Recent HIV infection and annualized HIV incidence rates among sexual and gender minorities in Brazil and Peru (ImPrEP seroincidence study): a cross-sectional, multicenter study

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Summary

Background HIV incidence estimation is critical for monitoring the HIV epidemic dynamics and the effectiveness of public health prevention interventions. We aimed to identify sexual and gender minorities (SGM) with recent HIV infections, factors associated with recent HIV infection, and to estimate annualised HIV incidence rates.

Methods Cross-sectional multicentre study in HIV testing services in Brazil and Peru (15 cities). Inclusion criteria: 18+ years, SGM assigned male at birth, not using pre-/post-exposure prophylaxis. We identified recent HIV infection using the Maxim HIV-1 LAg-Avidity EIA assay as part of a recent infection testing algorithm (RITA). Annualized HIV incidence was calculated using the UNAIDS/WHO incidence estimator tool. Multivariable logistic regression models were used to estimate factors associated with recent HIV infection. Trial registration: NCT05674682.

Findings From 31-Jan-2021 to 29-May-2022, 6899 individuals participated [Brazil: 4586 (66.5%); Peru: 2313 (33.5%)]; 5946 (86.2%) cisgender men, 751 (10.9%) transgender women and 202 (2.9%) non-binary/gender diverse. Median age was 27 (IQR: 23–34) years. HIV prevalence was 11.4% (N = 784/6899); 137 (2.0%) SGM were identified with recent HIV infection. The overall annualized HIV incidence rate was 3.88% (95% CI: 2.86–4.87); Brazil: 2.62%

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(95% CI: 1.78–3.43); Peru: 6.69% (95% CI: 4.62–8.69). Participants aged 18–24 years had higher odds of recent HIV infection compared to those aged 30+ years in both countries.

Interpretation Our results highlight the significant burden of HIV epidemic among SGM in large urban centres of Brazil and Peru. Public health policies and interventions to increase access to effective HIV prevention methods such as PrEP are urgently needed in Latin America.

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Keywords: HIV incidence rate; HIV seroincidence; HIV recency; Sexual and gender minorities; HIV; Latin America; Public health

Research in context

Evidence before this study

HIV in Latin America has overwhelmingly burdened sexual and gender minorities (SGM), such as gay, bisexual, and other men who have sex with men (MSM), and transgender women. The scale-up of pre-exposure prophylaxis (PrEP) has been slower in this region compared to Australia, Europe or the United States, but concrete efforts are starting to shift this trend. Documenting HIV incidence among these communities at different stages of the PrEP implementation process is key to informing resource allocation needs and program evaluations. We searched PubMed using the terms ("HIV incidence" OR "HIV recency" OR "HIV seroincidence") AND ("Brazil" OR "Peru" OR "Latin America") AND ("men who have sex with men" OR "MSM" OR "transgender women" OR "TGW" OR "sexual and gender minorities") on 20 April 2023 with no restriction of publication date or language, in addition to reviewing reference lists of relevant articles. We reviewed studies reporting HIV incidence or seroincidence among sexual and gender minorities in Latin America, focusing on Brazil and Peru.
We found 17 studies, four of them during PrEP clinical trials or implementation studies (iPrEX, PrEP Brasil, ImPrEP and HPTN083). Thirteen studies were conducted in Brazil (N = 5) and Peru (N = 8); only two of them after 2017 (both in Brazil), when PrEP had been incorporated in the Brazilian Public Health System. Only one study was conducted in multiple cities in Peru (Lima, Trujillo, and Chiclayo from 2002 to 2005), and no study was conducted in both countries.

Added value of this study

Recent HIV incidence estimates in Latin American countries among populations not under PrEP or PEP are scarce. Such data are of importance to provide information about PrEP effectiveness in real-life settings, allowing the estimation of the number of HIV infections averted in the context of PrEP scale-up. We conducted a large multi-city study in Brazil and Peru among SGM not using PrEP or PEP. We report high levels of HIV prevalence, recent HIV infection and annualized HIV incidence rates among SGM. We identified younger age as factor significantly associated with recent HIV infection in this population. Lastly, assuming the same rate of HIV infection as estimated in the current study by country, our results suggest that PrEP averted HIV infection among 148 (95% CI: 144–152) and 96 (95% CI: 92–100) study participants from the ImPrEP implementation study from Brazil and Peru, respectively.

Implications of all the available evidence

Public health policies and interventions to increase PrEP access in Latin America are urgently needed, especially among young and low income sexual and gender minorities. In Peru, the recent approval of the new combination prevention policy, including PrEP, may change this scenario. Implementation of injectable PrEP as an additional PrEP option may contribute to the reduction of new HIV cases in Latin America.

Introduction

In 2021, 2.2 million people were living with HIV in Latin America, with most new cases among sexual and gender minorities (SGM), such as gay, bisexual and other men who have sex with men (MSM), and transgender women.[1] HIV prevalence for MSM and transgender women in the region was estimated at 13.9% and 25.9%, respectively, with differences among and within countries.[1–3]

Challenges concerning HIV treatment (late antiretroviral therapy [ART] initiation and ART suboptimal adherence) and prevention (limited role of treatment as prevention, given ART challenges, and limited scale-up of preexposure prophylaxis [PrEP]) remain persistent in Latin America.[4] ART is available free-of-charge in both countries on a test and offer basis; in Brazil, oral PrEP has been available with no direct cost to users through the Public Health System (SUS) since December 2017, and is part of a new policy recently approved in Peru. Despite availability of PrEP and ART in Brazil, the number of new HIV cases increased among MSM younger than 30 years from 2015 to 2021.[5]

In addition, HIV self-testing is available in Brazil and Peru, and it is an important tool within the combination prevention package to increase HIV diagnosis.[6] However, awareness and willingness of HIV self-testing are still limited in both countries, being lower among SGM under social vulnerability.[7]

HIV incidence estimation is critical for monitoring the HIV epidemic dynamics, transmission trends and effectiveness of public health prevention interventions. During the iPrEX study (2007–2010) HIV incidence in the placebo arm was 5.0 (95% CI: 2.7–9.2) and 3.5 (95% CI: 2.7–4.6) per 100 person-years for Brazil and Peru, respectively.[8] The ImPrEP Project was the first transnational project in Latin America aiming to generate evidence on the feasibility, acceptability, and cost-effectiveness of PrEP among MSM and transgender women specific to the cultural contexts and health systems in Brazil, Mexico, and Peru.[9] Within ImPrEP, a PrEP implementation study (2018–2021) evaluated same-day initiation of daily oral PrEP among MSM and transgender women from these countries.[10,11] HIV incidence during the study was 0.85 (95% CI: 0.70–1.03) per 100 person-years, lower in Brazil (0.36 [95% CI: 0.24–0.54] per 100 person-years) and higher in Peru (2.62 [95% CI: 2.04–0.54] per 100 person-years).[10] HIV incidence was also higher among transgender women, participants aged 18–24 years, self-identified as Black or *Pardo/Mestizo*, and those with poor adherence to PrEP in both countries.[10]

Studies aiming to estimate HIV incidence among populations not using PrEP or postexposure prophylaxis (PEP) are of pivotal importance considering the increasing use of these prevention measures. A recent review of the Forum for Collaborative Research Recency Assay Working Group recommended the use of HIV recency assays and algorithms to derive a counterfactual incidence estimate in the context of clinical trials for new PrEP technologies.[12] Recent data from Latin America estimating HIV incidence among individuals not using PrEP/PEP is limited.

In this manuscript, we provide results from the ImPrEP seroincidence study, which aimed to identify SGM not using PrEP/PEP with recent HIV infection using recency testing, factors associated with recent HIV infection, and to estimate annualized HIV incidence in 18 large urban centres in Brazil and Peru. We also calculated the number of people with averted HIV infection in Brazil and Peru during the ImPrEP implementation study assuming HIV incidence rates estimated in this study.

Methods

Study design and participants

Cross-sectional study that enrolled a convenience sample of SGM at HIV counselling and testing units, sexually transmitted infections (STI) Clinics, and HIV Prevention Services from the Public Health System in Brazil (6 sites in 6 cities: Brasília, Manaus, Porto Alegre, Rio de Janeiro, Salvador, São Paulo) and Peru (12 sites in 9 cities: Callao, Chimbote, Huacho, Ica, Iquitos, Lima, Piura, Pucallpa, Sullana).

Eligible participants were aged 18+ years, assigned male at birth and who self-identified as gay, bisexual or other men who have sex with men (MSM), transgender women, non-binary, or gender diverse. Exclusion criteria included previous HIV positive result, current use of PrEP, PEP, or ART.

Institutional review boards at Instituto Nacional de Infectologia Evandro Chagas, Fundação Oswaldo Cruz (Rio de Janeiro, Brazil; #CAAE:20012619.9.1001.5262) and Universidad Peruana Cayetano Heredia (Lima, Peru; #104717) approved the study. Ethical approvals were also obtained from the WHO Research Ethics Review Committee ERC and local IRB at each Brazilian site. All study participants provided written informed consent in Portuguese (Brazil) or Spanish (Peru) before enrolment. ImPrEP community advisory board was involved in the development of study protocol and questionnaire. The study was registered at ClinicalTrials.gov, NCT05674682.

Procedures

All potentially eligible individuals who reached study sites requesting HIV testing were invited to participate in the study. After providing written informed consent, eligible participants were tested for HIV, syphilis, hepatitis B and hepatitis C. Following, study counsellors administered a questionnaire (38 questions) about demographics, HIV testing history, HIV prevention technologies, sexual behaviour, and substance use. Study counsellors provided HIV and sexually transmitted infection prevention pre-/post-test counselling, condoms, and lubricants.

HIV testing was done using a fourth-generation rapid test Alere Determine HIV-1/2 Ag/Ab Combo (Abbott, Chiba, Japan). A reactive result was confirmed using a second rapid test from a different manufacturer: in Brazil we used ABON HIV1/2/O Tri-line (Abon Biopharm, Hangzhou, China) in accordance with the Brazilian Ministry of Health algorithm; in Peru we used HIV Ag/Ab 4ta Gen. rapid Test (CTK Biotech, Poway, CA, USA) or SD Bioline HIV-1/2 3.0 (Abbott, Yongin, South Korea) in accordance with Peruvian Ministry of Health algorithm. For participants deemed HIV-positive, staff collected samples for HIV viral load (Brazil: Abbott RealTime HIV-1 m2000, Abbott, Wiesbaden, Germany; Peru: HIV Real-TM Quant DX-RUO, Sacace Biotechnologies, Como, Italy), CD4 cells count (Brazil: BD Multitest CD3/CD8/CD45/CD4; BD Biosciences, Crystal Lake, NJ, USA; Peru: Alere Pima™ Analyser and Pima™ CD4 Cartridges, Abbott, Wiesbaden, Germany) and dried blood spots (DBS) for recency and resistance testing using a WhatmanTM903 Protein saver Card (Maxim Biomedical, Rockville, MD, USA). All DBS specimens were allowed to air dry and then were stored at −80 °C.

Syphilis testing was performed using a rapid *Treponema pallidum* (TP) test and positive results were confirmed using nontreponemal tests (venereal disease research laboratory [VDRL] in Brazil; rapid plasma reagin [RPR] in Peru). Active/recent syphilis was defined as titers ≥1:8 and a positive TP micro-hemagglutination assay (MHA-TP). Hepatitis B and hepatitis C were assessed using HBsAg and anti-hepatitis C rapid tests, respectively (only Brazil).

During the study, participants diagnosed with HIV were referred to initiate ART according to the country's standard of care. STI treatment was provided at all study sites according to the country's standard of care. Individuals with negative hepatitis B test and reporting no previous vaccination were referred for vaccination. We offered PrEP to all individuals with HIV negative result.

Gender was stratified into cisgender man, transgender woman, and non-binary or gender diverse. Age was described as median and interquartile range (IQR), and in categorical ranges (18–24, 25–30, and >30 years). The rational for age stratification is based on the increase of new HIV cases among SGM aged 18–30 years in Latin America.[2,5,10] We categorised self-reported race or ethnicity as Asian, Black, Indigenous, *Pardo* or *Mestizo* (mix-race), and White. Education was stratified based on the highest completed degree in primary, secondary, and post-secondary. We calculated income per capita in number of minimum wages by dividing the family monthly income by the number of individuals living on this income. In 2022, the minimum wage per month was BRL 1212 (USD 230) in Brazil and 930 soles (USD 250) in Peru.

History of previous HIV testing was stratified into within the last 3 months, >3–6 months, >6–12 months, >12 months and never. We collected the main reason for attending the HIV testing service and for never testing for HIV before from a pre-defined list. We assessed awareness of PrEP, PEP and HIV self-testing with the question: "Have you ever heard of … ?" (yes/no). Willingness to use HIV self-testing was assessed with the question: "Would you use HIV self-testing if available at no cost?" (yes/no). Individuals were asked if they had used PrEP and PEP in the past 12 months.

HIV perceived risk was assessed with the question: "Based on your sexual behaviour, what is your risk of getting HIV in the next 12 months?" with 6-item Likert response options, categorised into low ("None" or "Low"), moderate, high ("High", "I am certain that I will acquire HIV infection" and "I think I am already living with HIV"). Sexual behaviour referred to the previous 6 months and was assessed with questions related to number of sex partners (0, 1–5, 6–10 and >10), condomless sex (no/yes), condomless receptive anal sex (yes/no) 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 2-h period in the previous three months?" (yes/no). Substance use was defined as use of cocaine, crack, marijuana, club drugs (e.g. ketamine, ecstasy, etc.), poppers or other inhalants within the previous three months. Participants were asked about STI symptoms or diagnoses within the previous 6 months (yes/no).

Outcome

Our primary outcome was recent HIV infection, identified using the Maxim HIV-1 LAg-Avidity EIA assay as part of a recent infection testing algorithm (RITA). All DBS specimens were initially run singularly on the LAg assay, and those with a normalized optical density (ODn) ≤2.0 were re-tested in triplicate for confirmation; the result was the median of the three ODn values. Samples with ODn values ≤1.5 were preliminarily classified as recent infections (https://maximbio.com). As laboratory assays can overestimate HIV incidence, classifying some long-standing infections as recent infections,[13] other biological markers were included in the multi-assay algorithm.[14] The RITA algorithm includes viral load (HIV viral load < 400 copies/mL), CD4 count < 200 cells/mm^3, the presence or history of an AIDS-defining illness, and prior or current use of ART to exclude long-standing HIV infection from those classified as recent. We assumed a mean duration of recent infection of 214 days (95% confidence interval [95% CI] 193–237 days) based on the Consortium for the Evaluation and Performance of HIV Incidence Assays (CEPHIA) evaluation panel.[15] The false recency rate (FRR) was calculated as the number of long-standing infections (defined as those with an interval between sample collection and a positive HIV test greater than the cut-off time *T*, set in this analysis as one year) preliminarily classified as recent by LAg divided by the number of long-standing infections.[16] We assumed FRR of 0.0% since we performed HIV testing and DBS collection on the same day. We performed sensitivity analyses to evaluate the impact of the FRR parameter on the estimated HIV incidence using three ranges of FRR: low (FRR = 0.5%), moderate (FRR = 1.0%) and high (FRR = 2.0%).

Statistical analyses

Characteristics of all study participants were provided overall and per country, and comparisons were performed using chi-square test, Fisher's exact test and Ranksum test, when applicable.

Annualised HIV incidence rate calculation overall and per country followed the updated UNAIDS/WHO Using Recency Assays for HIV Surveillance 2022 Technical Guidance, including an incidence estimator tool.[16] Estimated incidence 95% CI was calculated using a delta method variance approximation with this estimator, implemented in the "inctools" R package.[17] We provided annualized HIV incidence overall and according to country, age, gender (cisgender men and transgender women), race (White, *Pardo/Mestizo* and Black), education, and income per capita. All estimates were given in % per annum. Characteristics of participants according to HIV status (HIV negative, long-standing HIV infection, and recent HIV infection) were provided per country, and comparisons were performed using chi-square test.

Multivariable logistic regression models per country were used to estimate factors associated with recent HIV infection. We used a subset of the original dataset that excluded participants with long-standing HIV infection. We compared participants with recent HIV infection with those with HIV negative status to explore factors associated with recent HIV infection among those at risk of infection. We included age, gender, race, education, and income per capita in final multivariable models regardless of p-value in bivariate analyses, as HIV incidence was associated with these variables during the ImPrEP implementation study.[10]

Lastly, we used a previously published methodological approach[18] to estimate the number of people with averted HIV infection during the ImPrEP implementation study.[10] We calculated the number of people with averted HIV infection per country considering the HIV incidence estimated in the current study and the number of person-years followed during the ImPrEP implementation study.

The minimum sample size was calculated to estimate an incidence of 3% with a bilateral error of 0.6%, corresponding to approximately 3100 SGM in each country.

We performed all analyses using R software, version 4.2.2.

Role of the funding source

The funding body (Unitaid/WHO) had no role in study design, data collection, data analysis, or data interpretation. The corresponding author had full access to all the study data and had final responsibility for the decision to submit for publication.

Results

From 31-Jan-2021 to 19-May-2022, 7362 individuals were invited to participate in the study; 204 refused and 259 were excluded due to: previous HIV positive test: 202; cisgender men who have sex only with cisgender women: 19; female sex at birth: 9; on PrEP: 13; on PEP: 7; aged <18 years: 4; participated previously in the study: 4; did not provide sample for testing: 1. Of 6899 participants enrolled (Brazil: 4586, Peru: 2313); 5946 (86.2%) were cisgender men, 751 (10.9%) transgender women and 202 (2.9%) nonbinary or gender diverse individuals (Table 1). Median age was 27 years (IQR: 23–34); 4439 (64.4%) aged 18–30 years and 3577 (51.8%) self-defined as *Pardo/Mestizo* (Table 1). The majority had secondary education or less (4934; 71.5%) and 2919 (43.1%) had income per capita lower than one minimum wage per month. Compared to Peru, participants from Brazil were younger and more frequently reported as cisgender men, higher education, and higher income.

The main reason for attending the clinic for HIV testing was "I get tested regularly, regardless of thinking I am at risk or not" (2437; 35.3%) (Supplementary Table S1). A total of 839 (12.2%) reported no prior HIV testing, higher in Peru (N = 338/2313; 14.6%) compared to Brazil (N = 501/4586; 10.9%), and the main reason for never testing was "I was afraid of a positive result (206; 24.6%) (Supplementary Table S2). Only 1018 (14.8%) reported high HIV perceived risk, although 2436 (35.3%) reported 6 or more sex-partners, 5402 (78.3%) condomless sex, 3809 (55.2%) condomless receptive anal sex, 1365 (19.8%) STI symptoms or diagnoses and 931 (13.5%) transactional sex. Most reported binge drinking (3964; 57.5%) and 1842 (26.7%) any substance use (Table 1). Awareness of HIV prevention technologies and willingness to use HIV self-testing were higher in Brazil than Peru (Supplementary Table S3). For Brazil, prevalence of hepatitis B and hepatitis C were 0.3% (N = 12/4031) and 0.3% (N = 11/4080), respectively. Prevalence of active syphilis was 13.0% (N = 534/4097) in Brazil and 13.2% (N = 159/1206) in Peru.

Among all enrolled participants, 88.6% (N = 6115/6899) had a negative rapid test. HIV prevalence was 11.4% (N = 784/6899); 8.0% (N = 367/4586) in Brazil and 18.0% (N = 417/2313) in Peru. Out of 784 individuals who tested positive for HIV, 98.6% (N = 773/784) had stored DBS available and were evaluated using the LAg avidity test (Fig. 1). Of these, 24.1% (N = 186/773) had a LAg result consistent with a recent infection. After applying the RITA algorithm, 26.3% (N = 49/186) of individuals were reclassified as long-standing infected: 21 due to CD4 count < 200 cells/mm^3, 20 due to viral load < 400 copies/mL, and 8 due to CD4 and/or viral load not available. None of the samples were excluded due to ART exposure. Finally, after the reclassification process, we identified 636 individuals with long-standing HIV infection (N = 636/773; 82.3%) and 137 individuals with recent HIV infection (N = 137/773; 17.7%) (Fig. 1), 64 individuals in Brazil (Supplementary Figure S1) and 73 individuals in Peru (Supplementary Figure S2).

The overall HIV annualized incidence rate estimate was 3.88% (95% CI: 2.86–4.87); 2.62% (95% CI: 1.78–3.43) in Brazil and 6.69% (95% CI: 4.62–8.69) in Peru (Table 2). Disaggregating by gender, HIV annualized incidence rates were 3.99% (95% CI: 2.91–5.03) and 3.91% (95% CI: 1.76–6.03) among cisgender men

	Total N = 6899	Brazil N = 4586	Peru N = 2313	p-value
Age (years)				
Median (IQR)	27 (23–34)	27 (23–33)	28 (23–36)	<0.0001
18–24	2227 (32.3)	1514 (33.0)	713 (30.8)	<0.0001
25–30	2212 (32.1)	1562 (34.1)	650 (28.1)	
>30	2460 (35.6)	1510 (32.9)	950 (41.1)	
Gender				<0.0001
Cisgender men	5946 (86.2)	4015 (87.5)	1931 (83.5)	
Transgender women	751 (10.9)	470 (10.3)	281 (12.1)	
Non-binary or gender diverse	202 (2.9)	101 (2.2)	101 (4.4)	
Race				<0.0001
Asian	60 (0.9)	46 (1.0)	14 (0.6)	
Black	1282 (18.6)	1245 (27.1)	37 (1.6)	
Indigenous	69 (1.0)	32 (0.7)	37 (1.6)	
Pardo or *Mestizo* (mixed-race)	3577 (51.8)	1618 (35.3)	1959 (84.7)	
White	1911 (27.7)	1645 (35.9)	266 (11.5)	
Education (complete)				<0.0001
Primary	688 (10.0)	475 (10.4)	213 (9.2)	
Secondary	4246 (61.5)	2504 (54.6)	1742 (75.3)	
Post-secondary	1965 (28.5)	1607 (35.0)	358 (15.5)	
Income per capita[a]				<0.0001
<0.5	1047 (15.5)	454 (10.1)	593 (26.1)	
0.5–<1	1872 (27.6)	983 (21.8)	889 (39.1)	
1–<2	2417 (35.7)	1707 (37.9)	710 (31.2)	
≥2	1439 (21.2)	1357 (30.1)	82 (3.6)	
HIV testing				<0.0001
Never	839 (12.2)	501 (10.9)	338 (14.6)	
Last 3 months	1095 (15.9)	963 (21.0)	132 (5.7)	
>3–6 months	1435 (20.8)	915 (20.0)	520 (22.5)	
>6–12 months	1426 (20.7)	916 (20.0)	510 (22.0)	
>12 months	2104 (30.5)	1291 (28.2)	813 (35.1)	
Previous PEP use[b]	621 (9.0)	607 (13.2)	14 (0.6)	<0.0001
Previous PrEP use[b]	353 (5.1)	210 (4.6)	143 (6.2)	0.0040
HIV perceived risk (next 12 months)				<0.0001
Low	3701 (53.6)	2774 (60.5)	927 (40.1)	
Moderate	2180 (31.6)	1270 (27.7)	910 (39.3)	
High	1018 (14.8)	542 (11.8)	476 (20.6)	
Number of sex-partners[c]				<0.0001
0	198 (2.9)	127 (2.8)	71 (3.1)	
1–5	4265 (61.8)	2799 (61.0)	1466 (63.4)	
6–10	1179 (17.1)	764 (16.7)	415 (17.9)	
>10	1257 (18.2)	896 (19.5)	361 (15.6)	
Condomless sex[c]	5402 (78.3)	3553 (77.5)	1849 (79.9)	0.019
Condomless receptive anal sex[c]	3809 (55.2)	2619 (57.1)	1190 (51.4)	<0.0001
Transactional sex[c]	931 (13.5)	397 (8.7)	534 (23.1)	<0.0001
Substance use[c]	1842 (26.7)	1629 (35.5)	213 (9.2)	<0.0001
Binge drinking[c]	3964 (57.5)	2776 (60.5)	1188 (51.4)	<0.0001
Sexually transmitted infections symptoms or diagnoses[c]	1365 (19.8)	775 (16.9)	591 (25.6)	<0.0001

IQR: interquartile range. [a]Number of minimum wage (family per month)/number of persons living with this income. Minimum wage per month in Brazil in 2022 was R$1212 (USD 230) and in Peru the minimum wage was 930 soles (USD 250). [b]Used in the past 12 months but not currently using [c]Past 6 months.

Table 1: **Characteristics of individuals screened for HIV infection in Brazil and Peru in 2021–2022.**

and transgender women, respectively. Participants aged 18–24 and 25–30 years had a higher incidence rate (5.32% [95% CI: 3.58–7.01] and 4.32% [95% CI: 2.82–5.79], respectively) compared to those >30 years (2.21% [95% CI: 1.26–3.12]). Participants with lower income had higher incidence rates (<0.5 minimum

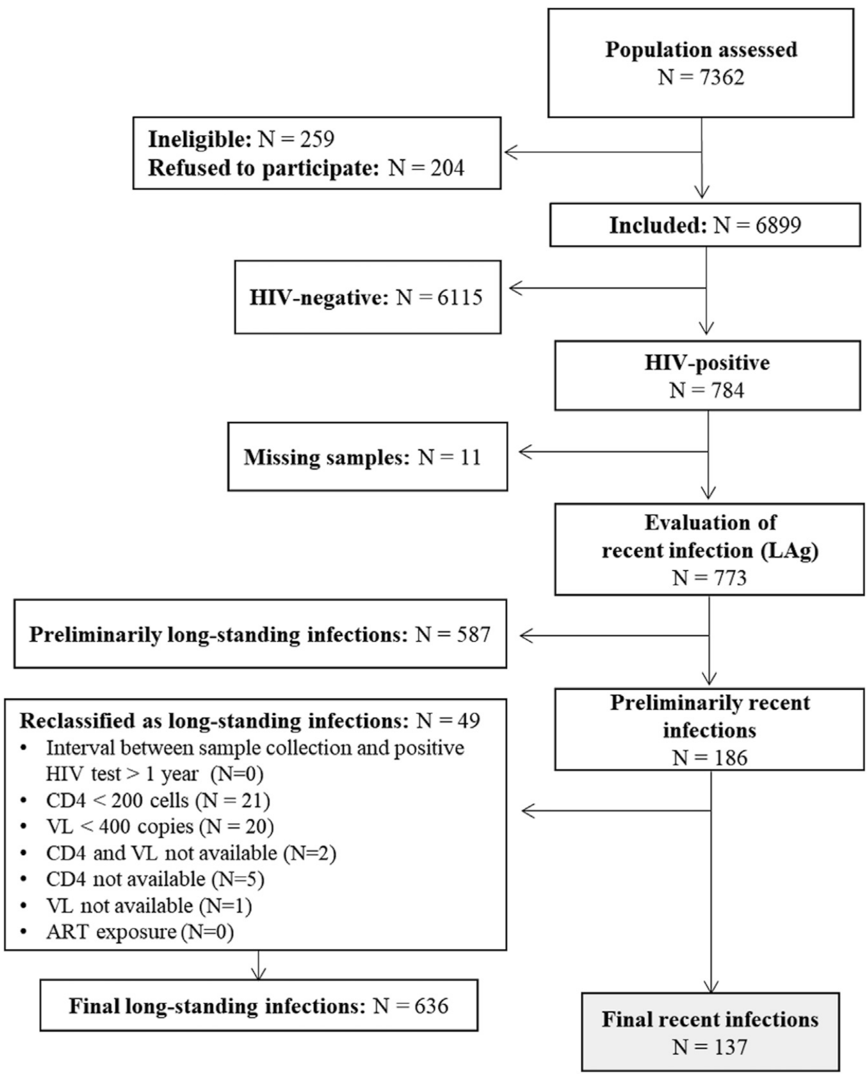

Fig. 1: Flow-chart for HIV recent infection screening among SGM from Brazil and Peru.

wages: 6.28% [95% CI: 3.69–8.80] than those with higher income (>2 minimum wages: 1.89% [95% CI: 0.85–2.91]). In Brazil, participants with primary education had higher incidence rates (3.42% [95% CI: 0.91–5.86]) than those with post-secondary education (1.78% [95% CI: 0.83–2.72]). In Peru, participants with primary education had lower incidence rate (3.92% [95% CI: 0.01–7.87]) than those with post-secondary education (11.88% [95% CI: 5.85–17.84]). Annualized incidence rates per city are shown in Supplementary Table S4. Of note, when including in the analysis the individuals who reported previous HIV positive test excluded at study entry (N = 202), 28 individuals with recent HIV infection would be additionally considered for overall HIV annualized incidence estimation [4.64% (95% CI: 3.47–5.78)].

In sensitivity analyses, using low (FRR = 0.5%), moderate (FRR = 1.0%) and high (FRR = 2.0%) FRR values, the overall HIV annualized incidence rate estimates were 3.81% (95% CI: 2.80–4.80), 3.74% (95% CI: 2.73–4.72) and 3.59% (95% CI: 2.58–4.55), respectively. In Brazil, 2.57% (95% CI: 1.74–3.39), 2.53% (95% CI: 1.69–3.33) and 2.43% (95% CI: 1.58–3.22), and in Peru, 6.57% (95% CI: 4.52–8.58), 6.45% (95% CI: 4.39–8.44) and 6.19% (95% CI: 4.13–8.16).

Sociodemographic and behavioural characteristics differed according to HIV status in Brazil and Peru (Table 3). The multivariable model showed that the odds of recent HIV infection was higher among participants aged 18–24 years in Brazil and Peru [aOR: 2.85 (95% CI: 1.38–6.46; aOR: 2.45 (95% CI: 1.34–4.63)] and 25–30 years in Brazil only [aOR: 2.52 (95% CI: 1.18–5.91)]

	Overall		Brazil		Peru	
	Recent HIV infection n (%)	HIV incidence % (95% CI)	Recent HIV infection n (%)	HIV incidence % (95% CI)	Recent HIV infection n (%)	HIV incidence % (95% CI)
Overall	137 (2.0)	3.88 (2.86–4.87)	64 (1.4)	2.62 (1.78–3.43)	73 (3.1)	6.69 (4.62–8.69)
Age (years)						
18–24	60 (2.7)	5.32 (3.58–7.01)	28 (1.8)	3.48 (1.99–4.94)	32 (4.5)	9.77 (5.77–13.69)
25–30	49 (2.2)	4.32 (2.82–5.79)	27 (1.7)	3.26 (1.85–4.64)	22 (3.4)	7.28 (3.83–10.66)
>30	28 (1.1)	2.21 (1.26–3.12)	9 (0.6)	1.11 (0.34–1.86)	19 (2.0)	4.13 (1.90–5.85)
Gender[a]						
Cisgender men	121 (2.0)	3.99 (2.91–5.03)	57 (1.4)	2.66 (1.78–3.52)	64 (3.3)	7.11 (4.82–9.33)
Transgender women	15 (2.0)	3.91 (1.76–6.03)	7 (1.5)	2.85 (0.64–5.04)	8 (2.8)	5.76 (1.54–9.96)
Race[b]						
Black	16 (1.2)	2.39 (1.11–3.64)	16 (1.3)	2.45 (1.13–3.73)	NA	NA
Pardo or *Mestizo* (mix-race)	84 (2.3)	4.69 (3.30–6.04)	22 (1.4)	2.53 (1.34–3.69)	62 (3.2)	6.69 (4.52–8.79)
White	34 (1.8)	3.40 (2.06–4.71)	25 (1.5)	2.89 (1.61–4.13)	9 (3.4)	7.28 (2.19–12.31)
Education (complete)						
Primary	12 (1.7)	3.57 (1.39–5.69)	8 (1.7)	3.42 (0.91–5.86)	4 (1.9)	3.92 (0.01–7.87)
Secondary	90 (2.1)	4.20 (2.98–5.39)	40 (1.6)	3.04 (1.91–4.15)	50 (2.9)	6.04 (3.94–8.07)
Post-secondary	35 (1.8)	3.30 (2.01–4.58)	16 (1.0)	1.78 (0.83–2.72	19 (5.3)	11.88 (5.85–17.84)
Income per capita[c]						
<0.5	31 (3.0)	6.28 (3.69–8.80)	11 (2.4)	4.89 (1.80–7.94)	20 (3.4)	7.43 (3.78)
0.5–<1	47 (2.5)	5.03 (3.25–6.76)	15 (1.5)	2.91 (1.31–4.49)	32 (3.6)	7.60 (4.50–10.63)
1–<2	42 (1.7)	3.36 (2.12–4.46)	24 (1.4)	2.65 (1.45–3.82)	18 (2.5)	5.25 (2.56–7.89)
≥2	15 (1.0)	1.89 (0.85–2.91)	14 (1.0)	1.85 (0.81–2.89)	1 (1.2)	2.51 (0.01–7.46)

CI: confidence interval, NA: not applicable [a]Non-binary or gender diverse individuals not included due to low sample size [b]Asian and Indigenous not included due to low sample size [c]Number of minimum wages (overall income of the family unit per month)/number of persons living with this income. Minimum wage per month in Brazil in 2022 was R$1212 (USD 230) and in Peru the minimum wage was 930 soles (USD250). All HIV incidence estimates are in % per annum.

Table 2: **HIV incidence according to age, gender, race, education, and income per capita in Brazil and Peru (2021–2022).**

compared to those aged 30+ years (Table 4). In Peru, the odds of recent HIV infection were lower among those with secondary education [aOR: 0.51 (95% CI: 0.29–0.95)] compared to those with post-secondary education.

As previously reported, the ImPrEP implementation study followed MSM and transgender women on PrEP for 6577.81 and 2365.36 person-years in Brazil and Peru, respectively.[10] Assuming these individuals had experienced the same rate of infection as estimated in the current study by country, we project that 172 (95% CI: 168–176) and 158 (95% CI: 152–164) infections would have occurred over the person-years of follow-up in Brazil and Peru, respectively. Given that 24 and 62 individuals living with HIV were identified in Brazil and Peru, respectively, our results suggest that PrEP averted HIV infection among 148 (95% CI: 144–152) and 96 (95% CI: 92–100) study participants from the ImPrEP implementation study from Brazil and Peru, respectively.

Discussion

This was a large, binational, and pioneer HIV seroincidence study among SGM not using PrEP or PEP seeking HIV testing and STI services in Latin America. We observed high levels of HIV prevalence, recent HIV infection and HIV incidence rate. Estimated incidence rates may serve as a reference to evaluate the number of people with averted HIV infection by HIV prevention programs in the context of PrEP scale-up in large urban centres of Latin America where the HIV epidemic resembles that of Brazil and Peru. Our results underscore the disproportional impact of the HIV epidemic among MSM and transgender women, in agreement with previous studies from Brazil from 2017 to 2020 (2.7%–9.2%)[19–22] and Peru from 2009 to 2015 (3.6%–6.0%).[23–25] We showed higher HIV incidence among young SGM in both countries, in accordance with incidence rates estimated during the iPrEX study[8] and the ImPrEP implementation study.[10] In addition, a high number of recent HIV infection among individuals with a previous HIV positive test (13.9%; N = 28/202) may be explained by HIV confirmatory test seeking, as most of participating sites are referral centres for HIV testing and diagnosis.

Our study estimated a higher HIV incidence rate among SGM from Peru than from Brazil. Compared to the placebo arm of the iPrEX study conducted between 2007 and 2010, incidence rates estimated in this study decreased in Brazil and increased in Peru.[8] In Brazil, this could be a result of the scale-up of the test-and-treat approach, adoption of dolutegravir as first-line ART and

	Brazil				Peru			
	HIV negative	Long-standing HIV infection	Recent HIV Infection	p-value	HIV negative	Long-standing HIV infection	Recent HIV infection	p-value
N (%)	4219 (92.0)	303 (6.6)	64 (1.4)	NA	1896 (82.0)	344 (14.9)	73 (3.1)	NA
Age (years)								
Median (IQR)	27 (23–33)	28 (23–34)	25.5 (22–29)	0.022	28 (23–37)	28 (23–34)	25 (22–31)	0.0010
18–24	1385 (32.8)	101 (33.3)	28 (43.7)	0.020	572 (30.2)	109 (31.7)	32 (43.8)	0.015
25–30	1440 (34.1)	95 (31.4)	27 (42.2)		520 (27.4)	108 (31.4)	22 (30.1)	
>30	1394 (33.0)	107 (35.3)	9 (14.1)		804 (42.4)	127 (36.9)	19 (26.0)	
Gender				0.14				0.054
Cisgender men	3689 (87.4)	269 (88.8)	57 (89.1)		1563 (82.4)	304 (88.4)	64 (87.7)	
Transgender women	430 (10.2)	33 (10.9)	7 (10.9)		243 (12.8)	30 (8.7)	8 (11.0)	
Non-binary or gender diverse	100 (2.4)	1 (0.3)	0 (0)		90 (4.7)	10 (2.9)	1 (1.4)	
Race				<0.0001				0.36
White	1547 (36.7)	73 (24.1)	25 (39.1)		211 (11.1)	46 (13.4)	9 (12.3)	
Black	1115 (26.4)	114 (37.6)	16 (25.0)		27 (1.4)	10 (2.9)	0 (0)	
Pardo or *Mestizo* (mix-race)	1485 (35.2)	111 (36.6)	22 (34.4)		1618 (85.3)	279 (81.1)	62 (84.9)	
Asian	42 (1.0)	4 (1.3)	0 (0)		12 (0.6)	2 (0.6)	0 (0)	
Indigenous	30 (0.7)	2 (0.3)	1 (1.6)		28 (1.5)	7 (2.0)	2 (2.7)	
Education (complete)				<0.0001				0.016
Primary	407 (9.6)	60 (19.8)	8 (12.5)		179 (9.4)	30 (8.7)	4 (5.5)	
Secondary	2277 (54.0)	187 (61.7)	40 (62.5)		1444 (76.2)	248 (72.1)	50 (68.5)	
Post-secondary	1535 (36.4)	56 (18.5)	16 (25.0)		273 (14.4)	66 (19.2)	19 (26.0)	
Income per capita[a]				<0.0001				0.63
<0.5	399 (9.6)	44 (14.7)	11 (17.2)		476 (25.6)	97 (28.5)	20 (28.2)	
0.5–<1	889 (21.5)	79 (26.3)	15 (23.4)		734 (39.4)	123 (36.2)	32 (45.1)	
1–<2	1560 (37.7)	123 (41.0)	24 (37.5)		585 (31.4)	107 (31.5)	18 (25.4)	
≥2	1289 (31.2)	54 (18.0)	14 (21.9)		68 (3.7)	13 (3.8)	1 (1.4)	
HIV testing				<0.0001				<0.0001
Never	421 (10.0)	75 (24.8)	5 (7.8)		235 (12.4)	95 (27.6)	8 (11.0)	
Last 3 months	937 (22.2)	15 (5.0)	11 (17.2)		115 (6.1)	12 (3.5)	5 (6.8)	
>3–6 months	875 (20.7)	28 (9.2)	12 (18.8)		476 (25.1)	31 (9.0)	13 (17.6)	
>6–12 months	853 (20.2)	49 (16.2)	14 (21.9)		441 (23.3)	49 (14.2)	20 (27.4)	
>12 months	1133 (26.9)	136 (44.9)	22 (34.4)		629 (33.2)	157 (45.6)	27 (37.0)	
HIV perceived risk (next 12 months)				<0.0001				<0.0001
Low	2634 (62.4)	118 (38.9)	22 (34.4)		824 (43.5)	79 (23.0)	24 (32.9)	
Moderate	1163 (27.6)	88 (29.0)	19 (29.7)		755 (39.8)	133 (38.7)	22 (30.1)	
High	422 (10.0)	97 (32.0)	23 (35.9)		317 (16.7)	132 (38.4)	27 (37.0)	
Number of sex-partners[b]				0.10				0.094
≤5 partners	2685 (63.6)	206 (68.0)	35 (54.7)		1241 (65.5)	245 (71.2)	51 (69.9)	
>5 partners	1534 (36.4)	97 (32.0)	29 (45.3)		655 (34.5)	99 (28.8)	22 (30.1)	
Condomless sex[b]				<0.0001				<0.0001
No	992 (23.5)	35 (11.6)	6 (9.4)		420 (22.2)	39 (11.3)	5 (6.8)	
Yes	3227 (76.5)	268 (88.4)	58 (90.6)		1476 (77.8)	305 (88.7)	68 (93.2)	
Condomless receptive anal sex[b]				<0.0001				<0.0001
No	1881 (44.6)	74 (24.4)	12 (18.8)		992 (52.3)	107 (31.1)	24 (32.9)	
Yes	2338 (55.4)	229 (75.6)	52 (81.2)		904 (47.7)	237 (68.9)	49 (67.1)	
Translactional sex[b]				0.012				0.0060
No	3869 (91.7)	265 (87.5)	55 (85.9)		1434 (75.6)	262 (82.0)	63 (86.3)	
Yes	350 (8.3)	38 (12.5)	9 (14.1)		462 (24.4)	62 (18.0)	10 (13.7)	
Substance use[b]				0.51				0.10
No	2722 (64.5)	198 (65.3)	37 (57.8)		1722 (90.8)	307 (89.2)	71 (97.3)	
Yes	1497 (35.5)	105 (34.7)	27 (42.2)		174 (9.2)	37 (10.8)	2 (2.7)	
Binge drinking[b]				0.21				0.66
No	1680 (39.8)	105 (34.7)	25 (39.1)		928 (48.9)	160 (46.5)	37 (50.7)	
Yes	2539 (60.2)	198 (65.3)	39 (60.9)		968 (51.1)	184 (53.5)	36 (49.3)	

(Table 3 continues on next page)

	Brazil				Peru			
	HIV negative	Long-standing HIV infection	Recent HIV Infection	p-value	HIV negative	Long-standing HIV infection	Recent HIV infection	p-value
(Continued from previous page)								
Sexually transmitted infections symptoms or diagnoses[b]				0.15				0.015
No	3517 (83.4)	240 (79.2)	55 (85.9)		1434 (75.6)	235 (68.3)	53 (72.6)	
Yes	702 (16.6)	63 (20.8)	9 (14.1)		462 (24.4)	109 (31.7)	20 (27.4)	

[a]Number of minimum wages (overall income of the family unit per month)/number of persons living on this income. Minimum wage per month in Brazil in 2022 was R$1212 (USD 230) and in Peru the minimum wage was 930 soles (USD250). [b]Past 6 months.

Table 3: **Characteristics of participants according to HIV status in Brazil and Peru (2021–2022).**

free PrEP availability as a public health policy since 2017. In Peru, this could be explained by the high prevalence of transactional sex in this study, no PrEP program implemented in a context of very low condom use, plus the late introduction of dolutegravir, a significantly more tolerable first-line regimen. Additionally, the COVID-19 pandemic restrictive measures have exceedingly affected SGM, including access to HIV prevention and treatment services.[26] This was more pronounced in Peru due to restrictive lockout measures, while in Brazil telehealth procedures including HIV self-testing distribution were made available, facilitating PrEP persistance.[27]

For both Brazil and Peru, the odds of recent HIV infection as well as HIV incidence rates in this study were higher among young participants (18–30 years) compared to older peers. In Brazil, almost 24% of new HIV cases occur among individuals aged 15–24 years,[5] while in Peru this proportion reached almost 50% among those aged 18–29 years,[28] reinforcing the need of targeted public policies prioritizing this population in both countries. As previously reported, young SGM in both countries have shown lower PrEP awareness, willingness, uptake, and adherence compared to older SGM.[9,10,29] Innovative approaches to recruit and retain young SGM in PrEP services should be urgently implemented in these settings, such as WhatsApp reminder messages, peer-led digital intervention, mHealth component for PrEP education and community engagement in the development of digital

	Brazil				Peru			
	OR (95% CI)	p-value	aOR (95% CI)	p-value	OR (95% CI)	p-value	aOR (95% CI)	p-value
Age (years)								
18–24	3.12 (1.52–7.04)	0.0033	2.85 (1.38–6.46)	0.0072	2.37 (1.33–4.35)	0.0040	2.45 (1.34–4.63)	0.0045
25–30	2.97 (1.45–6.71)	0.0049	2.52 (1.18–5.91)	0.023	1.64 (0.86–3.17)	0.13	1.68 (0.86–3.30)	0.13
>30	Ref.		Ref.		Ref.		Ref.	
Gender								
Cisgender men	Ref.		Ref.		Ref.		Ref.	
Transgender women	1.07 (0.44–2.22)	0.86	0.89 (0.35–1.95)	0.79	0.87 (0.38–1.73)	0.71	1.21 (0.52–2.53)	0.63
Race								
Black	0.89 (0.47–1.67)	0.73	0.75 (0.38–1.41)	0.38	NA		NA	
Pardo or *Mestizo*	0.91 (0.51–1.63)	0.76	0.84 (0.46–1.50)	0.56	0.92 (0.47–2.01)	0.82	1.06 (0.54–2.35)	0.87
White	Ref.		Ref.		Ref.		Ref.	
Education (complete)								
Primary	1.87 (0.75–4.28)	0.15	1.71 (0.62–4.36)	0.27	0.40 (0.11–1.10)	0.11	0.40 (0.11–1.14)	0.11
Secondary	1.67 (0.95–3.08)	0.086	1.37 (0.73–2.65)	0.36	0.53 (0.31–0.96)	0.028	0.51 (0.29–0.95)	0.027
Post-secondary	Ref.		Ref.		Ref.		Ref.	
Income per capita								
<0.5	2.23 (1.08–4.27)	0.021	1.86 (0.87–3.68)	0.087	1.66 (0.87–3.20)	0.13	1.63 (0.84–3.17)	0.15
0.5–<1	1.30 (0.69–2.34)	0.39	1.10 (0.58–2.02)	0.76	1.54 (0.86–2.84)	0.15	1.63 (0.90–3.03)	0.11
≥1	Ref.		Ref.		Ref.		Ref.	

Results from the multivariable logistic model using age-groups, gender, race, education, and income per capita as independent variables. The Odds-Ratio (OR) resulted from the comparison of participants with recent HIV infection with those with HIV negative status.

Table 4: **Factors associated with recent HIV infection compared with being HIV negative in Brazil and Peru (2021–2022).**

campaigns.[30,31] Long-acting PrEP is highly accepted among SGM from Brazil and Peru,[32,33] and could be an option for the youngest. Additionally, interventions to increase HIV self-testing use among young SGM could increase the detection of new HIV cases among this population.

We found a higher HIV incidence rate among participants with lower income in both countries, and of lower education in Brazil. Social determinants of health, such as race, income, and education, contribute to widen health inequalities.[34] SGM are exposed to homophobia and transphobia, being further impacted by intersectional discrimination related to racism and classism. Higher HIV incidence and worse PrEP outcomes were observed among participants with lower education from the ImPrEP implementation study.[10] We found a higher HIV incidence rate among individuals with post-secondary education compared to those with lower education in Peru. As discussed by Blair et al., in Peru, individuals with higher education may engage in sexual networks with higher number of individuals with non-diagnosed HIV.[35]

A major strength of this study was the inclusion of multiple sites in large urban cities, allowing estimation of HIV incidence at a country level. Another strength was the use of LAg as part of a RITA algorithm, including appropriated markers to reduce false recency. Our results suggest that our incidence estimates were robust to the assumed FRR value, as evidenced in our sensitivity analyses. Some limitations should be acknowledged. As a cross-sectional survey, conclusions cannot be made regarding the causality of identified associations with recent HIV infection. Self-reported responses may introduce the possibility of recall, response, or social desirability bias. We included a convenience sample of SGM recruited at HIV testing/prevention services. The demographic characteristics of our study population mirrors that of the ImPrEP implementation study population,[10] suggesting that we included SGM that would benefit from PrEP. Lack of official data on SGM from Brazil and Peru hindered comparisons of our sample with the broader population of SGM in these countries. However, respondent-driven sampling (RDS) studies conducted among MSM in Brazil (2016)[36] and transgender women in Peru (2009)[37] included individuals with similar demographic characteristics as our population. For instance, the national RDS-study conducted in Brazil included MSM with similar race distribution (Black or *Pardo*: 64% for ImPrEP seroincidence study vs. 68% for RDS) and education (secondary: 55% for ImPrEP seroincidence study vs. 59% for RDS). With regards to the age composition of the populations, participants from the RDS study were younger than those from the current study (age >25 years: 75% for ImPrEP seroincidence study vs. 42% for RDS). Given that our results indicated that incidence rate of HIV was higher among the younger groups, this difference in age composition could imply that our overall HIV incidence rate might be under-estimated. For Peru, similar age strata (18–24 years: 30% for ImPrEP seroincidence study vs. 28% for RDS) and education (post-secondary: 16% for ImPrEP seroincidence study vs. 17% for RDS) suggest that incidence rates might not be subject to bias. In Peru, the number of participants (N = 2313) did not reach the previously calculated minimum sample size (N = 3100). Lastly, we did not include persons assigned female at birth, precluding the inclusion of transgender men who have sex with men.

In conclusion, high levels of HIV prevalence, recent HIV infection and annualized HIV incidence rates among SGM in Brazil and Peru included in this study highlight the burden of the HIV epidemic among these populations. In Peru, the recent approval of the new combination prevention policy, including PrEP, may change this scenario. Public health policies and interventions to increase PrEP access in Latin America are urgently needed, especially among young SGM.

Contributors
BH, KAK, BG, CLS, CC and VGV conceived and designed the ImPrEP seroincidence study. MD and RIM have accessed and verified the data. TST did the statistical analyses. SLMT performed the recency (LAg) assays. SN and GMC supervised laboratory procedures. TST, SLMT, PML and CLS conceived and supervised the analysis. TST and SLMT drafted the manuscript. BH, KAK, PML, BG, CLS, CC and VGV interpreted the findings. JVG, MB, SV, CB, AB, JBAN, AF, MVGL, DARS, LCP, JVM, HJSF, GPB, CVOT, HTCA, CP and AB were involved in revising the manuscript for important intellectual content. All authors read and approved the final manuscript.

Data sharing statement
A complete deidentified dataset sufficient to reproduce study findings will be made available upon request to the corresponding author, following approval of a concept sheet summarizing the analyses to be done.

Declaration of interests
Nothing to declare.

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Appendix A. Supplementary data
Supplementary data related to this article can be found at https://doi.org/10.1016/j.lana.2023.100642.

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