

Interdisciplinarity in HIV prevention research: the experience of the PrEP1519 study protocol among adolescent MSM and TGW in Brazil

Interdisciplinaridade na pesquisa sobre prevenção do HIV: a experiência do protocolo de estudo PrEP1519 entre HSH adolescentes e mulheres trans no Brasil

Interdisciplinarietà en la investigación de la prevención del VIH: la experiencia del protocolo de estudio PrEP1519 entre adolescentes HSH y TGW en Brasil

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Abstract

At the end of 2017, Brazil adopted HIV pre-exposure prophylaxis (PrEP) as part of a combination prevention strategy for the most at-risk populations. However, Brazil does not have specific guidelines for PrEP use among adolescents aged < 18 years. Therefore, researchers from different health disciplines conducted PrEP1519, the first PrEP demonstration cohort study, ongoing in three Brazilian cities – Salvador, Belo Horizonte, and São Paulo – among adolescent men who have sex with men and transgender women, aged 15-19 years. This study aims to evaluate the effectiveness of PrEP in real-world settings. Quantitative and qualitative methods were integrated to obtain data on PrEP acceptability, uptake, use, and adherence. Moreover, comprehensive services and friendly environments were implemented in the PrEP1519 clinics. This study aims to describe the collaborative efforts of interdisciplinary practices in the development of the PrEP1519 study. The articulation of researchers from different institutions and areas is challenging; but it also allows for a broader outlook on questions regarding the direction of the research, while enriching the decisions needed to be taken during the interactions and negotiations among the different individuals, including the youth team and participants. Furthermore, it reflects on the communication process between cultures and languages considering the trans-epistemic arena of knowledge production about HIV, sexually transmitted infections, PrEP, and other combination prevention strategies for adolescents.

HIV; Pre-Exposure Prophylaxis; Adolescents; Men Who Have Sex With Men; Transgender Women

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Introduction

Pre-exposure prophylaxis (PrEP) is an effective HIV prevention method based on the use of an oral fixed-dose combination of nucleoside analogs, antiretroviral tenofovir disoproxil fumarate (TDF), and emtricitabine (FTC), coformulated in a single pill. The effectiveness of PrEP in preventing HIV has been demonstrated in randomized clinical trials ^{1,2,3,4} and demonstration studies ^{5,6}. In 2012, the U.S. Food and Drug Administration (FDA) approved TDF/FTC for HIV prevention. Likewise, the U.S. Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) have released clinical guidance on the use of PrEP by populations at risk of HIV infection ^{7,8}. Several countries have followed the same path. PrEP was introduced in the Brazilian Unified National Health System (SUS) in the late 2017 for populations at a high risk of infection, namely gay men, men who have sex with men (MSM), transgender individuals, sex workers, and drug users aged ≥ 18 years ⁹.

Recent data from the *HIV/AIDS Epidemiological Bulletin* (from the Brazilian Ministry of Health) ¹⁰ show an increase of 64.9% and 74.8% in AIDS detection rates among young men aged 15-19 years and 20-24 years, respectively, from 2009 to 2019. In 2019, the highest detection rate was 52 cases per 100,000 among people aged 25-29 years, which exceeded the detection rates in men aged 30-34 and 35-39 years, which were higher until 2015. Moreover, an increasing trend from 2000 onward has been observed among adolescents from key populations (AKP) such as MSM and transgender women (TGW) ^{11,12,13}.

Notably, adolescent MSM (AMSM) and adolescent TGW (ATGW) have little access to health services for various reasons, such as fear of discrimination, health provider bias, social “invisibility”, lack of specific health and educational programs, and lack of money for transportation to access health services. These factors, associated with inequalities in social, economic, organizational, and political power ^{14,15,16} and experiences of violence ¹⁷, increase their vulnerability to HIV.

Although PrEP is effective and safe among adolescents and adults at high risk for HIV ¹⁸, early evidence suggests that adolescents face challenges in initiating and continuing PrEP use. Some aspects are still unclear, including those on PrEP awareness and acceptability, strategies for recruitment and enrollment to PrEP services, retention, adherence, concerns about side effects, risk compensation, and HIV- and AIDS-related stigma associated with PrEP use among the youth ^{19,20}.

PrEP1519 was designed based on the epidemiological scenario for AKP described above and the urgent need for PrEP demonstration studies focused on AMSM and ATGW ^{21,22}. Furthermore, this study will produce data on PrEP use to help establish public policies among adolescents aged 15-17 years at higher risks for HIV infection in Brazil ²³. In this study, we aim to describe the collaborative efforts of interdisciplinary practice in the design and implementation of the PrEP1519 study.

Methodology processes

Building ties

Our efforts considered researchers with different scientific backgrounds (public health specialists, clinicians, and social scientists), youth activists, and public managers, in addition to integrating various research techniques. Furthermore, we aimed to implement a coherent and creative interaction of different techniques using quantitative and qualitative approaches in the production of data, aiming to capitalize on the respective strengths of each approach.

We defined PrEP1519 as a demonstration study, but it also implements several science elements as described in the U.S. President’s Emergency Plan for AIDS Relief as “*the study of methods to improve the uptake, implementation, and translation of research findings into routine and common practices*” ²⁴ (p. 199).

PrEP1519 was the first PrEP demonstration cohort study of AKP conducted in Latin America. It is carried out in three large Brazilian capitals: Belo Horizonte (Minas Gerais State), Salvador (Bahia State), and São Paulo. The primary objective was to analyze the effectiveness of daily oral PrEP use among AMSM and ATGW aged 15-19 years at high risk for HIV infection. PrEP1519 comprises six different components: (1) qualitative formative research; (2) demand generation strategies for recruitment, enrollment, and linkage to PrEP clinics; (3) HIV incidence estimated based on prevalence data

in the population encompassed by demand generation strategies; (4) demonstration study of PrEP effectiveness; (5) evaluation of the distribution and use of HIV self-testing (HIVST); and (6) cost-effectiveness of PrEP among adolescents. Components 2, 3, 4, and 5 involved mixed-method study designs.

Playing hide-and-seek: reaching adolescents where they are

- **Qualitative investigations on access, linkage, and retention in PrEP and combination prevention**

Qualitative techniques were used in different stages of the study. The first stage involved conducting formative research to comprehensively understand fieldwork processes²⁵. Formative research occurred from August 2018 to January 2019 for three purposes: (i) to understand the dynamics of social interaction among AMSM and ATGW in venues where they gather; (ii) to understand the needs and perceptions of AKP regarding study implementation; and (iii) to analyze AMSM and ATGW sexual behaviors – contexts that contribute to increasing their vulnerability to HIV and acceptability of PrEP and HIVST.

The mapping of adolescent and youth social venues and online spaces (e.g., social media, internet, dating apps) began with participant observation, followed by semi-structured interviews with key non-adolescent informants who worked in prevention programs for adolescents in either nongovernmental organizations (NGOs) or public services. The second step of the formative research was based on mapping schools and youth LGBTQIA+ gathering/venues to actively seek out sexually active AMSM and ATGW aged 15-19 years to participate in the interviews and the focus group discussion at the three sites. The focus group discussions were conducted to deepen the understanding of the acceptability of PrEP, HIVST, and the planned recruitment strategies.

The formative research was key to understand the socialization practices of AMSM and ATGW. This knowledge was used to planning other components of this study, especially the peer educator's activities in the LGBTQIA+ community and designing the communication plan. Understanding the acceptability of PrEP and HIVST among these groups was also vital in designing different approaches used throughout the study to recruit and retain participants. Adolescents had little knowledge about PrEP, specifically misunderstanding the concept of PrEP and HIV post-exposure prophylaxis (PEP) and doubts about PrEP use and its protective effect. Information on PrEP is mainly obtained from online social networks and LGBTQIA+ interaction spaces. Despite little knowledge, there was a high acceptability of PrEP associated with two types of motivation: (i) prevention of HIV infection among key populations by increasing their sense of safety, decreasing stigma inherent in the notion of “at-risk group”, fear of sex with a “potentially infected individual”, and concern with condom failures and (ii) protection for those who are most vulnerable to HIV infection, considering age, sex work, and non-regular condom use, especially for those who already dislike or do not want to use it and those who are “coming out of the closet”. Despite the high acceptability of PrEP, adolescents reported the following barriers: (i) distrust of PrEP effectiveness; (ii) concerns with daily pill regimens; and (iii) fear of side effects (a “possible feminization” of the MSM body and possible drug interactions with the hormone treatment used by TGW) and fear of being identified as promiscuous or as a person living with HIV²⁶.

Once the recruitment, enrollment, and demand generation strategies were implemented, we aimed to investigate the acceptability of interventions in the community by focusing on (i) adolescents' perception of how accessible interventions were; (ii) environment/setting in which interventions occurred; (iii) clarity and relevance of the information and prevention methods delivered; (iv) how culturally sensitive and appropriate to the specific needs of adolescents the delivered information and prevention methods were; and (v) participants' perception of interaction with peer and non-peer HIV prevention workers.

Other combination prevention strategies were also investigated among adolescents who chose not to use PrEP (non-PrEP branch) by focusing on the offer of prevention strategies not traditionally available in health centers, such as HIVST, HIV seroadaptive strategies²⁷, and HIV and sexually transmitted infection (STI) risk management strategies.

Qualitative research with adolescents using PrEP aimed to understand (i) management of sexual risk; (ii) daily effects of using PrEP (repercussions on their relationships, sexual practices, and experi-

ences of violence and discrimination due to PrEP use); and (iii) adherence to clinical follow-up care and PrEP use. To articulate these aspects with different patterns of adherence to PrEP, in-depth interviews were conducted with participants who (i) used PrEP regularly (i.e., as directed in the instructions); (ii) used PrEP irregularly (i.e., failing to pick up their medicine at least once in seven days after the previous prescription ran out); and (iii) had discontinued PrEP (i.e., discontinuing the medicine permanently or not picking up a new prescription 60 days after finishing the previous one).

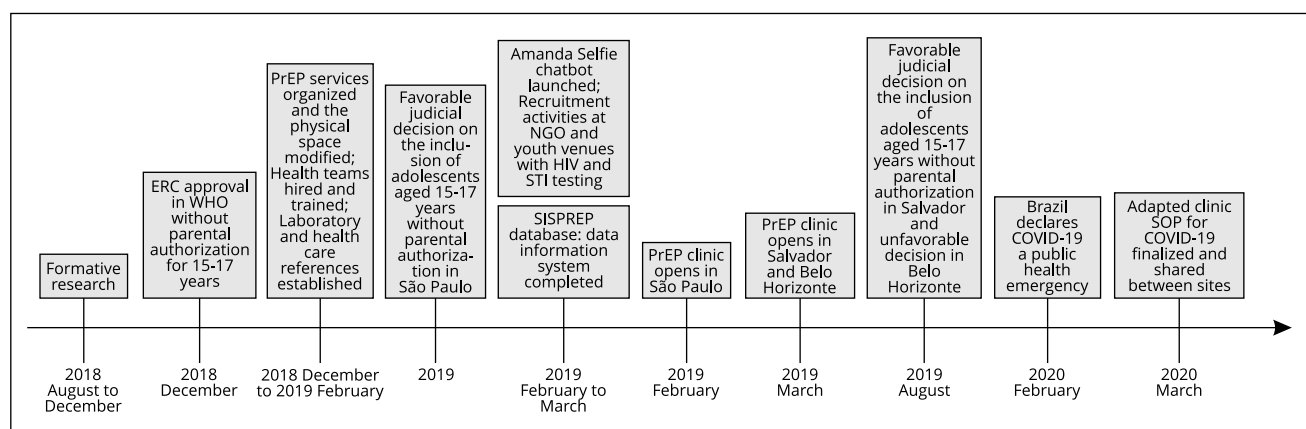
Across the board, we aimed to obtain a broad diversity of experiences that modulate the context in which adolescents with a high risk of STI live. We aimed to diversify participants regarding gender identity (e.g., cisgender, non-binary, *travestis*, and TGW), social class (adolescents who identify as middle/upper class and lower class), skin color (black, white, mixed-race, others), and vulnerability contexts such as violence and discrimination. As such, aspects of adolescents' mental health and well-being have consistently been explored. Among transgender adolescents, special attention has been given to the meanings and reasons for body modifications, barriers to access to healthcare, experiences of discrimination and violence, repercussions of body modifications in emotional/sexual interactions, STI risk perceptions, and expectations for the future.

Implementation model

The implementation of PrEP1519 clinics required adaptation/remodeling of physical spaces at all sites to make them friendly to AMSM and ATGW, with the inclusion of elements of LGBTQIA+ youth culture (Figure 1). Major adaptations were required in Salvador and Belo Horizonte. The teams chose to conduct the project in spaces alongside civil society initiatives partner with governmental organizations rather than in traditional health services, thus requiring more time to adapt the spaces and to conform to sanitary requirements. In Salvador, the PrEP clinic is located at the Diversity Center [Casarão da Diversidade], a space for promoting human rights among the LGBTQIA+ population. In Belo Horizonte, the PrEP clinic is located at a Youth Reference Center [Centro de Referência da Juventude], which is a public space located in the downtown with intense youth gatherings, especially those in social vulnerability, which are project main target population. In São Paulo, the PrEP clinic was initially located at the Henrique de Souza Filho Testing and Counseling Center [Centro de

Figure 1

PrEP1519 timeline. Brazil, 2019-2021.



ERC: Ethics Research Committee; NGO: nongovernmental organizations; PrEP: pre-exposure prophylaxis; SISPREP: PrEP data collection platform; SOP: standard operating procedures; STI: sexually transmitted infections; WHO: World Health Organization.

Testagem e Aconselhamento Henrique de Souza Filho – CTA-Henfil], located in the downtown area where the project target population was already actively gathering. Then, it expanded to two NGOs: (i) CASA 1 in the Central region and (ii) Periphery Identity [Identidade Periférica] in the Eastern region, which offers PrEP as an extramural activity performed by nurses and peer educators. Both NGOs are linked to the Extension Service for HIV/AIDS Patient Care of the Infectious Diseases Department of the Clinic Hospital, Faculty of Medicine, University of São Paulo.

Health professionals and researchers with LGBTQIA+ care profiles were trained. The teams were also composed of members of the LGBTQIA+ community to approximate care strategies to the needs and specificities of adolescents, creating friendlier and more effective environments. The participation of transgender people in the team has been a key point in recruiting ATGW to enroll in the PrEP.

Participants could choose one of two branches to participate in the demonstrative study: (a) the PrEP branch included those that enrolled in daily use of oral PrEP with the TDF/FTC combination; (b) the non-PrEP branch included those that were PrEP-eligible but chose not to use drug prophylaxis and opt to receive other HIV combination prevention methods (e.g., counseling, condoms, lubricant, douche, and HIVST). After PrEP initiation, participants were assigned a study peer navigator and they were monitored by the health team. These activities were conducted in person and online (over WhatsApp, Instagram, and Facebook messages).

PrEP1519 is integrated with other health service systems and provides participants with the SUS card, as well as HIV and other STI tests. Participants who tested positive for HIV or hepatitis were referred to specialized services and linked care and treatment. For bacterial STI, participants were treated at PrEP1519 clinics according to a point-of-care testing proposal²⁸ and treatment protocols of the Brazilian Ministry of Health. They also had access to PEP (if needed). Moreover, health professionals offered counseling, condoms, and HIVST (Box 1). All demands outside the scope of combination prevention services were referred to the SUS healthcare network and other public social assistance services.

- **Lessons learned of the implementation model**

The expansion of PrEP to the AMSM and ATGW populations required community mobilization and innovative strategies for searching, attracting, and recruiting adolescents. Additionally, speaking the language of adolescents, having a multiprofessional health teams, maintaining an interdisciplinary research work with qualitative and quantitative data production, and periodically monitoring activities were essential aspects for the work process. Finally, having a friendly LGBTQIA+ team and an environment that facilitates the enrollment of adolescents in HIV combination prevention, including PrEP, was fundamental.

PrEP1519 cohort

Participants were recruited from the three sites using several strategies, including engaging peer educators at schools; reaching out via venues where young people congregate and via hook up apps; in addition to using social media networks such as Instagram, Facebook, WhatsApp, word-of-mouth, and an artificial intelligence chatbot named “Amanda Selfie”, conceived as a transgender woman. This was the first Latin American transgender chatbot available 24/7 on Facebook Messenger. It emulates chat-based conversations on sensitive subjects such as sex, STI, PrEP, and combination prevention. The chatbot was designed to identify those at a higher risk for HIV infection and schedule appointments to PrEP1519 clinics. Demand generation strategies for recruitment, enrollment, and linkage to PrEP clinics use an action research approach^{29,30} (i) to enroll participants in the study and (ii) to analyze the effectiveness of different strategies for recruiting participants³¹.

PrEP1519 collects all data digitally; these data are fully integrated with an electronic record platform (<https://sisprep1519.org>). As a result, the team can monitor the participant’s follow-up and access the data in real time to ensure quality control of collected data concerning the participant’s confidentiality.

Box 1

Description of recruitment, navigation, pre-exposure prophylaxis (PrEP) initiation, and continuation in PrEP1519 study. Brazil, 2019-2021.

RECRUITMENT AND PEER EDUCATION
<ul style="list-style-type: none"> • Recruitment based on the activities of peer-educators with youth at venues and schools, on social media platforms (Instagram, Facebook, WhatsApp, YouTube, TikTok, Spotify), and on hook up apps (Grindr, Tinder, Hornet, and Badoo) • Artificial intelligence via the Amanda Selfie chatbot through sponsored posts in Instagram promoting key prevention messages (HIV and STI prevention) with focus on AMSM and ATGW • Community mobilization by promoting PrEP at LGBTQIA+ parties and venues, promotional videos and flyers on social media platforms (Instagram and YouTube), and radio programs on Spotify • Promotional videos on social media platforms, radio programs on Spotify and “livestreaming”, and IGTV in the Instagram, led by peer-educators featuring drag queens and digital influences. They use an LGBTQIA+ culture approach and talk about sex, hormone therapy, and art focused on AMSM and ATGW (https://www.instagram.com/preparasalvador/?hl=pt-br and https://instagram.com/vcprepsp?igshid=dyf76oj8lef7) • Moreover, messages, photos, podcasts, playlists, and flyers posted in Project Instagram has had great success in reaching new and young LGBTQIA+ followers
NAVIGATION AND PEER NAVIGATION
<ul style="list-style-type: none"> • After PrEP initiation, peer-navigators were assigned to follow-up the needs of each participant • The follow-up is mostly online, through social media platforms and smartphone text messages • Peer-navigators emphasize and monitor PrEP adherence at PrEP initiation, and PrEP continuation biweekly and monthly • The nurse and the doctor supervise this work • The communication channels between participants and peer-navigators are open to allow participants to initiate a conversation according to their needs • Peer-navigators help to schedule face-to-face appointments and/or telehealth
PrEP INITIATION
<ul style="list-style-type: none"> • For PrEP enrollment, a mix of telehealth appointment and face to face appointments are scheduled by the participant, or walk-ins • Eligibility assessment for PrEP use, clinical evaluation, HIV rapid tests, blood sample collection for STI tests and safety tests that assesses kidney and liver function for PrEP use, and distribution of PrEP for one month • In-person interviews were conducted for sociobehavioral questionnaires. Nevertheless, online interviews were conducted during COVID-19 pandemic • During COVID-19 pandemic some cares were adopted: on-site staff conducts phone calls to all participants scheduled for the day before their appointment to confirm their intention to attend the visit and to inquire about COVID-19 symptoms: fever (> 37.7°C), cough, runny nose, shortness of breath or difficulty breathing, muscle pain, or anosmia. If any of these symptoms are reported, their visit is postponed and they receive guidance on COVID-19 management and resources. The team informs on COVID-19 protection for in-person appointments. The temperature of all participants is measured on arrival
PrEP CONTINUATION
<ul style="list-style-type: none"> • Participants attended follow up visits after baseline (1st month and then every three months). At each visit: clinical evaluation, HIV rapid tests, collection of blood samples for STI serological tests such as HIV, syphilis, viral hepatitis and HTLV, and for safety tests that assesses kidney and liver function for PrEP use; collection of dried blood spots (DBS) for direct assessing cumulative adherence to TDF based therapy; pharyngeal, rectal and urethral swabs for chlamydia and gonorrhoea tests; and distribution of PrEP for three months • During COVID-19 pandemic, for participants who chose telehealth to continue their use of PrEP, the health team evaluates them for any clinical impediments. If none, two HIVST and 120 PrEP pills are mailed to the preferred address on online forms that also contain an informed consent to be checked. Health team reinforces that it is necessary to perform the HIVST, to send the negative HIV test result to the doctor before opening a new PrEP bottle, and to repeat this procedure quarterly until quarantine measures are over • In-person and sociobehavioral questionnaires are conducted. The online interviews (after COVID-19) are monitored by team members • Site staff conducts a phone call to all participants scheduled for the day before their appointment to confirm their intention to attend the visit, and inquire about COVID-19 symptoms: fever (> 37.7°C), cough, runny nose, shortness of breath or difficulty breathing, muscle pain, or anosmia. If any of these symptoms are reported, their visit is postponed and they receive guidance on COVID-19 management and resources. The team informs on COVID-19 protection for in-person appointments. The temperature of all participants is measured on arrival

AMSM: adolescent men who have sex with men; ATGW: adolescent transgender women; HIVST: HIV self-testing; STI: sexually transmitted infections; TDF: tenofovir disoproxil fumarate.

• Sample size of population using PrEP

The number of adolescents enrolled in PrEP was estimated based on the assumption that the prevalence of PrEP adherence in this population was 49% with 80% power and a 5% significance level. For this purpose, we used the Stata software (<https://www.stata.com>) to calculate the sample size, and the command `power proportion` was employed, varying the tolerable margin of error (from 10% to 50%) (Table 1).

Thus, it was estimated that by the end of the project, 816 adolescents would have enrolled in PrEP over three years.

• Enrollment and follow-up

Participant enrollment in the cohort was initiated in February 2019 in São Paulo, April 2019 in Salvador, and May 2019 in Belo Horizonte, and follow-up lasted up to December 2021 (Figure 2). The PrEP1519 services were open from Monday to Friday, from 9a.m. to 5p.m., in Salvador; 2p.m. to 7p.m., in Belo Horizonte; and from Monday to Friday, from 9a.m. to 9p.m., and Saturdays, from 1p.m. to 5p.m., in São Paulo. General inclusion criteria were AMSM and ATGW aged 15-19 years, who had at least one sexual intercourse with another cisgender man or transgender woman in the past 12 months and reported spending most of their time at the study site (i.e., living, studying, or working in one of the study sites). The exclusion criterion was consumption of alcohol or other drugs at the time of the interview. Adolescents enrolled in the non-PrEP branch followed the same general criteria and tested negative for anti-HIV.

Table 1

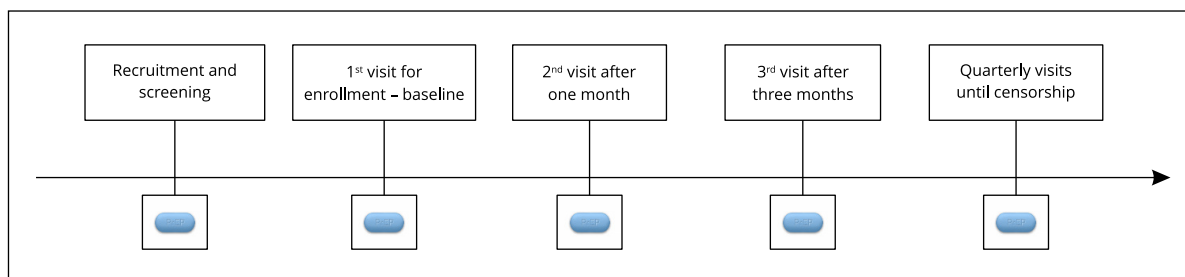
Calculation of the sample size.

Prevalence of PrEP adherence	Tolerable error margin	Sample size
49%	10%	816
	20%	203
	30%	89
	50%	31

PrEP: pre-exposure prophylaxis.

Figure 2

Follow-up time of the PrEP1519 cohort until censoring (loss of follow-up, study ends). Brazil, 2019-2021.



Those eligible for the PrEP branch had to test anti-HIV negative and meet at least one of the following criteria: unprotected anal sex in the last six months, episode of STI in the last 12 months, use of PEP in the last 12 months, frequent use of alcohol or drugs before or during sexual intercourse (chemsex), exchanging money or favor for sex, and any specific situation shared between adolescent and interviewer that is considered vulnerable to HIV and other STIs or reported experiences of violence and discrimination due to gender identity/sexual orientation. After eligibility criteria check and provision of information of the proposed steps for the study, those who agreed to participate in the study provided written informed consent (according to the court order decisions defined for each city). Participants were tested at the initial visit (baseline) and at quarterly visits for HIV, using a 4th generation rapid test (Ag/Ab) and a viral load whenever necessary; for hepatitis A, B, and C, via serology; and for syphilis, using the rapid treponemal test and venereal disease research laboratory. Additionally, participants were semiannually tested for *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, *Mycoplasma genitalium*, *Mycoplasma hominis*, *Ureaplasma urealyticum*, and *Ureaplasma parvum* via real-time polymerase chain reaction (PCR) tests in swab samples from oral, urethral, and anal sites. To evaluate the safety profile of those using PrEP, liver (AST and ALT) and renal (creatinine and urine albumin/creatinine ratio) tests were added, and all adverse events were assessed at each visit (i.e., quarterly), as defined by the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events*³². Those who had renal impairment (i.e., defined by glomerular filtration rate < 60mL/min/1.75m², using the Cockcroft-Galt formula for people aged over 17 years and Schwartz formula for people aged under 17 years), history of spontaneous bone fracture, clinical condition suggesting acute retroviral syndrome in the last 30 days, or risky sexual intercourse in the last 72h, were temporarily or permanently excluded from the group using PrEP; in the latter case, individuals were immediately referred for the use of PEP. Dried blood samples (DBS) were collected and stored at each visit for serum TDF/FTC measurements of direct PrEP adherence. Self-reported PrEP use, PrEP prescriptions, and withdrawal information were used as indirect adherence measures. A sociobehavioral questionnaire about gender identity, access to health services, sexual practices, drug and alcohol use, and situations of violence was administered at baseline and every three months (Figures 3 and 4).

The main outcomes to be analyzed are the incidence of HIV, adverse events, and rates of adherence and continuation of PrEP. All participants were observed until the third year of the study (December 2021) or until they stop participating by choice or in the event of HIV seroconversion.

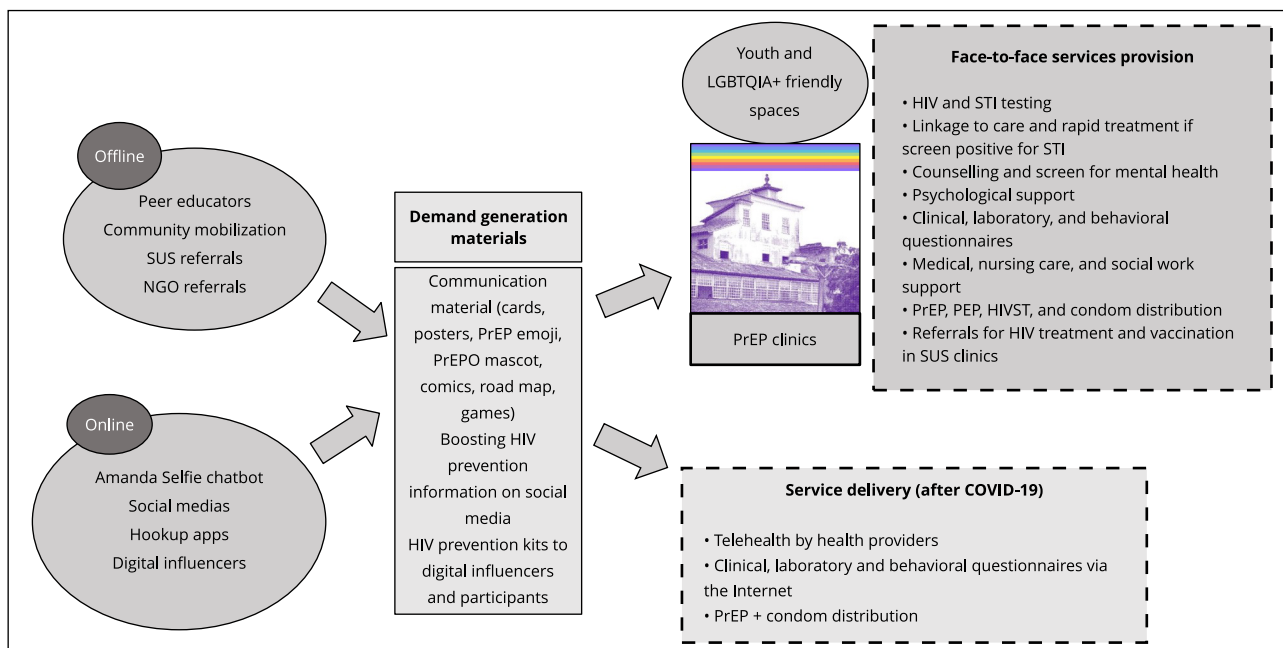
The PrEP1519 study team decided to continue its work during the COVID-19 pandemic and quickly adapted to the new situation with emphasis on social media and telemonitoring infrastructure set up to reach adolescents beforehand³³. Box 1 describes the provision of services, clinical follow-up, initiation of PrEP, and continuation of PrEP.

Outcomes (“lessons learned”): adolescents are dynamic and fluid; therefore, we must continually adapt to their contexts. Our study suggest the need for recruitment strategies that do not just depend on spontaneous demand from health services but that also actively seeks out adolescents among populations at greatest risk for HIV infection, respecting their specific needs, and adopting local strategies for demand generation, recruitment, disease surveillance, and dedicated healthcare.

Demonstration projects have found that one of the reasons for the lack of adherence to PrEP is the lack of scheduled follow-up appointments, causing a delay in receiving the medicine. For this reason, a specific routine was developed at each project site to remind individuals about the appointments (previous day or week) via text messages or telephone calls, making it easy to reschedule if necessary. Furthermore, conversations with peer navigators were held in which the adolescents can talk about their experiences with the medicine, helping improve the degree of interaction between them and the project teams and creating the habit of using the medicine. Adolescents at risk of non-adherence, missing follow-up care appointments, or both were identified, and the reasons for their non-adherence were mapped. Finally, the team created a multidisciplinary follow-up plan that included social, psychological, and clinical support for adolescents.

Figure 3

PrEP1519 implementation model: recruiting, linking, and enrolling adolescent men who have sex with men and adolescent transgender women to pre-exposure prophylaxis (PrEP) and HIV self-testing (HIVST). Brazil, 2019-2021.



NGO: nongovernmental organizations; PEP: post-exposure prophylaxis; STI: sexually transmitted infections; SUS: Brazilian Unified National Health System.

Ethical considerations

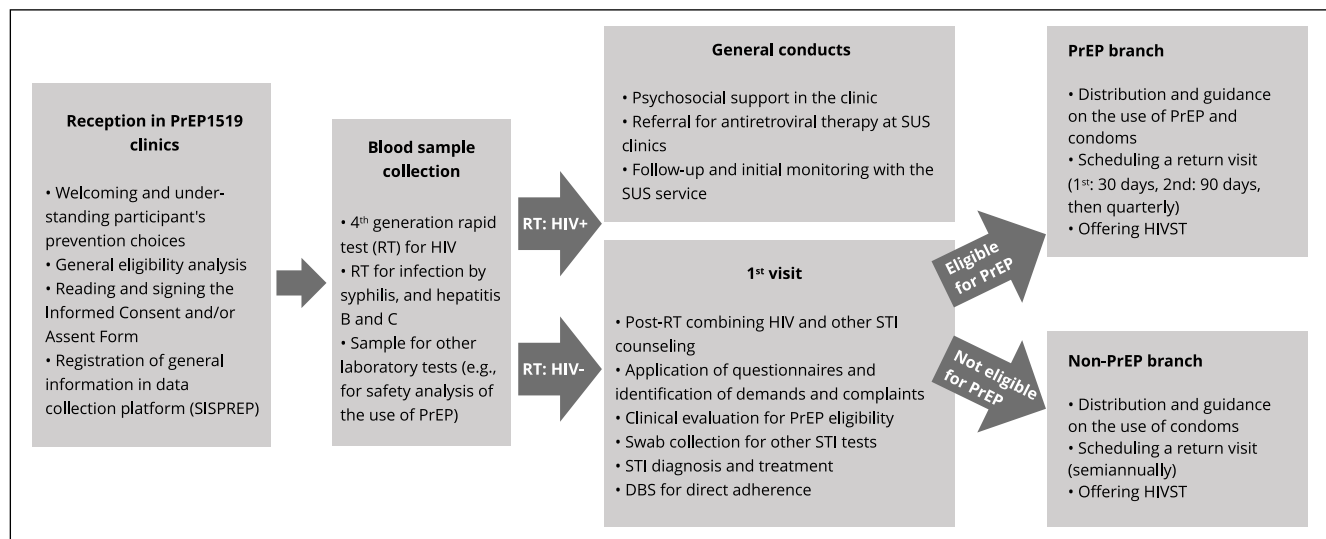
This study was conducted in accordance with the principles of the Brazilian Research Ethics Commission (CONEP), which complies with all Brazilian laws on adolescents' rights and the *Declaration of Helsinki*. The research protocol was approved by the WHO Ethics Review Committee (protocol ID: Fiotec-PrEP Adolescent study), and by the Ethics Review Committee from the study coordinating universities: University of São Paulo (#3,082,360), Federal University of Minas Gerais (#2,027,889), and Federal University of Bahia (#3,224,384). Participation was voluntary, and all collected data were kept confidential. An informed consent form explaining the research aims and procedures and participants' rights was presented to each participant before they decided to participate in this study. Special judicial authorization was obtained to allow for waiver of parental consent for individuals aged under 18 in São Paulo and Salvador. The waiver applies to adolescents deemed at risk of violence related to sexual and gender identity disclosure and in cases of breakage of family ties. In Belo Horizonte, legal guardians must sign the informed consent in all cases.

Interdisciplinarity in HIV prevention research

Interdisciplinary practice through the integration of quantitative and qualitative approaches in the PrEP1519 study serve as an example of demonstration studies of social groups with difficult access, such as adolescent gay men and TGW. Moreover, relevant evidence has been generated for combination prevention health programs/public policies to reduce HIV among key populations. The experience accumulated in this study will hopefully be useful for care and protection of such a vulnerable population and, at the same time, help them to be heard.

Figure 4

General service flow at PrEP1519 clinics in Belo Horizonte (Minas Gerais State), Salvador (Bahia State), and São Paulo, Brazil, 2019-2021.



DBS: dried blood spots; HIVST: HIV self-testing; PrEP: pre-exposure prophylaxis; SISPREP: PrEP data collection platform; STI: sexually transmitted infections; SUS: Brazilian Unified National Health System.

The production of quantitative and qualitative data on PrEP among AMSM and ATGW has been a challenge for our team. The return to daily life, pathways, and decisions that were taken throughout the interactions and negotiations between the different actors (including the adolescents) also have the additional objective of reflecting on the processes (challenges, limits, and possibilities) of communication between cultures and languages (scientific and non-scientific) given the trans-epistemic nature³⁴ of knowledge production. The reflexivity that can lead to quantitative and qualitative analyses and discussions is important.

In this sense, the daily interactions of the research team with the participants, governmental organizations, and NGOs have produced a series of reflections about the limitations of our concepts and categories for translating the diversity of practices and experiences. In contrast, these are the same reflections that enable us to review and to expand the language; materializing our scientific objectives into our research instruments.

Another important point is the conflict between the scientific and non-scientific communities³⁵. Tensions between research objectives and social needs must be continuously discussed and negotiated to allow for the research to advance. These tensions show a variety of interests, such as the demand from funding agencies and research institutions to produce data on the effective use of PrEP, the dynamic context of adolescents MSM and TGW within different contexts of stigma, discrimination, and violence, and expectations generated by the research protocol.

Finally, this diversity of interests, experiences, and practices seems to suggest multiple perceptions of reality. As Annemarie Mol emphasizes³⁶, with the concept of “ontological politics”, reality does not precede “worldly practice”; instead, it is formed within these practices and is therefore multiple. Hence, when considering the various moments and situations of participation and interaction, or the collaboration of so many actors, including materials and technologies, in realizing the research, reality no longer remains “untouched at the center”. Although it is possible to make (partial) connections, there are always points of escape that indicate movement, fluidity, change, or transformation.

Contributors

I. Dourado contributed to the study conceptualization, investigation, methodology, writing, and review; and approved the final version of the manuscript. L. Magno contributed to the study conceptualization, investigation, methodology, and review; and approved the final version of the manuscript. D. B. Greco contributed to the investigation, methodology, and review; and approved the final version of the manuscript. E. M. Zucchi contributed to the investigation, methodology, and review; and approved the final version of the manuscript. D. Ferraz contributed to the investigation, methodology, and review; and approved the final version of the manuscript. M. R. Westin contributed to the investigation, methodology, and review; and approved the final version of the manuscript. A. Grangeiro contributed to the study conceptualization, investigation, methodology, writing, and review; and approved the final version of the manuscript.

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Resumo

No final de 2017, Brasil adotou a profilaxia pré-exposição do HIV (PrEP) como parte de uma estratégia de prevenção combinada para as populações com maior risco de infecção. Entretanto, o país não dispõe de diretrizes específicas para o uso da PrEP entre adolescentes abaixo de 18 anos de idade. Assim, pesquisadores de diferentes disciplinas de saúde realizaram o PrEP1519, o primeiro estudo de coorte de demonstração da PrEP, atualmente em andamento em três cidades brasileiras – Salvador, Belo Horizonte e São Paulo – entre homens adolescentes que fazem sexo com homens e mulheres transgênero, entre 15 e 19 anos de idade. O estudo busca avaliar a efetividade da PrEP em contextos da vida real. Foram integrados métodos quantitativos e qualitativos para obter dados sobre a aceitabilidade, adoção, uso e adesão à PrEP. Além disso, foram implementados serviços integrados e ambientes acolhedores nas clínicas PrEP1519. O estudo busca descrever os esforços colaborativos das práticas interdisciplinares no desenvolvimento do estudo PrEP1519. A articulação de pesquisadores de diferentes instituições e áreas representa um desafio, mas permite um olhar mais abrangente sobre questões relativas à direção da pesquisa, ao mesmo tempo em que enriquece as decisões necessárias durante as interações e negociações entre diferentes indivíduos, inclusive a equipe de jovens e os participantes. Além disso, reflete o processo de comunicação entre culturas e línguas, considerando a arena trans-epistêmica da produção de conhecimento sobre HIV, infecções sexualmente transmissíveis, PrEP e outras estratégias de prevenção combinada para adolescentes.

HIV; Profilaxia Pré-Exposição; Adolescentes; Homens que Fazem Sexo com Homens; Mulher Transgênero

Resumen

A finales de 2017, Brasil adoptó la profilaxis previa a la exposición al VIH (PrEP) como parte de una estrategia de prevención combinada para las poblaciones de mayor riesgo. Sin embargo, Brasil no tiene directrices específicas para el uso de la PrEP entre los adolescentes < 18 años. Por lo tanto, investigadores de diferentes disciplinas sanitarias llevaron a cabo el PrEP1519, el primer estudio de cohorte de demostración de la PrEP, en curso en tres ciudades brasileñas -Salvador, Belo Horizonte y São Paulo- entre hombres adolescentes que tienen relaciones con hombres y mujeres transexuales, de entre 15 y 19 años. El objetivo de este estudio es evaluar la eficacia de la PPrE en entornos reales. Se integraron métodos cuantitativos y cualitativos para obtener datos sobre la aceptabilidad, la aceptación, el uso y la adherencia de la PrEP. Además, se implementaron servicios integrales y entornos amigables en las clínicas de PrEP1519. Este estudio pretende describir los esfuerzos de colaboración de las prácticas interdisciplinarias en el desarrollo del estudio PrEP1519. La articulación de investigadores de diferentes instituciones y áreas supone un reto; pero también permite ampliar la visión de las cuestiones relativas a la dirección de la investigación, a la vez que enriquece las decisiones que debían tomarse durante las interacciones y negociaciones entre los diferentes individuos, incluyendo el equipo de jóvenes y los participantes. Además, reflexiona sobre el proceso de comunicación entre culturas y lenguas teniendo en cuenta el ámbito trans-epistémico de la producción de conocimiento sobre el VIH, las infecciones de transmisión sexual, la PrEP y otras estrategias de prevención combinada para adolescentes.

VIH; Profilaxis Pre-Exposición; Adolescentes; Hombres que Hacen Sexo con Hombres; Mujer Transexual

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