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# Sociodemographic profile of users and discontinuation rate of HIV pre-exposure Prophylaxis after the expansion of access

Perfil sociodemográfico dos usuários e taxa de abandono da Profilaxia pré-exposição ao HIV após a ampliação do acesso

Perfil sociodemográfico de los usuarios y tasa de abandono de la Profilaxis previa a la exposición al VIH después de la ampliación del acceso

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**ABSTRACT**

**Objective:** To evaluate whether there was a change in the sociodemographic profile of users of Pre-exposure Prophylaxis (PrEP) for HIV and in the discontinuation/abandonment rate after the expansion of access to the entire population at increased risk of infection. **Methods:** This is a retrospective cross-sectional study conducted with 180 (Group 1) and 205 (Group 2) users who started PrEP before and after the expansion of access, respectively. **Results:** Both groups presented the same sociodemographic profile, characterized by men, cisgender, homosexual, white, aged between 18 and 24 years, with more than 12 years of education, residing in the central region, and belonging to the target population of homosexuals and other men who have sex with men. Comparing the groups, it was observed that after the expansion of access, users aged 40 to 49 adhered to prophylaxis more (p=0.025), as well as those with 4 to 7 years of education (p=0.037). There was a 6.8% increase in the discontinuation rate, exceeding 50% of users in Group 2. **Conclusion:** The same profile of PrEP users is observed before and after the expansion of access; however, older users and those with lower education levels are adhering more to prophylaxis. The discontinuity rate remains high.

**Keywords:** Pre-exposure prophylaxis, Public health, Disease prevention.

**RESUMO**

**Objetivo:** Avaliar se houve alteração do perfil sociodemográfico dos usuários da Profilaxia Pré-exposição (PrEP) ao HIV e na taxa de descontinuidade/abandono, após a ampliação do acesso à toda população com risco aumentado de infecção. **Métodos:** Trata-se de um estudo transversal retrospectivo, conduzido com 180 (Grupo 1) e 205 (Grupo 2) usuários que iniciaram a PrEP, antes e após a ampliação do acesso, respectivamente. **Resultados:** Ambos os grupos apresentaram o mesmo perfil sociodemográfico, caracterizado por homens, cisgêneros, homossexuais, brancos, com idade entre 18 e 24 anos, escolaridade superior a 12 anos, que residem na região central e pertencem a população-alvo de homossexuais e outros homens que fazem sexo com homens. Comparando os grupos, observou-se que após a ampliação do acesso, os usuários de 40 a 49 anos aderiram mais a Profilaxia (p=0,025), assim como, àqueles com tempo de estudo entre 4 e 7 anos (p=0,037). Houve aumento de 6,8% na taxa de descontinuidade, ultrapassando 50% dos

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usuários no Grupo 2. **Conclusão:** O mesmo perfil de usuários da PrEP é observado antes e após a ampliação do acesso, contudo, usuários de maior faixa etária e menor escolaridade estão aderindo mais à Profilaxia. A taxa de descontinuidade permanece elevada.

**Palavras-chave:** Profilaxia pré-exposição, Saúde pública, Prevenção de doenças.

**RESUMEN**

**Objetivo:** Evaluar si hubo un cambio en el perfil sociodemográfico de los usuarios de la Profilaxis Previa a la Exposición (PrEP) para el VIH y en la tasa de abandono después de la ampliación del acceso a toda la población en mayor riesgo de infección. **Métodos:** Este es un estudio transversal retrospectivo realizado con 180 (Grupo 1) y 205 (Grupo 2) usuarios que iniciaron PrEP antes y después de la ampliación del acceso, respectivamente. **Resultados:** Ambos grupos presentaron el mismo perfil sociodemográfico, caracterizado por hombres, cisgénero, homosexuales, blancos, de entre 18 y 24 años, con más de 12 años de educación, residentes en la región central y pertenecientes a la población objetivo de homosexuales y otros hombres que tienen sexo con hombres. Comparando los grupos, se observó que después de la ampliación del acceso, los usuarios de entre 40 y 49 años se adhirieron más a la profilaxis (p=0.025), así como aquellos con 4 a 7 años de educación (p=0.037). Hubo un aumento del 6.8% en la tasa de abandono, superando el 50% de los usuarios en el Grupo 2. **Conclusión:** Se observa el mismo perfil de usuarios de PrEP antes y después de la ampliación del acceso; sin embargo, los usuarios de mayor edad y aquellos con niveles educativos más bajos se están adhiriendo más a la profilaxis. La tasa de discontinuidad sigue siendo alta.

**Palabras clave:** Profilaxis previa a la exposición, Salud pública, La prevención de enfermedades.

## INTRODUCTION

Infection by the Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS) are part of the National Compulsory Notification List of Diseases. Since its discovery in the 1980s until today, more than 1 million cases of HIV and AIDS have been reported in Brazil, with approximately 52,415 young people aged 15 to 24 with HIV progressing to AIDS between 2012 and 2022. Additionally, the AIDS detection rate (per 100,000 inhabitants) in men increased from 30.6 to 33.7 among those aged 20 to 24 and from 46.0 to 54.4 among those aged 25 to 29 when comparing the years 2012 and 2022, demonstrating a concerning increase in cases in this age group (BRASIL, 2018).

Regarding AIDS mortality, a total of 10,994 deaths were recorded in 2022, with a rate of 4.1 deaths per 100,000 inhabitants, representing a decrease of 26.5% between 2012 and 2022. Access to antiretroviral treatment (ART) has contributed to reducing mortality; however, it is important to note that in 2020, part of this reduction may be related to decreased HIV testing and/or underreporting of cases due to the COVID-19 pandemic (BRASIL, 2024; DOURADO I, et al., 2023; SANTOS ACF, et al., 2020).

In addition to ART, which aims to reduce viral load to undetectable levels and increase the CD4+ T cell count in individuals with HIV infection, the Unified Health System (SUS) employs a combined prevention approach that includes a set of preventive strategies for sexually transmitted infections (STIs), including HIV (BRASIL, 2022a). HIV Pre-Exposure Prophylaxis (PrEP) corresponds to one of the combined prevention strategies (BRASIL, 2022b). The PrEP made available in Brazil starting in 2017, consists of the daily use of a combination of two antiretrovirals, tenofovir and emtricitabine, both inhibitors of the reverse transcriptase enzyme. It is estimated that regular use of PrEP reduces the risk of HIV infection by more than 90% (ZUCCHI EM, et al., 2018).

Initially, PrEP was offered only key populations, considered with greater risk of infection, such as homosexual and other men who have sex with men (MSM), transgender people, sex workers, and HIV-serodiscordant partners. However, as of August 2022, PrEP became available to the entire sexually active population at increased risk of HIV infection, including adolescents aged 15 and older, weighing 35 kilograms or more, without the need for parental consent (BRASIL, 2022a; 2022b; ZUCCHI EM, et al., 2018).

Additionally, for cisgender men and transgender individuals assigned male at birth who are not using estradiol-based hormones, there is the option of on-demand PrEP, which involves taking one tablet two to

twenty hours before sexual intercourse, one tablet after twenty hours from the initial dose, and another tablet after twenty-four hours from the second dose (BRASIL, 2022b). In June 2023, long-acting injectable cabotegravir (CAB-LA), known as injectable PrEP, was approved by the National Health Surveillance Agency for use in Brazil. The HPTN 083 study demonstrated that CAB-LA was superior to daily oral ARVs in preventing HIV infection among MSM and transgender women (LANDOVITZ RJ, et al., 2021).

However, only clinical trials have been conducted in the country, and it is not yet a medication available to the general population. Although, starting in August 2022, the use of PrEP has been expanded in Brazil, the key population remains the focus for reducing the number of HIV infection cases. The occurrence of discrimination, stigma, and prejudices increases vulnerability to HIV, in the same proportion as it intensifies the need to offer comprehensive support to this population, fully ensuring their rights to high-quality health care. In the context of the SUS, aiming to facilitate the expansion of access to PrEP in Health Care Networks, prescription has been extended to medical professionals and nurses.

Currently, the country has 966 PrEP dispensing 50 units, with 54 located in the State of Rio Grande do Sul (BRASIL, 2024). The city of Santa Maria, located in the central region of the state, has been one of the points of offering Prophylaxis since November 2020, and as of August 2022, the service has been decentralized, enabling the prescription and monitoring of PrEP in Basic Health Units (GALVÃO MR, et al., 2024).

Understanding the profile of users and the rate of PrEP discontinuation/abandonment enables the formulation of strategies that aim to integrate least assisted populations into available services, especially after the service expansion (QUEIROZ AAFLN e DE SOUSA AFL, 2017). These studies are crucial to understanding, implementing and optimizing the use of PrEP in HIV prevention, ensuring that interventions are evidence-based and tailored to the needs of the population. Thus, the present study aimed to compare the sociodemographic profile of users and the discontinuation/abandonment rate of PrEP in the city of Santa Maria, Rio Grande do Sul, Brazil, before and after the service expansion in August 2022.

## METHODS

This is a retrospective cross-sectional analytical study that complies with the recommendations described in the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for cross-sectional studies. The study was conducted in a Specialized Care Service and Testing and Counseling Center (SAE/CTA) in the municipality of Santa Maria. The SAE is a service provided by the Unified Health System, which assists users with viral hepatitis, people living with HIV (PVHIV), and those undergoing pre- and post-exposure prophylaxis for HIV, offering multiprofessional care.

The study population consisted of 385 PrEP users registered in the Drug Logistics Control System (SICLOM) database during the period from November 2020 to August 2023. Users were divided into two groups according to the start date of Prophylaxis use: November 2020 to August 25, 2022 (Group 1, *n*=180 users), when PrEP was intended only for key populations; and August 26, 2022, to August 26, 2023 (Group 2, *n*=205 users), when PrEP was extended to the entire population at risk of exposure to HIV. Information was collected between June and December 2023 at the SAE/CTA.

During the first PrEP consultation, testing for HIV and other STIs is conducted, and the user's interest and reasons for wanting to take prophylaxis are assessed. If the HIV test result is negative, the user receives medication for the first 30 days. After this period, the user returns to the service for a follow-up consultation and evaluation of laboratory tests. In the absence of changes in renal parameters, which would prevent the use of PrEP, the medication will be dispensed to the user every three months.

Thus, users who returned for their first follow-up appointment (30 days after starting PrEP) and continued medication were included in the study. Users with incomplete data or who did not return for the 30-day follow-up consultation were excluded. To determine the sociodemographic profile, the following criteria were analyzed: age, race/color, education level, region of residence, biological sex, sexual orientation, gender identity, and inclusion in a key population. Additionally, the number of users who discontinued to PrEP was determined. PrEP abandonment was defined as the user not returning to collect the medication during any of the follow-up consultations held every three months.

A database was developed using Microsoft Excel® version 10, with double data entry followed by validation to minimize measurement bias and promote data reliability. After validation of the spreadsheet with the identified corrections, the data were transferred to the final database for analysis in the Statistical Package for the Social Sciences (SPSS) software, version 24. For data analysis, descriptive statistics were applied through the categorization of variables: absolute (n) and relative (%), and association tests using Pearson's Chi-Square and Fisher's Exact Test, considering a significance level of 5% and a 95% confidence interval (95% CI).

The project was approved by the Center for Permanent Education in Health (NEPeS) and the Research Ethics Committee of the Franciscan University (CEP/UFN) under the opinion number 5.641.756 and Certificate of Presentation of Ethical Appreciation (CAAE) 61859622.9.0000.5306. In this regard, patient consent was waived since retrospective information was obtained from a database.

## RESULTS AND DISCUSSION

From the start of PrEP in the city of Santa Maria in November 2020 until August 26, 2023, 416 users were registered in SICLOM, and 385 were part of this study. From November 2020 to August 25, 2022, 203 users were registered for PrEP use in the city of Santa Maria (RS). Of these, seven moved to another municipality, and 16 had registered but did not collect the medication; thus, 180 users were included in Group 1 of this study. From August 26, 2022, to August 26, 2023, 213 users were registered, with 205 being part of this study (Group 2).

In this latter group, eight users were excluded: one due to changes in renal parameters that prevented the use of PrEP; one for starting PrEP during the immunological window, which resulted in HIV positivity at the 30-day return visit; three for moving to another municipality; and three for registering but not collecting the medication. Comparing Groups 1 and 2, there was a 14% increase in users who started PrEP.

Group division was carried out due to the new regulation that expanded PrEP to all individuals at increased risk of HIV infection, no longer restricting its use only to key populations (BRASIL, 2022a; ZUCCHI EM, et al., 2018). Additionally, the service in the city of Santa Maria was decentralized, allowing for PrEP prescription and monitoring in Basic Health Units (UBS). However, in the municipality of Santa Maria, the provision of this medication in UBS is challenging, as not all have pharmacies and qualified professionals (PIMENTA MC, et al., 2022).

**Table 1** demonstrates the criteria evaluated for determining the sociodemographic profile of PrEP users in Groups 1 and 2 and the significance analysis comparing the two groups. The same user profile is observed in both groups, characterized by men, cisgender, homosexual, white, aged 18 to 24 years, with ≥12 years of education, residing in the central region, and belonging to the target population of homosexual and other MSM. Comparing Groups 1 and 2, it was observed that after the expansion of access to PrEP (Group 2), users in the age group of 40 to 49 years started to adhere more to PrEP use (p=0.025), as well as those with shorter education time, between 4 and 7 years (p=0.037) (**Table 1**).

**Table 1 -** Comparison of the profile of PrEP users before (Group 1, n=180 users) and after (Group 2, n=205 users) the expansion of access. 2020 – 2023.

| Variable | Group 1 - n (%) | Group 2 – n (%) | p |
|---|---|---|---|
| **Age** | | | |
| < 18 years | - | 1 (0.5%) | 0.025[a] |
| 18 to 24 years | 69 (38.3%) | 68 (33.2%) | |
| 25 to 29 years | 50 (27.8%) | 55 (26.8%) | |
| 30 to 39 years | 45 (25.0%) | 51 (24.9%) | |
| 40 to 49 years | 14 (7.8%)[a] | 22 (10.7%)[a] | |
| ≥ 50 years | 2 (1.1%) | 8 (3.9%) | |
| **Race/Ethnicity** | | | |
| White | 130 (72.2%) | 158 (77.1%) | 0.157 |
| “Pardo”[b] | 23 (12.8%) | 26 (12.7%) | |

| | | | |
|---|---|---|---|
| Black | 27 (15.0%) | 21 (10.2%) | |
| **Years of Education** | | | |
| ≥ 12 years | 128 (71.1%) | 116 (56.8%) | 0.037[a] |
| 8 to 11 years | 46 (25.6%) | 67 (32.9%) | |
| 4 to 7 years | 5 (2.8%)[a] | 19 (9.3%)[a] | |
| 1 to 3 years | 1 (0.5%) | 3 (1.0%) | |
| **Region of Residence** | | | |
| Center | 89 (49.4%) | 117 (57.1%) | 0.213 |
| Periphery | 47 (26.1%) | 53 (25.9%) | |
| East | 42 (23.3%) | 32 (15.6%) | |
| Other district | 2 (1.2%) | 3 (1,4%) | |
| **Biological Sex** | | | |
| Masculine | 168 (93.3%) | 187 (91.2%) | 0.083 |
| Feminine | 12 (6.7%) | 18 (8.8%) | |
| **Sexual Orientation** | | | |
| Homosexual | 123 (68.3%) | 129 (62.9%) | 0.580 |
| Heterosexual | 32 (17.8%) | 46 (22.4%) | |
| Bisexual | 25 (13.9%) | 30 (14.7%) | |
| **Gender Identity** | | | |
| Cingender man | 157 (87.2%) | 180 (87,8%) | 0.199 |
| Cisgender woman | 12 (6.7%) | 17 (8.3%) | |
| Transgender woman | 9 (5.0%) | 6 (2.9%) | |
| Non-binary | 2 (1.1%) | 1 (0.5%) | |
| Transgender man | 0 | 1 (0.5%) | |
| **Target population*** ** | | | |
| Homosexual and other HSH | 142 (78.9%) | 145 (70.7%) | 0.220 |
| Serodiscordant couple | 29 (16.1%) | 29 (14.1%) | |
| Sex workers | 21 (11.7%) | 5 (2.4%) | |
| Other population | 10 (5.6%) | 19 (9.3%) | |
| Transgender | 9 (5.0%) | 7 (3.4%) | |
| Deprived of liberty | 0 | 4 (1.9%) | |

**Nota:** [a]p<0.05. [b]Mixture of two or more color/race, including white, black, and indigenous. [c]Users can belong to more than one group.
**Source:** NOGARA BL, et al., 2024.

Our results are consistent with studies conducted in other states and the Brazilian context regarding the sociodemographic profile of PrEP users (BIATTO MG, et al., 2022; GALVÃO MR, et al., 2024; PIMENTA MC, et al., 2022; SOUSA KE, et al., 2022). However, there is no description in the literature comparing users before and after service expansion, and this study appears to be the first to describe a significant increase in PrEP users with older age and lower education. This result is important considering that AIDS cases in Brazil are still concentrated in men aged 25 to 39, and lower education levels are associated with more vulnerable populations and greater difficulties in accessing healthcare services (DANTAS MN, et al., 2021; PIMENTA MC, et al., 2022).

Unfortunately, there was no significant increase in other priority groups such as transgender individuals and sex workers, nor in women and residents of the city's peripheral regions. There was also no increase in other populations that do not fit into priority groups, indicating that information about the expansion of service access may not have reached the entire population.

A positive aspect is the inclusion of the incarcerated population among PrEP users (Group 2), representing progress, as they are considered vulnerable to STIs due to legal barriers, stigma, and social marginalization (CARVALHO FF, et al., 2020). In Brazil, data indicate an HIV/AIDS epidemic in certain populations, such as transgender individuals, with prevalence rates of 30%, compared to 0.4% in the general population (GRINSZTEJN B, et al., 2017). Research also suggests that stigma and discrimination faced by these communities, including within healthcare facilities, pose obstacles to prevention strategies and treatments essential for preserving their lives (FARIAS AHT, et al., 2022; GRINSZTEJN B, et al., 2017; PIMENTA MC, et al., 2022).

In São Paulo (SP, Brazil), a strategy to engage transgender individuals in services and ensure PrEP adherence was the creation of an outpatient clinic within the facilities of the Reference and Training Center for STD/AIDS-SP, focused on the comprehensive health of transgender individuals. This clinic comprises a multidisciplinary team trained for humanized care, utilizing strategies such as teleconsultation and sending self-tests and medications by mail or home delivery (SOUSA RA, et al., 2023). Thus, the creation of specialized facilities to serve specific populations seems to be a promising strategy to ensure universal access to healthcare services, a cornerstone of the SUS.

In Group 1, among the 180 users evaluated in the study, 103 (57.3%) were correctly collecting PrEP (active users), and 77 (42.7%) did not return to the service in the stipulated month for PrEP collection, demonstrating discontinuation of use (inactive users). Among inactive users, 42.8% (n=33/77) and 36.3% (n=28/77) received only one and two dispensations, respectively. Regarding Group 2, out of 205 users, 112 (54.6%) were inactive users, and 90 (43.9%) were active users. Among inactive users, more than 50% (n=62/112) received only one medication dispensation. Additionally, one user seroconverted to HIV, and one had PrEP suspended due to renal function changes.

Regrettably, this study observed one HIV seroconversion, which occurred during the immunological window period when PrEP was initiated. The rapid test available at healthcare facilities detects antibodies, and the immunological window period for HIV can last from two to six weeks after exposure (BIATTO MG, et al., 2022). The Clinical Protocol and Therapeutic Guidelines for PrEP recommend viral load testing in cases of clinical suspicion of acute HIV infection with negative antibody tests to reduce the immunological window period.

Individuals at high risk of HIV infection, without signs and symptoms of acute infection, who have had recent exposure and are beyond the 72-hour window for PEP indication, can immediately initiate PrEP, provided they are closely monitored for seroconversion (BRASIL, 2022b). These strategies require increased attention from healthcare professionals, especially during the initial prophylaxis consultation, as it involves actively searching for signs and symptoms and assessing HIV infection risk perception. In relation the user who had renal function, changes had previously used the pos-exposition prophylaxis (PEP) to HIV and was continuously taking quetiapine and clonazepam, as well as reporting creatine use and low fluid intake.

Comparing Groups 1 and 2, there was a 6.8% increase in the discontinuation rate, with more than 50% of users who started PrEP discontinuing its use. Several factors may be associated with these results, including the fact that 25% of users initiated PrEP after PEP use (data not shown). Healthcare professionals often recommend PrEP to users who have used PEP, which may lead to use based solely on impulse rather than a genuine desire to start prophylaxis. Furthermore, 19.5% (data not shown) of users reported medication adherence failures, which may serve as a warning to healthcare professionals about the risk of infection and the possibility of abandonment. Significant proportions of HIV infections have been reported to occur during PrEP interruption periods (ZUCCHI EM, et al., 2018).

Studies also demonstrate that PrEP discontinuation may be associated with geographical factors, stigma, and low perception of HIV infection risk (BARBOSA LCA, et al., 2022; CALABRESE SK, et al., 2020; GOMES NL e LOPES CS, 2019; SULLIVAN PS, et al., 2019). The decentralization of the service may allow residents of non-central areas to access prophylaxis; however, as mentioned earlier, the city of Santa Maria still faces some challenges.

Stigma has been described as a critical factor hindering interest, acceptance, and continuation of prophylaxis (CALABRESE SK, et al., 2020). Therefore, it is important to actively search for and be attentive to the reasons users discontinue PrEP use, and collectively, to train healthcare professionals to provide the best possible support to all individuals seeking the service. Healthcare professionals' attitudes directly influence the decision to adhere to prophylaxis, thus they can either represent a barrier or a facilitator to PrEP access (HOAGLAND B, et al., 2017; OKEKE NL, et al., 2021; THONGSUTT T, et al., 2022; ZUCCHI EM, et al., 2018).

Given this, new research on the topic is essential for developing more effective strategies that improve adherence and expand PrEP services. Additionally, such research allows for understanding the reasons that lead users to discontinue prophylaxis, which enables the restructuring of services and the ongoing education of professionals in the field.

## CONCLUSION

This study demonstrates that there was no change in the sociodemographic profile of PrEP users after expanding access to the entire population at increased risk of HIV infection. However, there was an increase in PrEP users in the age group of 40 to 49 years and among those with 4 to 7 years of education following the expansion of the service, however, key priority groups such as transgender individuals and sex workers, as well as other populations (who do not fall into the priority categories), seem to continue having the same access conditions to PrEP. This study highlights the access of incarcerated populations to PrEP and the increasing rate of prophylaxis discontinuation, which exceeded 50% after the service was expanded to the broader population. It is evident that healthcare professionals can have a positive impact on adherence to and continuity of PrEP, and that new strategies are necessary to reach other populations, particularly key priority groups, those with low educational levels, and residents of peripheral regions; new research is important for this.

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