

**EVALUATIVE STUDY ON THE USE OF POST EXPOSURE PROPHYLAXIS (PEP) IN  
IGEGANIA SUB-COUNTY HOSPITAL TO PREVENT HIV INFECTION**

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**DECLARATION**

I confirm that this project is my original work and has not been presented for a degree in any other university. It has been complemented by referenced sources duly acknowledge where text, data graphics pictures or table have been borrowed from other sources, including internet, these are specifically accredited and referenced in according with anti-plagiarism regulation

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## **ABBREVIATION AND ACRONYMS**

PEP – post exposure prophylaxis

STDs-sexually transmitted diseases

HIV –Human immune deficiency virus

TDF – tenofovir

3TC- lamivudine

ZDV-zidovudine

HAART- Highly active antiretroviral therapy

ELISA- enzyme linked immunosorbent Assay

ATV - atazanavir

LPV- lopinavir

RAV- Raltegravir

PREP- pre- exposure prophylaxis

Ag-antibody

FTC-emtricitabine

RTV- ritonavir

## TABLE OF CONTENTS

DECLARATION .....	i
ACKNOWLEDGEMENT .....	iii
ABBREVIATION AND ACRONYMS .....	iv
TABLE OF CONTENTS .....	v
LIST OF TABLES .....	vii
LIST OF FIGURES .....	viii
<b>1.1. Back ground of the study</b> .....	1
<b>1.2. Problem Statement and Justification</b> .....	2
<b>1.3. Research Question</b> .....	2
<b>1.4. Research Hypothesis</b> .....	3
<b>1.5. Purpose of the study</b> .....	3
<b>1.6. Objectives</b> .....	3
<b>1.6.1. General Objectives</b> .....	3
<b>1.6.2. Specific objectives</b> .....	3
<b>1.7. Significance of the study</b> .....	4
<b>1.8. Limitation of the study</b> .....	4
<b>1.9. Delimitation of the study</b> .....	5
2.2. Groups of people who should be issued with post exposure prophylaxis.....	7
2.5. Failures of PEP Regimens.....	10
CHAPTER THREE: METHODOLOGY .....	11
3.1. Introduction.....	11
3.2. Research design .....	11
3.3 study variable .....	11
3.4. Location of study .....	12
3.5. Target population .....	12
3.6. Sampling techniques and sample size .....	12
3.6.1 Sampling techniques .....	12
3.6.2. Sample size determination .....	13
3.6 construction and research instrument.....	14
3.8. Validity of data collection instrument.....	14
3.9. Reliability of data.....	15

3.10 Data analysis .....	15
3.11 Ethical consideration.....	15
CHAPTER FOUR: DATA ANALYSIS , PRESENTATION AND INTERPRETATION.....	16
INTRODUCTION .....	16
4.1. The age category about usage of post exposure.....	16
4.2. Patients issued post-exposure prophylaxis drugs.....	17
4.3. Effectiveness of post – exposure (PEP) prophylaxis drugs .....	18
4.4 side effects experiences while taking post-exposure prophylaxis.....	20
CHAPTER FIVE: DISCUSSIONS CONCLUSION AND RECOMMENDATION .....	22
5.1 Introduction.....	22
5.2 Discussion.....	22
5.2.1 Overuse of post exposure prophylaxis, drugs .....	22
5.2.2 Issuance of post –exposure prophylaxis drugs to patients .....	23
5.2.3. Side effects of pep drugs .....	24
5.2.4 Effective of post-exposure prophylaxis drugs.....	25
5.3 CONCLUSION.....	27
5.4 RECOMMENDATIONS .....	28
REFERENCES .....	29
APPENDICES .....	32
APPENDIX 1: INFORMED CONSENT .....	32
APPENDIX II.....	34
QUESTIONNAIRES .....	34

**LIST OF TABLES**

Table 4.2: percentage of people who were on PEP drugs

Table 4.3: percentage effectiveness of patients who revisit the health facility for follow up.

Table 4.4: percentage of people who experience side effects of PEP drugs

## **LIST OF FIGURES**

Figure 4:1 the age category of people who were on PEP drugs

Figure 4.3 various groups of people issued with post-exposure prophylaxis drugs

Figure 4.4: effects experienced by patients while taking post-exposure prophylaxis drugs

## ABSTRACT

Post-exposure prophylaxis drugs are used within 72 hours after occupational and non-occupational exposure to prevent HIV infection. Health care providers should evaluate persons rapidly for PEP drugs when care is sought  $\leq$  72 hours after a potential non-occupation exposure that presents substantial risk for HIV infection. Persons to be considered for PEP should have their HIV status tested using a rapid combined Ag/Ab or anti-body blood test. Course of three anti-retroviral drugs regimen are provided which includes TDF/3TC+LPV/r or TDF/3TC+ATV/r. The objective of the study were to evaluate the effectiveness of the PEP drugs, to ascertain the people who are eligible for PEP drugs, to indicate the age category which abuses post exposure prophylaxis drugs. Data was obtained from record for representing age category of people who abuses PEP drugs and the questionnaire were administered to the health workers who have ever used PEP drugs to indicate the side effects they experience and those who issue PEP drugs also provide information regarding the patient they issue with PEP drugs. The study shows that the youth are the mostly people who abuses PEP drugs. Patients ranging from 41-50 years of age represent the lowest percentage. It shows that there was rising cases of unprotected sex which leads to highest percentage of PEP usage (68.18%), rape (4.54%), needle stick injuries (22.72%) and human bite (4.54%). The study also shows there is effectiveness of PEP drugs among the patients who revisit the health facility for baseline testing. Side effects reported when the study was being conducted include jaundice which was shown by almost all patients, nausea, bloating, diarrhea, and flatulence. From the study it was concluded that jaundice mostly occurs due to ATV/r, youth being the mostly people who abuses PEP drugs and patients are being encouraged to take PEP drug with food to avoid some of the side effects. For effectiveness the patients are supposed to be initiated with starter pack for 3-7 days and after completion of the dosage, patients should follow up for retesting.

PEP drugs are not issued to patients who engages in occupational exposure and non-occupational exposure  $>$  72 hours and those who are not in HAART drugs. For improvement of effectiveness health care providers were supposed to remain updated on the current guidelines of PEP drugs to prevent resistance. Counseling sessions should also be provided to people receiving PEP drugs to enable them to be aware of the side effects for completion of dosage. PEP drugs should be provided to partner in which one of the couple is HV positive and the other one is HIV negative.

## **CHAPTER ONE: INTRODUCTION**

This chapter discusses the study background, problem statement and justification, research questions, research hypothesis, purpose of the study, general and specific objectives, significance and anticipated outcomes, limitation and delimitations and conceptual or theoretical framework.

### **1.1.Back ground of the study**

Methods that prevent human immunodeficiency virus (HIV) infection are those that protect against exposure. Antiretroviral therapy cannot replace behaviors that help avoidance of HIV exposure e.g. sexual abstinence, consistent and correct use of condom. HIV can be prevented from patient to patient by allowing the victims of exposure to access PEP drug, in health facilities. Care pathway for people exposed to HIV includes assessment, counseling and support prescribing medications and follow up. Assessment of the source person's HIV status should be conducted to guide appropriate clinical action and inform the exposed individual. A full course of the drug should be administered for 28 days and patient is retested. Department of Health and Human Services (DHHS) released its first recommendation for PEP use to reduce the risk for HIV infection after non-occupational exposure to blood, genital secretion and other body fluids that might contain HIV. In the research the most common patients entitled to PEP includes the youth who are drug user and health care provider(HCP) who engage in accidental injury such as needle prick, blood contain from HIV exposed patient during delivery .

CDC scientists selected PEP subject matter experts from the food and Drugs administration (FDA) the National institute of Health (NIH), hospitals, clinics health departments and professional medical societies to participate as panelist to discuss recent developments in PEP practice by CDC teleconferences in December 2011 and April 2012

## **1.2.Problem Statement and Justification**

Some of the people who engage in occupational and non –occupational exposure may not be able to correlate the effects which may arise through these activities. Most health workers fail to conduct the study of unknown person when they come into contact with blood through injury. Due to this they may be allowed to have the person tested and if the results are negative, they are free from HIV and if the results are positive, they are allowed to seek prophylactic drug to prevent HIV infection.

Many youths who engage in unprotected sex seek prophylactic drug in health facility but they are not entitled to assessment, counseling before initiated the full course of post –exposure prophylaxis drugs and this may ended up some of them not completing the full course of the drug due to toxicities. Other people visit health facility to seek treatment for other sexually transmitted diseases (STDs) and fail to seek the PEP drugs to prevent HIV spread.

## **1.3.Research Question**

- i. Do post exposure prophylactic drugs (PEP) offer effectiveness after exposure is  $\leq 72$  hours and the drugs are used correctly for 28 days?
- ii. What are the side effects experienced while taking post exposure prophylaxis drugs and how they can be avoided?
- iii. What are the various methods used to prevent HIV infection and over use of post exposure prophylaxis drugs
- iv. How are sexually transmitted diseases (STDs) treated while one is on PEP drug therapy?
- v. Which categories of people are supposed to be issued with post- exposure prophylaxis drugs?

#### **1.4. Research Hypothesis**

The post –exposure prophylaxis drugs are effective when used correctly and effectively and within 72 hours of exposure and for duration of 28days

Effectiveness is also established if there's a follow up after every one month for a period of three months.

#### **1.5.Purpose of the study**

The study aims at providing ways to prevent HIV spread amongst health workers when engaged in occupational exposure when attending patient

It also helps the youth and rape victims to access prophylactic drugs during non-occupational exposure.

#### **1.6.Objectives**

##### **1.6.1. General Objectives**

To evaluate the effectiveness of post exposure prophylaxis drugs to prevent HIV infection.

##### **1.6.2. Specific objectives**

- i. To ascertain the group of people who are supposed to be issued with post-exposure prophylaxis drugs
- ii. Commonest side effects that may occur while using post exposure prophylaxis drugs.
- iii. Ways of reducing overuse of PEP drugs amongst the youths.
- iv. To indicate the age category which abuses post- exposure prophylaxis drugs.

### **1.7. Significance of the study**

This study will benefit the rape victims by allowing them to seek PEP drugs upon non-occupational exposure to a person to whom HIV status is unknown.

Healthcare workers and subordinate staff who usually engage in work involving sharp objects also benefit by allowing them to seek PEP drugs after occupational exposure

If the patient is able to have his HIV status checked and the results are negative, healthcare provider should not seek PEP drugs because they cannot acquire the HIV virus. This applies to health workers who also their results are negative

Youth who are sexual active can be able to obtain PEP drugs in health facility, in case of condom burst or breakage, this only applies to those whose partner refuses to have his status checked.

Before initiating PEP drugs, patients are initiated to guidance and counseling services to make them to complete the full course for a period 28 days

### **1.8. Limitation of the study**

Some of the patients who receive the PEP drugs fail to follow up the medication as required while others fail to go for baseline HIV testing, hence making it difficult to assess their HIV status.

Medication keep changing from time to time hence every health worker who issue PEP drug needs to be updated with current guidelines

### **1.9.Delimitation of the study**

The study is conducted only to patient who have been exposed to occupation and non-occupational exposure  $\leq 72$  hours

Infants and people receiving HAART are not included in the study

### **2.0. Theoretical framework**

HIV serodiscordant couples who want to conceive or attempted conception may confers a risk of HIV transmission to the uninfected partner. Informative – motivation behavioral skills model of HIV preventive behavior used to address the structural, individual and couple –level determinants of safer conception behavior. Serodiscordant couple should use condom, to prevent HIV spread, prep are also recommended if the women want to conceive and have children.

Structural model may involve early treatment of antiretroviral therapy for the infected partner. .

Viral load suppression through the use of antiretroviral reduces horizontal and vertical HIV transmission risk while local and systematic pre-exposure prophylaxis for the HIV negative partner confer additional protection

## **CHAPTER TWO: LITERATURE REVIEW**

## 2.1. Effectiveness of post-exposure prophylaxis

Efficacy of PEP leads to the reduction of odds of HIV transmission amongst health worker with percutaneous exposure. Zidovudine (ZDV) prophylaxis was the first to describe the efficacy of PEP. In various cases failure of PEP defined as HIV zero conversion was typically confirmed by a seronegative HIV ELISA test at baseline followed by a positive ELISA test and western blot or indirect fluorescent antibody (Ab) during a follow up visit.

Participant who were administered PEP which is Tenofovir (TDF) regimen were less likely to experience common side effect and are capable of completing their prophylaxis drugs as prescribed. Highest completion rates were observed for the TDF-3TC (87.5%) and TDF-emtricitabine (FTC) (72.7%) arms followed by the TDF-3 TC-ATV/RTV (57%) and ZDV-3TC. Fifteen of the 19 studies reported that both the number of participants who completed 28 days of PEP and a number of participants who HIV seroconverted after initiating PEP. In the studies 2,209 completed full course of PEP for 28 days at who at least 19 individual HIV seroconverted but only 1 seroconversion(CDC and prevention U.S department of Health and Human services, 2016)

In studies, with monkeys, treatment within 72 hours exposure to siv (simian immunodeficiency virus, which cause Aids in those animals reduces the risk of infection. Based on this and other results, researchers in san Francisco conducted a study about the ability of PEP to prevent sexual and needle –use transmission of HIV in people. In analyzing the data form 702 participant who were giving PEP within 72 hours of exposure, they found that most were protecting from developing. (Canada’s sources for HIV and hepatitis C information outbreak November 2005

## **2.2. Groups of people who should be issued with post exposure prophylaxis.**

Researchers in San Francisco conducted two studies and combined the data they collected for this analysis. In both studies, participants received PEP within 72 hours of possible exposure to HIV.

Some participants received two counseling sessions while others received up to five counseling sessions focusing on reducing the risk of transmitting HIV, along with adherence to PEP.

Eligible participants who have engaged in sex without condoms as follows: unprotected vaginal intercourse, receptive or insertive anal intercourse, receptive oral intercourse with ejaculation.

Other potential routes of exposures were considered include sharing of needles for street drug use, contact with a potential infectious body fluid on a mucous membrane or skin that was damaged because of a cut, scratch or abrasion. Participants in the study were given AZT formulated with 3TC, d4T and ddI (Canada's source for HIV and hepatitis C information Oct/Nov 2005)

The first dose of PEP should be administered within the first 72 hours of exposure and the risk evaluated as soon as possible. If the risk is insignificant, PEP could be discontinued, if commenced, two main factors determine the risk of infections; they include, the nature of exposure, the status of the source patient. (WHO/ILO guidelines on post exposure prophylaxis (2006) mild exposure- mucous membrane/ non- intact skin with small volumes or contact with eye or mucous membrane. Moderate exposure-cut or needle stick injury penetrating gloves Severe exposure- percutaneous with large volume e.g. an accident with a high caliber needle visible contaminated with blood, deep wound (hemorrhage wound, transmission of significant volume of blood (NACO guidelines, 2005)

### **2.3. Side effects of post- exposure prophylaxis drugs**

Studies of HCP taking PEP have reported more side effect than patients taking ART. Most commonly nausea and fatigue. Positive side effects occur mainly at the beginning of the treatment includes nausea, diarrhea, muscle pain and headache. The person taking the treatment should be informed that these may occur and should be dissuaded from stopping the treatment as most side effect are mild and transient though possibly uncomfortable. HCP did not complete the full course of PEP because of the side effects. Side effects can be reduced by prescribing regimens that do not include a protease inhibitor (PI), by giving medication to reduce nausea and gastritis and by educating client about how to reduce side effects e.g. taking PEP medication with food.(NACO guidelines 2015) TDF,3TC,NFV,IDV,LPV/r are reported to cause nausea, vomiting and diarrhea.(CDC guidelines 2016)

Commonly used medications in the observational studies of PEP published after 2005 includes ZDV, 3TC, LPV/r, TDF, FTC and RAL. The majority the regimes involved using 3 drugs (range 2-4 drugs) with a daily pill burden( range 1-3 pills) . The side effect profile include fatigue, nausea headache, diarrhea and other gastro intestinal complaints was similar across the studies of MSM having mainly consensual sex and studies of sexual assaults survivors (NACO guidelines, 2016) in a 2-arm open labels randomized multicenter clinical trials in EDS in 6 urban hospitals in Barcelona Spain comparing ZDV/3TC+ LPV/r with ZDV/ 3TC + ATZ 64% of PEP recipients in both arms completed the full course of PEP for 28 days and 92% of patients reported taking >90 % of scheduled doses. Adverse effects were reported in 46% of patients overall(49%LPV/r arm, 43% ART arm). Gastrointestinal problem were more common in the LPV/r arm.

## 2.4. Reducing overuse of PEP

Although PEP can reduce the risk of HIV infection it's not always effective, patient should practice protective behaviors with sexual partners (e.g. consistent condom use)

Or drug use partners (avoidance of shared injection equipment)

HIV education and counseling and ongoing behavioral reduction skills and support services.

(Center for disease control guidelines, 2016)

Inpatient and outpatient alcohol drug treatment services, family and mental health counseling services and support programs for HIV infected persons. Oral PREP containing TDF should be offered to HIV negative individuals at substantial ongoing risk of HIV infection

PEP may be offered to HIV seronegative partner in serodiscordant relationship during attempts to conceive. ( NASCOP guidelines 2016)people who inject drugs(PWID) should be offered regular HIV testing and counseling and be linked to comprehensive HIV treatment and prevention services including harm reduction counseling and support. All PWID should be linked to needle and syringe programs (NAS) to access sterile injecting equipment's. All PWID should be linked to medically assisted therapy (MAT) (NASCOP guidelines, 2016)

## **2.5. Failures of PEP Regimens**

A woman who was 20 years old presented with antiretroviral illness, she had involved in sexual intercourse and was provided with PEP she takes zidovudine+lamivudine and nelfinavir. After being tested for one month the result appears positive.

This was attributed by non – adherence, common side effect and persistence virus. Underlying mechanism which can also lead failure include development of new compound formulation and routes of administration.

Timing and initiation and duration of treatment are important when PEP is initiated. Prompt start within 72 hours and treatment duration of 28 days is necessary.

This is in order to maintain adequate drug levels of the active form of antiretroviral regimens that target tissues to prevent replication

It also important to manage the psychological consequences of the exposure and drug toxicities and tolerability as adherence can be impacted by both factors. Failure to follow the above guidance may attribute to PEP failure.

Symptoms such as sore throat, night sweats, loss of appetite, nausea, bloating may render some of the victims not to complete a full course of PEP drugs (center for disease control and prevention (CDC) (2014) US public health services. Pre-exposure prophylaxis of HIV infected in the United states a clinical practice guideline, Atlanta ,GA US. Department of Health and Human Services).

## **CHAPTER THREE: METHODOLOGY**

### **3.1. Introduction**

This chapter describes procedures that were followed in conducting this study. The person who was carrying this out the research gives a description of the research design, dependent and independent variables, study location, target population, sampling techniques and samples size, construction and research instrument, data variability and reliability , data collection techniques and methods of data analysis.

### **3.2. Research design**

The study was a cross- sectional in nature in which questionnaire were formulated and were given health care provides to fill them, self-checklist on post –exposure drugs on the PEP pharmacy register was used. The questionnaire sought information and side effects experienced by health providers and self-checklist indicate the age category of people who consume PEP most of the time.

Random sampling was employed to patients who are on post prophylaxis book register.

### **3.3 study variable**

The variables that were under measurement includes toxicities which arise due to the use of pep drugs. Efficacy and effectiveness was measured by aligning the data according to the results. The age category was measured by identifying the group of age which used PEP drug mostly.

Categories of people who were issued with PEP drugs were identified in the study.

Methods that prevent overuse of PEP drugs amongst the people were put into considerate during the study.

### **3.4. Location of study**

The study was conducted in Igegania Sub County hospital in Gatundu, Kiambu County

The facility was chosen due to availability of inpatient and outpatient clinic where mostly healthcare providers deals with sharp objects and was in close constant with the patients. The hospital handles a population of 100 patients per day, and according to the data from the pep register it was suggested 1 out of 100 patient were issued with PEP drugs per day. Most of the youth were drugs abusers in the locality and they ended up in engaging in unprotected sex hence rendering most of them to search for PEP drugs in the facility

### **3.5. Target population**

The study population includes 50 patients. This mostly includes the healthcare providers in the facility, mostly nurses, data form the PEP register for patients ranging from 20-50 years of age. Some data concerning the counseling and psychological support was obtained from the healthcare providers who issue PEP drugs.

### **3.6. Sampling techniques and sample size**

#### **3.6.1 Sampling techniques**

Purposive sampling; this is employed due to availability of staff who can be accessible within the facility.

Random sampling is also employed to extract data from PEP register; this is by choosing patients according to the age which corresponds to the data which is required and various groups of people who were issued with PEP drugs.

### 3.6.2. Sample size determination

Representation sample size was determined by the researcher using the formula (krejcie and Morgan 1970)

$$s = \frac{x^2 N p(1-p)}{d^2(N-1) + x^2 p(1-p)}$$

S = required sample

N = population size

P = population proportion (assumed to be 0.50)

Since this would provide the maximum sample size.

d= degree of accuracy as 0.05

X<sup>2</sup>= the table value of chi-square for one degree of freedom at the desired confidence level (3.841)

$$s = \frac{3.814 \times 50(0.5)(0.5)}{(0.05)^2(50-1) + 3.814(0.5)(0.5)}$$

$$s = \frac{3.814 \times 50(.25)}{0.005(49) + 3.814(0.25)}$$

$$= \frac{3.814 \times 12.5}{0.12225 + 0.9535} = \frac{47.675}{1.076}$$

$$= 44$$

Inclusion criteria: health workers who took PEP drugs were included in the study, health care providers who issue PEP drugs were also included in the study to assess whether they provide additional information.

Exclusion criteria: infants were not included in the study. Old aged people ranging from 51 and above were also not included since they did not provide enough information regarding their PEP usage.

### **3.6 construction and research instrument**

Questionnaire will be administered to Health care providers and they were allowed to fill them indicating the side effects they experience while using PEP. Health care's providers were also required to fill the questionnaire regarding the misuse of PEP and whether they offer counseling services and follow up.

Data from the records was obtained and analyzed to assess mostly used drugs for PEP and various groups of people who consume PEP mostly and also to indicate whether there was treatment of sexually transmitted disease for sexually associated individual and those involved in unprotected sex

In some instances open ended questions were used by the researcher to get some of the relevant information from HCP about the way they issue PEP drugs, they may indicate whether they offer a starter pack and then allow for follow up after completion of post exposure prophylaxis drugs.

### **3.8. Validity of data collection instrument**

The questionnaire which were filled by the healthcare professionals who used PEP drugs were able to correlate some of the side effect which may occur during use, and some of them are the same to those prescribed by the joint who/ILO guidelines(2016).

The study conducted by the National Aids and STI control Programs in 2016 also show PEP drugs offer effectiveness when used correctly, and according to the study the effectiveness was also established after various confirmatory test to the patients.

Health care providers who engaged in occupational exposure while attending a HIV positive patients, and are able to obtain PEP drugs from the health facility were able to ascertain the effectiveness after a confirmatory test.(NACO guidelines 2015)

### **3.9. Reliability of data**

Those who took PEP drugs especially the HCP were allowed to have baseline test after everyone month for a period of six month and there was 100% effectiveness. About eight HCP or 80% of them confirmed their result negative. 70% of those who took PEP drugs were able to report some of the may common side effect which include Nausea, bloating, diarrhea and jaundice.

Almost 80% of them report Jaundice which was attributed by ATV/r

### **3.10 Data analysis**

Data obtained was represented in tables as numbers and patient's percentage. It was also represented in form of bar graphs as number of patients and patient's percentage. The data was analyzed using Microsoft excel.

### **3.11 Ethical consideration**

The information collected form the questionnaires were used for the aim of the study and all the information collected was treated as confidential.

Participation is voluntary and the facility where the study was carried which includes pharmacy department was informed of the purpose and the objectives of the study. Information was only being obtained with the respondent's informed consent.

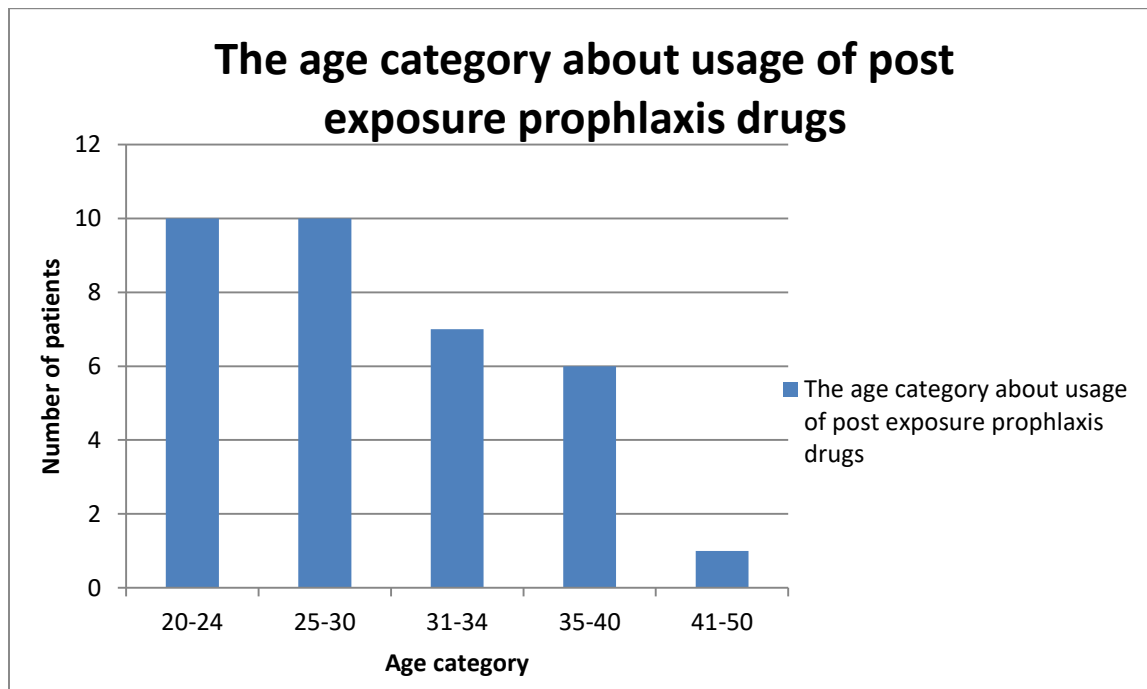
## CHAPTER FOUR: DATA ANALYSIS , PRESENTATION AND INTERPRETATION

### INTRODUCTION

The purpose of this study was to evaluate effectiveness of PEP drugs amongst the health workers, age category that used PEP frequently and side effects which are commonest among the people using PEP.

This chapter analyzed the finding which was obtained by the researcher according to the objectives. Among the data extracted from the PEP register, it was indicated 34 people were on PEP and questionnaire showed that all the health workers get a chance to fill them

#### 4.1. The age category about usage of post exposure



**FIGURE.4. 1** the age category of people who were on PEP drugs.

According to the study the youth ranging from 20-30 are the one who represent the highest percentage of pep usage. Youths ranging from 20-30 represents 58.82% followed by the youth ranging from 31-34 which represent 17.64% (7 patients)The age ranging from 41-50 years(1 patient)represents the lowest percentage of PEP usage.

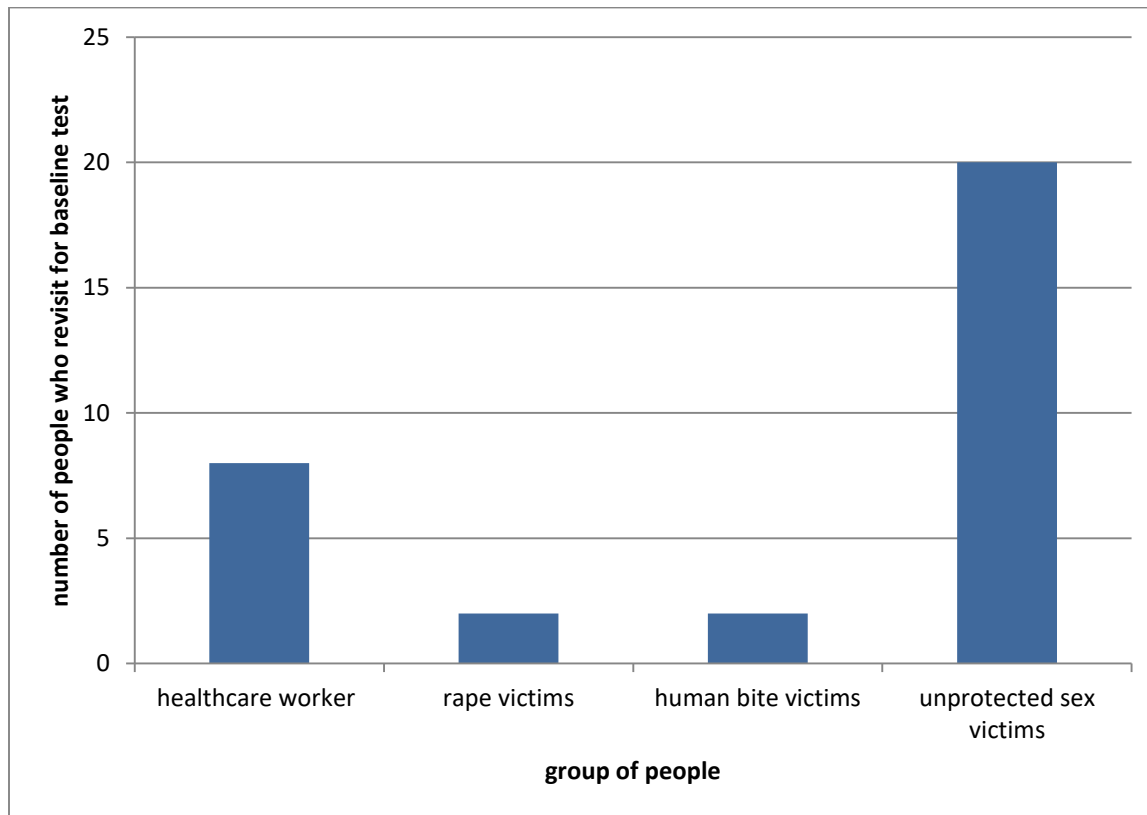
#### **4.2. Patients issued post-exposure prophylaxis drugs.**

Patient category	Number of patients	Percentage
Unprotected sex	30	68.18%
Rape cases	2	4.54%
Needle stick injury	10	22.72%
Human bite	2	4.54%
Total	44	100%

#### **Table 4.2 percentage category that were on PEP drugs**

According to the records accessed in PEP register and the information obtained from questionnaires it was observed that patients who engaged in unprotected sex represent the highest percentage of PEP usage. Health care provides follows with the percentage of 22.72% and this was attributed due to needle stick injury(occupational exposure) rape cases and human bite represents the lowest percentage of 4.54% each.

### 4.3. Effectiveness of post – exposure (PEP) prophylaxis drugs



**Figure 4.3: various groups of people issued with post- exposure prophylaxis**

Out of 44 patients surveyed, out 10 of health care workers only 8 who follow up for baseline test and their results was negative.

All rape cases victims visit the health facility for follow up and baseline test and the result also was negative,

Patients who have cases of human bite visits the health facility for follow up and none of them was recorded positive. The results for three months were negative.

Those patients who engaged in unprotected sex also turn negative after baseline test for three months. Its only 20 patients who revisit the health facility out of 32 of those who took PEP drugs.

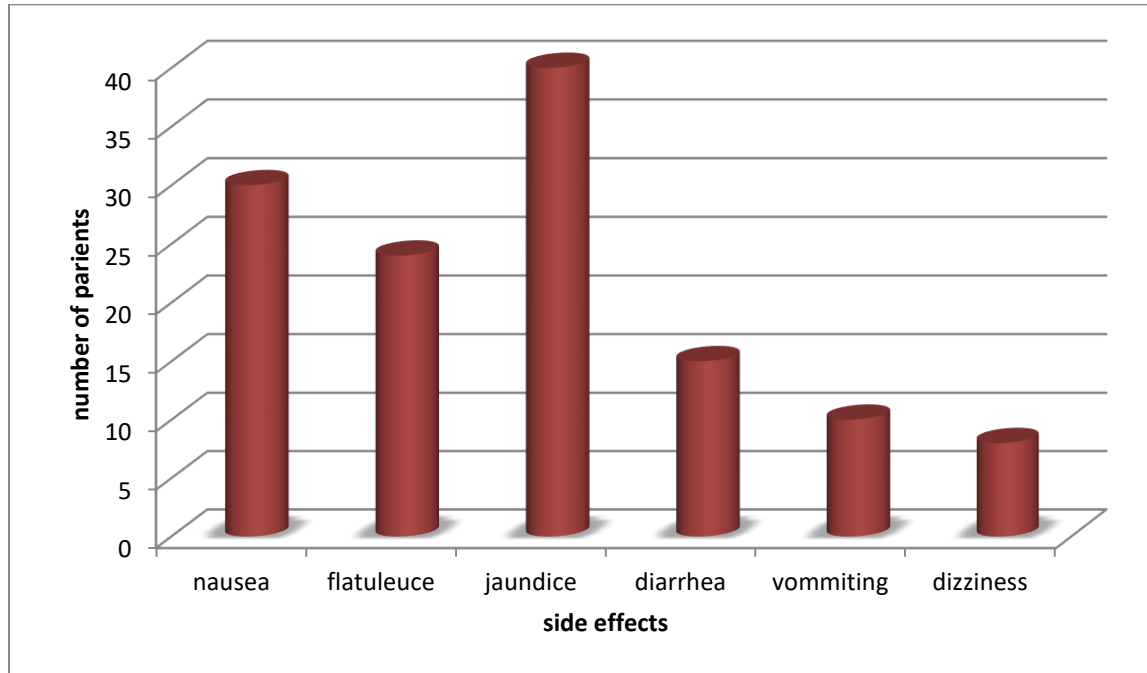
Patients issued with PEP drugs	Number of patients	Patients percentage
Healthcare worker	8	25%
Rape victims patients	2	6.25%
Human bite patients	2	6.25%
Unprotected sex	20	62.5%

**Table 4.3 effectiveness percentage of patients who revisit the health facility for follow up**

Only 8 out of 10 health workers who underwent follow up.(25%). Rape victim and human bites victim represents 6.25% each, in which all of them attended health facility for baseline test.

Out of 32 patients of unprotected sex and those issued with PEP drugs, only 20 patients managed to follow up for three months period

#### 4.4 side effects experiences while taking post-exposure prophylaxis



**Figure 4.4 effects experiences by patients while taking post-exposure prophylaxis**

Jaundice is almost experienced by all patients (40). It represents 90.9% of patients who are taking PEP. Only a few patients experience dizziness this attributes to 18.18% of patients. 24 patients experienced flatulence. 15 patient's experiences diarrhea, 10 patients have vomiting and 30 patients experience nausea.

Side effects	Number of patients	Patients percentage
jaundice	40	90.9%
nausea	30	68.18%
bloating	24	54%
Vomiting	10	22.72%
dizziness	8	18.18
diarrhea	15	15%

**Table 4.4: percentage of patient who experiences side effects of PEP drugs**

The highest side effects commonly experienced by most patient is jaundice, recording 90.9 % (40) followed by nausea which is 68.18%(30 patients) then bloating 54% (24patients), diarrhea 15%( 15 patients), vomiting 22.72% (10patients) and dizziness which recorded the lowest 18.18% (8).

## **CHAPTER FIVE: DISCUSSIONS CONCLUSION AND RECOMMENDATION**

### **5.1 Introduction**

This chapter represents the, discussion, conclusion and recommendation. It discusses the results discussed in chapter four, the conclusion of the results and the recommendations of the researcher according to the objectives.

### **5.2 Discussion**

#### **5.2.1 Overuse of post exposure prophylaxis, drugs**

According to the study, there is a high rate of abuse of PEP drugs; this mostly occurs in the youth ranging between 20-30 years of age .

Mostly this occurs due to involvement in unprotected sex and this renders them to seek PEP drugs within the health facility (NASCOP guidelines, 2016). The patient ranging from 41-50years of age present the lowest percentage. Overuse of PEP among the patients may render some of the youths not to complete the full dosage of PEP but they also pose a threat to incubating a resistant virus (daily nation nov5, 2013).the youths are engaging in unprotected sex and instead of using condoms, they go to public hospitals seeking the PEP emergency pill.

According to the PEP register, the demand occurs mostly on weekend and this correlate to the information given by Dr. martin Sirego, the head of NASCOP, this was observed in Kisii level Five Hospital(Daily nation Nov, 2013). According to the data, men are listed as the major patient who took post exposure prophylaxis drugs against women. This involves the ones engaged in unprotected sex.

### **5.2.2 Issuance of post –exposure prophylaxis drugs to patients**

Health workers represents 22.72% of those patient issued with PEP drugs. The reason behind the issuance of PEP drugs to health workers was mostly attributed to occupational exposure or needle stick injury while attending the patients.

PEP are mostly designed for people who have been sexually assaulted and health workers who involved in occupational exposure, but today they are mostly abused by youth who practice unsafe sex same as Canada source for HIV and hepatitis unsafe sex (Canada source for HIV and hepatitis information October/November 2005)

Rape cases represents 4.54% and mostly PEP are issued to curb HIV infection due to unknown status of the victim, according to the data only two rape cases were observed and guidance and counseling was provided to enable them to complete the full course of the drug, rape patients were first tested before issued with PEP drugs and if any case were found to be positive, they were referred to comprehensive care clinic for ART the therapy.

This study is the same as the one conducted by (joint WHO/ILO guidelines on PEP prophylaxis) Cases of unprotected sex represents percentage of 62.5% or 20 patients, this was attributed to youth engaging in unprotected sex.

According to hospital data, where youth engage in unprotected sex ,they are advised to present themselves with a partner, and in case they were found to be HIV negative they were not issued with PEP drugs. This study coincides with that one of NASCOP guidelines 2016).

Human bite has the same patient percentage of rape cases. Patients of human bite were issued with post –exposure prophylaxis drugs in case the victim may have an oral thrush and may introduce the HIV virus to the other person.

All the patient issue with post –exposure prophylaxis present themselves to health facility before 72 hours and they were first tested for HIV status (Guidelines for antiretroviral PEP after sexual, injection drugs use or other non-occupational exposure to HIV –united states, 2016). PEP drugs were issued for duration of 28 day.

### **5.2.3. Side effects of pep drugs**

The study indicates that jaundice was commonly reported by most patients. Those who report jaundice are evaluated on the type of drugs are taking and it was observed that ATV/r causes jaundice (NASCOP guidelines, 2006).

Almost nearly 90.9 % patients have jaundice. The study done by NASCOP (2016), indicates that nausea and vomiting may render the patients not completing the dose of PEP drugs.

To avoid nausea and vomiting the researchers recommends the patients to take drugs with food in order to enable them to complete the full course for 28days.

Nausea and vomiting are attributed to ATV/r and LPV/r drugs, this is according to the researcher (center for disease control and prevention, US department of the out and human services.

LPV/r represents percentage of 54.54% and this represent 24 out of 44 patient issued with PEP

According to study, failure of Pep mostly occur due to patients not completing the doses.

Bloating or flatulence was the main side effects reported by patients on LPV/r. Most patient were changed with regimen containing ATV/r instead of LPV/r for compliance of dosage.

Patients who were on ATV/r are advised not to mind about the jaundice as it resolves when one complete the drug. CDC guidelines 2016) Diarrhea was also observed by 15 patients and was reported to occur due to LPV/r. Patients are advised to report it when they suspects its severe and

they were changed to another regimes which contain a protease inhibitor, which does not have those effects.

Dizziness was also reported by some patients and was attributed to be the least side effects, the study indicated that it was a non-nucleoside inhibitor which is causing it, the drug was Tenofovir.

Patients are advised not to mind about all the effect which occurs unless they were severe. They were told the effects are not due to seroconversion as it occur in HIV individual (CDC guidelines, 2016)

#### **5.2.4 Effective of post-exposure prophylaxis drugs**

It was reported that 44 patients took PEP drugs, and it is only 32 patients who are able to follow up for retesting.

Most people who have reported to fail for retesting include the youths ranging from 20-30yrs of age. Rape cases victims and human bite patients were able to revisit the health facility after every one month and results were recorded negative after 3months

It was observed that effectiveness was established when the drugs were taken within 72hours and for a duration of 28days. Youths are initiated for guidance and counseling session to enable them to compare the dose (NACO guidelines 2015)

All the group category of patients who were issued with PEP are stated with starter pack of 7 days pill for efficient follow up until they complete the full course of drugs.

Effectiveness was established by inclusion of a protease inhibitor which includes ATV/r or LPV/r. three drugs regimen are considered to be more effective than the two drug regimes.

(WHO guidelines on post –exposure prophylaxis ,2007)

The adherence of health care worker was reported to be 80%, rape and human bite victim was 100%and that of patients involved in unprotected sex was recorded to be 62.5% (WHO/ILO guidelines on post- exposure prophylaxis 2007)

### 5.3 CONCLUSION

From the study, it can be concluded that post-exposure prophylaxis drugs offer effectiveness when used correctly within a period of 28 days and started early  $\leq 72$  hours after occupational and non-occupational exposure.

Starter pack of 3-7 days is considered as the most effective method of initiating PEP drug to enable regular follow of patients.

Many patients reported side effects emanate from the drug especially, yellowish of eyes which was reported due to ATV/r and are advised that its only for cosmetic purposes in which it disappears after completion of doses.

Youths are the most commonly affected individuals who abuses PEP drugs and they are initiated to guidance and counseling session to avoid misuse of PEP drugs and are allowed to use protective methods when indulging themselves in sexual activities.

Patients are encouraged to take PEP drugs with food to avoid commonest side effects which may lead to incompleteness of the doses.

There was no reported case of failure of PEP drugs from the study, from the study it can be concluded that most HCP who issues PEP drugs do not screen patients for sexually transmitted diseases (STDs) and this may pose a threat to the health of the patient. PEP drugs are not issued to patient who engage in occupational and non-occupational exposure within  $>72$  hour and those who are receiving HAART drugs.

Provision of medications to reduce the side effect such as nausea, vomiting and diarrhea might improve adherence to PEP drug

## 5.4 RECOMMENDATIONS

Baseline testing for HIV should be extended for a period of six months instead of three months and individual should be tested according to informed consent.

Liver function test should be performed after completion of PEP to assess the level of liver function for those who are taking pep drugs and are alcoholics.

Health care providers (HCP) who issue PEP drugs should remain updated on the current guidelines of PEP drugs combination to avoid resistant case.

Counseling session should be provided to all patients who are on PEP drugs in order to educate them about the side effect and to assist the youth on ways to use protective devices during sexual activities. If possible both partner should be tested for HIV status in case of unprotected sex and if found negative PEP drugs should not be initiated.

PEP( pre-exposure prophylactic drugs) should be given to partner in whom one couple is HIV positive instead of negative couple getting PEP drugs.

While using PEP drugs partner should practice protected sex until one complete the full dose of PEP and undergo HIV baseline test.

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## APPENDICES

### APPENDIX 1: INFORMED CONSENT

#### **Informed consent**

My name is Njoroge Charles Chege. I am a Bachelor of Pharmacy student in Mount Kenya University. I am conducting a study on post-exposure prophylaxis in Igegania Sub county Hospital.

#### **Procedures to be followed**

1. Participation in this study will require that I ask you some questions. You have the right to refuse Participation. Please remember that participation is voluntary. You may ask questions related to the study at any time and may refuse to respond to any questions asked. You may stop taking part in the study at any time.
2. If you accept to participate in this study, you will be provided with a questionnaire which you will be required to fill.

#### **Discomforts and risks**

Some of the questions may make you feel uncomfortable. If this happens feel free to refuse to answer the questions if you choose.

#### **Benefits**

If you participate in this study you will help understand the effects and effectiveness of post-exposure prophylaxis.

#### **Confidentiality**

Your name will not be recorded on the questionnaire. The questionnaires will be kept under lock and key for safe keeping. Everything will be kept private.

#### **Contact information**

If you have any questions you may contact PROF Ramalingam (0728742403) Head of Department of pharmaceutical chemistry

#### **Participant's statement**

The above information regarding my participation in the study is clear to me. I have been given a chance to ask questions and my questions have been answered to my satisfaction. My

participation is entirely voluntary. I understand my records will be kept private and that I can leave the study at any time.

Name of participant .

Signature . Date .

**Investigator's statement**

I, the undersigned, have explained to the volunteer in a language s/he understands, the procedures to be followed in the study and risks and benefits involved.

Name .

Signature . Date .

## APPENDIX II

### QUESTIONNAIRES

#### *Evaluative study on the use of PEP drugs*

My name is Njoroge Charles Chege student at Mount Kenya University Reg. No.

BPHARM/2014/74963 I am carrying out research for academic activities and to help the society to benefit from it in future. I hereby request you to fill and answer the following questions. The information you will give will be treated as confidential. Please tick where necessary in the box.

Respondent signature.....date .....

Researcher signature.....date.....

#### **Personal information**

(i) What is your gender

Male [ ]

Female [ ]

(ii) What is your age?

15-20 [ ]

20-25[ ]

25-30[ ]

30-35[ ]

35-40[ ]

40-45[ ]

(iii)What is your marital status?

Single [ ]

Married [ ]

(iv)What's your title?

Prof [ ]

Dr [ ]

Mrs. [ ]

Miss [ ]

Mr. [ ]

(v) What is your highest level of education?

Primary [ ]

Secondary [ ]

College [ ]

University [ ]

**Social demography****I. Evaluating the effectiveness of pep to health care**

(i) How many times have you been tested for HIV?

Two [ ]

Three [ ]

One [ ]

Four [ ]

(ii) Have you been tested before issued with post exposure prophylaxis drug ?

Yes [ ]

No [ ]

(iii) After completion of PEP drugs, do you follow up every one month?

Yes [ ]

No [ ]

(vi) Before taking of pep do you confirm the HIV status of the victim?

Yes [ ]

No [ ]

If yes what are the result/

Positive [ ]

Negative [ ]

If positive which drugs combination are you issued with?

Tenofovir+ lamivudine+ ATV/R [ ]

Tenofovir+ lamivudine+ LPV/R

After completion of PEP you confirm your result for a period of?

Three months [ ]

Six months [ ]

Two months [ ]

### **Prevention of PEP misuse**

(i) Which methods do you advice the youth to use while having sexual activity?

Condoms [ ]

Contraceptive [ ]

Prep [ ]

Abstinence [ ]

(ii) Do you offer counseling session?

Yes [ ]

No [ ]

(iii) Which class of people used PEP mostly?

Youths [ ]

Middle aged [ ]

(iv) Whom do you issued with PEP?

Those who have sexual assault [ ]

Those who have needle prick injury [ ]

Those have engaged in oral sex [ ]

(V) What other drugs do you give to people who want to bear children and one of the couple is HIV positive?

Antiretroviral[ ]

Prep[ ]

**Effects experienced while taking PEP**

(i) Do you experience any effects after taking PEP drugs?

Yes [ ]

No [ ]

If yes, which one's

Headache [ ]

Loss of appetite [ ]

Nausea [ ]

Bloating [ ]

(ii) Do you report to the health facility after experience the above effects?

Yes [ ]

No [ ]

(iii) Do you discontinue the drug?

Yes [ ]

No [ ]

If you have discontinued the drug what measures do you take?

- Confirm the result after one month
- Visit the health facility to report the result

If you visit the health facility, what action did they take?

- i. Change the regimen [ ]
- ii. Advise you to continue with the drug [ ]

### **Failure of PEP**

- (i) Have you ever experienced any failure of PEP drug?

Yes [ ]

No [ ]

If yes do you ask the patients whether has been tested before?

Yes [ ]

No [ ]

- (ii) What reason lead to failure a PEP?

No adherence [ ]

Side effect experienced and stop the drug [ ]

Taking PEP > 72 hours [ ]

I hereby confirm that the information presented in the above questionnaire are truthful and aimed at helping the researcher get accurate data on the record books and healthcare personnel

Involvement