

Original Article

Adherence to HIV post-exposure prophylaxis in a specialized service in São Paulo, BrazilMarcos Morais Santos Silva¹, Luciane Simões Duarte², Lucia Yasuko Izumi Nichiata¹¹ Public Health Nursing Department, School of Nursing, University of São Paulo, São Paulo, Brazil² Chronic Noncommunicable Diseases, Division of Disease Control Coordination of São Paulo State Department of Health, São Paulo, Brazil**Abstract**

Introduction: The effectiveness of human immunodeficiency virus (HIV) post-exposure prophylaxis (PEP) depends on adherence to the protocol, which includes taking antiretrovirals (ARVs) and attending visits. We examined the adherence rate to antiretroviral agents and follow-up visits identifying the associated characteristics of adherence and the reasons for not attending HIV PEP consultations in a specialized service in São Paulo, Brazil.

Methodology: This was a cross-sectional study with health service users who had an indication for PEP due to sexual exposure in an HIV/AIDS service from April to October 2019. The health service users were followed-up throughout the prophylaxis cycle. Adherence was determined through self-reports on antiretroviral agent use and attendance to follow-up consultations.

Results: Association measures were employed to identify adherence-related characteristics. The sample analyzed included 91 users. The mean age was 32.5 years old (SD = 9.8). The largest share was white-skinned (49.5%), men who have sex with other men (62.2%), male (86.8%), and undergraduate/graduate students (65.9%). Adherence totaled 56.7% and health insurance was the associated characteristic ($p = 0.039$). Work (55.9%), using a private service (15.2%), forgetfulness (11.8%) and considering follow-up unnecessary (11.8%) were the main reasons for not attending the follow-up appointments.

Conclusions: Few users do attend HIV PEP consultations. The users without health insurance had the highest adherence percentage whereas work was mentioned as a reason for not attending HIV PEP consultations.

Key words: HIV; medication; adherence; post-exposure prophylaxis; anti-retroviral agents.

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Introduction

This study focused on a globally indicated measure – post-exposure prophylaxis (PEP) for risk exposure to human immunodeficiency virus (HIV) infection, which includes the use of antiretroviral agents (ARVs) for 28 days, starting up to 72 hours from exposure to the virus [1]. This prophylaxis reduces the risk of HIV infection [2]; however, its efficacy depends on adherence to proper medication use, early initiation after exposure, and non-exposure to risks of HIV infection [3-5].

In addition to taking ARVs for the indicated time, the World Health Organization (WHO) recommends monitoring the healthcare user for three months after PEP is initiated [6], with the objective of maintaining guidance on prevention and performing follow-up tests.

Decades after PEP started to be used, medication use in different ARV regimens is well-understood, as are their respective side-effects [7,8]. However, there is scarcity of research studies monitoring healthcare users

throughout PEP, i.e., focusing not only on adherence to medication use, but also on the follow-up protocol. Furthermore, not much is known about non-adherence to ARVs and the reasons for insufficient follow-up [9].

The implementation of HIV/AIDS prevention measures such as PEP is a crucial challenge in Brazil, which had a mean of 368,000 new cases of this disease per year in the last five years [10], even though prophylaxis was implemented more than two decades ago in the Brazilian Unified Health System (Sistema Único de Saúde, SUS) [11]. In Brazil, the SUS is a public healthcare system which provides free, universal and comprehensive access to all individuals and, therefore, PEP is provided free of charge. The Brazilian Clinical Protocol and Therapeutic Guidelines (Protocolo Clínico e Diretrizes Terapêuticas, PCDT) recommend ARV use, a first visit, and two follow-up visits on the 30th and 90th days after PEP is initiated [11]. These follow-up visits enable health professionals

to provide counseling on the risk of infection with HIV and other sexually transmitted infections (STIs), in addition to monitoring adherence and performing tests to identify infections [11,12].

Worldwide, there are not many studies assessing adherence to medication among users who did not return for follow-up visits. In Brazil, there are few studies on adherence to PEP, in which it was investigated in restricted groups, such as women or men who have sex with other men (MSMs) [13,14], or whose study loci were health services in general, not those specialized in HIV/AIDS care [15]. Thus, the objective of this study was to examine the adherence rate to antiretroviral agents and follow-up visits, as well as to identify the associated characteristics of adherence and the reasons why users do not attend PEP visits in a specialized service in São Paulo, Brazil.

Methodology

Study design

This was a cross-sectional study.

Population

The study population comprised all healthcare users of an HIV/AIDS specialized facility who had an indication for PEP after sexual exposure during the period from April 1st to July 30th, 2019. The study was conducted in an HIV/AIDS specialized facility located in the central region of São Paulo city which provides treatment to people living with HIV (PLHIV), as well as PEP and HIV Pre-Exposure Prophylaxis (PrEP). It is located in an area marked by high social vulnerability, with deteriorated tenements, street people, prostitution and concentration of drug users, and has the highest HIV detection rate (DR) in São Paulo city: 74.9 new cases for every 100,000 citizens [16,17]. All individuals aged eighteen or more with an indication for PEP were included. Those who had an indication for PEP for sexual aggression or occupational reasons were excluded. They were not included due to the fact that most of such cases were monitored in specific facilities, namely: occupational exposure, in the patient's health institution; or exposure to sexual aggression, in reference facilities for sexual aggression victims. During the study, 97 health facility users had an indication for PEP, but 6 refused to participate in the study for allegedly being late for work. Thus, the final sample consisted of 91 users. The study assessed all the health facility users who had an indication for PEP during the data collection period and, therefore, probability sampling of this population was not performed.

Data collection

The study followed the Brazilian PCDT, which consists of one visit on the day PEP is provided and two follow-up consultations [11]. Thus, the study monitored the patients in their first visit, called Moment 0, and at both follow-up appointments, 30 days after PEP was initiated (Moment 1) and 90 days after PEP was initiated (Moment 2).

The users' data were collected at Moment 0, Moment 1 and Moment 2. Moment 0 lasted from April 1st to July 30th, 2019, when the users were included in the study. Subsequently, the users were monitored at Moment 1, from May 1st to August 30th, 2019, and at Moment 2, from July 1st to October 30th, 2019. Thus, the data collection period comprised the full protocol of visits/follow-up appointments for all users included at Moment 0.

The data were collected in the health facility by the main researcher through two types of contact: face to face interview, in a private room; and medical records, only at Moments 1 and 2, when the main researcher was absent. For the individuals who did not return to the health facility at Moments 1 and 2, the same form that was used in person was applied over the telephone with an additional question on the reasons for not returning to the health facility.

A structured form prepared by the researchers and that required an average of 30 minutes at Moment 0 and 10 minutes at Moments 1 and 2 was applied. At Moment 0, the instrument contained questions referring to sociodemographic characteristics, PEP and the risk of HIV infection. The questions about sociodemographic characteristics were not provided at the other study moments.

The dependent variable, adherence to PEP, was assessed based on the "Number of days on which the medication was taken" condition, whose answer was a number of days from 1 to 28, and based on the user's presence in at least one follow-up visit. Adherence to PEP was a dichotomous variable (adherence or non-adherence). Adherence was defined as complying with 23 to 28 days of prophylaxis and returning at least once to the health service at Moment 1 or Moment 2. Although there is no consensus in the literature of a criterion for PEP adherence, the reference adopted was a study that assessed adherence based on whether the users took 23 to 28 of the pills provided when PEP was initiated [3]. Adherence to follow-up visits was defined as being present in at least one of both follow-up appointments suggested by the Brazilian PEP PCPT [11]. As the adherence criterion includes ARV use and returning for at least one visit (Moment 1 or 2), the users

with lost information in one of the visits were not excluded. Non-adherence was defined as the cases in which the users did not meet this criterion. The independent variables of the form were related to sociodemographic characteristics, PEP and risk of HIV infection.

Data analysis and treatment

The dependent variable, adherence to PEP, and the independent variables, sociodemographic characteristics, PEP and risk of HIV infection, were presented through descriptive and analytic analysis. In the descriptive analysis, the distribution of absolute and relative frequencies was presented, as well as central tendency measures, to describe the quantitative variables. In the analytic phase, a univariate analysis was conducted employing Chi-square and Fisher's exact test between all the independent variables and the dependent one. Variables with $p < 0.05$ were considered statistically significant. The data were analyzed using STATA (Statistics/Data analysis), version 15.

Ethical aspects

This study was approved by the Research Ethics Committee (Comitê de Ética em Pesquisa, CEP) of the Nursing School at the University of São Paulo (Escola de Enfermagem da Universidade de São Paulo, EEUSP) under Opinion no. 3,167,045 and CAAE: 06245519.6.0000.5392, on 02/25/2019, and by the CEP of the São Paulo Municipal Health Department, under Opinion no. 3,180,010, and CAAE: 06245519.6.3001.0086, on 03/01/2019, abiding by Resolution no. 466/12 of the Brazilian National Health Council, which approves guidelines and norms on research involving human subjects. Before the interviews, all users included in this study were asked to provide their formal consent and sign the Informed Consent Form (ICF).

Results

Characteristics of the sample at Moment 0

When PEP was initiated, the mean age of the participants was 32.5 years (SD = 9.8). The largest share of users were male (86.8%), MSM (62.2%), white-skinned (49.5%) and undergraduate/ graduate students (65.9%). Most of them (84.6%) were working at that time: They were involved in management, in areas such as planning and organization (28.5%) or working as entrepreneurs, in direction and management (16.9%); and 13% were sex workers. More than half (69.2%) had no health insurance (Table 1).

Table 1. Characterization of the users according to sociodemographic variables, HIV post-exposure prophylaxis, and risk of HIV infection at Moment 0. São Paulo, 2019.

Variable	n
Sociodemographic characteristics	
Gender	
Male	79 (86.8)
Female	12 (13.2)
Age (years)	
15-24	19 (20.9)
25-44	59 (64.8)
≥ 45	13 (14.3)
Mean (SD)	32.5 (9.8)
Self-reported skin color	
White	45 (49.4)
Black	12 (13.2)
Brown	32 (35.2)
Asian/indigenous	2 (2.2)
Education	
Elementary/high school	31 (34.1)
Higher education/graduate studies	60 (65.9)
Sexual orientation¹	
Heterosexual	23 (25.6)
Man who has sex with other men	56 (62.2)
Bisexual	11 (12.2)
Occupation - currently working	
No	14 (15.4)
Yes	77 (84.6)
Occupation	
Sex worker	10 (13.0)
Planning and organization	22 (28.5)
Entrepreneur, direction and management	13 (16.9)
Not qualified for the job	11 (14.3)
Partially qualified for the job	6 (7.8)
Qualified for the job	10 (13.0)
General services	4 (5.2)
Unemployed/receiving support	1 (1.3)
Covered by health insurance	
No	53 (69.2)
Yes	24 (30.8)
Has a religious belief	
No	30 (33.0)
Yes	61 (67.0)
HIV Post-Exposure Prophylaxis	
How information on PEP was obtained ¹	
Health team	18 (22.8)
PEP advertisement	15 (19.0)
Sought information about PEP	20 (25.3)
Friends	26 (32.9)
How many times the person has used PEP¹	
1	52 (57.1)
2	23 (25.3)
≥ 3	16 (17.6)
Mean (SD) for those who used PEP more than once	1.8 (0.2)
Side-effects	
No	36 (53.8)
Yes	31 (46.2)
Sexual practice which indicated PEP¹	
Anal or vaginal	70 (93.3)
Oral	5 (6.7)
Risk of HIV infection	
Currently using drugs	
No	58 (63.7)
Yes	33 (36.3)
Time since last exposure to HIV (hours)	
≤ 24	44 (48.3)
25-48	30 (33.0)
49-72	17 (18.7)
Condom use during sexual relations	
No	19 (20.9)
Yes	72 (79.1)
Had access to condoms last year	
No	-
Yes	91 (100.0)
Health service providing condoms	
Public	12 (13.2)
Bought at a drugstore	36 (39.6)
Public or bought at a drugstore	43 (47.2)

¹ Information was not obtained from all users.

PEP was taken two or more times by 42.9%. Almost half had initiated PEP ≤ 24 hours (48.3%) and almost all (93.3%) reported anal or vaginal practice in the exposure for which PEP was indicated (Table 1). Regarding the risks of HIV infection, when PEP was initiated, 36.3% were drug users and 20.9% did not use condoms in their sexual relations. The users received information about PEP from friends (32.9%) or the health team (22.8%) and 46.2% had some side-effect when using the ARVs (Table 1). The most common effects were nausea (48.4%), followed by diarrhea (32.2%) and sleepiness (22.6%) (data not presented in the tables).

PEP follow-up at Moments 1 and 2

Figure 1 presents the follow-up of the users who had an indication for PEP. Among the users who returned for Moment 1, 20 reported that they would not continue PEP for the following reasons: 12 reported having initiated pre-exposure prophylaxis (PrEP) and 8 reported a new exposure instance and having initiated a new PEP protocol. Thus, the sample for Moment 2 comprised 71 users (Figure 1).

ARV use at Moment 1

In relation to ARV use, information was obtained from 67 users due to follow-up losses for the following reasons: 21 did not return at any moment and the attempted telephone contacts were unsuccessful; 3 returned, but the researcher was absent, and the health professional responsible for the visit did not record the information on medication use in the medical charts and the attempted telephone contacts were unsuccessful.

Of all 67 individuals with whom contact was possible, 66 reported having used the medication for 27

days and only 1 user used it for 4 days (data not presented in the tables).

Adherence

In relation to adherence to PEP, 66 users used prophylaxis for 23 to 28 days and, among them, 41 returned at Moment 1 or at Moment 2. Of 41 users, the data for 3 were missing, totaling 38 users whose data were available. Therefore, adherence totaled 56.7% according to the criterion adopted in this study – users taking 23 to 28 days of prophylaxis (not missing more than 5 doses) and returning at least once to the health facility.

Characteristics associated with adherence

The most frequently reported reasons for not returning at Moments 1 and 2 were as follows: work (55.9%), reported intention of moving to a private facility (15.2%), forgetfulness (11.8%), considering follow-up unnecessary (11.8%), distance between home and health service (6.0%), and need to commute (5.9%) (data not presented in the tables).

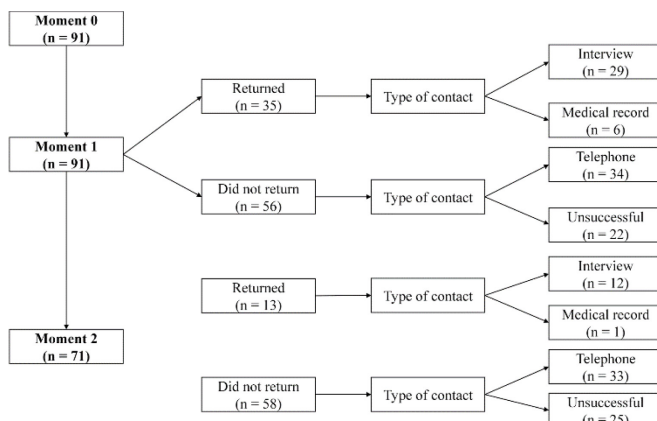
In the association analysis of adherence, only the “health insurance” variable was significantly associated with adherence to the Brazilian PEP protocol ($p = 0.039$ – Table 2). In the analysis, people who had private health insurance presented a lower percentage of adherence to PEP.

Discussion

The objective of this study was to examine the adherence rate to ARV and follow-up visits according to the Brazilian PEP protocol, in addition to identifying characteristics associated with adherence and the reasons why users did not attend the visits. The results indicate that most users take the medication but few return for the follow-up appointments suggested by the protocol.

Although slightly more than half of the users adhered to PEP, it should be noted that most studies consider adherence to PEP to be only medication use and do not include returning to meet the follow-up protocol as an adherence criterion [18]. Even so, the results regarding adherence are similar [18]. In this study, almost all the users that returned reported having taken the ARV. This result is also true for users that did not return and with whom the telephone contacts were successful, indicating that people who do not return to the service might be taking the medication. Literature reviews that assessed adherence to ARV have found variations between 40.3% – 48.1% and 68% – 87% [9,19]. Regarding return visits for follow-up

Figure 1. Follow-up of users who had an indication for PEP according to the Brazilian protocol at Moments 1 and 2. São Paulo 2019.



appointments, a literature review assessing longitudinal studies has pointed out that 41.2% of the patients did not return for follow-up consultations [9].

Since the health facility does not track missing users, having an open channel – through telephone or apps – for three months might be relevant to collect

Table 2. Association between sociodemographic variables and adherence to PEP during the 3-month follow-up protocol. São Paulo, 2019.

Variables	Adherence				p
	No n = 29	%	Yes n = 38	%	
Sociodemographic characteristics					
Gender²					
Male	26	89.7	35	92.1	1.000
Female	3	10.3	3	7.9	
Age²					
15-24	5	17.2	7	18.4	1.000
25-44	20	69.0	25	65.8	
≥ 45	4	13.8	6	15.8	
Self-reported skin color¹					
White	16	55.2	19	50.0	0.632
Black	4	13.8	3	7.9	
Brown	9	31.0	15	39.5	
Asian/Indigenous	0	0.0	1	2.6	
Education¹					
Elementary/High School	5	17.2	11	28.9	0.265
Higher Education/Graduate studies	24	82.8	27	71.1	
Sexual orientation^{1,3}					
Man who has sex with other men	20	69.0	23	62.2	0.437
Heterosexual	4	13.8	10	27.0	
Bisexual	5	17.2	4	10.8	
Covered by health insurance¹					
No	11	45.8	24	72.7	0.039
Yes	13	54.2	9	27.3	
Has a religious belief					
No	14	48.3	12	31.6	0.165
Yes	15	51.7	26	68.4	
HIV Post-Exposure Prophylaxis					
How information on PEP was obtained ^{2,1}					
Health team	1	3.6	7	22.6	0.160
PEP advertisement	7	25.0	8	25.8	
Sought information about PEP	8	28.6	8	25.8	
Friends	12	42.8	8	25.8	
How many times the person has used PEP²					
1	16	55.2	24	63.2	0.645
2	11	37.9	10	26.3	
≥ 3	2	6.9	4	10.5	
Sexual practice which indicated PEP^{2,3}					
Anal or vaginal	23	92.0	30	93.7	1.000
Oral	2	8.0	2	6.3	
Side-effects¹					
No	15	51.7	21	55.3	0.773
Yes	14	48.3	17	44.7	
Risk of HIV infection					
Currently using drugs ¹					
No	21	72.4	23	60.5	0.310
Yes	8	27.6	15	39.5	
Condom use during sexual relations ¹					
No	5	17.2	8	21.0	0.696
Yes	24	82.8	30	79.0	
Time since last exposure to HIV (hours) ²					
≤ 24	10	34.5	22	57.9	0.097
25 - 48	11	37.9	12	31.6	
49 - 72	8	27.6	4	10.5	

¹ Chi-square test; ² Fisher's exact test; ³ Information was not obtained from all users.

information on medication use and adverse effects. A study has shown that continuous assessment of adherence, counselling and data collection might be important to enhance adherence and to facilitate a more precise implementation of prevention interventions [19]. Moreover, as many users do not return to the health service due to forgetfulness, sending reminders of visit dates might maintain an open channel and improve tracking of other STIs and protocol adherence [12].

Adherence to PEP was associated with the health insurance variable and the users with no health insurance had the highest adherence percentage. Studies in the United States of America (USA) and Belgium had different results [20,21]. However, unlike these countries, in Brazil both PEP and PEP follow-ups are provided by the SUS free of charge, which might have influenced adherence. A study conducted in Canada and in the USA suggested that medication cost was the main barrier to providing PEP [22]. This shows the relevance of free of charge access to PEP, particularly among low-income individuals, as the HIV infection is highly prevalent among people with less access to education and black-/brown-skinned people [16]. Furthermore, as one of the adherence criteria in the study was returning to the health service, it is possible that individuals with access to health insurance might have had follow-up visits in a private health service.

Although other variables had no statistically significant relation with adherence, the differences among percentages are remarkable. Individuals who initiated PEP \leq 24 hours from exposure had a higher percentage of adherence to PEP. There might be more concerned with the health process among people who seek the service more promptly and are more active in understanding the health-disease process, thus presenting greater adherence to PEP [23]. It is therefore essential that health services be more cautious of users who initiate PEP after 24 hours since, in addition to the importance of adherence, there is a higher percentage of infection among people who start PEP later in time [5].

A higher adherence percentage was also found among users who received information about PEP from health professionals. A detailed explanation of the importance of finishing prophylaxis and support from a PEP specialist might contribute to better adherence [18]. This might be related to factors such as the health professionals' ability to provide more reliable information and more precise counseling regarding the importance of adherence. Therefore, providing information through apps and social networks might be

something to explore, as well as having an open communication channel for individuals to ask health professionals questions on PEP. This is an activity inherent to nursing professionals, who, according to Opinion no. 12/2020/CTAS/COFEN, in Brazil, are responsible for prescribing the ARV used in prophylaxis. In addition, nurses are responsible for monitoring users throughout PEP [24].

Having a religious belief was also indicative of a higher percentage of adherence to PEP. A study has shown that religious belief exerts a positive influence on adherence to antiretroviral therapy (ART) [25]. Although PEP is to be used within a brief period of time when compared to PLHIV medication, medication use might be complex and requires facilitating factors involving matters of life and treatment which, in turn, might be influenced by beliefs.

In this study, side-effects had no association with adherence. A similar result was found in a systematic review [9]. These findings might have been contributed to by ARVs with fewer side-effects and prescriptions of smaller daily doses. It is important that, if possible, health facilities prioritize prescriptions with fewer daily pills and that cause fewer side effects, in order to promote greater adherence [3,26]. In addition, it is essential that health professionals mention the side-effects which might emerge during prophylaxis.

Other variables did not present statistically significant percentages. These included sociodemographic variables, such as gender, age, skin color and schooling. However, other studies have observed that younger, female, less educated and black-skinned users had lower adherence to PEP [3,7,20]. These results might be related to the fact that, in this study, most users who were submitted to PEP were white-skinned and highly educated men.

The profile found in this study leads to question whether black-skinned people, those with low schooling and income levels, and street people have access to health services for HIV/AIDS testing, and particularly where PEP is available, as this is the exact population indicated by the Brazilian Ministry of Health as a priority for preventive actions against HIV/AIDS [11].

This study has several limitations. Firstly, only one health facility was studied and, although this service is one of the main PEP providers, the results may not reflect the reality of the city, particularly of its peripheral areas. Secondly, adherence was assessed through the answers given by the individuals (self-reported). Thirdly, the literature's lack of consensus on adherence criteria hinders comparison of the results,

although the most employed criterion, medication use [3], was adopted, as well as the PCDT criterion, i.e., returning at least once to the health facility [11]. Fourthly, in order to minimize loss of participants, it was decided to collect data from medical records. The use of different collection instruments may lead to information bias; however, the medical records were filled out by specialists in providing and counseling on PEP. Fifth, although the sample was non-probabilistic, which hinders generalization, the study provides findings which may foster changes in health services, with an impact on better adherence to PEP. Finally, the number of participants is small, which may have interfered with the analysis. However, sensitive themes, such as PEP assessment, pose difficulties to inclusion of the participants [9].

More studies should be thus conducted to fill these gaps. On the other hand, this study does have its strengths, as it has assessed adherence to PEP by all users who had an indication for this treatment, sociodemographic antecedents, and general PEP-related issues. In addition, the study population was diversified regarding race, sexual orientation, occupation and schooling, reflecting the local reality of the HIV epidemic [16].

This study indicates points for reflection regarding adherence to PEP. Higher adherence among individuals without health insurance reinforces the idea that PEP must be distributed free of charge. In addition, a higher adherence percentage among individuals who were advised by health professionals indicates a path to improve adherence to PEP. Further research exploring the use of apps to maintain an open communication channel with the users might be important to improve PEP adherence and follow-up.

Conclusions

This study emphasizes the different realities of adherence to PEP in a specialized facility in the central region of São Paulo city. The results indicate that adherence to PEP, regarding medication use, is higher than previously reported in the literature, even for those who did not attend the follow-up visits suggested by the Brazilian protocol. However, adherence was reduced when the follow-up visits were analyzed. Regarding the associated characteristics of adherence, the users without health insurance had the highest adherence percentage whereas work was mentioned as a reason for not attending HIV PEP consultations.

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Corresponding author

Marcos Silva, PhD Student
Public Health Nursing Department, School of Nursing, University of São Paulo,
Avenida Doutor Enéas de Carvalho Aguiar, 419, 05403-000, São Paulo, SP, Brazil.
Tel: +5511 997885724
Email: marcos.moraes.silva@usp.br

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