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Full Length Research Paper

Evaluation of HIV post-exposure prophylaxis (PEP) in a tertiary health institution in south-eastern Nigeria

Isah AbdulMuminu*, Igboeli Nneka Uchenna, Adibe Maxwell Ogochukwu and Ukwe Chinwe Victoria

Department of Clinical Pharmacy and Pharmacy Management, Faculty of Pharmaceutical Sciences, University of Nigeria, Nsukka, Enugu State, Nigeria.

This study aimed to evaluate the implementation of HIV post-exposure prophylaxis (PEP) guidelines and determine its clinical outcome in a PEPFAR (APIN-CDC) Clinic in south-eastern Nigeria from 2008 to 2012. It was a retrospective review of data of patients who accessed HIV PEP services from the clinic. Data on demographic and clinical characteristics of patients were retrieved from the database of the clinic and analyzed. Descriptive statistics and Chi-square test were applied to analyzed data at significance level of $p<0.05$. The result showed that thirty three (33) individuals were enrolled into PEP during the period. Thirty-one (31; 93.94%) were due to occupational exposure, while two (2; 6.06%) were due to non-occupational exposure. AZT+3TC 23 (69.70%), AZT+3TC+LPV/r 9 (27.27%) and AZT+3TC+ATV/r+RTV 1 (3.03%) were the ARVs used. The nature of exposure did not significantly determine the choice of the ARV. The study concludes that APIN/CDC Clinic, UNTH Enugu substantially followed recommendations of standard guidelines in HIV PEP management, but the absence of follow-up test results for majority of the enrollees was an impediment to any general statement on its clinical outcome.

Key words: HIV, post-exposure prophylaxis, Nigeria.

INTRODUCTION

Post-exposure prophylaxis (PEP) in human immunodeficiency virus (HIV) generally refers to the medical response given to prevent the transmission of blood-borne pathogens after a potential exposure (WHO, 2007). In relation to HIV, it refers to a set of services provided to manage specific aspect of exposure to HIV and prevent the transmission of HIV in cases where exposure occurs (WHO, 2007) after occupational injuries (Department of Health, 2004) or sexual exposure (Fisher et al., 2006). The set of services in PEP include provision of first aid, counseling, assessment of risk of exposure to the infection, HIV testing and depending on the outcome of the exposure assessment, the prescription of a 28-day course of antiretroviral drugs, with appropriate support and follow-up is instituted (WHO, 2007). Two nucleoside-analogue reverse-transcriptase inhibitors (NRTIs) with or

*Corresponding author. E-mail: abdalmumin2@gmail.com or abdalmumin2@yahoo.com. Tel: +234-803-626-7850 or +234-805-999-3533.

without a protease inhibitor (PI) are used for a total of four weeks post exposure, commencing not later than 72 h after the exposure. It is believed that PEP reduces the likelihood of infection after such an exposure by at least 80%, with evidences from animal model data and case control studies (Erhabor et al., 2007; Date and Fisher, 2007). PEP was commenced in the early 1990s for occupational exposures such as needle stick or cuts and has since been expanded to include all other means of exposure to HIV infection (WHO, 2007). It is noteworthy that 99.7% of needle sticks do not result in actual transmission of HIV infection (Becker, 1989).

The objectives of this study were to evaluate the implementation of post-exposure prophylaxis (PEP) guideline and determine its clinical outcome in a PEPFAR (APIN-CDC) Clinic in south-eastern Nigeria from 2008 to 2012.

MATERIALS AND METHODS

Study design

This study was a single-site descriptive hospital-based study in which retrospective data were abstracted from the clinic's database.

Study setting

The UNTH PEPFAR/APIN Plus Clinic situated at the permanent site of UNTH at Ituku Ozalla, Enugu was the centre used for this study.

Study size

Relevant data of all the patients that met the eligibility criteria of the study were used.

Eligibility criteria:
The inclusion criteria for the study were:

1. The data of individuals who accessed the PEP service completely at UNTH
2. The data of individuals who gave consent for the use of their information in studies.

Ethical consideration

Health Research Ethics Committee of the UNTH and the PEPFAR IRB, Harvard School of Public Health gave approval for the study. The researchers ensured strict confidentiality in the conduction of this study.

Source and method of data collection

The source of data for this study was the File-Maker Professional (FMPro) database of the PEPFAR/APIN Clinic, UNTH Enugu, managed and maintained daily by Data Managers. The FMPro database contained information on all patients who received treatment or care for HIV from the PEPFAR/APIN site. Such information included patients' demographics, medical history, physical examination including WHO staging, medications,

laboratory tests (CD4 count, viral load, complete blood count, liver function test, etc.), adherence information, pharmacy refill records, presence of opportunistic infections, among several others. Other information contained in the FMPro database was the number of doctors and pharmacists with whom the patients had contacts.

Variables retrieved

The data of the individuals needed from the database for this study which were abstracted include gender, age, nature of exposure, ARV regimen used and HIV antibody test results after the first, third and sixth months.

Data management and analysis

The data were abstracted from the clinic's database and input into Microsoft Excel where they were checked. The data were then analyzed using FMPro (Version 10) and IBM – SPSS (Version 21). Descriptive statistics and Chi-square test were applied to analyze data at significance level of P<0.05. Results of the study were expressed as frequency (percentage) and mean ± SD. Data were presented as tables and charts as applicable to the collected data.

RESULTS

Demographic characteristics of PEP enrollees

The total number of patients enrolled into PEP for the period studied based on the eligibility criteria of the study was thirty three (33), distributed over the years, as is in Figure 1. Of this number, thirty-one (31; 93.94%) were due to occupational exposure, while two (2; 6.06%) were due to non-occupational exposure (both being rape cases). Fifteen (15; 45.45%) were males while eighteen (18; 54.55%) were females (Table 1).
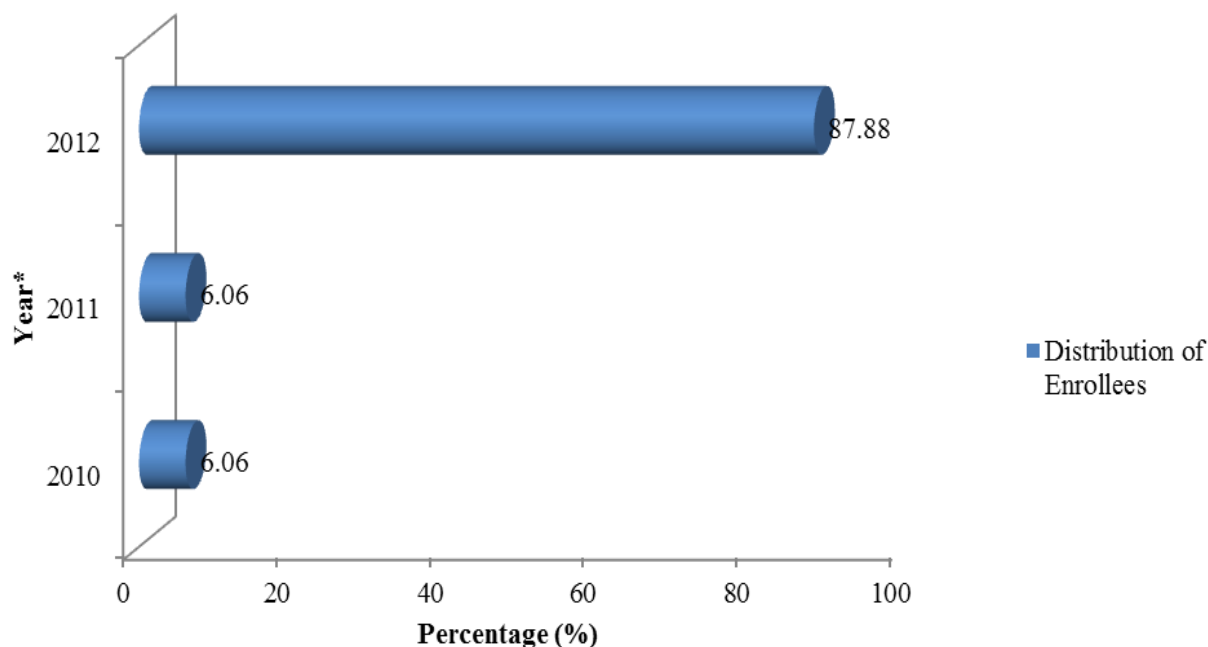
These demographic characteristics are some of the monitoring and evaluation indicators in the PEPFAR Programme Essential Indicators (PEPFAR Outcome Prevention Sub Area 6) (Becker, 1989).

PEP characteristics of the enrollees

The result of the study indicates that the APIN-CDC Clinic UNTH, Enugu used three ART regimens for PEP patients, viz.: AZT+3TC (23; 69.70%), AZT+3TC+LPV/r (9; 27.27%) and AZT+3TC+ATV/r +RTV (1; 3.03%) (Table 2). None of the demographic characteristics significantly determined the choice of ARV (Table 3).

HIV antibody test and result

HIV antibody testing is to be conducted three times after completion of the prescribed ART regimen: the first, third and sixth months. APIN-CDC UNTH Clinic, Enugu did not perform the HIV antibody tests at the stipulated times for the PEP enrollees. The percentage of PEP-enrollees that was later enrolled into HAART (after completing the

Figure 1. Distribution of the PEP enrollees at APIN-CDC Clinic, UNTH, Enugu (2008-2012).

Table 1. Demographic characteristics of the PEP enrollees at APIN-CDC Clinic, UNTH, Enugu (2008-2012).

		2010	2011	2012	Total
Sex	Male	2 (6.06)	1 (3.03)	12 (36.36)	15 (45.45)
	Female	0 (0.00)	1 (3.03)	17 (51.52)	18 (54.55)
	Total	2 (6.06)	2 (6.06)	29 (87.87)	33 (100.0)
Age (Years)	<20	0 (0.00)	0 (0.00)	1(3.03)	1 (3.03)
	20 – 29	0 (0.00)	0 (0.00)	21 (63.64)	21 (63.64)
	30 – 39	2 (6.06)	2 (6.06)	6 (18.18)	10 (30.30)
	40 – 49	0 (0.00)	0 (0.00)	1(3.03)	1 (3.03)
	≥50	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
	Total	2 (6.06)	2 (6.06)	29 (87.87)	33 (100.00)
	Mean ± SD				28.55 ± 6.87

specific regimen) for HIV infection, probably due to PEP failure was 0%.

DISCUSSION

Demographic characteristics of PEP enrollees

The study revealed that more females enrolled into the PEP programme than males, with the majority being in the youth age bracket. This result was similar to the findings of another study (Onyedum et al., 2011). Since most of the cases with reported nature of exposure were due to occupational exposure, the young age may be due to the naivety of healthcare workers beginning their practices. There were no individuals enrolled into PEP in 2008 and 2009 even though the service was available then. There was a gradual increase in the enrollment to the programme from 2010 to its peak in 2012. This development could be as a result of increased sensitization and awareness of the need for and the availability of PEP which is an important predictor of PEP enrollment (Varghese et al., 2003; Chacko and Isaac, 2007; Erhabor et al., 2007). The knowledge of most health workers on HIV PEP in third-world countries remains inadequate (Tebeje and Hailu, 2010).

Table 2. PEP characteristics of the enrollees at APIN-CDC Clinic, UNTH, Enugu (2008-2012).

Variables		2010	2011	2012	Total
Nature of Exposure	Occupational	2 (6.06)	1 (3.03)	28 (84.85)	31 (93.94)
	Non-occupational	0 (0.00)	1 (3.03)	1 (3.03)	2 (6.06)
	Total	2 (6.06)	2 (6.06)	29 (87.88)	33 (100.00)
ARV Regimen Used	AZT+3TC	2 (6.06)	1 (3.03)	20 (60.60)	23 (69.70)
	AZT+3TC+LPV/r	0 (0.00)	1 (3.03)	8 (24.24)	9 (27.27)
	AZT+3TC+ATV/r +RTV	0 (0.00)	0 (0.00)	1 (3.03)	1 (3.03)
	Total	2 (6.06)	2 (6.06)	29 (87.87)	33 (100.00)
HIV Antibody Test Result (1st Month)	Positive	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
	Negative	1 (3.03)	0 (0.00)	0 (0.00)	1 (3.03)
	Not Conducted	1 (0.00)	2 (0.00)	29 (87.88)	0 (0.00)
	Total	2 (6.06)	2 (6.06)	29 (87.88)	33 (100.00)
HIV Antibody Test Result (3rd Month)	Positive	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
	Negative	1 (3.03)	0 (0.00)	0 (0.00)	1 (3.03)
	Not Conducted	1 (3.03)	2 (6.06)	29 (87.88)	32 (96.97)
	Total	2 (6.06)	2 (6.06)	29 (87.88)	33 (100.00)
HIV Antibody Test Result (6th Month)	Positive	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
	Negative	1 (3.03)	0 (0.00)	0 (0.00)	1 (3.03)
	Not Conducted	1 (3.03)	2 (6.06)	29 (87.88)	32 (96.97)
	Total	2 (6.06)	2 (6.06)	29 (87.88)	33 (100.00)

PEP was available in 2008 and 2009, but no enrollee.

Compliance of APIN-CDC Clinic, UNTH, Enugu PEP practice with guidelines

The World Health Organization (WHO) and International Labour Organization (ILO) produced a joint guideline on PEP to prevent HIV in 2007. The guideline posits that the standard PEP regimen should comprise two nucleoside-analogue reverse-transcriptase inhibitors, with three-drug regimens, comprising two nucleoside-analogue reverse-transcriptase inhibitors plus a boosted protease inhibitor, only considered in situations where antiretroviral therapy resistance is known or suspected (WHO, 2007). A two drug regimen is preferred to a three drug regimen because, apart from the absence of any study that shows the relative efficacy of the two regimens, the relative ease of administration (resulting potentially in better adherence, fewer side effects and lower costs) and the ease of procurement, storage and dispensing makes the former the preferred and most recommended regimen (WHO, 2007).

The Nigerian Federal Ministry of Health (FMOH)'s National Guidelines for HIV and AIDS Treatment and Care in Adolescents and Adults in 2010 specified that the two drug regimen to be used in the country should contain zidovudine and lamivudine or zidovudine and abacavir or tenofovir and lamivudine or tenofovir and emtricitabine. The recommended three drug regimen in the guideline includes the addition of lopinavir with ritonavir boost or efavirenz to two NRTIs (Federal Ministry of Health, 2010). The guideline warns, however, that nevirapine should never be used in PEP due to the risk of toxicity (fatal hepatotoxicity) and efavirenz should be avoided in pregnancy or women of childbearing age due to the risk of teratogenicity, a position similar to that of WHO (2007) and Federal Ministry of Health (2010).

The APIN-CDC Clinic, UNTH, Enugu thus complied substantially with the WHO/ILO and Federal Government of Nigeria (FGN) guidelines on the selection of regimen and prescription of drugs in the selected regimens. Reviews in international online databases to evaluate the effects of HIV PEP concluded that two-drug regimens were more frequently used and had fewer incidences of adverse events as compared to three-drug regimens (Young et al., 2007).

In terms of the time of test during the period covered by PEP, both guidelines recommend that HIV antibody testing should be conducted after commencement of the therapy in the first, third and sixth months. The result of this study revealed that only one enrollee had the three post-PEP therapy HIV antibody tests conducted for.

Table 3. Choice of ART regimen based on the nature of exposure, age and gender of enrollees at APIN-CDC Clinic, UNTH, Enugu (2008-2012).

Variables		ARV regimen used			Total	χ^2
		AZT+3TC	(AZT+3TC)+LPV/r	(AZT+3TC)+ATV/r+RTV		
		Frequency (percentage)				
Nature of exposure	Occupational	23 (69.70)	7 (21.21)	1 (3.03)	31 (57.58)	0.15
	Non-occupational	0 (0.00)	2 (6.06)	0 (0.00)	2 (6.06)	
	Total	23 (69.70)	9 (27.27)	1 (3.03)	33 (100.00)	
Age (Years)	<20	1 (3.03)	0 (0.00)	0 (0.00)	1 (3.03)	0.71
	20-29	15 (45.45)	5 (15.15)	1(3.03)	21 (63.63)	
	30-39	7 (21.21)	3 (9.09)	0(0.00)	10 (30.30)	
	40-49	0 (0.00)	1 (3.03)	0 (0.00)	1 (3.03)	
	≥50	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	
	Total	23 (3.03)	9 (27.27)	1 (3.03)	33 (100.00)	
Gender	Male	11 (33.33)	3 (9.09)	1 (3.03)	15 (45.45)	0.41
	Female	12 (36.36)	6 (18.18)	0 (0.00)	18 (54.54)	
	Total	23 (3.03)	9 (27.27)	1 (3.03)	33 (100.00)	

There was no evidence to show that the other enrollees reported to the clinic for the follow-up such that the non-conduction of the tests cannot be solely blamed on the clinic. A study conducted in the same clinic vindicates the position as it showed that none of the enrollees returned to the clinic for follow-up counseling and test (Onyedum et al., 2011).

This behaviour is however in contradiction to the result of a study in San Francisco in which 75% of those enrolled returned for HIV antibody test at the sixth month follow-up (Khan et al., 2001). The difference in the setting could be the reason for the better habit. The fear of stigmatization upon knowing the result could also be responsible, more so that most of the enrollees were staff of the clinic that would not want the result of their tests known at their work place. It is thus difficult to conclude from this study whether the clinic complied (or did not comply) with the guidelines in terms of post-therapy tests on the PEP enrollees.

Evaluation of the clinical outcome of PEP at APIN-CDC Clinic, UNTH, Enugu

The aim of PEP in the APIN-CDC clinic, UNTH, Enugu is to prevent the transmission of HIV to persons exposed to probably HIV-infected individuals. The measure of this outcome is the enrollment of anyone PEP is prescribed into HAART. This is determined by the result of post-PEP therapy, HIV Antibody test. The tests were conducted for only one enrollee with the result being negative, showing a good outcome. A check of the database did not show the existence of any of the PEP enrollees later recruited for HAART, since the policy of the clinic was to use the same identity for an individual for PEP and HAART. The assumption was that since most of the PEP enrollees were due to occupational exposure by staff of UNTH, an enrollment to HAART within the period of the study will most probably be in the same clinic. This also showed a possible good outcome. This result should also be considered in the context that other studies have shown that PEP can reduce the risk of infection to HIV by 81% in resource rich settings (Gold and Tomkins, 2005), although the study in San Francisco revealed that there was no seroconversion in any of the enrollees (Khan et al., 2001). PEP should be seen as a cost-effective complement to existing HIV-preventive measures (Pinkerton et al., 2004), even when it is based on limited direct evidence of effect (Young et al., 2007).

Conclusion

APIN-CDC Clinic UNTH Enugu substantially complied with standard guidelines in ARV prescription for HIV PEP. This study however posits that the clinical outcome of PEP in the clinic could not be determined because its database had no result of the post-PEP HIV antibody test for majority of its enrollees. It is recommended that some policies should be introduced to check the issue of poor follow-up, such as the conduction of the follow-up tests at other clinics which are not directly related to the site and the introduction of a shorter duration to provide the ARVs instead of the 28 days as currently practised.

Limitations

There are some limitations to this study, in the light of which the work should be considered. The small study size is one of such limitations. The result of the clinical outcome evaluation is also limited by the lack of follow-up HIV antibody tests.

Conflict of Interests

The researchers declare that there is no conflict of interests regarding this publication.

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