Assessment of A Diabetes Symptom Screening Checklist and Associated Factors of Impaired Fasting Glucose among ART Patients on Copperbelt Province

BY

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MSc Epidemiology (51)

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DECLARATION

I **Perfect Shankalala** declare that this dissertation submitted hereby for the Degree of Masters of Public Health (Msc. Epidemiology) is my own work and has not been submitted either wholly or in part to for another degree to this or any other University or Institution of higher education.

Protocol Reference No. 00005948

Ethics Committee Approval Date. 08/09/2015

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CERTIFICATE OF APPROAL

The university of Zambia approves this dissertation by PERFECT SHANKALALA in partial fulfilment of the requirements of a master of science in epidemiology by the university of Zambia.

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Date

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Examiners

Name	Signature	Date
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2…..……	……	…….
3…..……	……	…….

DEDICATED TO

My wife: *Mwangala Mashewani Shankalala*

My daughters: *Namuunza & Kampakatwa Shankalala*

My parents: *Webby &Mervis Shankalala*

MY brothers: *(Timothy, Webby Jnr. and Kaitano)*

And

My sisters: *(Bethsheba, Nachongo and Faith)*

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ACRONYMS

ART	Antiretroviral Treatment
AIDS	Acquired Immunodeficiency Syndrome
CART	Combined Antiretroviral Treatment
BMI	Body Mass Index
CD4	Cluster Differentiation
DM	Diabetes Mellitus
HCW	Health Care Workers
HIV	Human Immunodeficiency Virus
HAART	Highly Active Antiretroviral therapy
IFG	Impaired Fasting Glucose
IDF	International Diabetes Federation
NNRTIs	Non-Nucleoside Reverse Transcriptase Inhibitors
NRTIs	Nucleoside Reverse Transcriptase Inhibitors
NCDs	Non-Communicable Diseases
PIs	Protease Inhibitors
PMTCT	Prevention of Mother to Child Transmission
PLWHA	People Living With HIV AIDS
SSA	Sub Saharan Africa
WHO	World Health Organization
ZDHS	Zambia Demographic and Health Survey
ZPCT II	Zambia Prevention and care treatment project

ABSTRACT

Background: There has been some evidence that because of life saving combination Antiretroviral therapy (cART), people living with HIV are living longer and it is apparent that they are at an increased risk of developing non communicable diseases (NCD) including diabetes mellitus. Despite this recognition, not much effort has been directed to introduce interventions that would mitigate this scenario. The main objective of this study was to assess the validity of the diabetes symptoms screening checklist and associated factors of impaired fasting glucose among adult ART patients.

Methods: This was a quantitative cross sectional study which employed systematic random sampling procedure on cART patients who had been in care for at least 2 years, aged 18 years and above in five selected health facilities of Copperbelt province from October to December 2015.Data was extracted using the diabetes symptoms screening checklist and a separate data collection form for records from patient files as secondary data. STATA version 14 was used to determine descriptive statistics in form of frequencies of social demographics and clinical characteristics of the study sample. Multivariate logistic regression was used to identify the best predictors of impaired fasting blood sugar.Sensitivity, Specificity,Positive Predictive Value and Negative Predictive Values were also calculated.

Results: Out of 272 ART patients who were screened for diabetes using the Chronic HIV Care Checklist, 80% had at least one symptom of diabetes mellitus. Among these, 43%, (95% CI: 37%-49%) had impaired random blood sugarand 15.3 % (95% CI: 11%- 20%) % had impaired fasting blood sugar greater than 6.1mmol/l. This study found sensitivity (80%), specificity (20.4%), Positive Predictive Value (18.2%), Negative Predictive Value (84.9%) and ROC value (0.75) for the Diabetes checklist. Among the factors found to be associated to Impaired fasting blood sugar were, Body Mass Index >30 (AOR 2.2, 95% CI: 1.7-7.8) , Baseline weight (AOR 1.07 95% CI: 1.01-1.13), Number of symptoms >3 ticked on the diabetes checklist (AOR 6.5 95% CI: 1.4-29.9%) and Age >45 (AOR 2.7 95% CI: 1.14-3.34)

Conclusion: The results of this study suggests an increase in the magnitude of ART patients with impaired fasting glucose compared to what is reported in the general population, suggesting a high prevalence of diabetes among this population. The diabetes symptoms screening checklist was effective in correct classification of ART patients who had impaired fasting glucose from those who had normal fasting glucose levels and therefore should be used within ART settings. Being 45 years and above, having at least 3 symptoms of diabetes and also having a body mass index greater or equal to 30 are important factors associated with impaired fasting glucose. In view of this glycaemic makers and risk reduction strategies especially for obese and aging ART patients is highlighted. Therefore, there is need for integrated care for HIV/AIDS and diabetes mellitus within ART platforms because of high proportion of ART patients being symptomatic of diabetes mellitus as evidenced in this study.

CHAPTER ONE

1.0 Background

1.1 The Burden of Diabetes Mellitus

Diabetes mellitus is a chronic condition affecting approximately 285 million people in the world and the figure is expected to rise by more than 50% in the next twenty years (Novato and Gross,2009). It has been estimated that more than 44 million adults in the US have impaired fasting blood glucose (IFG) and the numbers will likely continue to increase as a consequence of the ongoing obesity epidemic (Yeboah et al., 2011). Individuals with IFG (pre-diabetes) are at an increased risk of developing type 2 diabetes mellitus which is a risk factor for cardiovascular disease compared with subjects with normal fasting glucose. Diabetes remains one of the leading causes of adult mortality in the world and is among the top 10 leading causes of disability adjusted life years (Daly) losses globally.

The strong advocacy for managing non communicable diseases (NCD) appropriately, many of which are life-long, and the more general focus on health systems strengthening has catalysed attention for chronic care (Alliance, 2013). Despite this recognition, less efforts have been directed to screening programs aimed at detecting various NCDS that have a potential to complicate ART outcomes. In view of this many ART patients have experienced increase in morbidity and mortality from diabetes mellitus. A survey done in 2005 in Cambodia among HIV positive patients who were on ART estimated that between 5% and 11% of all adults had type II diabetes and the prevalence of impaired glucose intolerance was between 10% and 15% (World Health Organisation, 2012).These results are consistent with growing evidence that diabetes and other non-communicable diseases represent a significant and growing part of the disease burden in low-income countries.

Studies conducted in some sections of Zambia indicates that there is a growing burden of diabetes mellitus among the general population with minimal disparities in the prevalence between urban and rural areas, however it is not certain that this could be the same among ART patient. A study conducted in Kaoma and Kasama rural districts of Zambia by Siziya et al (2014), revealed that Overall, 4.1% of the participants in Kaoma and 1.8% of the participants in Kasama (p=0.004) had impaired fasting glucose level/diabetes, with no

significant differences between sex in both districts. Respondents who were aged less than 45 years were less likely to have impaired glucose level/diabetes compared to those who were aged 45 years or older (OR=0.56, 95% CI (0.39, 0.81) in Kaoma and OR=0.55, 95% CI (0.33, 0.89) in Kasama).

Although this study was able to estimate the prevalence of diabetes mellitus in the general population, it is not clear whether such estimates could explain the situation among ART patients and also the prevalence of impaired fasting glucose in these studies may have been underestimated because impaired fasting glucose test was not conducted.

1.2 Associated Factors of Impaired Fasting Glucose among ART Patients

The increasing realisation of antiretroviral therapy (ART) in controlling HIV replication and restoring immunity has been hardened by the recognition that metabolic diseases, such as diabetes mellitus (DM), are increasing in incidence among people living with HIV. Studies from high-income countries have reported that the incidence of diabetes in HIV-infected adults receiving ART to be between 1% and 10% (Yoon et al., 2004).

Prospective studies however, have reported that 10% of HIV patients treated with HAART developed diabetes during 4 years of follow-up, compared with 3% in HIV-seronegative men (Brown et al., 2005). These results show that there is a 4-fold increase in relative risk of developing diabetes after adjusting for age and body mass index. Other studies also have shown a 25% to 50% reduction in measures of insulin secretion and b-cell function after 12 weeks of protease inhibitor added to pre-existing NRTI or commenced in addition to NRTI (Woerle et al., 2003).

Recent studies in Botswana by (Moyo. D et al 2014), revealed that HIV infected adults on ART were 12.7 times more likely to have diabetes mellitus. These findings suggest a complex interrelation among host factors and treatment related metabolic changes in the prognosis of diabetes mellitus in patients receiving antiretroviral treatment.A study done by(Diouf et al., 2012) in Senegal showed that out of a sample of 284 HIV positive patients who were on HAART, 14.5% were found to be diabetic and factors such as long duration

of ART (≥119 months), older age, higher body mass index (BMI), and higher levels of total cholesterol were associated with higher risks of diabetes. Traditional risk factors, such as obesity, ageing and male sex, are important determinants of diabetes (Capeau et al., 2012). However, specific antiretroviral (ARVs) and ARV-related weight gain and lipodystrophy are recognised risk factors.

In recent times, work and living have become more sedentary and diets have shifted to foods high in fats and sugars increasing the risk for Diabetes. Physical inactivity increases the risk of many chronic diseases, such as type 2 diabetes (Dunstan et al, 2007). Data shows that there is an increase in obesity in developing countries with more than 30% of the populations in Latin America, the Caribbean, the Middle East and northern Africa being obese (Delpeuch and Maire, 1996). However, it is not clear whether the observed increase in obesity among ART patients could be attributed to sedentary life style or it could be as a result of ART complications. It can thus be argued that metabolic syndrome which is a group of disorders that include obesity, insulin resistance, glucose intolerance, abnormal lipids and hypertension has been associated with reduced physical activities (Gao et al., 2007).

High pre-ART viral loads and low baseline CD4 counts may also increase the risk of insulin resistance and accelerate the pathogenesis of diabetes (Capeau et al., 2012). The association between HIV infection and/or treatment of HIV and Diabetes Mellitus in Sub-Saharan Africa (SSA) has not been well documented. While diabetes incidence is increasing in the general population in southern Africa, it is not known whether the same is the case in people living with HIV or whether the determinants of diabetes are also on the increase among HIV-infected adults in this region.

1.3 Guidelines for Screening of Diabetes Mellitus

Screening for diabetes plays a significant role in HIV/AIDS management because it identifies individuals with intermediate hyperglycaemia (impaired fasting glucose) who may benefit from interventions to prevent or delay progression to diabetes, and to prevent cardiovascular disease (CVD) and other complications.There are several options for

strategies to screen for undiagnosed diabetes. The ultimate choice is based on available resources and a trade-off between sensitivity and specificity and the proportion of the population with a positive screening test which needs to proceed to diagnostic testing (International Dibetes Federation, 2012).

Combined screening strategies have sensitivity and specificity in the order of 75% and 25% of the population require diagnostic testing. People who screen negative should be re-tested after 3-5 years(International Diabetes Federation, 2012). These people should also be offered lifestyle advice to minimise their risk of developing diabetes. Screening for diabetes mellitus has important implications for individual health, day-to-day clinical practice, and public health policy, however there is currently no direct evidence as to whether or not this is beneficial to individuals. Despite this lack of direct evidence, early detection through screening is taking place and is recommended by a number of organisations throughout the world. A study done by (Group, 2002), study found that to predict drug-treated diabetes, the score value >9 had sensitivity of 0.78, specificity of 0.77 and positive predictive value of 0.13 in the 1987 cohorts, and the area under ROC curve was 0.85 suggesting that these finding could not have happened through chance findings (Lindström and Tuomilehto, 2003)

In response to the above challenges of diabetes mellitus in HIV AIDS management, Family Health International Zambia (FHI 360)/ Zambia Prevention and Care Treatment project (ZPCTII) piloted a Chronic HIV screening checklist which looks at various chronic conditions affecting HIV patients. The Chronic HIV/AIDS Care checklist(CHC) comprises screening and/or key take home messages for several conditions. This checklist is meant for **Chronic HIV Care** (CHC) so as to show evidence of clients receiving services or screening for 6 different conditions namely; **Diabetes Mellitus** symptom checklist, **Nutrition Assessment using Body Mass Index (BMI), Gender Based Violence (GBV)** checklist, **Hypertension** symptom checklist, **Tuberculosis** symptom checklist and **Prevention with positives (PWP)** checklist. It is administered by frontline health care workers (professional or volunteers) according to the instructions as provided under its

section A and B for each eligible client(s) or patient(s) in the clinic. It is used in Prevention of Mother to Child Transmission (PMTC) and ART clinical service areas.

However, this study only concentrated on the diabetes symptom screening checklist. This checklist is designed to detect diabetes symptomatic HIV patients by asking necessary questions which helps to determine if the patients have either increased frequent urination, increased thirsty, increased water (fluid) intake, increased tendency to fell hungry, increased tendency to eat a lot, or if patients have a worsening sight. Despite being in operation since 2011, nothing is known yet on how sensitive this screening tool is in detecting symptomatic ART patients. Against this background, the main objective of this study was to validate the diabetes symptoms screening checklist and determine associated factors of impaired fasting glucose among adult ART patients on the Copperbelt province of Zambia.

CHAPTER TWO

2.0 Research Focus

2.1 Rationale for the study

Screening interventions for diabetes mellitus within ART platforms need continuous monitoring and evaluation in order to determine their scientific validity and avoid misclassification of patients. In Zambia, Family Health International (FHI360), developed a diabetes symptoms screening checklist which has been implemented since 2011, however no published studies have been done to determine its operational usefulness. There has been some evidence that because of life saving combination Antiretroviral therapy, people living with HIV are living longer and it is apparent that they are at an increased risk of developing non communicable diseases (NCD) including diabetes mellitus, if unchecked, this may complicate clinical management and ART outcomes. This study aimed at validating the screening check list for diabetes mellitus and the associated factors of impaired fasting blood sugar among ART patients.

The findings in this study have helped to validate the diabetes symptoms screening checklist and also identified factors associated to impaired fasting blood sugar among adult ART patients. The results from this study also identified areas of ART care services that need improvement and thus influencing public health policy for integrated care for HIV/AIDS and diabetes mellitus within ART platforms. This study will also advocate for screening and testing of diabetes mellitus at baseline of HIV testing in order to have an early diagnosis which will enhance proper follow up care and treatment and also suggested programmes to improve care and control of this condition.

2.2 Research Questions

1. What is the validity of the diabetic symptomatic screening checklist?
2. What is the proportion of ART patients found with impaired random and fasting blood sugar level?

2.3 General Objective

To determine the validity of the diabetes symptomatic screening checklist and proportion of patients found with impaired fasting blood glucose level

2.4 Specific Objectives

1. To establish the proportion of ART patients found symptomatic using Diabetic symptom screening checklist
2. To determine the proportion of ART patients found with abnormally raised blood glucose after both
   a) A random blood sugar test and
   b) Fasting blood sugar test
3. To determine social-demographic and associated factors of Impaired Glucose Fasting among ART patients.
4. To determine the validity of a Diabetic symptom screening checklist developed by FHI360/Zambia to help diagnose Diabetes Mellitus among ART (Sensitivity, Specificity, PPV, NPV)

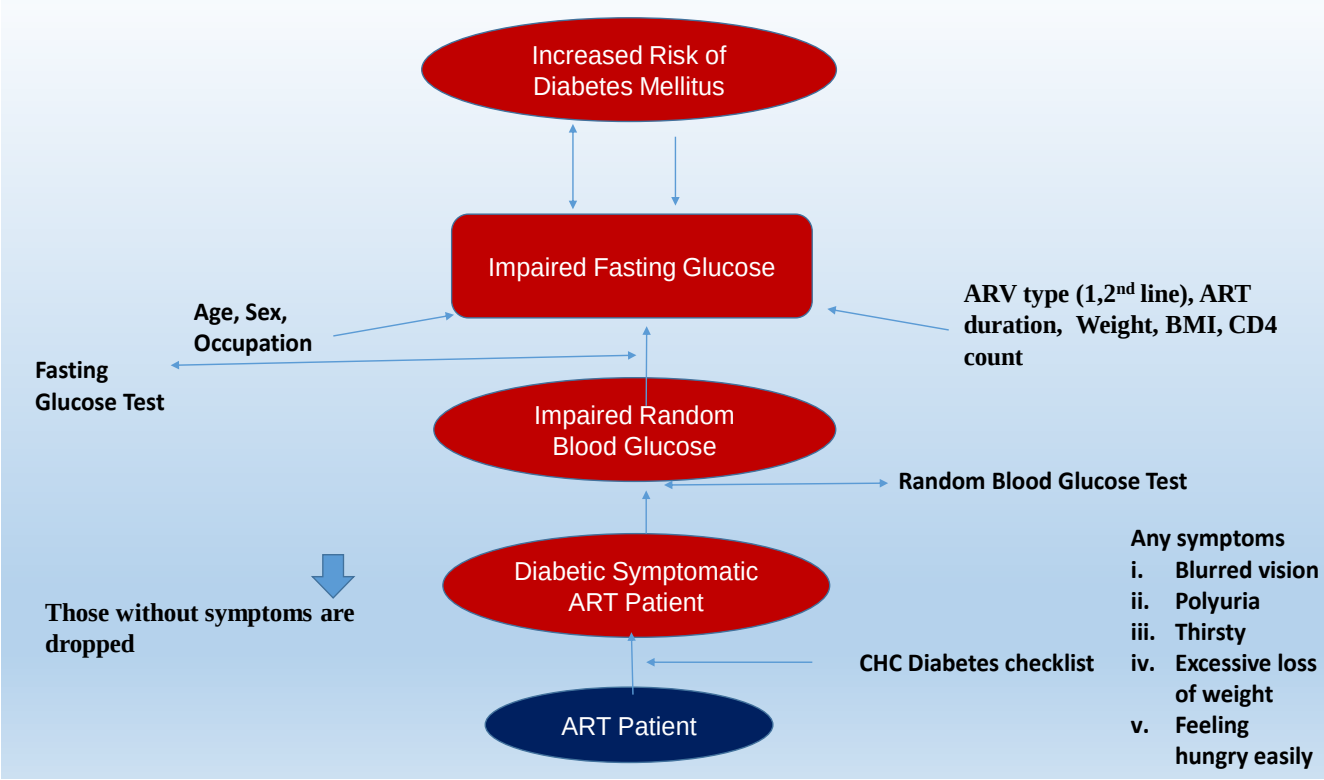


Figure 1: Conceptual framework for evaluating IFG in ART patients

Source: Self-developed

Figure 1 portrays a conceptual framework that showed how impaired fasting blood sugar was evaluated in this study. Firstly all ART patients that meet the inclusion criteria were subjected to a diabetes symptom screening checklist and consequently underwent a simple random blood sugar test to determine those with elevated blood glucose levels (>5.6 mmol/l and <11.1 mmol/l) (IDF 2012). After 10 hours of fasting, glucometer readings were taken to determine ART patients with impaired fasting blood sugar levels.

CHAPTER THREE

3.0 Methods

3.1 Study Setting

This study was conducted at 5 ART sites on the Copperbelt province of Zambia mainly because Copperbelt has one of the highest prevalence of HIV/AIDS of about 18% (ZDHS 2013-2014). The sites chosen were Twapia Health Center in Ndola, ChawamaClnic in Chingola, Nchanga North General hospital in Chingola, Ndola Central Hospital in Ndola and Thompson District Healthin Luanshya. We conveniently chose these study sites because this is where glucometers were placed for checking random blood sugar levels after using the Chronic HIV Care screening Checklist for symptomatic diabetes mellitus. The chosen study sites gave sufficient numbers required for the study to be completed within the study period.

3.2 Study Design

This was a cross sectional study of selected health facilities of Copperbelt provinces of Zambia on the number of HIV patients on ART aged 18 years and above from October to December 2015.A cross sectional study was most appropriate for reasons of economy of time, noting that the researcher intended to explore issues that are unknown in the settings, withstanding the fact that the design severely limited researcher's ability to address developmental issues or offer causal interpretations.

3.3 Study Population

This study recruitedall HIV positive patients who have been on ART for more than two years aged between 18 years and above attending the named health facilities above. All the 5 ART centres chosen were high volume centres and serve geographically and socially discrete catchment populations.

3.4 Eligibility Criteria of the Study

The inclusion criteria consisted of all HIV/AIDS patients who were on ART for more than 2 years, aged 18 and above. This study excluded Patients with primary Diabetes mellitus currently on Diabetes treatment and ART patients who didn't consent to the study protocol.

3.5 Sample Size Estimation

A sample size of **272** adult subjects aged between 18 years and above was considered adequate to determine the proportion of impaired fasting glucose and related associated factors in these individuals. We used the sample size calculation formula which is suitable for cross-sectional studies using prevalence of health disorders in previous prevalence studies (Shen et al, 2013). In sample size calculation, the precision was at 5%, with 80% power. The Diabetes Mellitus prevalence in HIV-AIDS patients on ART aged 18 years and above in Africa is estimated to between 2% to 14%, with confidence level set at 95% giving Z the value of 1.96

A total sample size of at least **233** was reached using this sample size calculation formula**:**

$n = (z/\Delta)^2 \, p \, (1-p)$

$Z = 1.96$

$\Delta = 0.05$

$P = 0.14$ Therefore $n = (1.96/0.05)^2 \, 0.14 \, (1-0.14)$

$= 1536.64 \times 0.12$

$=$ **186**

At 80% 186/0.80 Sample size will be **233**

The minimum sample size required was **233**, but we managed to enrol **272** study participants.

3.6 Sampling Procedure

This study conveniently sampled 5 health facilities on the Copperbelt province. We chose 5 health facilities because this is where the Chronic HIV Care screening Checklist for symptomatic diabetes and glucometers were placed for checking random glucose levels. A proportional sampling process was carried out in order to determine the number of participants to be sampled at each health facility. Through the use of sampling frames which were created at each health facility, participants who met the inclusion criteria were selected using systematic random sampling procedure.

Table 1: Sample size allocation

The sampling interval was derived for each health facility from the formula as follows:

$$k = \frac{N}{n}$$

Where k = sampling interval,

n = sample size

N = population size

Copperbelt Province	**Population**	**Sample (Sampling Interval)**
Ndola Central Hospital	11000	71 (every 5th ART patients)
Tompson General Hospital	8300	53 (every 7th ART patients)
Nchanga North General Hospital	9320	60 (Every 6th ART patients)
Twapia Health Centre	4000	26 (Every 14th ART patients)
Chawama Health Centre	3600	23 (Every 15th ART patient)
Total	**36220**	**233**

3.7 Data Collection

Five employees of FHI360 who are stationed at the ART centres were used as research assistants for data collection. These were chosen because they have had previous experience in collecting routine and research data for FHI360 and were well familiar with the patient records and files. This study used both primary and secondary data. Demographic data was collected using a data collection form attached at appendices 5.0. This allowed non-medical data to be considered during the analysis. The following demographic data were collected; age, sex and marital status. Past medical history was taken to identify if the patient had a history of Diabetes mellitus in their family. Clinical characteristics such ART types, CD4 count, BMI, ART initiation date were extracted from the patients ART records. Random glucose levels and fasting blood sugar levels were obtained using glucometers and were extracted from the diabetes symptoms screening checklist. This checklist was designed to detect diabetes symptomatic HIV patients by asking necessary questions which helps to determine if the patients have either increased frequent urination (1), increased thirsty (2), increased water (fluid) intake (3), increased tendency to fell hungry (4), increased tendency to eat a lot (5), or if patients have a worsening sight (6). Patients who presented at least one symptom stated above were classified as being symptomatic of diabetes while those without any of these symptoms were classified as asymptomatic

3.8 Data Management

After collection of data variables from patients ART records as well as patients screening checklist and files by Data entry clerks, the raw data was checked for accuracy and completeness by their immediate supervisors and entered into Microsoft access database with inbuilt quality checks and which was password protected. This was then forwarded to the Principle Investigator centrally in Lusaka for merging and verification of completeness including linking service statistics and number of records submitted.Data was kept under password protected computers and accessibility was restricted to the senior data manager and principle investigator only.

3.9 Data Analysis Plan

After checking for completeness and accuracy, data was entered into Microsoft access database and then exported to STATA version 14.0 for analysis. The analysis included running cross-tabulations and descriptive statistics. The main statistical analysis consisted of univariate and multivariate logistic regression to identify the best predictors of impaired fasting blood sugar.Normality assumptions for continuous variables werechecked using the Q-Q plot. For normally distributed continuous variable, the means and their respective standard deviations were reported and for variables that were not normally distributed, the descriptive statistics for continuous variables included median and inter quartile range. To test for any differences in the median proportions of continuous predictors, a non-parametric Wilcoxon rank sum (Mann–Whitney) was used. A chi-squared test was used to examine the independent categorical variables with the outcome variable after meeting the expectedassumptions. An investigator led step wise variable selection method in multivariate logistic regression was used to determine independent predictors for Impaired Fasting Glucose (IFG). Adjusted odds ratios (AOR) and their 95%CI were presented. To determine the validity of the checklist, Sensitivity, Specificity, PPV, NPV and ROC curve were calculated using a dummy table

3.10 Ethical Considerations

ERES ethics committee approved the protocol (I.R.B No. 00005948), after having demonstrated respect for participant's right to self-determination, privacy, anonymity, confidentiality, and protection from harm and discomfort. In view of this, the study participants gave consent for participation. The testing for impaired fasting blood sugar complied with the WHO guidelines for diagnosis of diabetes mellitus. Permission was also granted by the Ministry of Health to conduct this study at the 5 ART sites which fall under the ministry.

CHAPTER FOUR

4.0 Results

A total of 270 ART patients from five selected health facilities on the Copperbelt province were investigated in order to assess the validity of the diabetes symptoms screening checklist and associated factors of impaired fasting glucose. The socio-demographic and clinical characteristics of the participants are summarized as descriptive statistics in table 4.1 and table 4.2, respectively, while table 4.3 shows predictors of impaired fasting glucose. These are presented as follows:

Table 2: Socio-demographic and Clinical Characteristics of ART Patient for Impaired Fasting Glucose (n=272)

Characteristic		Frequency	Percentages
Sex	Male	84	(31.1%)
	Female	186	(68.9%)
Age (years)	20-35	44	(16.2%)
	35-45	137	(50.4%)
	>45	91	(33.5%)
Marital Status	Married	183	(67.5%)
	Single	26	(9.6%)
	Divorced	23	(8.5%)
	Widowed	39	(14.4%)
Smoking Status			
	Smoker	13	(4.9%)
	Non-smokers	255	(95.2%)
ART Regimen			
	1st line ART	252	(92.7%)
	2nd line ART	20	(7.3%)
Screening checklist for Diabetes			
	Asymptomatic	53	(20%)
	Symptomatic	209	(80%)
Random Blood Sugar levels			
	Normal (< 6.0 mmol/l)	112	(42.9%)
	Impaired (>6.0 mmol/l)	149	(57.1%)
Fasting Blood Sugar levels			
	Normal (< 6.0 mmol/l)	221	(84.7%)
	Impaired (>6.0 mmol/l< 7.1mmol/l)	40	(15.3%)

Note: total sample (n) = 272

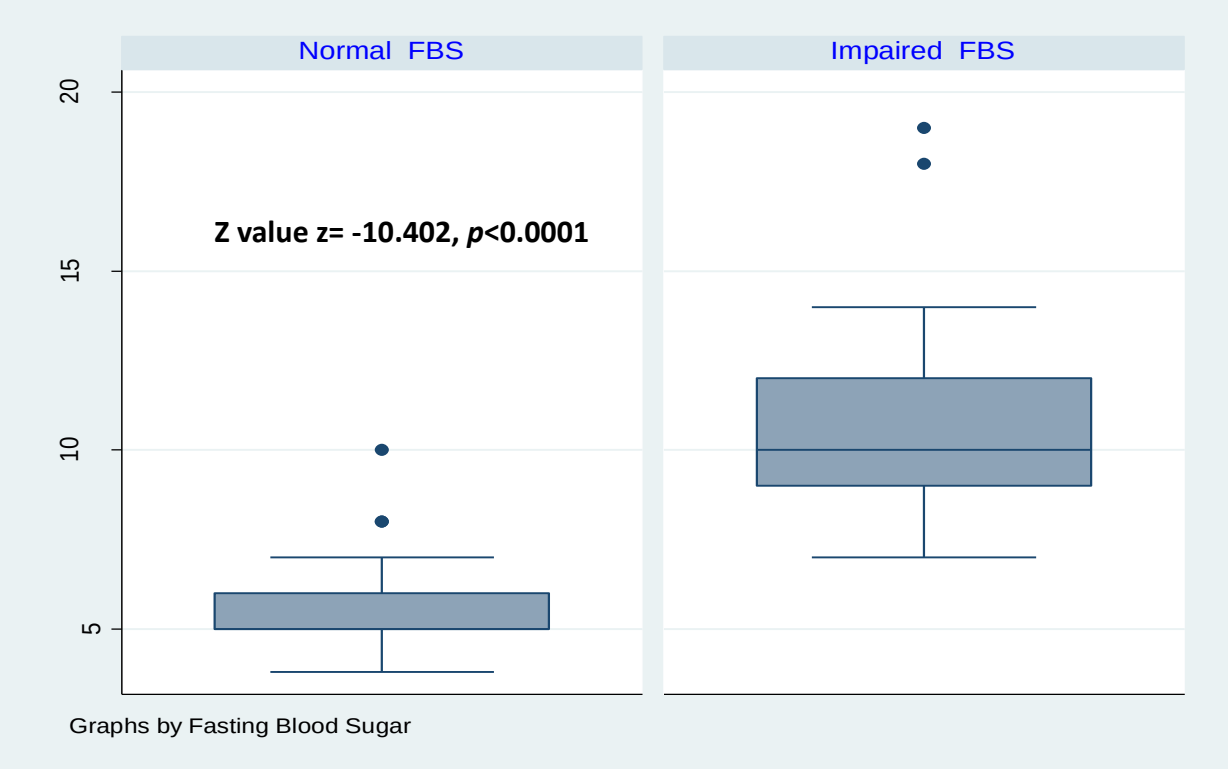
Table 2above shows the social-demographic and clinical characteristics of ART patients that were included in this study. Out of 272 ART patients that were eligible for this study**,** 186 (68.9 %) were females while only 84 (31.1) were males. The mean age of the participants was 45 years with 10 years standard deviation.The majority of patients in this study were symptomatic of diabetes (80%) and about 43% had impaired random blood sugar whereas 15.3% had impaired fasting blood sugar after 10 hours of fasting.

Table 3: Basic Characteristics of ART Patients Sorted According To Impaired Fasting Glucose (n=261).

Factors		**IFG (YES) n=40 (15.4%)**	**IFG (NO) n= 221 (84.6%)**	**P-value**
Sex				0.08 |a
	Male	17 (42.5%)	63 (28.8%)	
	Female	23 (57.5%)	158 (71.5%)	
Age (Group)				0.001|b
20-35		2 (2.5%)	27 (12.2%)	
35-45		8 (20.0%)	94 (42.5%)	
>45		30 (77.5%)	100 (30.8%)	
No. Symptoms Ticked on CHC				<0.0001|a
	0	8 (20.0%)	45 (20.4%)	
	1-3	12 (30.0%)	164(74.2%)	
	>3	20 (50.0%)	12(5.4%)	
ART Regimen				0.002|a
1st line treatment		32 (80.0%)	210 (95.0%)	
2nd line treatment		8(20.0%)	11 (5.0%)	
BMI (kg/m2)				
Underweight		1(2.5%)	29(12.5%)	<0.0001|b
Normal weight		3(45.0%)	126(54.5%)	
Over weight		1(2.5%)	41(17.5%)	
Obese		35(87.5%)	35(15.2%)	

Meanings; |a=Chi-squared test, |b=Fisher's exact test, IFG=Impaired Fasting Glucose.

Table 4.2 above shows the description of basic characteristics of study participants sorted by the outcome variable. A total of 23 females (57.5%) were found with impaired fasting glucose compared to 17 males (42.5). The mean baseline weight for patients with impaired fasting glucose was 60kg compared to 50 kg for those with normal fasting glucose. Age group greater than 45 years had the highest number of people with Impaired fasting blood sugar compared to those in the age group 20-35 (1) and 35-45 (8). Variables such as age, number of symptoms, ART regimen, Baseline weight and Body Mass Index showed significant difference between those that were found with impaired fasting glucose and those with normal fasting glucose (P-value p=0.001, p< 0.0001, p=0.002, p=0.015 and p <0.0001 respectively).



Note: normal FBS n=221, impaired fasting blood sugar n=40

Figure 2: Distribution of Random Blood Sugar Levels by Fasting Blood Sugar

Figure 2 above shows the distribution of random blood sugar levels among those who had a fasting blood sugar test. The median random blood sugar level in ART patients with a normal fasting blood sugar test was 5 mmol/l IQR (3-7) whereas the median random blood sugar levels was 10 mmol/l (IQR 7-14) .

Table 4: Predictors of Impaired Glucose for Adult Patients on ART Fasting for at Least 2 Years

Variable		Univariate OR (95% CI)	P-value	Multivariate aOR (95% CI)	P-value
Age (Years)					
20-35		1.	1.	1.	1.
35-45		1.15 (0.338 3.88)	0.826	0.76 (0.18- 3.27)	0.714
>45		2.72 (1.89 8.24)	0.049*	2.68 (1.14- 3.34)	0.036*
Sex					
Male		1.	1.	1.	1.
Female		0.64 (0.32 1.26)	0.080	0.36 (0.10 1.28)	0.117
Baseline weight (Kg)					
		1.04 (1.01 1.07)	0.002*	1.07 (1.01 1.13)	0.011*
Number of Symptoms					
	0	1.	1.	1.	1.
	1-3	0.17(.005 .49)	0.001*	0.14 (0.04 0.53)	0.004*
	>3	7.44 (2.78 19.9)	<0.0001*	6.55 (1.43 -29.9)	0.015*
ART duration (Years)					
		1.17 (1.05 1.31)	0.006*	1.01 (0.82 1.24)	0.844
ART Regimen					
1st line treatment		1.	1.	1.	1.
2nd line treatment		4.02 (1.79 9.04)	0.001*	0.82 (0.11-5.92)	0.840
Body Mass Index (Kg/m2)					
	Underweight	1.	1.	1.	1.
	Normal weight	0.69 (0.13 3.59)	0.660	0.25 (0.03 2.06)	0.198
	Overweight	0.70 (0.09 5.32)	0.736	0.17 (0.01 2.18)	0.174
	Obese	2.27 (1.99-3.07)	0.039*	2.15 (1.73-7.85)	0.005*
Baseline CD4 count (T-cells/ul)					
	≤350	1.	1.	1.	1.
	>350	2.44 (1.23 4.81)	0.010*	0.44 (0.11 1.66)	0.226

*=***Variables that were statistically significant at 5% alpha, aOR= adjusted odds ratio, OR= unadjusted odds ratio***

Table 4shows predictors of impaired fasting glucose levels. At multivariate analysis four variables showed increased association with impaired fasting glucose and these include,

Body Mass Index greater than 30 (AOR 2.2, 95% CI: 1.7-7.8) , Baseline weight (AOR 1.07 95% CI: 1.01-1.13), Number of symptoms greater than 3 ticked on the diabetes checklist (AOR 6.5 95% CI: 1.4-29.9%) and Age greater than 45 (AOR 2.7 95% CI: 1.14-3.34) while number of symptoms between 1 and 3 ticked on the checklist showed a reduced association with the outcome (AOR 0.14 95% CI 0.04 0.53).Variables such as Sex, ART duration, ART regimen and baseline CD4 count were not statistically significant (P-value p=0.117, p=0.844, p=0.840and p=0.226respectively).

Table 5: Adjusted Predictors of Impaired Fasting Glucose from the Best Fit Model

Predictors of IFBS	**Odds Ratio**	**95% C.I**	**P-value**
Baseline weight (kg)	1.05	1.01 1.09	0.012
No of Symptoms Ticked on CHC	2.4	1.78 3.28	0.001
Age	1.3	1.11-3.25	0.041
Body Mass Index (kg/m²)	2.11	1.34 3.32	0.001

Table 5 shows predictors of impaired fasting glucose which includeBaseline weight, Number of symptoms ticked on the Chronic HIV Care checklist, Age and Body Mass Index (BMI) (P-Value : p=0.012, p=0.001, p=0.041 and p=0.001 respectively).

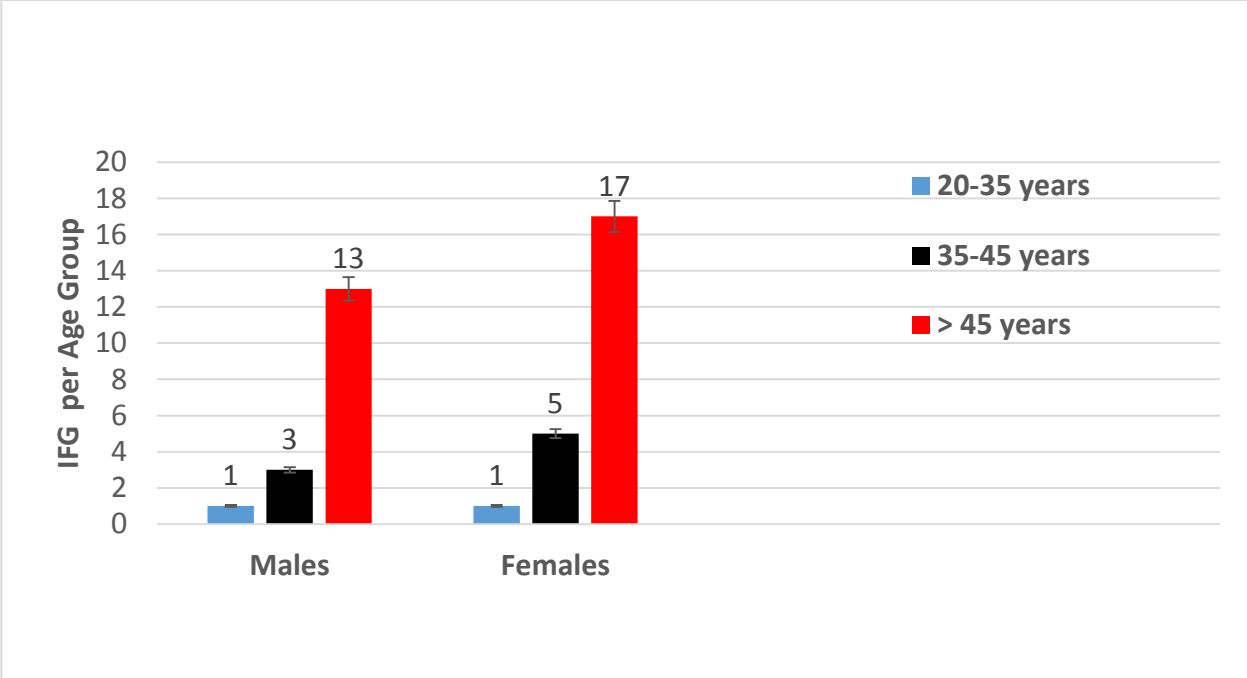


Figure 3: Distribution of impaired fasting glucose stratified by age in groups and sex (n=40)

Figure 3 above shows ART patients with impaired fasting glucose stratified by age in groups and sex. Impaired fasting glucose increased with increasing age group for both males (13) and female (17). The mean age for impaired fasting glucose was 45 years with 10 years standard deviation.

Table 6: Validating the Chronic HIV Care Screening Checklist for Diabetes (n=261)

	Impaired Fasting Glucose	**Without Impaired Fasting Glucose**	**Total**
Test positive	**32**	**176**	**208**
Test negative	**8**	**45**	**53**
	40	**221**	**261**

Sensitivity =32/40*100=80%, specificity=45/221*100=20.4, PPV=32/176*100=18.2%, NPV=45/53*100=84.9%

Table 4.5 above shows a validity test for the Chronic HIV care screening checklist. In this table the exposure was Chronic HIV Care screening checklist and the outcome was Impaired Fasting glucose. Out of 40 ART patients that had impaired fasting blood sugar, 32 tested positive after being screened with the checklist while 8 tested negative. The table above shows sensitivity of (80.0%), specificity (20.4%), Positive Predictive Value (18.2%) and Negative Predictive Value (84.9%)

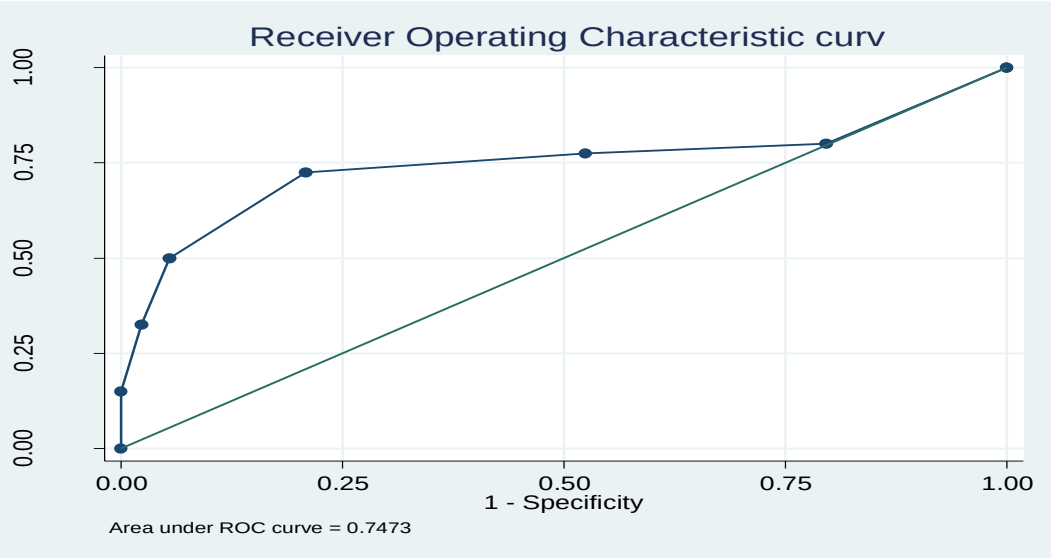


Figure 4 above shows the receiver operating characteristics curve which measures validity. The overall predictive ability for impaired fasting blood sugar measured by the area under the ROC curve was 0.75.

CHAPTER FIVE

5.0 Discussion

In this study, we aimed at assessing the validity of the diabetes symptoms screening checklist among adult HIV/AIDS patients on ART in Copperbelt province. The findings in this study revealed that out of all ART patients who were screened for diabetes using the Chronic HIV Care Checklist, 80% had atleast one diabetes symptom. Among these, 43%, (95% CI: 37%-49%) were found with impaired random blood sugar and 15.3 % (95% CI: 11%- 20%) % had impaired fasting glucose. The study also showed that more females 23 (57.5%) were found with Impaired fasting glucose compared to males 17 (42.5%). The mean age for patients with impaired fasting glucose was 45 years with 10 years standard deviation and had a mean ART duration of 7.1 years with 3.5 years standard deviation. Among the factors found to be associated to Impaired fasting blood sugar were, Body Mass Index >30 (AOR 2.2, 95% CI: 1.7-7.8) , Baseline weight (AOR 1.07 95% CI: 1.01-1.13), Number of symptoms >3 ticked on the diabetes checklist (AOR 6.5 95% CI: 1.4-29.9%) and Age >45 (AOR 2.7 95% CI: 1.14-3.34). This study found sensitivity (80%), specificity (20.4%), Positive Predictive Value (18.2%) and Negative Predictive Value (84.9%) and ROC value of 0.75 for the diabetes symptoms screening checklist.

We have also found a significant increase in the proportion of ART patients with impaired fasting blood sugar levels, suggesting a higher prevalence of diabetes among ART patients compared to the general population.We also speculated that the underlying causes and origin of diabetes in HIV/AIDS patients differ from that of the general population. However this maybe contrary to the findings of a recent study involving 4010 patients from seven countries in Latin America who found an overall prevalence of 3.6% for type 2 diabetes (Cahn et al., 2010). The lower prevalence found in these studies when compared to ours can be explained in part by two factors: a younger population and, in some cases, a shorter duration of ARV exposure. We also argue that the underlying causes and origin of diabetes in HIV/AIDS patients in our study may differ from that of the general population.

This study found that the diabetes symptom screening checklist had a high Sensitivity and a low specificity. Sensitivity in this study represented proportion of correct classification of ART patients that tested positive for symptoms who eventually had impaired fasting blood

sugar whereas specificity represented ART patients that tested negative for symptoms and truly had no impaired fasting blood sugar. These findings are consistent with the postulated sensitivity and specificity values of 75%, and 25% respectively by the International Diabetes Federation (International Diabetes Federation, 2012). Given the fact that Impaired Fasting glucose level is seemingly not common among ART patients with estimated prevalence less than 20%(Brown, et al 2010), the values for sensitivity and specificity found in this study could be held valid or real. With regards to predictability of the diabetes symptoms screening checklist, findings showed that the likelihood of ART patients being screened having impaired fasting glucose is about 18.2% and the likelihood of them not having impaired fasting glucose is 84.9% as seen in the values of Positive Predictive Value (PPV) and Negative Predictive Value (NPV) respectively. It is not surprising to find positive predictive value to be this low considering the fact that the prevalence of impaired fasting glucose was seemingly too low in this study.However, to predict impaired fasting glucose, patients with at least three symptoms on the Chronic HIV Care Screening were 6 times more likely to have impaired fasting glucose compared to those without any symptoms.Although it is desirable to have a test that is both highly sensitive and highly specific, this usually not possible and therefore, depending on the availability of resources for screening interventions, there is always a trade-off between sensitivity and specificity. The Chronic HIV Screening Checklist had a high sensitivity and low specificity. These findings are consistent with those found in a study done by (Group, 2002), which suggested that to predict drug-treated diabetes, the score value >9 had sensitivity of 0.78, specificity of 0.77 and positive predictive value of 0.13.

The Roc value of 0.75 in this study indicates that the finding of sensitivity and specificity are not due to chance. In view of this, our clinical prediction rule would be considered to be of ‘good accuracy’ at separating ART patients with impaired fasting glucose from ART patients without impaired fasting glucose, according to the traditional academic point system: fail, poor, fair, good, and excellent. In this regard, the Diabetes symptom screening checklist was effective in correctly classifying ART patients who had impaired fasting blood sugar considering the values of sensitivity.

The results also showed that patients who had diabetes symptoms greater than 3 were 6.5 times more likely to have impaired fasting glucose compared to patients who reported not having any symptoms adjusting for other variables. We also found that patients who had between 1 and 3 diabetes symptoms were 86% less likely to have impaired fasting glucose compared to patients who were asymptomatic.

We have also found that one unit increase in baseline weight increases impaired fasting glucose levels by 7% and this increase was statistically significant in that we can rule out chance finding given that the estimate was statistically significant. Such a finding is consistent with established data that insulin resistance is associated with increased weight gain and obesity (Samaras k et al 2012). This is an important finding because initiation of ART correlates with rapid weight gain and as such risk reduction strategies for overweight and obese individuals should be of primary focus. Moyo D, et al (2013) in Botswana found that weight at initiation of ART was significantly associated with increased risk of diabetes. In their study the odds of DM with a pre-ART body weight of greater than70 kg was over 12 times that for a body weight of less than 50 kg.

Finding that most patients with impaired fasting blood sugar in this study were females, is not surprising as the pattern in the health seeking behaviour where HIV/AIDS epidemic is concerned has shown that women are more likely to utilize ART care services more than men and hence more likely to be screened for diabetes (Dako-Gyeke et al., 2012). This is however contrary to the findings of a Swiss HIV cohort study which showed that men were more likely to have impaired fasting glucose compared to women and that the prevalence of diabetes was slightly higher among men than women (Ledergerber et al., 2007).

In this study, the proportion of impaired fasting blood sugar increased in all age group but the increase was more convincing in older people aged 45 years and above because this age group apparently had a longer duration on treatment compared to those aged between 20 and 30 years. We found that ART patients who were aged 45 years and above were 2.6 times more likely to have impaired fasting glucose compared to those who were aged between 20 and 35 years adjusting for other variables. This increase is statistically significant in that we can rule out chance finding given that the estimate was statistically

significant. Although these findings are consistent with a study which was done by (Diouf et al., 2012), we did not have sufficient evidence to suggest that longer duration on ART was associated to impaired fasting glucose.

Surprisingly, our study showed that patients on second line regimen were less likely to have IFBS compared to those on first line treatment, however we didn't have enough evidence to support this association. This is contrary to the findings in a Swiss HIV cohort study which found that the incidence of diabetes in patients receiving ART was 4.42 cases per 1000 person-years of follow-up (Ledergerber et al., 2007). In the same Swiss study, current treatment with protease inhibitor and nucleoside reverse transcriptase inhibitor containing regimens was associated with the risk of developing type 2 diabetes. In our study however, we didn't analyse the specific combinations of ART regimens that the study participants were exposed to.

With respect to BMI, we have found that patients with a BMI greater than 30 were 2.4 times more likely to have IFBS compared to patients who were underweight after adjusting for other variables in the model. This is a real increase in that we can rule out chance finding given that the estimate was statistically significant. This finding is consistent with what was reported in a study in Senegal which showed that factors such as long duration of ART (≥119 months), older age, higher body mass index (BMI), and higher levels of total cholesterol were associated with higher risks of diabetes (Diouf et al., 2012).

Interpretation of our results must take into account several limitations. This is a cross-sectional study,as such, could only identify associated factors and could not offer causal interpretation. Moreover, some potentially confounding factors were not taken into account in the analysis such as patient's lifestyle as this could be related to the study outcome.

The use of glucometers for measuring fasting blood sugar could have under estimated our results because glucometers are sensitive to calibrations and therefore, it is possible that high blood sugar levels could not be read. This could have potentially infused measurement bias in our study. The use of a smaller sample size potentially reduced the power of this study due to categorisation of the study variables, therefore a bigger sample size could have strengthen our study further.

However, although we think that these limitations are present, we do not think they are important in explaining the findings. One of this study's strengths was its validation of the diabetes symptom screening checklist which will help in correct classification of ART patients and thereby channelling interventions on to a population that has the attribute. This will help to improve follow up care within ART platforms.Another strength is having used definitions for impaired fasting blood sugar that took into account several successive measurements in accordance with WHO guidelines or those of specialized International Diabetes Federation. This study has also helped in quantifying the magnitude of Non communicable diseases such as diabetes among ART patients and this will help in advocating for more aid to enhance the integration of NCDs within ART platforms.

5.1 Conclusions

We have found a significant increase in the magnitude of ART patients with impaired fasting glucose compared to what is reported in the general population, suggesting a high prevalence of diabetes among this population. The diabetes symptoms screening checklist was effective in correct classification of ART patients who had impaired fasting glucose from those who had normal fasting glucose levels and therefore should be used within ART settings. Being 45 years and above, having at least 3 symptoms of diabetes and also having a body mass index greater or equal to 30 are important factors associated with impaired fasting glucose.In view of this glycaemic makers and risk reduction strategies especially for obese individuals and aging HIV patients is highlighted.

5.2 Study Implications and Recommendations

1. Finding that baseline weight was associated to impaired fasting glucose, we suggest that screening for diabetes mellitus at baseline of ARTbe recommended in order to have an early diagnosis which will enhance proper follow up care and improve ART outcomes.
2. We recommend that the diabetes symptoms screening checklist be used to identify symptomatic ART patients that require further investigations. The CHC achieved higher sensitivity (80%), although specificity appeared to be low (20.4%), this is not clinically important when considering that the primary objective is not to miss cases of diabetes.

3. Glycaemic makers should be monitored closely especially for aging ART patients and those with a higher BMI, this could help in detecting the condition early and avoid further complications.
4. There is need for integrated care for HIV/AIDS and diabetes mellitus within ART platforms because of high proportion of ART patients being symptomatic of diabetes mellitus as evidenced in this study.
5. Prospective research with bigger sample size is recommended to consolidate the implications of these findings both clinically and programmatically.

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8th September, 2015

Ref. No. 2015-June-019

The Principal Investigator
Mr. Perfect Shankalala
University of Zambia
School of Medicine
Dept. of Public Health
P.O. Box 50110,
LUSAKA.

Dear Mr. Shankalala,

RE: ASSESSMENT OF A DIABETES SYMPTOM SCREENING CHECKLIST AND ASSOCIATED FACTORS OF IMPAIRED FASTING GLUCOSE AMONG ART PATIENTS IN COPPERBELT PROVINCE OF ZAMBIA.

Reference is made to your corrections dated 27th August, 2015. The IRB resolved to approve this study and your participation as principal investigator for a period of one year.

Review Type	**Ordinary**	Approval No. **2015-June-019**
Approval and Expiry Date	Approval Date: 2nd September, 2015	Expiry Date: 1st September, 2016
Protocol Version and Date	Version-Nil	1st September, 2016
Information Sheet, Consent Forms and Dates	• English	1st September, 2016
Consent form ID and Date	Version-Nil	1st September, 2016
Recruitment Materials	Nil	1st September, 2016
Other Study Documents	Data Collection form.	1st September, 2016
Number of participants approved for study	233	1st September, 2016

Specific conditions will apply to this approval. As Principal Investigator it is your responsibility to ensure that the contents of this letter are adhered to. If these are not adhered to, the approval may be suspended. Should the study be suspended, study sponsors and other regulatory authorities will be informed.

Conditions of Approval

- No participant may be involved in any study procedure prior to the study approval or after the expiration date.
- All unanticipated or Serious Adverse Events (SAEs) must be reported to the IRB within 5 days.
- All protocol modifications must be IRB approved prior to implementation unless they are intended to reduce risk (but must still be reported for approval). Modifications will include any change of investigator/s or site address.
- All protocol deviations must be reported to the IRB within 5 working days.
- All recruitment materials must be approved by the IRB prior to being used.
- Principal investigators are responsible for initiating Continuing Review proceedings. Documents must be received by the IRB at least 30 days before the expiry date. This is for the purpose of facilitating the review process. Any documents received less than 30 days before expiry will be labelled "late submissions" and will incur a penalty.
- Every 6 (six) months a progress report form supplied by ERES IRB must be filled in and submitted to us.
- ERES Converge IRB does not "stamp" approval letters, consent forms or study documents unless requested for in writing. This is because the approval letter clearly indicates the documents approved by the IRB as well as other elements and conditions of approval.

Should you have any questions regarding anything indicated in this letter, please do not hesitate to get in touch with us at the above indicated address.

On behalf of ERES Converge IRB, we would like to wish you all the success as you carry out your study.

Yours faithfully,
ERES CONVERGE IRB

Dr. E. Munalula-Nkandu
BSc (Hons), MSc, MA Bioethics, PgD R/Ethics, PhD
CHAIRPERSON

APPENDIX I - INFORMATION SHEET

Dear Participant,

My name is Perfect Shankalala

I am a Master of Public Health student at the University of Zambia, School of Medicine. In partial fulfilment of the program study, I am expected to undertake a research that will contribute to the provision of quality health care and contribute to the body of knowledge.

The aim of this study is to assess the validity of a diabetes symptom screening checklist and associated factors of impaired fasting glucose among ART patients on Copperbelt province

What will happen if I take part?

You will be asked to fill in a questionnaire about your personal details as well as answer questions contained in the diabetes symptom screening checklist. If you are positive with any of the symptoms contained in the checklist, then you will be asked to do a random glucose test using a glucometer. If your blood glucose levels are above normal (> 5.5 mmol/l) then you will be requested to undergo a 10 hours fasting after which a fasting glucose test will be done. The blood samples of about 5mls that will be collected from you will be used **ONLY** for measuring your fasting glucose levels. You will be asked to come to your ART health facility once a week (1 hour each) for 8 weeks. You will be given transport reimbursement and also provided with refreshments.

Do you have to participant?

Your participation in this study is voluntary. You are free to withdraw from the study at any time if you wish to do so without any consequences and without giving any reasons whatsoever. Information that will be obtained from this study shall be submitted to UNZA, Department of Public Health and will be made available to FHI360/ ZPCT II and at each respective ART health facility where the study will be conducted. The findings will also be

of great importance as it would validate the diabetes screening checklist and also help in correctly identifying those who are symptomatic and hence improving follow up care.

What will happen to the information I give?

The information that you will give shall be handled with utmost confidentiality. You are not required to write your name or initials on the questionnaire to give identity. The research will not identify you individually and no one other than the researcher will know what you have said.

Risk and discomforts: Physical risks maybe be experienced as a result of pricking and blood sample collection which might cause discomfort to you, however the laboratory methods will use standard operating procedures in collecting blood samples and therefore you will be subjected to routine clinical practice and the blood samples will be used for measuring your random and fasting glucose levels **only.**

Benefits: There are no monetary benefits that will be given in exchange for your participation. However, taking part in this study will generate information that will contribute to the provision of quality health services among ART patients and once validate, the checklist will help in **correctly** classifying those with symptoms and those without symptoms hence improving follow up care.

Clarification: Should you need any clarifications do not hesitate to contact the researcher on the contacts that have been given below.

Mr. Perfect Shankalala
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You can also get in touch with the Chairperson of **ERES CONVERGE IRB** Ethics Committee on
33 Joseph Mwilwa Road
Rhodes Park
LUSAKA
Tel: 0955 155633/4
E-mail: eresconverge@yahoo.co.uk

Appendix II: Informed Consent

THE UNIVERSITY OF ZAMBIA

SCHOOL OF MEDICINE

INFORMED CONSENT DOCUMENT

Study Title: Study Title: Assessment of A Diabetic Symptom Screening ChecklistAnd Associated Factors Of Impaired Fasting Glucose Among ART Patients In Copperbelt Province.

Principal Investigator: Mr. Perfect Shankalala

IRB No.:

Purpose of research project

This study is part of my requirement for my training in MSc Epidemiology, which I am doing with the University of Zambia, School of medicine. The purpose of the study is to assessing the validity of a diabetic symptom screening checklist and associated factors of impaired fasting glucose among ART patients in Copperbelt province. To do so, I first want to find out the proportion of ART patient found symptomatic of diabetes mellitus after being subjected to a diabetes symptom screening checklist and thereafter those who present with one or more symptoms will be subjected to a random glucose test using a glucometer. Further i will ask those found with high glucose levels above normal to undergo a 10 hours fasting after which about 5mls of blood sample will be collected to determine impaired fasting glucose levels using a laboratory method.

I will ask participants to provide information with regards to their age, sex, marital status and smoking status while clinical characteristics such CD4 count, ART type, weight, ART duration and ART combination will be extracted from the participants ART files.

Why you are being asked to participate?

Potential participants for this study are all HIV positive patients who have been on ART for more than 2 years that have no primary diabetes. You have been asked to participate because you fit these descriptions. Overall, I expect about 40 ART patients at each health facility to participate in this study and 233 participants from all the six health centres.

Procedures

If you agree to participate in this study:

You will be asked to fill in a questionnaire about your personal details as well as answer questions contained in the diabetes symptom screening checklist. If you are positive with any of the symptoms contained in the checklist, then you will be asked to do a random glucose test using a glucometer. If your blood glucose levels are above normal (> 5.5 mmol/l) then you will be requested to undergo a 10 hours fasting after which a fasting glucose test will be done. The blood samples of about 5mls that will be collected from you will be used **ONLY** for measuring your fasting glucose levels. You will be asked to come to your ART health facility once a week (1 hour each) for 8 weeks. You will be given transport reimbursement and also provided with refreshments.

Risks/discomforts

Physical risks maybe be experienced as a result of pricking and blood sample collection which might cause discomfort to you, however the laboratory method will use standard operating procedures in collecting blood samples and therefore you will be subjected to routine clinical practice and the blood samples will be used for measuring your random and fasting glucose levels **only.** I recognize some information you may tell me or fill in in the questionnaires may be personal or maybe sensitive to other people. However, I would like to assure you the information that we get from you will not be shared with anyone outside the research team.

Benefits

There are no monetary benefits that will be given in exchange for your participation. However, taking part in this study will generate information that will contribute to the provision of quality health services among ART patients and once validate, the checklist will help in **correctly** classifying those with symptoms and those without symptoms hence improving follow up care.

Payment

There is no payment for participating in this study. However, refreshments and snacks may be provided during training.

Protecting data confidentiality

I have put up steps to protect the information I will get from you. First, only my assistant and I will have access to the information. The collected data will be locked in a secure place. I will destroy all data within 3 years after typing the information. I will keep copies typed information on CDs in case we have a problem with the computer.

What happens if you do not want to participate in the study?

You are free to decide whether you want to take part in the study or not. This will not bring any problem to you.

Who do I call if I have questions or problems?

- Call me, <<Mr. Perfect Shankalala>>, at <<+260-977-341291>> if you have questions and complaints about the program.
- Call or contact the ERES Ethics Committee office for any ethical queries. The Ethics Committee contact information is:

The Chairperson of **ERES CONVERGE IRB** Ethics Committee on
33 Joseph Mwilwa Road
Rhodes Park
LUSAKA
Tel: 0955 155633/4

E-mail: eresconverge@yahoo.uk

What does your signature (or thumbprint/mark) on this consent form mean?

Your signature (or thumbprint/mark) on this form means:

- You have been informed about the program's purpose, procedures, possible benefits and risks.
- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to be in this program

_____ _____ _____

Print name of Adult Participant Signature of Adult Participant Date

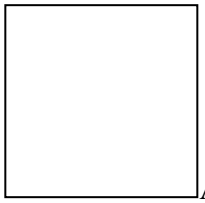
_____ _____ _____

Print name of Person Obtaining Signature of Person Obtaining Consent Date

Consent

_____ _____ _____

Print name of WitnessSignature of WitnessDate

 Ask the participant to mark a "left thumb impression" in this box if the participant (or participant's parent) is unable to provide a signature above.