Co-morbidity of Diabetes Mellitus and HIV in Patients attending the ART clinic

Parirenyatwa Hospital 2015

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Abstract

**Background:** Zimbabwe has a double burden of diseases, with HIV epidemic and increased prevalence of diabetes mellitus. Since the roll out of Anti Retroviral Therapy in 2004 at Parirenyatwa OI clinic, Nucleoside Reverse Transcriptase Inhibitors have been the backbone of antiretroviral therapy. At least 10% of OI clients at the institution are on 2\textsuperscript{nd} line regimen with Protease Inhibitors. These drugs cause metabolic derangements which are potentially Diabetogenic. With improved care in HIV management, patients are living long enough to experience environmental and behavioural risk factors for diabetes mellitus. However diabetic screening is not done at Parirenyatwa OI clinic and the disease burden of HIV/Diabetes co-morbidity is not known.

**Methods:** An analytic cross-sectional study was conducted. Questionnaires were used to collect data on patient’s socio-demographic characteristics, medical history and symptoms of diabetes mellitus. Random blood sugar and glycated haemoglobin tests were done to ascertain diabetes status.

**Results:** Prevalence of diabetes was 15.42%. Treatment with Protease inhibitors (POR 2.36; 95% CI 1.06-5.23) and a CD4 count at diagnosis of HIV greater than 500 (POR 3.74; 95% CI 1.26-11.09) were associated with development of diabetes mellitus with statistical significance. Smoking (POR 2.34; 95% CI 0.69-7.96), alcohol abuse (POR 1.81; 95% CI 0.74-4.40) being overweight (POR 1.79; 95% CI 0.85-3.79), were also associated with the development of diabetes but not statistically significant.

**Conclusions:** Behavioural risk factors like smoking, alcohol use and being overweight were associated with developing diabetes. Protease inhibitors use was also associated with the development of diabetes mellitus.
Acknowledgements

This project would not have been successful without the support, guidance and dedication of the following people to whom i would like to express my sincere gratitude.

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- My wife Kudzanai and our daughter Zoya for their encouragement and support
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<td>Acronym</td>
<td>Description</td>
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<tr>
<td>---------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>ART</td>
<td>Antiretroviral Therapy</td>
</tr>
<tr>
<td>CD4</td>
<td>Cluster of Differentiation 4</td>
</tr>
<tr>
<td>DBP</td>
<td>Diastolic Blood Pressure</td>
</tr>
<tr>
<td>DM</td>
<td>Diabetes Mellitus</td>
</tr>
<tr>
<td>EDC</td>
<td>Epidemiology and Disease Control</td>
</tr>
<tr>
<td>HIV</td>
<td>Human Immune Virus</td>
</tr>
<tr>
<td>IR</td>
<td>Insulin Resistance</td>
</tr>
<tr>
<td>IDF</td>
<td>International Diabetic Federation</td>
</tr>
<tr>
<td>NAC</td>
<td>National AIDS Council</td>
</tr>
<tr>
<td>NRTI</td>
<td>Nucleotide/Nucleoside Reverse Transcriptase Inhibitors</td>
</tr>
<tr>
<td>NNRTI</td>
<td>Non-Nucleoside Reverse Transcriptase Inhibitors</td>
</tr>
<tr>
<td>OI</td>
<td>Opportunistic Infections</td>
</tr>
<tr>
<td>PI</td>
<td>Protease Inhibitors</td>
</tr>
<tr>
<td>SBP</td>
<td>Systolic Blood Pressure</td>
</tr>
<tr>
<td>UNAIDS</td>
<td>Joint United Nations Programme on HIV/AIDS</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organisation</td>
</tr>
</tbody>
</table>
CHAPTER ONE

1. Introduction

1.1.1 Epidemiology of Diabetes Mellitus and HIV

The world is currently faced with a double burden of non-communicable and communicable diseases. With the continued epidemic of infectious diseases like HIV which is disproportionately higher in Sub-Saharan Africa, there is an increase in the prevalence of non-communicable diseases (NCDs) such as Diabetes Mellitus (DM). The World Health Organisation (WHO) estimates that the global adult prevalence of diabetes will double by the year 2025 from the current 135 million people to more than 300 million adults. The increase will be marked in low to medium income countries where the prevalence is predicted to increase three-fold, from 84 million to 228 million people living with diabetes by the year 2025.\(^1\) Zimbabwe, like most low to middle income countries, is faced with a double burden of diseases, with the continued epidemic of HIV and an increased prevalence of non-communicable diseases. For example, the prevalence of DM (Type 1 and 2) found in the ZIMSTEP-wise survey was 10%.\(^2\) The prevalence may be higher because this figure was obtained in the only community survey in Zimbabwe which was done ten years ago. The WHO estimates that the prevalence of DM is projected to increase three-fold by 2030 in Zimbabwe.\(^2\)

1.1.2 HIV and Diabetes co-morbidity

The prevalence of DM in HIV-positive patients is estimated by the WHO to be approximately 18%. In sub-Saharan Africa patients with HIV are said to have a five times increased risk of developing Type 2 Diabetes Mellitus compared to the general population.\(^2\)
Improved quality of care and treatment with antiretroviral therapy (ART) means that people living with HIV have a longer life expectancy and therefore have equivalent risks as HIV negative population groups to develop DM. These population risk factors include old age, malnutrition and obesity. HIV infection is recognised to be directly diabetogenic through increasing the levels of inflammatory cytokines like tumour necrosis factor alpha which in turn causes insulin resistance. HIV infection is also associated with co-infection with Hepatitis C virus which directly affects the pancreas and may result in DM. The treatment of HIV with antiretroviral therapy may cause metabolic disorders like the metabolic syndrome, lipodystrophy and impaired glucose metabolism. Treatment with protease inhibitors and nucleoside reverse transcriptase inhibitors has been implicated to be potentially diabetogenic.5.

1.1.3 Effects of diabetes/HIV co-morbidity

The link between infectious diseases and chronic conditions has become more established both in aetiology and susceptibility, for example viral infections and cancers. Co-morbidity also leads to higher prevalence and risk of complications. People with diabetes have a threefold independent risk of developing tuberculosis and other opportunistic infections that occur in HIV-positive patients. The aim of ART therapy in HIV treatment is to restore immune function but in patients who are diabetic, high glucose levels interfere with host immune response promoting the occurrence of opportunistic infections in patients who are otherwise virally suppressed with ART. The clinical benefits achieved through treatment of HIV may be undermined by co-morbidity resulting from either living longer with HIV or from the treatment itself. HIV-positive patients with DM have a two-fold increased risk of developing nephropathy and micro-vascular complications than HIV-positive patients without DM. There is also an increased risk of developing cardiovascular complications like hypertension in HIV-positive patients with DM compared to those without DM.4.
1.2 Background of study setting

The Parirenyatwa Hospital in Harare is one of the main tertiary teaching hospitals in Zimbabwe. The Opportunistic Infections (OI) clinic is a referral HIV treatment and follow-up facility that caters for both adults and paediatrics. At this clinic, clients receive their ART treatment, have routine clinical tests done and are managed for any OIs as out-patients.

Since the roll out of ART in 2004 at this clinic, nucleoside reverse transcriptase inhibitors (NRTIs) such as Stavudine have been the backbone of antiretroviral therapy. At least 10% of patients on ART at the OI clinic are on 2nd line regimen with Protease Inhibitors such as ritonavir. This means that there is a significant population of HIV-positive who have been on ART for at least ten years. Both these groups of drugs cause metabolic derangements which are potentially diabetogenic.

1.3 Problem Statement

A review of the patient records at the Parirenyatwa Hospital OI clinic showed a threefold increase in the number of patients referred to the diabetic clinic for diabetes related complications, from 23 in 2013 to 61 as of December 2014. These patients were only investigated for DM after diabetic complications had occurred. Routine screening DM is apparently not being done. This raises concern about the possibility of HIV-positive patients who may be developing DM but are yet to be diagnosed. Routine screening for DM in high risk populations is justified in that early detection may prevent onset of complications that could be life threatening or cause disability.
1.4 Study justification

There is currently no available data on the magnitude of HIV/DM co-morbidity in Zimbabwe. With improved quality of care in HIV management and use of ART, with their association with aetiology of non-communicable conditions, there is need to identify the determinants associated with HIV and co-morbid DM and to quantify the burden of these co-morbidities. Findings from such a study will help guide current quality of care initiatives on how to incorporate screening and management of HIV associated with DM.

1.5 Research Questions

This study seeks to address the following research questions

1. What are the prevalence and determinants of developing DM among HIV-positive clients enrolled in care on ART?
2. Are health workers screening for DM in HIV-positive patients?

\( H_0:\) 

There is no association between ART regimen and developing DM among HIV-positive patients.

\( H_1:\) 

There is an association between ART regimen and developing DM among HIV-positive patients.
1.6.1 Broad objective:

To determine the factors associated with the development of DM among HIV-positive patients.

1.6.2 Specific objectives

1. To determine the prevalence of DM among HIV-positive patients at Parirenyatwa Hospital in 2015.

2. To identify the socio-demographic factors associated with the development of DM among HIV-positive patients at Parirenyatwa Hospital in 2015.

3. To assess whether treatment with ART regimen is associated with developing DM among HIV-positive patients at Parirenyatwa Hospital in 2015.

4. To determine the practices of healthcare workers on screening for DM among HIV-positive patients at Parirenyatwa Hospital OI clinic in 2015.
CHAPTER TWO

2. Literature review

This chapter looked at the available literature on diabetes mellitus and HIV co-morbidity. The internet was used to find articles, review papers and policy documents. Publications included were less than 20 years old. The key words for literature search were diabetes mellitus and HIV co-morbidity, metabolic syndrome, prevalence of diabetes in HIV and complications of ART.

2.1 Global, regional and national prevalence

Co-morbidity of diabetes mellitus and HIV is receiving more attention and concern because of the emergence of DM as a chronic disease of public health concern. This is more so in low to middle income countries such as sub-Saharan Africa that already have a high prevalence of HIV. According to the Zimbabwe National AIDS Council’s situational report of 2014, the current HIV prevalence in Zimbabwe is 15% which translates to 1 390 211 people living with HIV. The WHO estimates that the global prevalence of DM among HIV-positive people is around 18%. In sub-Saharan Africa HIV-positive patients are 5 times more likely to develop type 2 diabetes mellitus compared to HIV-negative people.

In a systematic review on the prevalence of HIV and DM co-morbidity, 12 studies from Botswana, Europe and North America were reviewed giving prevalence and incidence data for DM in HIV-positive patients. In the 7 prevalence studies, the prevalence of DM in HIV-positive subjects ranged from 5.72% to 23.8%. In the same systematic review 5 studies reported incidence of DM ranging from 4.42% to 36.26% on subjects who were HIV-positive.
In Africa, a cross sectional study was conducted at St Peter's hospital in Addis Ababa Ethiopia, to assess the prevalence of DM among patients with pulmonary tuberculosis. Of the 120 subjects recruited, 89.5% were found to have both DM and tuberculosis. Prevalence of HIV and DM co-morbidity in this study was found to be 15.9%.

### 2.2 Risk factors for Diabetes in HIV

A study done in Botswana on 610 HIV-positive patients showed that HIV-positive patients above the age of 40 had a higher prevalence of Diabetes Mellitus at 10.8% compared 7.2% in the general population in that age group. Patients with Body Mass Indices of greater than 22.5 kg/m² had a higher prevalence of diabetes as well. A Swiss study which assessed 6531 HIV-positive patients found DM to be more prevalent in men who smoked, were black, Asian, older than 60 years of age and those who were obese.

Increased exposure to ART medication increases the risk of developing DM. An Australian study that followed up 744 HIV-positive patients showed that there was an increased risk of developing DM with increased cumulative exposure to ART.

In 2009 a follow up of HIV-positive patients in Italy using routine clinical and laboratory data demonstrated a 4.5% higher prevalence of DM in HIV-positive patients with longer exposure to ART compared to ART naive patients. A clinical trial done in France showed a three-fold increase in the development of DM among HIV-positive patients on protease inhibitors compared to HIV-negative patients. In 1998, Carr et al designed a cross-sectional study to characterise the association with PI use in HIV treatment or in non HIV related treatments and the risk of developing Diabetes Mellitus. Healthy individuals, PI naïve HIV+ patients and HIV+ patients on PIs, were compared. It was already known that PIs cause metabolic abnormalities such as hyperglycaemia but, this publication was the first to report that HIV-positive patients on PIs had an increased risk of developing a syndrome of
lipodystrophy with hyper-lipidaemia and Insulin resistance (IR) resulting in Diabetes Mellitus.\textsuperscript{13.}

It is also known that HIV-positive patients are at increased risk of (IR) due to the direct inflammatory effects of HIV, the direct effects of ART and indirect consequences of ART on for example body fat distribution changes. The mechanism of ART-induced IR has been the focus of much debate. Evidence suggests that body fat distribution changes lead to increased fat deposition in muscle which is accompanied by impaired insulin sensitivity. It has been shown that ART regimens impair glucose tolerance in one of two ways; induction of peripheral insulin resistance in skeletal muscle and adipose tissue and impairment of pancreatic beta cells to compensate.\textsuperscript{14.}
CHAPTER THREE

3.1 Methodology

Study type:

An analytic cross-sectional study was conducted.

Study population:

Patients enrolled at the Parirenyatwa Hospital OI clinic on ART were included in the study. Health care workers working at the OI clinic were interviewed for assessment of health care worker knowledge and practices on screening for diabetes.

3.2 Data Collection

Interviewer administered questionnaires were used to collect data on patients socio-demographic characteristics and medical history. They were also used to assess health worker knowledge and practices on diabetic screening. Patients’ medical records were used to add to patients’ medical histories. Anthropometric measurements of height, weight, and BMI were taken.

After obtaining consent, a glucometer was used to take capillary blood for glucose measurements from participating patients. Patients found to have diabetes, to be obese or underweight were referred to appropriate clinics for further management. If patients were found to be hypoglycaemic, emergency management was instituted urgently.
3.3 Measurements

Ascertainment of Diabetes Mellitus

Patients with a diagnosis of HIV on ART at the OI clinic were screened for DM. Patients meeting the above criteria with known diagnoses of DM were also included in the study. In accordance with the WHO and the International Diabetic Federation Guidelines and standards, patients were identified as having DM if they had either one of the following:

- Random blood sugar of greater than or equal to 11.1 mmol/l while exhibiting symptoms of DM, (polyuria, polydypsia, polyphagia).
- Fasting blood glucose of greater than or equal to 7.0 mmol/l where fasting is defined as 0 calorie intake for at least 8 hours.
- HbA1C of greater than or equal to 6.5%.

Fasting blood sugar were not feasible to conduct because this is an outpatient site with patients on three monthly appointments.

Random blood sugar and HbA1C measurements

After explaining the study and completion of the interviews, patients were asked to have their blood sugar tested. Upon receiving consent the thump of the patient was swabbed with a 75% alcohol solution to achieve sterility. A lancet was used to prick the thump and a single drop of blood was applied to a test strip connected to an AccuCheck™ glucometer machine which gave a blood sugar reading after 15 seconds.

A second drop of blood was added into a glass capillary tube and inserted into a DCA™ Systems HbA1C machine for HbA1C measurements which gave a result within 5 minutes.
**Height, weight and BMI**

Body Mass Index (BMI) is an index of weight for height that is used to generally classify people as either underweight, overweight or obese. It is defined as the weight in kilograms divided by the square of the height in metres (kg/m$^2$)

$$BMI = \frac{W}{H^2}$$

$W=$ weight (Kg), $H=$ height (m)

**Table 1: International classification of adult underweight, overweight and obesity according to BMI**

<table>
<thead>
<tr>
<th>Classification</th>
<th>BMI (kg/m$^2$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underweight</td>
<td>&lt;18.50</td>
</tr>
<tr>
<td>Normal weight</td>
<td>18.50-24.99</td>
</tr>
<tr>
<td>Overweight</td>
<td>25.00-29.99</td>
</tr>
<tr>
<td>Obese</td>
<td>&gt;30.00</td>
</tr>
</tbody>
</table>

Source: Adapted from WHO 2004.

A Charder™ BMI calculator was used to record patients BMI. Patients were asked to stand on the platform of the machine barefoot whereupon it automatically recorded patients’ weight, height and BMI in 2 seconds.
**Blood pressure**

Blood pressure is the pressure in the circulatory system. It is measured by two readings; a Systolic Blood Pressure (SBP) and a Diastolic Blood Pressure (DBP) it is classified according to WHO as shown in the table below.

**Table 2: Classification of Hypertension**

<table>
<thead>
<tr>
<th>Category</th>
<th>Blood pressure (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>SBP 90-119</td>
</tr>
<tr>
<td></td>
<td>DBP 60-79</td>
</tr>
<tr>
<td>Pre-hypertension</td>
<td>SBP 120-139</td>
</tr>
<tr>
<td></td>
<td>DBP 80-89</td>
</tr>
<tr>
<td>Stage 1 hypertension</td>
<td>SBP 140-159</td>
</tr>
<tr>
<td></td>
<td>DBP 90-99</td>
</tr>
<tr>
<td>Stage 2 hypertension</td>
<td>SBP ≥ 160</td>
</tr>
<tr>
<td></td>
<td>DBP ≥ 100</td>
</tr>
</tbody>
</table>

Source: Adapted from WHO 2004.

This was measured using an MX™ KINGYIELD brachial cuff blood pressure machine.

Patients were asked to relax for 10 minutes after which a blood pressure reading was taken.

**3.4 Data analysis**

Data was analysed using Epi-info 7 for means, frequencies, prevalence odds ratios (PRO), P values and confidence intervals (CI).
3.5 Sample size

Using Dobson formula

\[(n = Z^2 p (1-p)/\Delta^2)\]

where \(p=0.158\) (based on a cross sectional study by Carr et al to characterise the relationship between use of PIs and the development of IR.) Using a prevalence of 15.8% of DM in the exposed, at 95% confidence level, a minimum sample size of 205 patients was calculated. Factoring in a 10% attrition rate gives a sample size of 226.

3.6 Sampling procedure

Adult HIV-positive patients presenting at Parirenyatwa Hospital OI clinic who gave consent were selected using convenience sampling as they came to the clinic. There was self selection of study participants. The aim of the study was explained to patients in the waiting hall. Those who were interested were invited to a private consultation room for individual interviews and tests.

All healthcare workers available at the time of the study who were directly involved in the management of HIV-positive patients were considered for the study.

3.7 Permission to proceed

Permission to carry out the study was granted by the following:

- Parirenyatwa Group of Hospitals,
- Health Studies Office
- Ministry of Health and Child Care
- Joint Ethical Review Committee (JREC:160/15)
- Medical Research Council of Zimbabwe (MRCZ/B898)
3.8 Ethical considerations

Informed written consent was sought from all persons who were interviewed during the study. Completed forms were kept under lock and key at the Epidemiology and Disease Control (EDC) office at the MoHCC and will be destroyed 6 months after publication of results. Participants were free to refuse to participate without any consequences arising from their refusal. Confidentiality of responses was assured and maintained by keeping all identities anonymous. No names were recorded and questionnaire numbers were used to identify participants.

The proposal was presented to the Joint Review Ethics Committee for ethical clearance and was approved.
CHAPTER FOUR

4. Results

4.1 Demographic characteristics of study participants

It took a cumulative period of three weeks to conduct the interviews. Of the 226 patients interviewed, 51.13% were between the ages of 45 to 64, the majority were women (73.45%) and the median age was 46 (Q1=37; Q3=51) 83.70% were urban dwellers and 70.04% had secondary education.
Table 3: Demographic characteristics of study participants n=226.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Frequency n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
</tr>
<tr>
<td>&lt;24</td>
<td>2 (0.8%)</td>
</tr>
<tr>
<td>25-44</td>
<td>108 (43.66%)</td>
</tr>
<tr>
<td>45-64</td>
<td>106 (51.13%)</td>
</tr>
<tr>
<td>&gt;65</td>
<td>10 (4.41%)</td>
</tr>
<tr>
<td><strong>Median age in years 46 Q1=37, Q3=51</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>60 (26.45%)</td>
</tr>
<tr>
<td>Female</td>
<td>166 (73.55%)</td>
</tr>
<tr>
<td><strong>Residence</strong></td>
<td></td>
</tr>
<tr>
<td>Urban</td>
<td>190 (83.70%)</td>
</tr>
<tr>
<td>Rural</td>
<td>37 (16.30%)</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>30 (13.22%)</td>
</tr>
<tr>
<td>Secondary</td>
<td>159 (70.04%)</td>
</tr>
<tr>
<td>Tertiary</td>
<td>38 (16.74%)</td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
</tr>
<tr>
<td>Divorced</td>
<td>25 (11.90%)</td>
</tr>
<tr>
<td>Married</td>
<td>132 (62.86%)</td>
</tr>
<tr>
<td>Single</td>
<td>17 (8.10%)</td>
</tr>
<tr>
<td>Widowed</td>
<td>36 (17.14%)</td>
</tr>
</tbody>
</table>
4.2 Prevalence of Diabetes Mellitus

Figure 1: Prevalence of Diabetes in people attending Parirenyatwa OI clinic 2015

The prevalence of diabetes in this population was 15.42%. Women found to be diabetic constituted 11.43% (74.14% of all diabetics in the sample) of the sample compared to 3.99% of men. The diagnosis of DM was based on an elevated glycated haemoglobin level of greater than 6.5% in 80% of the patients. 35.29% of the patients diagnosed with diabetes had random blood glucose greater than 11.1 and were symptomatic.
4.3 Risk Factors for developing Diabetes Mellitus

Table 4: Demographic risk factors for developing Diabetes Mellitus

<table>
<thead>
<tr>
<th>Variable</th>
<th>DM n (%)</th>
<th>Non DM n (%)</th>
<th>POR(95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>male</td>
<td>8 (13.33%)</td>
<td>52 (86.67%)</td>
<td>0.79(0.34-1.84)</td>
<td>0.305</td>
</tr>
<tr>
<td>female</td>
<td>27 (16.27%)</td>
<td>139 (87.74%)</td>
<td>1.26(0.53-2.96)</td>
<td>0.305</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;24</td>
<td>0 (0%)</td>
<td>2 (100%)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>25-44</td>
<td>16 (14.81%)</td>
<td>92 (85.19%)</td>
<td>0.91(0.43-1.86)</td>
<td>0.390</td>
</tr>
<tr>
<td>45-64</td>
<td>16 (14.95%)</td>
<td>91 (85.05%)</td>
<td>0.92(0.44-1.90)</td>
<td>0.410</td>
</tr>
<tr>
<td>&gt;65</td>
<td>3 (30.00%)</td>
<td>7 (70.00%)</td>
<td>2.46(0.61-10.08)</td>
<td>0.119</td>
</tr>
<tr>
<td><strong>Family history</strong></td>
<td>8 (13.79%)</td>
<td>50 (86.21)</td>
<td>0.84(0.36-1.97)</td>
<td>0.356</td>
</tr>
</tbody>
</table>

Female sex (POR 1.26; 95% CI 0.53-2.96) and being older than 65 (POR 2.46; 95% CI 0.61-10.08) were factors found to be associated with the development of diabetes. These factors were however not statistically significant.
Table 5: Behavioural risk factors for developing Diabetes Mellitus

<table>
<thead>
<tr>
<th>Variable</th>
<th>DM n (%)</th>
<th>Non DM n (%)</th>
<th>POR(95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking</td>
<td>4 (28.57%)</td>
<td>10 (71.43%)</td>
<td>2.34(0.69-7.96)</td>
<td>0.099</td>
</tr>
<tr>
<td>Alcohol use</td>
<td>8 (22.86%)</td>
<td>27 (77.14%)</td>
<td>1.81(0.74-4.40)</td>
<td>0.102</td>
</tr>
<tr>
<td>Obesity</td>
<td>8 (14.81%)</td>
<td>48 (85.19%)</td>
<td>0.94(0.39-2.21)</td>
<td>0.455</td>
</tr>
<tr>
<td>Overweight</td>
<td>14 (21.21%)</td>
<td>52 (78.79%)</td>
<td>1.79(0.85-3.79)</td>
<td>0.066</td>
</tr>
<tr>
<td>Hypertension</td>
<td>13 (17.57%)</td>
<td>61 (82.43%)</td>
<td>1.27(0.60-2.69)</td>
<td>0.267</td>
</tr>
<tr>
<td>History of exercise</td>
<td>13 (12.50%)</td>
<td>91 (87.50%)</td>
<td>0.65(0.31-1.38)</td>
<td>0.135</td>
</tr>
</tbody>
</table>

Smoking (POR 2.34; 95% CI 0.69-7.96), alcohol abuse (POR 1.81; 95% CI 0.74-4.40) being overweight (POR 1.79; 95% CI 0.85-3.79) and being hypertensive (POR 1.27; 95% CI 0.60-2.69). These factors were however not statistically significant.
Table 6: HIV/ART risk factors for developing Diabetes Mellitus

<table>
<thead>
<tr>
<th>Variable</th>
<th>DM n (%)</th>
<th>Non DM n (%)</th>
<th>POR(95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CD4 count at diagnoses.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;400</td>
<td>27 (13.43%)</td>
<td>174 (86.56%)</td>
<td>0.27(0.10-0.71)</td>
<td>0.006</td>
</tr>
<tr>
<td>&gt;400</td>
<td>8 (36.36%)</td>
<td>14 (63.64%)</td>
<td>3.68(1.41-9.60)</td>
<td>0.006</td>
</tr>
<tr>
<td>nNRTI</td>
<td>27 (13.85%)</td>
<td>168 (86.15%)</td>
<td>0.51(0.96-1.29)</td>
<td>0.086</td>
</tr>
<tr>
<td>NRTI</td>
<td>35 (15.49%)</td>
<td>191 (84.51%)</td>
<td>undefined</td>
<td>undefined</td>
</tr>
<tr>
<td>PI</td>
<td>12 (26.09%)</td>
<td>34 (73.91%)</td>
<td>2.36(1.06-5.23)</td>
<td>0.021</td>
</tr>
</tbody>
</table>

Treatment with Protease inhibitors (POR 2.36; 95% CI 1.06-5.23) and having a CD4 count at diagnosis of HIV greater than 400 (POR 3.68; 95% CI 1.41-9.60) were also associated with development of DM and they were statistically significant with p values of 0.008 and 0.01 respectively. Having a CD4 count at diagnosis of HIV of less than 400 was protective of developing DM (POR 0.27; 95% CI 0.10-0.71) and this was statistically significant with a P value of 0.006.
Table 7: Demographic characteristics of health workers (n=22)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Category</th>
<th>Frequency n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>Male</td>
<td>6 (26.27%)</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>16 (72.73%)</td>
</tr>
<tr>
<td>Designation</td>
<td>Senior House Officers</td>
<td>2 (9.09%)</td>
</tr>
<tr>
<td></td>
<td>Junior resident medical officer</td>
<td>4 (18.18%)</td>
</tr>
<tr>
<td></td>
<td>Registered general nurse</td>
<td>11 (50.00%)</td>
</tr>
<tr>
<td></td>
<td>Primary care councillor</td>
<td>2 (9.09%)</td>
</tr>
<tr>
<td></td>
<td>Nurse aide</td>
<td>3 (13.64%)</td>
</tr>
</tbody>
</table>

Median duration in service (months) = 24 $Q_1$ =12 $Q_3$=60

A total of 22 health workers were interviewed. The majority were women (72.73%) and the median duration in service was 60 months.
Table 8: Health worker practices on screening for DM (n=22)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correctly state diagnostic criteria for DM</td>
<td>6 (27.27%)</td>
</tr>
<tr>
<td>Routinely ask patients history of DM</td>
<td>2 (9.09%)</td>
</tr>
<tr>
<td>Ever referred patient to DM clinic</td>
<td>1 (4.55%)</td>
</tr>
<tr>
<td>Ever prescribed DM medication at OI clinic</td>
<td>2 (9.09%)</td>
</tr>
</tbody>
</table>

Only one health worker had ever referred a patient to the DM clinic and 6 health workers could correctly state the diagnostic criteria for DM.
CHAPTER FIVE

5.1 Discussion

In this study, the prevalence of diabetes as defined by the WHO and IDF guidelines among HIV-positive patients on treatment was found to be 15.42% and it was higher in women at 74.14% of all patients with diabetes. There were associations between developing diabetes and being overweight, smoking and alcohol use which were not statistically significant. There was a statistically significant association between PI use, and diagnoses of HIV at a CD4 count greater than 400. A CD4 count at diagnoses of HIV which was less than 400 was protective of developing diabetes. Reported exercise and NNRTI use were protective though not statistically significant.

The prevalence of diabetes in this sample (15.42%) was higher than the last recorded population prevalence of Zimbabwe of 10%. Several studies have demonstrated a higher prevalence of DM in HIV-positive patients than the general population. Findings by the WHO showed that the global prevalence of DM is up to three times higher in the HIV-positive population than in the general population. The higher risk of DM may be due to HIV itself or due to treatment with ART. With improved quality of care in HIV treatment, patients are living longer and thus have the similar risks for developing diabetes as HIV negative people of the same age in addition to the risks they have from the HIV itself and the treatments associated with it.

The higher prevalence among women (71.4% of all diabetics) maybe a reflection of the excess risk women have for developing NCDs like diabetes mellitus. Gender and social norms in this country present a woman with lesser opportunities for active lifestyles compared to men. The industrialisation of food processing and the increased marketing of alcohol to women could also pose additional risks for them to develop diabetes mellitus.
This study also showed an association between developing diabetes and age. Older age is a well recognised risk factor for developing type 2 diabetes mellitus.\textsuperscript{7, 9} While this is a demonstration of increased lifespan among HIV-positive patients it is also an indication of the need to have comprehensive care that addresses other non communicable co-morbidities that come with improved ART treatment outcomes. The increase in DM among HIV-positive patients hence presents further treatment dimensions due to the varied spectrum of manifestations and treatment options. This then calls for multidisciplinary approach in the management of HIV.\textsuperscript{20}

Behavioural risk factors were also associated with developing diabetes mellitus among HIV-positive patients, albeit were not statistically significant. These included smoking, alcohol abuse and being overweight. According to UNAIDS, over a third of all HIV-positive patients were obese and had high blood pressure at initial HIV testing in sub-Saharan Africa.\textsuperscript{21} This probably highlights the paucity of health education programs for HIV-positive patients which focus exclusively on safe sex education. Obesity levels in Sub-Saharan Africa are on the rise and high-risk behaviour like smoking occurs in 40% to 70% of HIV-positive patients.\textsuperscript{22} These same behavioural influences could also increase risk for other non communicable diseases and increase the challenges for programs to quickly have an impact.

Increased exposure to ART is a well recognised predictor of diabetes mellitus among HIV-positive patients.\textsuperscript{10, 11, 12, 13} In this study there was a statistically significant association between developing DM and using a combination therapy containing PIs. PIs are known to cause metabolic abnormalities such as hyperglycemia, lipodystrophy with hyper-lipidaemia and insulin resistance resulting in Diabetes Mellitus. Use of therapies containing nNRTI was protective without statistical significance. It was however not possible to assess individual drugs because all patients are on combination therapies of at least three different types of drugs. At Parirenyatwa OI clinic many patients have been switched several times because of
erratic ART supplies. It was thus difficult to compare type of treatment and duration on therapy and their relative contribution to DM.

I observed a statistically significant association between development of DM and having a base line CD4 count greater than 400. This was consistent with findings of a study in Botswana that demonstrated an increased risk of Diabetes with higher baseline CD4 counts. However, in Taiwan, a lower baseline CD4 count was associated with an increased risk of development of Diabetes and many other studies have failed to demonstrate an association. It is possible that ART improves the CD4 count at the same time as predisposing the person to DM in the same process. This prompts further research to determine the relationship between immune reconstitution and impaired glucose tolerance.23, 24.

Health workers at the ART clinic should start routinely screening patients for DM. In this study, 35% of the diabetic patients were picked up by symptom inquiry and an RBS test. If health were to start routinely asking patients for history of DM symptoms, they could potentially diagnose that many patients using this inexpensive method.

The magnitude of co-morbidity brings to question the current HIV and AIDS Quality of Care systems currently in place. Of the global expenditure in health care, only 1% is spent in Africa while 60% of the world’s ‘disease burden is in Africa.17 80% of the global expenditure on diabetes occurs in rich countries but 76% of diabetes is in Africa. Most health expenditure is donor funded and directed towards HIV programs which are subsidized. This highlights the need to include other chronic diseases like DM in subsidized health care financing programs. This co-morbidity is also an opportunity to offer integrated universal health care that addresses both NCDs and CDs. In Tanzania, Rwanda and Zambia, expansion of existing personnel and assets available in HIV clinics to prevent and manage NCDs has demonstrated rapid impact.18 Many of the gains in life expectancy and quality of life indicators from
improved management of HIV-related conditions could be reversed due to complications of unrecognised and untreated diabetes.
CHAPTER SIX

6.1 Conclusion

The prevalence of Diabetes mellitus was 15.42% and it was higher in women. Behavioural risk factors like smoking, alcohol use and being overweight were associated with developing diabetes but without statistical significance. Patients who were hypertensive, on PIs and were diagnosed HIV with CD4 counts greater than 400 were more likely to also have developed DM.

6.2 Recommendation

1. The Director Epidemiology and Disease Control MoHCC should urgently roll out the NCDs strategy, including action on diabetes in people on ART

2. Head of Department Parirenyatwa OI Clinic should implement routine screening for diabetes for patients on ART attending OI clinic

3. Director AIDS and TB unit should incorporate NCDs prevention, treatment and control strategies in HIV treatment and care programs
   - Health promotion in ART clinics to provide advice and education on healthy eating and physical fitness to avoid obesity
   - Increased awareness of the risk of diabetes both from the direct effect of HIV and from ART at all ART clinics. HIV services and self-help groups working with persons living with HIV
   - Holistic care of the whole person living with HIV to manage co-morbidities rather than parallel services for chronic diseases and HIV services
   - Renewal of safe injection practices and infection control education on safe disposal of needles in insulin therapy for diabetes
6.3 Study limitations

1. Patients’ records are still manual which made it difficult to get accurate drug histories of patients.

2. Patients have also been transferred from several sites and change regimen frequently because of drug shortages and inconsistencies of available regimen at different sites.

3. Fasting blood glucose tests were not feasible to conduct because this was an outpatient site with patients on three monthly appointments.
References


15. Executive Summary: standards for Medical Care in Diabetes. Care Diabetes Journal 2013, 36(3):54-59.


www.economistinsights.com (Accessed 08/06/15)


ANNEXES

Annex I: Questionnaires

Health worker Questionnaire- English

1. Number …………………

2. Age…………………

3. Sex……………………

4. Designation………………

5. Duration of service…………………………

6. Duration of service in current post…………………………

7. State the diagnostic criteria for diabetes mellitus?...............................................................................................................................
...........................................................................................................................................................................................
...........................................................................................................................................................................................
( if responded mentions at least two of the four current Diagnostic criteria then response considered correct)

8. Do you routinely ask for history of DM? Yes [ ] No [ ]

9. Have you ever screened a patient for Diabetes mellitus? Yes [ ] No [ ]

10. Have you ever prescribed Diabetes Medication? Yes [ ] No [ ]

11. Have you ever referred a patient to a diabetic clinic? [ ] No [ ]
Health worker Questionnaire Shona

Number ......................

1. Makore eku berekwa.........................
2. Rudzi rwekuberekwa.........................
3. Chigaro pabasa..............................
4. Makore ekushanda pabasa....................
5. Makore ekushanda basa ramuinaro ikezvino.........................
6. Chirwere che sugar chinobatwa
    sei?.................................................................................................................................
    ...........................................................................................................................................(if
    responded mentions at least two of the four current Diagnostic criteria then response
    considered correct)
7. Munombobvunza varwere nhoroondo yavo yearwere hwe sugar? Hongu [ ]
   kwete [ ]
8. Makambo tsvakiridza chirwere che sugar pavarwere venyu? hongu [ ] kwete [ ]
9. Makambonyorera murwere mapiritsi kana mushonga wechirwere che sugar? Hongu [ ] kwete [ ]
10. Makambo tumira murwere ku chipatara chinoona nezve sugar? Hongu [ ] kwete [ ]

Patient Questionnaire English

39
Participants consent forms English

1. Age………

2. Gender  male [ ]  female [ ]

3. Residence………………………………………

4. Marital status………………

5. Occupation……………………………………

6. Race …………………………………………..

7. Religion………………………………………

8. Level of education?  Primary[ ]  Secondary[ ]  Tertiary [ ]  Other………

9. Have you ever been diagnosed of Diabetes mellitus before? Yes [ ]  No [ ]

10. Do you have a Family history of Diabetes? Yes [ ]  No [ ]

11. Do you take Alcohol? Yes [ ]  No [ ]

12. If so how much do you drink and how often? Normal [ ]  Excessive [ ]

   (patient taking more than 21 units a week will be regarded as excessive drinker and
   patient taking less than 21 units a week will regarded normal drinker)

13. Do you smoke? Yes [ ]  No [ ]

   If so how many cigarettes a day and how long have you been smoking?

14. Have you ever been diagnosed with Hypertension? Yes [ ]  No [ ]

15. If so when and are you on treatment? Yes [ ]  No [ ]

16. Do you regularly exercise? Yes [ ]  No [ ]

17. When were you diagnosed of HIV?..............................................................

Symptoms of Diabetes Mellitus

18. Do you have urinary frequency? Yes [ ]  No [ ]
19. Do you have increased appetite? Yes [ ] No [ ]

20. Do you have increased thirst? Yes [ ] No [ ]

21. Do you have a problem with wounds that take long to heal? Yes [ ] No [ ]

22. Do you have any numbness of feet or hands? Yes [ ] No [ ]
Participants Patient Questionnaire Shona

1. Questionnaire number ............... 

2. Mune makore mangani ekuberekwa? .................

3. Rudzi rwenyu rwekuberekwa? Murume [ ] mukadzi [ ]

4. Munogara kupi? ........................................

5. Makaroorwa kana kuroora here? Hongu [ ] kwete [ ]

6. Munoshanda kupi? ....................................

7. Rudzi rweganda? ................................

8. Chitendero chenyu ndechipi? ........................................


10. Makambobatwa ne urwere hwe sugar?) Hongu [ ] kwete [ ]

11. Mumhuri menyu, pane akambobatwa nechirwere Che Sugar? Hongu [ ] kwete [ ]

12. Munomwa hwahwa? Hongu [ ] kwete [ ]

13. Kana muchinwa, munomwa rwerudzii uye hwakawanda zvakadii? Normal[ ]

   Excessive [ ] (Patient taking more than 21 units a week will be regarded as excessive 

   drinker and patient taking less than 21 units a week will regarded normal drinker)

14. Munoputa Fodya? Hongu [ ] kwete [ ]

15. Makambobatwa nechirwere che BP here? Hongu [ ] kwete [ ]

16. Kana muinacho, makabatwa rini uye munomwa mushonga upi? Hongu [ ] kwete [ ]

17. Munomboita mabasa eku exerciser hongu [ ] kwete [ ]

18. Makabatwa ne chirwere che utachiona hwe HIV 

   rini? ..........................................................

19. Symptoms of Diabetes Mellitus
20. Munoenda kunorasa mvura zvakanya here? Hongu [ ] kwete [ ]

21. Ko munonzwa Nzara zvakapfurikidza here? Hongu [ ] kwete [ ]

22. Munonzwa nyota zvakapfurikidza? Hongu [ ] kwete [ ]

23. Munombo shushikana nema ronda anononoka kupora? Hongu [ ] kwete [ ]

24. Munombonzwa chiveve kunyanya kuma kumbo ne kuma woko? Hongu [ ] kwete [ ]
ANNEX 2: Consent forms

Participants English consent form

PARTICIPANT’S INFORMED CONSENT

PROTOCOL TITLE: Factors Associated with the development of Diabetes mellitus among HIV positive patients enrolled in care at Parirenyatwa Hospital OI Clinic 2015.

NAME OF RESEARCHER: Tafadzwa Tsikira

PHONE: 0771296179

PROJECT DESCRIPTION:
You have decided to take part in the research study named above. The study will collect your information about your age, gender and place of residence and risk factors for developing Diabetes mellitus. The study also involves conducting a blood finger prick test for blood sugar. The whole process should take approximately 20 minutes of your time. This consent form gives you information about the collection, storage and future use of data collected from you. Please ask if you have any questions. You will be asked to sign or make your mark on this form to indicate whether or not you agree to participate in the study. You will be offered a copy of this form to keep and will keep the other form for at least 3 years.

YOUR RIGHTS
Before you decide whether or not to volunteer for this study, you must understand its purpose, how it may help you, the risks to you, and what is expected of you. This process is called informed consent.

**PURPOSE OF RESEARCH STUDY**

The study seeks to determine Factors Associated with the development of Diabetes mellitus among HIV-positive patients enrolled in care at Parirenyatwa Hospital OI Clinic 2015. The factors being looked at are divided into client related, health service related, economic and cultural. You will also be tested for diabetes mellitus.

**PROCEEDURES INVOLVED IN THE STUDY**

Data will be collected using an interviewer administered questionnaire and checklists. The questionnaire you will respond to consists of open ended and closed ended questions. You will also be tested for Diabetes Mellitus using a Glucometer. A finger prick test of your blood will be done on your finger to test for random blood sugar and Glycated Hemoglobin.

**DISCOMFORTS AND RISKS**

There are ethical risks related to storing your information. It is possible that if others find out information about you in the questionnaire, it could cause you problems of stigmatization. To minimize this risk your information will be strictly put under lock and key. Information collected from you will be used only for academic purposes.

**POTENTIAL BENEFITS**

There are no immediate benefits to you from having your information stored. You and others could benefit in the future from research done on you. You can also benefit from early diagnosis and treatment if you were not aware of your diabetes status already.

**STUDY WITHDRAWAL**
You may choose not to enter the study or withdraw from the study at any time without loss of benefits entitled to you.

CONFIDENTIALITY OF RECORDS

Completed questionnaires and checklists will be kept under lock and key for at least 3 years after which they may be destroyed. To keep your information private, your name will not be written on the questionnaire.

PROBLEMS/QUESTIONS

Please ask about this research or consent now. If you have any questions in future please ask.

AUTHORIZATION

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I know being in this study is voluntary. I choose to be in this study. I know I can stop to be in this study and I know I will not lose any benefits entitled to me. I will get a copy of this consent form

____________________________________
Participant’s Signature or Mark       Date

____________________________________
Participant’s Name (Printed)

____________________________________
Researcher Signature                  Date

____________________________________
Witness Signature                    Date

YOU WILL BE OFFERED A COPY OF THIS CONSENT FORM TO KEEP.

If you have any questions concerning this study or consent form beyond those answered by the investigator, including questions about the research, your rights as a research participant
or research-related injuries; or if you feel that you have been treated unfairly and would like to talk to someone other than a member of the research team, please feel free to contact the Medical Research Council of Zimbabwe (MRCZ) on telephone (04)791792 or (04) 791193 and cell phone lines 0772 433 166 or 0779 439 564. The MRCZ Offices are located at the National Institute of Health Research premises at Corner Josiah Tongogara and Mazowe Avenue in Harare.
FOMU RECHIVUMIRANO

PROTOCOL TITLE: Factors Associated with the development of Diabetes mellitus among HIV positive patients enrolled in care at Parirenyatwa Hospital OI Clinic 2015.

NAME OF RESEARCHER: Tafadzwa Tsikira

PHONE: 0771296179

GWARO RECHIVUMIRANO

Zvamunofanira kuziva pamusoro petsvagiridzo ino:


Mune kodzero yekuramba kupinda muchirongwa, kana kubvuma kupinda iko zvino kana kuzoshandura pfungwa dzenyu pamberi.

Kupinda kwenyu mutsvagiridzo ino kana kusapinda kwenyu hakukanganise marapirwo enyu pano pachipatara.
Mibvunzo yamuchabvunzwa patsvagiridzo ino ichakutorera zvikamu zvemaminitsi aripakati pemashanu(5) kusvika makumi maviri(20) enguva yenyu.

CHINANGWA

Muri kukumbirwa kuti mupinde mutsvagiridzo yekuda kuziva zvikonzero zvinoita kuti vanhu vane chirwere che HIV vaite urwere hwe Sugar. Masarudzwa kuti mupinde mutsvagiridzo iyi nekuti mune Chirwere che hutachiona hweHIV uye muri pama piritsi ema ARV.

Kana mabvuma kupinda mutsvagiridzo iti muchabvunzwa mibvunzo maererana ne zera renyu, maramiro enyu uye nekurapwa kwenyu. Mucha vhenekwa kuti hamuna chirwere che sugar here. Vheneko yacho ndeye kubayayi pachigunwe chenu tichitora ropa rekutsvagidzira kuti hamuna chirwere che sugar here.

BETSERO

Hatikwanisi uye hativimbisi kuti muchawana betsero kubva mutsvagiridzo ino. Tsvagiridzo ino irikuitirwa kuti vaiti vetsvagiridzo vadzidze pamusoro pezvikonzero zvinoita kuti vanhu vane utachiona hwe HIV vabate chirwere che sugar.

NJODZI YAMUNGASANGANA NAYO PATSVAGIRIDZO INO

Mubvunzo hwezveutachiwana hweHIV kunemi hunokwanisa kukushungurudzai mupfungwa kana kusemwa nevamwe vanhu vangangoziva kuti makaongororwa hutachiwana uhwu.

TSINDIDZO

Zvose zvamuchatiudza zvicha chengetwa pakavanzika. Hapana munhu arikunze kwetsvagiridzo ino kusanganisira vemhuri achaziva zvinenge zvabuda muhurukuro yenyu.

Zvose zvamuchatiudza zvichaiswa munokiwa kana kuchengeterwa mumakombiyuta akaiswa mavara akavanzika. Zita renyu kana mamwe mashoko angaite kuti muzivikanwe haazoshandiswi muzvinyorwa zvinoratidzwa ruzhinji zvichabva mutsvagiridzo ino uye
mavara esese ndiwo acha-handiswa kuti hapana munhu akaziva kuti ndimi mapanda mutsvagiridzo ino.

**KUZVIPIRA KUPINDA MUCHIRONGWA**


**MUKANA WEKUBVUNZA MIBVUNZO**

Musati masaina gwaro rino, tapota bvunzai pamusoro pechipi nechipo zvacho chetsvagiridzo ino chisina kuje kwa kwari.  

**KUPA MASIMBA**

Ndirikutu sarudzo yekupinda kana kusapinda mutsvagiridzo ino. Kusaina kwangu kunoratidza kuti ndaverenga uye ndanzwisisa zvose zviri pamusoro; mibvunzo yangu yose yapindurwa uye ndasarudza kupinda muchirongwa.

Signature of research participant…………………………………….. Date …../……/………

Signature staff witnessing………………………………………….. Date …../……/………

Signature of investigator………………………………………… Date …../……/………

YOU WILL BE OFFERED A COPY OF THIS CONSENT FORM TO KEEP.
If you have any questions concerning this study or consent form beyond those answered by the investigator, including questions about the research, your rights as a research participant or research-related injuries; or if you feel that you have been treated unfairly and would like to talk to someone other than a member of the research team, please feel free to contact the Medical Research Council of Zimbabwe (MRCZ) on telephone (04)791792 or (04) 791193 and cell phone lines 0772 433 166 or 0779 439 564. The MRCZ Offices are located at the National Institute of Health Research premises at Corner Josiah Tongogara and Mazowe Avenue in Harare.
Health worker consent for Shona

FOMU RECHIVUMIRANO REVASHANDI VEUTANO

PROTOCOL TITLE: Factors Associated with the development of Diabetes mellitus among HIV positive patients enrolled in care at Parirenyatwa Hospital OI Clinic 2015.

NAME OF RESEARCHER: Tafadzwa Tsikira

PHONE: 0771296179

GWARO RECHIVUMIRANO

Zvamunofanira kuziva pamusoro petsvagiridzo ino:


Mune kodzero yekuramba kupinda muchirongwa, kana kubvuma kupinda iko zvino kana kuzoshandura pfungwa dzenyu pamberi.

Kupinda kwenyu mutsvagiridzo ino kana kusapinda kwenyu hakukanganise mampilwo enyu pano pachipatara.
Mibvunzo yamuchabvunzwa patsvagiridzo ino ichakutorerai zvikamu zvemaminitsi aripakati pemashanu(5) kusvika makumi maviri(20) enguva yenyu.

CHINANGWA

Muri kukumbirwa kuti mupinde mutsvagiridzo yekuda kuziva zvikonzero zvinoita kuti vanhu vane chirwere che HIV vaite urwere hwe Sugar. Masarudzwa kuti mupinde mutsvagiridzo iyi nekuti mune Chirwere che hutachiona hweHIV uye muri pama piritsi ema ARV.

Kana mabvuma kupinda mutsvagiridzo iti muchabvunzwa mibvunzo maererana ne zera renyu, maramiro enyu uye nekurapwa kwenyu. Muchabvunzwa maererano nema rapiro uye mabetsero amunoita vanhu vanechirwere che sugar.

BETSERO

Hatikwanisi uye hativimbisi kuti muchawana betsero kubva mutsvagiridzo ino. Tsvagiridzo ino irikuitirwa kuti vaiti vetsvagiridzo vadzidze pamusoro pezvikonzero zvinoita kuti vanhu vane utachiona hwe HIV vabate chirwere che sugar.

NJODZI YAMUNGASANGANA NAYO PATSVAGIRIDZO INO

Mubvunzo hwezveutachiwana hweHIV kunemi hunokwanisa kukushungurudzai mupfungwa kana kusemwa nevamwe vanhu vangangoziva kuti makaongororwa hutachiwana uhwu.

TSINDIDZO

Zvose zvamuchatiudza zvicha chengetwa pakavanzika. Hapana munhu arikunze kwetsvagiridzo ino kusanganisira vemhuri achaziva zvinenge zvabuda muhurukuro yenyu.

Zvose zvamuchatiudza zvichaiswa munokiiwa kana kuchengereterwa mumakombiyuta akaiswa mavara akavanzika. Zita renyu kana mamwe mashoko angaite kuti muzivikanwe haazoshandiswi muzvinyorwa zvinoratidzwa ruzhinji zvichabva mutsvagiridzo ino uye
mavara esese ndiwo achainDISwa kuti hapana munhu akaziva kuti ndimi mapanda
mutsvagiridzo ino.

KUZVIPIRA KUPINDA MUCHIRONGWA
Kupinda muchirongwa isarudzo yenyu. Pane ipi nguva munogona kuramba kuva
muchirongwa, uye sarudzoenyu haizokanganisi hukama hwenyu nezvipatara zvemuno
muHarare uye nezvese zvirimunyika ino, vashandi vazvo nevamwe vanoita nezvekuona
hurwere hwevanhu. Kana mukasarudza kupinda mutsvagiridzo iyi makasunungunga kuramba
kupindura mubvunzo umwe neumwe kana kusapindura mibvunzo yose. Makasunungukazve
kubuda mutsvagiridzo chero nguva yamungada. Zvakadaro, tingazvifirira zvikuru kana
mukapinda mutsvagiridzo ino.

MUKANA WEKUBVUNZA MIBVUNZO
Musati masaina gwaro rino, tapota bvunzai pamusoro pechipi nechipo zvacho chetsvagiridzo
ino chisina kujeka kwamuri.

KUPA MASIMBA
Ndirikuita sarudzo yekupinda kana kusapinda mutsvagiridzo ino. Kusaina kwangu
kunoratidza kuti ndaverenga uye ndanzwisisa zvose zviri pamusoro; mibvunzo yangu yose
yapindurwa uye ndasarudza kupinda muchirongwa.

Signature of research participant………………………………………… Date …./////..………

Signature staff witnessing……………………………………………….. Date …./////..………

Signature of investigator……………………………………………….. Date …./////..………

YOU WILL BE OFFERED A COPY OF THIS CONSENT FORM TO KEEP.
If you have any questions concerning this study or consent form beyond those answered by the investigator, including questions about the research, your rights as a research participant or research-related injuries; or if you feel that you have been treated unfairly and would like to talk to someone other than a member of the research team, please feel free to contact the Medical Research Council of Zimbabwe (MRCZ) on telephone (04)791792 or (04) 791193 and cell phone lines 0772 433 166 or 0779 439 564. The MRCZ Offices are located at the National Institute of Health Research premises at Corner Josiah Tongogara and Mazowe Avenue in Harare.
HEALTH WORKER’S INFORMED CONSENT

PROTOCOL TITLE: Factors Associated with the development of Diabetes mellitus among HIV positive patients enrolled in care at Parirenyatwa Hospital OI Clinic 2015.

NAME OF RESEARCHER: Tafadzwa Tsikira

PHONE : 0771296179

PROJECT DESCRIPTION:
You have decided to take part in the research study named above. The study will collect your information about your age, gender and place of residence and knowledge and practices about the treatment and diagnoses of diabetes mellitus. The whole process should take approximately 20 minutes of your time. This consent form gives you information about the collection, storage and future use of data collected from you. Please ask if you have any questions. You will be asked to sign or make your mark on this form to indicate whether or not you agree to participate in the study. You will be offered a copy of this form to keep and will keep the other form for at least 3 years.

YOUR RIGHTS
Before you decide whether or not to volunteer for this study, you must understand its purpose, how it may help you, the risks to you, and what is expected of you. This process is called informed consent.
PURPOSE OF RESEARCH STUDY

The study seeks to determine Factors Associated with the development of Diabetes mellitus among HIV-positive patients enrolled in care at Parirenyatwa Hospital OI Clinic 2015. The factors being looked at are divided into client related, health service related, economic and cultural. We also wish to know health worker practices on management of Diabetes Mellitus.

PROCEDURES INVOLVED IN THE STUDY

Data will be collected using an interviewer administered questionnaire and checklists. The questionnaire you will respond to consists of open ended and closed ended questions.

DISCOMFORTS AND RISKS

There are ethical risks related to storing your information. It is possible that if others find out information about you in the questionnaire, it could cause you problems of stigmatization. To minimize this risk your information will be strictly put under lock and key. Information collected from you will be used only for academic purposes.

POTENTIAL BENEFITS

There are no immediate benefits to you from having your information stored. You and others could benefit in the future from research done on you. You can also benefit from early diagnosis and treatment if you were not aware of your diabetes status already.

STUDY WITHDRAWAL

You may choose not to enter the study or withdraw from the study at any time without loss of benefits entitled to you.

CONFIDENTIALITY OF RECORDS
Completed questionnaires and checklists will be kept under lock and key for at least 3 years after which they may be destroyed. To keep your information private, your name will not be written on the questionnaire.

**PROBLEMS/QUESTIONS**

Please ask about this research or consent now. If you have any questions in future please ask.

**AUTHORIZATION**

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I know being in this study is voluntary. I choose to be in this study. I know I can stop to be in this study and I know I will not lose any benefits entitled to me. I will get a copy of this consent form

_________________________________________________________________________

Participant’s Signature or Mark       Date

_________________________________________________________________________

Participant’s Name (Printed)

_________________________________________________________________________

Researcher Signature       Date

_________________________________________________________________________

Witness Signature       Date

YOU WILL BE OFFERED A COPY OF THIS CONSENT FORM TO KEEP.

If you have any questions concerning this study or consent form beyond those answered by the investigator, including questions about the research, your rights as a research participant or research-related injuries; or if you feel that you have been treated unfairly and would like to talk to someone other than a member of the research team, please feel free to contact the Medical Research Council of Zimbabwe (MRCZ) on telephone (04)791792 or (04) 791193
and cell phone lines 0772 433 166 or 0779 439 564. The MRCZ Offices are located at the National Institute of Health Research premises at Corner Josiah Tongogara and Mazowe Avenue in Harare.
Annex 3: MRCZ approval letter

Medical Research Council of Zimbabwe
Jadah Tongogara/Mazoe Street
P. O. Box CY 973
Causeway
Harare

APPROVAL

REF: MRCZ/B/898 12 August, 2015

Tafadzwa Tsikira
University Of Zimbabwe
Department Of Community medicine
Harare

REF: Factors Associated with the Development of Diabetes mellitus Among HIV Positive Patients Enrolled in Care at Parirenyatwa Hospital Of Clinic 2015

Thank you for the application for review of Research Activity that you submitted to the Medical Research Council of Zimbabwe (MRCZ). Please be advised that the Medical Research Council of Zimbabwe has reviewed and approved your application to conduct the above titled study.

This approval is based on the review and approval of the following documents that were submitted to MRCZ for review:
- a) Study proposal
- b) Study summary
- c) English and Shona Informed consent form
- d) English and Shona Informed consent form for Health care workers
- e) English and Shona Questionnaires

• APPROVAL NUMBER : MRCZ/B/898

The above details should be used on all correspondences, consent forms and documents as appropriate

• TYPE OF MEETING : Expedited
• EFFECTIVE APPROVAL DATE : 12 August, 2015
• EXPIRATION DATE : 11 August, 2016

After this date, this project may only continue upon renewal. For purposes of renewal, a progress report on a standard form obtainable from the MRCZ offices should be submitted three months before the expiration date for continuing review.

• SERIOUS ADVERSE EVENT REPORTING: All serious problems having to do with subject safety must be reported to the Institutional Ethical Review Committee (IERC) as well as the MRCZ within 3 working days using standard forms obtainable from the MRCZ offices or website.
• MODIFICATIONS: Prior MRCZ and IERC approval using standard forms obtainable from the MRCZ offices is required before implementing any changes in the Protocol (including changes in the consent documents).
• TERMINATION OF STUDY: On termination of a study, a report has to be submitted to the MRCZ using standard forms obtainable from the MRCZ offices or website.
• QUESTIONS: Please contact the MRCZ on Telephone No. (04) 791792, 791193 or by e-mail on mrcz@mrcz.org.zw

Other

• Please be reminded to send in copies of your research results for our records as well as for Health Research Database.
• You’re also encouraged to submit electronic copies of your publications in peer-reviewed journals that may emanate from this study.

Yours Faithfully

[Signature]

MRCZ SECRETARIAT
FOR CHAIRPERSON
MEDICAL RESEARCH COUNCIL OF ZIMBABWE

PROMOTING THE ETHICAL CONDUCT OF HEALTH RESEARCH

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Annex 4: JREC Approval letter

Joint Research Ethics Committee
For The University of Zimbabwe,
College of Health Sciences and
Parirenyatwa Group of Hospitals

APPROVAL LETTER

Date: 13th July 2015
JREC Ref: 160/15

Name of Researcher: Dr Tafadzwa Tsikira
Address: University of Zimbabwe, Department of Community Medicine

Re: Factors Associated With The Development Of Diabetes Mellitus Among HIV Positive Patients Enrolled In Care At Parirenyatwa Hospital Of Clinic 2015.

Thank you for your application for ethical review of the above mentioned research to the Joint Research Ethics Committee. Please be advised that the Joint Research Ethics Committee has reviewed and approved your application to conduct the above named study. You are still required to obtain MRCZ approval and if required by the nature of your study, RCZ approval as well, before you commence the study.

- APPROVAL NUMBER JREC/160/15
- APPROVAL DATE: 13th June 2015
- EXPIRY DATE: 12th June 2016

This approval is based on the review and approval of the following documents that were submitted to the Joint Ethics Committee:

a) Completed application form
b) Full Study Protocol
c) Informed Consent in English and/or appropriate local language
d) Data collection tool version:

After this date the study may only continue upon renewal. For purposes of renewal please submit a completed renewal form (obtainable from the JREC office) and the following documents before the expiry date:

a. A Progress report
b. A Summary of adverse events.
c. A DSMB report

OHRP IRB Number: IORG 00008914
PARIRENYATWA GROUP OF HOSPITALS FWA: 00019350
• MODIFICATIONS:

Prior approval is required before implementing any changes in the protocol including changes in the informed consent.

• TERMINATION OF STUDY

On termination of the study you are required to submit a completed request for termination form and a summary of the research findings/results.

Yours sincerely

Dr N Madziva
For JREC Chairman

PAPERSHAINA GROUP OF HOSPITALS
CLINICAL DIRECTOR
PO. BOX CY198, CAUSEWAY
HARARE

4 JUL 2015
Annex 5: Institution permission letter

INSTITUTIONAL ETHICAL REVIEW BOARD REVIEW AND ENDORSEMENT REQUIRED

Statement from the Institutional Ethical Review Board:
The MRCZ will only accept for review and approval research proposals that have been found both scientifically and ethically acceptable by an Institutional Ethical Review Board (IERB) appointed and operating in accordance with the Guidelines on Institutional Ethical Review Boards. The acceptable IEB will be that from the Institution in which the research is to be conducted or one from the institution conducting the research. In the case of institutions without IERBs, investigators are advised to seek advice from the MRCZ Office.

We, the Institutional Ethical Review Committee established by

Joint Parirenyatwa Hospital and College of Health Sciences Committee
(Name of Institution conducting the research in which the research is to be conducted)
do certify that we have reviewed the research proposal titled

Factors Associated With The Development Of Diabetes Mellitus Among HIV Positive Patients Enrolled In Care At Parirenyatwa Hospital OI Clinic 2015

submitted by

Dr Tafadzwa Tsikira

We attest to the scientific and ethical merit of this study and the competency of the investigator(s) to conduct the project and do hereby recommend the proposal to the MRCZ for approval.

SIGNATURES

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<thead>
<tr>
<th>Signature</th>
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<tbody>
<tr>
<td>Ethics Committee representative</td>
<td>16/07/15</td>
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<tr>
<td>Name (Please Print)</td>
<td>Sr L Chiyaka</td>
</tr>
<tr>
<td>Signature: Head of Ethics Committee</td>
<td>16/07/15</td>
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<tr>
<td>(or other authorized signatory)</td>
<td>Professor M M Chizonga</td>
</tr>
<tr>
<td>Name (Please Print)</td>
<td>v+263 4 708149</td>
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<tr>
<td>Contact Tel. Number</td>
<td><a href="mailto:jrec@medsch.uw.ac.zw">jrec@medsch.uw.ac.zw</a>/jrec.office@gmail.com</td>
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<tr>
<td>E-mail address</td>
<td><a href="mailto:jrec.office@gmail.com">jrec.office@gmail.com</a></td>
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OFFICIAL STAMP OF INSTITUTION

*Institution includes Universities, Hospitals, Research Institutes or Companies.
Annex 7: Anti-plagiarism report

Anti-plagiarism report on dissertation

Details of Thesis

Title of Thesis: Co-morbidity of diabetes and HIV at Parirenyatwa ART Clinic, 2015

1. Author: Tafadzwa Tsikira
2. Programme: MPH
3. Faculty: College of Health Sciences
4. Supervisor: Prof. S. Ray

Report from Ephorus

Document title Tsikira_Final_Results_dibetes in HIV finale-1.docx
Submit date Fri 28 Aug 2015 03:19:58 PM CEST

1%

1% http://openaccess.sgu.ac.uk/1433/1/1744-8603-5-9.pdf

Interpretation of report

I considered the report and realized that the output from Ephorus reflected mainly the titles of references which cannot be altered.

Conclusion

In my opinion the student's research project, as analyzed by Ephorus, is free of plagiarism.

The student was informed of the Ephorus report and this is the final report.

J. January
Dept. of Com. Med.

Prof. Rusakaniko
Chair-Dept. of Com. Med.

Dr. Gilford T Hapanyengwi
Director Computer Centre