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Utilization of Post Exposure Prophylaxis among HIV Exposed Health Care Workers and Non Occupational Exposure at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia

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Abstract **Background:** HIV is a major global public health issue, having claimed 38 million lives so far. HIV infection in health care facilities has become a major health problem, especially in resource- poor setting. Health care workers are at risk of many diseases in health setups. There is a small but definite occupational risk of HIV transmission to health care workers. Post exposure prophylaxis is recommended to prevent transmission of pathogens after potential exposure and further development of infection. If started soon after exposure PEP can reduce the risk of HIV infection by over 80%. Although studies have found that awareness of PEP, so far there is no publication assesses utilization practice and subsequent follow up at Tikur Anbessa Specialized Hospital. **Objective:** The objective of this study was to evaluate post-exposure prophylaxis (PEP) utilization among HIV-exposed health care workers and non-occupational exposures.**Methods:** A retrospective cross-sectional study was conducted by reviewing the PEP registry book from January 1, 2017- July 30, 2021 and follow up data is collected by interviewing the exposed case. Data were entered using SPSS version 26 and descriptive analysis was done. **Result:** A total of 353 cases of occupational and non-occupational exposure were reported to the ART clinic; PEP was prescribed for 352 subjects with an average of 77 subjects/year. The mean age of the study participant was 27.3 ±7, the majority (57.2%) was male, Most (86.7%) of the exposure was occupational, 27% of occupational exposure was reported by residents, followed by nurses 26.1%. Of the occupational exposure, 30.4% were from different wards, followed by emergency OPD (17.1%), and operating theater (7. 2%). Of non-occupational exposure, 48.9% of cases were due to sexual assault. Most (42.7%) of the exposure risk type was EC2 code type followed by EC3 code type (37.6%). The source patient HIV status was unknown in 65.9% for non-occupational and 30% for occupational exposure. Two drugs (TDF/3TC) regimen was prescribed for 87.8% of cases. Over 90% of the exposures were reported within 24hrs of the incident, and 45.2% of the exposed cases had an adverse reaction. No sero-conversion was reported.**Conclusion:** At the TASH ART clinic, PEP antiretroviral drugs were prescribed for both occupational and non-occupational HIV exposures. The utilization rate of PEP has been decreasing annually. In TASH, the ART clinic risk assessment and PEP initiation followed the national occupational and non-occupational exposure guidelines. The selection of the regimen was based on a case-by-case analysis, with the two-drug regimen TDF/3TC being the most commonly used. PEP was initiated within 72 hours of exposure. While most cases completed the full PEP regimen, documentation on follow-up and adverse reactions was inadequate.

Keywords: *Post exposure prophylaxis, Occupational, Non-occpational, Healthcare workers, HIV exposure, Tikur Anbessa Hospital*

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1. Introduction

Human immunodeficiency virus (HIV) is an infection that attacks the body's immune system, specifically the white blood cells called CD4 cells. [1] HIV continues to be a significant global public health issue, in 2019, an estimated 38 million people were living with HIV, with a

global HIV prevalence of 0.7% among adults. Most people living with HIV are located in low and middle income countries. Of the 4,500 people who contract HIV every day globally, 59% live in sub-Saharan Africa [2] Ethiopia is one of the countries long known for having a generalized HIV epidemic caused by unprotected sexual intercourse, similar to many East African countries. [3] Current adult HIV prevalence of 1.55%. [4]

HIV is transmitted primarily via unprotected sexual intercourse, contaminated blood transmission, hypodermic needles, skin contact with potentially infectious body fluids, and from mother to child. [5] Health care workers (HCWs) are at risk of many infections in health setups, such as exposures to human blood and body fluids, placing them at risk for numerous blood borne diseases, including HIV .There is a small but definite occupational risk of HIV transmission to health care workers. The average risk of HIV transmission after percutaneous exposure to HIV-infected blood is approximately 0.3%, mucocutaneous exposures, 0.09% if the injured and/or exposed person is not treated within 24 h with antiretroviral drugs. [6]

According to the World Health Organization (WHO), it is estimated that about 3 million HCWs are exposed to blood borne pathogens each year—occupational exposure causes approximately 170,000 HIV infections [7]. The global number of HIV infections among health care workers attributable to sharps injuries has been estimated to be 1000 cases (range, 200–5000) per year [8]. Prevention of virus transmission through the appropriate utilization of post-exposure prophylaxis is one of the effective strategies.

Animal models show that HIV replicates within dendritic cells of the skin and mucosa after initial exposure before spreading through lymphatic vessels and developing into a systemic infection [8]. This delay in systemic spread leaves a "window of opportunity" for post‐exposure prophylaxis (PEP) using antiretroviral drugs designed to block replication of HIV [8]. PEP aims to inhibit the replication of the initial inoculums of the virus and thereby prevent the establishment of chronic HIV infection. [9]. Post-exposure prophylaxis (PEP) uses short-term antiretroviral therapy (ART) to reduce the risk of acquiring HIV infection following accidental occupational or non-occupational exposure. [10] The objective of the current study was to evaluate post-exposure prophylaxis utilization among HIV-exposed health care workers and non-occupational exposures at Tikur Anbessa Specialized Hospital (TASH) Antiretroviral Treatment (ART) clinic from January 1, 2017- July 30, 2021.

2. Methods

Study area

The study was conducted in TASH, situated in Addis Ababa, Ethiopia's capital and largest city. This main government-owned tertiary teaching hospital offers comprehensive health care service for more than half a million patients per year through specialty clinics and inpatient service. It serves as teaching center for undergraduates and post graduate medical students, dentist, nurses, midwives, pharmacy, medical laboratory technologist. The study was conducted in ART Clinic at TASH; where HIV exposed subjects seek Post exposure prophylaxis.

Study design and period

A hospital-based retrospective cross-sectional registry review conducted at ART clinic in TASH, all registered victims from January 1, 2017-July 30, 2021, included.

Source Population

The source population consists of all healthcare workers (HCWs) who were exposed to potentially infectious sources of HIV, as well as all individuals who visited the ART clinic at TASH seeking post-exposure prophylaxis (PEP). The study population includes victims who were potentially exposed to infectious sources and initiated PEP treatment between January 1, 2017, and July 30, 2021, at the TASH ART clinic. The inclusion and exclusion criteria encompass all occupational exposures reported to the TASH ART clinic and requested PEP during the specified time frame, as well as non-occupational exposures reported to the same clinic and individuals who sought PEP within the same period.

Study Variables

Independent Variables: Age, Gender, Occupation of the exposed HCW, Ward

Dependent Variables: Type of exposure, ARV drugs initiation time, ARV regimen, Duration of ARV drugs, adverse events and outcome

Sampling

All occupational and non-occupational HIV exposure recorded on registry book from January 1, 2017-July 30, 2021, is included.

Data Collection Method and Tool

After getting an approval letter from the department research and ethics committee, the PEP registry review was done using the data abstraction form. Follow-up data were collected by interviewing voluntary exposed cases after getting oral consent.

Data analysis technique

After checking the collected data for completeness, data were analyzed using SPSS version 26, comparison b/n groups for the categorical variable were analyzed using Chi-Square, and frequency was done. The result was presented as graphs, tables, and figures

Ethical clearance

After obtaining ethical approval from the department's research and ethics committee, the study was conducted. Data were checked from the registry book using the patient ID number. The names not included, on data abstraction format again coded with different numbers, and for the follow-up data explanation on the purposes and importance of the study were given to willing participant and after getting oral consent follow up data like, completion of PEP and post exposure test result collected.

Operational Definitions

Occupational Exposure - Procedures that expose the HCWs and other occupational accidentally to risks of infection during their work.

Non-occupational Exposure- Conditions that expose people other than HCWs to a risk of infection

Healthcare Workers- Health professionals working in healthcare settings who have the potential risk for exposure to infectious materials or conditions

Exposure to HIV Risk Conditions- HCWs and other occupational exposure to HIV risk sources, such as blood, patients'/clients' body fluids, needle prick/sharps injury at their workplace

Post-Exposure Prophylaxis- PEP is an emergency medical response that can protect individuals exposed to HIV and short-term ART drugs to reduce the likelihood of HIV infection after potential exposure, either occupational or through sexual intercourse. It consists of counseling, laboratory tests and/or medication.

Regimen-This is the prescribed course of medical treatment, diet, or exercise to promote or restore health.

Ward- A division in a hospital, which is a large room in a hospital with a number of patients often requiring similar treatment.

3. Results

Socio-demographic characteristics and pattern of PEP prescription

In this study, 353 cases of occupational and non-occupational exposure to possible HIV infection were reported to the ART clinic during the 55-month study period from January 2017 to July 2021. PEP ARV drug was prescribed for 352 cases, for a mean of 76.8 subjects per year with decreasing pattern 91case/yr. in 2017 to 31 subjects in 2021(7months) (Figure 1). The mean ±SD age of the study participants was 27.3 ±7. The majority of 202 (57.2%) was male, and most (86.7%) of the exposure was occupational (Table 1).

Of the occupational exposure, 84(27.45 %) were Residents by profession, 80(26.1%) were nurses, 52 (17 %) were Interns, 35(11.4%) were cleaners, 20(6.5%) were lab technicians, 8(2.3 %) were midwives and others (11.4%). Of 47 non-occupational exposures, 23(48.9%) cases were rape, and 24 (51.1%) cases were other types of non-occupational exposure. Among the residents 26(31.1%) were surgery residents, 13(15.5) were internal medicine resident, 11(13.1%) were orthopedics residents, 10 (11.9%) Emergency medicine residents, 8(9.5%) Gyn/OBS, 7(8.3%) were pediatrics resident and others (11%)

92 (30.1%) of occupational exposure occurred at different wards, 70 (22.9%) occurred at Emergency OPD, 52 (17%) occurred at the operating theater, 22 (7.5%) occurred at laboratory case team, 21(6%) OPD and other case teams (15.7%).

Table 1. Socio-demographic characteristics and Type of Exposure

		Count	Percentage %
Sex	Male	202	57.2%
	Female	151	42.8%
Age categorized	11-25	160	45.3%
	26-40	172	48.7%
	>40	21	5.9%
Cause of exposure	Occupational	306	86.7%
	Non-occupational	47	13.3%

Seasonality of PEP prescription

The year 2021 was not assessed for seasonal pattern of PEP prescription because we include only 7 month from 2021 and difficult to see whole year pattern. Of the total exposures within the 48 months, by dividing the 4 years into four seasons (season1- 65cases (78.3%) – January –march/4yrs, season 2- 73cases (84.3%) April- June, /4yrs season 3 -80cases (90.9%) July – September/4yrs, season 4-59cases (92.2%) October-December/4yrs) was occupational cases, with an increasing pattern of occupational cases seen in season 3 and season 4, with (P<0.05).

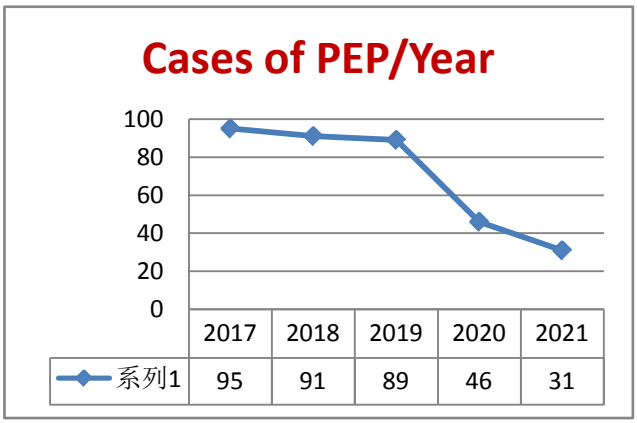

Figure 1. Case of PEP /Year

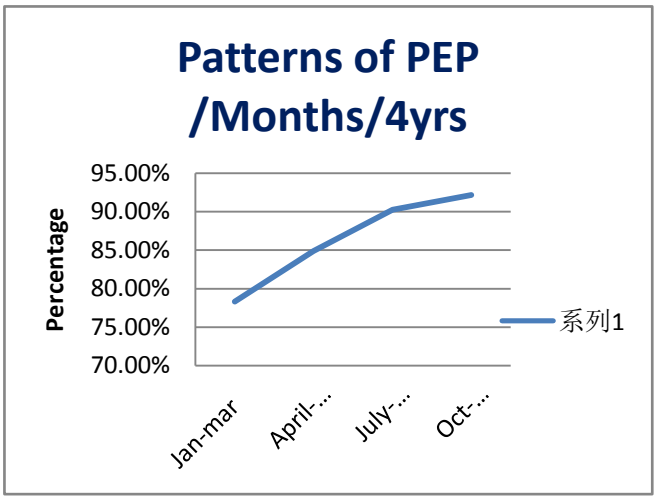

Figure 2. Patterns of PEP cases /Months/4yrs

Type of exposure and source status

Most (n: 150, 42.7%) of the exposure risk type was a major mucocutaneous exposure to a large volume of blood for longer duration or Mild percutaneous exposure, Exposure code (EC2) code type according to the national compressive HIV guideline definition, Severe percutaneous exposure (EC3) accounted (n; 132, 37.6%) of cases and Mucocutaneous Exposure to small volume, (EC1) type occurred in (n: 42, (12.2%) of cases, and 23 (6.6%)was rape case (Table 2).

Of 47 non-occupational exposures, the majority 31(65.9%), the source HIV status was unknown, and 16 (34%) were positive for HIV. For occupational exposure, 109(35.6%), the source patient's HIV status was positive with good immune status, 104 (33.9%) was HIV Positive with advanced disease, 92 (30 %.) of the source HIV status

was unknown and one source tested negative for HIV (Table 2). Baseline HIV test was negative in 339 (96%) cases, and there was no documentation for 14 (4%) cases.

Table 2. Source patient HIV status * Type of Exposure

Count							
		Type of Exposure					Total
		EC1	EC2	EC3	Rape	other	
Source patient HIV status	HIV positive good immune status(SC1)	23	61	34	2	0	120
	HIV positive advanced disease(SC2)	5	42	61	0	0	108
	Unknown	14	47	37	21	4	123
Total		42	150	132	23	4	351

Type of PEP regimen

Two drug regimen (TDF/3TC) was prescribed for most 310 (87.8 %) cases, three-drug regimen TDF/3TC/DTG and TDF/ 3TC/EFV used in 21(5.9%) and 19(5.4%) of cases, respectively. Another regimen (TDF/3TC, TDF/FTC) was prescribed for 2 cases, and one cases deferred PEP after the source patient tested negative.

Table 3. PEP regimen

Type of Regimen		Number	Percent (%)
Valid	TDF/ 3TC	310	87.8
	TDF/3TC/DTG	21	5.9
	TDF/ 3TC/ EFV	19	5.4
	AZT/3TC	1	.3
	TDF/FTC	1	.3
	Not given	1	.3
	Total	353	100.0

Time initiation of PEP and follow up

The precise time from exposure to initiation of PEP was not documented on the registry book, but after interviewing the exposed person through telephone, could access 182 cases and of this 167 /182(91.7%) visit ART clinic within 24 hrs., 14 /182 (7.6%) visit within 24 - 48hr, one case presented after 72hr, the other 171/353 come within 72 hrs. but no documentation on the precise time of PEP initiation. Of 189 cases available data from the registry and telephone, 174(92%) took the entire course 28 days of PEP, 15(7.9%) didn't complete the entire course.

Table 4. Adverse reaction status

Adverse reaction status		Number	Percent (%)
Interviewed	Yes	95	27
	no	87	24.7
Not interviewed	unknown	170	48.3
	Total	352	100.0

Follow-up HIV test was documented on registry book only for 34(9.6%)/352 of cases at 6 weeks, 3 month and six months (n; 22, 9, 3) respectively. All tested were negative for HIV after completing the PEP course. Totally from the registry book and interviewing the exposed cases 174 cases tested at one time and the HIV test post-exposure was negative,178/352(50.5 %) cases, there is no documentation, and couldn't access their sero-status after the PEP was given.

Documentation on adverse reactions was not available. However, among the exposed cases interviewed, 95 out of 182 (52.1%) reported experiencing adverse reactions, while 87 out of 182 (47.8%) reported no adverse reactions. For 170 out of 352 cases (48.3%), data could not be accessed.

4. Discussion

PEP is provided at TASH ART Clinic free of charge for five days per week and 8hr/day, and a starter pack is available at each case team for emergency exposure. According to the National consolidated guidelines for compressive HIV prevention care and treatment, PEP is recommended for exposure code type (Source code (SC) 1-Exposure code (EC)1,SC1-EC2, SC1-EC3), (SC2-EC1, SC2- EC2, SC2-EC3) within 72 hrs. of exposure for both occupational and non-occupational exposure.[11] Two or three-drug regimen is recommended according to the severity of risk exposure and background drug resistance at the population level.

This study evaluated the utilization of PEP among occupational and non-occupational exposure who visited the TASH ART clinic from 2017- 2021GC, and 353 exposures was reported to ART clinic with a mean of 76.8 PEP cases /year. This result is relatively higher than that of Denmark's research; the PEP case was 29.4/yr. The higher PEP cases in our study could be due to the relatively higher prevalence of HIV, 0.9% [3] compared to the prevalence in Denmark,0.1%[12]. Lack of protective equipment and high workload could also increase exposure risk. [13]

A year-on-year decrease in PEP utilization was also observed. This declining pattern could be linked to a relative reduction in HIV prevalence across the country and the impact of the COVID-19 pandemic, which led to fewer patient admissions and elective procedures, thereby reducing exposure risk among healthcare workers.

The pattern of PEP requests shows a relative increase during the months of July to December among occupational exposures. Most occupational injuries were reported by physicians (residents and intern doctors), nurses, and cleaners, with a mean age of 27. This trend could be attributed to several factors. Firstly, individuals in these roles often have fewer years of experience, which may increase their risk of exposure. Secondly, as a teaching hospital, there is frequent patient contact and a high volume of procedures, which heightens the risk of occupational injuries.

Most of the exposures were determined to be high risk according to the national comprehensive HIV treatment guideline. Major mucocutaneous exposure to a large volume of blood for a longer duration or mild percutaneous exposure (EC2) accounted for 42.7%. Severe percutaneous exposure (EC3) is 13.2%, which needs a case-by-case decision by a clinician to select an ARV regimen. The need for strict adherence and early initiation of PEP was comparable to a study done at Tanzania that revealed blood splash and needle stick injury 47.1% and 37.2%, respectively.[14], difficult to compare to other studies due to documentation in this study registry book being labeled as risk type code.

The initiation of post-exposure prophylaxis should not be delayed by the availability of the source HIV test results in the settings with generalized HIV epidemics; it is reasonable to assume that all sources of unknown HIV status may pose a risk of infection. [15] Therefore, PEP should be provided, and efforts should be made to ensure the early test of a source patient with an unknown status to ensure that PEP is stopped, following the negative test of the source patient. [16] Our study from all types of exposure found that 64.9 % of the source patients were HIV positive, and the source patient HIV statuses were unknown in 34.8 % of cases. PEP was offered for both groups and deferred for one case after the source tasted negative for HIV, according to the national guideline.

This result is comparable to the Danish registry review study where 67.2% of the sources were known-HIV-positive [12]. However, a similar study done at Gondar University in Ethiopia, 56.63% of the source weren't tested for HIV [17]. PEP was offered for 4% of exposed persons without knowing baseline serostatus, which isn't recommended by the national HIV guideline.

Two ARV drugs containing TDF/3TC (FTC) is effective and recommended by recent WHO HIV PEP guideline. [18] The National comprehensive HIV treatment guidelines for PEP recommend a three-drug regimen adding the newer drug dolutegravir (DTG) as the third drug. It is preferred in a high risk of ARV drug resistance, high-risk exposure, and when the source patient's HIV status is positive and advanced disease. [11,18] In this study, the two-drug regimen TDF/3TC was prescribed for 87.8 % of cases, and three-drug regimens TDF/3TC/DTG/ , TDF/3TC /EFV were prescribed for 5.9% and 5.4% of cases, respectively. DTG containing a three-drug regimen was prescribed in recent exposure that occurred after 2019. Other studies in Brazil and the US military trauma hospital in Afghanistan show that two-drug regimens were prescribed 72% and 95 % of cases, respectively. [19,20]

But a study done in Gondar university hospital in Ethiopia [17] shows three (TDF/3TC/EFV) ARV regimens were prescribed in 85.2%, which is quite different from our study result. [21]

PEP should be initiated as early as possible (within 1-2hr) and not considered after 72hr of exposure to prevent transmission after potential exposure. The precise time from exposure to initiation of PEP was not documented on the registry book, interviewing from available data 91.7% of subjects initiated with 24hr. one case presented after 72hr and offered PEP because she insisted, but after72hr HIV infection may be established.

If PEP is prescribed then discontinued after 28 days, the risk of viral rebound with that inadvertent interruption in ART is significant, the associated risk of developing resistance to ART also .[22] It is also not recommended by the guidelines. From Brazil studies, 52% of the HCWs started PEP within two hour of the exposure, and in another study at Gondar University Hospital, 79.3% of exposed cases started PEP with 24 hours.

In this study, follow-up documentation on HIV status after PEP is prescribed is poor; only 34 cases have documentation at six weeks, three months, and six months. However, there is a small but definitive risk of HIV transmission after occupational exposure; PEP is not 100% effective. Various factors influence PEP effectiveness like time starting of PEP after exposure, adherence, Source virus, and penetration of drugs into tissue compartments. [10] Adherence to an entire 28-day course of ARVs is critical to the effectiveness of the intervention and should be initiated as early as possible, ideally within 72 hr. [11] Adherence to 28 days of the entire PEP course was higher than Ghana study. Only 17.9 % were adhering among health care workers. [23], few data is available on adverse effects of PEP among occupational and non-occupational exposure with the most commonly used drug TDF/3TC. In our study, 52% of the study participant had an adverse reaction.

5. Conclusion

At the TASH ART clinic, post-exposure prophylaxis (PEP) antiretroviral drugs were prescribed for both occupational and non-occupational HIV exposures. The utilization rate of PEP has been decreasing annually. Most PEP prescriptions were for resident physicians, nurses, and interns due to occupational exposures, and for rape cases in non-occupational exposures. In TASH, the ART clinic risk assessment and PEP initiation followed the national occupational and non-occupational exposure guidelines. The selection of the regimen was based on a case-by-case analysis, with the two-drug regimen TDF/3TC being the most commonly used. PEP was initiated within 72 hours of exposure, although the exact initiation time was not documented. While most cases completed the full PEP regimen, documentation on follow-up and adverse reactions was inadequate.

Recommendation

We recommend clinicians should follow-up exposed individuals within 48 hours and ongoing follow-up, either by telephone call or if possible in person, to assess PEP tolerability and adherence.

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