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**Rodrigo Augusto Mastrella Curado Fleury**  
Evangelical University of Goiás -  
UniEVANGÉLICA, Anápolis, Goiás,  
Brazil

**Helena Diniz Matos**  
Evangelical University of Goiás -  
UniEVANGÉLICA, Anápolis, Goiás,  
Brazil

**Beatriz Rodrigues Torres**  
Evangelical University of Goiás -  
UniEVANGÉLICA, Anápolis, Goiás,  
Brazil

**Ana Vitória Resende Brito**  
Evangelical University of Goiás -  
UniEVANGÉLICA, Anápolis, Goiás,  
Brazil

**Anna Victoria Gonçalves Martins**  
Evangelical University of Goiás -  
UniEVANGÉLICA, Anápolis, Goiás,  
Brazil

**Marcelo Cecílio Daher**  
Evangelical University of Goiás -  
UniEVANGÉLICA, Anápolis, Goiás,  
Brazil

**Osmar Nascimento Silva**  
Evangelical University of Goiás -  
UniEVANGÉLICA, Anápolis, Goiás,  
Brazil

**Edvande Xavier dos Santos Filho**  
Academic Institute of Health and  
Biological Sciences, State University  
of Goiás, Itumbiara, Goiás, Brazil

**Emerith Mayra Hungria Pinto**  
a) Evangelical University of Goiás -  
UniEVANGÉLICA, Anápolis, Goiás,  
Brazil  
b) Academic Institute of Health and  
Biological Sciences, State University  
of Goiás, Itumbiara, Goiás, Brazil  
c) Federal University of Grande  
Dourados, Dourados, Mato Grosso do  
Sul, Brazil

**Corresponding Author:**  
**Emerith Mayra Hungria Pinto**  
a) Evangelical University of Goiás -  
UniEVANGÉLICA, Anápolis, Goiás,  
Brazil  
b) Academic Institute of Health and  
Biological Sciences, State University  
of Goiás, Itumbiara, Goiás, Brazil  
c) Federal University of Grande  
Dourados, Dourados, Mato Grosso do  
Sul, Brazil

## Socioepidemiological and clinical profile of pre-exposure prophylaxis (PrEP) users for HIV: an assessment of adverse effects, drug interactions, and sexually transmitted infections (STIs) incidence

**Rodrigo Augusto Mastrella Curado Fleury, Helena Diniz Matos, Beatriz Rodrigues Torres, Ana Vitória Resende Brito, Anna Victoria Gonçalves Martins, Marcelo Cecílio Daher, Osmar Nascimento Silva, Edvande Xavier dos Santos Filho and Emerith Mayra Hungria Pinto**

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### Abstract

Pre-Exposure Prophylaxis (PrEP) for HIV is a preventive strategy that involves administering antiretroviral medications to individuals at risk of human immunodeficiency virus (HIV) infection before exposure. This study aimed to assess the socioepidemiological and clinical profile of PrEP users, focusing on investigating adverse effects, drug interactions and the emergence of Sexually Transmitted Infections (STIs). Homosexuals, men who have sex with men (MSM), people who use drugs, sex workers, transgender people and HIV serodiscordant couples were the priority population segments for the use of PrEP. The objective was to identify the profile of users of Pre-Exposure Prophylaxis (PrEP) to HIV in the city of Anápolis, Goiás, Brazil. This is a retrospective quantitative descriptive study carried out in a reference unit in Sexually Transmitted Infections (STIs) at Anápolis, Goiás, Brazil, on coinfections, adverse effects and drug interactions. From 319 records analyzed, 84% were male (n=269), with mean age of 33 years and 62% (n=199) declared themselves to be men who have sex with men (MSM) and we observed a sparse number of transsexual individuals (n=2) using PrEP during the study period. Most PrEP users had an elevated level of education and were single. The presence of STIs was observed in 31.6%, with a predominance of syphilis (98%). In most users, no adverse effects were observed, and no drug interactions were detected between PrEP and other drugs used, data bolstering the safety of PrEP. Thus, results collaborated to identify groups less assisted by this approach and it is expected to favor the implementation of public policies that improve the reception of these groups. In addition, it is reinforced the need for actions to reduce the number of STIs among PrEP users.

**Keywords:** Chhani, consumption, fuel-wood, households, Lanchaan

### Introduction

Globally, approximately 37.7 million people were living with HIV and an additional 1.5 million people newly acquired HIV in 2020. Regarding deaths due to diseases associated with acquired immunodeficiency syndrome (AIDS), in 2021, there were about 680,000 deaths worldwide (Govender *et al.*, 2021) <sup>[14]</sup>. In Brazil, there were approximately 11,238 reported deaths in 2022 (Bezerra *et al.* 2020) <sup>[14]</sup>.

According to the Information System for Notifiable Diseases (Sinan) from 2007 until June 2022, approximately 434,803 cases of HIV infection were reported in Brazil. The distribution by region was as follows: 183,901 (42.3%) in the Southeast, 89,988 (20.7%) in the Northeast, 84,242 (19.4%) in the South, 42,957 (9.9%) in the North, and 33,715 (7.7%) in the Midwest. Among these cases, approximately 305,197 were in men and 129,473 in women, with 102,869 (23.7%) cases reported in young individuals aged 15 to 24 years (Bezerra *et al.* 2022; DE SÁ Pinheiro *et al.* 2022; Batista *et al.* 2023; Aguiar *et al.* 2021) <sup>[1, 8, 3]</sup>. In recent years, new HIV prevention strategies have emerged, with Pre-Exposure Prophylaxis (PrEP) considered one of the most important advances in HIV prevention.

PrEP involves the use of antiretroviral medications in high-risk HIV-negative patients to prevent future HIV infections. This strategy has been adopted by the Unified Health System (SUS) Since 2017, and it involves the daily administration of a single tablet containing Tenofovir Disoproxil Fumarate (TDF) and Emtricitabine, orally (Queiroz *et al.* 2017; Brasil 2022) [27, 5]. The PrEP has proven to be effective and safe for individuals at high risk, with HIV protection greater than 90% among those with high rates of medication compliance (Chou *et al.* 2019) [7]. It is one of the strategies of combined HIV prevention, which involves the integration of various actions for prophylaxis against sexually transmitted infections (STIs), HIV, and associated factors (Sousa *et al.* 2021) [30].

Despite the benefits provided by the use of PrEP and Brazil's quantitative progress in terms of the number of individuals served and the availability of PrEP through the Unified Health System (SUS) (Luz *et al.*, 2018) [21], there are still obstacles to the effective implementation and coverage of susceptible populations. Issues such as prejudice against gender identities, structural factors such as low income, gender-based treatment disparities and the illegality of sex work hinder the broader establishment of PrEP (Syvertsen *et al.*, 2014) [31]. Furthermore, there are barriers that involve health professionals, such as a lack of knowledge about PrEP and when to prescribe it, as well as concerns about the clinical and laboratory monitoring of users (Lamônica *et al.*, 2023) [20].

The regional characterization of PrEP users aims to assess the extent to which this HIV prophylaxis measure reaches populations considered most vulnerable to infection. Additionally, it seeks to identify possible gaps in the information provided to the population, allowing the implementation or improvement of targeted actions to increase adherence to the prophylactic regimen. Thus, the present study was carried out with the objective of identifying the socioepidemiological and clinical profile of PrEP users from the municipality of Anápolis, Goiás, Brazil.

## Methodology

### Study Design

This is a retrospective quantitative descriptive study conducted at a reference unit for Sexually Transmitted Infections, Dr. Ilion Fleury Jr. Health Unit in the City of Anápolis, Goiás State (398.869 inhabitants – IBGE 2022).

### Study Population and Sampling

This research was conducted at the Dr. Ilion Fleury Jr. Health Unit in the municipality of Anápolis, GO. Medical records and patient follow-up forms of individuals who used PrEP were analyzed for a period of five years, from 2017 to 2021. All medical records and follow-up forms were included in a convenience sampling, sorted in alphabetical order, resulting in a total of 319 records/follow-up forms evaluated.

### Data Collection

The present study was conducted through the review of follow-up forms and medical records of participants who were users of Pre-Exposure Prophylaxis (PrEP). Socioepidemiological information was collected, including data on gender, age, race/ethnicity, education level, city of residence, marital status, reasons for seeking PrEP, number

of sexual partners in the last 3 months, condom use, and use of abuse substance.

Additionally, information regarding adverse effects related to PrEP, particularly renal toxicity, was obtained. These effects were analyzed based on data from the laboratory evaluations conducted during PrEP follow-up, specifically focusing on urea and creatinine levels.

The review of follow-up forms also allowed for the assessment of the occurrence of Sexually Transmitted Infections (STIs) during the use of PrEP. The following STIs were investigated based on the results of laboratory tests during follow-up: rapid test (TR) for the detection of specific antibodies for HIV-1 and HIV-2 using Double Perforation Immunochromatography; Non-Treponemal Test (Venereal Disease Research VDRL) for syphilis using the Flocculation method; anti-HCV using Immunochromatography Lateral Flow Test for detecting hepatitis C virus infection; detection of Hepatitis B surface antigen (HBsAg) using Immunochromatography Lateral Flow, viral core antigen (Anti-HBc) using Chemiluminescence, and anti-Hepatitis B surface antigen antibody (Anti-HBs) using Enzyme Immunoassay (Elisa) for detecting hepatitis B virus infection. Other STIs such as gonorrhea and chlamydia were also evaluated.

In the follow-up forms and medical records, a survey of other medications used by the participants was conducted. Subsequently, a review of potential drug interactions was performed using the 'HIV Drugs Interactions' platform from the University of Liverpool.

### Ethical Aspects

This study was conducted based on the ethical principles and guidelines of Resolution 466/12 and ensures the protection of the participants' rights, as well as the privacy and confidentiality of data. The study was approved by the Research Ethics Committee of the Universidade Evangélica de Goiás - UniEVANGÉLICA (protocol number: 5,786.642).

### Data Analysis

The information obtained from medical records and monitoring forms, including socio-epidemiological data, was collected and analyzed using statistical software packages (Microsoft Office Excel 2016), and mean and frequency calculations were performed. Therefore, this study used descriptive analysis to identify the main characteristics of individuals related to the use of PrEP.

### Results

A total of 319 medical records and monitoring forms of PrEP users were analyzed for the period between 2017 and 2021. The average use of PrEP was 29 months, with a minimum duration of 1 month and a maximum of 60 months. Of the 319 patients, 84% (n=269) were male, and 16% (n=50) were female. Most patients self-identified as white, representing 52% (n=168). Specifically, 44% (n=142) were white males, 8% (n=26) were white females, and 18% (n=58) were of mixed race. Of the records analyzed, 36% (n=116) were from PrEP users with an undergraduate degree and 40% (n=129) had completed high school.

The average age of users in the period evaluated was 33 years old, with a minimum of 19 years and a maximum of 70 years. Most of PrEP users, 95.6% (n=305), were from Anápolis/GO, while 4.4% were from nearby cities.

Regarding marital status, 71% (n=226) of users were single, while 14% (n=45) identified as married.

Regarding the classification of risk groups, 62% (n=199) were men who have sex with men (MSM) and 22% (n=70) were serodiscordant couples. In addition to these, 1.2% (n=4) were sex workers, 0.6% (n=2) were transgender individuals, with 1 individual declaring himself simultaneously as transgender and a sex worker. Finally, 1.2% (n=4) declared themselves bisexual, while 0.9% (n=3) were heterosexual, and information on sexual orientation was not provided in 12% (n=38) of the records.

The analysis of the reasons for seeking PrEP indicated that 41.7% (n=132) sought it by their own decision, 21.9% (n=70) due to serodiscordance with their partner, 9.7% (n=31) after doing rapid test (RT) and were considered eligible, 4.3% (n=14) were referred by a health professional, 3.8% (n=12) started using PrEP after a situation of possible exposure to the virus, 3.1% (n=10) showed risky behavior, 0.9% (n=3) were transferred from another health unit, 0.6% (n=2) after searching for information, 0.6% (n=2) were influenced by the internet and, finally, 0.6% (n=2) were considered candidates for PrEP after using PEP (Post-Exposure Prophylaxis). Furthermore, 12.5% (n=40) of patients did not have this information recorded in their medical records.

Regarding the time of use of PrEP, 39.5% (n=126) of users used it for a period of up to 6 months. In addition to these, 26% (n=83) used PrEP between 6 months and one year, 16.3% (n=52) between one and two years and 14.4% (n=46) used it for more than 2 years. In 3.8% (n=12) of the records this information was not available. Table 1 describes the sociodemographic data of the study group.

**Table 1.** Socio-epidemiological characteristics of PrEP users treated at a reference center in Anápolis, Goiás, Brazil, from 2017 to 2021 (n=319).

	Number (n)	Percentage (%)
<b>Sex</b>		
Male	269	84
Female	50	16
<b>Age (years)</b>		
19–40	259	81
41–59	57	18
>60	3	1
<b>Education level</b>		
College education	116	36
High school	129	40
Elementary School	10	3
Technical education	1	0.3
Uninformed	63	19.7
<b>Marital status</b>		
not married	226	71
married/cohabitation	45	14
divorce	3	1
Other (widow)	1	0.3
Uninformed	44	13.7
<b>Group</b>		
Men who have sex with men (MSM)	199	62
Heterosexual	3	1
Bisexual	4	1.2
Transsexual	2	0.6
Sex worker	4	1.2
Serodiscordant couple	70	22
Uninformed	38	12
Total	319	100

### Presence of sexually transmitted infections (STIs), sexual partners, and condom use during use of PrEP

Based on the data from outpatient follow-up, among the 319 PrEP users analyzed, 31.66% (101/319) presented STIs. The majority (86.13%, 87/101) of patients with STIs were male. The most frequent STI was syphilis (98.01%, 99/101), followed by hepatitis C (1.98%, 2/101), and hepatitis B (0.99%, 1/101). There were no cases of HIV seroconversion among the analyzed users.

Among the PrEP users who presented syphilis (n=99), the majority were male (n=87), and the average age was 32 years. Additionally, the mean number of sexual partners was 4.7 individuals, with the vast majority being homosexual, representing 64.64% (64/99).

Regarding the number of sexual partners during the use of PrEP, information was available in 125 of the analyzed medical records. Among the users, 0.3% (n=1) had no partners at the time of data collection, 29.2% (n=93) had between one and two partners, 2.8% (n=9) had between three and four partners, 1.9% (n=6) had between five and six partners, 1.6% (n=5) had between seven and eight partners, and 3.4% (n=11) had ten or more partners.

Finally, data related to condom use were available in 82 medical records, with 10.3% (n=33) of participants always using condoms when having sex with someone, 5.3% (n=17) using condoms more often than not. half of the time, 1.6% (n=5) use a condom half of the time, 1.6% (n=5) use a condom less than half of the time and 6.9% (n=22) do not use a condom at all no circumstances.

### Characterization of adverse effects and drug interactions

Among the 319 medical records analyzed, the results of the urea level were available for 273 users. The average urea level was 28.74 mg/dL. Only 3 (0.94%, 3/319) users had values slightly above the normal range, with 2 having a value of 47 mg/dL, and 1 having a value of 50 mg/dL. Regarding the creatinine level, the results were available for 273 medical records. The mean creatinine level was 1.08 mg/dL. Only 7 patients (2.19%, 7/319) displayed creatinine values above the normal range, with values ranging from 1.41 to 1.52 mg/dL. The average time of PrEP use among these users with available urea and creatinine levels was 15 months.

Regarding the use of substances of abuse, 90.5% (n=289) of the records did not indicate the use of any substance, while 9.5% (n=30) mentioned the simultaneous use of one or more substances, including alcohol, tobacco, marijuana, club drugs (such as ketamine, ecstasy, LSD, GHB, bath salts) and anabolic steroids.

Regarding adverse effects, in 96.5% (n=308) of the records there was no report of adverse effects, while 3.5% (n=11) of users mentioned having experienced some adverse effect. Reported adverse effects included headache, renal colic, gastric discomfort, diarrhea, sore throat, urinary tract infection, myalgia, edema, and thrombocytopenia.

Regarding the concomitant use of other medications, 93.1% (n=297) of the records did not mention the concomitant use of medications during PrEP. Analysis of the remaining 6.9% (n=22) of the medical records revealed the use of other medications or supplements, including creatine (n=5), penicillin (n=10), allopurinol (n=1), iron and vitamin D (n=1), anabolic steroids (n=1), bupropion (n=1), contraceptive (n=1), sildenafil (n=1), fluoxetine (n=1) and amfepramone (n=1). None of the medications, vitamins or



supplements mentioned showed potential for drug interactions, based on the literature and the HIV drugs interactions platform.

### Discussion

The profile of PrEP users was predominantly men, self-declared white, belonging to the MSM risk group, with a high level of education and an average age of 33 years. This profile is consistent with the observations made by Moussa and Cavalli in their study, which analyzed the profile of PrEP users in Brazil from 2016 to 2021. Their study indicated that of a total of 22,000 PrEP users, approximately 18,960 were MSM and 12,841 (56.34%) of users were white (Moussa; Cavalli, 2022) [23]. Furthermore, two other studies carried out in Brazil provided comparable results, reporting percentages predominantly for males above 92%, MSM above 78% and white individuals above 71% (Pereira *et al.* 2021) [25].

Regarding to education level, it was observed that most of the population seeking PrEP has undergraduate degree or high school, indicating good education and the importance of providing information that enables a better quality of life for individuals (Santana *et al.* 2021; De Sousa *et al.* 2022) [28-29, 9]. However, not all studies emphasize that education is a crucial parameter, as there are individuals with higher education who may not be aware of this preventive measure. Therefore, it is evident that there is a lack of information at all levels of education when it comes to HIV prophylaxis measures (Mantovanelli *et al.* 2021) [22].

We showed that much of the population used prophylaxis for a period of up to 6 months, while a minority used it for more than 2 consecutive years. The duration of PrEP use is recommended as long as there is a risk context for acquiring HIV and should be interrupted in case of a positive test for HIV and/or creatinine clearance below 60 mL/min (Pimenta *et al.* 2022; Moussa; Cavalli, 2022) [26, 23]. If there is a risk situation, it is essential to encourage adherence to the use of PrEP. Factors associated with low adherence involve a lack of understanding and awareness about the use of PrEP, highlighting the need for greater support and guidance throughout treatment (Frankis *et al.* 2016; John *et al.* 2017) [12, 17].

Individuals who declared themselves as transsexuals (n=2) constituted the minority group in our study, indicating that strategies should be targeted to this group. (Zohar *et al.* 2021; Zucchi *et al.* 2018) [33-34]. The high prevalence of syphilis found in our study reflects the inconsistent use of condoms and other measures to prevent sexually transmitted infections (STIs). Other studies also reported syphilis as a predominant STI in PrEP users (Hart *et al.* 2023; Fernandes *et al.* 2015) [16, 11]. Understanding the factors associated with syphilis prevalence can help healthcare professionals to promptly implement syphilis treatment in PrEP users. Additionally, other studies indicate that PrEP users are at a higher risk of syphilis infection compared to the general population. (Varshney *et al.* 2022) [32]. In this sense, the education factor contradicted the results found, since users who were infected with syphilis had completed secondary or higher education.

Haberer and colleagues (Haberer *et al.* 2023) [15] suggest a shift in condom use before and after starting PrEP. It is possible to infer that a significant proportion of individuals who start PrEP experience a change in their sexual behavior. Before starting the prophylactic regimen, many participants

seem concerned about the possibility of HIV infection, leading them to use protective methods during sexual intercourse. However, after starting PrEP, there is a reduction in concern about acquiring infections among many individuals. In our study, a minority of users indicated regular use of condoms during sexual intercourse, even though many had multiple sexual partners.

Few adverse effects were identified among PrEP users in our study and when present, it was of low intensity. Furthermore, no drug interactions were found. These results suggest that adverse effects did not significantly affect PrEP adherence and reinforce the safety of PrEP. Other studies also confirm the safety of PrEP, even in patients with hepatitis B. Unexpected and potentially serious adverse effects are mainly associated with chemsex users (Kibengo *et al.* 2013; Nascimento 2011) [19, 24]. More serious adverse effects are linked to long-term use, including loss of bone mineral density and kidney damage (Ascher *et al.* 2020; Chang *et al.* 2022) [2, 6].

### Conclusion

In this study, most participants declared themselves to be white, with an average age of 33 years old and having completed high school to higher education, being mainly men who have sex with other men. However, it was observed that in other groups considered to be at high risk, such as transsexuals, sex workers and couples, serodiscordant patients require greater attention from health professionals and local health authorities.

No serious adverse effects or drug interactions were observed, a fact that reinforces the safety of PrEP. However, a high percentage of syphilis was observed among PrEP users.

It is essential that government actions are expanded, including awareness and education campaigns on the topic, so that this prophylaxis measure reaches more people, especially those considered at greater risk and who receive less assistance, such as transsexuals.

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### Declaration of interest statement

Authors report no declarations of interest.

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