PREVALENCE OF DIABETIC RETINOPATHY AT PARIRENYATWA HOSPITAL

BY

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ABSTRACT

TITLE: Prevalence of diabetic retinopathy at Parirenyatwa Hospital

BACKGROUND: There is a global epidemic of diabetes mellitus. Diabetes mellitus causes a myriad of microvascular and macrovascular complications. Diabetic retinopathy is one of the main microvascular complications. It is preventable. However the extent of diabetic retinopathy in Zimbabwe is unknown.

METHODS: This was a cross-sectional study carried out on consenting participants, ≥ 18 years old at Parirenyatwa Group of Hospitals Diabetic Clinic. Retinopathy was assessed taking retinal photographs using an iExaminer® which is a device comprising of a Welch Allyn Pan-optic, an indirect ophthalmoscope attached to an iPhone 4 using an adapter. Retinopathy was classified as: No Retinopathy, Non-proliferative Diabetic Retinopathy and Proliferative Diabetic Retinopathy.

RESULTS: 150 study participants were recruited with a mean age of 52.6 ± 16.4 years. The prevalence of diabetic retinopathy was observed to be 38% (n = 57) with 30.7% (n = 46) having non-proliferative diabetic retinopathy and 7.3% (n = 11) with proliferative retinopathy. Significant risk factors for diabetic retinopathy were hypertension OR 2.8 (95% CI 1.23 – 6.42), p = 0.015; age O.R 1.02 (95% CI 1.00 -1.04), p = 0.048; Diet OR 4.71 (95% CI 1.80 – 12.34), p = 0.002 and Exercise OR 11.33 (95% CI 2.62 – 49.05), p = 0.001.

CONCLUSION: The prevalence of diabetic retinopathy was 38%. Diabetic retinopathy is therefore common and largely unrecognised. Regular and appropriate easy to use screening methods are highly recommended for early detection of diabetic retinopathy so as to reduce progressive visual impairment.
ACKNOWLEDGEMENTS

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- Special mention goes to Dr JC Mangwiro, Dr S Guramatunhu and Dr Woodward for interesting me with the idea of diabetes in general but in particular researching on diabetic retinopathy. I am grateful to Dr JC Mangwiro and the Zimbabwe Diabetes Association for loaning me ophthalmologic equipment used in this project for free.

DEDICATION

This work is specially dedicated to the following family members of mine:

My late grandparents Mr FF and Mrs E Maboreke Gone but not forgotten. I have stayed guided and motivated by the foundation you laid in me.

My parents Mr BN and Mrs GB Maboreke

My wife Tafadzwa and my two “bunnies” Tendekayi and Tamiranaishe whose love and patience motivated me throughout this project and my MMED training.

CONTENTS.................................................................PAGE
### ABSTRACT

2

### ACKNOWLEDGEMENTS

3

### TABLE OF CONTENTS

4

### LIST OF TABLES AND FIGURES

6

### LISTS OF ABBREVIATIONS

7

### 1. INTRODUCTION

8

#### 1.1 Justification

9

### 2. LITERATURE REVIEW

11

#### 2.1. COMPLICATIONS OF DIABETES MELLITUS

11

#### 2.2. DIABETES MELLITUS AND THE EYE

13

#### 2.3. EPIDEMIOLOGY OF DIABETIC RETINOPATHY

14

##### 2.3.1. Global view

14

##### 2.3.2. Retinopathy in Africa

16

#### 2.4. PATHOPHYSIOLOGY OF DIABETIC RETINOPATHY

18

#### 2.5. CLINICAL FEATURES OF DIABETIC RETINOPATHY

17

#### 2.6 NATURAL HISTORY OF DIABETIC RETINOPATHY

22

#### 2.7 DIAGNOSIS OF DIABETIC RETINOPATHY

24

##### 2.7.1. Ophthalmoscopy

24

##### 2.7.2. Digital stereoscopic retinal imaging

26

##### 2.7.3. Fluorescein angiography

27

##### 2.7.4. Novel uses of smart phones in ophthalmology

28

#### 2.8. PREVENTION AND TREATMENT OF DIABETIC RETINOPATHY

30

#### 2.9. SCREENING GUIDELINES FOR DIABETIC RETINOPATHY

34

#### 2.10. COMBATING DIABETIC RETINOPATHY

37

### 3. AIMS AND OBJECTIVES

39

### 5. STUDY QUESTION

39

### 6. STUDY HYPOTHESIS

39

### 7. RESEARCH METHODS

40
1. Table 1: Complications of diabetes…………………………………………..11
2. Table 2: Prevalence of diabetic complications……………………………12
3. Fig 1: Normal Retina and Non-proliferative diabetic retinopathy………19
4. Fig 2: Proliferative diabetic retinopathy……………………………………21
5. Fig 3: Optical coherence tomography: A. Diabetic macular edema-
   retinal thickening & large numerous cysts within the macula (arrows) B. Normal Retina………………………………………………………………………………21
6. Table 3: Eye examination schedule………………………………………….34
7. Table 4: Regional diabetes declaration blocs and their diabetes
   prevalence………………………………………………………………………37
8. Table 5: International Clinical Diabetic Retinopathy Disease Severity
   Scale……………………………………………………………………………41
9. Fig 4: Welch Allyn iExaminer®………………………………………………43
10. Table 6: Socio-demographic data……………………………………………47
11. Table 7: Clinical characteristics……………………………………………47
12. Table 8: Fundus photo findings……………………………………………50
13. Table 9: Diabetes retinopathy and duration of diabetes mellitus………50
14. Table 10: Diabetes retinopathy and age……………………………………50
15. Table 11: Diabetes retinopathy and hypertension………………………51
16. Table 12: Diabetes retinopathy and HBA1C……………………………51
17. Table 13: Diabetes retinopathy and Glucose……………………………52
18. Table 14: Univariate analysis of risk factors for retinopathy………..53

LIST OF ABBREVIATIONS
<table>
<thead>
<tr>
<th></th>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>ACCORD</td>
<td>Action to Control Cardiovascular Risk in Diabetes</td>
</tr>
<tr>
<td>2.</td>
<td>ADA</td>
<td>American Diabetes Association</td>
</tr>
<tr>
<td>3.</td>
<td>AGE</td>
<td>Advanced glycosylation products</td>
</tr>
<tr>
<td>4.</td>
<td>CI</td>
<td>Confidence Interval</td>
</tr>
<tr>
<td>5.</td>
<td>DCCT</td>
<td>Diabetes Complications and Control Trial</td>
</tr>
<tr>
<td>6.</td>
<td>DR</td>
<td>Diabetic Retinopathy</td>
</tr>
<tr>
<td>7.</td>
<td>DRS</td>
<td>Diabetic Retinopathy Study</td>
</tr>
<tr>
<td>8.</td>
<td>DRVS</td>
<td>Diabetic Retinopathy Vitrectomy Study</td>
</tr>
<tr>
<td>9.</td>
<td>ETDRS</td>
<td>Early Treatment of Diabetic Retinopathy Study</td>
</tr>
<tr>
<td>10.</td>
<td>EASD</td>
<td>European Association for the Study of Diabetes</td>
</tr>
<tr>
<td>11.</td>
<td>HBA1C</td>
<td>Glycated Haemoglobin</td>
</tr>
<tr>
<td>12.</td>
<td>IAPB</td>
<td>International Agency for the Prevention of Blindness</td>
</tr>
<tr>
<td>13.</td>
<td>NHNES</td>
<td>National Health and Nutrition Examination Survey</td>
</tr>
<tr>
<td>14.</td>
<td>NPDR</td>
<td>Non-proliferative diabetic retinopathy</td>
</tr>
<tr>
<td>15.</td>
<td>OR</td>
<td>Odds ratio</td>
</tr>
<tr>
<td>16.</td>
<td>VEGF</td>
<td>Vascular Endothelial Growth Factor</td>
</tr>
<tr>
<td>17.</td>
<td>WESDR</td>
<td>Wisconsin Epidemiologic Study of Diabetic Retinopathy</td>
</tr>
<tr>
<td>18.</td>
<td>WHO</td>
<td>World Health Organisation</td>
</tr>
<tr>
<td>19.</td>
<td>UKPDS</td>
<td>United Kingdom Prospective Diabetes Study</td>
</tr>
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1. INTRODUCTION
Diabetes mellitus is a chronic debilitating metabolic disorder that has reached epidemic proportions in the developed and developing world. Both prevalence and incidence of diabetes continues to rise inexorably with no region in the world spared. Diabetes poses the most important threat to public health in the 21st century consuming a disproportionate share of health care resources owing to its deleterious effects on the micro and macro vasculature with effects on every organ of the body.\textsuperscript{1}

Globally there is an increase in non-communicable diseases.\textsuperscript{2} The epidemic has affected Sub-Saharan Africa insurmountably as a result of urbanization, sedentary lifestyle combined with longevity, calorie rich diet, smoking, and environmental factors. Unfortunately diabetes is at the epicenter of this public health dilemma. In 2004, Wild suggested that the most important demographic change to the diabetes landscape across the globe was the increase in proportion of people more than 65 years of age.\textsuperscript{3} Obesity also increases the risk of developing diabetes by 80-100 times. Statistics from the International Diabetes Federation has estimated that the number of adults with diabetes in Africa will double in 20 years, from 12 million in 2010 to 24 million in 2030.\textsuperscript{4}

The bulk of disease burden amounting to 70% reside in low-income to middle-income countries and this negatively impacts the level of care.

Diabetes is a metabolic disorder characterized by hyperglycemia. Two forms of diabetes mellitus are recognized.
Type 1, previously called juvenile-onset or insulin-dependent diabetes, is characterised by cellular-mediated autoimmune destruction of the beta cells in the pancreas and usually leads to severe insulin-dependent diabetes. Type 2 is characterised by a range of disease from insulin resistance with relative insulin deficiency to predominantly an insulin secretory defect combined with insulin resistance.

Between 90-95% of all patients with diabetes have Type 2 diabetes.\(^5\)

1.1. Justification

Chronic hyperglycaemia induces multiple organ dysfunction and injury, which results in significant morbidity and mortality.

Diabetes retinopathy is one of the most disabling complications that can arise and is the basis for this study.

Zimbabwe is not spared from the diabetes mellitus epidemic and its related complications and in particular visual impairment. Type 2 Diabetes Mellitus is on the rise because of increasing obesity, high calorie rich diets, an aging population, and reduced physical activity due to industrialisation.

With dwindling financial resources across all health sectors a smart way to optimize a clinic visit seems logical.
This present study was aimed at carrying out an in-expensive, acceptable and reproducible point of care retinal exam and by so doing motivate for a roll out of fundus photography as a screening tool. Diabetic retinopathy is asymptomatic for a long time and hence patient attitudes towards routine screening program have been poor. In our setting rarely do patients get fundus examination in the general physician clinic or diabetes clinic. Patients are usually prompted to attend the local eye unit for a dilated fundus examination but in reality only a few with visual impairment attend. An attempt to redress the approach in diabetic eye screening is being sought in this study.
2. LITERATURE REVIEW

2.1 COMPLICATIONS OF DIABETES MELLITUS

Diabetes mellitus describes several diseases of abnormal carbohydrate metabolism that are characterised by hyperglycaemia due to absolute or relative insulin deficiency along with varying degrees of insulin resistance. Diabetes mellitus causes metabolic dysregulation and leads to acute and chronic complications. Diabetes ketoacidosis and hyperglycaemia hyperosmolar state are the two important acute diabetic emergencies. The chronic effects of diabetes mellitus affect multiple organs. The chronic complications are divided into vascular and non-vascular.

The vascular complications are further classified into microvascular and macrovascular.

Table 1: Complications of diabetes

<table>
<thead>
<tr>
<th>Microvascular</th>
<th>Macrovascular</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye disease</td>
<td>Coronary Heart Disease</td>
<td>Gastrointestinal</td>
</tr>
<tr>
<td>Retinopathy (nonproliferative/proliferative)</td>
<td>Peripheral artery disease</td>
<td>Genitourinary (Uropathy, sexual dysfunction)</td>
</tr>
<tr>
<td>Macular edema</td>
<td>Cerebrovascular disease</td>
<td>Dermatological</td>
</tr>
<tr>
<td>Neuropathy</td>
<td></td>
<td>Infectious</td>
</tr>
<tr>
<td>Sensory and motor (mono &amp; polyneuropathy)</td>
<td></td>
<td>Cataracts</td>
</tr>
<tr>
<td>Nephropathy</td>
<td></td>
<td>Glaucoma</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Periodontal disease</td>
</tr>
</tbody>
</table>
Deckert et al provided vital epidemiologic data when he followed 307 patients for 40 years from 1933 to 1973 and documented the cumulative prevalence of complications in patients with insulin dependent diabetes mellitus. (See Table 2)\textsuperscript{6}.

This study demonstrated that of all the complications attributable to diabetes mellitus, vision-threatening effects accounted for the highest complication rate of 30%.

<table>
<thead>
<tr>
<th>COMPLICATION</th>
<th>CUMULATIVE PREVALENCE %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual Impairment</td>
<td>14</td>
</tr>
<tr>
<td>Blindness</td>
<td>16</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>22</td>
</tr>
<tr>
<td>Stroke</td>
<td>10</td>
</tr>
<tr>
<td>Amputation</td>
<td>12</td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>21</td>
</tr>
<tr>
<td>Median survival after diagnosis of IDDM (yr)</td>
<td>36</td>
</tr>
<tr>
<td>Median age at death (yr)</td>
<td>49</td>
</tr>
</tbody>
</table>

In microvascular complications the patho-physiologic hallmark is driven by a chronic state of hyperglycaemia. Intracellular hyperglycaemia activates the enzyme aldose reductase, which drives the formation of sorbitol and subsequently reduces cellular Na\textsuperscript{+}-K\textsuperscript{+} ATPase.

Additionally, intracellular glucose can be converted to so-called “Amadori products” and these in turn can form advanced glycosylation end products (AGEs) which cross-link matrix proteins. This adds to microvasculature injury. The advanced glycosylation end products also interfere with the leukocyte response to infection.\textsuperscript{7}
2.2. DIABETES MELLITUS AND THE EYE

The end result of this metabolic dysregulation is injury to multiple organs and importantly vision-threatening complications. Diabetes mellitus is the leading cause of blindness between the ages of 20 and 75 in the United States. The finding that individuals with diabetes mellitus are 25 times more likely to become legally blind than individuals without diabetes mellitus highlights the gravity of this problem.

Diabetes causes visual impairment through early onset cataract formation and diabetic retinopathy. Diabetic retinopathy is a progressive disease of the retinal microvasculature. Cataract and diabetes retinopathy are the second and sixth leading cause of global visual impairment respectively.

Blindness is primarily the result of progressive diabetic retinopathy (D.R) and occurrence of clinically significant macular edema. The tragedy is that Type 2 DM and therefore diabetic retinopathy are avoidable. Early treatment and appropriate intervention in diabetic retinopathy may dramatically influence the prognosis of this condition.
2.3 EPIDEMIOLOGY OF DIABETIC RETINOPATHY

2.3.1 Global view

Diabetic retinopathy is on the World Health Organisation (WHO) list of eye conditions, which can be partly prevented and treated. It is recommended that eye care services for diabetic patients be incorporated into the strategic VISION 2020 national plans. VISION 2020 is a global initiative for the elimination of avoidable blindness, a joint program of the World Health Organisation and International Agency for the Prevention of Blindness (IAPB) with an international membership of non-governmental organisations, professional associations, eye care institutions and corporations.\(^\text{10}\) Vision 2020 aims to eliminate avoidable blindness by the year 2020. Estimates by World Health Organisation reports the prevalence of blindness in all age groups as 1%, and 9% among people aged 50 years and above.\(^\text{11}\)

All WHO member countries are encouraged to develop accessible and affordable screening programs for diabetic retinopathy. Screening programs should aim for retention in care. The key message here is that screening for diabetic retinopathy prevents blindness and is more cost effective.

Prevalence of retinopathy according to the International Diabetes Federation from 33 countries showed large variations, from as low as 10% in Norway to as high as 61% in South Africa and from 1.5% in African Americans in the United States of America to 31% in China.\(^\text{12,13}\)
There are not many good quality studies with good design in respect of study characteristics and methodology to make clear comparisons. In 15 of 23 studies reported by the International Diabetes Federation in developing countries, the prevalence of diabetes retinopathy was over 35% (93 million people), while the extent of vision threatening diabetes retinopathy is 10.2% (28 million people).  

In the American National Health and Nutrition Examination Survey (NHINES, 2005 – 2008), 28.5 % of diabetic patients had some degree of diabetes retinopathy and 4.4% had Vision Threatening Diabetes Retinopathy.  

The disease burden from diabetic retinopathy is alarming at the time of diagnosis of diabetes mellitus as demonstrated by several studies, with Mbanya J et al showing a rate of 21-25% for type 2 diabetes mellitus and 9.5% in type 1 diabetes mellitus.  

2.3.2 Diabetes retinopathy in Africa

Africa has the highest prevalence of blindness in the world, with global estimates reaching 45 million people. The overall prevalence of diabetic retinopathy varies from 9-55% depending on the duration of diabetes and glycaemic control.  

To achieve an African perspective of diabetic retinopathy and to zero in on specific regions in the continent, a wide literature search was done and
targeted studies were appraised from the North in Egypt, from the East in Kenya and the South in Tanzania and South Africa.

In the Northern Africa, in a study in 2011 Macky TA et al reported the prevalence of diabetic retinopathy of 20.5% at Cairo University and Sixth of October University hospitals. This was a large study with 1 325 participants. An important finding was that most patients were not aware of the hazards of diabetes mellitus to the eye. The prevalence of diabetes retinopathy was significantly higher in females (22% vs 17%, p <0.05). Recommendations in this study were consistent with various international guidelines on screening for retinopathy. Regular screening was recommended as part of standard of care since it provided for early detection of diabetic retinopathy and provision for laser photocoagulation, which is known to reduce the risk of visual loss in these patients.\textsuperscript{18}

In Eastern Africa, in a population based survey (n= 4414) in Kenya, Nakuru et al identified prevalence of “any DR” of 35.9%(95% CI: 29.7, 42.6) and of severe non-proliferative diabetic retinopathy or proliferative diabetic retinopathy of 13.9% (95% CI: 10.0, 18.8) in 277 people with diabetes mellitus.\textsuperscript{4,19}

In a large community clinic in South Africa, Kalk WJ et al found that at the time of diagnosis 21-25% of type 2 diabetes patients and 9.5% of type 1 diabetes mellitus patients had diabetes retinopathy. Overall prevalence
stratified according to ethnicity was more or less similar at 37% in Africans, 41% in Europeans and 37% in Indians.  

A population based study in 2012 done in Cape Town, South Africa on visual loss using World Health Organisation criteria identified diabetic retinopathy as the cause of 8% blindness and 11% of severe visual loss in persons ≥ 50 years.

To the East of Zimbabwe in Tanzania, Lutale et al in 2009 showed a prevalence of diabetic retinopathy of 18.1% in a hospital based study. The study was conducted at Muhimbili Hospital, which is the main national referral and university teaching hospital for Tanzania. Two hundred and twenty seven patients were recruited consecutively in an outpatient diabetic clinic. Their conclusion was that diabetic retinopathy had correlation with duration of diabetes, blood pressure control and albuminuria. The study setting and participants had similar characteristics to our own setting here at Parirenyatwa Hospital.

There is a tendency to record all forms of visual impairment into one category regardless whether it is due to diabetic retinopathy or rectifiable causes such as cataract.

Macheka BM in his MMED (Ophthalmology) thesis showed a prevalence of diabetic retinopathy of 27.5% in a diabetic clinic setting in 1996. The exact extent of diabetes retinopathy in Zimbabwe is unknown.
2.4. PATHOPHYSIOLOGY OF DIABETIC RETINOPATHY

The retina is one of the most metabolically active organs in the body and is particularly susceptible to substrate imbalance or ischemia.\textsuperscript{22}

Vision loss in diabetes retinopathy may be secondary to macula edema, hemorrhage from new vessels, retinal detachment or neovascular glaucoma. Tragically the vast majority of patients who develop diabetes have no symptoms until the very late stages, by which time it is too late for effective treatment. This underscores the importance to screen patients with diabetes regularly for the development of retinal disease. The development of retinopathy depends on the duration of the disease.\textsuperscript{18 23 24}

Diabetes mellitus damages retinal capillaries through prolonged exposure to hyperglycemia. This leads to loss of pericyte cells and tight junctions between endothelial cells causing leakage from capillaries; resulting in retinal edema, capillary closure, and ischemia with production of Vascular Endothelial Growth Factor (VEGF). An edematous or ischemic retina loses its function leading to visual impairment if the central retina or macula is involved. The combined effect of this process is proliferative retinopathy and diabetic maculopathy.\textsuperscript{4 25}

The early feature in the pathogenesis of diabetic retinopathy is the development of small microaneurysms, with a diameter of less than 100 micrometers arising from the terminal capillaries of the retina. Dot and blot haemorrhages appear when erythrocytes escape from the microaneurysms.
Diabetic retinopathy is classified into two stages: nonproliferative and proliferative, named for the absence or presence of abnormal new blood vessel formation emanating from the retina.

Non-proliferative diabetic retinopathy consists of a display of nerve-fiber infarcts described as cotton wool spots, intra-retinal hemorrhages and hard exudates, and microvascular abnormalities including microaneurysms, occluded vessels, dilated and tortuous vessels primarily in the macula and posterior retina. Visual loss in non-proliferative diabetic retinopathy is primarily through the development of macular edema. These findings are well illustrated below in Fig 1 on the right side. The first image demonstrates a normal retina.

Figure 1: Normal Retina and Non-proliferative diabetic retinopathy
Proliferative Retinopathy as shown on Fig 2\textsuperscript{26} characterized is by presence of neo-vascularisation arising from the disc and or retinal vessels and consequences of this neo-vascularisation, including pre-retinal and vitreous hemorrhage, subsequent fibrosis and traction retinal detachment. Proliferative diabetic retinopathy may develop in the setting of prior or coexisting severe non-proliferative changes, or may arise without substantial non-proliferative diabetic retinopathy.

**Figure 2: Proliferative diabetic retinopathy**
Macula edema, Fig 3\textsuperscript{26}, can occur at any stage of diabetic retinopathy and is defined as retinal thickening and edema involving the macula. It is visualised by a specialised fundus exam with stereoscopic viewing, Fluorescein angiography and most directly by optical coherence tomography.

**Figure 3: Optical coherence tomography:** A. Diabetic macular edema- retinal thickening & large numerous cysts within the macula (arrows) B. Normal Retina

Duration of diabetes mellitus and degree of glycaemic control are the best predictors of the development of retinopathy; hypertension is also a risk factor.\textsuperscript{18,23–25}

Non-proliferative retinopathy is found in many individuals who have diabetes mellitus for > 20 years: 25% incidence with 5 years, 80% incidence with 15 years of type 1 diabetes mellitus.\textsuperscript{4}
2.5. CLINICAL FEATURES OF DIABETIC RETINOPATHY

Diabetic retinopathy has a very long latent asymptomatic phase where patients do not report anything.

In the advanced stages, patients may experience symptoms that include floaters, blurred vision, distortion, and progressive visual acuity loss.

2.6. NATURAL HISTORY OF DIABETIC RETINOPATHY

Several studies have provided evidence that sight-threatening diabetic retinopathy has a recognisable latent and early symptomatic stage.\textsuperscript{27,24,28}

The Wisconsin Epidemiologic Study of Diabetic Retinopathy (WESDR) was a landmark study outlining the natural history of retinal disease in diabetic patients. The WESDR began in 1979 and has generated over 230 reports. Among younger-onset patients with diabetes in the WESDR, the prevalence of any retinopathy was 8% at 3 years, 25% at 5 years, 60% at 10 years, and 80% at 15 years. The prevalence of proliferative diabetic retinopathy was 0% at 3 years and increased to 25% at 15 years.\textsuperscript{24}

In a longitudinal analysis of the WESDR study in 1984 and 1989, Klein reported that for 154 patients with type 1 diabetes mellitus aged 30 years and above with no diabetes retinopathy at first visit, 47% developed diabetic retinopathy after 4 years.
In the other subgroup of patients with type 1 diabetes aged 30 years and above with no proliferative diabetes retinopathy at baseline, 7% developed proliferative diabetes retinopathy after 4 years and worsening of diabetic retinopathy in 34%. For the type 2 group that constituted 486 patients, with no proliferative diabetic retinopathy at baseline, 2% developed proliferative diabetes retinopathy after 4 years and exacerbation of diabetic retinopathy in 25%.

The date of onset of type 1 diabetes mellitus can be ascertained precisely and this has provided data on the chronology and course of diabetic retinopathy. In the group of patients with type 1 diabetes mellitus, diabetic retinopathy does not appear until after three to five years. After seven years approximately 50% of patients with type 1 diabetes mellitus have some degree of retinopathy detectable by stereoscopic fundus photography. Stereo techniques maximises photographic visual information by detailing the level of retinal involvement. The depth-enhanced images are useful in detecting subretinal neovascularisation and clinically significant macula oedema.
Diabetic retinopathy can be diagnosed through a comprehensive eye examination. This involves a good history and evaluation of the retina and macula.

The following steps are taken:

- Patient history to determine complaints of visual impairment
- Visual acuity measurements to determine the extent of central vision impairment
- Refraction if required
- Measurement of the intraocular pressure to evaluate for glaucoma
- Evaluation of the ocular structures
- Retinal examination via the following modalities: dilated direct fundoscopy/ophthalmoscopy, retinal photography and/or tomography, Fluorescein angiography.

2.7.1 Ophthalmoscopy

This is examination of the ocular fundus using an ophthalmoscope or fundoscope, which has been the most common and standard instrument. This is a monocular viewer with various settings that allow focusing and adjustment of the light source to accommodate the viewer and to evaluate various features of the fundus. Ophthalmoscopy requires a fair amount of training. Generally the primary care physician is not well skilled to perform direct
fundoscopy and the accuracy is low. In a study by O’Hare JP et al showed the limitations of direct fundoscopy. One thousand and ten patients in a primary care setting were examined by ophthalmoscopy by general practitioners or opticians without fundal photographs and again with photographs, and assessments were compared to those of an ophthalmologist. Two hundred and five patients (20.5%) had diabetic retinopathy that was detected by an ophthalmologist and those with proliferative diabetic retinopathy requiring referral accounted for 49 patients (4.9%). The sensitivity by the general practitioners and opticians for referrable retinopathy was 65%, and improved to 84% with retinal photographs. This study showed the limitations of direct ophthalmoscopy and why it is important to combine fundal photography with specialist review in addition to direct ophthalmoscopy.29

In another study, Harding SP et al, through a community-based study analysed the use of fundus photography vs ophthalmoscopy. Sensitivity of detection of eye disease by photography was 89% (95% Confidence Interval 80% to 98%), significantly better than for direct ophthalmoscopy (65% CI 51% to 79%). The recommendation from the study was that since high sensitivity is essential for an effective screening program, a photographic method should be considered in most screening programmes.30
2.7.2. Digital stereoscopic retinal imaging

The gold standard for the detection of diabetic retinopathy consists of a 30-degree stereoscopic photography of seven fields on colour film, as developed for the Early Treatment of Diabetic Retinopathy Study – Classification of Diabetic Retinopathy.\(^3\)

Carmichael T R et al undertook an important study to establish whether an experienced endocrinologist could screen accurately for diabetic retinopathy using a mydriatic 60° fundus photographs compared with a reference standard, viz. the combined highest scores of two ophthalmologists. The prevalence of retinopathy was approximately 30%. There was 97% agreement with the standard reference and this validated the screening strategy conducted by a non-ophthalmologist.\(^3\)

This has a sensitivity and specificity for the detection of diabetic retinopathy that is superior to direct and indirect ophthalmoscopy by ophthalmologists\(^3\). The use of digital retinal photos can allow clinicians to keep up with the rising diabetes epidemic. Trained photographers, trained readers and telemedicine can provide the required skill set to screen for diabetic retinopathy.

In a report by the American Academy of Ophthalmology in 2004, Williams GA, et al analysed peer-reviewed literature on single field fundus photography as a screening tool to identify diabetic retinopathy for referral for further ophthalmic care. Williams analysed literature from 1968 to 2001 including the Cochrane Library, yielding 145 articles. The panel of reviewer's
selected 32 articles as level I evidence and 4 were classified as level II evidence. Evidence from level I studies demonstrates that as a tool to detect vision-threatening retinopathy, single field fundus photography interpreted by trained readers has a sensitivity ranging from 61% to 90% and specificity ranging from 85% to 97% when compared to the gold standard reference of stereophotographs of 7 standard fields. In a study by Joannou et al, retinal photography compared to ophthalmologist’s assessment, had a sensitivity of 93% and a specificity of 89% for any retinopathy, and 100 and 75%, respectively for severe retinopathy. In another well-designed study Boucher et al compared the use of nonmydriatic cameras and the standard seven stereoscopic 30 degrees fields. There was substantial agreement in the grading of retinopathy with nonmydriatic camera imaging and with the seven standard stereoscopic photography. An additional benefit was the cost effectiveness of this method.

2.7.3. Fluorescein angiography
This test evaluates the blood circulation of the retina and choroid using fluorescent dye and a specialised camera. This technique is used for retinal or choroidal vascular diseases such as diabetic retinopathy, age-related macular degeneration, hypertensive retinopathy and vascular occlusions. In diabetic retinopathy, fluorescein angiography identifies extent of ischaemia, the location of microaneurysms, the presence of neovascularisation and the extent of macula oedema.
2.7.4. Novel uses of smart phones in ophthalmology

Smart-phones are now valuable tools in the field of ophthalmology. In a survey of mobile phone ownership, 99% of health professionals own a mobile phone with 81% of these being a smart-phone.\textsuperscript{36,37}

Mobile phones and the Internet have arguably been the two most exciting and innovative developments in this millennium. Smart-phones have evolved far and beyond their initial design of voice and text to feature extended functions such as electronic references, provide advanced computing, geo-positioning and digital photography. All smart-phones have great utility in the field of medicine and ophthalmology.

However the iPhone (Apple Inc, Cupertino, CA) stands out as the market leader because of its vast interest from third party developers who partner to incorporate their add-on software.

Smart-phones are indeed smart clinical “tool boxes”. At the press of a button one can access clinical evaluation algorithms and educational tools that enhance the patient-doctor experience.

A near vision card, Amsler grid, Ishihara color plates, and a pupil gauge are some examples of simple to use applications that are readily accessible on a smart-phone.
In summary, smart-phones can achieve the following:

- Patient assessment tools
- Patient education/ visual aids
- Health care profession education and reference
- Patient record/ administrative tools
- Multiple add-on functionalities

The utility of fundus photography can never be overstated. Fundus photos are useful for capturing baseline characteristics, documenting the course of the disease, record keeping, patient/client education and afford specialist care to previously inaccessible areas through telemedicine and telehealth.

Telemedicine is use of telecommunication for diagnostic and therapeutic intervention and Telehealth is telecommunication to promote health. This evolution in medicine has allowed bridging the barrier to retinopathy care.

Fundus photography is simple, accessible and cost effective. Commercially available fundus cameras are very expensive and out of reach for many public funded health care centres. This barrier can be breached by using a reasonably well priced gadget which incorporates smart phones to be attached to the Welch Allyn® panoptic indirect ophthalmoscope (IMT, 2011).

Using the built in camera on a smart phone it is possible to record high-resolution fundus images.
Several multicentre randomized controlled trials demonstrated that diabetic retinopathy could be prevented.

In the Diabetes Control and Complications Trial (DCCT) involved 1,441 subjects with type 1 diabetes, ages 13-39 years, at 29 medical centres in the United States and Canada. Study participants had either no disease or early diabetic or early diabetic retinopathy and were randomized to either intensive blood glucose control (mean A1C 7.2%) or conventional blood glucose control (mean A1C 9.1%). The study demonstrated that intensive blood glucose control reduced the risk of progression of diabetic retinopathy by 54%, reduced the development of severe non-proliferative diabetic retinopathy or proliferative diabetic retinopathy by 47%, reduced the need for laser surgery by 56% and reduced the risk of diabetic macular oedema by 23%.\(^\text{3839}\)

The United Kingdom Prospective Diabetes Study (UKPDS) confirmed the protective effect of intensive blood glucose control in patients with type 2 diabetes mellitus and also evaluated the effect of hypertension. A total of 1,148 patients with type 2 diabetes mellitus and hypertension were enrolled and treated with either an angiotensin-converting enzyme inhibitor (captopril) or a beta-blocker (atenolol).

Patients with a tight blood pressure control (<150/85mmHg) compared to patients with less tightly controlled (<180/95) were found to have a 37% risk
reduction in microvascular changes, 34% risk reduction in the need for laser
treatment, and 47% risk reduction in decreased vision.\textsuperscript{4041}

On the basis of the findings from ACCORD (Action to Control Cardiovascular
Risk in Diabetes study) and other studies, the American Diabetes Association
and the European Association for the Study of Diabetes (EASD) issued a joint
statement emphasising patient-specific treatment of hyperglycaemia in
persons with type 2 diabetes mellitus.

The mainstay for any type 2 diabetes treatment programme is a combination
of diet, exercise and education. In the absence of contraindications,
Metformin is the preferred first-line drug.

Most guidelines recommend an individualised approach.
A reasonable glycaemic goal for most patients is a glycated haemoglobin
(HBA1C) ≤ 7% in non-pregnant adults to reduce microvascular and macro-
vascular disease complications (Level B). A slightly liberal goal of
HBA1C ≤ 8% is acceptable for those with previous severe hypoglycaemia,
limited life expectancy, advanced microvascular or microvascular
complications, and long-standing difficult-to-control diabetes mellitus despite
appropriate education and multiple agents including insulin (Level B).

A target blood pressure of less than 140/90mmHg is desirable.\textsuperscript{42}
Mohamed Q et al, in a meta-analysis of Management of diabetic retinopathy in 2007 further showed that tight glycaemic and blood pressure control remains the cornerstone in the primary prevention of diabetic retinopathy.

The study ACCORD provided further evidence on the value of escalating tight glycaemic and blood pressure control. From this study, a subset of 2856 adults was analysed. Progression of diabetic retinopathy was defined by a three or more step progression on the Early Treatment Diabetic Retinopathy Study (ETDRS) Severity Scale, or the development of proliferative retinopathy requiring photocoagulation or vitrectomy. The results showed a reduction in the proportion of patients with progression of retinopathy in the intensive glycaemic therapy group.

Once diabetic retinopathy is established, additional treatment strategies using surgical and pharmacological interventions are required. The overall goal is to maximise vision preservation and minimise side effects.

Patients with mild and moderate non-proliferative diabetic retinopathy are generally not treated but a strategy of intensifying glycaemic control and blood pressure control is instituted. However in the setting of clinically significant macular oedema, the use of laser treatment or intra-vitreal Anti-Vascular Endothelial Growth Factor (VEGF) is used. Examples of Vascular Endothelial Growth Factor inhibitors are pegaptanib, bevacizumab, ranibizumab, and aflibercept.
Patients with severe and very severe proliferative diabetic retinopathy are treated with pan-retinal photocoagulation rather than pharmacological treatment. (Grade 1B)\textsuperscript{43}

Photocoagulation was successfully introduced in 1959 by Meyer-Schwickerath and indeed revolutionised treatment of diabetic retinopathy. This procedure is used to finely cauterise ocular blood vessels and this abates diabetic retinopathy.

Landmark clinical trials such as Diabetic Retinopathy Study (DRS) and the Early Treatment Diabetic Retinopathy Study (ETDRS) demonstrated that effective laser photocoagulation treatment of diabetic retinopathy could reduce vision loss by 90%.

For patients with severe proliferative diabetic retinopathy with vitreous haemorrhage and/ or traction involving the retina, expeditious vitrectomy is advised. (Grade 1 B)\textsuperscript{44,45} This recommendation came from The Diabetic Retinopathy Vitrectomy Study (DRVS) that showed that there was benefit to early vitrectomy (surgical removal of vitreous) in severe proliferative diabetic retinopathy in patients with type 1 diabetes.\textsuperscript{46}

Laser treatment ablates the peripheral retina with 1000 to 5000 spaced burns to reduce the amount of ischaemic retina and the Vascular Endothelial Growth Factor it produces. Gentle laser is used for macular oedema.
Additional strategies continue to be explored towards preventing diabetes retinopathy through the understanding of the underlying pathophysiology. It being a vascular phenomenon, aspirin was also evaluated in the Early Treatment of Diabetes Retinopathy Study to see if it was protective. The results showed no benefit in retarding or altering the course of diabetes retinopathy. \(^{47}\)

### 2.9 SCREENING GUIDELINES FOR DIABETIC RETINOPATHY

Recommended eye examination schedule for patients with diabetes is shown below in table 3. \(^{48}\)

<table>
<thead>
<tr>
<th>Patient group</th>
<th>Recommended first examination</th>
<th>Minimum routine follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type 1 diabetes</strong></td>
<td>Within 5 years after diagnosis of diabetes once patient is age 10 years or older</td>
<td>Yearly, if retinopathy present. Every 2 years if there is no evidence of retinopathy</td>
</tr>
<tr>
<td><strong>Type 2 diabetes</strong></td>
<td>At the time of diagnosis</td>
<td>As above</td>
</tr>
<tr>
<td><strong>Pregnancy in preexisting diabetes</strong></td>
<td>Prior to conception and during the first trimester. Counsel on the risk of development and/or progression of retinopathy.</td>
<td>Close follow-up throughout pregnancy and one year postpartum.</td>
</tr>
</tbody>
</table>

In support of this, Bek et al showed that if one screens for type 2 diabetes, the prevalence of diabetic retinopathy in screen positive patients (6.8%) was much lower than the prevalence in the known population of people with diabetes. 49

Studies have shown that screening programmes using digital retinal images taken with or without dilatation may enable early detection of diabetic retinopathy and permit timely referral for ophthalmologic care.5051 It was also noted that there was a positive association between participating in a photographic screening programme and subsequent adherence to receiving ophthalmologic care.52

Studies with a cost-benefit analysis on diabetic retinopathy have been done and to illustrate the cost effectiveness for a screening for programme, in a large cohort of 6 598 cases of diabetic retinopathy Savolainen EA, et al showed that 61% of patients had bilateral diabetic retinopathy and 20% required photocoagulation. This represented a large number of patients requiring treatment and more so at a significant cost. The key outcome and recommendation from this study was that it is cheaper to prevent diabetes retinopathy, but once established it was further cheaper to treat the diabetic retinopathy than to look after a blind person.53
Africa is a complex place with inherent socio-economic problems and as such barriers to diabetic retinopathy care exist, notably:

1. Lack of ophthalmologists
2. A few ophthalmologists with training and experience in management of diabetic retinopathy
3. A few number of opticians and ophthalmic clinical officers to perform opportunistic screening; commercial opticians are only accessible to the wealthy
4. Opticians and ophthalmic ocular officers with inadequate training in fundoscopy
5. Inadequate referral systems from primary to secondary care and from medical departments to ophthalmic services
6. Non-existent systematic screening programs
7. Limited access to imaging technology including fluorescein angiography and optical coherence tomography
8. Lack of treatment infrastructure including lasers and laser maintenance
9. Lack of national policies and low government priority
2.10. COMBATING DIABETIC RETINOPATHY

A strategic approach in combating diabetes retinopathy has been adapted by various regional blocs. Table 4 shows the regions that have made a diabetic declaration and estimated prevalence of diabetes mellitus.

Table 4: Regional diabetes declaration blocs and their diabetes prevalence

<table>
<thead>
<tr>
<th>REGIONAL DIABETES DECLARATION</th>
<th>PREVALENCE OF DIABETES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes Declaration &amp; Diabetes strategy for Africa$^{54}$</td>
<td>3.1% adults</td>
</tr>
<tr>
<td>Saint Vincent Declaration in Europe$^{55}$</td>
<td>7.8% adults</td>
</tr>
<tr>
<td>Eastern Mediterranean Region$^{56}$</td>
<td>15-25%</td>
</tr>
<tr>
<td>Pan American Health Organization$^{57}$</td>
<td>10-15% adults</td>
</tr>
<tr>
<td>American Diabetes Association$^{52}$</td>
<td>7% ≥20years</td>
</tr>
</tbody>
</table>

All these regional bodies have similar objectives, namely, to advocate for the early detection, treatment and prevention of diabetes and its complications. The economic impact of diabetes to Africa is significant and is rising rapidly. Kirigia et al estimated that the total economic cost, direct and indirect, of diabetes in WHO Africa region in 2000 was US$67 billion: equivalent to US8 836 per person with diabetes per year.$^{58}$

The burden of diabetes and its complications is borne predominantly by the working age population and is the commonest cause of blindness in this group.
Analyses from clinical trials show that the treatment for diabetic retinopathy may be 90% effective in preventing severe vision loss using current therapeutic treatment strategies.\textsuperscript{47}

Primary care physicians rarely refer patients for ophthalmic care despite available effective treatments.

There is good quality evidence from resource rich settings that an integrated diabetes retinopathy-screening program works.\textsuperscript{4,11} Adopting these strategies to the context of Sub-Saharan Africa and more specifically to Zimbabwe can provide effective and comprehensive management of diabetic retinopathy.
3. AIMS AND OBJECTIVES

Primary objective
- To determine the prevalence of diabetic retinopathy in patients at Parirenyatwa Group of Hospitals attending follow-up in the diabetic clinic.

Secondary objectives
- Determine the risk factors of developing diabetic retinopathy
- To determine the pattern of diabetes retinopathy and visual impairment in diabetes patients
- Determine the level of diabetes control.
- Determine the degree of diabetes treatment optimisation.

5. STUDY QUESTION

What is the prevalence of diabetes retinopathy in patients attending the diabetes clinic at Parirenyatwa Hospital?

6. STUDY HYPOTHESIS

Null hypothesis:
In a cross-sectional study of consenting diabetes participants attending the diabetes clinic the prevalence of diabetes retinopathy will be \( \leq 18.6\% \).
Alternative hypothesis:
In a cross-sectional study of consenting diabetes participants attending the diabetes clinic the prevalence of diabetes retinopathy will be ≥18.6%.

(18.6% was the prevalence of diabetic retinopathy found by Lutale J K et al in a similar study in Tanzania)

7. RESEARCH METHODS

7.1. Study design
Cross-sectional study

7.2. Study setting
The study was conducted at Parirenyatwa Group of Hospitals. Parirenyatwa Group of Hospitals was established, as a small hospital in 1890 and grew over the millennium and to date comprises of 4 complexes: The Main Complex, Sekuru Kaguvi Eye Hospital, Mbuya Nehanda Maternity Home and Annex Psychiatry Unit. The hospital comprises of 1800 beds. The hospital is affiliated to the University of Zimbabwe and is the premier teaching and research facility for various healthcare programmes.

The study setting was in the diabetes outpatient clinic. The diabetic clinic at Parirenyatwa hospital is run once a week and attends to an average of 30 patients per clinic. Patients are referred from various services within the hospital and from external healthcare facilities including primary care facilities.
and private general practitioners. A mixture of personnel run the clinic, which comprises of junior doctors, senior house officers, registrars, dieticians and a dedicated Specialist Consultant Physician, who provides overall supervision. Unfortunately there is no registry for patients and therefore it is difficult to ascertain the exact number of patients who attend this clinic. An estimate provided by the medical records department suggests a figure not exceeding 450 patients. The majority of attending patients reside in Harare.

**7.3. STUDY PARTICIPANTS AND PROCEDURES**

Consecutive patients attending the diabetic clinic were recruited if they met the inclusion criteria, outlined below. Diabetes was defined based on the 1999 classification published by WHO\(^{59}\), while diabetic retinopathy was defined by modifying the International Clinical Diabetic Retinopathy Disease Severity Scale shown on Table 5.

**Table 5: International Clinical Diabetic Retinopathy Disease Severity Scale**

<table>
<thead>
<tr>
<th>Proposed Disease Severity Level</th>
<th>Observed findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>No apparent diabetic retinopathy</td>
<td>No abnormalities</td>
</tr>
<tr>
<td>Non-proliferative diabetic retinopathy</td>
<td>Microaneurysms, dot &amp; blot haemorrhages</td>
</tr>
<tr>
<td>Proliferative DR</td>
<td>1 or more of the following:</td>
</tr>
<tr>
<td></td>
<td>-Definite neovascularisation</td>
</tr>
<tr>
<td></td>
<td>-Preretinal or vitreous hemorrhage</td>
</tr>
</tbody>
</table>

Patients attending the diabetes clinic were recruited after they had consulted the physician in the diabetic clinic and after providing written informed consent to participate in the study.
Demographic data was recorded and medical data extracted from the outpatient booklet. The following characteristics were recorded:

1. Personal information: age, sex, and highest education attained
2. Medical history: duration of diabetes and co-existence of other chronic illnesses such as hypertension
3. Drug History
4. Glucometer reading during the visit
5. Laboratory data if available such as HBA1C of less than three months
6. Level of planned physical exercise
7. Dietary behaviour and social history
8. Fundus photos of each eye were captured using a Welch Allyn panoptic iExaminer ®. See Fig 4.
9. Blood pressure during the visit: two blood pressure readings were done, one on each arm. The reading from the right arm was recorded if there was no significant variation, that is, within 5mmHg for both systolic and diastolic readings.

7.4. About the Welch Allyn iExaminer

Retinal images were captured using the Welch Allyn iExaminer, shown below in Fig 4. The Welch Allyn iExaminer is an ophthalmic camera that is used to capture images of the eye as seen through an iPhone 4 and a panoptic device. It comprises of an adaptor, an iPhone 4 or 4S and a software application.
The software application allows the user to capture, store, send and retrieve images of the eye as seen through the Panoptic.

**Figure 4: Welch Allyn iExaminer**

![Welch Allyn iExaminer](image)

The developers of this ophthalmic camera performed verification and validation tests to ensure expected performance of the Welch Allyn iExaminer and compliance to applicable standards. Non-clinical tests confirm that the Welch Allyn iExaminer compares favourably to other validated devices as approved by the Food and Drug Administration in terms of technology, intended use and indications for use.\(^6^0\) The iExaminer has an inherent advantage of being able to electronically send / transfer images to other Information Technology Equipment via email, wirelessly or Bluetooth.
7.5. Inclusion criteria

- Diabetic patients attending the out patient diabetic clinic
- Patient above 18 years or above

7.6. Exclusion criteria

- Patients with external eye disease obscuring retinal visualisation

7.8. Sample size

The sample size was calculated using this sample size formula:

\[ n = \left( \frac{Z^2 \times P (1 - P)}{e^2} \right) \]

\( Z \) = value from standard normal distribution corresponding to desired confidence level (\( Z = 1.96 \) for 95% Confidence Interval)

\( P \) is expected true proportion

\( e \) is desired precision

The hypothesized prevalence of diabetic retinopathy is 18.6% as found by Lutale J K\textsuperscript{61} et al in a similar study. The desired statistical power in this calculation was 80% at a 5% significance level. The minimum sample size determined to achieve this was 233 participants.
7.8. Statistical analysis

Statistical analysis was done using Epi Info™ 7. Means and standard deviations were generated for normally distributed variables and inter-quartile ranges were used on asymmetrical data. Statistical significance was assessed using the student t-test and the median test was used on asymmetrical data. Univariate Logistic Regression was used to assess the association between the dependent variable, which is presence of diabetic retinopathy, and associated factors. Variables with p-value less than 0.05 were significant, while those above were not. Odds ratio with their Confidence Intervals were generated and used to explain the risk factors.

7.8. Data management

The data collected was recorded onto data collection sheets (Appendix 1). Each participant was allocated an identity number and his or her true identity was concealed. Epi Info™ 7 was used to electronically manage the data.

7.9. Ethical considerations

The Joint Research Ethics Committee for the University of Zimbabwe, College of Health Sciences and Parirenyatwa Group of Hospitals granted approval for this study. Patients were individually provided with detailed information regarding the objectives and procedures of this study and why this study was important for both the patient and the researcher. It was explained to the
patient that this was a practice improving study and expanded our knowledge on diabetes research. The benefit to the patient was that of being afforded a good quality retinal exam and referral to halt any potentially vision-threatening damage if detected.
8. RESULTS

The desired sample size could not be achieved because of the limited number of patients attending the diabetes clinic. By the third month, study participants recruited earlier were turning up for review. Out of a desired sample size of 233 participants attending the diabetic clinic, 150 (64%) participants were recruited and analysed in this study. The socio-demographic data is shown in Table 6.

Table 6 Socio-demographic data (N=150)

<table>
<thead>
<tr>
<th>CHARACTERISTIC</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>GENDER</td>
<td>N (%)</td>
</tr>
<tr>
<td>Male</td>
<td>43 (28.7)</td>
</tr>
<tr>
<td>Female</td>
<td>107 (71.3)</td>
</tr>
<tr>
<td>AGE in years (Mean ± sd)</td>
<td>52.6 ± 16</td>
</tr>
<tr>
<td>LEVEL OF EDUCATION</td>
<td>N (%)</td>
</tr>
<tr>
<td>None</td>
<td>3 (2)</td>
</tr>
<tr>
<td>Primary</td>
<td>51 (34)</td>
</tr>
<tr>
<td>Form 2</td>
<td>24 (16)</td>
</tr>
<tr>
<td>Ordinary Level</td>
<td>64 (42.7)</td>
</tr>
<tr>
<td>Advanced Level</td>
<td>3 (2.0)</td>
</tr>
<tr>
<td>Tertiary</td>
<td>5 (3.3)</td>
</tr>
<tr>
<td>EXERCISE</td>
<td>N (%)</td>
</tr>
<tr>
<td>Frequently</td>
<td>21 (15.3)</td>
</tr>
<tr>
<td>Sometimes</td>
<td>90 (65.7)</td>
</tr>
<tr>
<td>Rarely</td>
<td>26 (19)</td>
</tr>
<tr>
<td>DIET</td>
<td>N (%)</td>
</tr>
<tr>
<td>Strict</td>
<td>39 (28.5)</td>
</tr>
<tr>
<td>Average</td>
<td>91 (66.4)</td>
</tr>
<tr>
<td>Non-selective</td>
<td>7 (5.1)</td>
</tr>
<tr>
<td>ALCOHOL</td>
<td>N (%)</td>
</tr>
<tr>
<td>None</td>
<td>119 (86.9)</td>
</tr>
<tr>
<td>Moderate</td>
<td>17 (12.4)</td>
</tr>
<tr>
<td>Excessive</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>SMOKING</td>
<td>N (%)</td>
</tr>
<tr>
<td>Smoker</td>
<td>5 (3.3)</td>
</tr>
<tr>
<td>Non-smoker</td>
<td>145 (96.7)</td>
</tr>
</tbody>
</table>
More than two thirds of the recruited participants comprised of females and the average age for both males and females was 52.6 ± 16 with no significant age difference between the two groups, male mean age was 52.2 ± 17.1 and 52.7 ± 16.2 for females, p = 0.870.

Three participants (2%) had never been formally educated.

Nearly a third (28%) of the participants required insulin as part of their diabetes care.

Table 7: Clinical characteristics

<table>
<thead>
<tr>
<th>CLINICAL DATA</th>
<th>N = 150</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 1 diabetes mellitus</td>
<td>25 (16.7)</td>
</tr>
<tr>
<td>Type 2 diabetes mellitus</td>
<td>125 (83.3)</td>
</tr>
<tr>
<td>DURATION OF DIABETES Median IQR</td>
<td>6 years (3-10)</td>
</tr>
<tr>
<td>COMORBIDITIES</td>
<td>N (%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>109 (72.7)</td>
</tr>
<tr>
<td>Dyslipidaemia</td>
<td>3 (2)</td>
</tr>
<tr>
<td>MEDICATIONS</td>
<td>N (%)</td>
</tr>
<tr>
<td>Oral Hypoglycaemic agents</td>
<td>110 (73.3)</td>
</tr>
<tr>
<td>Insulin</td>
<td>43 (28.7)</td>
</tr>
<tr>
<td>Calcium channel blocker</td>
<td>60 (46)</td>
</tr>
<tr>
<td>Angiotensin Converting Enzyme Inhibitor</td>
<td>85 (56.7)</td>
</tr>
<tr>
<td>Angiotensin Receptor Blocker</td>
<td>7 (4.7)</td>
</tr>
<tr>
<td>Beta blocker</td>
<td>5 (3.3)</td>
</tr>
<tr>
<td>Thiazide</td>
<td>38 (25.3)</td>
</tr>
<tr>
<td>Asprin</td>
<td>28 (18.7)</td>
</tr>
<tr>
<td>Statin</td>
<td>45 (30.0)</td>
</tr>
<tr>
<td>BMI kg/m2</td>
<td>Mean ± sd</td>
</tr>
<tr>
<td>Type 1 diabetes mellitus</td>
<td>22.1 ± 5.6</td>
</tr>
<tr>
<td>Type 2 diabetes mellitus</td>
<td>29.4 ± 4.8</td>
</tr>
<tr>
<td>Blood Pressure</td>
<td>Mean ± sd</td>
</tr>
<tr>
<td>Systolic Blood Pressure</td>
<td>136 ± 23.7</td>
</tr>
<tr>
<td>Diastolic Blood Pressure</td>
<td>80.5 ± 11.3</td>
</tr>
</tbody>
</table>
Type 2 Diabetes Mellitus accounted for 83% (125) of the study participants and were generally overweight, which is in keeping with epidemiologic stratification of diabetes mellitus. The mean duration of diabetes was 6 years with an inter-quartile range of 3-10 years.

Hypertension was a significant co-morbidity with more than two thirds of participants being affected. The average blood pressure control was impressively adequate at 136/81mmHg, which is in keeping with the 2014 American Diabetes Association guidelines.

Only 30% of the study participants were on a Statin, which is far below the expected in view of the American Diabetes Association guidelines. 42

Only 5 out of 150 study participants had a smoking history.

8.1. Prevalence of Diabetic Retinopathy

The overall prevalence of diabetic retinopathy amongst the study population was 38% (n = 57), with 11 participants (7.3%) discovered to have proliferative diabetic retinopathy and required urgent ophthalmologic referral, and 46 (30.7%) had non-proliferative diabetic retinopathy. (See Table 9) Type 1 accounted for 6.7% (4) and type 2 accounted for 31.3% (18) of diabetic retinopathy in this study.
Table 8: Fundus Photo findings

<table>
<thead>
<tr>
<th>FUNDUS EXAMINATION</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>93 (62)</td>
</tr>
<tr>
<td>Non-proliferative diabetic retinopathy</td>
<td>46 (30.7)</td>
</tr>
<tr>
<td>Proliferative diabetic retinopathy</td>
<td>11 (7.3)</td>
</tr>
<tr>
<td>Overall diabetic retinopathy</td>
<td>57 (38)</td>
</tr>
</tbody>
</table>

8.2. Association of diabetic retinopathy and duration of diabetes

In the present study two thirds of patients (n=102) had diabetes for less than 10 years, while a third (n=48) had diabetes for more than 10 years. **Table 9:**

Diabetic retinopathy and duration of diabetes mellitus

<table>
<thead>
<tr>
<th>Duration (years)</th>
<th>N = 150</th>
<th>Retinopathy present</th>
<th>Retinopathy absent</th>
<th>Prevalence of diabetic retinopathy (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;5</td>
<td>22</td>
<td>7</td>
<td>15</td>
<td>4.7</td>
</tr>
<tr>
<td>5-10</td>
<td>80</td>
<td>23</td>
<td>57</td>
<td>15.3</td>
</tr>
<tr>
<td>11-20</td>
<td>42</td>
<td>23</td>
<td>19</td>
<td>15.3</td>
</tr>
<tr>
<td>&gt;20</td>
<td>6</td>
<td>4</td>
<td>2</td>
<td>2.7</td>
</tr>
</tbody>
</table>

8.3. Association of diabetes retinopathy and age

The majority of the study participants were in the fifth decade of life with a mean age of 52.6 ±16.4 years. The development of diabetic retinopathy was strongly associated with age as observed in this study where the prevalence was just 2% in the young group of under thirties, 9.3% in the 30-50 year age group and 26.6% in the above 50’s.

**Table 10 Diabetic retinopathy and age**

<table>
<thead>
<tr>
<th>Age</th>
<th>N (%)</th>
<th>Retinopathy present: n (%)</th>
<th>Retinopathy absent n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;30</td>
<td>14 (9)</td>
<td>3 (2)</td>
<td>11 (7)</td>
</tr>
<tr>
<td>30-50</td>
<td>50 (33)</td>
<td>14 (9)</td>
<td>36 (24)</td>
</tr>
<tr>
<td>51-70</td>
<td>67 (45)</td>
<td>32 (21)</td>
<td>35 (23)</td>
</tr>
<tr>
<td>&gt;70</td>
<td>19 (13)</td>
<td>8 (5)</td>
<td>11 (7)</td>
</tr>
</tbody>
</table>
8.4. Association of diabetic retinopathy and hypertension

The majority of the study participants in excess of two thirds had co-existing hypertension. There was a strong association of diabetic retinopathy in the setting of hypertension as shown in Table 11.

Table 11: Diabetic retinopathy and hypertension

<table>
<thead>
<tr>
<th>Hypertension</th>
<th>Retinopathy present n(%)</th>
<th>Retinopathy absent n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes (n = 109)</td>
<td>48 (32)</td>
<td>61 (41)</td>
</tr>
<tr>
<td>No (n = 41)</td>
<td>9 (6)</td>
<td>32 (21)</td>
</tr>
</tbody>
</table>

Univariate logistic regression analysis shown in Table 15 shows a strong association of diabetic retinopathy and hypertension with an odds ratio (95% CI) of 2.80 (1.23-6.42), p = 0.015 which was statistically significant.

8.5. Association of diabetic retinopathy and HBA1C and Glycaemic control

Only 60 study participants had a current HBA1C. Out of the 60 participants, 52 (86.7%) had an abnormal HBA1C and of these 22 (36.7%) had diabetic retinopathy as shown in Table 13.

Table 12: Diabetic retinopathy and HBA1C

<table>
<thead>
<tr>
<th>HBA1C</th>
<th>N = 60</th>
<th>Retinopathy Present: n(%)</th>
<th>Retinopathy Absent: n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;7</td>
<td>8</td>
<td>3 (5)</td>
<td>5 (8)</td>
</tr>
<tr>
<td>7-10</td>
<td>27</td>
<td>10 (17)</td>
<td>17 (28)</td>
</tr>
<tr>
<td>&gt;10</td>
<td>25</td>
<td>11 (18)</td>
<td>14 (23)</td>
</tr>
</tbody>
</table>

125 study participants had a glucometer reading the clinic visit. The mean glucometer reading observed during the clinic visit was 9.7± 4.8 mmol/L. A third of the study participants had an elevated blood sugar of more than 10 mmol/L. (See Table 14)
Table 13 Association of diabetic retinopathy and glycaemic control

<table>
<thead>
<tr>
<th>Glucometer (mmol/L)</th>
<th>N=125</th>
<th>Retinopathy Present: n(%)</th>
<th>Retinopathy Absent: n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;5</td>
<td>14</td>
<td>5 (4)</td>
<td>9 (7.2)</td>
</tr>
<tr>
<td>5-10</td>
<td>68</td>
<td>18 (14.4)</td>
<td>50 (40)</td>
</tr>
<tr>
<td>11-15</td>
<td>26</td>
<td>17 (13.6)</td>
<td>9 (7.2)</td>
</tr>
<tr>
<td>16-20</td>
<td>8</td>
<td>6 (4.8)</td>
<td>2 (1.6)</td>
</tr>
<tr>
<td>&gt;20</td>
<td>9</td>
<td>6 (4.8)</td>
<td>3 (2.4)</td>
</tr>
</tbody>
</table>

Only 3 (2%) study participants had urine micro-albumin evaluated in this study and had normal values.
8.6. Logistic regression analysis

Univariate logistic regression analysis was done on the study participants assessing the association of having diabetes retinopathy and various baseline characteristics, which are associated with the development of diabetes retinopathy as covariates. (See Table 14)

Table 14: Univariate analysis of risk factors for retinopathy

<table>
<thead>
<tr>
<th>FACTOR</th>
<th>RETINOPATHY</th>
<th>UNIVARIATE ANALYSIS</th>
<th>MULTIVARIATE ANALYSIS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>YES</td>
<td>NO</td>
<td>OR (95% CI)</td>
</tr>
<tr>
<td>GENDER</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>20</td>
<td>23</td>
<td>1.65 (0.80 – 3.38)</td>
</tr>
<tr>
<td>Female</td>
<td>37</td>
<td>70</td>
<td>1</td>
</tr>
<tr>
<td>AGE, MEAN (SD)</td>
<td></td>
<td></td>
<td>56.0±14.7</td>
</tr>
<tr>
<td>Diabetic Type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type 1</td>
<td>10</td>
<td>15</td>
<td>1</td>
</tr>
<tr>
<td>Type 2</td>
<td>47</td>
<td>78</td>
<td>0.90 (0.38 – 2.18)</td>
</tr>
<tr>
<td>DURATION OF DM (yrs), Median (IQR)</td>
<td>7 (5 –15.5)</td>
<td>5 (2-8)</td>
<td>1.10 (1.0 – 1.01)</td>
</tr>
<tr>
<td>HYPERTENSION</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>48</td>
<td>61</td>
<td>2.80 (1.23 – 6.42)</td>
</tr>
<tr>
<td>No</td>
<td>9</td>
<td>32</td>
<td>1</td>
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<td>ALCOHOL</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>10</td>
<td>8</td>
<td>2.38 (0.87-6.49)</td>
</tr>
<tr>
<td>No</td>
<td>41</td>
<td>78</td>
<td>1</td>
</tr>
<tr>
<td>SMOKING</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>4</td>
<td>1</td>
<td>7.23 (0.79-66.61)</td>
</tr>
<tr>
<td>No</td>
<td>47</td>
<td>85</td>
<td>1</td>
</tr>
<tr>
<td>DIET</td>
<td></td>
<td></td>
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<tr>
<td>Strict diet</td>
<td>6</td>
<td>33</td>
<td>1</td>
</tr>
<tr>
<td>Moderate</td>
<td>42</td>
<td>49</td>
<td>4.71 (1.80-12.34)</td>
</tr>
<tr>
<td>Non-selective</td>
<td>3</td>
<td>4</td>
<td>4.13 (0.73-23.3)</td>
</tr>
<tr>
<td>EXERCISE</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Frequently</td>
<td>3</td>
<td>18</td>
<td>1</td>
</tr>
<tr>
<td>Sometimes</td>
<td>31</td>
<td>59</td>
<td>3.15 (0.86-11.54)</td>
</tr>
<tr>
<td>Rarely</td>
<td>17</td>
<td>9</td>
<td>11.33 (2.62-49.05)</td>
</tr>
</tbody>
</table>
9. DISCUSSION

This study determined the prevalence of diabetic retinopathy at Parirenyatwa Hospital Diabetic Clinic to be 38% (57), with 7.4%(11) having proliferative diabetic retinopathy and 30.9% (46) having non-proliferative diabetic retinopathy. Type 1 diabetes mellitus accounted for 6.7% while Type 2 diabetes mellitus accounted for 31.3%. The results from this study are consistent with the reported diabetic retinopathy prevalence rates in Africa of 9-55%. The prevalence rate in this study was higher than that shown by Macheka BM in a similar unpublished study in 1996 of 27.5%. The observed difference between the two studies could be a reflection of the changing landscape of diabetes mellitus, which is attributed to the global increase in the diabetes mellitus epidemic driven by sedentary lifestyle, urbanisation, high calorie diets (carbohydrates are cheaper than protein in Zimbabwe) and obesity. Additionally the socio-economic changes in Zimbabwe have impacted negatively on healthcare delivery and consequently the quality of diabetes care.

Significant predictors of developing diabetic retinopathy were: age OR 1.02 (95% CI 1.00 – 1.04), duration of diabetes OR 1.10 (95% CI 1.00 – 1.01), presence of hypertension OR 2.80 (95% CI 1.23 – 6.42), p = 0.015, physical inactivity 11.33 (95% CI 2.62 – 49.05), p = 0.001, and a suboptimal diet was associated with developing diabetic retinopathy with an OR 4.71 (95% CI 11.80 – 12.34), p = 0.002.
The prevalence of diabetic retinopathy was more frequent with a longer
duration of diabetes of 7 years vs 5 years, and this was statistically significant
in a Univariate logistic regression analysis OR 1.10 (95% CI 1.00 – 1.01),
p = 0.011. This mirrored fairly well to the Wisconsin Epidemiologic Study of
Diabetic Retinopathy (WESDR), which observed retinopathy in 8% at 3 years,
but increased in a stepwise manner from 5 years onwards.24,27

It was interesting to note that life-style interventions of diet and physical
exercise stood out as the strongest factors contributing to the development of
diabetic retinopathy.

In a multivariate logistic regression analysis, factors strongly associated with
predicting developing diabetic retinopathy were: duration of diabetes mellitus
OR 1.01 (95% CI 1.00 – 1.01), being hypertensive OR 1.92 (95% 0.50 – 7.37)
and a sub-optimal diet stood out as the strongest predictor OR 7.55 (1.84 –
31.1), p = 0.005.

The finding of a strong association between developing diabetes retinopathy
and a longer duration of diabetes mellitus is a reflection of the
pathophysiology of diabetic retinopathy and the effect of prolonged exposure
to hyperglycaemia.

Routine ophthalmoscopy in the diabetic clinic was rarely done largely because
of skill inadequacy by attending and unavailability of ophthalmoscopes.
Also, referral to Sekuru Kaguvi Hospital, which is an eye unit, was not followed through because of long waiting lists and additional consultation fees required. These factors impeded the quality of diabetes eye care and as such could add to the increase in diabetic retinopathy.

This study confirmed similar findings observed in other studies that the longer duration of diabetes one had the high the risk of developing diabetic retinopathy. 27,38,40

Prolonged hyperglycaemia drives the on-going development of retinopathy. The best monitoring tool is to use is the HBA1C. In this study, 60 (40%) out of 150 participants had a current HBA1C, which is far from acceptable. The cost of an HBA1C is about US$20, and most study participants could not afford the test.

If one is forty years or older, The American Diabetes Association recommends addition of statins as part of standard care unless contraindicated. 42 Statins lower the associated cardiovascular complications in diabetes. Less than a third (30%) of the study participants were on statins, which represented a suboptimal care plan given that the mean age in this study was 52.6 years.
10. STUDY LIMITATIONS AND STRENGTHS

A single Investigator who also independently read the retinal photos led this present study. The Investigator has no formal training in ophthalmology. As a result there is a theoretical possibility of error on reporting the results.

There is no laid out criterion for referring patients to the diabetes clinic and one could imagine that difficult to control cases would be referred to the diabetic clinic and as such more diabetes related complications would be expected. However the observed baseline characteristics were quite varied which deviated from an expected referral pattern.

Conclusions from this study cannot be extrapolated to the generality of Zimbabwe because of the sampling procedure used. Most patients came from Harare and therefore are not reflective of the entire country.

The lack of a registry really impacted this study negatively, as the desired sample size was not achieved. A registry allows statistical adjustments to be made to the calculated sample size and by so doing can scientifically achieve the desired purpose of communicating a generalisable phenomenon. This was not the case in this study. Out of a calculated sample size of 233 participants, 150 were successfully recruited.
Most of the patients recruited in the first three to four months of the study appeared to be the same cohort continuously revisiting the clinic and as such were not re-examined in this study. Despite the failure to achieve the desired sample size the results observed are consistent with most diabetic retinopathy studies.\textsuperscript{18,19,32}

Another limitation for this present study is that retinal examination using an iExaminer has not been fully validated in clinical trials to assess the sensitivity and specificity. As such confirmatory diagnostic tests are required using the gold standard of stereoscopic fundus photography. However, for screening purposes, the iExaminer provides a useful point of care test. It requires minimal training and would come at no additional cost to the patient. Fundus photography also canvases the anxiety of fundoscopy faced by many clinicians.

Most patients did not have current biochemical monitoring tests like HBA1C, lipid profile, and urine protein/creatinine ratio or urinalysis at the least, which are so critical for diabetic care. Specifically urine microalbuminuria has an excellent predictive value in diabetic retinopathy. Failure to measure the association of these factors with diabetic retinopathy potentially made the study miss out on important data.

The inherent strength of this study was the ability to capture and store digitally the retinal images. This permits real time storage of patient retinal findings
electronically which can be used to monitor development and progress of any diabetic retinopathy.

With the explosion of information technology patient files are being stored electronically and this study can be used to spearhead the use of electronic medical records our current practice. Digital retinal photography can be achieved with minimal training and use on inexpensive devices as shown in this study. The iExaminer has the inherent capacity to transmit the retinal images via the Internet and therefore permits the opportunity for telemedicine.
11. CONCLUSION AND RECOMMENDATIONS

Visual impairment resulting from diabetic retinopathy has a long asymptomatic phase and therefore strategies to identify and halt the on-going injury can be made and therefore prevent blindness.

By addressing the established risk factors through adherence to existing guidelines, the diabetic clinic can achieve the VISION 2020 goals set out by the World Health Organisation and the International Agency for the Prevention of Blindness.\(^{10}\)

Fundoscopy was rarely done in the diabetes clinic and referrals to the eye unit were poorly followed through. Most doctors are uncomfortable with fundoscopy and this contributed to this sub-optimal eye care in the diabetic clinic. The cost attached to visiting the eye unit deterred patients. To avert this, I strongly recommend the introduction of the iExaminer or any such point of care devices that can photograph retinas in the diabetic clinic.

This study showed a strong association of diabetic retinopathy and sub-optimal diet and physical inactivity. Lifestyle intervention must take centre stage in diabetes care. While these are relatively difficult to implement in patients, I believe they are cost effective and achievable.

Continuous linkage with a dietician is key and persistent diabetes education. There is a role to introduce a Diabetes Educator.
An individualised care plan is the cornerstone of diabetes care provided reference is made to guidelines. Most patients were not on statins despite good quality evidence regarding their use and this was attributable to an oversight by the attending physician. Adherence to an algorithmic or protocolised plan can avert this blind spot.

The diabetic clinic is meant to be a sub-specialised service aimed at sorting out difficult cases and provide guidance in this field and as such criteria should be developed as to who is seen in the clinic.

Policy implementation relies on various epidemiological indices and creating a Registry would be one such way of improving the service in the diabetic clinic.

Finally, advocacy for more accessible biochemical testing for diabetics is important. This can be achieved by formulating a concise and collaborative financing plan engaging all stakeholders; the patients, the public laboratory services, the hospital administration, the non-governmental organisations and fostering good relationships with the private sector.
13. REFERENCES


21. Macheka BM. Diabetic Retinopathy in Harare (Prevalence) and risk factors in patients attending the diabetic clinic at Parirenyatwa Group of Hospitals.


27. Klein R, Klein BE, Moss SE, Cruickshanks KJ. The Wisconsin Epidemiologic Study of Diabetic Retinopathy: XVII. The 14-year incidence and progression


60. Jamie Arnold. Welch Allyn iExaminer™ Receives 510(k) Clearance from the United States Food and Drug Administration.

## 14. APPENDICES

### Appendix 1

**PREVALENCE OF DIABETES RETINOPATHY STUDY AT PGH**

**DATA COLLECTION FORM**

<table>
<thead>
<tr>
<th>Demographic Data</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study number</td>
<td>Age</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Marital Status**

- Never Married
- Married
- Separated
- Divorced
- Widowed
- Living with Partner

**Educational Level**

- None
- Primary
- Form 2
- O Level
- A Level
- Tertiary

**CLINICAL DATA**

**Type of Diabetes**

- T1DM
- T2DM
- Duration of DM

**Other Medical condition**

- Hypertension
- Dyslipidaemia
- Asthma
- HIV
- Arthritis
- Renal Failure
- Other

**Medications:**

- OHA
- Insulin
- CCB
- ACE-I
- ARB
- Beta Blocker/alpha blocker
- Thiazide
- Asprin
- Statin

**COMPLICATIONS:**

- Retinopathy
- Neuropathy
- Nephropathy
- Other
- Background/Proliferative
- Peripheral/Autonomic

**SOCIAL HABITS**

**EXERCISE**

- Rarely
- Sometimes
- Frequently

**DIET**

- Non-selective
- Moderate
- Strict diabetic diet

**ALCOHOL**

- None
- Moderate
- Excessive

**SMOKING**

- Yes
- No

**PHYSICAL EXAMINATION**

<table>
<thead>
<tr>
<th>General</th>
</tr>
</thead>
<tbody>
<tr>
<td>BP</td>
</tr>
<tr>
<td>Height</td>
</tr>
<tr>
<td>Weight</td>
</tr>
</tbody>
</table>

**EYE ASSESSMENT**

- Retinal Photo
- Normal
- NPDR
- PDR

**LABORATORY TESTS**
Appendix 2

TITLE OF RESEARCH: “Prevalence of Diabetes Retinopathy at Parirenyatwa Group of Hospitals”.

NAME OF RESEARCHER: DR N P MABOREKE

INTRODUCTION: You are being asked to participate in the research study named above because you suffer from Diabetes Mellitus and this can affect your eyes.

This informed consent document gives you information about the study and you can discuss aspects of it with the research Doctor. If you understand the study, and if you agree to take part, you will be asked to sign this consent or make your mark in front of some one. You will be given a copy to keep.

Please note that your participation in this research is entirely voluntary and you may decide not to take part or to withdraw from the study at any time without losing any of the benefits of your standard medical care.

PURPOSE OF THE STUDY: Diabetes is a multisystem disease with several potential complications. Importantly for this study is that diabetes causes diabetic retinopathy, which is a leading cause of visual impairment. This is both preventable and treatable. The purpose of the study is to measure the extent of diabetes retinopathy and therefore develop policies and protocols for both treating and preventing Diabetes Retinopathy.

Inclusion Criteria
- Diabetic patients attending the out medical clinics
- > 18 years
Exclusion Criteria

- Non-consenting patients

STUDY PROCEDURES: If you agree to join the study, you will have your eyes tested. This involves what we call Visual acuity testing and retinal photographs will be captured using a special eye camera. Additionally the Investigator will ask you a few questions about your diabetic care and review your medical records to document various factors regarding your diabetes care.

RISKS AND/OR DISCOMFORT: The eye examination is painless and comes with no risks. The capturing of the retinal photographs takes a few minutes.

BENEFITS: The study provides an opportunity to assess the health of your eyes. If the Investigator discovers abnormalities with your eyes you will be referred to the Ophthalmologists for treatment to arrest the development or worsening of visual impairment. Furthermore the information discovered can potentially be used to develop local eye care guidelines for diabetic patients.

COSTS OF THE STUDY: There is no cost to you.

CONFIDENTIALITY

Your research records will be confidential to the extent permitted by the law. Only a code number will identify you, and personal information from your records will not be released without your written permission. You will not be personally identified in any publication about this study.

No persons other than the research staff and the health workers overseeing your care will have right of entry of any information that identifies you individually. Only the Investigator will have the key to connect your retinal images and information attached to your name.

TREATMENT
Results for your retinal images will be shared with your treating physician and appropriate advise for referral to ophthalmologists will be provided.

PERSONS TO CONTACT FOR PROBLEMS OR QUESTIONS
If you ever have any questions about this study, you should contact Dr Nyasha P Maboreke on 0772 863 708.
If you ever have questions about your rights as a research participant you may contact the Medical Research Council of Zimbabwe, Corner Josiah Tongogara/ Mazoe Street, Harare at phone number 04 791792 or 04 791193.

SIGNATURE PAGE

Title of the research: “Prevalence of Diabetes Retinopathy at Parirenyatwa Group of Hospitals”.

Statement of agreement to participate in study
You have read this consent form or had it read to you in a language that you understand, and its contents explained to you. All of your questions have been answered. You understand that your rights and privacy will be maintained. You freely and voluntarily choose to participate in this study.

By signing your name or making your mark in the space below you voluntarily agree to join this study.

-------------------------------
Participant’s Name                       Participant’s Signature                Date

-------------------------------
Witness’ Name                          Witness’ Signature                             Date

70
Appendix 3

INFORMED CONSENT FORM (SHONA)
GWARO RETENDERANO

MUSORO WECHIDZIDZO: “Prevalence of Diabetes Retinopathy at Parirenyatwa Group of Hospitals”

ZITA REMUONGORORORI: DR N P MABOREKE

Nhanganyaya: Muri kukumbirwa kuti mupinde muchirongwa cheongororo chataurwa pamusoro nekuti munechirwere che “Diabetes Mellitus” (DM) uyezve chinogona kukanganisa maziso.

Chinangwa chechirongwa: Diabetes Mellitus chirwere cheshuga chinobata nekukanganisa nhengo zhinji. Zvaka nyanyo nananga netsvakurudzo iyi chirwere chemaziso chinodzikisa maonero muvanhu vazhinji pasirose, vamwe vachitoita mapofu. Chirwere ichi chehupofu chino dzivirika nekurapika zvakare. Chinangwa chechirongwa ichi ndechekuda kuona huwandu nemamiriro echichirwere chemaziso chinokonzerwa neDM. Zviwanikwa zvechirongwa ichi zvichabatsira kunzira dzekurapa chirwere chemaziso akonzerwa ne DM.

Zvinodiwa kuti mukwanise kupinda muchirongwa:
- Mune chirwere cheDiabetes Mellitus
- Makore gumi nemanowe kana pamusoro

Zisingaite kuti mupinde muchirongwa:
- Hamuna chirwere cheDiabetes Mellitus
- Hamukwanise kupa mvumo yokupinda pachirongwa

Njodzi ne/kana kusagadzikana: Kuongoroora maziso pamwe nekutora mifananidzo yemaziso enyu hazvirwadzi uyezve hazvi kanganise maziso enyu. Izvi chinguvana chidikidiki.

Zvamungangowana kubva muchirongwa: Muchabatsitsirikana muchirongwa ichi nokuti ongororo ichaburitsa hutano wemaziso enyu. Kana paine kukanganisika kunobabtwa mumaziso kuridziwira kunoona vanamazikokota nenyanzi dzinorapa maziso. Uyezve ongororo iyi ichawedzera ruzivo rwedu rwechirwere chemaziso izvi zvichabatsira kugadzirwa kwenzira dzemarapiro evanhu vanEDM.

Mibhadharo yechirongwa: Hapana mari yamubhadhariswa kuongororwa maziso enyu.

Zvakavanzika
Zvinyorwa zvenyu zveongororo zvichachengetedzwa zvikuverenga nemutemo. Muchazivikanwa nenhamba chete, uye zviwanikwa zvose zvemayerano nehupenyu hwenyu kubva muzvinyorwazvenyu, hazvizoburitswa pasina mvumo yenyu yakanyorwa. Hamuzozivikanwa nezita chero mune zvipi zvinyorwa zviri moyero nechirongwa ichi.

Vakuru vechirongwa naavo varikukurapai ndivo chete vanogona kuona ongororo dzenyu dzinenge dzinezita renyu.

Kurapwa
Chiremba wenyu ndiye achatora chinhano chokuti okurapai here kana kwete. Zvichabuda mukuongororwa kwemaziso enyu zvichapiwa chiremba wenyu uyo achaona kana zvakakodzera kukurairai kuti muonekwe nanamazvikokota vanorapana maziso.

Kuramaba kupinda kana kubuda muchirongwa
Tapota, zivai kuti kupinda kwenyu muchirongwa cheongororo iyi kuda kwenyu kwakazara uye mungangosarudza kusapinda muchirongwa kana kubuda chero ipi
nguva musingarasikirwe nezvamunowana pakurapwa kwenyu. Kana mabuda muchirongwa mifananidzo yemaziso enyu tinorasa.

Vanhu vekuona kana muine zvinonetsa kana kuti mibvunzo Kana muchinge mangoita mibvunzo iri mayerano nechirongwa ichi munofanira kuona kana kuchaya runhare kuna Dr Nyasha Maboreke pa 0772 863 708.

Kana muchinge mangoita mibvunzo iri mayerano nekodzero dzenyu semunhu ari muongororo, mungangogona kunoona kana kuchaya runhare kuMedical Research Council of Zimbabwe (MRCZ), corner Josiah Tongogara Street/ Mazoe Avenue, Harare, pa runhare 04 7917920r 04 791193.

**Peji yekusaina**

**Title of research:** “Prevalence of Diabetes Retinopathy at Parirenyatwa Group of Hospitals”.


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