

Research Article



Evaluation of Compliance to Post-exposure Prophylaxis Treatment Guidelines: A Multi-site Retrospective Study of the US Presidents' Emergency Plan for AIDS Relief (PEPFAR)-AIDS Prevention Initiative in Nigeria (APIN) Clinics in Nigerian Teaching Hospitals

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ABSTRACT

This study was conducted to evaluate the level of compliance of four teaching hospitals in Nigeria to post-exposure prophylaxis (PEP) guidelines. A multi-site retrospective design was used in this study to collate data from Ahmadu Bello University Teaching Hospital (ABUTH), Jos University Teaching Hospital (JUTH), University of Maiduguri Teaching Hospital (UMTH), and University College Hospital (UCH). Appropriate descriptive and inferential statistics were conducted on the data. The data of 575 patients were identified for PEP services. PEP was commenced in 507(88.17%) patients within 24-hours after exposure. Fourteen ARV regimens were prescribed. Guideline-approved Tenofovir/Lamivudine/ritonavir-boosted Atazanavir was prescribed for 230(40.00%) patients. None of the hospitals documented compulsory pre-PEP test. The first test after completing PEP was conducted for 185(32.20%) patients. JUTH had a total compliance of 83.95%. The group mean was 71.90(4.14) [F(3,0)=0.00, p<0.0001]. The compliance to PEP treatment guideline in Nigerian hospital is impressive.

Keywords: Compliance, HIV, Nigeria, Post-exposure Prophylaxis, Treatment Guideline.

INTRODUCTION

Post-exposure prophylaxis (PEP) is an emergency HIV treatment¹ in which antiretroviral drugs (ARVs) are prescribed to previously HIV-negative persons after being potentially exposed to HIV with the aim of preventing the exposed person from becoming infected with HIV². It began as a recommendation after occupational exposure to HIV by health workers in the early 1990s which was later extended to non-occupational exposures, including unprotected sexual exposure, injecting drug use, and exposure following sexual assault³. No empirical research underlines the recommendation and guidelines for the use of PEP. Instead, results from animal models and other HIV preventive measures form the bases for its use.

PEP usually involves administering ARVs for 28 days, starting within the first 72 hours of HIV exposure. The timing of PEP is extremely important. Studies in animal models have shown that the efficacy of PEP is reduced when treatment was delayed for more than 24 hours⁴. Adherence to the full 28-day course is also critical to the success of PEP. Findings from animal studies showed that less than four weeks of treatment was less effective than the 28 days treatment⁵.

The World Health Organization (WHO) currently recommends the use of a dual or triple combination antiretrovirals (ARVs) for post-exposure prophylaxis. The regimen contains tenofovir (TDF) and lamivudine (3TC), alone as a two-drug regimen, or with dolutegravir (DTG) as the third drug, serving as the backbone of a three-drug regimen. Where available, ritonavir-boosted protease

inhibitors such as atazanavir (ATV/r), darunavir (DRV/r), and lopinavir (LPV/r) as well as Raltegravir (RAL) may be considered as an alternative backbone⁶.

Although the short-term use of ARVs in PEP prevents or reduces the risk of transmission of HIV infection in persons exposed to the potential risk of acquiring the infection^{7,8}, there are assessment criteria to be used in classifying the exposures. The exposures for which PEP is recommended can be non-occupational, commonly sexual^{9,10}, or occupational. It was, however, first used for occupational HIV exposures (in the late 1980s)¹¹, with the Center for Disease Control and Prevention (CDC) releasing her first guideline for its use in 1990^{12,13}. The use of PEP in sexual exposure is recommended in a number of guidelines too, but evidence supporting its use mainly stem from animals models, observational studies on prevention of mother-to-child transmission (PMTCT) and occupational exposures^{7,9,14-17}.

PEP was deployed for use in Nigeria in the mid-2000s. Notwithstanding the long history of the implementation of the provisions of PEP, there is a paucity of researches that have documented the compliance to existing guidelines by the different hospitals that pioneered the service in the country. Therefore, this study was conducted to evaluate the level of compliance of the major teaching hospitals in Nigeria to treatment guidelines.



METHODS

Study Design

This part was a multi-site retrospective study, involving the use of the PEP databases of the selected healthcare facilities.

Study Settings

Using purposive sampling, this study was conducted in the tertiary healthcare facilities that had the longest history of provision of HIV/AIDS treatment and care, with the highest number of clients. They also had comprehensive electronic medical databases managed by the United States President's Emergency Plan for AIDS Relief – AIDS Prevention Initiative in Nigeria (PEPFAR - APIN). The centres that met the criteria representing different zones of the country were: Ahmadu Bello University Teaching Hospital (ABUTH) Zaria, Jos University Teaching Hospital (JUTH) Jos, University of Maiduguri Teaching Hospital (UMTH) Maiduguri, and University College Hospital (UCH) Ibadan

Study Sample and Source of Data

Relevant data of all the patients that met the eligibility criteria of the study from 2009 to 2016 were used for the study. The requirements for inclusion were: data of clients whose demographic information were provided, and those who assessed the service from only one of the centres during a regimen.

The source of data for this study was the File-Maker Professional (FMPro) database of the HIV Clinics of the healthcare facilities. The FMPro database contained demographic and clinical information about all patients who received treatment and care for HIV from the sites. The data was abstracted from the FMPro into Microsoft Excel (2016).

The following variables were abstracted from the database: age, gender, educational level, occupation, timing of first dose of PEP (e.g. < 24 hrs., 24 - 48 hrs., 48 - 72 hrs., and > 72 hrs.), status of source person (ARV and/or HIV status), type of exposure (occupational or

non-occupational), ARVs used, duration of therapy, and post-PEP HIV infection status.

Data Analysis

The abstracted data in Microsoft Excel (2016) were checked for correctness before been exported to IBM SPSS (Version 25) for appropriate descriptive and inferential statistical analysis. In determining the guideline compliance, a scoring method was designed using different components of the services after collating opinions from a Delphi panel. The scoring criteria designed produced: provision of recommended PEP ARVs (30%), enrollment within the allowed time (40%), conduct of 1st post-PEP test (20%), conduct of 2nd post-PEP test (5%), and conduct of 3rd post-PEP test (5%). Results of the descriptive analysis were presented in frequencies (percentages) and/or mean \pm standard error of mean. The level of compliance to guideline was computed as a mean score for each hospital, before using one-way analysis of variance (ANOVA) to compare their performances. $P < 0.05$ was considered to be statistically significant.

Ethical Consideration

Ethical approval was obtained from the Institutional Review Boards (IRBs) of PEPFAR (Appendix I) and APIN (Appendix II) who managed the databases that were used for the study. Strict confidentiality was ensured in the conduct of this study. All data gotten throughout the course of this study that related directly or indirectly to the identification of the subjects were concealed from any third party, and never included in any results that were reported.

RESULTS AND DISCUSSION

Results

The data of 575 patients were identified for PEP services. Data from ABUTH, JUTH, UCH and UMTH account for 90, 185, 280, and 20 patients for the period of the study. Enrolment in the hospitals peaked at 2011 (ABUTH), 2013 (JUTH), 2012 (UCH), and 2010 (UMTH). The trend of patient enrolment to PEP service in the four hospitals between 2009 and 2016 are shown in Figure 1.

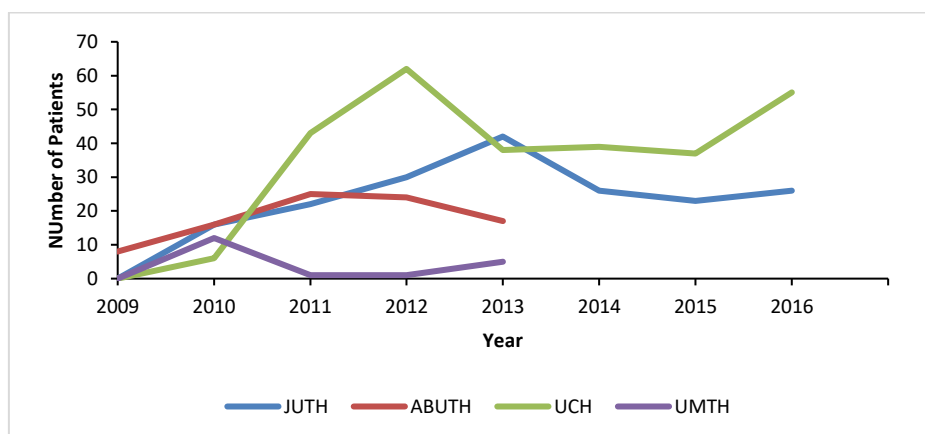


Figure 1: Trend of Enrolment for PEP in the Four Hospitals

Time between Exposure and Commencement of PEP

PEP was commenced for 507 (88.17 %) patients within 24 hours after possible exposure to HIV. There was no record of starting any patient beyond the 72-hours post-

exposure deadline. The time period between exposure and initiation of PEP for 51 (8.87 %) patients was not indicated. Table 1 contains the details of patient enrolment to PEP after exposure in the four hospitals.

Table 1: Enrolment of Patients for PEP based on Time after Exposure

Time after Exposure	JUTH		ABUTH		UCH		UMTH		Total	
	n	%	n	%	n	%	n	%	n	%
Less than 24 hrs.	177	95.7	60	66.7	250	89.3	20	100.0	507	88.2
24 - 48 hrs.	4	1.6	3	2.2	3	0.7	-	-	10	1.7
48 - 72 hrs.	4	2.2	-	-	3	1.1	-	-	7	1.2
Not indicated	-	-	27	30.0	24	8.6	-	-	51	8.9
Total	185	100.0	90	100.0	280	100.0	-	-	575	100.0

ARVs Prescription

Fourteen PEP ARV regimens were prescribed for patients in the hospitals. Guideline-approved Tenofovir (TDF) + Lamivudine (3TC) + ritonavir-boosted Atazanavir (ATV/r)

was prescribed for 230 (40.00 %) patients. NVP-based ARVs that are contraindicated for PEP were prescribed for 11 (1.90 %) patients. The distribution of the prescribed drugs for each hospital is presented in Table 2.

Table 2: Prescribed Antiretroviral Drugs for PEP Patients in the Hospitals

Regimens	Facilities				Total
	JUTH	ABUTH	UCH	UMTH	
	n (%)				
AZT+3TC+LPV/r	28 (15.1)	8 (8.9)	41 (14.6)	1 (5.0)	78 (13.6)
AZT+3TC+ATV/r	92 (49.7)	0 (0.0)	12 (4.3)	0 (0.0)	104 (18.1)
TDF+3TC+ATV/r	24 (13.0)	34 (37.8)	172 (61.4)	0 (0.0)	230 (40.0)
TDF+3TC+EFV	36 (19.5)	1 (1.1)	9 (3.2)	9 (45.0)	55 (9.6)
TDF+FTC+LPV/r	0 (0.0)	14 (15.6)	0 (0.0)	0 (0.0)	14 (2.4)
AZT+3TC	0 (0.0)	1 (1.1)	16 (5.7)	0 (0.0)	17 (3.0)
TDF+3TC	0 (0.0)	0 (0.0)	15 (5.4)	0 (0.0)	15 (2.6)
AZT+3TC+EFV	0 (0.0)	0 (0.0)	5 (1.8)	0 (0.0)	5 (0.9)
TDF+3TC+LPV/r	5 (2.7)	32 (35.6)	3 (1.1)	0 (0.0)	40 (7.0)
TDF+FTC+NVP	0 (0.0)	0 (0.0)	0 (0.0)	2 (10.0)	2 (0.3)
AZT+3TC+NVP	0 (0.0)	0 (0.0)	1 (0.4)	7 (35.0)	8 (1.4)
ABC+3TC+LPV/r	0 (0.0)	0 (0.0)	5 (1.8)	0 (0.0)	5 (0.9)
AZT+3TC+ABC	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)
TDF+3TC+NVP	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	1 (0.2)
Total	185 (100.0)	90 (100.0)	280 (100.0)	20 (100.0)	575 (100.0)

HIV Tests before and after PEP

None of the hospitals documented the results of the compulsory pre-PEP test for patients. The first test after completing PEP was conducted for 185 (32.20 %) patients. There was no record of the post-therapy test for any of the 280 patients in UCH, but UMTH conducted the test for all its 20 (100.00%) patients. JUTH and ABUTH conducted test for 129 (69.7 %) and 36 (40.00 %) of their patients respectively. No hospital conducted any of the remaining two tests after the first one post-therapy.

Overall Compliance to PEP Guideline

JUTH had a total compliance to PEP guideline of 83.95 %, while ABUTH had a total compliance of 66.00 %. The total compliance scores of the hospital to the components of the PEP guideline and overall are as presented in Table 3.

Discussion

In this study that sought to determine the compliance to PEP treatment guideline in Nigeria, a considerable size of data was retrieved in ABUTH, JUTH, UCH, and UMTH. The highest enrollment was in UCH, followed by JUTH before ABUTH. UMTH had the least sample size.



Table 3: Overall Compliance to PEP Guideline in the Hospitals

Facility	PEP ARV (30%)	Enrolment Time (40%)	1st Test after PEP (20%)	2nd Test after PEP (5%)	3rd Test after PEP (5%)	Total (100.00%)
ABUTH	30.00	28.00	8.00	0.00	0.00	66.00
JUTH	30.00	40.00	13.95	0.00	0.00	83.95
UCH	29.84	36.57	0.00	0.00	0.00	66.41
UMTH	11.25	40.00	20.00	0.00	0.00	71.25
Mean = 71.90 (4.14); F (3,0) = 0.00, p ≤ 0.0001						

The trend of enrollment of patients in all the hospitals was not steady. There was a consistent rise and fall in the number of patients enrolled in PEP programmes. All the hospitals had a peak in enrollment at different years, with the last two years in UCH and JUTH witnessing a remarkable increment in the number of enrollees.

A vast majority of the patients enrolled in the PEP programme in the four hospitals were prescribed PEP regimen within 24 hours of possible exposure to HIV infection. A small proportion of patients in ABUTH and UCH did not have the time interval between exposure and prescription of PEP ARVs documented; there was no record of any patient in any of the hospitals commencing PEP beyond the guideline-approved 72-hour post-exposure deadline.

Standard treatment guidelines-approved PEP ARVs were used in almost all the patients enrolled in the PEP programme. Most of the regimens prescribed for the patients had ritonavir-boosted protease inhibitors as the backbone of the combination. However, a very small proportion of the patients were prescribed nevirapine-based ARVs, which are contraindicated in PEP. Against treatment guidelines, none of the hospitals whose databases were evaluated documented that they conducted HIV tests for their patients before enrollment in the PEP programme. HIV test was conducted for only a few proportions of the patients after completing the PEP regimen in JUTH and ABUTH. Whereas all the patients that were enrolled in PEP at UMTH had their HIV status determined six weeks after completing PEP, there was no documentation of the conduct of HIV test in all the patients in UCH.

The data that was used for this study showed an inconsistent enrolment of clients for the period that was reviewed. However, all the four hospitals that were used for the PEP section of the compliance study had data for the period covered (2009 – 2016). The overall number of clients enrolled in the PEP programme was low, obviously because possible exposures that require PEP are products of accidents which do not occur as often as incidences of pregnancy. The distributions according to the hospitals were based on the years of commencement of the services in the hospital, as earlier stated: UCH, in this case, had the highest number of clients for being the first hospital to start providing the service.

The guideline used for the management of PEP in Nigerian hospitals is stipulated in the Nigeria Integrated Guidelines for HIV Prevention, Treatment, and Care^{18,19}. PEP is recommended for exposure types that are associated with a risk of HIV transmissions such as needle-stick injury, mucosal exposure of body part by body fluids, broken skin that is exposed to blood or other infectious fluids. It is also recommended due to non-occupational exposures to HIV like sexual assault. In the treatment guideline, PEP is recommended to be prescribed for a client after possible exposure to HIV infection, most preferably within 1 hour of contact to the suspected source but not later than 72 hours after the exposure. The guideline, however, leaves a caveat that healthcare professionals can still consider a client for PEP enrolment even if the clients report after 72 hours of exposure. This is allowed if the clinicians' clinical judgment is that such a client will still benefit from the prescription of PEP. The results of the present study show that the four hospitals abided by the guideline since all the patients with the documented period between exposure and prescription of PEP reported within the 72 hours limit. Although a minute proportion of the patients did not have the time of their exposure and reporting for PEP documented, it cannot be inferred that they reported after the 72-hour limit, even though the opposite cannot also be inferred. It is, however, a practice against the guideline that the time was not documented since it is required for follow-up monitoring and evaluation purposes.

There is no evidence in the literature about a study that specifically aimed to assess the degree of compliance to PEP guidelines by healthcare facilities. This is despite the known fact that PEP is an evidence-based strategy that can prevent the transmission of HIV after possible exposures, either alone or in combination with other preventive strategies¹⁶. However, some studies that aimed to evaluate other outcomes related to PEP have documented variables that are comparable to the findings of this study. In a study conducted at UNTH, Onyedum *et al.* characterized the patients who reported for PEP in their hospitals. Their results showed that although most of the clients reported and were placed on a PEP regimen within the 72-hour deadline recommended by the guideline, some patients reported after 72 hours. Unlike in this study, the authors documented that the baseline

HIV status of the exposed persons was documented, with 7 (6.0 %) of the 116 persons having positive results for HIV tests and 15 (13.0 %) refusing to be tested²⁰. Their study also showed that their study site documented other important socio demographic and clinical characteristics of the patients, which were not available in the databases of the hospitals used for this study. In Abubakar *et al.*'s study that evaluated the utilization and outcome of PEP among healthcare workers in a tertiary health institution in Nigeria, they did not report the results of any pre-PEP HIV tests among their patients, just as it was in this present study. However, the majority of the patients in their study had results of only the first post-PEP HIV test. They concluded that the other patients might have been lost to follow-up²¹. Thomas *et al.* conducted a retrospective study among PEP clients in a significant North American cohort. Their results showed that almost all the PEP clients, except just one, reported and were prescribed PEP drugs within the 72-hour limit recommended in the guideline. Their results also showed that the majority of the patients were prescribed guideline-approved ARVs combination²². The paucity of information in PEP databases of health institutions, as seen in the present study, has been reported as a problem in many hospitals. In a systematic review of research evidence and practice of PEP in Nigeria, Iloanusi *et al.* reported that there is little research evidence on the utilization of PEP in Nigerian hospitals²³. Although their focus was mainly non-occupational exposures to HIV, they documented that most of the centres documented the use of the right ARVs for PEP and the commencement of PEP within the stipulated time. Pattanaphesaj and Teerawattananon also reported the low level of data in their systematic review that sought to determine the effectiveness and cost-effectiveness of HIV prevention strategies in healthcare facilities in Thailand²⁴.

PEP has been proven to be an evidence-based strategy to prevent the transmission of HIV in persons who are accidentally exposed to possible infection by the virus. Its outcome is related to full compliance with evidence-based treatment guidelines. Thus, a total, and not just a high percentage of compliance to the guideline is the ideal expectation from the healthcare professionals. The level reported for the sites studied in this work is thus below the requirement of the treatment guideline. This requires an urgent intervention because if the level of compliance to guidelines in national tertiary hospitals is below standard, the compliance level in lower healthcare facilities can only be imagined.

The retrospective design of this study is a limitation, as the findings were not able to identify the causes of non-compliance; neither did it give the opportunity to correct the non-compliance. The compliance study also determined the level of compliance for a very long period during which different guidelines were used. However, the findings of the level of compliance were not separated into different sub-period based on the existing guidelines.

CONCLUSION

The compliance to PEP treatment guideline that was evaluated in this study was good. But being a HIV-related treatment and care service, optimal compliance to guidelines is required to produce excellent outcome. Nonetheless, the study has established baseline information that clinicians, policy, makers, and all stakeholders involved in the treatment and care of PEP patients in Nigeria towards providing better service delivery.

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