ERECTILE DYSFUNCTION IN MALE EBOLA VIRUS DISEASE SURVIVORS IN WESTERN SIERRA LEONE A HEALTH FACILITY BASED DESCRIPTIVE - CROSS SECTIONAL STUDY

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DECLARATION

The research is undertaken as part of the requirement for the Masters of Medicine degree, Department of Obstetrics and Gynecology, University of Nairobi. It is a native work by me and has never been undertaken and submitted for a Master's degree in other Universities.

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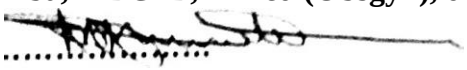
Hnorary  Lecturer, Department of Obstetrics and Gynaecology,

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CERTIFICATE OF AUTHENTICITY

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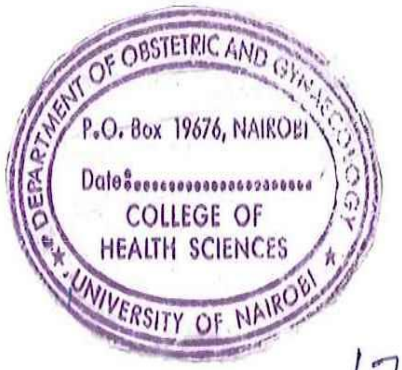

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DEDICATION

To Professor Zahida Qureshi who has always stood out for me as a mother and to my late son Waleed Ahmad whose sudden demise ignited the empathy in Prof which has connected us forever**.**

LIST OF ABBREVIATIONS

CVD Cardiovascular Disease

DM Diabetes Mellitus

ED Erectile Dysfunction

EVD Ebola Virus Disease

ETC Ebola Treatment Centre

HBV Hepatitis B Virus

HC Holding Centre

HCV Hepatitis C Virus

HIMS Health Information Management System

HIV Human Immunodeficiency Virus

HPN Hypertension

IIEF-S International Index of Erectile Function-Score

KNH/UoN-ERC Kenyatta National Hospital/University of Nairobi- Ethics & Research Committee

NPT Nocturnal Penile Tumescence

PDE-5 Phosphodiesterase type-5 inhibitor

PGE1 Prostaglandin E1

PTSS Post Traumatic Stress Syndrome

RT-PCR Test Reverse Transcriptase Enzyme Polymerase Chain Reaction Test

SD Sexual Dysfunction

TB Tuberculosis

WHO World Health Organization

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DEFINITION OF TERMS

Erectile Dysfunction (ED) is the continuous helplessness to attain and keep an erection strong enough to enhance adequate sexual conduct.

A diagnosed **EVD survivor** is an individual who has been lab-confirmed RTPCR-positive on any, body fluid, treated at an Ebola Treatment Centre (ETC), and plasma tested PCR-negative and discharged from that Centre with a **laboratory-issued EVD survivor certificate.**

Undiagnosed EVD survivor: Individual who contracted EVD infection, suffered acute severe Ebola, but went through disease without being diagnosed or treated at an Ebola Treatment Centre (ETC), and was later confirmed to be Ebola antibody positive (IgG – IgM) by serological testing and has not been vaccinated against Ebola virus, with a **government-issued EVD survivor certificate**.

NPT (Nocturnal Penile Tumescence): Is an Erection Self-Test procedure which a man can do by himself to determine if the cause of his ED is of physical or psychological origin.

ABSTRACT

Background: A normal sexual function requires intact neurological and vascular systems and their coordinated complex interactions. Ebola Virus Disease (EVD) is presumed to cause ED via both neurogenic and vasculogenic pathways.
EVD survivors suffer a variety of complications including reduced libido (sexual dysfunction). The prevalence of Erectile Dysfunction (ED) is unknown among male EVD survivors, partly because 85% of men with ED are quiet about it.

Setting: The Hospitals and the public health facilities in Western Sierra Leone that registered and cared for the EVD survivors.

Objective: To establish the currency (prevalence), characteristics and management options of ED among male EVD survivors in Western Sierra Leone.

Methodology: This was a Health facility base descriptive Cross-sectional study **that interviewed male EVD survivors, by using the IIEF-5 Scores questionnaire, taking their sexual history, screening them for DM, HIV and Hepatitis B, and by clinically examining them to identify the magnitude of the ED, if any, and to recommend specialist care.**
A total of 400 male EVD survivors were consecutively sampled and the resulting data was uploaded into an excel sheet for analysis using SPSS version 21.
The eligibility criteria for inclusion of these subjects were male EVD survivors aged 15-49yrs, who were either laboratory-confirmed or the undiagnosed EVD survivors (whose serum showed EVD antibodies later after surviving) and carried discharge certificates from Ebola Treatment Centres.

Results: The mean age of the 400 participants studied, was 31.1yrs. Most of the EVD survivors studied were within the age of 25-29yrs (20%); most were married (55.5%), but of low-socio-economic status (58.5%), 41.5% had no formal education, non-smokers (73.5%) and non-alcoholics (82.5%). 54.5%(218) of them had ED.
Of those who had ED, 31.2% (68) had mild ED, 45.0% (98) had mild-to-moderate ED, 19.7% (43) had moderate ED and 4.1%(9) had severe ED.
Of those who had ED 52.3% (114) used no therapy, 46.3% (101) used drug therapy and only 1.4% (3) of them used sex therapy for their ED

Conclusions: Age in Years and marital status significantly explained the Presence of ED among the Men, with every increase in an additional year in age, the likelihood of developing ED increased by about 0.9 points (p-value<0.001) while compared to single men, married and cohabiting men significantly explained the ED (p-value 0.007 & 0.023) respectively.

Keywords: Ebola virus disease, EVD survivors, Erectile Dysfunction, sequelae of EVD, IIEF Scores, Freetown, Sierra Leo

1.0 INTRODUCTION

1.1 BACKGROUND

Ebola virus disease (EVD) is a grave, hugely deadly, filovirus infection which belongs to diseases known as viral haemorrhagic fevers[1]. The disease spreads by getting in touch with body fluids of infected persons, and it can, therefore, unfurl like wildfire and with high case fatality[2, 3], particularly where health systems are weak. Environmental factors, such as, poor sanitation, low socioeconomic settings, migration, high climate conditions, all help the physical, biological and chemical factors that amplify the spread of Ebola virus disease[4].

The 2013-2016 Ebola eruption (outbreak) commenced during the December of 2013 in rural Guinea and quickly extended to Liberia, Sierra Leone and beyond[5]. By January 3rd, 2016, about 29,000 victims of the disease had been reported in the West African sub-region, with 11,315 deaths[6]. The extent of this outbreak persuaded the World Health Organisation (WHO) to declare in August 2014, as a "Public Health Emergency of International Concern[7]".

Sierra Leone was the most severely afflicted country housing about 50% of the cases[6]. The outbreak culminated in an approximated 4,000 deaths and about 10,168 survivors in Sierra Leone[8].

Before the Ebola outbreak, the Republic of Sierra Leone was toiling to recuperate from a rebel war, health system constraints and significant limitations in its health worker force[2, 9] and Ebola noxiously strained the standard of health-care delivery services and the community's health-seeking behaviour[10, 11].

After 7th November 2015, Sierra Leone had few sporadic cases of EVD. But the country was free of Ebola in March 2016[6], and the challenging road to recovery began[12], coupled with Ebola survivor care.

The virus may live in immunologically advantaged sites of the human body for a few months post-acute infection[13]. These sites include the central nervous system, the eyes, the testes/semen and within the cerebrospinal fluid[13].

The presence of the virus and the longevity of persistence in these body compartments varies according to survivor characteristics[14]. The onset, duration and severity of complications among EVD survivors also depend on survivor characteristics[14]. The complications of EVD are devastating and may include sexual dysfunction (SD)[15].

ED is a constituent of SD. But ED hasn't been hived out in any study as an association with EVD.

The study, therefore is an exploration of an association between EVD and ED, because of the latter's proven cause-effect relationship with other viral infections. We, therefore, inferred that the same mechanism occurs for EVD.

Viral infections cause ED in patients largely via organic (vasculogenic, neurogenic and hormonal pathways)[16]. ED is a symptom of damage to the vascular endothelium which synthesizes Nitric Oxide, a powerful vasodilator which facilitates erection. Age, disease and psychology inhibit NO release[17]. Because of the devastating nature of this outbreak, we presume that both organic and psychological effects are present in the EVD survivors. When age is the major determinant of ED, it occurs late in life and worsens with age. But when ED is a symptom of an underlying disorder or combined with a psychological effect as in EVD, it occurs at a very young age.

Hence the choice of the age bracket (15-49years old) for this study. It, therefore, goes without say, that if ED occurs in the young, there must be an underlying disorder.

There is no documented numerical change, in the cohort of EVD survivors or the prevalence of EVD, even in the face of ongoing management of the long term sequelae of same.

2.0 LITERATURE REVIEW

2.1 Erectile Dysfunction (ED)

Erectile function is the intricate interaction mainly between the neurological, endocrine and vascular systems[16]. ED is the continuous helplessness in achieving and sustaining a penile erection good enough to enhance adequate sex[16].

2.2 Pathophysiology

Penile erection and flaccidity/relaxation is a neurovascular event which involves a complex interaction of the CNS, PNS, and genital vasculature and trabecular smooth muscle. Areas of the CNS receive and integrate tactile, visual and cognitive impulses from the genitalia, and activate neuronal outflow (involving neurotransmitters, enzymes) to the genitourinary tract via the spinal cord, peripheral nerves and the ANS (parasympathetic=erection/tumescence, sympathetic=detumescence) to effect contraction/relaxation of the penis.

Any disease conditions that are anatomical (vasculogenic, neurogenic, psychogenic, hormonal), drug-induced, or events (accidents/trauma, pelvic surgery, chemo-radiation) that disrupt the above physiology, may lead to ED[16].

2.3 Epidemiology of ED

The global prevalence of ED varies widely between 3-76.5%. 52% of men between 40 and 70 years, among the general population report some measure of erectile dysfunction at some point in their lives. Over 20% of men over 50 years, experience significant erectile dysfunction[18]. 85% of men with ED prefer to suffer in silence and do not seek help[18].

2.4 Classification of ED

Erectile Dysfunction is generally classified into three groups depending on the aetiology[16].

1. Physical,
2. Psychological and
3. Combined ED

2.5 Causes of ED

It is highly unlikely to find one problem that is causing 100% of the problem[18]. It is not common to take one solution that will fix 100% of the problem[18]. Male erectile dysfunction is more common than presented[18].

Physical causes: Hypertension, Diabetes, cardiovascular, neurological disorders, imbalances of hormone levels, infections, such as (TB, HIV, Mumps, viral hepatitis), alcohol intake and substance abuse. Also, the adverse reactions of some medications, such as some Antipsychotic and CVD drugs, may impair erectile function.

Psychological causes: These involve depression, anxiety, Post Traumatic Stress Syndrome (PTSS) concerns about (sexual act, or souring conjugal ties), guilty consciousness, body built concerns, and the thoughts of past traumatic sex.

Mixed (both physical and psychological causes): Most cases of ED are a mixture of physical/organic and psychological aetiology[18].

EVD is presumed to cause ED in the survivors via both an organic cause (neurogenic and vasculogenic pathways) and psychological effects. ED is a chronic event when it stems from an organic cause. But it can be temporary as a result of a psychological effect. With EVD, because both organic and psychological effects are presumed to be present, it is a chronic event in the survivors.

2.6 Evaluation of Patient with Erectile Dysfunction

The WHO and the American Urological Association suggest that an evaluation for an ED involves:

1. Administering the simplified and shortened design of the IIEF-5 Score Questionnaire, followed by the person' attitude towards sex
2. A comprehensive history (including medications, substance abuse and medical problems that contribute to ED)
3. The focused clinical examination
4. Diagnostic tests, if needed. (But lab testing adds little to the diagnosis of ED)

2.7 Management of Erectile Dysfunction

2.7.1 Patients respond to the same treatment modalities regardless of the cause[18].

1. Medical (sildenafil/Viagra)
2. Mechanical aids/vacuum devices
3. Sex therapy
4. Education and communication

5. Behavioural therapy/ Psychosociotherapy

2.7.2 Summary of Management

- Start with: Viagra 50mg (a PDE-5 inhibitor)
- If 50mg Viagra failed, give repeated high doses of Viagra (100 mg)
- If Viagra failed, then Alprostadil (PGE1), intracavernous injection or intraurethral, Vacuum Pump
- If PGE1 failed, then give Triple therapy (Trimix =papaverine+ phentolamine+ alprostadil)
- If medical therapy failed, then Penile Implant Surgery can be done.

2.8 Summary of related studies

A cross-sectional study which was done by Gomes TV, et al, in Salvador, Brazil, published in September 2019, looked at the **Prevalence and risk factors for ED in HIV infected patients[19].** 134 men, who satisfied the criteria for inclusion, were added consecutively in the study. ED was noted in 21.6% of them. They were mostly single and among the black Brazilians. The ED was also found to be associated with low socioeconomic status. The only tool used was the IIEF-5 questionnaire.

A prospective study, done by Ivan Gentile, et al, in Naples, Italy, published in July 2018, looked at the **Prevalence and risk factors for ED in patients with HBV, HCV or chronic liver disease[20]**. Of the 89 men studied, ED was found in 76.4% of them. They were older. DM and the stage of liver disease were the only independent predictors of ED. ED was found in old patients only, and increased age was a potential confounder.

An analytical Observational study, done by Aiman J, et al, looked at **Androgen and estrogen**

production in ageable men with gynecomastia and testicular atrophy after mumps orchitis[21]. Of the 3 men followed up, atrophy of the testicles, reduced libido, impotence, and gynecomastia was linked with ↓testosterone and ↑LH and ↑FSH levels. The sample size was very small.

A Prospective, consecutive, cross-sectional study, which included HIV+ patients, done by Claramonte M, et al, at the Saint Francis Hospital, Buluba, Uganda, published in September 2012, looked at, **the Prevalence and risk factors of ED and testosterone deficiency symptoms in a rural population in Uganda**[22]. Of the 902 patients studied, ED rate was noted to be 47.8% [Mild ED =28.8%; Moderate ED=14%; Severe ED=5%]. When HIV+ patients (204) were excluded, ED was at 36.8%. [Mild ED =23%, Moderate ED = 10.2%, Severe ED = 3.6%]

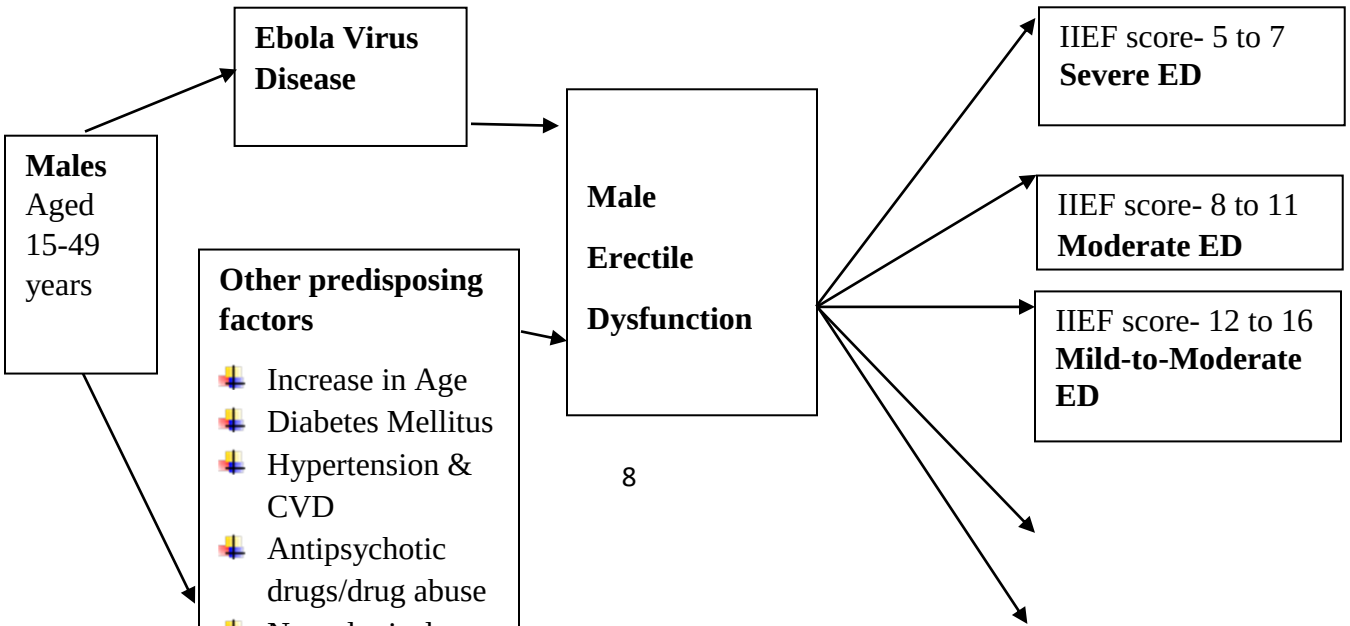
A cross-sectional study, done by Hoang Mingh et al. A comprehensive review of the literature on ED in young men, published in June 2017, looked at, **Erectile Dysfunction in Young Men—A Review of the Prevalence and Risk Factors[23].** The prevalence of ED in young men was noted to be at 30%. The study was on young people. But ED is a problem of both young and old.

A descriptive study, done by Hunter SS, et al, at the Cairo University, Faculty of Medicine, Cairo, Egypt, published in March 2014, looked at, **ED in patients with chronic HCV[24].**
150 subjects who were eligible, per took of the study. Amongst patients with chronic HCV, the prevalence of ED was found to be 29.3%. More correlation between ED and chronic liver disease was noted. There was no mention of medical history and clinical examination in the evaluation of the patients, however.
An observational cohort study titled **'Ebola Survivors affected by a variety of neurologic symptoms'[15]** done by the Partnership for Research on Ebola Vaccines in Liberia III (PREVAIL

III), published in Oct 2017. Of the 1500 survivors studied, 10.6% suffered Sexual Dysfunction (SD). This includes both male and female survivors. The proportion of male survivors who suffered SD, was, however, not documented. ED which a constituent of SD was not hived out.

3.0 CONCEPTUAL FRAMEWORK

Erectile Dysfunction can be a debilitating condition with associated psychological and sexual effects on a couple's relationship. A combination of psychological factors such as stress, fatigue, depression and organic factors such as viral illnesses stroke, spinal injury, diabetes and cardiovascular disease have been shown to influence the management outcomes of people with ED as shown in the figure below. **It has been proven that viral diseases such as HIV, HBV and HCV affect erectile function negatively. It is, therefore, inferred that the same mechanism occurs for EVD.**



IIEF score- 17 to 21
Mild ED

IIEF score- 22 to 25
No ED

Figure1. Showing the Conceptual Framework

4.0 PROBLEM STATEMENT

The majority, if not all of Ebola survivors suffer from one kind of complication or the other[14]. **The sequelae of viral persistence in immune-privileged sites have prompted in, described cases of inflammation of either one of or both testicles, menstrual cycle disturbances, impotence, reduced libido (decreased or lost interest in sex), or sexual dysfunction, etc[14]**. With sexual dysfunction/ED, partner satisfaction is lost[14, 15,16], which can adversely affect family harmony resulting in broken homes.

5.0 JUSTIFICATION

1. The full extent of the sequelae of EVD is still being studied. The molecular intricacies involved in EVD especially in the reproductive system is under thorough scientific research.

2. Data are scarce on the sequelae of EVD in survivors.

3. Furthermore, no specific studies have been carried out in Sierra Leone on Erectile Dysfunction in male EVD survivors. **Studies documented so far have only highlighted**

sexual dysfunction in EVD survivors (including both males and females). The findings of this study may, therefore, inform practice.

4. Because the sequelae of EVD can be devastating and extensive, in Sierra Leone, the Government has extended the Free Health Care Services to Ebola survivors at all public health institutions across the country to address the sequelae of the viral infection**.** Subjects might benefit enormously from this study, **depending on the severity of the erectile dysfunction, as found**; they **might be given a trial course of therapy, be referred for specialist evaluation and care, sent for laboratory investigation of serum sex hormone measures of say, androgens and prolactin, imaging studies and/or for psychosexual counselling.**

5. 85% of men with Erectile Dysfunction are quiet about it and do not seek help. Rather, they often-times prefer to suffer in silence[16].

6.0 RESEARCH QUESTION

What is the prevalence, characteristics and interventions of ED amongst Male EVD survivors in Western Sierra Leone?

7.0 STUDY OBJECTIVES

7.1 General Objective

To determine the prevalence, characteristics and management interventions of ED as a physical association of EVD amongst the male survivors in Western Sierra Leone.

7.2 Specific Objectives

1. **Describe the socio-demographic and reproductive characteristics of male EVD survivors in Western Sierra Leone.**

2. **Determine the prevalence of ED among male EVD Survivors in Western Sierra Leone.**
3. **Using the IIEF–5 tool, to characterize the ED presentation among EVD Survivors in Western Sierra Leone.**
4. **Describe the management interventions used among male survivors of EVD with ED in Western Sierra Leone.**

8.0 METHODOLOGY

8.1 Study Design

This was a Health Facility Based descriptive cross-sectional study to determine an association between Ebola Virus Disease and Erectile Dysfunction in male EVD survivors in Western Sierra Leone, by using a validated questionnaire, the International Index of Erectile Function which contains five questions (IIEF-5 Scores) with a closed-ended format, taking a focused clinical history and examination and doing targeted investigations to exclude the possible confounders.

8.2 Study Site and Setting

Sierra Leone is one of the smallest countries in West Africa. It is bordered by Guinea, Liberia and the Atlantic Ocean. The country occupies a land area of 71,740 square km and has a population of approximately 7,092,113[25,] according to the national census in 2015.

Freetown, the capital of the country is in Western Sierra Leone and has a population of 1,055,964[25]. It also has the largest population of EVD survivors in the country. The Military Hospital which had a special unit dedicated to managing Post Ebola Syndrome, and which registered the largest number of EVD survivors, is located in Freetown. Other public health

facilities in the western area also had units dedicated to same. These units offered symptomatic care, Ebola viral monitoring, and imaging studies and have counsellors who offered psychosocial therapy.

Culturally, Sierra Leoneans can start a regular sexual relationship as early as 15years old especially in the face of the aftermath of the devastating Ebola outbreak.

8.3 Study Population

The sample for the study was selected from male EVD Survivors 15-49years old, who were EVD laboratory-confirmed, treated and discharged from Ebola Treatment Centres (ETC) from June 2014 through July 2015. **Both the diagnosed (Lab-confirmed) and the undiagnosed (the seroconverted, who did not show up for testing but had Post-Ebola symptoms) cases,** who were registered and cared for, after surviving, for Post-Ebola symptoms, in the Military Hospital and the public health facilities in the Western area of Sierra Leone, from July 2015 through August 2020. EVD patients and survivors managed in Freetown were largely those from the Western Area Rural (WAR) district and the Western Area Urban (WAU) Centre, which is Freetown and part of the Port Loko District in the North-West. During this period, the total number of laboratory-confirmed Ebola and the Undiagnosed cases in the Western Area (WA) was 3, 996[26].

8.4 Sample Size Calculation

The prevalence of ED in this category of subjects is unknown. Notwithstanding, an empirical value of 50% was taken as the proportion of subjects who had EVD and who are likely to develop ED.

Applying this in the formula of proportions, the sample size as calculated will be as follows:

$$n = \frac{Z^2_{1-\alpha/2} \times p\,(1-p)}{d^2}$$

n= sample size

Z= level of statistical difference = 1.96

P = Assumed proportion of subjects with ED, 50%

d= Estimated error, taken as 0.05

Substituting this in the formula gives a sample size of **385** as shown below:

$$n = \frac{1.96^2 \times 0.5\,(1-0.5)}{} \rightarrow 0.05 \times 0.05 = \mathbf{385}$$

Assuming a 10% data incompleteness, the recalculated sample size will be

100/90 * 385 = **430**

8.5 Sampling Procedure

We got help from the Sierra Leone Association of Ebola Survivors (SLAES) who located, called and verified the participants.

A consecutive sampling procedure was used at all the targeted data collection sites, confirming the participants' identity by discharge certificates from the ETCs and by Ebola survivor identity cards, to get the 430 study participants that were included in the study.

Any participant that satisfied the criteria for inclusion, was added to the study, to reach the estimated sample size.

8.6 ELIGIBILITY CRITERIA

8.6.1 Inclusion Criteria

Male EVD survivors who were:

- ***aged 15- 49yrs***
- ***laboratory-confirmed EVD patients***
- ***Undiagnosed EVD survivors***
- ***WHO certified as virus-free***
- ***registered as EVD survivors in the Government Health facilities***
- ***married or cohabiting or in a stable sexual relationship***8.6.2 **Exclusion Criteria**

Male EVD survivors who;

- ***had Erectile Dysfunction before the EVD***
- ***only had Erectile Dysfunction more than one year after surviving EVD***
- ***are on antidepressant drugs or are drug/substance abusers***
- ***developed co-morbidities like cardiovascular and/or neurological conditions, BMI≥30 DM+, HIV+, Viral Hepatitis+ before/during/ after the EVD***

8.7 Data Variables

The table below shows the data variables used to collect the data during the study:

Table1. Data variables

Objective	Data variables
Describe the socio-demographic and reproductive characteristics of ED	Age, Marital status, alcohol intake, smoking (cigarettes, marijuana, others), Monthly income, Educational level and employment
Determine the prevalence of ED	Total number of Male EVD survivors diagnosed with ED Total number of Male EVD survivors in the sample
Characterize the ED (using the IIEF-5 tool)	Severe ED, Moderate ED, Mild to moderate ED, Mild ED, and No ED
Describe the management interventions used with ED	Medication, devices, Psychotherapy/behavioural therapy, Education and communication, Surgery, mixed/combined therapy, None

8.8 STUDY PROCEDURES

8.8.1 Sources of Data

Data were drawn from the:

- Ebola survivor registers at the Military Hospital and the other public health facilities in Freetown.
- WHO Ebola survivors register
- Health Management Information System (HMIS) in Freetown
- The Sierra Leone Association of Ebola Survivors (SLAES) database

8.8.2 Data collection procedure

Data from the HMIS, WHO and the health facilities where the EVD survivors were managed were used to identify and locate them for the administration of the interviewer guided questionnaire. Clinical history was obtained from each eligible participant, focused clinical examination and targeted laboratory investigations were done. **The Data was collated by the Principal Investigator (PI) and two Research Assistants (RAs) with a diploma in clinical medicine and training on data collection, confidentiality and the**

use of Microsoft excel. Also, the physical examination was done by the PI and the RAs. The Laboratory investigations were done by five Laboratory Technicians.

8.8.3 Data collection period

Data was collected in the data collection summary forms and then transferred to an Excel database from August through September 2020.

8.8.4 Training of data collection clerks

The research assistants had a three-day instruction in the foundations of conducting an observational study and the protocols of the study. Additionally, they had two days of coaching in the fundamental concepts of data collection including the use of Microsoft Excel, data cleaning and confidentiality.

8.8.5 Data collection tools

1. Screening for HIV, Hepatitis B and Diabetes Mellitus status was done.

2. Additionally, a detailed medical and sexual history were taken and a focused clinical examination was done [vitals, BMI, sensation for touch (T) Temperature (T◦) and Pain (P) and the genitalia].

3. The International Index of Erectile Function (IIEF-15) questionnaire is the WHO and FDA validated and globally accepted gold standard instrument for assessing ED. It meets international standards for validity, consistency and reliability.

A shortened design of the IIEF-15 (IIEF-5 score which has only five sections with 15 questions) was adopted for this study. It describes five areas of male sexual performance over a previous specific period. Viz: **erectile & orgasmic functions, sexual aspiration, intercourse gratification, and general contentment.** Four out of the five items of IIEF-5 were copied verbatim from the erectile function field of IIEF-15.

Table2. **The IIEF-5 scoring system**

Score	**Classification**
5 to 7	Severe ED
8 to 11	Moderate ED
12 to 16	Mild-to-Moderate ED
17 to 21	Mild ED
22 to 25	No ED

These tools were piloted first in one of the health facilities which prompted minor modifications.

9.0 ETHICAL CONSIDERATIONS

9.1 Approval of Ethics and Research Committee*:*

Permission for the conduct of the study was secured from the KNH/UON-ERC and the Sierra Leone National Ethics and Research Committee (SLNERC).

The **Data is primarily owned by the UoN. Outcomes of the study may be shared with the Ministry of Health of Sierra Leone in consultation with and permission by the UoN, to allow the former for policy planning and improvement on EVD survivor care.**

The patients found with ED are to be referred to a multidisciplinary team including a Urologist, an Andrologist, a Gynaecologist, a counsellor and a fertility specialist for further evaluation and appropriate management option and support.

9.2 Consent of the participants

Each participant appended a signature to written consent, or right thumb-print, voluntarily.

9.3 Data confidentiality:

These are aggregate data and no names were used. Furthermore, confidentiality is maintained by saving the electronic data file in a password secured computer for at least five years.

9.4 FLOW CHART OF STUDY POPULATION

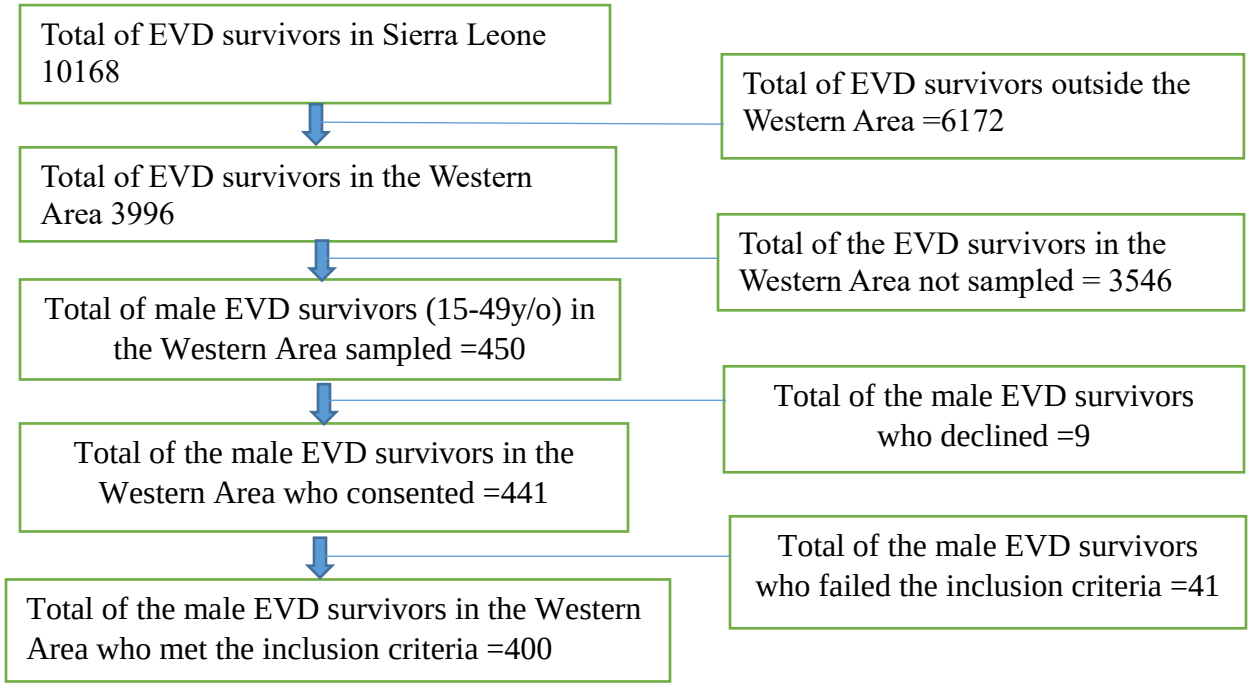


Figure2. Showing flow chat of EVD survivors in Western Sierra Leone

10.0 DATA MANAGEMENT, ANALYSIS, AND STATISTICS

The data was analysed by the SPSS version 21 software in keeping with the objectives of the study.

1. The socio-demographic and reproductive characteristics of the study participants were described and displayed in tables
2. The prevalence of ED among EVD survivors was calculated by the proportion of subjects with confirmed ED to the total number of participants in the study. Categorical variables were expressed as frequencies and percentages. Continuous variables were presented as means ±SD. Levels of significance were set at a P-value of < 5% ($P<0.05$)
3. The degree of ED was also presented in tabular form.
4. A description of the management options was described using tables

10.1 Study Results Dissemination Plan

10.1.1 Precise patient and community benefits*:*

The outcome of this study will increase awareness of ED among EVD survivors and in the community. More patients would now seek care and support. The spouse of the Ebola survivors and the community will benefit from the fact that the ED in question and the likely subsequent sub-fertility resulted from the EVD and not from any witchcraft, as is widely believed.

Subjects found with ED are to be referred for specialist care, supported by the Government of Sierra Leone. The management and care of ED patients would help rebuild fragile relationships.

10.1.2 Feedback and dissemination of results.

The results of the study are submitted to the UoN and may be shared with the Ministry of Health & Sanitation in Sierra Leone. The results will also be presented at national and international conferences and submitted to a peer-reviewed journal for publication.

The dissemination of this study would unearth an untold story of the EVD survivors

10.1.3 Implications for policy and practice:

There are implications for policy and practice according to the results of the study. Though the causality is not established, a linear relationship is established between EVD and ED.

10.2 Collaborative partnerships: These will be between the UoN and the Ministry of Health and Sanitation, Sierra Leone.

11.0 RESULTS

Out of the 400 participants studied, most EVD survivors were within the age of 25-29yrs (20%). 55.5% married, 62.75% unemployed, 30.75% self-employed and 58.5% without monthly income. 41.5% had no formal education, 73.5% non-smokers and 82.5% non-alcoholics.

54.5% (218) of them had ED.

Of those who had ED 54.5% [mild, mild-to-moderate, moderate and severe degrees of ED were at 17%, 24.5%, 10.75% and 2.25% respectively]

Of those who had ED 54.5% [28.5% used no therapy, 25.25% used drug therapy and only 0.75% of them used sex therapy for their ED].

11.1 Table3. Frequency Table. Socio-demographic characteristics of the Male EVD Survivors in Western Sierra Leone, according to age distribution

Characteristics	Age groups, N=400 (%)							
Age	**15-19**	**20-24**	**25-29**	**30-34**	**35-39**	**40-44**	**45-49**	**Total**
Total Number	42(10.5)	61(15.3)	80(20.0)	70(17.5)	54(13.5)	51(12.8)	42(10.5)	400(100.0)
Marital status								
Single	31(73.8)	23(37.7)	16(20.0)	2(2.9)	4(7.4)	1(2.0)	1(2.4)	78 (19.5)
Married	2(4.8)	10(16.4)	35(43.8)	48(68.6)	42(77.8)	47(92.2)	38(90.5)	222(55.5)
Cohabiting	9(21.4)	28(45.9)	29(36.3)	20(28.6)	8(14.8)	3(5.9)	3(7.1)	100(25.0)
Employment								
Employed	-	-	2(2.5)	11(15.7)	4(7.4)	5(9.8)	4(9.5)	26 (6.5)
Unemployed	41(97.6)	54(88.5)	48(60.0)	34(48.6)	31(57.4)	21(41.2)	22(52.4)	251(62.75)
Self-Employed	1(2.4)	7(11.5)	30(37.5)	25(35.7)	19(35.2)	25(49.0)	16(38.1)	123(30.75)
Level of Education								

None	4(9.5)	10(16.4)	39(48.8)	33(47.1)	27(50.0)	29(56.9)	24(57.1)	166(41.5)
Primary	6(14.3)	2(3.3)	3(3.8)	2(2.9)	9(16.7)	1(2.0)	5(11.9)	28 (7.0)
Secondary	31(73.8)	43(70.5)	28(35.0)	15(21.4)	9(16.7)	10(19.6)	6(14.3)	142(35.5)
Tertiary	1(2.4)	6(9.8)	10(12.5)	20(28.6)	9(16.7)	11(21.6)	7(16.7)	64 (16.0)
Monthly income								
Yes	5(11.9)	8(13.1)	35(43.8)	39(55.7)	24(44.4)	33(64.7)	22(52.4)	166(41.5)
No	37(88.1)	53(86.9)	45(56.3)	31(44.3)	30(55.6)	18(35.3)	20(47.6)	234(58.5)
Alcohol intake								
No	39(92.9)	53(86.9)	68(85.0)	56(80.0)	46(85.2)	39(76.5)	36(85.7)	337(84.25)
Yes	3(7.1)	8(13.1)	12(15.0)	14(20.0)	8(14.8)	12(23.5)	6(14.3)	63 (15.75)
<21U/wk.	3(100.0)	8(100.0)	12(100.0)	14(100.0)	8(100.0)	12(100.0)	6(100.0)	400(100.0)
≥21 U/wk.	-	-	-	-	-	-	-	0 (0.0)
Smoking								
No	39(92.9)	53(86.9)	64(80.0)	52(74.3)	27(50.0)	33(64.7)	27(64.3)	295(73.75)
Yes	3(7.1)	8(13.1)	16(20.0)	18(25.7)	27(50.0)	18(35.3)	15(35.7)	105(26.25)
< 5 pk-yrs	3(100.0)	8(100.0)	16(100.0)	18(100.0)	27(100.0)	18(100.0)	15(100)	400(100.0)
≥5 pk-yrs	-	-	-	-	-	-	-	0 (0.0)

11.2 Table 4. Frequency Table. Socio-demographic characteristics of the Male EVD survivors according to the presence of ED in Western Sierra Leone

Characteristics	With ED N=218 (%)	Without ED N=182 (%)	P-value
Age (mean ±SD)	34.6(8.4)	26.8 (7.7)	<0.001
Marital Status			
Single	18 (8.3)	60 (33.0)	Ref.
Married	152 (69.7)	70 (38.5)	<0.001
Cohabiting	48 (22.0)	52 (28.6)	<0.001
Employment			
Employed	15 (6.9)	11 (6.0)	Ref.
Unemployed	128 (58.7)	123 (67.6)	0.515
Self-employed	75 (34.4)	48 (26.4)	0.756

Educational Level			
None	100 (45.9)	66 (36.3)	Ref.
Primary	17 (7.8)	11 (6.0)	0.962
Secondary	66 (30.3)	76 (41.8)	0.010
Tertiary	35 (16.1)	29 (15.9)	0.443
Monthly income			
Yes	102 (46.8)	64 (35.2)	Ref.
No	116 (53.2)	118 (64.8)	0.019
Alcohol intake			
No	176 (80.7)	161(88.5)	0.034
Yes	42 (19.3)	21 (11.5)	Ref.
<21 U/wk.	42 (100.0)	21 (100.0)	-
≥21 U/wk.	-	-	-
Smoking			
No	146 (67.9)	147 (80.8)	0.003
Yes	70 (32.1)	35 (19.2)	Ref.
< 5 pk-yrs	70 (100.0)	35 (100.0)	
≥5 pk-yrs	-	-	-

11.3 Table5: Frequency Table. The Prevalence of ED in the male EVD survivors in Western Sierra Leone, according to age distribution

Age group	With ED N=218(%)	Without ED N=182(%)	P-Value
15-19	7 (3.2)	35 (19.2)	1
20-24	16 (7.3)	45 (24.7)	0.256
25-29	44 (20.2)	36 (19.8)	<0.001
30-34	38 (17.4)	32 (17.6)	<0.001
35-39	38 (17.4)	16 (8.8)	<0.001
40-44	36 (16.5)	15 (8.2)	<0.001
45-49	39 (17.9)	3 (1.6)	<0.001
Total	**218**	**182**	

Figure3 Pie Chart showing the Prevalence of ED amongst the male EVD Survivors in Western Sierra Leone

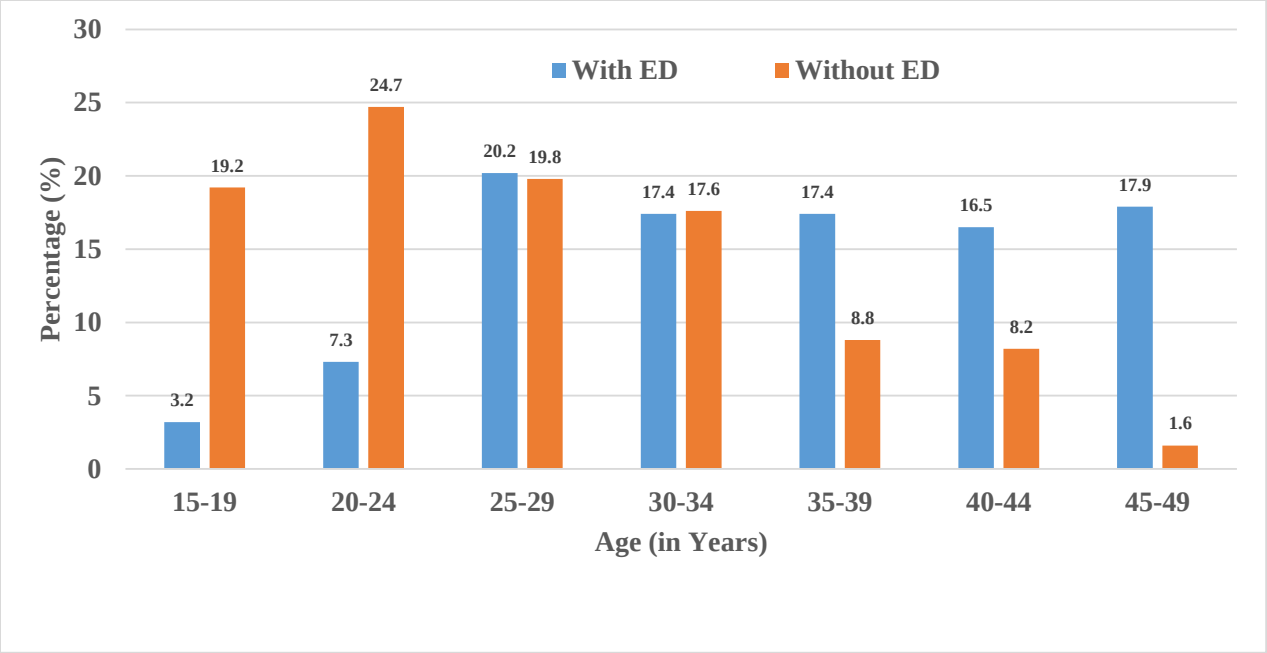


Figure4. Bar chart showing the Prevalence of ED in the male EVD survivors in Western Sierra Leone, according to age distribution.

11.4 Table6: The Degree of ED in the Male EVD survivors in Western Sierra Leone, according to age distribution (using the IIEF-5 scoring system)

Age group	Degree of ED =N (%)				
	No ED	**Mild ED**	**Mild-to-moderate ED**	**Moderate ED**	**Severe ED**
15-19	35 (19.2)	3 (4.4)	3 (3.1)	1 (2.3)	-
20-24	45 (24.7)	6 (8.8)	6 (6.1)	4 (9.3)	-
25-29	36 (19.8)	16 (23.5)	18 (18.4)	7 (16.3)	3 (3.3)
30-34	32 (17.6)	10 (14.7)	21 (21.4)	6 (14.0)	1 (11.1)
35-39	16 (8.8)	14 (20.6)	20 (20.4)	3 (7.0)	1 (11.1)
40-44	15 (8.2)	7 (10.3)	18 (18.4)	10 (23.3)	1 (11.1)
45-49	3 (1.6)	12 (17.6)	12 (12.2)	12 (27.9)	3 (33.3)
TOTAL	**182**	**68**	**98**	**43**	**9**

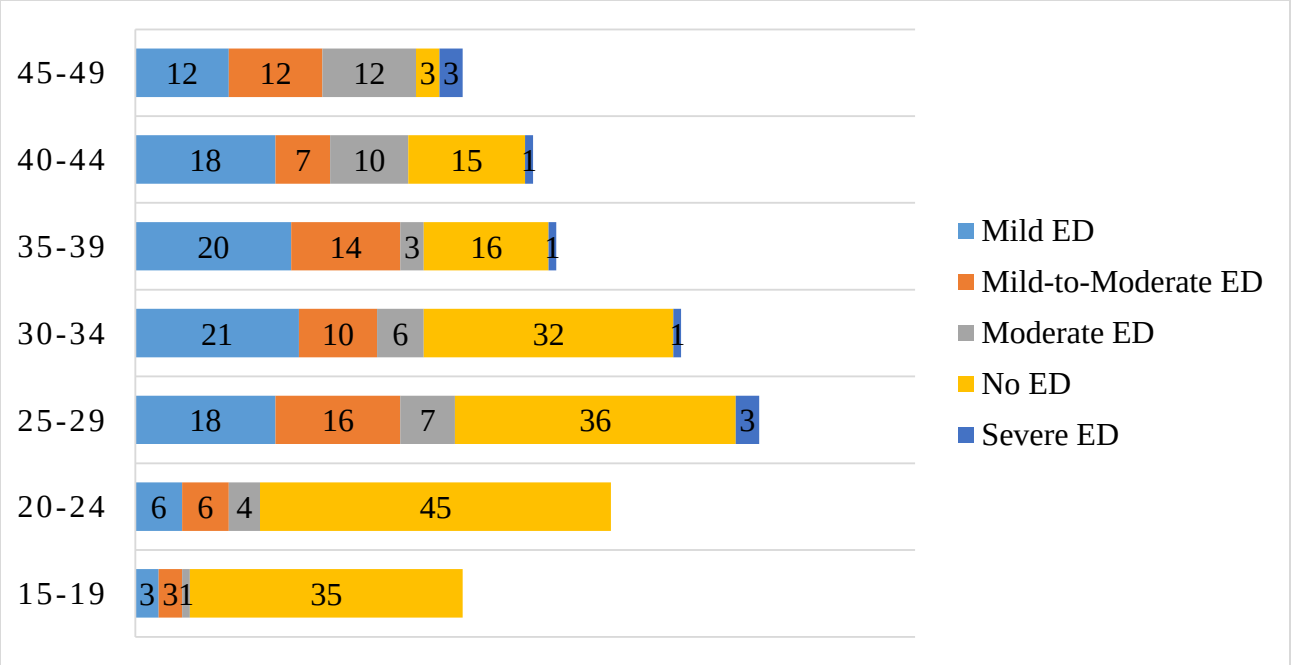


Figure5 Horizontal bar chart showing the Degree of ED in the Male EVD survivors in Western Sierra Leone, according to age distribution (using the IIEF-5 scoring system)

11.5 Table7: The management interventions used with ED in the Male EVD survivors in Western Sierra Leone

Age Groups	*Medication only	Devices only	Sex Therapy only	Psychotherapy/ Behavioral therapy only	Surgery only	No therapy
15-19	1 (14.3)	-	-	-	-	6(85.7)
20-24	8 (50.0)	-	-	-	-	8(50.0)
25-29	23 (52.3)	-	1 (2.3)	-	-	20(45.4)
30-34	15 (39.5)	-	1 (2.6)	-	-	22(57.9)
35-39	17 (44.74)	-	1 (2.63)	-	-	20(52.63)
40-44	17 (47.2)	-	-	-	-	19(52.8)
45-49	20 (51.3)	-	-	-	-	19(48.7)
TOTAL	**101**	-	**3**	-	-	**114**

***Medication used is the Phosphodiesterase type-5 inhibitors (sildenafil/Viagra)**

12.0 DISCUSSION

The mean age (±SD) of all 400 participants in this study was 31.1(9.0), with a median age at 30. Most of them were young, within the age of 25-29yrs. Most were married, but of low-socio-economic status, no formal schooling, non-smokers and non-alcoholics.

It came out clear from this study that increasing age (≥40yrs), married men and smokers were associated with ED.

This is comparable to almost all the studies done globally on erectile dysfunction.

However, alcohol intake has not been found associated with ED in this study. This is because our participants who consume alcohol do so occasionally and in small amounts.

Alcohol in small amounts improves erection and increases libido because of its vasodilator effect and anxiety suppression. Notwithstanding, if taken, in large amounts and chronically, can

lead to sedation, reduced sexual drive, and transient ED. Chronic alcoholism can cause hypogonadism and polyneuropathy, which can affect penile nerve function[27].

Cigarette has nicotine which is a vasoconstrictor which reduces blood supply to the penile vasculature, thereby impacting negatively on erectile function.

The prevalence of ED among the male EVD survivors (Aged 15-49years) in this study was 54.5% and the degrees of ED was at 17%, 24.5%, 10.75% and 2.25% for mild, mild-to-moderate, moderate and severe ED, respectively.

The worldwide estimates of the prevalence of ED as assessed by the MMAS, the IIEF/IIEF-5 derived questionnaire and other questionnaires are comparatively close (15.5–69.2% and13.1–71.2%, 3-76.5% respectively) Europe has the highest prevalence of ED (10–76.5%), Asia 8–71.2%), Africa 24–58.9%), North America (20.7–57.8%), and South America has the least (14–55.2%)[28]. The differences in the estimates can be alluded to racial/ cultural differences, social and behavioural differences and hugely due to the different ED assessment tools used and the study design.

Our figures are also comparable with those obtained from a hospital-based prospective cross-sectional study in a rural population in Uganda which looked at the prevalence of ED and testosterone deficiency symptoms among 902men (among the general population including HIV+ patients)[23]. In the Uganda studies, the prevalence of ED was noted to be 47.8% [Mild ED =28.8%; Moderate ED=14%; Severe ED=5%]. When HIV+ patients (204) were excluded, ED was at 36.8%. [Mild ED =23%, Moderate ED = 10.2%, Severe ED = 3.6%]. The difference in the figures can be attributed to regional differences of culture and largely because the Ugandan study used the Aging Male Symptoms Scale to assess ED, whilst we used the IIEF-5. Also, the Ugandan study incorporated different (General population &HIV+) and older subjects than ours.

Comparable prevalence and patterns of ED are also found in the region. In Nigeria a hospital-based cross-sectional study which looked at the prevalence and correlates of ED among male attendees of a primary care clinic (450 participants aged 18-70 years)[29]. The prevalence of ED was at 55.1% of the 450 participants (mild, moderate and severe were 32.6%, 17.8% and 4.7% respectively). The difference in the pattern of the ED is partly due to the younger age of our study subjects and partly because our subjects are EVD survivors whilst those of the Nigeria study are older and among the general population.

The proportion of those who used intervention for their ED was 23% [medication/drug (phosphodiesterase type 5 inhibitors) use = 22.25%, sex therapy=0.75%] as opposed to the 28.5% who used no therapy at all. This is comparable with figures obtained from the Naples study[19] which reported the use of phosphodiesterase type 5 inhibitors by 21.3% of the subjects.

Study strength and limitation

Strength:

1. The first study to be undertaken, looking at ED in EVD survivors in the West African sub-region.
2. The study sites contain the largest concentration of EVD survivors in Sierra Leone.
3. The study took account of ED from the time of infection with the EVD to the time of assessment, five years down the line. This drives more towards an organic related cause or combined organic and psychologic causes like in viral illnesses (HIV, HBV and EVD).
4. The data was collected complete at the same place and time which prevented the risk of lost to follow up.

Limitation

1. All the laboratory tests conducted to rid the potential confounders were screening tests.
2. We might have missed genuine cases of ED by regarding early presentations of ED, who later recovered, as mere psychology. Because ED improves with time, we might have missed genuine organic causes of ED related to EVD, due to the long time it took, from the time of recovery of the survivors to the time of the start of this study.
3. The NPT test is obsolete. But we did not have the modern methods of testing (e.g. RigiScan) to reliably differentiate between the psychological and organic cause of ED. We only relied on the subjects telling us whether or not they had nocturnal penile erections.
4. There were limited resources to do routine lab tests to identify associated risk factors of ED or specific tests to establish the causality of ED in the survivors.

13.0 CONCLUSION

What is generally known about ED and also found in this study

Viral illnesses like HBV, HIV are associated with ED as is EVD. However, there are always several factors causing ED in an individual. Therefore, it is not uncommon to use a multidisciplinary approach to fix 100% of the problem.

Male ED is more common than presented. Because subjects with ED feel shy about sharing their condition.

Age, cigarette smoking and married status were also found to be risk factors for ED in this study and the likelihood of developing ED increased with Age, with those aged 40 years and above, at the highest risk. Age in Years and marital status significantly explained the Presence of ED

among the Men. With every increase in an additional year in age, the likelihood of developing ED increased by about 0.9 points (p-value<0.001). Compared to single men, married and cohabiting men significantly explained the ED (p-value 0.007 & 0.023) respectively.

What are the new findings in this study?

The duration of ED in these subjects has lingered on since 2014/2015, nearly six years down the line. Majority of those who suffer from ED used no therapy, followed by a few who use drug (sildenafil/Viagra) therapy for their ailment.

Low socioeconomic condition and non-formal education were not found associated with ED in this study.

EVD was found associated with ED and by a considerable prevalence of 54.5% of the 400 subjects assessed.

14.0 RECOMMENDATIONS

1. The causality is not established between EVD and ED in this study. But the latter can be a symptom of more severe cases of hypogonadism and therefore, screening for hypogonadism in these subjects with ED is essential.
2. Laboratory tests including sex hormone profile, Glucose-Lipid profile and early morning testosterone level would help identify any modifiable or reversible risk factors associated with the ED.
3. There is a need to conduct specific tests, say, imaging studies on penile vasculature (RigiScan, Duplex Doppler scan), neurologic studies and sex hormone profile to detect whether the pathologic pathway of their ED is vasculogenic, neurogenic or hormonal

respectively. This may be a further dig into the intricacies of the sequelae of EVD and will aid in improving the current quality of care and in the event of any future Ebola outbreak.

4. Because more of the EVD survivors that were studied had ED and were quiet about it, often-times prefer to suffer in silence, support to their reproductive health should be pleaded with the Government of Sierra Leone and her health partners, including psychotherapists and counsellors.
5. More management options of ED should be made available to those affected and be encouraged to use what best fit them.

15.0 STUDY TIMELINE AND BUDGET

15.1 **Table3. Showing Study Timeline**

Activity	Apr-Jun 2019	Jul-Sep 2019	Oct 2019-May 2020	Jun-Sept 2020	Sept-Nov 2020	Nov 2020	Dec 2020
Development of proposal							
Presentation &corrections							
Ethics							
Data collection							
Data analysis							
Presentation of results							
Submission							

15.2 Table4. Showing Study Budget

Sr. No	Description of Activity	Number of units	Unit cost in SLL	Total cost in SLL	Total cost in Ksh	Total cost in US Dollars
1.	Training of 15 field data collectors for 5 days (lunch and transport refund)	15	500,000	7,500,000	75,000	750
2.	Hall rental for the training for 5days	5	500,000	2,500,000	25,000	250
3.	Transport refund and DSA for 15 field data collectors in Freetown for 10 days	15	3,000,000	45,000,000	450,000	4,500
4.	Transport refund and Lunch to 430 participants	430	100,000	43,000,000	43,000	4,300
5.	Notepads, pens, flip charts, papers, for the meetings and the pieces of training	1	1,500,000	1,500,000	15,000	150
6.	Printing of 430 questionnaires + 430 consent forms	1	100,000	100,000	1,000	10
7.	Research Assistants	2	1,500,000	3,000,000	30,000	300
8.	Data entry clerks for 10 days	2	1,000,000	2,000,000	20,000	200
9.	Hepatitis B surface Antigen (HBsAg) testing for 430 participants	430	25,000	10,750,000	107,500	1,075
10.	Communication: internet connectivity and telephone calls (March through July 2020)	5	550,000 + 250,000= 800, 000	4,000,000	40,000	400
11.	Data analysis clerk for 10 days	10	400,000	4,000,000	40,000	400
12.	The Final compilation of data	1	1,500,000	1,500,000	15,000	150
13.	Random blood sugar testing for 430	430	10,000	4,300,000	43,000	430
	Total			**129,150,000**	**1,291,500**	**12,915**

NOTE: Total cost in SLL = 129,150,000
SLL= Sierra Leone Leones. Ksh= Kenyan Shillings

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17.0 ANNEXES

Annexe 17.1 Data collection summary form for export into SPSS software version 21

Name of Health Facility	
Year	
Month	
EVD Survivor Identification	1= ID Card 2= Discharge Certificate
Code of Participant (Survivor)	
Gender	1= Male 2= Female
Age (yrs.)	1= 15-19, 2= 20-24, 3= 25-29, 4= 30-34, 5= 35-39, 6= 40-44, 7= 45-49
Date of Ebola in the survivor	
Date of Ebola free state of the survivor	
Chronic infection/disease	1= Present, 2= Absent, 3= Unaware
Marital status	1= Single, 2= Married, 3= Cohabiting
Employment	1= Employed, 2= Unemployed, 3= Self-Employed
Monthly income	1= None, 2= Lower, 3= Middle, 4= Higher
Alcohol intake	1= Yes, 2=No
Alcohol intake (number of units per week)	1= < 21 units per week, 2 = ≥ 21 units per week, 3=Non-alcoholic
Smoking	1=Yes, 2=No
Smoking (number of pack-years)	1= <5 pk-yrs, 2= ≥5 pk-yrs, 3= Non-smoker
Educational standard	1=None, 2=Primary, 3=Secondary, 4=Tertiary
Date of ED in Survivor after EVD	1= ≤ 1yr after EVD, 2= after >1yr, 3= N/A
Presence of ED since surviving EVD	1=No, 2=Yes, 3=Recovered
Presence of Nocturnal Penile Erections	1=No, 2 =Yes

Characteristics of ED using the IIEF-5 scoring system	1=No ED, 2=Mild ED, 3=Mild–to-moderate ED, 4= Moderate ED, 5= Severe ED
Management interventions used with ED	1= Medication/drug, 2=Devices, 3= Sex therapy, 4= Behavioural/Psychosociotherapy, 5= Surgery, 6= Mixed/combined therapy, 6= No therapy
Had ED before contracting EVD	1= No 2= Yes

Annexe 17.2 Focused Clinical Examination

Blood pressure (mmHg)	1=<120/80, 2=120-139/80-89, 3=≥140/90
Pulse Rate (Normal=60-100bpm)	1=normal, 2= abnormal
Pulse Rhythm	1= regular, 2= irregular
Pulse volume	1= full volume, 2= weak
Pulse Character	1= normal= abnormal
Temperature (degrees Celsius)	1=<37, 2=37-37.9, 3= ≥38
Respiratory rate (Normal=12-18cpm)	1=normal, 2= abnormal
Body Mass Index (BMI) in kg/m^2	1= <18.5, 2= 18.5-25, 3= 25-30, 4= >30
Touch sensation	1= normal, 2= abnormal
Temperature sensation	1= normal, 2= abnormal
Pain sensation	1= normal, 2= abnormal
Penis (size, curvature/strictures, plaques, epi-/hypospadias	1= present and normal, 2= present but abnormal, 3= absent
Testicles (sizes, bilateral presence, symmetry, inflammatory changes consistency)	1= bilaterally present and normal, 2=bilaterally present but abnormal, 3=only one present and normal, 4= only one present but abnormal, 5= both absent
Epididymis (bilateral presence, enlarged, tender, cystic changes, indurations)	1= bilaterally present and normal, 2= bilaterally present but abnormal, 3= only one present and normal, 4= only one

	present but abnormal, 5= both absent
Vas deferens (bilateral presence, dysplastic changes, indurations, nodularity, inflammatory changes)	1= bilaterally present and normal, 2= bilaterally present but abnormal, 3=only one present and normal, 4= only one present but abnormal, 5=both absent
Spermatic cord (presence or absence of varicocele)	1= absent, 2= present

Annexe 17.3 International Index of Erectile Function (IIEF-5) Questionnaire
Participant's name/code…….

DOB/Age……

Address…….

Over the past four weeks	**SCORES**				
	1	**2**	**3**	**4**	**5**
What is your measure of **conviction** to achieve and maintain an erection?	Too low	Low	Average	High	Too High
When sexual arousal affected erections in you, **how frequent** were the erections strong enough to enhance penetration?	Seldom/not at all	< 50% of the time	Around 50% of the time	> 50% of the time	Nearly all the time/always
When mating, after you had penetrated your partner **how frequent** were you capable of maintaining your erections	Seldom/not at all	< 50% of the time	Around 50% of the time	> 50% of the time	Nearly all the time/always
When mating, **how hard** was it to keep your erection to reach the end of the intercourse?	Exceedingly strenuous	Very strenuous	Strenuous	Slightly strenuous	Not strenuous
After mating, **how**	Seldom/not	< 50% of	Around	>50% of	Nearly all the

frequent was it gratifying to you?	at all	the time	50% of the time	the time	time/always

Annexe 17.4 Boxes:

17.4.1 Box1. Case Definitions

Suspected case:

An acutely ill patient of fever ≥38.5°C within 21days coming down with vomiting and diarrhoea, associated with or without one or more of the following presentations: abdominal pains, haemorrhagic symptoms (epistaxis, hematemesis, melena, hemoptysis, or any other bleeding sites), general body weakness, myalgia, arthralgia, haemorrhagic or purpuric rash, conjunctival infections, and without any established triggering elements for the haemorrhagic presentations.

Probable case:

An individual satisfying the criteria for the suspected case definition and has come in touch with a suspected, probable or a confirmed case/death within the last 21 days of start of the symptoms of the disease; or an inexplicable death.

Confirmed case:

A suspected or probable case that is laboratory-confirmed by one or more of the undermentioned tests:

1. Evidence of Ebola antigen detection in body fluids and/or body tissue
2. ELISA or PCR confirmation of blood IgM or IgG antibodies
3. Immunohistochemistry
4. RT-PCR to detect Ebola nucleic acid

- Suspected and/or Probable cases are quarantined for a 21day period, managed at **Holding**

Centres (HC) or sent for laboratory confirmation of EVD.

- Laboratory confirmed cases were treated at the **Ebola Treatment Centres (ETC)**

17.4.2 Box2. The Sierra Leone Government Policies on Ebola survivors

1. **The National Ebola Recovery Strategy (ERS) – 2015**

This is the nuclear policy designed to direct the first 24 months of the Ebola recovery scheme following the end of the outbreak in November of 2015.

2. **Comprehensive Programme for Ebola Survivors (CPES) – 2015**

This is jointly designed by NGOs and the government to address the health, psychosocial and the welfare of the survivors

3. **Clinical Care for Survivors of EVD –2016**

This is a validated tool designed and customised by the WHO Survivors Clinical guide for Sierra Leone

3**The EVD survivors** were, therefore, those who carry a discharge certificate from the ETC; and were admitted into the survivors' programme on that basis, as a matter of the Sierra Leone Government's policy.

- **Undiagnosed EVD survivors**, who contracted EVD, suffered acute severe Ebola, but went through disease without being diagnosed or treated at an Ebola Treatment Centre (ETC), but were later confirmed to be Ebola antibody positive (IgG– IgM) by serological testing and who were not given any vaccine against Ebola virus, were also included.
- An implementation of the policies afforded free health care to all Ebola survivors carrying an authentic discharge card from an ETC, or an authentic undiagnosed EVD survivor card, at all Public Health Facilities in the country.

.

17.4.3 Box 3: The rejection criteria parameters at analysis for potential confounders

1. **Diabetes mellitus:**
   This study used the laboratory cut off point of ≥ 7.0 mmols/l of fasting blood sugar for the diagnosis of diabetes mellitus and/or a known history of Diabetes mellitus.

2. **Hepatitis B virus infection**
   This study used the reactivity of HBsAg from participant blood/serum for the presence of HBV infection without further laboratory tests.

3. **Hypertension**
   With a known history of hypertension/ CVD and/or a single blood pressure measurement of >160/100mmHg (>160/100 or systolic BP of >160mmHg or diastolic BP of >100mmHg) with symptoms, was regarded as the presence of stageII hypertension/CVD for this study. Those subjects were excluded at the analysis

4. **Body Mass Index (BMI)**
   A participant with a BMI of ≥ 30kg/m^2 was regarded as obese and was excluded.

5. **Neurological disorder**
   The loss of sensation of Touch, Temperature and Pain (TTP) was considered as the presence of neurological disorder in this study. All such participants were rejected during the analysis.

6. **Cigarette smoking**
   Pack-year means smoking 20 sticks (1packet) of cigarettes a day for one year. ≥5pk-yrs is heavy and chronic smoking. This quantification was done during data collection

7. **Alcohol intake**
   We asked specifically about the number of pints of higher-strength alcohol intake per week, irrespective of the age bracket (15-49yrs) for inclusion to this study. A pint (568ml) contains 3 units of alcohol. Intake of ≥21 units per week was regarded as heavy intake. But they were included.

8. **Participants who developed ED immediately after surviving EVD, but had occasional nocturnal penile erections, and/ or became symptom-free with time were considered psychological and not related to an organic cause by EVD. And by extension, were considered a transient ED that became ED-free.**

9. **The participants that developed ED more than one year after surviving EVD were regarded as caused by confounders. These were rejected at the time of the data analysis.**

Annexe 17.5 Data analysis (Dummy Tables)

17.5.1 Dummy Table1. Socio-demographic characteristics of Male EVD Survivors in Western Sierra Leone according to age group

Characteristics	Age groups							
Age Group	**15-19**	**20-24**	**25-29**	**30-34**	**35-39**	**40-44**	**45-49**	**Total**
Total Number								
Marital status								
Single								
Married								
Cohabiting								
Employment								
Employed								
Unemployed								
Self-Employed								
Level of Education								
None								
Primary								
Secondary								
Tertiary								
Monthly income								
Yes								
No								
Alcohol intake								
No								
Yes								
<21U/wk.								
≥21 U/wk.								
Smoking								
No								
Yes								
< 5 pk-yrs								
≥5 pk-yrs								

17.5.2 Dummy Table2. Socio-demographic characteristics of the Male EVD survivors in Western Sierra Leone, according to the presence of ED

Characteristics	With ED N= (%)	Without ED N= (%)	P-value
Age (mean±SD)			
Marital status			
Single			
Married			
Cohabiting			
Employment			
Employed			
Unemployed			
Self-Employed			
Educational Level			
None			
Primary			
Secondary			
Tertiary			
Monthly income			
Yes			
No			
Alcohol intake			
No			
Yes			
<21 U/wk.			
≥21 U/wk.			
Smoking			
No			
Yes			
< 5 pk-yrs			
≥5 pk-yrs			

17.5.3 Dummy Table3: The Prevalence of ED in male EVD survivors in Western Sierra Leone, according to age distribution.

Age group	With ED	Without ED	P-Value
15-19			
20-24			
25-29			
30-34			
35-39			
40-44			
45-49			
Total			

17.5.4 Dummy Table4: The Degree of ED in Male EVD survivors in Western Sierra Leone, according to age distribution (using the IIEF-5 scoring system)

Age group	Degree of ED				
	No ED	Mild ED	Mild-to-moderate ED	Moderate ED	Severe ED
15-19					
20-24					
25-29					
30-34					
35-39					
40-44					
45-49					
TOTAL					

17.5.5 Dummy Table5: The management interventions used with ED in Male EVD survivors in Western Sierra Leone

Age Groups	Medication only	Devices only	Sex Therapy only	Psychotherapy/Behavioral therapy only	Surgery only	Mixed Therapy	No therapy
15-19							
20-24							
25-29							
30-34							
35-39							
40-44							
45-49							
TOTAL							

Annexe 17.6. Consent Forms

UNIVERSITY OF NAIROBI

ADULT CONSENT FORM

Title of Study: ERECTILE DYSFUNCTION IN MALE EVD SURVIVORS, IN WESTERN SIERRA LEONE

Principal Investigator\and institutional affiliation: ABDUL HAMEED GAMANGA

Department of Obstetrics and Gynaecology, University of Nairobi, Kenya

Co-Investigators and institutional affiliation: NONE

Introduction:

Dr Abdul Hameed Gamanga is a post-graduate doctor in the Department of Obstetrics and Gynaecology, University of Nairobi.

Currently, he is doing a research study on the association of Ebola Virus Disease and Erectile Dysfunction in the male survivors, in all public health facilities in Western Sierra Leone that registered and cared for the EVD survivors.

You are invited as an Ebola survivor to participate in this study on your own accord. There are no punitive consequences in the event you resolve to pull out of the study at any stage.

You are requested to read this document thoroughly, at your own pace or entrust someone to interpret it to your fullest understanding.

The research study has the blessing of the Kenyatta National Hospital-University of Nairobi Ethics and Research Committee and the Sierra Leone Ethics and Research Committee. It bears the Protocol No. P942/11/2019

It’s my pleasure if you allow me to proceed… YES / NO

The motive of the Study

The study aims at establishing a linear relationship between Ebola Virus Disease and male Erectile Dysfunction.

Approach

If you accept to take part in the study, you will be requested to append your signature/thumbprint as evidence of your free will to participate. A copy of the completed form will be made and given to you for safe-keeping.

Next, you will be required to complete a questionnaire that will be given to you. Any of us, (the research team members) will be present, in case you want clarification on any issue/s that will be unclear to you. The questionnaire contains enquiry on your sexual performance before you became infected with the EVD compared to your performance after you survived. Also, your genitalia will be examined to exclude any problem related to the study.

You have the onus to decline to answer any question/s that may seem embarrassing to you and the right to decline the clinical examination.

Potential risks

Except for the apparent loss of privacy during clinical examination, we do not anticipate any risks in this study.

Potential benefits

If the study shows that you suffer erectile dysfunction, depending on the severity of the problem, a precise plan can be adopted to add to or modify your management. Besides, the info you give us may aid us to understand better, the prevalence, the degree of, and the types of interventions used to reverse or manage Erectile Dysfunction. This information may unearth an untold story of you, the survivors.

Costs

You will incur no cost by your participation in this study. You will be requested to sacrifice your time to participate in the study. No compensation is given to you by your participation.

Confidentiality

We guarantee that the information you give will be very confidential. Your names will not be used after consenting, but you will be assigned a unique identification number. The information you give will remain safe with us. Only the research team, will be privy to the info. On the conclusion of the research, the information is analysed and the result shared only to the relevant parties.

Part B: Consent

I have fully understood the info as outlined above. I am well informed about the study and have had the privilege to pose questions and content with the answers provided. I have agreed to per take of this study voluntarily, devoid of any coercion/manipulation or bribe in any way.

Appending my signature to this consent form does not deprive me of the legitimate rights that behoves me as a participant in research.

I consent that I will be examined clinically.

I accept giving my contact details in case of any check-back or continuation:

Participant's

Full name…….Signature/……Date……...

and OR Thump print……. Date……

Witness's name.....Signature…… Date…….

Statement by Researcher

I have fully informed the participant about the study. The participant has been given the free will to pose questions relevant to the study, and I have provided adequate answers to the best of my abilities.

I attest that the participant has given consent voluntarily.

Researcher's Name Signature Date

Contact for correspondence

1. Dr Abdul Hameed Gamanga

   Principal Investigator

   Cell phone number: **+254743300367, +23276288700**

   E-mail address: hameedgamanga@gmail.com

2. Secretary, KNH-UoN ERC

   P.O. Box 19679-00202

   Telephone (254-020) 2726300-9)

   E-mail address: uonknherc@uonbi.ac.ke

UNIVERSITY OF NAIROBI (UoN)

STUDIES INVOLVING CHILDREN

MINOR Assent Form (15-17years)

Project Title: **Erectile dysfunction in male EVD survivors in Western Sierra Leone.**

A Health Facility Based Descriptive Cross-Sectional study

Principal Investigator: **Dr Abdul Hameed Gamanga**

We are doing a research study about (***The prevalence, characteristics and intervention use of Erectile Dysfunction in male Ebola survivors in Western Sierra Leone)***.

Authorisation to undertake the study has been given by the KNH-UoN ERC with Protocol No. P942/11/2019.

The study is a means of learning things about people.

Male Ebola survivors aged 18-49years will be participating alongside you in this research.

Once you agree willingly, to per take of this study, you will be required to complete a questionnaire on your sexual performance after surviving the outbreak.

You will be clinically examined at the genital region with your kind permission and you will be screened for Diabetes Mellitus (DM), HIV and Hepatitis B**.** The results will be confidential.

The entire study is strictly private and confidential.

If we detect that you have erectile dysfunction, depending on the severity of the condition, we can recommend a trial of medical therapy, refer you for further evaluation and management and/or for counselling.

If we detect any incidental clinical conditions, not related to this study, we can refer you to the appropriate specialities for further evaluation and care.

When we complete this study, a report on the findings will be written. The report will not indicate your name and/or your participation.

Your participation in this study will be wholly and solely your wish. You have the right to abandon the study at any stage. Your parents/guardian are well informed about the study too.

If you willingly decide to per take in this study, you are kindly required to indicate your name hereunder.

I, _____, wish to per take of this research.

_____ _____

(Signature/Thumbprint) (Date)

GOVERNMENT OF SIERRA LEONE
Office of the Sierra Leone Ethics and Scientific Review Committee
Directorate of Training and Research
5th Floor, Youyi Building Brookfields, Freetown
Ministry of Health and Sanitation

10th December, 2019

To: **Dr. Abdul H. Gamanga** (MMed Student) **Principal Investigator**
Department of Obstetrics and Gynaecology
University of Nairobi, Kenya
hameedgamanga@gmail.com

Study Title: **Erectile Dysfunction in Male Ebola Virus Disease Survivors in Freetown, Sierra Leone: A Descriptive Cross-Sectional Study**

Version: November 2019

Supervisor: **Assistant Professor Zahida Qureshi**
Department of Obstetrics and Gynaecology
University of Nairobi, Kenya

Data Sources:

- 34 Military Hospital, Wilberforce
- Public Health Facilities which registered and cared for Ebola Victims
- WHO Ebola survivors register in Freetown

Collaborative Partnerships:

- MoHS, SL
- University of Nairobi

Submission Type: First protocol version submitted for review

Committee Action: Expedited Review

Approval Date: 10 December, 2019

GOVERNMENT OF SIERRA LEONE
Office of the Sierra Leone Ethics and Scientific Review Committee
Directorate of Training and Research
5th Floor, Youyi Building Brookfields, Freetown
Ministry of Health and Sanitation

The Sierra Leone Ethics and Scientific Review Committee (SLESRC) having conducted an expedited review of the above study protocol and determined that it presents minimal risk to subjects, **hereby grants ethical and scientific approval for it to be conducted in Sierra Leone.** The approval is valid for the period, **10 December, 2019 – 09 December, 2020.** It is your responsibility to obtain re-approval/extension for any on-going research prior to its expiration date. The request for re-approval/extension must be supported by a progress report.

Review Comments:

- **Amendments:** Intended changes to the approved protocol such as the informed consent documents, study design, recruitment of participants and key study personnel, must be submitted for approval by the SLESRC prior to implementation.

- **Termination of the study:** When study procedures and data analyses are fully complete, please inform the SLESRC that you are terminating the study and submit a brief report covering the protocol activities. Individual identifying information should be destroyed unless there is sufficient justification to retain, approved by the SLESRC. All findings should be based on de-identified aggregate data and all published results in aggregate or group form. A copy of any publication be submitted to the SLESRC for its archive.

- ***Information for Enrolment (Consent/Assent: Annexe 12.6): Add a paragraph subtitled contact if you have a complaint about how the study is being conducted: call the Sierra Leone Ethics Committee on 076629251 or 078366493***

Professor Hector G. Morgan
Chair

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Ref: KNH-ERC/A/215

10th July 2020

Dr.Abdul Hameed Gamanga
Reg. No. H58/10674/2018
Dept.of Obstetrics and Gynecology
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Gamanga

RESEARCH PROPOSAL – ERECTILE DYSFUNCTION IN MALE EBOLA VIRUS DISEASE(EVD) SURVIVORS IN FREETOWN, SIERRA LEONE (DESCRIPTIVE CROSS-SECTIONAL STUDY) (P942/11/2019)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 10th July 2020 – 9th July 2021.

This approval is subject to compliance with the following requirements:

a. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
c. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
g. Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website**http://www.erc.uonbi.ac.ke**

Yours sincerely,

PROF. M. L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine, UoN
The Chair, Dept. of Obstetrics and Gynaecology, UoN
Supervisors: Prof.Zahida Qureshi, Dept. of Obstetrics and Gynaecology, UON
Dr.Alfred M. Mokomba, Dept.of Reproductive Health,KNH
Dr.George Gwako, Dept.of Obstetrics and Gynaecology, UoN