KNOWLEDGE, ATTITUDE AND PRACTICE ON OPHTHALMIC FEATURES OF HIV/AIDS AMONG CLINICIANS IN COMPREHENSIVE CARE CENTRES IN NYANZA

A dissertation submitted in part fulfillment for the Degree of Master

Of Medicine in Ophthalmology

UNIVERSITY OF NAIROBI

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2014

DECLARATION

This dissertation is my original work and has not been presented for a degree at any other university.

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DEDICATION

To My husband Dr. Jared Anyonafor his love and support and the children; Ruth, Maxwell, Fiona and Faith,for the precious moments missed.

To My late parents,Mrs.MarthaK.Onyango and Eng.WinstonO.Orwenyofor valueing education.

ACKNOWLEDGEMENT

I wish to acknowledge the following for their support towards this dissertation:

My supervisors: Dr.M.Njuguna and Dr.M.Kariuki for their continuous guidance and advice.

Christian Blind Mission for their sponsorship.

Dr.JacksonKioko, PPHDMS, Nyanza for granting me permission to carry out the study in Nyanza region.

Mr.StephenMailu for analysing the data.

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LIST OF ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
ARC	Acquired immune deficiency syndrome-related complex
ARN	Acute retinal necrosis
ART	Anti retroviral therapy
CCC	Comprehensive care centre
CD4	Cluster of differentiation 4
CD8	Cluster of differentiation 8
CO	Clinical Officer
CMV	Cytomegalovirus
DH	District Hospital
DRV	Darunavir
D4T	Stavudine
EFV	Efavirenz
EIA	Enzyme immunoassay
ELISA	Enzyme-linked immunosorbent assay
ETV	Etravirine
FTC	Emtricitabine
HAART	Highly Active Anti-Retroviral Therapy
HIV	Human Immune Deficiency virus
HSV	Herpes simplex virus
HZO	Herpes zoster ophthalmicus
KAIS	Kenya AIDS Indicator Survey
KAP	Knowledge Attitude and Practice
KDHS	Kenya Demographic Health Survey

MO	Medical Officer
NNRTI	Non nucleoside Reverse Transcriptase Inhibitor
NRTI	Nucleoside Reverse Transcriptase Inhibitor
NVP	Nevirapine
OBR	Optimized background regimen
PARTO	Provincial Anti-retroviral Therapy Officer
PCR	Polymerase chain reaction
PORN	Progressive outer retinal necrosis
RAL	Raltegravir
RNA	Ribonucleic Acid
TB	Tuberculosis
3TC	Lamivudine
TDF	Tenofovir
UNAIDS	United Nations Program for HIV/AIDS
VZV	Varicella zoster virus
WHO	World Health Organization

ABSTRACT

Background:1.33 million Kenyans are infected with HIV/AIDS.The prevalence is highest in Nyanza region (13.9%). There is no data on knowledge, attitude and practice on ophthalmic features of HIV/AIDS among clinical officers/medical officers.Being the primary physicians,it,s prudent to evaluate their skills in assessing and referring patients with these features.

Design: A cross-sectional study

Objective:Assessknowledge, attitude and practice onophthalmic features of HIV/AIDS in adults among clinicians.

Methodology: The study was carried out in Nyanza, Kenya and the study participants were clinical officers and medical officers working in comprehensive care centres.

One on one interview was performed using a questionnaire and data collected was coded and entered in pre-designed Microsoft access database.Analysis was done using SPSS version 17 software.The results were presented in tables and graphs.

Results: 73 clinicians were interviewed over a period of 2 months.Their ages ranged from 22 to 55 years.93.2% were clinical officers and 6.8% were medical officers while the male to female ratio was 2:1 and 1:4 respectively.

89.7% of clinical officers (CO) compared to all the medical officers (MO) had knowledge on ophthalmic features of HIV/AIDS.Herpes zoster was the commonest ophthalmic feature of HIV/AIDS that was known by 50.8% of COs and 80% of MOs.57.4% of COs compared to 80% of MOs were aware that the ocular adnexae was affected by HIV/AIDS infection while 86.8% and 100% respectively knew that the level of CD4 count determined occurrence.Majority did not know ophthalmic features of HIV/AIDS that occurred at different levels of CD4 counts.

The practice was poor with 72.1% of the COs and 60% of MOs not taking ocular history while 72.1% and 80% respectively were not performing an ocular examination.However, majority of them referred patients with complaints.

Conclusion:The study established that the clinicians had adequate general knowledge on ophthalmic features of HIV/AIDS though gaps existed on the specific features and on role of the CD4 count as a determinant of occurrence. The attitudes were good though this did not reflect on practice.

1.0 INTRODUCTION

Kenya is a country found in East Africa. Previously, it was subdivided into 8 provinces: Nairobi, Central, Eastern, Western, North Eastern, Coast, Rift valley and Nyanza. Currently, it is divided into 47 counties (figure 1).Nyanza region presentlyhas Siaya, Migori,Homabay,Kisii,Kisumu and Nyamira counties which overall have the highest number of HIV/AIDS cases in Kenya.[2]

A comprehensive care centreis an outpatient clinic that offers people living with HIV/AIDS treatment and supportive services. The ones based in government hospitals were started in 2003 and they offer free services. They are run by qualified clinical officers and in a few hospitals, medical officers who both are commonly referred to as clinicians.

HIV/AIDS effects on the eye can be categorized into: anterior segment, posterior segment, ocular adnexae, neuro-ophthalmic features, orbital and ocular toxicity due to drugs like didanosine (an antiretroviral) administered to the patients.[13, 14]

Research shows that a lot of knowledge gaps exist on various aspects of HIV/AIDS care.[27, 28, 29] No study to the best of our knowledge has assessed knowledge, attitude and practice on ophthalmic manifestations of HIV/AIDS among clinicians.

Figure 1: Map of Kenya depicting the 47 counties

1.1 Natural History of HIV/AIDS

The first confirmed case of HIV infection was made from analysis of a blood sample of a man from Congo who died of unidentified illness in 1959.In United States of America, the first cases of AIDS were reported among gay men in New York, Los Angeles and San Francisco who had pneumocystis carinii pneumonia and Kaposi sarcoma in 1981.[1]For Kenya it is over two decades since the first case was described.[2]

The human immunodeficiency virus is a retrovirus that infects the human body through contact with infected blood and other body fluids. This can occur through sexual contact (anal, vaginal or oral), use of unsterile needles or sharp objects, blood transfusion or mother to child transmission.

Once an individual gets infected with the HIV virus, rapid replication of the virus occurs after the virus gains entry into cells with CD4 + markers. This leads to a high viral load, decline of amount of CD4 + cell count and a seroconversion illness (primary infection) in 70-80% of patients. This period is characterized by symptoms ranging from fever to neurological complications.

After seroconversion, recovery in CD4+ cell count occurs and the viral load remains stable with the patient being asymptomatic.This asymptomatic period varies from 6 months to several years.[3]

Without HIV therapy the CD4 + count declines and once it is below 350 cells /mm^3, the patient becomes susceptible to opportunistic infections, developing symptoms and AIDS (appendix C). AIDS is defined by a CD4 count < 200cells/µl or < 14% of total lymphocyte count.[4]

1.2 Laboratory tests

HIV virus testing has revolved from only testing of donor blood before transfusion to voluntary counseling and testing of individuals.[3]Diagnosis of HIV infection can be done by testing antibodies to the virus using enzyme-linked immunosorbent assay (ELISA) also called enzyme immunoassay (EIA).ELISA test has a specificity of 98.1% - 99.5% and sensitivity of 99.3% - 100% hence a positive test requires a confirmatory test to be done.[5, 6, 7]

Western blot is the common confirmatory test used due to its high specificity (96% -100%) by identifying antibodies to specific viral proteins.[5, 7]

P24 antigen testing detects viral antigen in blood before seroconversion takes place.It is highly specific (99% vs. 97%) but less sensitive (79% vs. 100%) than HIV RNA tests like PCR.[8]

1.3 Management of HIV/AIDS in adults

There are three levels of prevention in the spread of HIV/AIDS: primary, secondary, and tertiary.

The goal of primary prevention is to prevent, reduce and delay HIV infection. This can be achieved through safe sex practices, changing of behaviors and use of condoms in high risk groups. Safe use of needles especially in intravenous drug users should also be practiced.

Secondary prevention provides treatment to individuals already infected with the virus in order to retard disease progress and encourages them to avoid transmitting the disease.

Tertiary prevention aims at preventing disabling aspects of AIDS hence keeping the patients healthy for as long as possible.[9]

Antiretroviral therapy in Adults

New evidence on when to initiate anti retroviral therapy (ART), optimal ART regimen, HIV/Tuberculosis co-infection, viral hepatitis and management of ART failure formed the basis behind the 2010 WHO adult ART initiating guidelines update (Table 1).In settings where CD4 count assessment is not available, the WHO clinical staging (Appendix C) should be used to determine when to initiate ART.[10]

Table 1: WHO criteria for initiating ART in adults and adolescents.[10]

Target population	Clinical condition	Recommendation
Asymptomatic individuals (including pregnant women)	WHO clinical stage 1	Start ART if CD4 ≤350
Symptomatic individuals (including pregnant women	WHO clinical stage 2 WHO clinical stage 3 or 4	Start ART if CD4 ≤350 Start ART irrespective of CD4 cell count
TB and hepatitis B Co-infections	Active TB disease Hepatitis B virus infection requiring treatment	Start ART irrespective of CD4 cell count Start ART irrespective of CD4 cell count

Choice of ART

First-line regimen for adults and adolescents should consist of one non-nucleoside reverse transcriptase inhibitor (NNRTI) plus two nucleoside reverse transcriptase inhibitors (NRTI), one of which should be zidovudine (AZT) or tenofovir (TDF).Stavudine (d4T) has been faced out due to toxicity.

With treatment failure evidenced by persistent viral load of > 5000 copies/ml or immunological failure (CD4 count persistent below 100 cells/µl), the patient should be changed to second-line regimen.A ritonavir-boosted protease inhibitor (atazanavir or lopinavir) plus two NRTIs (AZT or TDF) are the options available for second line depending on what was used for first line.

For patients with HIV/hepatitis B virus co-infection, the regimen should contain TDF and Lamivudine (3TC) or emtricitabine (FTC) that have anti hepatitis B activity. In tuberculosis/HIV co-infection, the same adult regimen can be used if rifabutin is available but if not available, the NNRTI should be changed to a boosted protease inhibitor.The dose of the booster (ritonavir) should be adjusted.

The criteria for diagnosing second-line failure is the same as for first-line failure.Darunavir (DRV) /ritonavir plus an optimized background regimen (OBR) chosen by genotyping and phenotypingis recommended.Raltegravir (RAL) can be combined with DRV andEtravirine (ETV).ETV is used in place of nevirapine (NVP) or efavirenz (EFV).[10]

1.4 Epidemiology of HIV/AIDS

A global summary of the HIV/AIDS epidemic for 2012 by joint United Nations Programme for HIV/AIDS (UNAIDS) and World Health Organization (WHO) estimated that 35.3 million people worldwide to be infected with this virus, with 2.3 million new cases and 1.6 million deaths.71% of these patients live in sub-Saharan Africa.[11]The 2012 Kenya AIDS Indicator Survey (KAIS) showed that 5.6% of Kenyans between the ages of 15-64 years are infected with the virus.Kenya Demographic Health Survey (KDHS) for 2008-09 showed that HIV/AIDS prevalence in Kenya varies by province ranging from 0.9% in North Eastern province to 13.9% in Nyanza province.[12]

1.5 Pattern and prevalence of ophthalmic features of HIV/AIDS

The level of $CD4^+$ cell counts is the main predictive parameter for the occurrence of most ophthalmic features in patients who are HIV positive. A few of the features however, occurs regardless of this. (Table 2)

Table 2:CD4 + cell count in patients presenting with common HIV-associated disorders of the eye.[14]

CD4 $^+$ COUNT	EYE DISORDER
250-500 cells/mm^3	Kaposi sarcoma
	Lymphoma
	TB
100-250 cells/mm^3	Pneumocystis carini
	Toxoplasmosis
<100 cells/mm^3	Retinal/conjuctivalmicrovasculopathy
	Cytomegalovirus retinitis
	Keratoconjuctivitissicca
	Varicella zoster virus retinitis
	Mycobacterium avium complex infection
	Cryptococcosis
	Microsporiodiosis
	HIV encephalopathy
	Progressive Multifocal Leucoencephalopathy
Any CD4 Count	Conjuctival squamous cell carcinoma
	Molluscumcontagiosum
	Acute retinal necrosis

Ophthalmic features of HIV/AIDS infection can be categorized into:

1. Anterior segment manifestations: keratoconjuctivitissicca, infectious keratitis, iridocyclitis, microsporidia keratitis

2. Ocular adnexae: herpes zoster ophthalmicus, kaposi sarcoma, molluscumcontagiosum, conjuctivalmicrovasculopathy, conjuctival squamous cell carcinoma

3. Posterior segment: they are grouped into manifestations on the retina, choroid, and optic nerve head.They include HIV retinopathy, infectious retinitis and choroiditis caused by cytomegalovirus (CMV),varicella zoster virus (VZV) and herpes simplex virus (HSV) which causes acute retinal necrosis (ARN), progressive outer retinal necrosis (PORN) associated with VZV, syphilis, tuberculosis, cryptococcosis, histoplasmosis, toxoplasmosis, and pneumocystosis.

4.Neuro-ophthalmologic manifestations: ocular movement abnormalities, visual field defects, optic neuropathy/atrophy, papilloedema, ocular nerve palsies and cortical blindness.

5. Orbital manifestation: orbital cellulitis, orbital lymphoma, kaposi sarcoma, pseudotumour, and metastatic carcinoma.

6. Ocular toxicity of drugs used in HIV/AIDS patients: antiretroviral drugs and drugs used to manage opportunistic infections. They include cidofovir, rifabutin, ethambutol, didanosine, clofazamine, atovaquone, gancyclovir, acyclovir, linezolid, voriconazole.

13, 14, 15, 22

Ocular manifestations of HIV/AIDS were first reported by Holland et al in 1982 .[17]70-80% of HIV/AIDS patients will develop ocular features of this disease during the course of their illness especially with the use of Highly Active Anti Retroviral Therapy (HAART) that prolongs their life.[13]

A review of 1163 HIV /AIDS patients seen at John Hopkins University School of Medicine by Jabs D found HIV retinopathy in 50% of AIDS patients, 34% in ARC patients and 3% in asymptomatic patients. Cytomegalovirus retinitis affected 37% of AIDS patients while herpes zoster ophthalmicus was found in 3% of all patients. Neuro-ophthalmic lesions occurred in 6% of AIDS patients with 25% of patients with cryptococcal meningitis developing a neuro-ophthalmic complications.[16]

In Kenya, Awan HR et al reviewed 102 HIV/AIDS patients found 67% of them with ocular features. The commonest ocular findings were cotton-wool spots in 25% (now thought to be part of the HIV retinopathy spectrum[17]) and herpes zoster in 23%.Cytomegalovirus (CMV) retinitis was observed in 3% of patients.[18]

Listo et al in his study in Kenya on ocular manifestation of HIV/AIDS found that 77% of the 200 adults reviewed had ocular features.Posterior segment findings occurred in 53% of patients with retinal microvasculopathy being the commonest finding .CMV retinitis was observed in 2.5% of cases. Anterior segment findings in 36.5% of cases were mainly herpetic keratis and herpes zoster ophthalmicus. Adnexal manifestations noted in 26.5 % were squamous cell carcinoma, HZO, Kaposi sarcoma, conjunctival microvasculopathy, molluscumcontagiosum and suspicious conjunctival growth while the neuro ophthalmic manifestations in 11 % of patients were optic atrophy, papilloedemaand papilitis. [19]

In Mali, Koneet al reviewed 63 HIV/AIDS patients and found 61.9% of them with ophthalmic features.The main lesions in anterior segment were herpes keratitis and HZO. For posterior segment the main findings were CMV retinitis and uveitis.[20]

Biswas J et al in India reviewed 70 patients and found 45.7% with ophthalmic manifestations. The commonest ocular finding was CMV retinitis in 21.45% of patients. Other lesions included cotton-wool spots (12.8%), chorioretinitis (5.7%), endogenous endophthalmitis (8.5%), anterior uveitis (4.2%), and molluscumcontagiosum (1.4%). [21]

In Korea, Kim JS et al reviewed 200 patients with AIDS and found 57% of them had ocular features. The commonest findings were retinal microvasculopathy in 40.3% and CMV retinitis in 38.5%.[23]

1.8 Knowledge, Attitude and Practice (KAP) on HIV/AIDS

Knowledge refers to the understanding of any given topic, while attituderefers to the feelings and preconceived ideas towards this topic.Practiceis the way in which knowledge and attitude is demonstrated through action.

Kuruvila M et al assessed the level of knowledge about HIV/AIDS among 171 first year medical students of New Delhi University at the point of entry to medical course and found the overall level of knowledge about AIDS to be 64.91%.The assessment was about the mode of transmission, prevention aspect and knowledge about disease.[24]

Dobe M interviewed 400 health care professionals at the medical college and hospital in Calcutta,India on their level of awareness about HIV/AIDS. The health care professionals included surgeons, gynecologists, pathologists, internal medicine specialists, blood bank workers, recent medical school graduates, clinical students, preclinical students, nurses, and technologists. He found that 40-60% of preclinical students knew little about the natural history of HIV infection and its clinical manifestations, 20% of students and 40% of physicians knew that there were HIV tests available.50-60% of paramedical personnel had misconceptions about HIV/AIDS.

A similar study by Wu Z et al in China found 3% to 68% of health professionals giving correct responses with public health workers having more knowledge than clinicians.[26]

Brachman et al made assessed Knowledge and attitudes of hospital-based physicians and trainees about HIV infection in the United States, Canada, India, and Thailand. He found that respondents from India had the lowest previous contact with HIV/AIDS patients and highest in United States.67% of Indian health care professionals had knowledge on false-negative screening serologic test, compared with 98% of Canadian health care professionals. Awareness of an asymptomatic stage of HIV infection was lowest (32%) in India and highest (74%) in Canada. Respondents from India had the lowest amount of information on HIV/AIDS despite having a high prevalence of the disease compared to a country like Canada.[27]

Torabi MR in United States assessed 500 family physicians' knowledge, attitude and practice regarding HIV/AIDS prevention and found the mean knowledge score was 67%. They had knowledge gaps regarding central nervous system involvement in AIDS, zidovudine prophylaxis, health care workers needle stick injuries, HIV transmission to newborns and new AIDS cases in minority groups. This was more evident in physicians who had practiced for more than 30 years.[28]These findings were similar to those of Quach et al who interviewed 151 physiciansin public hospitals in QuangNinh, Vietnam where he found younger physicians or those who saw many patients tended to be better informed though the older physicians had a more positive attitude towards taking care of HIV/AIDS patients. The overall knowledge about HIV transmission among the physicians was 88.1% while knowledge on the biology of HIV was 66.2%.[29]

In California Lewis C et al studied AIDS related competence among 600 primary care physicians and he found majority of the physicians lackingin knowledge and skills required to care for these patients. Positive responses were 44% on knowledge of the AIDS-related complex (ARC) , 16% on specificity of screening tests, 17% on diagnostic work-up (history and physical examination) forAIDS-related disorders, 34% on knowledge of risk factors and 35% on counseling practices.[30]

These data suggests that a lot of knowledge gaps exist on various aspects of HIV/AIDS. No study has looked at knowledge, attitude and practice of ophthalmic manifestations of HIV/AIDS among clinicians. Our study seeks to establish this particular aspect.

2. RATIONALE

- Currently there is no literature on Knowledge, Atttitude and Practice on ophthalmic features of HIV/AIDS among clinicians in comprehensive care centres.
- Research shows that 10-20% of HIV/AIDS patientslose vision due to these features.[31]
- The issue on whether these clinicians have adequate knowledge, attitude and practice prompted this study.

3.0 STUDY OBJECTIVES

3.1 MAIN OBJECTIVE

To determine and assessknowledge, attitude and practice onophthalmic features of HIV/AIDS in adults among clinicians working in comprehensive care centre in Nyanza region.

3.2 SPECIFIC OBJECTIVES

1. To assess knowledge of the different ophthalmic features of HIV/AIDS among clinicians.

2. To determine the attitude of clinicians towards ophthalmic features of HIV/AIDS.

3. To find out the practice of clinicians on ophthalmic features of HIV/AIDS.

4. 0 METHODOLOGY

4.1Study design: cross-sectionaldescriptive study.

4.2Study population: Clinical Officers and Medical Officers working in comprehensive care centers (CCC) in sub-district, district and provincial hospitals in Nyanza region.

The estimate obtained from the office of the Provincial Anti-Retroviral Therapy Officer (PARTO) put the number of Clinical Officers and Medical Officers working in the CCC at 83.

4.3 Study setting

Kenya's health care system has an organized referral structure that is made of:

Level 1: Dispensaries and private clinics

Level 2: Health centers

Level 3: Sub-district hospitals and nursing homes

Level 4: District hospitals and private hospitals

Level 5: Provincial hospitals

Level 6: National hospitals

The sub-district hospital is the lowest level that has a comprehensive care centre.

Distribution of hospitals in the counties:

Kisumu-The provincial hospital

1 DistrictHospital (DH)

Siaya-1 DH

Migori-1 DH

Homabay-1 DH

Kisii-Level 5

Nyamira-1 DH

Each district hospital has at least 2 Clinical officers/Medical Officer(CO/MO)based in the CCC

The total number of sub-district hospitals in Nyanza is 49 and each has at least 1 CO in the CCC.

The total number of hospitals visited was 56

4.4Study period: October 2012-March2014

4.5 Sample size

The number of Clinical Officers/Medical officers working in the CCC in Nyanza region was estimated at 83. The minimum sample size required for this study was calculated using the modified fisher formula as follows:

$$n' = \frac{NZ^2P(1-P)}{d^2(N-1)+Z^2P(1-P)} \longrightarrow \text{(Daniel, 1999)}$$

Where

n'= sample size with finite population correction,

N = size of the target population = 83

Z = Z statistic for 95% level of confidence = 1.96

P = Estimated proportion with knowledge on ocular manifestations among HIV patients = 50% (no previous study on the same).

d = margin of error = 5%

$$= \frac{83 \times 1.96^2 \times 0.5 \times 0.5}{0.05^2 (83-1) + 1.96^2 \times 0.5 \times 0.5}$$

= 68

A minimum number of 68 Clinical Officers/Medical Officers were to be sampled for this study.

4.6 Sampling method

All clinical officers and medical officers working in CCC were included in the study as their population was less than 100.

4.7 Inclusion criteria

- All Clinical Officers and Medical Officers who were working in CCC in Nyanza and who consent to the study.

4.8 Exclusion criteria

- None

5. MATERIALS

5.1 Questionnaire (Appendix A)

One on one interview was done using a pre-designed questionnaire.

5.2 Data collection and analysis

Data collected was coded and entered in pre-designed Microsoft access database.

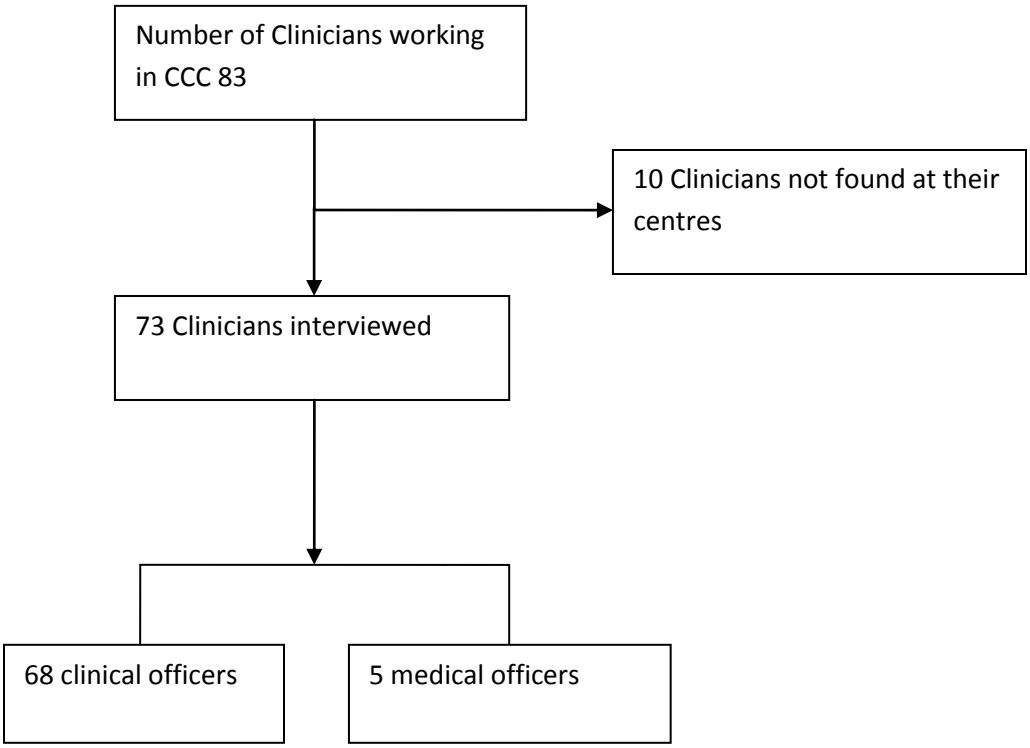
Analysis was done using SPSS version 17.0 software.

5.3 Ethical considerations

- The study proposal was approved by the KNH /UON ethical committee.
- Informed consent was obtained from the participants.
- An introductory letter was obtained from the head of ophthalmic services.
- Permission was sort from the Provincial Public Health Director of Medical Services to carry out the study in Nyanza region.
- Confidentiality was maintainedat all levels of data management.
- Feedback of results to relevant authorities will be given.

6. RESULTS

THE FLOW CHART



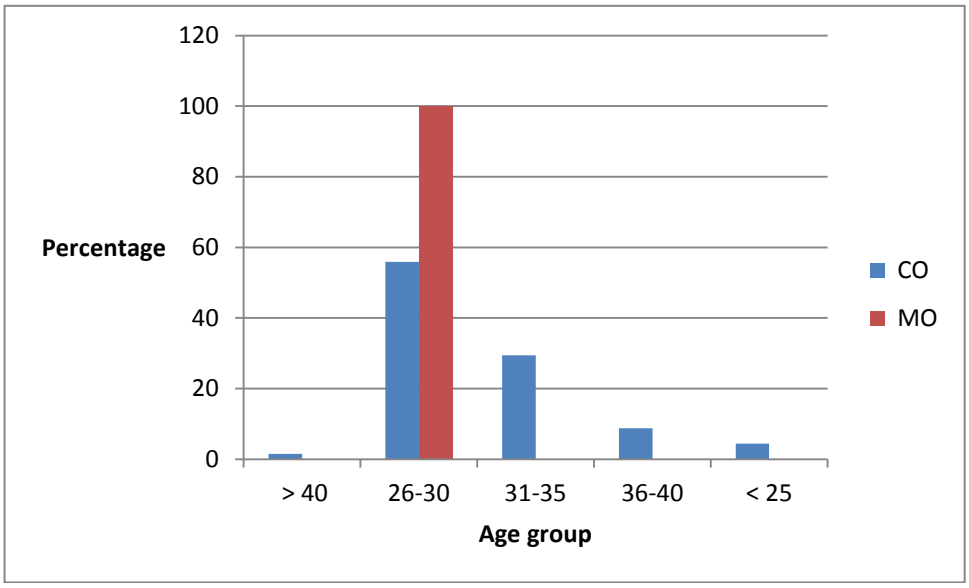
Seventy three Clinicians were recruited, from the 56 hospitals visited, into the study after giving informed consent.68 of them were clinical officers while 5 were medical officers.10 participants were not found at their place of work at the time of the study. The response rate was 88%.

Table 1: Demographic characteristics of the participants

Variable	**Clinical officers (%)** n =68(93.2)	**Medical officers (%)** n= 5(6.8)
Sex		
Male	45(66.2)	1(20)
Female	23(33.8)	4(80)
Age group		
>40	1(1.5)	
36-40	6(8.8)	
31-35	20(29.4)	
26-30	38(55.9)	5(100)
<25	3(4.4)	

Majority of the study participants were clinical officers (93.2%)

Figure 1: Age of participants



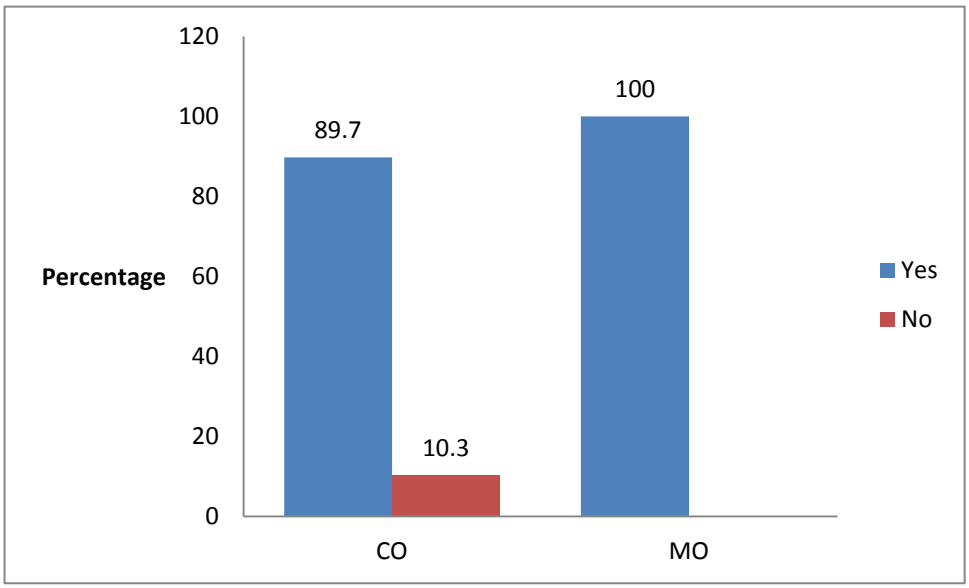
More than half of the clinical officerscompared to all the medical officers were aged between 26 and 30 years

Table 2:Duration the participants had worked in the CCC (In years)

Duration	Clinical officers	Medical officers
<1	12(16.4)	2(40.0)
1-3	35(47.9)	1(20.0)
4-6	18(24.7)	1(20.0)
7-9	4(5.5)	1(20.0)
>10	4(5.5)	
Total	73(100.0)	5(100.0)

47.9% of the clinical officers had worked for 1-3 years in the CCC while 40% of the medical officers had worked for less than 1 year.

Figure 2: Knowledge of ophthalmic features of HIV/AIDS



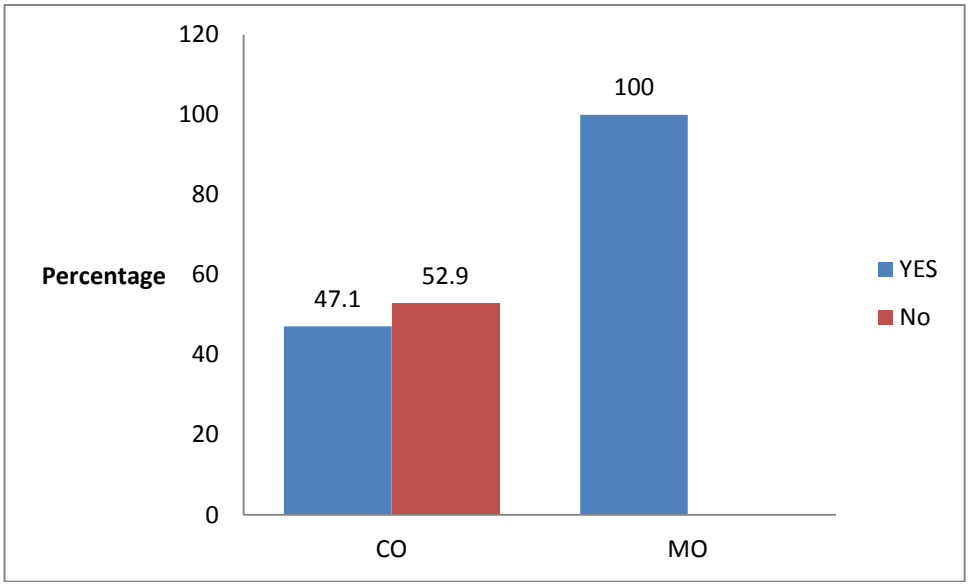
89.7% of clinical officers comparedto all the medical officers were aware of ophthalmic features of HIV/AIDS.

Table 3: Knowledge on the types of ophthalmic features

Responses	Clinical officers n=61	Medical Officers n=5
Herpes zoster	32(50.8)	4(80.0)
Conjuctivitis	26(42.6)	
CMV retinitis	16(26.2)	3(60.0)
Kaposi sarcoma	13(21.3)	
cryptococcus	12(19.7)	
Toxoplasmosis	6(9.8)	1(20.0)
HIV retinitis	5(8.2)	
Optic neuritis	3(4.9)	2(40.0)
Facial nerve palsy	3(4.9)	
Tuberculosis	3(4.9)	
uveitis	3(4.9)	1(20.0)
Proptosis	2(3.3)	
Deformities	2(3.3)	
stye	2(3.3)	
MolluscumContagiosum	2(3.3)	
Keratitis	1(1.6)	
Pain	1(1.6)	
Preseptal cellulitis		1(20.0)
Orbital cellulitis		1(20.0)

Herpes zoster was named by 50.8% of clinical officers and 80% of medical officers as an ophthalmic feature of HIV/AIDS infection.

Figure 3: Knowledge on ophthalmic features of HIV/AIDS that are an emergency



47.1% of clinical officerscompared to all medical officers were aware of ophthalmic features of HIV/AIDS that were an emergency.

Table 4: Knowledge on the types of ophthalmic features that are an emergency

Responses	**No. of clinical officers (%) n=32**	**No. of medical officer(%) n=5**
Herpes zoster	17(53.1)	4(80)
CMV retinitis	13(40.6)	3(60)
Cryptococcalmenengitis	2(6.3)	
Conjuctivitis	2(6.3)	
Optic neuritis	1(3.1)	2(40)
Kaposi sarcoma	1(3.1)	
Pain	1(3.1)	
Toxoplasmosis	1(3.1)	1(20)
Preseptal cellulitis		1(20)
Orbital cellulitis		1(20)
Uveitis		1(20)

Half of the clinical officers (53.1%) compared to 80% of medical officers named herpes zoster as an ophthalmic feature of HIV/AIDS that was an emergency.

Table 5: Knowledge on the parts of the eye that are affected by HIV/AIDS infection

Response	**No. of clinical officers(%) n=68**	**No. of Medical officers(%) n=5**
Ocular adnexae	39(57.4)	3(60)
Anterior segment	29(42.6)	4(80)
Posterior segment	27(39.7)	3(60)
Neuro-ophthalmic manifestations	14(20.6)	3(60)
Orbit		3(60)

57.4% of the clinical officers named ocular adnexae while 80% of the medical officers named the anterior segment as a part of the eye that is affected by HIV/AIDS infection.

Table 6: Knowledge on CD4 count as a determinant of occurrence of ophthalmic features

Response	No.of Clinical officers (%)	No. of medical officers (%)
Yes	59(86.8)	5(100)
No	9(13.2)	
Total	68(100)	5(100)

86.8% of the clinical officers compared to all the medical officers knew that the level of CD4 count determined the occurrence of ophthalmic features of HIV/AIDS

Table 7: Ophthalmic features that occurregardless of the level of CD4 count

	No.ofClinical officers (%) n=59	No.of medical officers(%) n=5
HIV retinopathy		1(20)
PJP choroidopathy		1(20)
Conjuctivitis		1(20)

HIV retinopathy,PJPchoroidopathy and conjuctivitis were each named by 1 medical officer as features that occur regardless of the level of CD4 count.No feature was named by the clinical officers.

Table 8: Ophthalmic features of HIV/AIDS that occur with CD4 count <100 cells/mm^3

Responses	No.of clinical officers (%) n=59	No.of medical officers(%) n=5
CMV retinitis	14(23.7)	2(40)
KS of the eye	7(11.9)	
cryptococcus	4(6.8)	
uveitis	1(1.7)	
Microangiopathy		1(20)
Toxoplasmosis	1(1.7)	
Herpes zoster	1(1.7)	

23.7% of clinical officers compared to 40% of medical officers named CMV retinitis as a feature that occurs when CD4 count is<100 cells/mm^3

Table 9:Ophthalmic features of HIV/AIDS that occur with CD4 count between 100-250 cells/mm^3

Responses	No.ofclinical officers (%) n=59	No.of Medical officers (%) n=5
Toxoplasmosis of eye	2(3.4)	1(20)
KS	3(5.1)	
CMV retinitis	2(3.4)	1(20)
Herpes zoster	13(22)	1(20)
uveitis	1(1.7)	

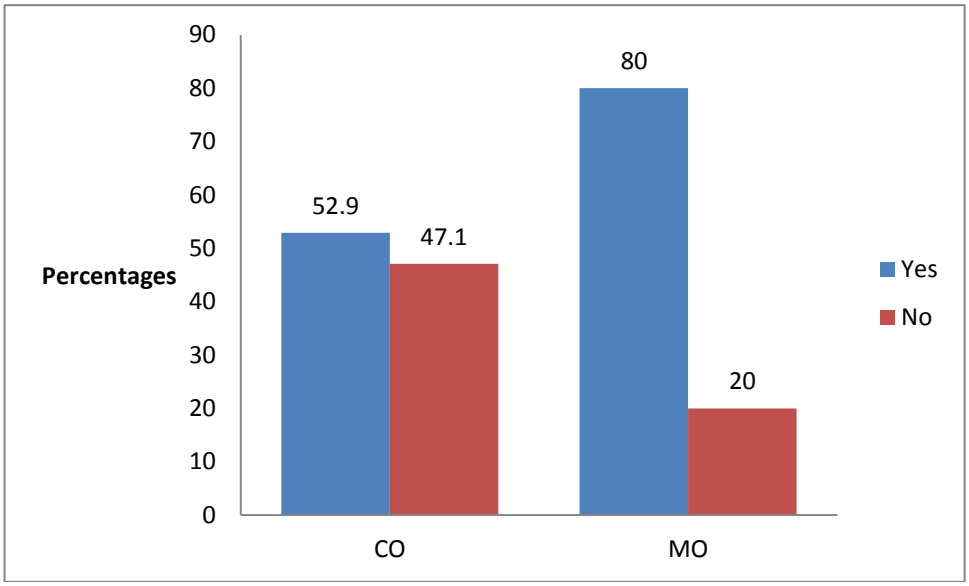
22%of the clinical officers compared to 20% of medical officers named herpes zoster as a feature that occurs when CD4count is between 100-250 cells/mm^3

Table 10: Ophthalmic features of HIV/AIDS that occur with CD4 count between 250-500 cells/mm^3

	No.of Clinical officers(%) n=59	No. of Medical officers(%) n=5
Kaposi sarcoma		1(20)
Ocular TB	2(3.4)	1(20)
Herpes zoster	6(10.2)	1(20)
uveitis		1(20)

10.2% of the clinical officers compared to 20% of medical officers named herpes zoster to occur when CD4 count is between 250-500 cells/mm^3

Figure 4: Knowledge ondrugs given to patients with HIV/AIDS that cause ocular toxicity (n=73)



Half of the clinical officers (52.9%) compared to 80% of medical officers knew of drugs given to HIV/AIDS patients that caused ocular toxicity.

Table 11: Knowledge on the types of drugs given to HIV/AIDS patients that cause ocular toxicity

Type of drug *	No.of Clinical officers (%) n=36	No.of medical officers (%) n=4
Ethambutol	23(63.9)	4(80)
Streptomycin	4(13.9)	
stavudine	4(11.1)	1(20)
Nevirapine	4(11.1)	1(20)
Septrin	5(13.9)	
Rifampicin	1(2.8)	
Quinine	1(2.8)	

*Drugs known to cause ocular toxicity in HIV/AIDS patients include ethambutol, rifabutin, didanosine,clofazamine,acyclovir,gangcyclovir,linezolid,atovaquone,cidofovir,variconazole

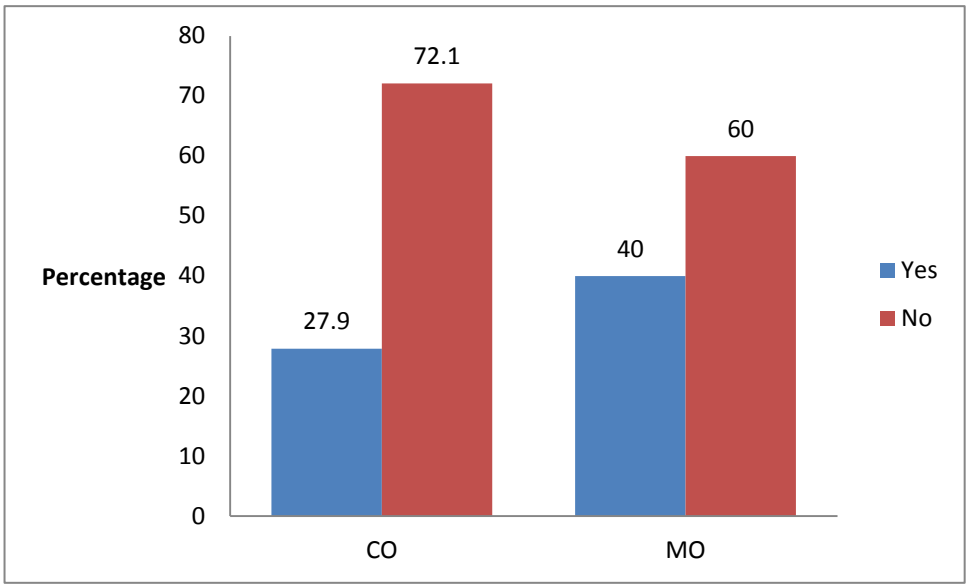
63.9% of the clinical officers compared to 80% of medical officers named Ethambutolas a drug given to HIV/AIDS patients that causes ocular toxicity.

Table 12: How often patients with HIV/AIDS needed to be reviewed by an eye specialist (n=71)

Response	No.ofClinical officers (n=66)	No.of medical officers (n=5)
When they have an eye complain	41(62.1)	3(60)
Every 6 months	12(18.2)	2(40)
3 Months	5(7.6)	
CD4 100cells/mm3	3(4.5)	1(20)
Monthly	3(4.5)	
on enrollment	1(1.5)	
every 2 Months	1(1.5)	

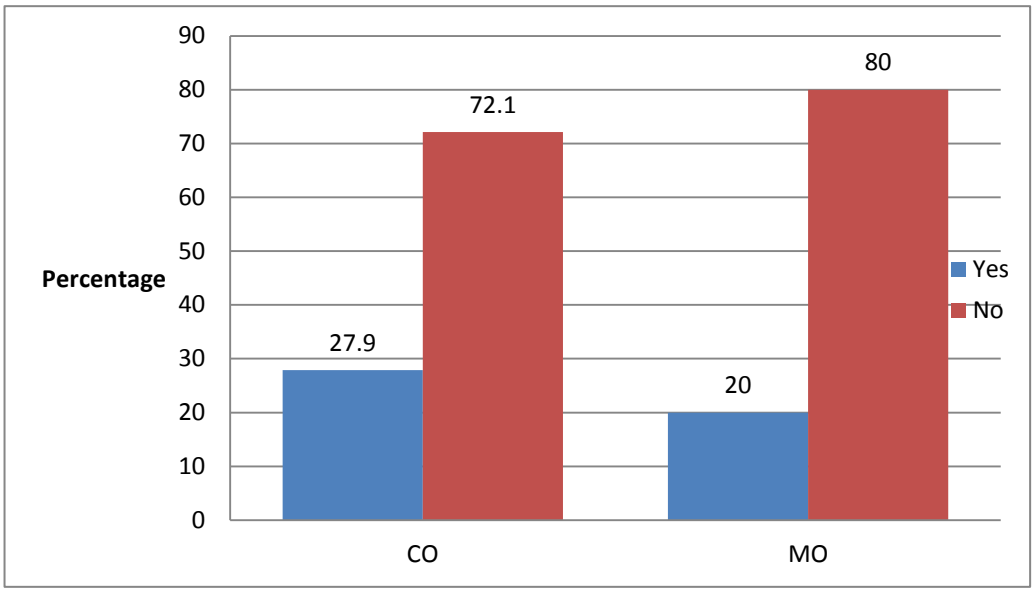
Almost all the clinical officers and all medical officers (66/68, 5/5 respectively) knew that a HIV/AIDS patient needed to be reviewed by an eye specialist.60% of them stated that this should be done when a patient complains.

Figure 5: The practice of taking ocular history when seeing HIV/AIDS patients



72.1% of the clinical officers(CO) compared to 60% of medical officers(MO) were not taking ocular history when reviewing HIV/AIDS patients.

Figure 6: The practice of examining the eye when a patient has an eye complain



72.1% of the clinical officerscompared to 80% of medical officers did not examine HIV/AIDS patients with ocular complains

Table 13: Tools available for eye examination

Tools	No.of Clinical officers n=19	No.of clinical officers n=1
Torch	11(57.9)	1(1)
Snellen's Chart	13(68.4)	
Colour vision	2(10.5)	
Confrontational Visual field	1(5.3)	

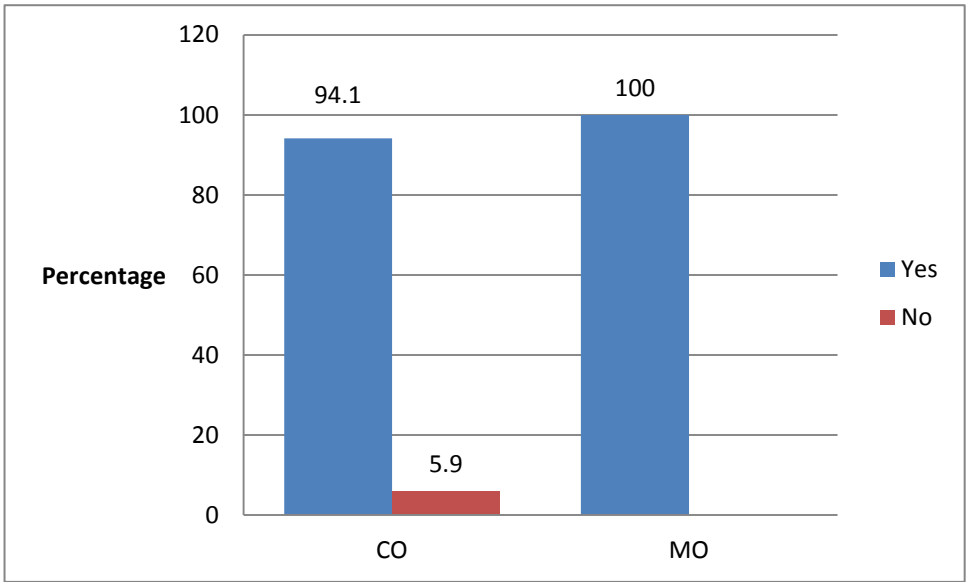
68.4% of the clinical officers had snellen,s chartwhile 1 medical officer had a torch for examining the eye.

Table 14: Reasons for not examining the eye

Reasons	No.of Clinical officers(n=49)	No.of Medical officers(n=4)
Lack of tools	31(63.3)	2(50)
Lack of skills	44(89.8)	3(75)
Too much work load	1(0.02)	

Lack of skills on eye examination was named by 89.8% of the clinical officers and 75% of medical officers as reasons for not examining the eye.

Figure 7: Referral of patients to an eye specialist



94.1% of clinical officers compared to all the medical officers referred patients to an eye specialist.

Table 15: When to refer patients to an eye specialist

	Clinical officers (n=64)	Medical officers(n=5)
Routinely	4(6.3)	
When the patient complains	60(93.8)	5(100)

93.8% of the clinical officers compared to all the medical officers referred patients with an ocular complain.

Table 16: Attitude towards ophthalmic features of HIV/AIDS among clinicians

Variable	Strongly Disagree		Moderately disagree		Neutral		Moderately agree		Strongly agree	
	CO	**MO**	**CO**	**MO**	**CO**	**MO**	**CO**	**MO**	**CO**	**MO**
Ophthalmic features can cause blindness	0	0	0	0	1(1.4)	0	19(27.9)	1(20)	48(70.6)	4(80)
A clinician needs to examine a patient with an ocular complain	0	0	0	0	0	0	4(5.9)	19(20)	64(94.1)	4(80)
HIV/AIDS patients need review by eye specialist	0	0	1(1.5)	0	2(2.9)	0	5(7.4)	0	60(88.2)	5(100)

N/B.MO is an abbreviation for Medical Officer while CO stands for Clinical Officer

70.6% of clinical officers compared to 80% of medical officers strongly agreed that ophthalmic features could cause blindness. Majority of the clinical officers (94.1%) compared to 80% of medical officers strongly agreed that a clinician needed to examine a patient with an ocular complain.All the medical officers as opposed to 88.2% of clinical officers, strongly agreed that HIV/AIDS patients needed an eye specialist review.

Table 17: **Association between age, sex and the practice of taking ocular history by clinical officers when seeing HIV/AIDS patients**

Variable	**Ocular history taken when seeing HIV/AIDS patients**		**P value**
	Yes	**No**	
Age group			
>40	0	1(1.5%)	0.284
36-40	3(4.4%)	3(4.4%)	
31-35	8(11.8%)	12(17.6%)	
26-30	7(10.3%)	31(45.6%)	
<25	1(1.5%)	2(2.9%)	
Sex			
Male	12(17.6%)	33(48.5%)	0.509
Female	7(10.3%)	16(23.5%)	

Since p-values were more than alpha (0.05), we failed to reject the null hypothesis and concluded that there was no significant relationship between age,sex and the practice of taking ocular history by clinical officers when seeing HIV/AIDS patients.

Table 18: Association between the age, sex, and the practice of eye examination by clinical officers when a patient has an eye complaint

Variable	Examining the eye when a patient has an eye complaint		P value
	Yes	No	
Age group			
>40	1(1.5%)	0	0.078
36-40	2(2.9%)	4(5.9%)	
31-35	9(13.2%)	11(16.2%)	
26-30	6(8.8%)	32(47.1%)	
<25	1(1.5%)	2(2.9%)	
Sex			
Male	14(20.6%)	31(45.6%)	0.415
Female	5(7.4%)	18(26.5%)	

Since p-values were more than alpha (0.05), we failed to reject the null hypothesis and concluded that there was no significant relationship between age, sex, and the practice of eye examination by clinical officers,when a patient had an eye complain.

Table 19: Association between the age, sex, and the practice of referral to an eye specialist by clinical officers

Variable	Practice of referral to an eye specialist		P value
	Yes	No	
Age group			
>40	0	1(1.5%)	0.002
36-40	6(8.8%)	0	
31-35	19(27.9%)	1(1.5%)	
26-30	36(52.9%)	2(2.9%)	
<25	3(4.4%)	0	
Sex			
Male	44(64.7%)	1(1.5%)	0.073
Female	20(29.4%)	3(4.4%)	

Since p-value (p=0.002) was less than alpha (0.05), we rejected the null hypothesis and concluded that there was a significant relationship between age and the practice of referring patients to an eye specialist by the clinical officers.

Table 20:Association between the sex, and the practice of taking ocular history and eye examination by medical officers

	SEX		P value
	Male	**Female**	
Ocular history taken when seeing HIV/AIDS patients Yes No	0 1(20)	2(40) 2(40)	0.361
Examining the eye when a patient has an eye complaint Yes No	0 1(20)	1(20) 3(60)	0.576

Since p-values were more than alpha (0.05), we failed to reject the null hypothesis and concluded that there was no significant relationship between sex, the practice of taking ocular history and eye examination by medical officers.

N/B No associations were computed between age group and the practice of referring patients to an eye specialist by medical officers sincethese variables were constant.

7. DISCUSSION

This study recruited seventy three clinical officers and medical officers from 56 sub-district, district hospitals and provincial hospital in Nyanza region, which has the highest prevalence of HIV/AIDS in Kenya. The main objective of the study was to assess knowledge, attitude and practice on ophthalmic features of HIV/AIDS in adults among Clinical Officers and Medical Officers working in comprehensive care centres.

The male to female ratio was two to one for the clinical officers while for medical officers it was 1 to 4.About half the clinical officer compared to all the medical officers were aged between 26 and 30 years.The term clinician is a general term used to refer to clinical officers and medical officers who are in general practice.In this study, 93.2% were clinical officers while6.8% were medical officers.This is because most outpatient clinics in districts hospitals are run by clinical officers while the wards and theatres are run by the medical officers.Most sub-district hospitals are run by clinical officers and this can be attributed to insufficient number of medical officers working in the government hospitals.(Table 1)

89.7% of clinical officers had general knowledge on ophthalmic feature of HIV/AIDS.In contrast, all the medical officers who had this particular knowledge.This compares to a study done in Vietnam by Quach et al where 88.1% of the physicians had knowledge on HIV transmission.[29]50.8% of the clinical officerscompared to 80% of medical officers named herpes zoster ophthalmicus as a feature.This can be attributed to the fact that this particular infection on the eye lids can be diagnosed easily on examination.However,despite the increase in the cases of conjuctival squamous cell carcinoma with late presentation, none of clinicians named it as feature (Figure 2 and table 3).

Regarding knowledge on ophthalmic features of HIV/AIDS that are an emergency, all medical officers in comparison to 47.1% of the clinical officers agreed that there were ophthalmic features that needed urgent intervention like herpes zoster ophthalmicus (53.1%).The participants were more conversant with the external parts of the eye as opposed to the internal parts, with 57.4% of the clinical officers naming the ocular adnexae while 80% of the medical officers named the anterior segment as a part of the eye that is affected by HIV/AIDS infection(Figure 3,table 4 and 5).

The clinical officers and medical officers interviewed in this study knew that the level of CD4 count determined the occurence of the various ophthalmic features (86.8%).However majority of the participants could not correctly name the particular ophthalmic features of HIV/AIDS that occurred at different levels of CD4 counts. This compares to a study done in India by Dobe who found that50-60% of paramedical personnel had misconceptions about HIV/AIDS.[25](Table 6,7,8,9 and 10)

63.9% of the clinical officers in the study compared to 80% of medical officers named ethambutol as a drug that causes ocular toxicity. This can be attributed to the frequent use of the drug in this setting due to the high prevalence of 41.8% of tuberculosis/HIV&AIDS co-infection as found by Nyamogaba et al in his study of TB/HIV co-infection rate in the western part of Kenya.[32](Figure 4 and table 11)

The vast majority of the participants stated that HIV/AIDS patients needed to be reviewed by an eye specialist with 62.1% of clinical officers and 60% of medical officers saying that the review should be when the patient has a complaint. Others stated every month, every 2 monthly, every 3 monthly, every 6 monthly, when the CD4 count is <100 cells/µl or at enrollment. So far there are no guidelines on how often the HIV/AIDS patients should be reviewed by an ophthalmologist considering the disease progression and ocular toxicity due to drugs administered to them(Table 12).

With regards toattitude, 70.6% of clinical officersand 80% of medical officers strongly agreed that ophthalmic features of HIV/AIDS can cause blindness. Despite most of them having a positive attitude towards examining a patient with an ocular complain, a large number of them (72.1% of clinical officers and 80% of medical officers) did not examine the patients in this scenario.88.2% of the clinical officers and all the medical officers strongly agreed that HIV/AIDS patients needed to be reviewed by an eye specialist and this reflected in their referral practice with (93.8%,100%) mostof them referring the patients(Figure 7,table 15 & 16).

There was disparity between the level of knowledge of the clinicians on ophthalmic features of HIV/AIDS and their practice.72.1% of clinical officers and 60% of medical officers had never taken ocular history from the patients while 72.1%and 80% respectively never examined a patient with an ocular complain. This may be attributed to lack of skillsfor eye examination named by 89.8% of the clinical officers and 75% of medical officers as reasons for not examining the eye.The lack of skills can be attributed to the fact that majority of the clinicians were clinical officers whose training curriculum has no ophthalmic segment or a rotation through the ophthalmology department as opposed to their Medical Officer counterparts (Figure 5&6, Table 13 &14).

There was a significant relationship between age and the practice of referring patients to an eye specialist by the clinical officers.Majority of the clinicians who were referring were between 26 and 30 years.However, sex and qualification did not influence the practice of clinical officers and medical officers regarding ophthalmic features of HIV/AIDS (Tables 17,18,19&20).

8. STUDY LIMITATION

- Majority of the participants in this study were clinical officers. The findings might be different if these were mainly medical officers.
- The participants may not have been providing accurate information.

9.CONCLUSION

- 89.7% of clinical officers and all the medical officers had general knowledge on ophthalmic features of HIV/AIDS.
- All medical officers compared to 47.1% of clinical officers knew ofophthalmic features of HIV/AIDS that are an emergency.However, there were gaps on the specific features and on the role of CD4 count as a determinant.
- The attitude of the clinicians towards ophthalmic features of HIV/AIDS was good though this did not reflect on their practices.
- On practice, lack of knowledge and tools for eye examination werefound to be their main barriers to effectively review HIV/AIDS patients.

10.RECOMMENDATIONS

- Continuous training of clinicians on need to examine all HIV patients with ocular complains through in-service trainings and workshops.
- Addressing Gaps in the training of clinical officers with regards to ophthalmic care.
- Attitude of the clinicians was good on patient care and this should be sustained through continous medical education.
- Provision of basic eye examination equipments like torches and visual charts accompanied by training on how to use them.
- Appropriate referral of patients to an eye specialist for intervention

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APPENDIX A:

WHO clinical staging of HIV/AIDS for adults and adolescents with confirmed HIV infection

CLINICAL STAGE 1

Asymptomatic
Persistent generalized lymphadenopathy

CLINICAL STAGE 2

Unexplained moderate weight loss (<10% of presumed or measured body weight)
Recurrent respiratory tract infections (sinusitis, tonsillitis, otitis media and pharyngitis)
Herpes zoster
Angular cheilitis
Recurrent oral ulceration
Papular pruritic eruptions
Seborrhoeic dermatitis
Fungal nail infections

CLINICAL STAGE 3

Unexplainedsevere weight loss (>10% of presumed or measured body weight)
Unexplained chronic diarrhoea for longer than one month
Unexplained persistent fever (above 37.5°C intermittent or constant,for longer than one month)
Persistent oral candidiasis
Oral hairy leukoplakia
Pulmonary tuberculosis
Severe bacterial infections (such as pneumonia, empyema, pyomyositis,bone or joint infection, meningitis or bacteraemia)
Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis
Unexplained anaemia (<8 g/dl), neutropenia (<0.5 × 109 per litre)
And/or chronic thrombocytopenia (<50 × 109 per litre)

CLINICAL STAGE 4

HIV wasting syndrome
Pneumocystis pneumonia
Recurrent severe bacterial pneumonia
Chronic herpes simplex infection (orolabial, genital or anorectalof more than one month's duration or visceral at any site)
Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs)
Extrapulmonary tuberculosis
Kaposi's sarcoma

CONTINUED:CLINICAL STAGE 4

Cytomegalovirus infection (retinitis or infection of other organs)
Central nervous system toxoplasmosis
HIV encephalopathy
Extrapulmonarycryptococcosis including meningitis
Disseminated non-tuberculous mycobacterial infection
Progressive multifocal leukoencephalopathy
Chronic cryptosporidiosis
Chronic isosporiasis
Disseminated mycosis (extrapulmonaryhistoplasmosis or coccidiomycosis)
Recurrent septicaemia (including non-typhoidal*Salmonella*)
Lymphoma (cerebral or B-cell non-Hodgkin)
Invasive cervical carcinoma
Atypical disseminated leishmaniasis
Symptomatic HIV-associated nephropathy or symptomatic HIV-associatedcardiomyopathy

APPENDIX B: **Questionnaire**

Study on knowledge, attitudes and practices of ophthalmic features of HIV/AIDS in adults, among clinicians in comprehensive care centres in Nyanza, Kenya

Date:_____ NO._____

Demographics

1. Age : _____

2. Gender:
   Male [ ] Female [ ]

3. Qualification
   A.Clinical Officer [ ]

   B.Medical Officer [ ]

How long(in years) have you been working in the CCC?

_____

KNOWLEDGE

1. Do you know any ophthalmic features of HIV/AIDS?

Yes [ ] No [ ]Not sure[ ]

2. If yes, which ones do you know?_____

3.Are there ophthalmic features of HIV/AIDS that are an emergency?

Yes [ ] No[ ] Not sure [ ]

4.If the answer in Q3 above is "Yes", which ones are they?

_____

5.Which parts of the eye are affected in HIV/AIDS infection?

A. Ocular adnexae[ ]

B. Anterior segment [ ]

C. Posterior segment [ ]

D.Neuro-ophthalmic manifestation [ ]

E. Orbital manifestation [ ]

6.Does the level of CD4 count determine the occurrence of ophthalmic features of HIV/AIDS?

Yes [ ] No[ ] Not sure [ ]

7.If the answer in Q6 above is "Yes",fill in the table below.

CD4 COUNT	OCULAR FEATURES OF HIV/AIDS
250-500 cells/mm3	_____ _____ _____
100-250 cell/mm3	_____ _____ _____
<100 cells/mm3	_____ _____ _____ _____ _____
Any CD4 Count	_____ _____ _____

8. Do you know any drugsgiven to patients with HIV/AIDS that cause ocular toxicity?

Yes [ ] No [ ]Not sure [ ]

9. If yes, name them.

_____

10. Does a patient with HIV/AIDS need to be reviewed by an eye specialist?

Yes [ ] No [ ] Not sure [ ]

11. If answer in Q10 above is "Yes",how often?

A.When they have an eye complain [ ]

B.When the CD4 count is below 500 cells/mm^3 [ ]

C.Every 6 months [ ]

D. Other _____

PRACTICE

1.Do you take ocular history when seeing HIV/AIDS patients?

Yes [ ] No[ ]

2. Do you examine the eye when a patient has an eye complain?

Yes [ ] No[ ]

3. If yes,name the tools that are available to you for eye examination.

_____

4. If no,why?

_____

5.Do you refer patients to an eye specialist?

Yes [ ] No [ ]

6. When do you refer patients to an eye specialist?

A. Routinely [ ]

B. When the patient complains [ ]

C. When a patient is on ART [ ]

D. Patients with a low CD4 count [ ]

ATTITUDE

For each of these questions below indicate whether you strongly disagree, moderately disagree, neutral, moderately agree or strongly agree.

1. Ophthalmic features of HIV/AIDS can cause blindness.

Strongly disagree [ ]

Moderately disagree [ ]

Neutral [ ]

Moderately agree [ ]

Strongly agree [ ]

2.A clinician needs to exam the eye of a HIV/AIDS patient who has an ocular complain.

Strongly disagree [ ]

Moderately disagree [ ]

Neutral [ ]

Moderately disagree [ ]

Strongly agree [ ]

3.HIV/AIDS patients need to be reviewed by an eye specialist?

Strongly disagree [ ]

Moderately disagree [ ]

Neutral [ ]

Moderately agree [ ]

Strongly agree [ ]

APPENDIX C:Consent form.

I am Dr. Clarice Onyango, a postgraduate student at the University ofNairobi, Kenya. I am conducting a study on the knowledge, attitudes and practices of ophthalmic features of HIV/AIDS among clinicians in comprehensive care centres in Nyanza,Kenya. Participation in this study is voluntary and the information gathered will be kept confidential and used solely for academic purposes and improvement of health services. Your name or identity is not required in this questionnaire.

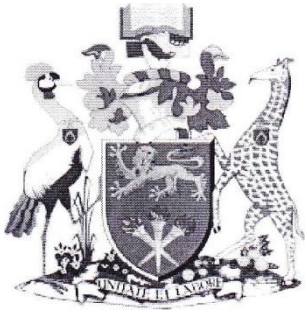
Thank you for participating.

Declaration

I …… accept that I have read and understood the above explanation and I am willing to participate in the study voluntarily.

Signature……..

APPENDIX D:Approval letter from the Ethics Review Committee



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Telegrams:NIEDSUP,Nairobi

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19thJune2013

Dr.ClariceOnyango
SchoolofMedicine
UniversityofNairobi.

DearDr.Onyango

RESEARCHPROPOSAL: OPHTHALMIC FEATURESOFHIV/AIDSINADULTS: KNOWLEDGE,ATTITUDEANDPRACTICEAMONG CLINICIANS COMPREHENSIVE CARECENTRES INNYANZA,KENYA(P26/1/2013)

ThisistoinformyouthattheKNH/UoN-Ethics&ResearchCommittee(KNH/U0N-ERC)hasreviewed andapprovedyourabovepropoSal. Theapprovalperiodsare19thJune2013to18thJune2014.

Thisapprovalissubjecttocompliancewiththefollowingrequirements:

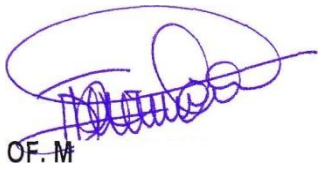
a) Onlyapproveddocuments(informedconsents,studyinstruments,advertisingmaterialsetc)willbeused.
b) Allchanges(amendments,deviations,violationsetc)aresubmittedforreviewandapprovalbyKNH{JoNERCbefore implementation.
c) Deathandlifethreateningproblemsandsevereadverseevents(SAEs)orunexpectedadverseeventswhetherrelate dorunrelatedtothestudymustbereportedtotheKNH/UoNERCwithin72hoursofnotification.
d) Anychanges,anticipatedorotherwisethatmayincreasetherisksoraffectsafetyorwelfareofstudyparticipantsandothe rsoraffecttheintegrityoftheresearchmustbereportedtoKNH/UoNERCwithin72 hours.
e) Submissionofarequest forrenewalofapprovalatleast60daysprior toexpiryoftheapprovalperiod. *(Attachacomprehensiveproqressreporttosupporttherenewal).*

f) Clearanceforexportofbiologicalspecimensmustbeobtainedfrom KNH/UoN-Ethics&Research Committeeforeachbatchofshipment.

g) Submissionof an*executivesummaty*reportwithin90daysuponcompletionofthestudy Thisinformationwillformpartof thedatabasethatwillbeconsultedinfuturewhenprocessingrelatedresearchstudiessoastominimizechancesofstu dyduplicationand/orplagiarism

FormoredetailsconsulttheKNH!U0NERGwebsite**www.uonbi.ac.kelactivitieslKNHUoN.**

Yours sincerely



PR CHINDIA
SECRETARY, KNHIUON-ERC

cc.

Prof.AN.Guantai,Chairperson,KNH/UoN-ERCTheDeputyDirectorCS,KNHTheHOD,Records,KNHPrincipal,CollegeofHealthSciences,UoNTheDean,SchoolofMedicine,UoNChairman,Dept.ofOphthalmology,UoN