PROPORTION, TYPES OF OTOLOGICAL DISORDERS AND ITS RELATION WITH VIRAL LOAD AMONG ADULT HIV PATIENTS RECEIVING ANTIRETROVIRAL THERAPY SERVICES AT TUMBI REGIONAL REFERRAL HOSPITAL

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A Dissertation Submitted in Partial Fulfillment of the Requirements for the

Degree of Master of Medicine in Otorhinolaryngology of the

Muhimbili University of Health and Allied Sciences

October, 2024

CERTIFICATION

The undersigned certifies that she/he has read and hereby recommends for the acceptance examination of dissertation entitled **"PROPORTION, TYPES OF OTOLOGICAL DISORDERS AND ITS RELATION WITH VIRAL LOAD AMONG ADULT HIV PATIENTS RECEIVING ANTIRETROVIRAL THERAPY SERVICES AT TUMBI REGIONAL REFERRAL HOSPITAL"** in partial fulfilment of the requirements for the degree of Master of Medicine in Otorhinolaryngology of Muhimbili University of Health and Allied Sciences**.**

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(Supervisor)

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Date

_____

Dr Perfect Kishevo

(Co-supervisor)

_____

Date

DECLARATION

I **ANNA-NSANYA ALPHONCE MWANGWALE,** declare that this **dissertation** is my original work and that it has not been presented and will not be presented to any other university for a similar or any other degree award.

Signature……Date…….

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DEDICATION:

To my beloved father and my role model Mr Alphonce T Mwangwale, my amazing mother Hadija Mwangwale, brother Njavala, sisters Yenala and Mpululu for their endless love, prayers, support and constant encouragement.

ABSTRACT

***Background*:** Otological disorders are among the infections a person living with human immunodeficiency virus may encounter during his lifetime due to immunosuppresion. They may be the first presentation in acquired immunodeficiency syndrome patients hence alerting a clinician on the status of the body immunity**.** Limited research has been conducted to comprehensively assess these disorders.

Objectives: The aim of this study was to determine proportion, types of otological disorders and its relation with viral load among adult HIV patients receiving antiretroviral therapy services at Tumbi Regional Referral Hospital.

***Methodology*:** This cross-sectional, hospital-based study was conducted over six months, August 2023 to January 2024 involving adult HIV patients aged 18 and above at Tumbi Regional Referral Hospital. Questionnaire was used to collect demographic data and otological symptoms.Ear examinations was performed using an otoscope and tuning fork for hearing loss. The relation between otological disorders and viral load was analyzed using SPSS version 23

***Results*:** This study involved 111 adult human immunodeficiency virus patients and proportion of otological disorders in the study population was found to be 48.6%, with age range of study participants from 23-73 years and median age of 47 years. Female to male ratio was 3.4:1 .The most common otological disorder observed was wax impaction 30.5% followed by otitis externa and tinnitus each with 26.4%.The least one were myringosclerosis and pre auricular swelling each 1.4%.There was a noted association between viral load and presence of otological disorder; more in the patients with 40-1000 copies/ml of viral load.

Conclusion: The burden of otological disorders was observed to be 48.6% .Wax impaction was seen in 30.5% followed by otitis externa and tinnitus each with 26.4%.The least one were myringosclerosis and pre auricular swelling each with 1.4%. Elevated viral load count was found to be associated with presence of these disorders.

Recommendations: Raising awareness of otological disorders among healthcare workers is vital for timely referrals to ear,nose and throat clinic. Also promoting antiretroviral therapy adherence which helps to reduce these disorders. Future research should include larger sample sizes and longer study periods to strengthen the findings.

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ABBREVIATIONS

AOM	Acute otitis media
CD4	Cluster of differentiation 4
CMV	Cytomegalovirus
CSOM	Chronic suppurative otitis media
CSF	Cerebrospinal fluid
CTC	Care and treatment center
CTX	Co-trimoxazole
EBV	Epstein-Barr Virus
EAC	External auditory canal
IgE	Immunoglobulin E
KCMC	Kilimanjaro Christian Medical Centre
KS	Kaposi Sarcoma
MUHAS	Muhimbili University of Health and Allied Sciences
NRTIs	Nucleoside/Nucleotide Reverse Transcriptase Inhibitors
OME	Otitis media with effusion
RNA	Ribonucleic acid
SNHL	Sensorineural Hearing Loss
WHO	World Health Orgnization

DEFINITION OF TERMS

CONDUCTIVE HEARING LOSS-Decreased hearing due to pathologies in the external or middle ear.

CHOLESTEATOMA: It is defined as a mass of keratin which is producing squamous epithelium located in the middle ear.

DISORDER: Disturbance of a normal function of a body.

NEUROTROPIC: Ability to cause neurological symptoms.

OTOLOGICAL: Science dealing with ear and its diseases.

SENSORINEURAL HEARING LOSS: Hearing loss due to pathologies involving inner ear and nerve pathway up to the auditory cortex.

SEROMUCOUS OTITIS: It defined as presence of middle ear effusion.

1.0 INTRODUCTION

1.1 BACKGROUND:

More than 30 years after its discovery, Human Immunodefficiency Virus (HIV) remains a global pandemic, with up to 80% of patients experiencing otorhinolaryngological disorders at some point. These disorders occur in both HIV-positive and negative patients, making them unreliable for diagnosing HIV. However, they can provide insights into a patient's immune status and, in HIV-positive individuals, may indicate disease progression and treatment response.(7,8)

According to The Joint United Nations Programme on HIV/AIDS(UNAIDS) in 2021, 38.4 million people were living with HIV,of these, 36.7 million were adults. In Tanzania, prevalence decreased from 7% to 4.6% from 2018 data, with adults aged 15-49 being most affected. The Coastal region in Tanzania has a 5.5% infection rate. While otological disorders are rare in HIV, a study done in Guinea found 43.7% of HIV patients attending Ear Nose and Throat(ENT) clinics had such disorders.(3,4,11,12)

Otological disorders in HIV can result from infections like chronic suppurative otitis media and otitis media with effusion, leading to conductive hearing loss, ear fullness, and pain. Inner ear involvement causes sensorineural hearing loss, affecting 49% of adults with HIV, likely due to the virus's neurotropic properties. Oligoclonal bands targeting HIV-1 p24 antigen in the CSF suggest the virus infects the central nervous system, including the vestibulocochlear nerve. Opportunistic infections, such as CMV, can damage both the middle and inner ear, while Kaposi Sarcoma affects the cochlear nerve directly.(7,8,9,10)

Otitis externa, otomycosis, and herpes zoster oticus are also common in HIV patients. Otomycosis, a fungal infection affecting the external ear canal, rarely spreads to the middle ear. HIV weakens the immune system, reducing granulocytes and macrophages that protect against fungal infections, increasing the risk. A study done in Uganda by Itabangi H et al found that HIV is a risk factor for developing otomycosis in 25% of cases, with those aged 19-45 most affected. The most common organisms are *Candida albicans*, followed by *Aspergillus niger* and *Aspergillus fumigatus*. (11,12,13)

Predominance of these disorders varies across different regions and studies. A study done by Prasad et al found that 20% of HIV patients had otological disorders and among them 13% had CSOM, while others found that otitis external, tympanic membrane perforation were the commonest. Linstrom et al found that facial nerve palsy and otitis media to be common.(14)

The use of Antiretroviral Therapy (ART) helps to improve life expectancy and it has been associated with reduction of these disorders.Good adherence to ART have been associated with increase in CD4 hence improving body's ability to fight infections including those affecting the ear as a result of decrease in the number of viral load. Therefore presence of otological disorders may alert clinician on the chance of patient having treatment failure.(15)

This study will help to determine the pattern of otological disorders in adult HIV patients, establish accurate estimate of the prevalence of these disorders and which types are common in our setting. Henceforth encourage a routine otological evaluation as a protocol of management.

1.2 PROBLEM STATEMENT

Human Immunodeficiency Virus (HIV) infection continues to be a global health concern, and it affects millions of people worldwide. The advancements has been made in Antiretroviral therapy, and this has led to the increase in the life expectancy of HIV-infected patients but also the emergence of health issues impacting various organ systems, including the auditory system. There is growing evidence suggesting otological disease in patients with HIV occurs frequently.(16)

The exact mechanisms underlying the relationship between HIV and otological conditions remain unclear. Possible explanation include direct viral effects on the auditory system, opportunistic infections, effects of ART and immune dysfunction. And the consequences of these conditions among adult HIV patients are far-reaching. Patient with hearing loss can face difficulties in communication, social interactions, employment opportunities, and

overall quality of life. Vestibular disorders may result in impaired balance, increased risk of falling, hence compromising their daily activities and independence.

Despite the potential significance of this issue, limited research has been conducted to comprehensively assess these otological conditions in the adult HIV population. Moreover, existing studies have not consider the broader spectrum of otological disorders that might be affecting this vulnerable group.

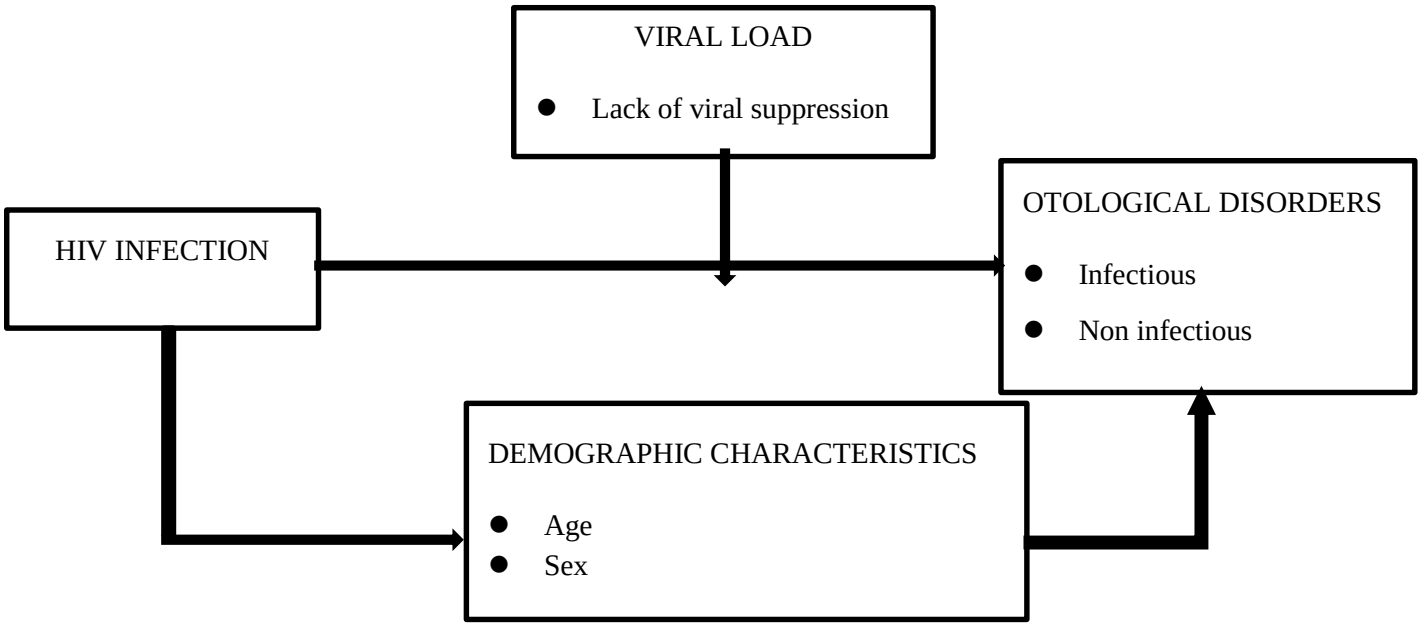
1.3 RATIONALE

Currently there is no updated information in the burden and types of otological disorders among adult HIV patients hence this study will fill this gap and hence bring more awareness to health care providers.

Also this study will assist in formulating policies by the Ministry of Health personnel and other policy makers in the planning, funds allocation on issues concerning with otology health especially in the HIV patients hence improve on guidelines for the management of these patients. Not only that but also it has helped patients who participated in this study to have more positive outlook on their health status particularly on otological disorders.

Furthermore this study has been done as a fulfillment of regulations for the award of Master of Medicine degree in Otorhinolaryngology at Muhimbili University of Health and allied sciences (MUHAS).

1.4 CONCEPTUAL FRAMEWORK:



The above framework briefly explains on pattern of otological disorders in patients with HIV. Age and sex were used to make descriptive statistics of the sample population. Once a patient is exposed to HIV, will undergo seroconversion and once tested will be diagnosed to be HIV positive. Virus will replicate attacking immunity leading to predisposition towards opportunistic infections and non-infectious conditions amongst which are otological disorders (otitis media, otitis external, hearing loss, impacted wax, vestibular disorders).

1.5 RESEARCH QUESTIONS:

1.5.1 General research question:

What are the proportion, types of otological disorders and its relation with viral load among adult HIV patients receiving antiretroviral therapy services at Tumbi Regional Referral Hospital?

1.5.2 Specific research questions:

1. What is the proportion of otological disorders among adult HIV patients receiving antiretroviral therapy services at Tumbi Regional Referral Hospital?

2. What are the types of otological disorders among adult HIV patients receiving antiretroviral therapy services at Tumbi Regional Referral Hospital?

3. What is the relation between otological disorders and viral load among adult HIV patients receiving antiretroviral therapy services at Tumbi Regional Referral Hospital?

1.6 BROAD OBJECTIVE:

To determine proportion, types of otological disorders and its relation with viral load among adult HIV patients receiving antiretroviral therapy services at Tumbi Regional Referral Hospital.

1.6.1 SPECIFIC OBJECTIVES

1. To determine proportion of otological disorders among adult HIV patients receiving antiretroviral therapy services at Tumbi Regional Referral Hospital.
2. To determine types of otological disorders among adult HIV patients receiving antiretroviral therapy services at Tumbi Regional Referral Hospital.
3. To determine the relation between otological disorders and viral load among adult HIV patients receiving antiretroviral therapy services at Tumbi Regional Referral Hospital. .

2.0 LITERATURE REVIEW

HIV has both lymphotropic and neurotropic effect which is a result of immunodeficiency state. This will be followed by a period at which patient will suffer from opportunistic infections including those affecting the There is difference in proportion and types of these otological disorders worldwide even in the studies which have been done in Tanzania.(17)

- ***Proportion of otological disorders among adult HIV patients receiving ART services***

In western part of the world Chandrasekhar et al did a study involving adult HIV patients aged 22-58 years old, whereby 27 were female and 23 male .Otological conditions were unexpectedly high and was found to be 33%. These patients presented with aural fullness, hearing loss, dizziness, ringing sensation, ear discharge and ear pain. The most common diagnosed condition was otitis media.(7)

In accordance to studies done in Asia H, K.C Prasad et al did a study in India from January 1996-December 2004.He recruited 968 patients and among them 171 adults above 20 years with male predominance. Majority of patients diagnosed to have otological conditions were in the 20-40 age group. The proportion of otological disorders was 20% in the study population. However Y.K. Kirti found that these disorders were slightly higher,31% had otological disorders.(34,35).

In western part of Africa study done in Guinea by Abdoulaye Keita et al did a descriptive study with prospective data collection and he found that among 522 HIV positive patients 43.7% had otological disorders. With age extremities of 16-24 years, 62.5% were female and the dominant group. In Nigeria, Alabi Biodun Sulyman et al found that very large number almost three quarter which is 79.8% had otological conditions. These conditions were still high 11 years later when Ibekwe Uju did a study on adult HIV patients whereby he found that 61.1% had otological disorders. They all concluded that there is high proportion of otological conditions in HIV patients. (11,32,36).

These above mentioned studies shows the burden of these disorders varies worldwide and is increasing especially in Africa hence this study will give the updated data and show the situation in Tanzania.

- ***Types of otological disorders among adult HIV patients receiving ART services***

In New York study by Chandrasekhar et al found that some patients had more than one disorder. The most frequent diagnosed condition was sensorineural hearing loss which was found in 18.9% (N=7). The second most common diagnosis was otitis externa and AOM each had 16.2% (N=6). Otitis media with effusion was found in 13.5% (N=5). Cerumen impaction in 10.8% (N=4), Herpes Zoster myringitis, and aural polyps with *Pneumocystic carinii*, mastoiditis, tympanic membrane perforation each involved 5.4% (N=2).The least finding was cholesteatoma involving 2.7% (N=1). (17)

A study done in India by Prasad et al found that the most common manifestation was otitis media involving 64.7% (N=125).This was followed by otomycosis in 24.9% (N=48).The least one was sensory neural hearing loss which was found in 10.4% (N=20).They concluded that due to an increase in number of AIDS cases it is important for otorhinolaryngologist to be aware of these disorders so at to diagnose and manage them early.(18)

Two studies were done in Nigeria one by Uju I M et al who found that the most common otological condition was cerumen impaction found in 14.2% followed by otitis externa in13% and the least ones were otomycosis and sclerotic tympanic membrane which occurred in 2.1% (N=5) and 0.4% (N=1) cases respectively. However Alabi Biodun Sulyman et al found that the most common condition was hearing loss in 16% and the least one was otitis externa in 3.4%.(32,37).

In Cameroon study by Abdoulaye Keita et al found that 61.7% had cochlear neuritis, 10.7% had otitis externa, 10.7% had seromucous otitis and 7.2% had chronic open ear drum otitis media. Patients with acute otitis media were 3.5% and 5.5% had peripheral facial palsy, cerumen plug was found in 6.2%.(5)

Two studies were done in South Africa, one by Yolande V.W et al found that 55% had otoscopic abnormalities and 8% had tympanic membrane perforation and or ear discharge. Majority of patients had ear canal pruritus 38%.Hearing loss was found in 27.5%, tinnitus in 26%, vertigo in 25% and the least had ear pain which was 19%. However in another study by M Tshifularo patients they had a different presentation. They found that the

leading type of otological disorders was CSOM having 27.27% which followed by 15.58% having OME and the least one was mastoiditis in 0.65%. (38,39)

In Central Africa a retrospective was done from January 2017 - December 2017 in Democratic Republic of Congo by Franck K.S et al. Among patient who presented with otological disorders majority had otitis media with effusion which was 66.7% and 33.3% had otitis externa. (24)

In East Africa, Mohammed NK et al did a descriptive cross sectional study at Kenyatta Hospital. The types of otological disorders which were found were facial nerve palsy which was found in 4.6% and 2.6% had otitis externa. In Tanzania, a study done by Shija et al, sensorineural hearing loss was the leading otological condition followed by chronic suppurative otitis media and otitis externa in 4:3:1 ratio contrary to a study done by Henry Swai who found that CSOM was the leading otological condition in 21% followed by necrotizing otitis extern and hearing loss in 2.3% and 3.15% respectively.(41,42,43).

Due to the disparity in these two studies done by Henry Swai and Shija et al, this research will provide updated information on types of otological conditions among HIV patients in our setting.

- ***Relation of otological disorders to viral load among patients with HIV receiving ART services***

A study was done in Peru between 2009-2010 by Christina K.C et al on assessing immunodeficiency status and presence of hearing loss, ear infections based on the level of viral load (VL). The study findings were, having lower or undetectable number of VL associates with otological disorder by 67% compared to only 33% with detectable VL. And this was explained by the association of VL level and duration of HIV disease. In this study they suggested patients with longer duration of HIV had received effective treatment by ART but at the same time increase time of being at risk for recurrent of ear disorders. (28)

A study by Palacios et al. concluded that patients who were having hearing loss had higher VL. In cases who were having VL greater than 400 copies/ml it was linked to the distortion product oto-acoustic emission test. And this was also emphasized by Buriti et al and Makar et al.Another study found that only 7% of patients having less than 50 copies/ml had

otological condition compared to 29% who had from 50 copies/ml and above. Among these 28% had 50-250,000 copies/ml and 2% had above 250,000 copies/ml. (45,46)

However in West Africa a different conclusion was made, a study was done in Nigeria by Babatunde et al on association between otological disorder and viral load among patients with HIV and found that the higher the VL the higher the chance of having these conditions. Majority of these cases,39.39% had 10,000-100,000 copies and 15.15% had above 100,000copies/ml and 18.18% had 1000-10,000 copies/ml and only 27.27% had viral load less than 1000.(31)

The above study was not different from a study by A.J. Fasunla et al. This study found that otological disorders associates with higher number of 29,653 - 76,983 copies/ml and least associated with 201 – 4,500 copies/ml.(32)

In Tanzania no study has ever been done to link immunological status based on viral load and these disorders.

3.0 METHODOLOGY

3.1 Study design:

This study was a descriptive cross sectional hospital based.

3.2 Study duration:

The study was done in the period of six months from August 2023 to January 2024.

3.3 Study area:

Study was done at Tumbi Regional Referral Hospital, Care and Treatment center. Tumbi Hospital is located in Coastal Region and it is a tertiary hospital. It has both inpatient and outpatient departments. Outpatient department has a total of 14 clinics including CTC and ENT clinic. It receives referral cases from surrounding health facilities as well as self-referrals.

Currently there are 11,135 patients enrolled at CTC and 6999 HIV positive patients are on treatment with 2290 being male and 4709 being female.

3.4 Study population

All HIV positive patients receiving ART services at Tumbi Regional Referral Hospital in Coastal Region, CTC unit.

3.5 Eligibility criteria

3.5.1 Inclusion criteria

All adult (18 years old and above) HIV patients receiving ART services at Tumbi Hospital during the study duration.

3.5.2 Exclusion criteria

Patients less than 18 years old

Patients unable to give full consent.

3.6 Sample size and sampling technique (Slovin formula)

By using a convenience sampling technique which offers easy accessibility of research participant, 109 participants attending CTC from August 2023 to January 2024 were recruited into the study based on the defined inclusion and exclusion criteria.

The formula used to calculate sample size (Slovin Formula) (33)

n=N/ (1+ (Ne2)

(Where: n = Number of samples, N = Total population and e = Error tolerance.)

N-number of new cases in 6 months (6*25=150)

n=150/ (1+ (150*0.052))

n=109 (20)

3.7 Data collection technique

By using a structured questionnaire, social demographic information on age, sex and viral load count (done within six months from study period, obtained from CTC card) were recorded. Otological symptoms such as ear pain, ear discharge, tinnitus and hearing loss were obtained. Examination of each ear was done separately by using headlight, while otoscope was used for examination of external auditory canal and tympanic membrane. Diagnosis of all infectious diseases was syndromic. No sample was collected from patients. Acute otitis media was diagnosed by presence of ear pain associating with either erythema or bulging of the tympanic membrane with or without presence of mucopurulent discharge in less than 3 weeks. CSOM was diagnosed with presence of mucopurulent discharge of more than 3 weeks with tympanic membrane perforation. Presence of retracted tympanic membrane with loss of translucency, aural fullness and crackling or popping sounds was used to diagnose Otitis media with effusion.

Hearing assessment was done using tuning fork test (Rinne and Weber) with frequency of 512Hz in patients who reported hearing loss.By using consecutive sampling technique all the patients who met the inclusion criteria were recruited until the desired sample size was achieved.

Noninfectious disorders were diagnosed based on otoscopic findings and history. Impacted cerumen was seen as brownish-gray thick collection and patient reporting aural fullness and hearing loss. Exostoses was diagnosed by presence of smooth whitish smooth bone growth in external part of ear. Vestibular disorders were be diagnosed by postural

instability and dizziness. Myringosclerosis was diagnosed based on presence of whitish patches behind intact tympanic membrane.

3.8 Research tools

Questionnaire, otoscope with aural specula of variable sizes, tuning fork 512Hz, cerumen hook, headlight and gloves.

3.9 Description of Study Variables

The independent variables are age, sex and recent viral load count while the dependent variables are the otological disorders which were diagnosed clinically from history of presenting symptoms, otoscope and tuning fork findings.

3.10 Data analysis

Descriptive analysis was performed using SPSS, and for the continuous variable of age, the median and range were determined due to the asymmetrical distribution of the data. For the categorical variable of sex, the analysis involved determining the ratio, with the results presented in tables

The first objective was to determine the proportion of otological disorders among adult HIV patients. Descriptive analysis was carried out using SPSS version 23, and the findings were also presented in tables.

For the second objective, which focused on identifying the types of otological disorders in this patient group, descriptive analysis was conducted, with the results displayed in frequency distribution tables.

The third objective aimed to explore the relationship between otological disorders and viral load among HIV patients. A cross-tabulation of viral suppression levels and otological conditions was performed to illustrate their association, and the results were presented in tables. A P-value of less than 0.05 was considered statistically significant.

3.11 Ethical clearance

It was sought from MUHAS Ethical Committee .Permission to do the study was also obtained from the management of Tumbi Regional Referral Hospital. Informed consent was obtained from all study participants who were willing to participate. Unique number

was given to each study participant instead of their names. All information corrected was confidential.

3.12 Study limitation:

Since the study is hospital based the information obtained is not the representation of HIV patients in the whole population of Tanzania but a local tendency in Coastal region. Also Tumbi Hospital being a regional referral facility receiving mostly emergency or complicated referred cases, some might have been captured and managed at a lower facility level.

4.0 RESULTS

A total number of 111 adult patients were enrolled during the study period. The age range of the patients was between 23 and 73 with a median age of 47 years and interquartile range (IQR) equal to 42, 55 years. The age group 40-50 years was the most seen comprising 46 %(N= 51) while the least was 73-83 years, 0.9 %(N=1).The female to male ratio was 3.4:1 of which, 77.5% (N=86) were females, with the female to male ratio being 3.4:1. (Table 1)

Table 1: Demographic characteristics of adult HIV patients receiving antiretroviral therapy services at Tumbi Regional Referral Hospital (N=111)

Variable	Frequency(N)	Percentage (%)
Age Groups(in years)		
18-28	5	4.5
29-39	14	12.6
40-50	51	46.0
51-61	26	23.4
62-72	14	12.6
73-83	1	0.9
The median Age, in years(IQR) 47 (42,55)		
Sex		
Male	25	22.5
Female	86	77.5
Total	**111**	**100**

4.1 Proportion of otological disorders among adult HIV patients receiving antiretroviral therapy services at Tumbi Regional Referral Hospital.

Among 111 adult HIV patients, the proportion of otological disorders was recorded at 48.6% (N=54) majority of them were males, whereby 76% (N=19) of males were diagnosed to have otological disorders, this was statistical significant with P value of 0.002.

The most affected age group was 51-61 years, with a proportion of 65.4% (N=17) followed by 29-39 years who had 64.3% (N=9) .However the difference was NOT statistically significant and P-value was 0.106. (Table 2)

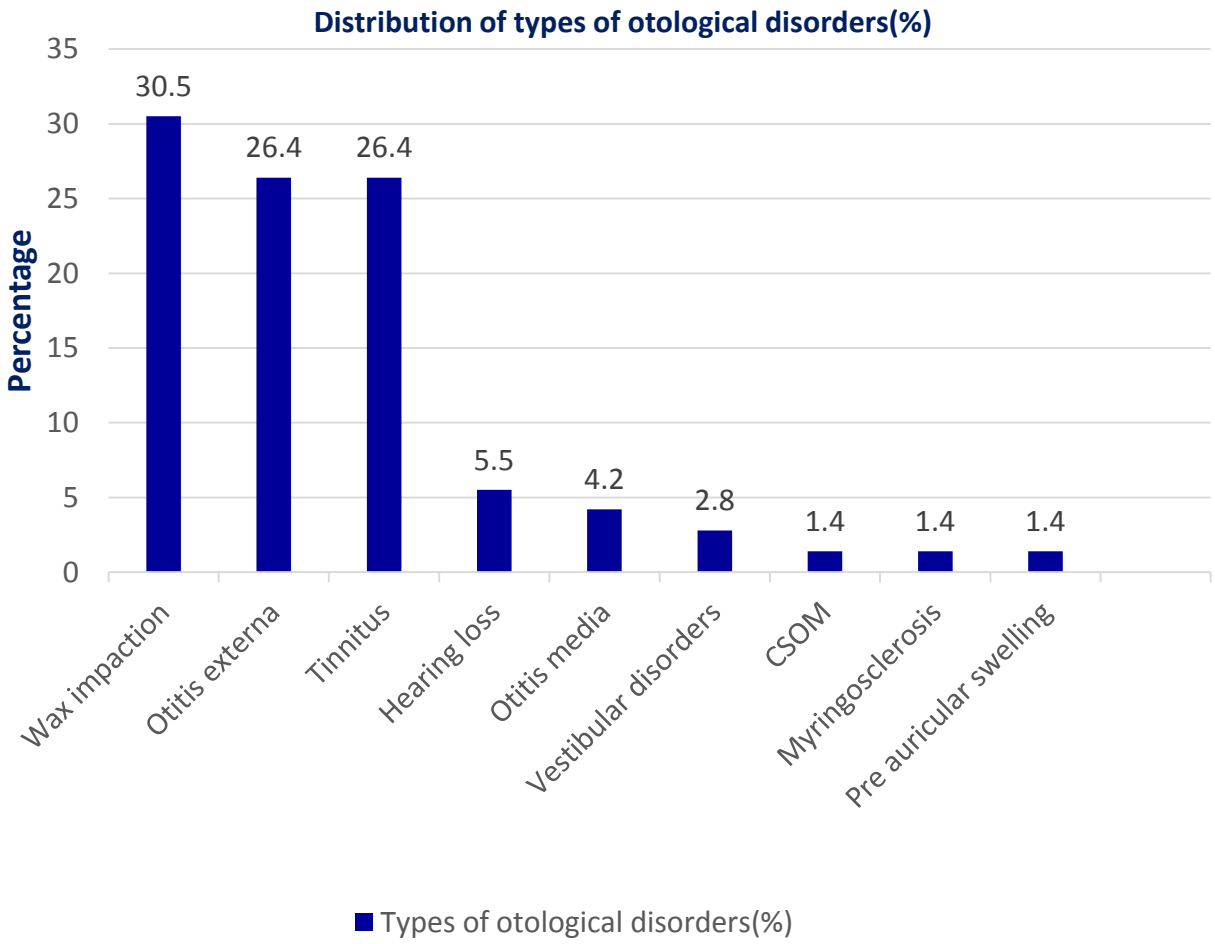
Table 2: Proportion of otological disorders by Age and Sex (N=111)

Variable	Yes N (%)	No N (%)	Total N (%)	P-value
Age Groups(in years)				
18-28	3(60.0)	2(40.0)	5(4.5)	
29-39	9(64.3)	5 (35.7)	14(12.6)	
40-50	19(37.3)	32(62.7)	51(46.0)	
51-61	17(65.4)	9(34.6)	26(23.4)	
62-72	6(42.9)	8(57.1)	14(12.6)	0.106
73-83	0(0.0)	1(100.0)	1(0.9)	
Sex				
Male	19(76.0)	6(24.0)	25(22.5)	
Female	35(40.7)	51 (59.3)	86(77.5)	0.002
Total	**54 (48.6)**	**57(51.4)**	**111(100)**	

4.2 The types of otological disorders among adult HIV patients receiving antiretroviral therapy at Tumbi Regional Referral Hospital.

A total of 72 otological disorders were diagnosed in 54 patients (some had more than one otological disorder). The most common otological disorder seen was wax impaction, 30.5 %(N=22) followed by otitis externa and tinnitus each with 26.4 %(N=19)
The least proportion was in pre auricular swelling, CSOM and myringosclerosis each had 1 case equivalent to 1.4 %(N=1). (Figure 1)

Figure 1: Distribution of types of otological disorders among adult HIV patients receiving antiretroviral therapy services at Tumbi Regional Referral Hospital (N=72)



4.3 The relation between otological disorders and viral load among adult HIV patients receiving antiretroviral therapy services at Tumbi Regional Referral hospital.

Of 111 adult HIV patients receiving ART services at Tumbi Regional Referral Hospital, majority had undetected viral load, 77.5% (N=86)

Otological disorders were found more in the suppressed group 57.9 %(N=11) and were unexpectedly fewer in patients with unsuppressed viral load count, by 33.3 %(N=2) although the differences were not statistically significant, P value was 0.536

Table 3: Relation between otological disorders and viral load (N=111)

	Otological disorder			**P-value**
Viral load count	YES	NO	TOTAL	
Undetected ≤40	41(47.7%)	45(52.3%)	86 (77.5%)	
Supressed 41-1000	11(57.9%)	8(42.1%)	19(17.1%)	0.536
Unsupressed >1000	2(33.3%)	4 (66.7%)	6(5.4%)	
Total	54 (48.6%)	57(51.4%)	111(100%)	

5.0 DISCUSSION

5.1 Age and sex distribution of adult HIV patients receiving antiretroviral therapy services at Tumbi Regional Referral hospital

Over the years there has been much effort to improve access to ART to the HIV population so as to tackle the pandemic by doing so improving body immunity hence reducing the burden of opportunistic infections which includes those affecting the ear. At the end of December 2021, 28.7 million people had an access to antiretroviral therapy, from 7.8 million in 2010. As it is known that 80% of patients living with HIV aids will have manifestations involving otorhinolaryngology and there have been some variations regional wise as well as with respect to socio and demographic characteristics.(2,3)

In this study period among 111 patients who were recruited females were 3.4 times more than males which was equivalent to a proportion of 77.5%. This reflects the gender which is mostly affected by HIV according to the published data whereby in the sub-Saharan part of Africa it is documented that 63% of all new infections were contributed by girls and women. Otological manifestations were more in the male group and these findings were similar to study done by Swai at Muhimbili National hospital who found that 35.7% of male study participants had the disorders, as well as Uju who did a study in Nigeria and Kohan et al in New York also had the same dominancy. This can be explained by the fact that health seeking behavior is more common in female than male group hence early intervention and management of these disorders to this group associates with its low incidence. However Shija et al conducted a study at KCMC and had a different outcome whereby prevalence was higher in females by 34.8% .(3,19,25,26,32)

The most affected age group among adult study participants was 51-61 years which had a proportion of 65.4%(N=17) followed by 29-39 age group having 64.3%(N=9) and the least age group which was 40-50 years contributed by 37.3%(N=19) .This was similar to Uju in Nigeria who found that majority were above 50 years and the second most common age group was 30-39 years. This was contrary to Swai who found that the most affected age group was between 40-49 who had 28.1% .This variation could be explained by the difference in study population size.(19,26)

5.2 The proportion of otological disorders among adult HIV patients receiving antiretroviral therapy services at Tumbi Regional Referral Hospital

From this study otological disorders were present in 48.6% of all study participants. Some had more than one disorder. This proportional finding was similar to a study done in West Africa by Keita et al who found the proportion of otological disorders to be 43.7% (5).However this was different and slightly lower compared to findings of a study done by Uju in Nigeria and S. Jafari et al in Iran who found the proportion of otological conditions to be 61.1% and this could be explained by difference in number of recruited participants and different race for the case of Iranian . Another reason for a slightly lower proportion in my study could be the role of ART as majority of the patients had undetected viral load which associates with reduced risk of body being attacked by infections including the ones attacking the ear as observed in this study. (19, 33)

However these findings were statistically significant, p value was 0.02 therefore it is important to note the burden of these disorders at our settings so as to improve clinical care of adult patients living with HIV.

5.3 The types of otological disorders among adult HIV patients receiving antiretroviral therapy services at Tumbi Regional Referral Hospital.

Otological disorders affecting patients with HIV are similar to those in HIV negative population. Majority of studies done found infectious causes to be more prevalent but there are still some variations across different published studies. This study focused in the adult age group and found the commonest disorder to fall in the noninfectious group. Most of the patients had wax impaction, 30.5 %(N=22 cases). This can be explained by the fact that in this study most of these disorders were in the elderly group 51 years and above. The process of aging associates with the decrease of apocrine glands which are found in the auditory canal as a result cerumen becomes drier in this population. Also impacted wax associates with ringing sensation and dizziness, as it has been observed in this study tinnitus also had higher frequency (34,35,36)

The second most common disorder was otitis externa and tinnitus each with 26.4%.(N=19). Tinnitus also associates with impacted wax .The prevalence of tinnitus observed in my study was similar to the findings by Chandrasekhar et al, 26% . Otitis externa associates with geographic behavior of my study area where there is higher temperature and humidity which favors diseases of the ear.(39)

Only 5.5% (N=44) cases had hearing loss and this was due to sensorineural cause, otitis media was found in 4.2% (N=3) and CSOM, pre auricular swelling, and myringosclerosis had the least proportion each had 1.4% (N=1).This could be explained by the fact that otitis media is commonly found in children who were not included in my study. (7, 22)

Findings of this study were similar to I.Uju who found the most prevalent otological disorder was impacted wax 14.2% followed by otitis externa 13% and the least one was sclerotic tympanic membrane equivalent to 0.4%(N=1). Impacted wax is found in both seroconverted and HIV negative patients but there is no scientific explanation on its association with HIV hence the normal causes like abnormalities of external auditory canal, cleaning the ear with pointed objects, excessive cerumen production, associated infection, cotton buds do play a role(19, 33)

5.4 The relation between viral load and otological disorders among adult HIV patients receiving antiretroviral therapy services at Tumbi Regional Referral Hospital

Among the study participants ,majority had undetected viral load,77.5% and this displays effectiveness of treatment by using ART .Otological disorders were found more in the suppressed group and were unexpectedly fewer in patients with unsuppressed VL count, by 33.3%.Although the differences were not statistically significant. This could be explained by the fact that majority of these otological disorders were noninfectious and only N=6 cases had unsuppressed viral load. Contrary to this Babatunde et al found that the higher the VL the higher the chance of developing otological disorders, 89.39% of patients with otological disorders had VL ≥10,000 copies/ml. (30)

6.0 CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

This study offers a glance of otological disorders in adult HIV patients at Tumbi Regional Referral Hospital. It was observed that the prevalence of otological disorders were high in adult patients by 48.6% (N=54). Among these disorders, impacted wax was the most common followed by tinnitus and otitis externa. The least common were myringosclerosis and pre auricular swelling. Males were more involved as compared to females, and patients aged 51-61 years were more affected. This study also found that increase in viral load associates with development of otological disorders.

6.2 Recommendations

To increase awareness of otological disorders among CTC workers so as to ensure early link to ENT clinic and management with the aim of reducing morbidity and improve the quality of life for adult HIV patients.

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8.0 APPENDICES:

8.1 APPENDIX I: Data collection tool (English version)

PROPORTION AND TYPES OF OTOLOGICAL DISORDERS AND RELATION WITH VIRAL LOAD MONG AULT HIV PATIENTS RECEIVING ART SERVICES AT TUMBI REGIONAL REFERRAL HOSPITAL.

PATIENT UNIQUE NO: ____AGE:___ SEX: ____VIRAL LOAD COUNT: _____

DISORDER	**SIGNS AND SYMPTOMS**	**RIGHT EAR**	**LEFT EAR**
OTITIS EXTERNA(Normal tympanic membrane with visible cone of light, pearly white color)	Ear pain		
	Ear discharge		
	Hearing loss		
	Lesion on external ear		
OTITIS MEDIA(Symptoms < 3 weeks)Depending on disease stage	Hearing loss and :		
	History of ear pain with bulging tympanic membrane		
	History of decreased pain with tympanic membrane rupture		
	Fever		
OTITIS MEDIA WITH EFFUSION	**Tympanic membrane: Retracted, bluish in color with loss of cone of light**		
	Aural fullness		
	Air bubbles in the middle ear		
	Crackling/popping sounds		
	Tympanic membrane perforation		

CHRONIC SUPPURATIVE OTITIS MEDIA(symptoms > 3WEEKS)	Ear suppurative discharge		
HEARING LOSS	**Rinne**: POSITIVE (SNHL /NORMAL)		
	NEGATIVE(CHL)		
	Weber: CHL-LATERALIZATION TO ABNORMAL EAR		
	SNHL-LATERALIZATION TO NORMAL EAR		
WAX IMPACTION	Visible brownish/blackish thick ear collection		
	Hearing loss		
	Aural fullness		
EXOSTOSIS	Whitish smooth bone overgrowth		
VESTIBULAR DISORDERS	Vertigo		
	Postural instability		
TINNITUS	**Ringing sensation in the ear**		
NEOPLASM	**Available histology data supporting diagnosis of ear neoplasm**		
OTHERS			

8.2 APPENDIX II: Orodha ya ukaguzi (Kiswahili)

UWIANO NA AINA YA MAGONJWA YA MASIKIO KWA WAGONJWA WATU WAZIMA WENYE MAAMBUKIZI YA VVU WANAOHUDUMIWA KATIKA HOSPITALI YA MKOA YA RUFAA TUMBI NA UHUSIANO NA KIWANGO CHA VIRUSI

NAMBARI YA MGONJWA: ___UMRI____JINSIA_____WINGI WA VIRUSI _____

UGONJWA	**DALILI ZA UGONJWA**	**SIKIO(KULIA**	**SIKIO(KUSHOTO**
KUUMWA SIKIO LA NJE (Ngoma nzima ya sikio yenye mwale wa mwanga unaoonekana)	Maumivu ya sikio		
	Kutoka majimaji sikioni		
	Upungufu wa usikivu		
	Mabaka sikio la nje		
KUUMWA SIKIO LAKATI(dalili chini ya wiki 3)Kutegemeana na hatua ya ugonjwa	Upungufu wa usikivu na:		
	Maumivu ya sikio na ngoma kujaa		
	Maumivu yanayopungua na ngoma iliyopasuka		
	Homa ya mwili		
MAJIMAJI KWENYE SIKIO LA KATI	Ngoma ya sikio-Imeingia ndani na Rangi ya ubuluu na kupoteza mwale wa mwanga		
	Hisia za sikio kujaa		
	Uonekanaji wa hewa sikio la kati		
	Sauti za mpasuko ndani ya sikio		
UGONJWA SUGU WA SIKIO LA KATI(ZAIDI YA WIKI 3	Ngoma ya sikio imepasuka		
	Kutoka usaha		

UPUNGUFU WA USIKIVU	**Rinne**: **I.** Ipo/ chanya (upotevu wa usikivu kwa sababu za ndani ya sikio au hakuna tatizo **au**		
	II. Haipo/hasi (upotevu wa usikivu kwa sababu za sikio la kati na nje)		
	Weber: **I.** Amesikia vizuri sikio lenye upungufu wa usikivu **au**		
	II. Amesikia vizuri sikio lisilo na tatizo		

8.3 APPENDIX III: Consent form (English version)

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES (MUHAS)

SCHOOL OF MEDICINE.

DIRECTORATE OF RESEARCH AND PUBLICATIONS.

BOX 65001

Department of Otorhinolaryngology

INFORMED CONSENT FORM NO---------- DATE----------

Consent to participate in a research study: Greetings, I am Anna A Mwangwale, a postgraduate student of master of medicine in Otorhinolaryngology at Muhimbili University of Health and Allied Sciences. I am researching on proportion and types of otological disorders among adult HIV patients receiving services at Tumbi Regional Referral Hospital.

Purpose of the study: To determine proportion and types of otological disorders and relation with viral load among adult HIV patients receiving services at Tumbi Regional Referral Hospital.

Participants of the study: All adult HIV patients, 18 years old and above receiving services at Tumbi Hospital.

Confidentiality: No names will be used but unique numbers for patient's identification and data collected will be confidential accessed only by the principle investigator and discarded after dissertation acceptance.

Risk:

No harm will be done during the study period. **No sample will be collected from the study.**

Benefits:

Data obtained from this study will help to increase awareness in the community and help improve on patient's care.

Right to withdraw

Decision to participate under this study is under patient's choice and have a right to decide not to participate and withdraw at any time. You can refuse to respond to any question in the questionnaire or to undergo a certain diagnostic procedure and this won't affect your care.

Whom to contact:

If you have any concern or questions about the research, contact the following:

Investigator:

Dr Anna Mwangwale P.O.BOX 65001 Dar es Salaam, Tel 0719110172, Email address**:** **mnsanya@yahoo.com**

Supervisor:

Dr Aveline Kahinga (P.O.BOX 65001 Dar es salaam, Tel 0764608917, Email address: avelynek@yahoo.co,uk

Co supervisor:

Dr Perfect Kishevo (P.O. BOX 65001, Dar es Salaam. Tel: 0787709516 Email address: perfectus76@yahoo.co.uk

Dr. Nahya Salim the Chairperson of the Muhimbili University Senate Research and Publications Committee, P.O.BOX 65001, Dar es Salaam, Tel: Telephone; 255 713250074 (Direct), 2150302-6 (General) Email address: drp@muhas.ac.tz for any matters concerning ethical violation of the study.

DECLARATION

I ……have read and understood the information in this form. Under my own will I have accepted to participate in this study.

Participant signature----------.

Investigator/assistant investigator signature…….

8.4 APPENDIX IV: Consent form: (Swahili version)

CHUO KIKUU SHIRIKISHI CHA AFYA CHA MUHIMBILI

KURUGENZI YA UTAFITI NA UCHAPISHAJI

Box 65001

Kitengo cha magonjwa ya pua, koo na masikio

FOMU NAMBARI---------- **TAREHE----------**

Ridhaa ya kushiriki kwenye utafiti: Habari,Mimi Anna A Mwangwale, mwanafunzi wa shahada ya uzamili katika chuo kikuu shirikishi cha afya Muhimbili.Nnafanya utafiti wa kiwango na aina ya matatizo ya masikio kwa wagonjwa watu wazima wanaoishi na maambukizi ya virusi vya ukimwi katika hospitali ya rufaa ya Tumbi mkoa wa Pwani na uhusiano na kiwango cha virusi mwilini.

Dhumuni la utafiti: Kuangalia uwiano Na aina ya matatizo ya masikio Kwa wagonjwa watu wazima wanaoishi Na virusi vya maambukizi ya ugonjwa WA ukimwi katika hospitali ya rufaa ya Tumbi mkoa wa Pwani na uhusiano na kiwango cha virusi mwilini

Wahusika wa utafiti : Wagonjwa watu wazima wenye maambukizi ya VVU wanaohudumiwa katika hospitali ya Tumbi.

Usiri : Majina hayatatumika bali namba kwa ajili ya utambuzi na taarifa itahayokusanywa itakua ni ya siri na kufikiwa na mfanya utafiti huu na kuangamizwa baada ya kukubaliwa na chuo.

Athari: Hamna athari itakayotokea kipindi cha utafiti..Hamna vipimo vya damu vitakavyofanyika.

Faida: Taarifa itakayopatikana na huu utafiti itatumika kuongeza utambuzi na kuboresha huduma za wagonjwa.

Ushiriki: Uamuzi wa kushiriki katika huu utafiti ni wa hiari na mgonjwa an uamuzi wa kujitoa mda wowote.

Mawasiliano:

Kwa swali lolote kuhusu utafiti huu wafuatao watakua tayari kwa ushirikiano:

- Dk Anna Mwangwale ,sanduku la barua 65001 Dar es Salam,Namba ya simu 0719110172,
  Barua pepe:**:mnsanya@yahoo.com**
- Dk Aveline Kahinga (P.O.BOX 65001 Dar es Salam, Namba ya simu 0764608917,

  Barua pepe:avelynek@yahoo.co,uk

- Dk Perfect Kishevo(P.O. BOX 65001, Dar es Salam. Namba ya simu :0787709516
  Email address:perfectus76@yahoo.co.uk

Ikiwa kuna suala lolote linalohusu mwenendo wa kimaadili wa utafiti wasiliana na Mwenyekiti wa kamati ya Tafiti na machapisho wa chuo kikuu shirkishi cha Muhimbili Dr. Nahya Salim Sanduku la barua 65001, Dar es Salaam, Simu no 255 713250074, 2150302-6
Barua pepe: drp@muhas.ac.tz .

UTHIBITISHO

Mimi …… ……nimesoma na kuelewa taarifa kwenye hili karatasi.Bila kushurutishwa nimekubali kushiriki.

Sahihi ya mshiriki----------

Sahihi ya mtafiti/msaidizi wa utafiti…….

APPENDIX V: ETHICAL CLEARANCE

UNITED REPUBLIC OF TANZANIA

MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR – RESEARCH, PUBLICATIONS AND INNOVATION

Ref. No.DA.282/298/01.C/1926 Date: 03/10/2023

MUHAS-REC-10-2023-1926
ANNA-NSANYA ALPHONCE MWANGWALE
SCHOOL OF MEDICINE
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: PROPORTION AND TYPES OF OTOLOGICAL DISORDERS AND CD4 COUNT AMONG HIV PATIENTS RECEIVING CARE AND TREATMENT SERVICES AT TUMBI REGIONAL REFERRAL HOSPITAL

Reference is made to the above heading

I am pleased to inform you that the Chairman has on behalf of the University Senate, approved ethical clearance of the above-mentioned study, on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.

APPROVAL DATE: 03/10/2023
EXPIRATION DATE OF APPROVAL: 03/10/2024

STUDY DESCRIPTION:
Purpose:

The purpose of this cross sectional study is to determine proportion and types of otological disorders among adult HIV patients receiving ART services at Tumbi Regional Referral Hospital.

The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided:
https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%2014801.pdf and in the MUHAS archives

The PI is required to:

1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain data transfer agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Apply for and obtain material transfer agreement (MTA) from NIMR, if research materials (samples) will be shipped to a foreign country,
8. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III section 10 (2)
9. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
10. PI is required to be versed with necessary laws and regulatory policies that govern research in Tanzania. Some guidance is available on our website https://drp.muhas.ac.tz/.

Dr. Nahya Salim Masoud,
Chairperson, MUHAS Research and Ethics Committee

Muhimbili University of Health and Allied Sciences
DIRECTOR
Research, Publications & Innovations
Box 65001

APPENDIX VI: INTRODUCTION LETTER

UNITED REPUBLIC OF TANZANIA
MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY
MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR – POSTGRADUATE STUDIES

In reply quote;
Ref. No. HD/MUH/T.181/2021

05th October, 2023

The Executive Director,
Tumbi Regional Referral Hospital,
P.O. Box 30041,
KIBAHA

Re: INTRODUCTION LETTER

We would like to inform you that the bearer of this letter is Anna-Nsanya Alphonce Mwangwale with Reg. No. HD/MUH/T.181/2021 is a student at Muhimbili University of Health and Allied Sciences (MUHAS) "pursuing MMed. Otorhinolaryngology.

As part of her studies, she will be doing an elective research titled: "**Proportion and Types of Otological Disorders and CD4 Count Among HIV Patients Receiving Care and Treatment Services at Tumbi Regional Referral Hospital.**"

The research has been approved by the Chairman of University Senate.

Kindly provide her the necessary assistance to facilitate the conduct of her research.

We thank you for your cooperation.

Ms. Victoria Mwanilwa
For: DIRECTOR, POSTGRADUATE STUDIES

c.c Anna-Nsanya Alphonce

9 United Nations Road; Upanga West; P.O. Box 65001, Dar Es Salaam: Tel. G/Line: +255-22-2150302/6; Ext. 1015; Direct Line:+255-22-2151378;Telefax:+255-22-2150465;E-mail:dpgs@muhas.ac.tz;Web:https://www.muhas.ac.tz

APPENDIX VII: PERMISSION LETTER

THE UNITED REPUBLIC OF TANZANIA
Ministry of Health

Telegram" AFYA" KIBAHA
Tell Phonce no: +255 026-2323267
FAX Na:
(All letter should be addressed to the permanent Secretary)

Medical Officer In charge
Tumbi Regional Referral Hospital
P.O.Box 30041
KIBAHA.

In reply please quote:

REF: NO:TDRRH/AB.144/247/01 16/10/2023

Principal,
Muhimbili National Hospital,
P.O.Box 65001,

DAR ES SALAAM.

REF:STUDENT INTRODUCTION FOR RESEARCH WORK.

Reference is made to your letter with Ref no HD/MUH/T.181/2021 dated 05/10/2023

2. I would like to authenticate your letter which introduces Anna Nsanya Alphonce Mwangwale as a student in your institution, who is aspired to collect research Data in our Hospital.

3. It's here to inform you, she has been permitted to do her research work within one month from today, and with a due respect, she is required to abide with all the policies and practice of Tumbi hospital during her run through.

4. Your Sincerely,

Fatuma Mkupula
For: MEDICAL OFFICER INCHARGE
TUMBI REGIONAL REFEERAL HOSPITAL.

FOR: MEDICAL OFFICER INCHARGE
TUMBI REGIONAL REFERRAL HOSPITAL
P. O. Box 30041
KIBAHA - PWANI