to traumatic experiences. If trauma was assessed in the study, it should be investigated as a potential influence on study outcomes.

Given the high rates of trauma and violence experienced by TGD individuals and the impact of trauma on health, HIV research that includes TGD individuals should employ a trauma-informed approach across the entire research process. Further, other groups that are disproportionately burdened by HIV may also have high rates of diverse experiences with trauma, making a trauma-informed approach potentially

beneficial across all HIV research. Research teams should include those with expertise in trauma and sensitivity to the unique needs of TGD individuals, including those who are cognizant of the local and country context within which the research is being conducted. A trauma-informed research approach should be adopted to address the significant HIV disparities among TGD individuals.

AUTHORS' AFFILIATIONS

[1]National Institute of Mental Health, National Institutes of Health, Rockville, Maryland, USA; [2]Sexual and Gender Minority Research Office, National Institutes of Health, Rockville, Maryland, USA

COMPETING INTERESTS

The authors declare that they have no competing interests.

AUTHORS' CONTRIBUTIONS

SMA, KLP and TES contributed to the conceptualization of the manuscript, were involved in drafting the manuscript and critically revised the manuscript. All authors have read and approved the final manuscript.

ACKNOWLEDGEMENTS

None.

DISCLAIMER

The views expressed in this paper are those of the authors, and these views do not necessarily represent the official views of the National Institute of Mental Health, the Sexual and Gender Minority Research Office, the National Institutes of Health or the U.S. government.

REFERENCES

1. Newcomb ME, Hill R, Buehler K, Ryan DT, Whitton SW, Mustanski B. High burden of mental health problems, substance use, violence, and related psychosocial factors in transgender, non-binary, and gender diverse youth and young adults. Arch Sex Behav. 2020;49:645–59.
2. Reisner SL, White Hughto JM, Gamarel KE, Keuroghlian AS, Mizock L, Pachankis JE. Discriminatory experiences associated with posttraumatic stress disorder symptoms among transgender adults. J Couns Psychol. 2016;63:509–19.
3. Budhwani H, Hearld KR, Milner AN, Charow R, McGlaughlin EM, Rodriquez-Lauzurique M, et al. Transgender women's experiences with stigma, trauma, and attempted suicide in the Dominican Republic. Suicide Life Threat Behav. 2018;48:788–96.
4. Substance Abuse and Mental Health Services Administration. SAMHSA's concept of trauma and guidance for a trauma-informed approach. HHS Publication No. (SMA) 14–4884. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2014.
5. Quijada Y, Inostroza C, Vaccari P, Riese J, Hausmann-Stabile C. Infusing the trauma-informed approach in youth suicide research: lessons from the field. Am J Orthopsychiatry. 2021;91:579–88.
6. Bouman WP, Schwend AS, Motmans J, Smiley A, Safer JD, Deutsch MB, et al. Language and trans health. Int J Transgend. 2017;18:1–6.
7. Asquith A, Sava L, Harris AB, Radix AE, Pardee DJ, Reisner SL. Patient-centered practices for engaging transgender and gender diverse patients in clinical research studies. BMC Med Res Methodol. 2021;21:202.
8. Peitzmeier SM, Hughto JMW, Potter J, Deutsch MB, Reisner SL. Development of a novel tool to assess intimate partner violence against transgender individuals. J Interpers Violence. 2019;34:2376–97.
9. Raviola G, Naslund JA, Smith SL, Patel V. Innovative models in mental health delivery systems: task sharing care with non-specialist providers to close the mental health treatment gap. Curr Psychiatry Rep. 2019;21:44.
10. Demena BA, Artavia-Mora L, Ouedraogo D, Thiombiano BA, Wagner N. A systematic review of mobile phone interventions (SMS/IVR/Calls) to improve adherence and retention to antiretroviral treatment in low- and middle-income countries. AIDS Patient Care STDs. 2020;34:59–71.
11. Najavits LM. Seeking safety: a treatment manual for PTSD and substance abuse. New York: Guilford Press; 2002.
12. Wesp LM, Malcoe LH, Elliott A, Poteat T. Intersectionality research for transgender health justice: a theory-driven conceptual framework for structural analysis of transgender health inequities. Transgend Health. 2019;4:287–96.

Klein A and Golub SA *Journal of the International AIDS Society* 2022, **25**(S5):e25971
http://onlinelibrary.wiley.com/doi/10.1002/jia2.25971/full | https://doi.org/10.1002/jia2.25971

COMMENTARY

Ethical HIV research with transgender and non-binary communities in the United States

Augustus Klein[1,§] and Sarit A. Golub[1,2,3]

[§]**Corresponding author**: Augustus Klein, Hunter Alliance for Research and Translation, Hunter College, 695 Park Ave, New York, NY 10065, USA. Tel: 212-396-6084. (augustus.klein@hunter.cuny.edu)

Abstract

Introduction: Because transgender individuals experience disproportionately high rates of HIV infection, this population is an increasing focus of epidemiological and implementation science research to combat the epidemic. However, study participants, providers and other advocates have become increasingly concerned about research practices that may alienate, objectify, exploit or even re-traumatize the communities they are designed to benefit. This commentary explores the common pitfalls of HIV research with transgender communities and provides a potential framework for ethical, community-engaged research practice.

Discussion: We review some of the critical challenges to HIV research with transgender and non-binary communities that limit the potential for such studies to improve practice. For example, scales that measure stigma perceptions/experiences often include activating language, while the consistent focus in research on risk and trauma can often feel judgemental and redundant. Because of limited employment opportunities, some participants may feel undue influence by research stipends; others may perceive their participation as fuelling the larger research economy without providing research jobs to community members. Questions remain regarding optimal strategies for authentic research partnership beyond community advisory boards or focus groups. Transgender and non-binary researchers are under-represented and may be tokenized. Many demonstration projects provide much-needed services that disappear when the research funding is over, and community-based dissemination efforts are often perceived as "too little, too late" to effect change.

Conclusions: Based on this review and input from study participants across the United States, we detail six recommendations for ethical HIV research with transgender and non-binary communities, including (1) equitable budgeting with community-based programme partners; (2) representation in the development of both research agenda and methods; (3) integration of research activities into the ongoing work of any clinical or service site, so that individuals' needs as "clients" can continue to be prioritized over their role as "participants;" (4) mindfully considered compensation that values the contributions of community members, but avoids undue influence; (5) transparent, community-focused and timely communication at every stage of the study, including research purpose, data usage, preliminary findings and full-scale results; and (6) planning for sustainability of any programme or services beyond the life of the research project.

Keywords: HIV prevention and treatment; community-engaged research; transgender; non-binary; stigma; ethical considerations

Received 28 December 2021; **Accepted** 19 July 2022

1 | INTRODUCTION

Over the past two decades, transgender individuals, particularly African American/Black and Latinx/Hispanic transgender women, have received increasing attention in HIV research [1–8]. This research has documented how multiple intersecting structural factors, including racism, sexism, transphobia, homophobia and other systems of oppression, contribute to the disproportionately high rates of HIV infection among this population [9–14]. However, the proliferation of transgender HIV research has brought significant scientific and ethical concerns about research practices that may erase, alienate, objectify, exploit or re-traumatize the communities they are designed to benefit [7, 13, 15–18]. A growing number of voices within the transgender and non-binary communities (TGNBCs) have begun to openly challenge the scientific rigour, public health benefit, ethical principles and research practice within trans-focused HIV science by advocating for systemic change that prioritizes, promotes and sustains meaningful trans leadership and engagement at all levels of the research process [15, 19–24].

Table 1. Critical challenges to addressing methodological and ethical concerns in HIV research with transgender and non-binary individuals

Methodological and ethical concerns	Critical challenges
Overemphasis on descriptive documentation of risk, pathology and "vulnerabilities" among transgender and non-binary communities.	Committing to integrated, multi-level approaches that emphasize contextual drivers of individual-level behaviour and focus on identifying targets for disruption of intersectional structural oppression.
Continuous recapitulation of known facilitators and barriers to HIV prevention and treatment.	Empowering researchers not to re-establish barriers and facilitators but instead identify and test strategies for addressing them.
Studies that examine stigma and trauma may include activating, re-traumatizing language and/or may be measured in ways that feel judgemental, out of touch and demoralizing.	Ensuring that research methods are trauma-informed and actively de-stigmatizing.
Lack of reflection about power dynamics and potential undue influence inherent in research compensation.	Developing compensation strategies that recognize and value contributions without being exploitative.
Under-representation or tokenization of transgender and non-binary individuals in all stages of the research process.	Developing structures and accountability for genuine research partnership that promotes and sustains leadership of transgender and non-binary individuals.
Lack of durable impact of HIV research on transgender and non-binary communities.	Ensuring sustained access to needed programmes or services and multi-level dissemination that focuses on maximizing the impact of research findings.

As part of this challenge, it is essential to acknowledge the diversity of populations outside a traditional cisgender focus. While the focus has been on transfeminine people in HIV research, transmasculine individuals have historically been marginalized due to assumptions about their sexual partners and activities, low estimates of HIV prevalence compared to transgender women and a lack of adequate and standardized HIV surveillance data collection about gender identity. Non-binary and gender diverse individuals are almost entirely absent from research representation due to binary assumptions about gender identity, a lack of expansive measures of gender identity in existing research and the conflation of sexual and gender identity. This commentary explores the persistent problems and critical challenges of HIV research with TGNBCs and provides a potential framework for ethical, community-engaged research practice.

2 | DISCUSSION

Table 1 presents six methodological and ethical concerns in HIV research with TGNBCs and identifies the critical challenges our field must embrace to make equity-focused progress. This analysis emerges from our combined 30 years of experience working in community-based healthcare, social services and advocacy within HIV and our more recent experience conducting community-driven implementation science research. Most recently (September 2020–August 2021), we facilitated a convening of five community health centres across the United States serving LGBTQ+ communities. We engaged in a multi-stage collaborative process that included over 350 diverse stakeholders (over 50% of whom were patients) and culminated in a 4-day virtual convening in which 49 representatives from all five health centres (41% patients; 34% transgender/non-binary; and 49% People of Colour) came together to discuss the past and future of equity-focused, community-engaged research. We acknowledge this history as the lens through which we understand and articulate the concerns and challenges below. We invite others with distinct and complementary perspectives to engage, critique and add to the conversation.

2.1 | Methodological and ethical concerns

The first concern is the extent to which trans-HIV research has emphasized descriptive documentation of risk, pathology and "vulnerabilities" among TGNBCs associated with potential HIV exposure, including sex work, lack of employment opportunities, housing instability, incarceration, violence, substance use and depression [7, 11, 13, 17, 25, 26]. On the one hand, this focus has enabled a greater understanding of several acute challenges faced by TGNBCs, and some findings have been used as essential advocacy tools. However, research focused merely on *describing* health disparities has the potential to further stigmatize TGNBCs by reducing them to their marginalized identities and the contextual factors they must navigate to survive. Moreover, much of this research does not adequately analyse systemic drivers of HIV exposure; for example, in a recent scoping review of articles measuring anti-trans stigma in the United States [27], only 35/126 (28%) measured stigma at the structural level and only four (3%) provided a specific definition of structural anti-trans stigma. One critical challenge in this area is committing to integrated, multi-level approaches that emphasize contextual drivers of individual-level behaviour and focus on *identifying targets* for disrupting intersectional structural oppression.

Relatedly, the second concern is the continuous recapitulation of known facilitators and barriers to HIV prevention and treatment for TGNBCs. Almost all publications in this area document the same barriers and facilitators, including

healthcare access, financial need, social support and intersecting multi-level stigma and discrimination [28–35]. However, this line of inquiry has failed to fully identify specific mechanisms and manifestations that could serve as intervention targets for increasing engagement and equity. For example, little attention has been given to examining the processes and mechanisms *within HIV treatment and prevention programmes* that perpetuate structural oppression and contribute to a lack of access and uptake of services, such as the continued use of HIV risk assessment tools, outreach materials or programme delivery models that "lump" TGNBC together with gay men [36, 37]. One critical challenge is empowering researchers to accept existing research on healthcare access among TGNBCs as a framework for intervention development without re-establishing identical or similar barriers and facilitators in each research context. We must prioritize research that identifies and tests strategies for addressing known barriers and facilitators to care, accelerating research designed to solve the problems we already know exist.

The third concern is the extent to which some research strategies may recreate or activate the traumatic or stigmatizing experiences they are designed to understand. Stigma and minority stress scales [38–41] often include items that can be experienced as stigmatizing in and of themselves (e.g. "Whenever I think of being transgender, I feel depressed;" "Most transgender people end up lonely and isolated;" "Being transgender is disgusting to me") [40] or ask participants to recount and relive stigmatizing experiences (e.g. history of physical and sexual violence, family rejection, incidents of discrimination and harassment) to document their association with negative affect or health behaviour [5]. While some studies complement these measures with measures of self-esteem, community-connectedness or other "protective factors," [42, 43] there is limited research analysing how the remarkable strength and resilience exhibited by TGNBCs in response to systemic oppression can be translated into specific supportive interventions and programmes. To move towards a strengths-based health equity framework, it is incumbent on researchers to consider the reasons why we are asking certain research questions (especially if we already know the answers) and whether the utility of including certain measures outweighs the potential harm to study participants. One critical challenge for the future is to ensure that research methods are trauma-informed and actively de-stigmatizing by (1) focusing on resiliency, strength and joy; (2) ensuring that study language is person-centred and non-stigmatizing; and (3) building in active support mechanisms for TGNBCs participating in studies dealing with stigma and trauma.

The fourth concern relates to the need to be reflective and deliberate about research compensation in the context of a complicated risk/benefit calculus for many TGNBC research participants. From the researcher's perspective, participation is compensated for the time and travel involved in "data collection," not the participant's information. However, given the extent to which financial need has been identified as a particular vulnerability of TGNBCs, our community partners encourage researchers to be particularly vigilant about the potentially predatory nature of collecting highly sensitive and often traumatic information in exchange for monetary compensation. Our community partners recommend two strategies to offset concerns about power dynamics and undue influence. First, participants want to feel motivated to participate in research even if they are not being financially compensated. To the extent that TGNBCs think that the research mission and findings have the potential to benefit their community, financial compensation for their time makes them feel valued rather than exploited. Second, participants want to be offered other incentives in addition to monetary compensation, such as access to resources or services, connection to other participants as a form of social support and opportunities to shape research progress. One critical challenge for the future is the development of creative compensation strategies that recognize and value participant contributions without undue influence.

The fifth concern is the under-representation or tokenization of TGNBCs at all levels of the research process [7, 15, 20–22]. In the current landscape of HIV research, cisgender researchers receive much of the funding for transgender research [15]. Despite a growing number of TGNB researchers trained in academia or community-based settings, there are few opportunities for genuine professional development, training and mentorship [15, 21]. When TGNBCs are represented in research, they are often relegated to community advisor or "consultant" roles and asked to speak for or connect researchers to "the community" only once funding has been received, and the study design is complete [15, 20–22]. This practice undervalues or erases the substantive training and expertise of TGNBCs, reducing their importance to their willingness to perform their transgender identity. One critical challenge is for researchers and funders to develop accountability structures for genuine research partnerships that promote and sustain TGNBC leadership and involvement at all stages of the research process.

The sixth concern is the lack of durable impact of HIV research on communities. This concern manifests along two dimensions. First, many HIV intervention or demonstration projects provide much-needed services (e.g. pre-exposure prophylaxis) to TGNBCs that disappear when research funding ends [19]. From the research perspective, such studies are conceptualized as a means to an end, intended to generate findings that can be used to enhance care at some point in the future. But this perspective neglects the short-term reality that research participants will lose access to vital resources and services. Second, even community-based research projects are often not "nimble" enough to respond to the immediate or shifting needs of TGNBCs. Due to the urgent need for competent healthcare, TGNBCs cannot wait years to learn whether a particular intervention or treatment is effective. Many community-based dissemination efforts are perceived as "too little, too late" to effect change. One critical challenge is for all research projects to include (1) a dissemination plan that can provide ongoing reports of study findings in an accelerated time frame designed to maximize impact; (2) an adaptability plan that can pivot in response to new developments or unexpected study findings; and (3) a sustainability plan, which ensures that efficacious services offered as part of a research study can be sustained after the research is completed.

3 | CONCLUSIONS

To address the methodological and ethical concerns discussed in this commentary, HIV research must create mechanisms to centre the values, needs and priorities of TGNBCs at all stages of the research process. Without this commitment, HIV research will continue to perpetuate the inequities it has been funded to address. The following recommendations below represent six "take-home" messages that we believe are most important to consider. While these recommendations do not represent a one-to-one relationship to the specific concerns detailed above, they are provided as an overarching framework to begin addressing these critical challenges.

1. **Ensure equitable budgeting with community-based programme partners**. Community-based organizations (CBOs) serving TGNBCs play an integral role in HIV research. However, CBOs are inherently disadvantaged in legal and financial power when receiving research requests from outside researchers, particularly at large academic institutions. Many institutions which fund HIV research perpetuate this power dynamic by not requiring researchers to actively consider the programmatic and financial investment necessary for organizations to successfully support and engage in research, such as staffing, prioritization of care provision versus research responsibilities, service reimbursement structures and the technological infrastructure needed for data collection or abstraction. CBOs which provide services to TGNBCs most impacted by HIV are often underfunded, understaffed and politically vulnerable. HIV research that centres health equity must intervene at the structural and programmatic level by designing equitable compensation structures that are based on (1) the amount of research funding received; (2) the organization's mission, infrastructure and services provided; and (3) the research responsibilities and expectations requested.
2. **Increase representation of TGNBCs in developing both research agenda and methods**. Central to meeting all critical challenges outlined in this commentary is a renewed commitment from HIV researchers to create and foster true research partnerships and for funders to require and incentivize formal research engagement plans that concretely outline how TGNBCs will participate at all stages of the research process.
3. **Integration of research activities into the ongoing work of CBOs, focusing on prioritizing individuals' roles as "clients" over their requirements as "participants."** The co-location of research within CBOs can answer research questions that are most pertinent to TGNBCs and allow organizations to put research findings into action in a timely and sustainable manner, providing an opportunity to build a rigorous evidence base for effective practice-based strategies/interventions that have a lasting impact on the lives of TGNBCs. However, in this context, researchers must ensure that research needs do not eclipse or threaten patient care. Funders and researchers must value and prioritize research that actively engages CBOs as research leaders and acknowledges the importance of the care they provide.
4. **Mindfully considered compensation that values the contributions of community members but avoids undue influence**. As discussed above, compensation strategies must align with the tasks participants are asked to complete and the types of information being collected. Compensating participants does not mean we can continually ask intimate, stigmatizing questions. There is a need for greater transparency around the reasons for asking such questions and how this information will be used to benefit study participants and the community. It is also incumbent on researchers to consider providing opportunities for research participants beyond financial incentives. For example, participation in research can be an opportunity for forging connections among individuals with shared experiences and interests. Researchers should consider innovative ways to provide much-needed social support and community-building opportunities.
5. **Transparent, community-focused and timely communication at every stage of the research process**. Conceptualizing dissemination as a process that begins at the inception of a research project and continues throughout implementation is a key to meeting the critical challenges outlined in this commentary that demand *timely and useful* research for TGNBCs. Dissemination activities and protocols should (1) build trust around and enhance the applicability of findings; (2) include standardized "report-back" protocols for timely and ongoing dissemination of study information and findings; (3) facilitate real-time feedback, questions and concerns from study participants and programme staff; and (4) ensure study information and findings reach beyond academic and scientific communities.
6. **Planning for the sustainability of any programme or service beyond the life of the research project**. To ensure that HIV research with TGNBCs does not perpetuate the health disparities it has documented, it is vital for all research projects that provide access to services or treatment to develop and execute a plan for sustainability of services once the project has ended. This work requires creative, thoughtful pre-planning in collaboration with CBOs and TGNBCs. Funders could require sustainability plans as a core component of ethical practice and sustainability in the event of efficacious findings.

The above recommendations are based on our ongoing work and input from TGNBCs, including study participants, researchers and healthcare providers across the United States. We encourage the reader to reflect on how the above recommendations may be implemented to enhance current and future research. The ideas presented in this paper are designed to be a call to action for improving ethical, community-based research practice with TGNBCs that is best equipped to enhance health equity in HIV prevention and treatment. The overarching challenge for our field is incentivizing action-oriented research that centres health equity by developing and evaluating real-world strategies that mitigate against inequity in HIV prevention and care access, utilization and efficacy among TGNBCs.

AUTHORS' AFFILIATIONS

[1]Hunter Alliance for Research and Translation, Hunter College, New York City, New York, USA; [2]Department of Psychology, Hunter College, New York City, New York, USA; [3]Department of Basic and Applied Social Psychology, The Graduate Center of the City University of New York, New York City, New York, USA

COMPETING INTERESTS

The authors declare no competing interests.

AUTHORS' CONTRIBUTIONS

Both AK and SAG developed the concept for this paper and contributed to the writing, revision and table development.

ACKNOWLEDGEMENTS

The authors thank our collaborative research partners and the thousands of individuals who have participated in our research for their trust, openness and commitment to ensuring that HIV research with transgender and non-binary communities is ethical, person-centred and solution-focused. This work was supported in part by a Patient-Centered Outcomes Research Institute (PCORI) Eugene Washington PCORI Engagement Award (EACC #18813; Golub).

REFERENCES

1. Herbst JH, Jacobs ED, Finlayson TJ, McKleroy VS, Neumann MS, Crepaz N, et al. Estimating HIV prevalence and risk behaviors of transgender persons in the United States: a systematic review. AIDS Behav. 2008;12(1):1–7.
2. Baral SD, Poteat T, Strömdahl S, Wirtz AL, Guadamuz TE, Beyrer C. Worldwide burden of HIV in transgender women: a systematic review and meta-analysis. Lancet Infect Dis. 2013;13(3):214–22.
3. Poteat T, Reisner SL, Radix A. HIV epidemics among transgender women. Curr Opin HIV AIDS. 2014;9(2):168.
4. Clark H, Babu AS, Wiewel EW, Opoku J, Crepaz N. Diagnosed HIV infection in transgender adults and adolescents: results from the National HIV Surveillance System, 2009–2014. AIDS Behav. 2017;21(9):2774–83.
5. Becasen JS, Denard CL, Mullins MM, Higa DH, Sipe TA. Estimating the prevalence of HIV and sexual behaviors among the US transgender population: a systematic review and meta-analysis, 2006–2017. Am J Public Health. 2019;109(1):e1–8.
6. Reisner SL, Murchison GR. A global research synthesis of HIV and STI biobehavioural risks in female-to-male transgender adults. Glob Public Health. 2016;11(7–8):866–87.
7. Del Río-González AM, Lameiras-Fernández M, Modrakovic D, Aguayo-Romero R, Glickman C, Bowleg L, et al. Global scoping review of HIV prevention research with transgender people: transcending from trans-subsumed to trans-centered research. J Int AIDS Soc. 2021;24(9):e25786.
8. Stephenson R, Riley E, Rogers E, Suarez N, Metheny N, Senda J, et al. The sexual health of transgender men: a scoping review. J Sex Res. 2017;54(4–5):424–45.
9. Brennan J, Kuhns LM, Johnson AK, Belzer M, Wilson EC, Garofalo R, et al. Syndemic theory and HIV-related risk among young transgender women: the role of multiple, co-occurring health problems and social marginalization. Am J Public Health. 2012;102(9):1751–7.
10. Lemons A, Beer L, Finlayson T, McCree DH, Lentine D, Shouse RL, et al.; Medical Monitoring Project. Characteristics of HIV-positive transgender men receiving medical care: United States, 2009–2014. Am J Public Health. 2018;108(1):128–30.
11. Neumann MS, Finlayson TJ, Pitts NL, Keatley J. Comprehensive HIV prevention for transgender persons. Am J Public Health. 2017;107(2):207–12.
12. Poteat T, Malik M, Scheim A, Elliott A. HIV prevention among transgender populations: knowledge gaps and evidence for action. Curr HIV/AIDS Rep. 2017;14(4):141–52.
13. Sevelius JM, Reznick OG, Hart SL, Schwarcz S. Informing interventions: the importance of contextual factors in the prediction of sexual risk behaviors among transgender women. AIDS Educ Prev. 2009;21(2):113–27.
14. Operario D, Nemoto T. HIV in transgender communities: syndemic dynamics and a need for multicomponent interventions. J Acquir Immune Defic Syndr. 2010;55(2):S91.
15. Scheim AI, Appenroth MN, Beckham SW, Goldstein Z, Grinspan MC, Keatley JG, et al. Transgender HIV research: nothing about us without us. Lancet HIV. 2019;6(9):e566–7.
16. Perez-Brumer AG, Oldenburg CE, Reisner SL, Clark JL, Parker RG. Towards 'reflexive epidemiology': conflation of cisgender male and transgender women sex workers and implications for global understandings of HIV prevalence. Glob Public Health. 2016;11(7–8):849–65.
17. Poteat T, Wirtz AL, Radix A, Borquez A, Silva-Santisteban A, Deutsch MB, et al. HIV risk and preventive interventions in transgender women sex workers. Lancet North Am Ed. 2015;385(9964):274–86.
18. Radix AE, Harris AB, Goldstein ZG. How can we improve uptake of oral HIV pre-exposure prophylaxis for transgender individuals? Expert Rev Anti Infect Ther. 2020;18(9):835–8.
19. Reisner SL, Radix A, Deutsch MB. Integrated and gender-affirming transgender clinical care and research. J Acquir Immune Defic Syndr. 2016;72(3):S235.
20. Adams N, Pearce R, Veale J, Radix A, Castro D, Sarkar A, et al. Guidance and ethical considerations for undertaking transgender health research and institutional review boards adjudicating this research. Transgend Health. 2017;2(1):165–75.
21. Rosenberg S, Tilley PM. 'A point of reference': the insider/outsider research staircase and transgender people's experiences of participating in trans-led research. Qual Res. 2021;21(6):923–38.
22. Vincent BW. Studying trans: recommendations for ethical recruitment and collaboration with transgender participants in academic research. Psychol Sex. 2018;9(2):102–16.
23. Seekaew P, Janumnuaysook R, Lujintanon S, Pongtriang P, Nonnoi S, Hongchookait P, et al. Perspectives of transgender women toward study recruitment and retention: thematic analysis from Thailand. Sex Res Soc Policy. 2022;19(2):638–46.
24. Veale JF, Deutsch MB, Devor AH, Kuper LE, Motmans J, Radix AE, et al. Setting a research agenda in trans health: an expert assessment of priorities and issues by trans and nonbinary researchers. Int J Transgend Health. 2022;19:1–7.
25. Fletcher JB, Kisler KA, Reback CJ. Housing status and HIV risk behaviors among transgender women in Los Angeles. Arch Sex Behav. 2014;43(8):1651–61.
26. Reback CJ, Fletcher JB. HIV prevalence, substance use, and sexual risk behaviors among transgender women recruited through outreach. AIDS Behav. 2014;18(7):1359–67.
27. King WM, Hughto JM, Operario D. Transgender stigma: a critical scoping review of definitions, domains, and measures used in empirical research. Soc Sci Med. 2020;250:112867.
28. Fontanari AM, Zanella GI, Feijó M, Churchill S, Lobato MI, Costa AB. HIV-related care for transgender people: a systematic review of studies from around the world. Soc Sci Med. 2019;230:280–94.
29. Pacífico de Carvalho N, Mendicino CC, Cândido RC, Alecrim DJ, Menezes de Pádua CA. HIV pre-exposure prophylaxis (PrEP) awareness and acceptability among trans women: a review. AIDS Care. 2019;31(10):1234–40.
30. Andrasik MP, Yoon R, Mooney J, Broder G, Bolton M, Votto T, et al. Exploring barriers and facilitators to participation of male-to-female transgender persons in preventive HIV vaccine clinical trials. Prev Sci. 2014;15(3):268–76.
31. Lacombe-Duncan A, Kia H, Logie CH, Todd KP, Persad Y, Leblanc G, et al. A qualitative exploration of barriers to HIV prevention, treatment, and support: perspectives of transgender women and service providers. Health Soc Care Community. 2021;29(5):e33–46.
32. Auerbach JD, Moran L, Watson C, Weber S, Keatley J, Sevelius J. We are all women: barriers and facilitators to inclusion of transgender women in HIV treatment and support services designed for cisgender women. AIDS Patient Care STDs. 2020;34(9):392–8.
33. Maiorana A, Sevelius J, Keatley J, Rebchook G. "She is like a sister to me." Gender-affirming services and relationships are key to the implementation of HIV care engagement interventions with transgender women of color. AIDS Behav. 2021;25(1):72–83.
34. Sevelius JM, Patouhas E, Keatley JG, Johnson MO. Barriers and facilitators to engagement and retention in care among transgender women living with human immunodeficiency virus. Ann Behav Med. 2014;47(1):5–16.
35. Sevelius JM, Keatley J, Calma N, Arnold E. 'I am not a man': trans-specific barriers and facilitators to PrEP acceptability among transgender women. Glob Public Health. 2016;11(7–8):1060–75.
36. Veronese V, Clouse E, Wirtz AL, Thu KH, Naing S, Baral SD, et al. "We are not gays… don't tell me those things": engaging 'hidden' men who have sex with men and transgender women in HIV prevention in Myanmar. BMC Public Health. 2019;19(1):1–2.
37. Sevelius JM, Keatley J, Calma N, Arnold E. 'I am not a man': trans-specific barriers and facilitators to PrEP acceptability among transgender women. Glob Public Health. 2016;11(7–8):1060–75.

38. Austin A, Goodman R. The impact of social connectedness and internalized transphobic stigma on self-esteem among transgender and gender non-conforming adults. J Homosex. 2017;64(6):825–41.
39. Bockting WO, Miner MH, Swinburne Romine RE, Dolezal C, Robinson BB, Rosser BS, et al. The Transgender Identity Survey: a measure of internalized transphobia. LGBT Health. 2020;7(1):15–27.
40. Rendina HJ, Cain DN, López-Matos J, Ray M, Gurung S, Parsons JT. Measuring experiences of minority stress for transgender women: adaptation and evaluation of internalized and anticipated transgender stigma scales. Transgend Health. 2020;5(1):42–9.
41. Reisner SL, Moore CS, Asquith A, Pardee DJ, Mayer KH. Gender non-affirmation from cisgender male partners: development and validation of a brief stigma scale for HIV research with transgender men who have sex with men (trans MSM). AIDS Behav. 2020;24(1):331–43.
42. Goldenberg T, Kahle EM, Stephenson R. Stigma, resilience, and health care use among transgender and other gender diverse youth in the United States. Transgend Health. 2020;5(3):173–81.
43. Watson RJ, Veale JF, Gordon AR, Clark BA, Saewyc EM. Risk and protective factors for transgender youths' substance use. Prev Med Rep. 2019;15:100905.

JIAS
JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

AUTHOR INDEX

W

X

Y

Journal Information

About the journal

The *Journal of the International AIDS Society*, the official journal of the Society, provides a peer-reviewed, open access forum for essential and innovative HIV research, across all disciplines. All articles published by the *Journal of the International AIDS Society* are freely accessible online. The editorial decisions are made independently by the journal's Editors-in-Chief.

Website: www.jiasociety.org

eISSN: 1758-2652

Contact details

Editorial office:
Avenue de France, 23
CH-1202 Geneva
Switzerland

Email: editorial@jiasociety.org

Tel: +41 (0) 22 710 0800

Publisher

The *Journal of the International AIDS Society* is published by John Wiley & Sons Ltd on behalf of the IAS - International AIDS Society

John Wiley & Sons Ltd
9600 Garsington Road
Oxford, OX4 2DQ UK

Telephone: +44 1865 776868

Email: customer@wiley.com

Production Editor

Gowthamantony Raja (Email: gr@wiley.com)

Abstracting and Indexing Services

The *Journal of the International AIDS Society* is indexed in a variety of databases including PubMed, PubMed Central, MEDLINE, Science Citation Index Expanded and Google Scholar. The 2020 Journal Impact Factor is 5.396, Journal Citation Reports (Clarivate Analytics, 2021).

Advertising, sponsorship and donations

Please contact the editorial office if you are interested in advertising on our journal's website. We also gladly receive inquiries on sponsorship and donations to support open access publications from authors in low- and middle-income countries.

Supplements

The *Journal of the International AIDS Society* publishes supplements and thematic series on its own initiative or based on proposals by external organisations or authors. Inquiries can be sent to the editorial office at editorial@jiasociety.org.

All articles submitted for publication in supplements are subject to peer review. Published supplements are freely accessible online and can also be produced in print.

Disclaimer

The Publisher, IAS - the International AIDS Society and Editors cannot be held responsible for errors or any consequences arising from the use of information contained in this journal; the views and opinions expressed do not necessarily reflect those of the Publisher, IAS and Editors, neither does the publication of advertisements constitute any endorsement by the Publisher, IAS and Editors of the products advertised.

Copyright and Copying

Wiley's Corporate Citizenship Initiative

Wiley's Corporate Citizenship Initiative seeks to address the environmental, social, economic, and ethical challenges faced in our business and which are important to our diverse stakeholder groups. Since launching the initiative, we have focused on sharing our content with those in need, enhancing community philanthropy, reducing our carbon impact, creating global guidelines and best practices for paper use, establishing a vendor code of ethics, and engaging our colleagues and other stakeholders in our efforts. Follow our progress at www.wiley.com/go/citizenship.

Research4Life

Wiley is a founding member of the UN-backed HINARI, AGORA, and OARE initiatives. They are now collectively known as Research4Life, making online scientific content available free or at nominal cost to researchers in developing countries.

Please visit Wiley's Content Access – Corporate Citizenship site:
www.wiley.com/WileyCDA/Section/id-390082.html

Editors