PREVALENCE OF DIABETIC RETINOPATHY IN A GROUP OF DIABETIC CLINIC PATIENTS AT NATIONAL DISTRICT HOSPITAL, BLOEMFONTEIN

by

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2017

PREVALENCE OF DIABETIC RETINOPATHY IN A GROUP OF DIABETIC CLINIC PATIENTS AT NATIONAL DISTRICT HOSPITAL, BLOEMFONTEIN

by

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Extensive mini-dissertation submitted in partial fulfilment of the requirements for the degree

Master of Medicine (Family Medicine)

in the

Department of Family Medicine
School of Medicine
Faculty of Health Sciences
University of the Free State
Bloemfontein

Supervisor: Prof WJ Steinberg
Co-Supervisor: Dr MJ Labuschagne
Biostatistician: Dr JE Raubenheimer

2017

DECLARATION

I herewith declare this extensive mini-dissertation, and the content thereof, to be my own original work. The report is based on research conducted by myself. Where help and input was received, acknowledgment was given. I further declare that this research has not been submitted to any other university or institution for the purpose of obtaining a degree, which is not part of the requirements for the MMED (Family Medicine) qualification of the University of the Free State.

....

J.P. Cairncross Date

I hereby cede copyright of this product in favour of the University of the Free State.

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J.P. Cairncross Date

DEDICATION

I dedicate this mini-dissertation to my family for their support and encouragement.

ACKNOWLEDGMENTS

I wish to convey my sincere gratitude and appreciation to the following persons:

- Prof WJ Steinberg, my study leader and principal Family Physician at the Department of Family Medicine, University of the Free State, for his support, guidance and patience during the entire period of this project.
- Dr MJ Labuschagne, my co-study leader and Head of the Unit: Clinical Simulation Centre, Faculty of Health Sciences, University of the Free State, for his support and encouragement.
- Dr JE Raubenheimer, my biostatistician, for his input during the project planning and data analysis.
- Discovery Foundation, who provided funding which made it possible to purchase a Canon fundus camera and iCare tonometer that were used for the purpose of this study.
- Personnel and patients at National District Hospital for their cooperation. Without them the project would never have succeeded.
- Dr Annemie Grobler, Language practitioner, for assistance with the language editing.
- Mr Johan Botes, Senior officer at Department of Family Medicine, for assistance with the formatting of the mini-dissertation.

ABSTRACT

Prevalence of diabetic retinopathy in a group of diabetic clinic patients at National District Hospital, Bloemfontein

J Cairncross, WJ Steinberg, M Labuschagne

Introduction:

Uncontrolled diabetes may lead to multi-organ disease in patients. In South Africa diabetic retinopathy accounts for 8% of cases of blindness. It is the third most common cause for blindness after cataract and glaucoma. Primary health care interventions with the provision of eye care services play an important role in preventing these eye complications in diabetic patients. Eye complications can be identified and treated as part of routine diabetic care.

Aim:

The aim of this study was to determine the prevalence of eye pathology in a group of diabetic clinic patients at National District Hospital (NDH) by using non-mydriatic digital fundus photography as a screening tool.

Methodology:

Two hundred and three diabetic patients participated in the study. A short interview with patients was conducted to obtain a diabetic and previous retinopathy screening history. Visual acuity was assessed, intra-ocular pressure was measured and non-mydriatic digital fundus photography was used as the screening method.

Results:

Over the last year 46 (23.0%) of the 203 patients included in this study complained to their health care practitioner about their vision. 170 (85.0%) patients' vision problems were not investigate by the doctor, 191 (95.5%) did not

have their vision checked with a Snellen chart, and 164 (82.0%) were not examined with an ophthalmoscope. Since their diagnosis of diabetes, only 31 (15.5%) of patients were referred to an ophthalmologist. Only 136 (68.0%) of patients knew that diabetes could exacerbate their vision. Of the 203 patients screened, 97 (48.0%) were referred to ophthalmic specialists and 87 (42.9%) to optometrists. Of those referred to ophthalmologists, 37 (18.2%) had suspected glaucoma, 30 (14.8%) had cataracts and 22 (10.8%) were referred for diabetic retinopathy.

Conclusion:

This study confirms that glaucoma, cataracts and diabetic retinopathy are prevalent eye conditions amongst diabetic patients presenting for follow-up examinations at NDH. Just less than a half needed referral. Offering eye screening at primary healthcare level leads to early detection and early referral for sight-saving treatment.

Word count = 302 (excluding headings)

ETHICS no: 79/2014

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CHAPTER 1: INTRODUCTION

1.1 Background

It has been estimated that 415 million people globally suffer from diabetes and of those, 14 million people are from the African region. It is predicted that this number will double by 2040. In 2015, 2.28 million cases of diabetes were reported in South African adults between the ages of 20-79 years.[1]

In 1999, the World Health Organization (WHO) launched a global plan for the elimination of avoidable blindness by the year 2020, following a review that concluded that 180 million people globally were visually impaired. At this time the cause of blindness was cataracts in more than 50% of the cases. The remaining causes were identified as uncorrected refractive error, glaucoma, diabetic retinopathy and age-related macular degeneration. It was further highlighted that 80% of cases of blindness was preventable. Vision 2020, a worldwide initiative, was launched to address this problem.[2]

In 2010 the WHO estimated an increase with 285 million people globally visually impaired – of those an estimated 39 million people would become blind. If control measures for the two main causes of visual impairment, were consistently implemented, providing refractive services and the availability of cataract surgery, this could lead to an improvement in sight of two thirds of visually impaired people.

It has been suggested that visual impairment can be effectively controlled by providing accessible and effective eye care services. These services should become an integral part of primary healthcare delivery. There is also the possibility of promoting eye care alongside general health promotion.[3] About 90% of the global number of visually impaired persons are living in low-income

settings. Cataracts still remain the primary cause of blindness in middle and low income countries. As mentioned, the three major causes for blindness were uncorrected refractive errors (43%), unoperated cataracts (33%) and glaucoma (2%).[4]

In South Africa, diabetic retinopathy accounts for 8% of cases of blindness. It is the third most common cause for blindness in diabetics after cataract and glaucoma. The *South African National Prevention of Blindness Programme* is a component of this global initiative, and is committed to the elimination of avoidable blindness in South Africa by the year 2020. The current magnitude of visual disability in South Africa and its projected exponential increase over the coming decades have potentially far-reaching social, economic and wellness implications for the affected individuals, their families and communities. To quote from the programme: "The elimination of avoidable blindness is thus both a social, as well as moral imperative". As part of secondary prevention all diabetic patients should have a fundal examination by a trained ophthalmic nurse, optometrist, or ophthalmic medical officer once a year.[5]

In the Free State, diabetic retinopathy screening is mainly performed at tertiary level at the Endocrinology and Ophthalomology Clinics. However, it should also be performed at secondary level and at primary healthcare centres.

1.2 Literature Review

According to the WHO, diabetes is the result of the pancreas not producing sufficient insulin or when the body is unable to efficiently use the insulin it produces. Subsequently there is a higher concentration of glucose in the blood. Insulin is the hormone that is responsible for regulating blood sugar.[6] Elevated blood sugar, hyperglycaemia, is a common result of uncontrolled diabetes and over time leads to serious damage to many of the body's systems: heart, blood vessels, eyes, kidneys, and nerves. Diabetic retinopathy is an important cause of blindness, and occurs as a result of long-term accumulated damage to the small

blood vessels in the retina. Other complications include diabetic neuropathy, and in the presence of impaired blood flow to the feet, the risk of foot ulcers and limb amputation is increased.

Diabetes is one of the major causes of kidney failure and it also increases the risk of heart disease and stroke in diabetics. After 15 years of diabetes, approximately 2% of people become blind, and about 10% develop severe visual impairment. Diabetes and its complications have a significant economic impact on individuals, families, health systems and countries. The WHO aims to stimulate and support the adoption of effective measures for the surveillance, prevention and control of diabetes and its complications, particularly in low and middle income countries. Screening and treatment for retinopathy (which causes blindness) are mentioned as effective cost-saving interventions.[7]

The WHO's strategy for prevention of avoidable blindness and visual impairment is based on three core elements: (1) strengthening disease control, (2) human resource development and (3) infrastructure and technology. Primary health care and community-based interventions with the provision of high-quality eye care services play an important role. Despite efforts to strengthen human resources for eye health, a crucial shortage of eye care personnel persists in many low income countries. Many countries in the African region, for instance, have less than one ophthalmologist per million inhabitants.[8] An example of the progress over the last 20 years where these strategies have been implemented is Oman where eye care service provision have been integrated into the primary healthcare framework over the past decade. Since 1995 India has made funds available at district level for eye care service provision for the poorest. The WHO hopes that by 2019 there will be a 25% reduction of avoidable visual impairments.[4]

South Africa has not prioritised the targets set out by the Global Diabetes Scorecard of the International Diabetes Foundation and remains more focused on

tuberculosis and HIV. For the surveillance of diabetes there is still no official framework. Due to maladministration and lack of funds, comprehensive services for diabetes care and prevention is not implemented universally. Although funds for diabetes are allocated by government, these do not apply to diabetes education, prevention or supplies needed by non-governmental organisations (NGO's).[9]

A major clinical study, the *Diabetes Control and Complications Trial* (DCCT) was conducted from 1983-1993 in the United States and Canada. It included 1 441 participants. Study participants had either no disease or early diabetic retinopathy and were randomised to either intensive blood glucose control (HbA_{1c} close to 6%) or conventional blood glucose control. The study demonstrated that intensive blood glucose control reduced the risk by 76% of developing diabetic retinopathy. In participants who had some diabetic retinopathy changes at the beginning of the study, intensive management slowed the progression of the disease by 54%. The *Epidemiology of Diabetes Interventions and Complications* (EDIC) study in 2005 continued the follow-up of 90% of the participants from the DCCT study and found that the benefits of tight glucose control on the eye, kidney and nerve problems persisted long after the DCCT ended. Researchers call the long-lasting benefit of tight control "metabolic memory".[10]

Diabetic retinopathy can be classified as: none, background diabetic retinopathy, pre-proliferative diabetic retinopathy, proliferative diabetic retinopathy and maculopathy. Currently screening can be done with dilated direct ophthalmoscopy (ophthalmoscope, panoptic ophthalmoscope) at primary health care level, dilated indirect ophthalmoscopy (slit lamp by an ophthalmologist) and photographs with a fundus camera (can be done at any level by someone trained to use the fundus camera). Available treatment depending on the severity of the diabetic retinopathy are laser photocoagulation and surgery (pars plana vitrectomy).[11]

The *Early Treatment of Diabetic Retinopathy Study* (EDTRS) enrolled 3 711 patients. It demonstrated that pan retinal photocoagulation (PRP) can reduce the risk of severe vision loss to <2% if administered at the appropriate stage (severe non-proliferative diabetic retinopathy or proliferative diabetic retinopathy). Focal laser treatment (treatment to the macular area with an argon laser) was found to reduce moderate visual loss.[12]

Diabetic eye disease, mainly consisting of diabetic retinopathy and cataract formation, is a prominent cause of visual disturbance in the developing world. Diabetic retinopathy is preventable and/or treatable. Regular and thorough eye examination through dilated pupils and testing of visual acuity should identify patients at risk of sight-threatening complications in time for appropriate referral to an ophthalmologist. Following the 2012 guidelines of the Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA), well-organised clinics, with adequate staff suitably trained in diabetes care that use effective protocols and appropriate tools, will facilitate improved quality of diabetes care. The target audience of the guideline consists mainly of primary healthcare providers. However, the guideline will only be effective if it is widely followed.[13]

The policy of the Ophthalmological Society of South Africa (OSAA) is that every diabetic person should have his or her eyes screened at least once a year for diabetic retinopathy. This should consist of a dilated retinal examination by an ophthalmologist. Alternatively a dilated fundus photograph should be evaluated by an ophthalmologist, medical doctor, nurse or optometrist properly certified by OSSA. If any sign of diabetic retinopathy is noted on the photograph, the patient is to be referred to an ophthalmologist. The recommended screening methods available are: direct ophthalmoscopy, dilated slit lamp indirect ophthalmoscopy and photographic method (fundus camera).[14] The OSSA plans to develop a patient-driven diabetic screening programme that identifies and encourages high-risk patients to adopt health-seeking behaviour. This programme will include nursing sisters, optometrists, general practitioners, endocrinologists and

ophthalmologists. The 4 key elements are: (1) a common diabetic retinopathy screening grading system, (2) an internet-based diabetic retinopathy database and patient tracking system, (3) a patient-held record (PHR) and (4) a question and answer system to evaluate graders.[15]

Screening guidelines developed by the American Diabetes Association and American Academy of Ophthalmology stipulate that adults and children ≥ 10yrs of age with type 1 diabetes should have an initial dilated examination by an ophthalmologist within 5 years of the onset of diabetes; and yearly examinations thereafter. With type 2 diabetes, 20% of patients may have retinopathy at the time of diagnosis. These individuals should have an initial dilated examination by an ophthalmologist at the time of diagnosis followed by subsequent annual examinations or more frequently if retinopathy is progressing. Pregnant women with pre-existing diabetes should have a dilated eye examination early in the first trimester of pregnancy because pregnancy can potentiate the rapid progression of retinopathy. Close follow-up should continue throughout pregnancy and one year postpartum.[16]

A study in America determined what factors influence the reception of eye care so that screening and education programmes can be designed to promote early detection and treatment. It indicated that attitudes about eyesight and eye exams influence the reception of preventative eye care. Limited knowledge about certain eye diseases and conditions was reported. Participants stated that their primary care providers did not communicate information with them about eyesight, nor did they conduct basic eye screening. The study suggested that improving provider-patient interactions and developing public health messages about eye diseases and preventative eye care can facilitate and increase in the use of appropriate eye care services. It highlighted the need to educate both the general public and healthcare professionals about eye diseases and conditions such as glaucoma, diabetic eye disease, age-related macular degeneration and low vision. [17]

One of the objectives in the *Rwanda National Plan for the Prevention of Blindness* is to integrate primary eye care (PEC) into the primary health care provided at each health centre. In 2007 a comprehensive eye care programme was established in Rubavu district. An eye clinic was established at the local government hospital. The eye care programme comprised of diagnostic and treatment services, a surgical service, health promotion, training of health centre nurses and village health workers (VHW) and regular visits by eye professionals to the health centres. An ophthalmic clinical officer (OCO) is a trained ophthalmic nurse, capable of carrying out minor surgery and some medical treatment and based at the hospital's eye clinic. Two nurses from each of the eight health centres in Rubavu received 5-day PEC training. In practice one of the nurses carries out patient examinations while the other is responsible for administration. 84 VHW served by the health centres in Rubavu district received 1-day training to promote eye care at community level. VHW trained in PEC would sensitise the population to visit health centres for primary consultations. They are expected to promote eye care and to accompany patients to the health centres to be seen by a nurse or visiting eye specialist.[18]

Screening with a mobile fundus camera has improved the quality of care of diabetic patients and is feasible in the South African public primary care setting. A pilot project screening for diabetic retinopathy in primary care at three Cape Town community health care centres screened 400 participants with the aid of a mobile fundus camera. Of these patients, 84% had significantly reduced visual acuity, 63% had retinopathy (22% severe non-proliferative, 6% proliferative and 15% maculopathy). Referral for cataracts was necessary in 27% of cases, in 7% for laser treatment and in 4% for other specialist services. Repeat photography was needed in 8% and urgent follow-up in 12% of the patients.[19]

A study conducted at a university hospital in France concluded that an endocrinologist with specific training for diabetic retinopathy detection using a three-field digital fundus camera with pupillary dilatation can perform a reliable

diabetic retinopathy screening without any loss of chance for the patients, when compared with an identical evaluation performed by experienced ophthalmologists. The patients do not have to wait for the ophthalmologist's diagnosis with a complete diabetes work-up, glycaemic control, and possible complications screening, but can address the problem in a single appointment. The endocrinologist can perform a preliminary screening and refer only pathological or doubtful cases to the ophthalmologist for a comprehensive examination. In this way ophthalmologists' workload can be reduced, and there is a greater availability of specialist care when requested.[20]

In England, diabetic eye screening training courses are available as part of the *National Health Service Diabetic Eye Screening Programme*. This takes place at a seminar room and a grading lab with sufficient work stations to train up to 25 participants at a time. *Introduction to Diabetic Retinopathy Grading* is one of the most popular and established courses as it provides the candidate with in-depth training on diabetic retinopathy grading, with lectures including: workshop, future prospects for diabetes, mydriasis, an introduction to the National Diabetic Retinopathy Screening Programme, the patient's perspective, how to grade, other eye diseases encountered in retinal screening, and quizzes to assess the candidate's progress throughout.[21]

Formal courses like these are currently not available in South Africa. A cross-sectional survey done in Cape Town comprised of 140 general practitioners who answered 10 primary care level ophthalmology questions. The mean test score was 52.5% and the mean self-rating score was 51.9%. The general practitioners agreed that there was a need for ophthalmology refresher courses and 99.9% of them would attend such courses. Of the general practitioners, 82% felt that primary care doctors, not optometrists, should deliver primary eye care. The study concluded that general practitioners appear to lack sufficient knowledge to manage primary health eye care problems, presumably due to a lack of adequate

training. Clinical refresher courses are therefore needed to improve core knowledge in ophthalmology.[22]

In Australia a general practice-based diabetic retinopathy screening model was evaluated. General practitioners completed an online refresher programme that included diabetic retinopathy grading and development of appropriate management plans. At each practice a non-mydriatic camera and video conferencing equipment was installed. An important aspect of developing a specific management plan was videoconferencing between the general practitioner and partner ophthalmologist. This plan required the detailed regular review of the patient's diabetic retinopathy and the suggestion of a timeframe for the next tele-ophthalmic consultation. The study proposed the development of chronic disease models of care that shift the emphasis from hospital or ambulatory specialist care to primary care with specialist support. Another benefit was that general practitioners were able to give immediate feedback to their patients, using the image to reinforce the message about the importance of glycaemic control. This resulted in improving patient compliance with prescribed treatment and lifestyle advice.[23]

Not many studies have been done to evaluate whether retinal images can be used to motivate behavioural change in diabetic patients. A small pilot study of twenty-five participants showed promising results for future research. It provided preliminary evidence that visual feedback of personal retinal images may offer a practical educational strategy for clinicians in eye care services to improve diabetes outcomes in non-target compliant patients.[24]

According to the 2012 Guidelines from the Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA), for the majority of diabetic patients a glycaemic target with an HbA_{1c} <7% is recommended. The society also suggests that HbA_{1c} should be measured every six months if it is at target. However, if it is

not at target, or therapy changes, it should be measured every three months. An eye examination should be performed every year with a funduscopy or fundus photographs, or more frequently if significant retinopathy is present.[13]

There is a need to identify the following things regarding diabetic patients attending the outpatients clinic at National District Hospital: (1) are they being screened for diabetic retinopathy, (2) how diabetic eye screening can be improved in collaboration with the Departments of Ophthalmology and Optometry and (3) to create an initiative between registrars at Family Medicine and registrars at Ophthalmology and Optometry Departments to start a diabetic eye screening programme at the Outpatients Department at National Hospital, Bloemfontein. The aim of these preventative and early interventions is to reduce the morbidity of diabetic retinopathy with regard to patients, while this will also act as a cost-saving measure to the Free State Department of Health.

Diabetic patients usually present at the Department of Ophthalmology, Bloemfontein with significant diabetic retinopathy and some with uncontrolled diabetes. This could indicate that the diabetic screening programme in the Free State at primary health care level is not optimally functional and needs to be revised.

At the Outpatients Department, National District Hospital, Bloemfontein, 180-220 diabetic patients are seen on average per month. It is not known how many of these patients are screened for diabetic retinopathy by the attending doctor in the Outpatients Department, nor the number of patients who are referred to the Department of Ophthalmology, Bloemfontein, for diabetic retinopathy screening.

This study proposes to establish the prevalence of diabetic retinopathy in a group of diabetic clinic patients attending the Outpatients Department at National District Hospital by using non-mydriatic digital fundus photography as a screening tool.

1.3 Aim and Objectives

The aim of this study is to describe the prevalence of diabetic retinopathy in a group of diabetic patients attending the Outpatients Department at National District Hospital by using non-mydriatic digital fundus photography as a screening tool.

The specific objectives of this study:

- To measure the prevalence of diabetic retinopathy with eye screening in a group of diabetic patients at National Hospital Outpatients Department.
- To determine if eye screening of diabetic patients at National Hospital will improve early detection and referral to appropriate services (Ophthalmology and Optometry).
- To asses if diabetic patients had undergone a previous eye screening.
- To evaluate the correlation between the stage of diabetic retinopathy and blood Haemoglobin A_{1c} (HbA_{1c}) levels.

CHAPTER 2: RESEARCH METHODOLOGY

2.1 Pilot study

During the first week of June 2014, the non-mydriatic (no need for pharmacological dilation of the pupil) fundus camera was tested on doctors and nursing staff in the Outpatients Department at NDH to assess image quality and level of difficulty to obtain quality images. The questionnaire and data sheet were analysed by the researcher and the registrar from the Ophthalmology Department. The abovementioned findings were reviewed with a biostatistician and no further amendments were needed.

2.2 Study design

A prospective descriptive study design was used.

2.3 The study population

The study was conducted at the Outpatients Department, National District Hospital, Bloemfontein. The time period was June – July 2014. Both type 1 and type 2 diabetic patients are seen at the Outpatients Department. Patients attending the Outpatients are referred by smaller clinics in Mangaung district and also come from National District Hospital wards and Casualty departments. Diabetic patients are seen daily, and on average 180 – 220 patients are seen every month.

2.4 Sampling

A sample of convenience was selected from the routine diabetic follow-up patients at National District Hospital Outpatients Department. Eye care screening was added to the routine follow-up care. All patients presenting at the Outpatients Department during the study period who were eligible for inclusion after consideration of the criteria were sampled. Two hundred and three patients were sampled during the study period.

The inclusion criteria for the study were:

- Patients with confirmed type 1 or type 2 diabetes mellitus on medication.
- Patients aged 18 years or older.

The exclusion criterion for the study was:

- Patients who declined to participate.

2.5 Measurement

Information for this study was collected by means of an interview with the patient to obtain demographic information, diabetic history and previous diabetic retinopathy screening. Non-mydriatic digital fundus photography was used as the screening method. Intra-ocular pressure was measured with a tonometer. Patient record review or blood sample was taken to obtain $HbA1_c$ blood level within the last three months. The information collected was captured on a questionnaire and data sheet by the researcher (see appendix A3 and A4). Diabetic retinopathy grading and identification of any other ocular disease were done with the assistance of a senior ophthalmology registrar who reviewed the data sheet and digital fundus photography images that were stored on the

computer. Where indicated, referral of patients to Departments Optometry or Ophthalmology was done by the researcher. The researcher telephonically contacted patients and informed them of their referral.

A unique reference number was allocated to each patient to avoid using personal identifiers. Fundus photography images were stored on the computer hard drive by using the unique reference number and date of birth of each patient. The reference number was linked to the patient's name on a separate datasheet that only was available to the researcher. In the event of patient referral, identifying information was included.

2.5.1 Patient interview

The researcher screened all patients that gave consent daily from 08h00 until all patients on that specific day had been screened. The researcher conducted a short interview with each patient which included demographic information, the duration of diabetes treatment, duration of attending National District Hospital Outpatients, number of yearly visits, as well as past diabetic retinopathy screening. The information was captured on a questionnaire by the researcher (see appendix 1).

2.5.2 Eye examination

Visual acuity of each patient was assessed with a Snellen chart and performed by the researcher. The definition of blindness and visual impairment of the SA National Prevention of Blindness Programme was used (Table 1). The WHO guideline of 2012 uses the same parameters to define visual impairment and blindness. Intra-ocular pressure as screening for glaucoma was measured with an iCare tonometer. An ophthalmoscope was used to assess pupil reflexes, appearance of red reflex and an eclipse test were performed. The eclipse test was performed to exclude occludable anterior chamber angles. There is a small risk of

acute closed angle glaucoma when Tropicamide is used for pupillary dilation. The researcher documented all findings on a datasheet (see appendix 2).

Table 1. Definition of visual impairment and blindness (SA National Prevention of Blindness. 2002)

Visual acuity in better eye with best correction (with a Snellen chart)	
6/6 – 6/18	"Normal"
<6/18 – 6/60	"Visual impairment"
<6/60 – 3/60	"Severe visual impairment"
<3/60	"Blind"

2.5.3 Non-mydriatic fundus photography

Screening for diabetic retinopathy was done by means of non-mydriatic digital fundus photography. Where poor view of the retina was present, the researcher would administer one drop of 1% Tropicamide in both eyes of a patient to ensure dilation of pupils after an eclipse test had been performed. Fundus photographs were taken by the researcher and images were stored as JPEG files on the computer hard drive and a flash drive. Only the patient's study number and date of birth were used to label the images.

At weekly intervals a senior registrar from the Department of Ophthalmology would review the data sheet and fundus photography images stored on the computer and grade the diabetic retinopathy. Patients meeting the referral criteria to the Department of Ophthalmology for diabetic retinopathy or other ocular pathology were subsequently referred where appropriate. Where the ocular pathology was mainly a refractive error, patients were referred to the Department of Optometry. The researcher contacted each participant telephonically to arrange further treatment.

In the event of photos which could not be graded, patients were referred to the Ophthalmology Clinic for diabetic retinopathy screening.

The diabetic retinopathy grading scale of the Ophthalmology Society of South Africa (OSSA) was used to classify patients as shown in table 2.

Table 2. Ophthalmology Society of South Africa. Diabetic retinopathy grading.

R0	**No diabetic retinopathy anywhere**	
R1	Mild background diabetic retinopathy	At least one dot haemorrhage or micro aneurysm, with or without hard exudates
R2	Observable background diabetic retinopathy	Four or more blot haemorrhages, in one hemi-field only
R3	Referable background diabetic retinopathy	Four or more blot haemorrhages, in both inferior and superior hemi-fields
R4	Proliferative diabetic retinopathy	Active new vessels, vitreous haemorrhages
R5	Inadequate	Not adequately visualised
M1	Observable maculopathy	Lesions in a radius of >1 but < 2 disc diameters of centre of fovea, hard exudates
M2	Referrable maculopathy	Lesions in a radius of < 1 disc diameter of centre of fovea, blot haemorrhages, hard exudates

Referral guidelines used in the Free State Department of Ophthalmology during this study were:

- Visual acuity normal and no signs of diabetic retinopathy (background or pre-proliferative or proliferative changes) should be referred within three months.

- Visual acuity reduced and no signs of diabetic retinopathy (background or pre-proliferative or proliferative changes) should be referred within one month.
- Possible maculopathy, irrespective of visual acuity and with signs of diabetic retinopathy (background or pre-proliferative changes) should be seen within one month by an ophthalmologist.
- Irrespective of visual acuity and with signs of proliferative diabetic retinopathy should be seen immediately by an ophthalmologist.

2.5.4 Diabetic control measure

The researcher used HbA_{1c} blood level as a proxy for diabetic control. A blood sample for HbA_{1c} level was taken if no results were available within the last three months. The blood sample was taken by any doctor in the Outpatients Department. Patients were given a follow-up date at Outpatients to review blood HbA_{1c} levels and manage accordingly.

2.6 Data Analysis

The analysis was performed by the Department of Biostatistics, UFS. Descriptive data was reported using frequencies and percentages, or, where relevant, medians, means and standard deviations. The relationship between stages of diabetic retinopathy and HbA_{1C} values will be examined by means of an analysis of variance. Where necessary, descriptive variables may be compared with Chi-square tests or t-tests.

2.7 Ethical Issues

2.7.1 Participant confidentiality

To ensure patient confidentiality the researcher allocated a specific reference number to each patient. The patient's reference number, name, surname, date of birth, file number and contact number were documented on a master datasheet. Only the researcher has access to the master datasheet. Only the patient reference number was indicated on the questionnaire and datasheet. Retinal images were stored on a computer hard drive at the Outpatients Department labelled only the reference number and date of birth. The researcher also stored retinal images on a flash drive using only the reference number and date of birth.

2.7.2 Informed consent

Signed informed consent for each patient was obtained by the researcher before commencement of the study. Consent forms were available in English, Afrikaans and SeSotho.

2.7.3 Ethical consideration imposed by offering screening to a patient

Patient consent was required for participation. An information document describing the purpose and procedures of the study was provided to all patients. This was available in English, Afrikaans and SeSotho. During discussion with all eligible patients, details were given about the purpose of the study. This discussion provided clarification on confidentiality, voluntary participation and sharing of the data with the Departments of Ophthalmology, Optometry and Outpatients in the interest of improving the patient health care.

If there was no blood HbA_{1c} level within the last three months available in the patient's record, this test was repeated. No experimentation took place. If blood

HbA_{1C} was above 7%, a review of the medication and health education was given under the supervision of the treating doctor.

As part of routine treatment, each patient was informed telephonically by the researcher of the results of the diabetic retinopathy grading, other eye diseases and the management plan.

All data collected on the questionnaires and data sheets will be stored for a period of five years at the researcher's residence. Retinal images will be stored at the Outpatients Department and on a USB flash drive.

After dilation of a patient's eyes, there is a small risk that it may cause acute closed angle glaucoma. The researcher minimised the risk by performing an eclipse test to exclude the shallow anterior chamber angle of the eye, which is a risk to develop acute closed angle glaucoma. The researcher explained to each patient the risks and the symptoms of acute closed angle glaucoma. The researcher advised patients on appropriate action to be taken if complications should arise.

2.7.4 Research Ethics Committee approval

Consent for research was obtained from the Research Ethics Committee of the Faculty of Health Sciences, University of Free State, before the study was conducted (appendix 3).

2.7.5 Authority approval

Consent was obtained from the Head of the Free State Department of Health, the Family Medicine consultant in charge of the Outpatients Department at National District Hospital and the Heads of the Departments of Ophthalmology and Optometry at UFS (appendix 4).

CHAPTER 3: RESULTS

3.1 Patient interview

During this study period 203 patients from a possible 240 patients participated. During the study period 3 questionnaires were lost.

3.1.1 Demographic information of patients

As demonstrated in table 3, the majority of the patients who participated were female (72.5%). The home language of patients was predominantly SeSotho (60.0%) and Afrikaans at a minority (17.0%).

Table 3. Gender and home language of patients (n=200)

Variable	Categories	Frequency	Percent (%)
Gender	Males	55.0	27.5
(n= 200)	Females	145.0	72.5
Home language	Afrikaans	34.0	17.0
(n= 200)	English	7.0	3.5
	Sesotho	20.0	60.0
	isiXhosa	18.0	9.0
	Setswana	19.0	9.5
	isiZulu	1.0	0.5
	Bangli	1.0	0.5

The mean age of patients participating in this study was 57 years. The youngest patient was 30 and the oldest 88 years of age.

3.1.2 Diabetic medical history

The diabetic medical history and attendance of patients are demonstrated in Table 4. The mean duration of treatment for diabetes was 8.4 years, with the shortest duration one month and the longest 40 years.

The mean duration for attendance at NDH Outpatients department was 5.2 years, with the shortest duration one month and the longest duration 30 years.
Mean visits per year to see the doctor at NDH Outpatients Department were 3.4, the lowest number of visits per year was zero and highest number of visits per year was 20.

One patient was seen as a first visit and was diagnosed and started on treatment one month earlier.

Table 4. Diabetic medical history

Variable	Mean	Median	SD	Min	Max
Diabetes treatment duration (years)	8.4	6.0	7.3	0.1	40.0
Attending NDH Outpatients for diabetes (years)	5.2	4.0	4.7	0.1	30.0
Routine visits per year	3.4	2.0	2.6	0.0	20.0

3.1.3 Past diabetic retinopathy screening

Figure 1 shows patients' response to questions related to their visits at the NDH Outpatients department over the last year of attendance.

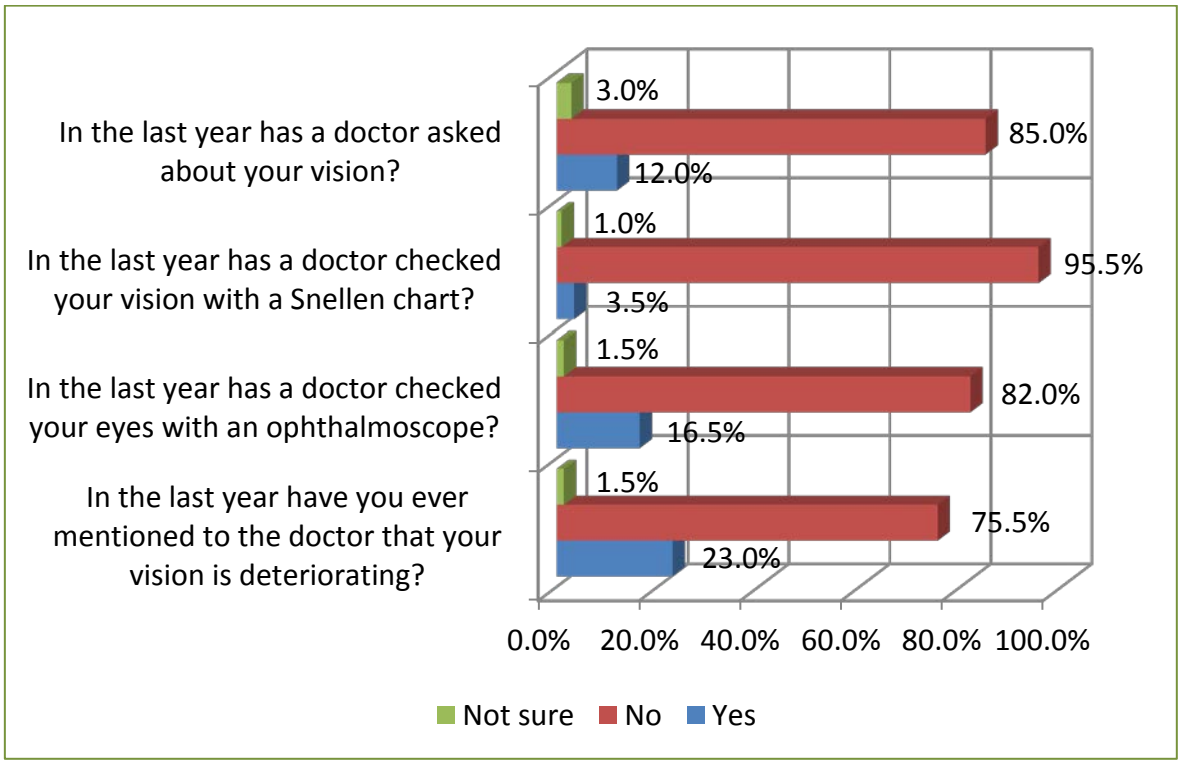

Figure 1. Past diabetic retinopathy screening (n=200)

In 12.0% (24/200) of patients the doctor enquired about their vision, 85.0% (170/200) were never asked about their vision and 3.0% (6/200) were not sure if the doctor asked about their vision.

Only 3.5% (7/200) of patients had their visual acuity checked with a Snellen chart. For 95.5% (191/200) of patients this was not done and 1.0% (2/200) was not sure if their visual acuity had ever been checked.

Only 16.5% (33/200) of patients' eyes were examined with an ophthalmoscope, in 82.0% (164/200) this was not done and 1.5% (3/200) of patients were not sure if their eyes were checked with an ophthalmoscope.

Only 23.0% (46/200) of patients mentioned to their doctor that their vision was deteriorating, 75.5% (151/200) had never complained about deteriorating vision

and 1.5% (3/200) were not sure if they had mentioned to their doctor that their vision was deteriorating.

As illustrated in figure 2, the majority of patients, 68.0% (136/200) were aware that diabetes could decrease their vision. However, 27.5% (55/200) were not sure and 4.5% (9/200) of patients were not aware that diabetes could adversely affect their vision.

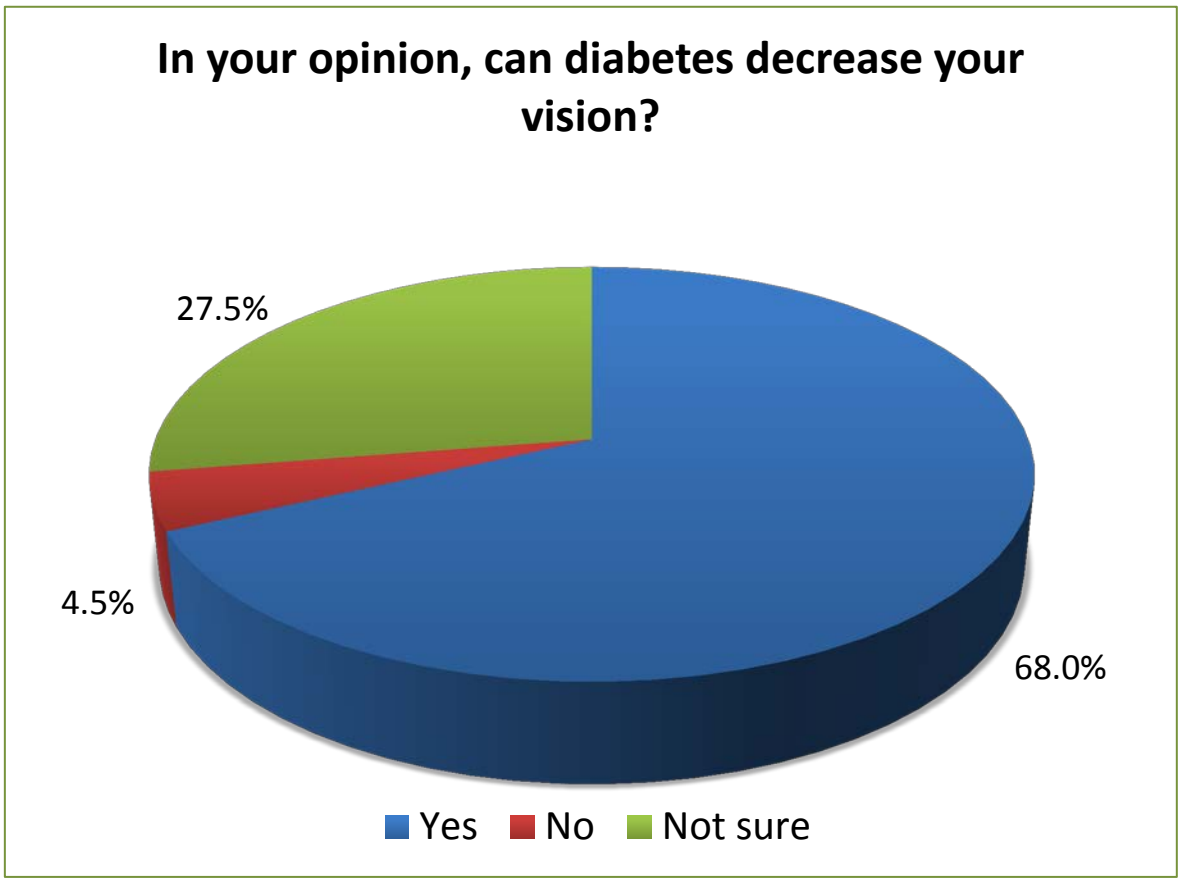

Figure 2. Patient knowledge (n=200)

Figure 3 illustrates past referrals to Ophthalmology for diabetic retinopathy screening. Only 15.5% (31/200) of patients screened had ever been referred to Ophthalmology since the diagnosis of diabetes, 79.5% (159/200) had never been referred and 5.0% (10/200) were not sure if they had ever been referred.

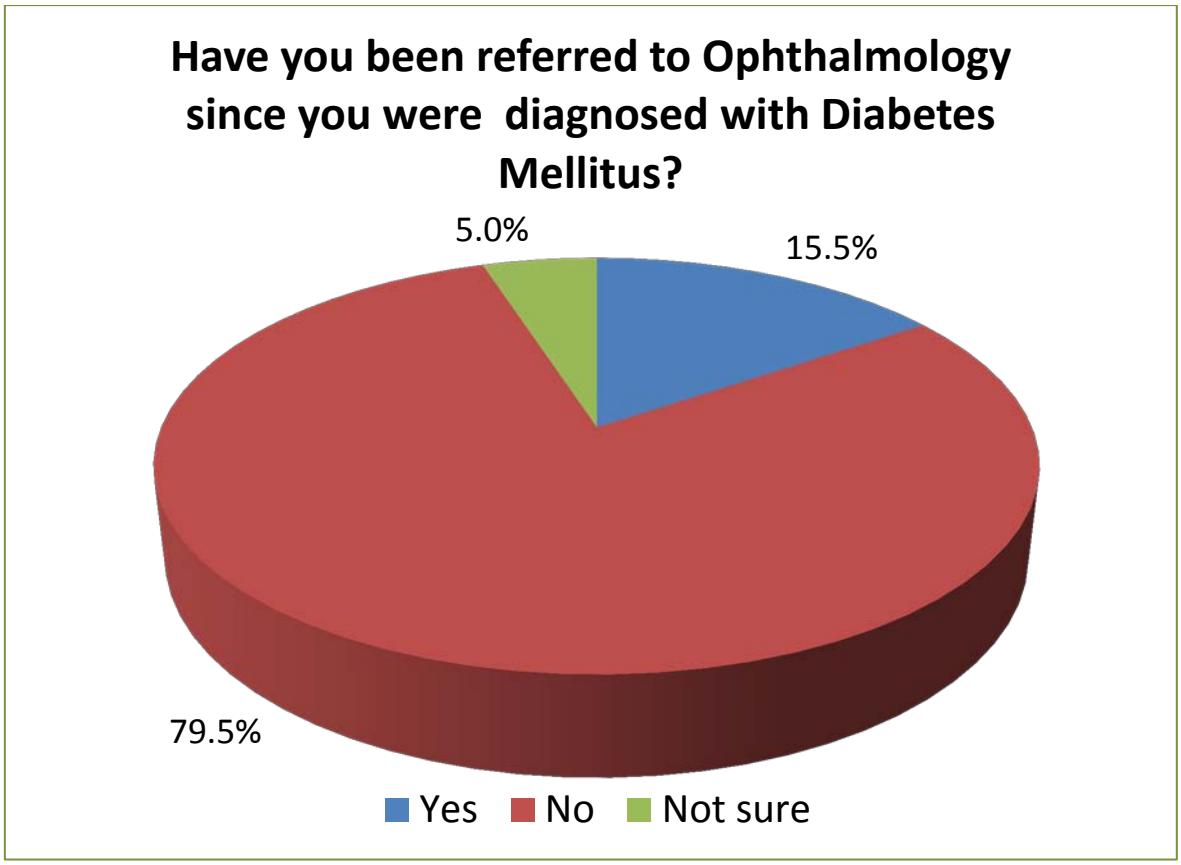

Figure 3. Previous referral to Ophthalmology (n=200)

3.2 Eye examination

The following describes the eye examination that was performed on each patient. One patient had a prosthetic left eye.

3.2.1 Visual acuity

Visual acuity measurement will be reported in table 5. Although 203 patients participated in the study, one patient had a left prosthetic eye and four patients left before their visual acuity measurement could be done. To be able to drive a standard car (motor vehicle) the minimum best visual acuity is 6/12 for each eye. Below this standard were right eyes =35.2% (70/199) and left eyes =36.9% (73/198). As shown, the patients' visual acuity of 6/12 and 6/9 improved with spectacles/pinhole which suggests a disorder of refraction. The other patients had no improvement with spectacles/pinhole which suggests eye pathology and not a refractory disorder. Severe visual impairment was found in 1.0% (2/199) of right

eyes and 1.5% (3/198) of left eyes with no light perception and 0.5% (1/198) of left eyes with light perception only. Normal to mild visual impairment was found in 83.0% of right eyes and 83.2% of left eyes. It needs to be noted that although visual acuity of 199 patients was tested, eyes were tested and counted separately for each patient.

Table 5. Visual acuity of patients (n=199)

	Visual acuity		Visual acuity (spectacles/pinhole)	
V/A	**Right eye (%) n=199**	**Left eye (%) N=198**	**Right eye (%) n=199**	**Left eye (%) N=198**
No light perception	1.0	1.5	1.0	1.5
Light perception	0.0	0.5	0.0	0.5
Finger counting	4.9	3.9	4.4	3.0
6/60	7.4	6.9	1.0	2.0
6/36	8.9	9.4	3.0	3.5
6/24	13.8	6.4	5.9	4.4
6/18	20.2	27.6	19.2	21.2
6/12	19.7	19.2	26.6	24.6
6/9	20.2	17.7	33.0	31.5
6/6	2.0	4.9	3.9	5.9
No V/A tested	2.0	2.0	2.0	2.0

3.2.2 Pupil reflexes, appearance of red reflex and eclipse test

Examinations performed with an ophthalmoscope showed that a relative afferent pupillary defect was present in 0.5% (1/203) of right eyes and 1.0% (2/202) of left eyes. This is an indication of optic nerve dysfunction in these eyes. The red reflex was present (includes present, but reduced) in 97.0% (197/203) of both

eyes and absent in 3.0% (6/203). This test is used to screen for any opacification (for example a cataract). The eclipse test is done to screen for a shallow anterior chamber of an eye. This determines whether pharmacological dilation of a pupil can safely be performed without the risk of precipitating acute closed angle glaucoma. The eclipse test was negative in 100% (202/202) of left eyes and 98.5% (200/203) of right eyes.

3.2.3 Intra-ocular pressure

The intra-ocular pressure (IOP) measured in patients' eyes are shown in Table 6. This was measured with an iCare tonometer. The upper limit of normal IOP is considered to be 20 mmHg. Above 20mmHg is considered raised and susceptible to glaucoma.

Table 6. Intra-ocular pressure (mmHg)

	n	Mean	Median	Std Dev	Min	Max
Right eyes	202	17.3	17.0	6.4	8.0	68.0
Left eyes	200	17.1	16.0	5.9	8.0	60.0

One patient had a prosthetic left eye, one patient left without the IOP having been measured and in one patient it was difficult to perform the IOP in both eyes; therefore only the right eye was measured. The mean measurement in the right eye was 17.3 mmHg and the left eye 17.1 mmHg. 23.7% (48/202) of patients had a raised IOP: in the right eye, 17.3% (35/202) were raised and 18.5% (37/200) in the left. The highest measurement (incidentally, in the same patient) was 68 mmHg in the right eye and 60 mmHg in the left eye.

3.2.4 Non-mydriatic fundus photography

Eyes were counted separately and the number of patients was not considered. Fundus images were graded according to the OSSA diabetic retinopathy grading scale (refer to section *4.4.3*). Only one patient's pupils needed pharmacological dilation for a better view.

From the 203 patients in this study, not all patients had fundus photography. Four patients left the clinic before the photos could be taken. One patient had a prosthetic left eye. Poor image quality (inadequate view) was due to cataracts, vitreous haemorrhages, the researcher learning how to operate the equipment and poor patient co-operation.

Table 7. Images obtained with non-mydriatic fundus camera

	Right eye fundus	**Left eye fundus**	**Right eye macula**	**Left eye macula**
Inadequate view	7.4% (15)	9.9% (20)	4.4% (9)	5.9% (12)
No photo	1.5% (3)	2.0% (4)	2.0% (4)	2.0% (4)
Gradeable images	91.1% (185)	88.1% (179)	93.6% (190)	92.1% (187)

As shown in figure 4 and 5, from the images which could be graded, the degree of diabetic retinopathy is illustrated per eye. The OSSA diabetic retinopathy grading system (table 2) was used. From the 185 right eye images which were gradable, 80% (148/185) had no lesions on retina, 10.3% had mild diabetic retinopathy (19/185), 4.3% (8/185) had observable background diabetic retinopathy, 2.7% (5/185) had referable background diabetic retinopathy and proliferative diabetic retinopathy was present in 2.7% (5/185).

From the right eye macula images, 190 were gradable. Of those 86.8% had no evidence of maculopathy, 6.3% (12/190) had observable maculopathy and 6.8% (13/190) had referable maculopathy. From the 179 gradable images of the left retina no diabetic retinopathy was found in 81.6% (146/179) of left eyes. Mild diabetic retinopathy was found in 10.1% (18/179), observable background diabetic retinopathy in 2.8% (5/179), referable background diabetic retinopathy in 2.2% (4/179) and proliferative diabetic retinopathy in 3.4% (6/179).

Of the left macula images, 187 were gradable. Of those 87.7% (164/187) had no evidence of maculopathy, 7.0% (13/187) had observable maculopathy and 5.3% had referable maculopathy.

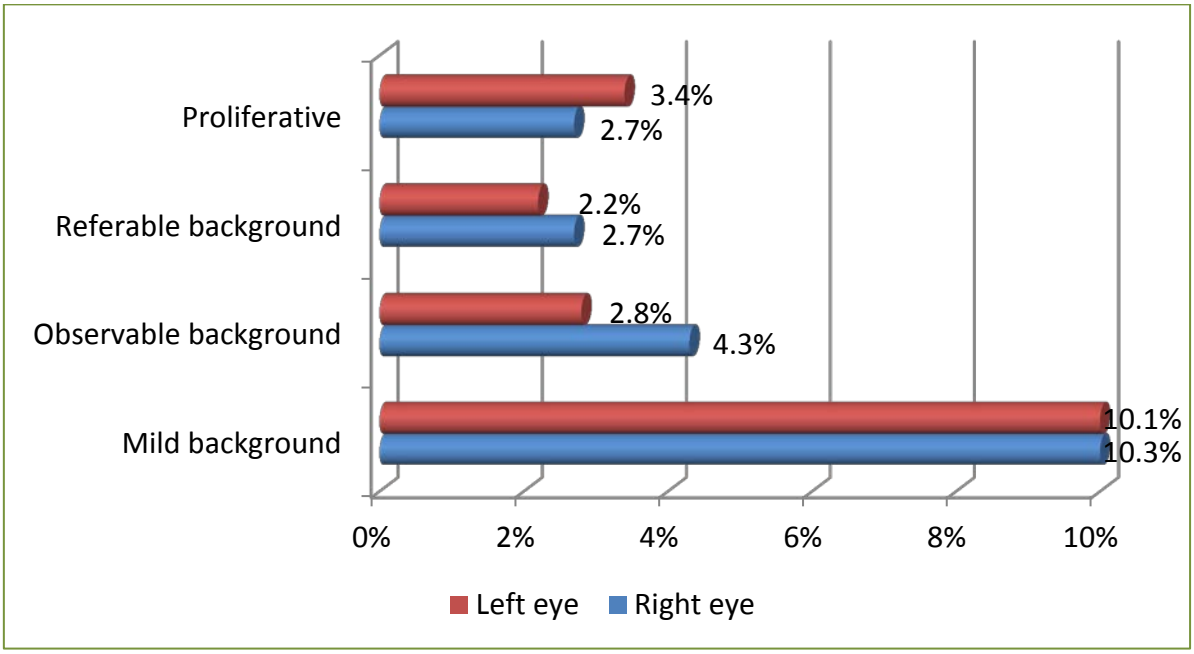

Figure 4. Degree of diabetic retinopathy (excluding the macula) from images which could be graded (n=185 right eyes and 179 left eyes)

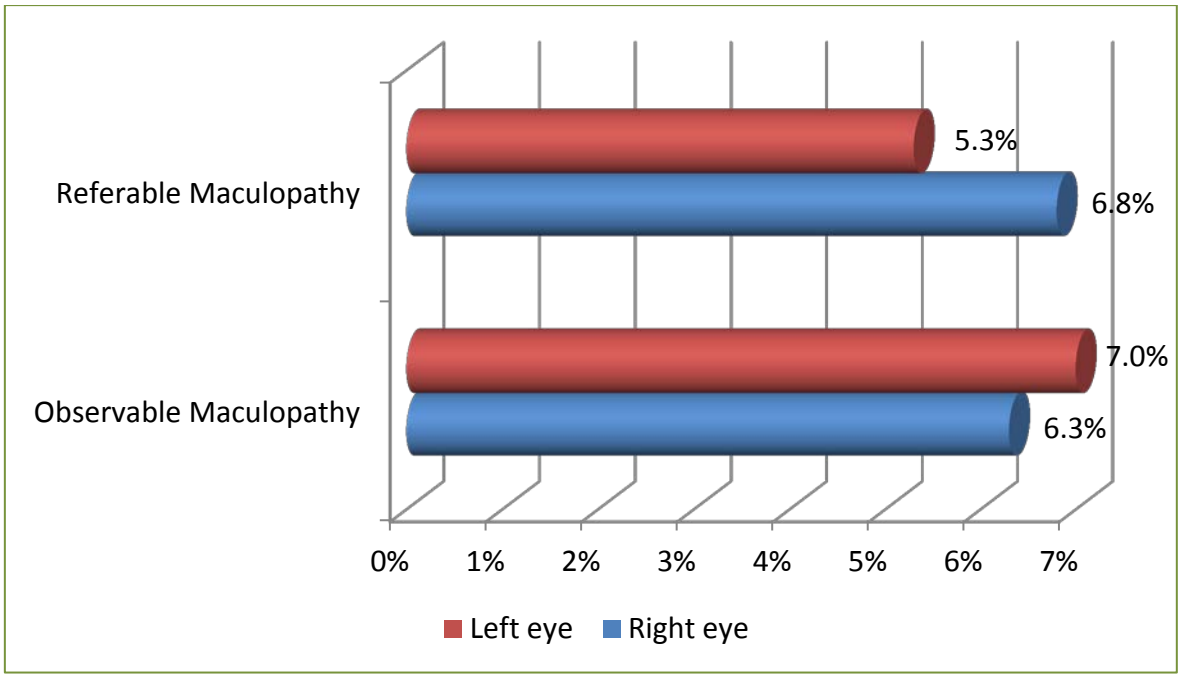

Figure 5. Degree of maculopathy from images which could be graded (n=190 right eyes and n=187 left eyes)

Other ocular pathology identified is shown in figure 6. In some patients more than one ocular pathology was diagnosed. Disorder of refraction was found in 43.2% (86/199) of patients, cataract in 27.6% (56/203), glaucoma was suspected in 18.2% (37/203) and hypertensive retinopathy in 11.8% (24/203). The 24.1% (49/203) include ocular pathology such as blindness, age-related macular degeneration, suspected meningioma, macular hole, macular scar, pterygium, penguecula, strabismus, chorioretinal disorders, disorders of vitreous body, other disorders of lens, other disorders of optic nerve and visual pathways, asteroid hyalosis and tessellated fundus.

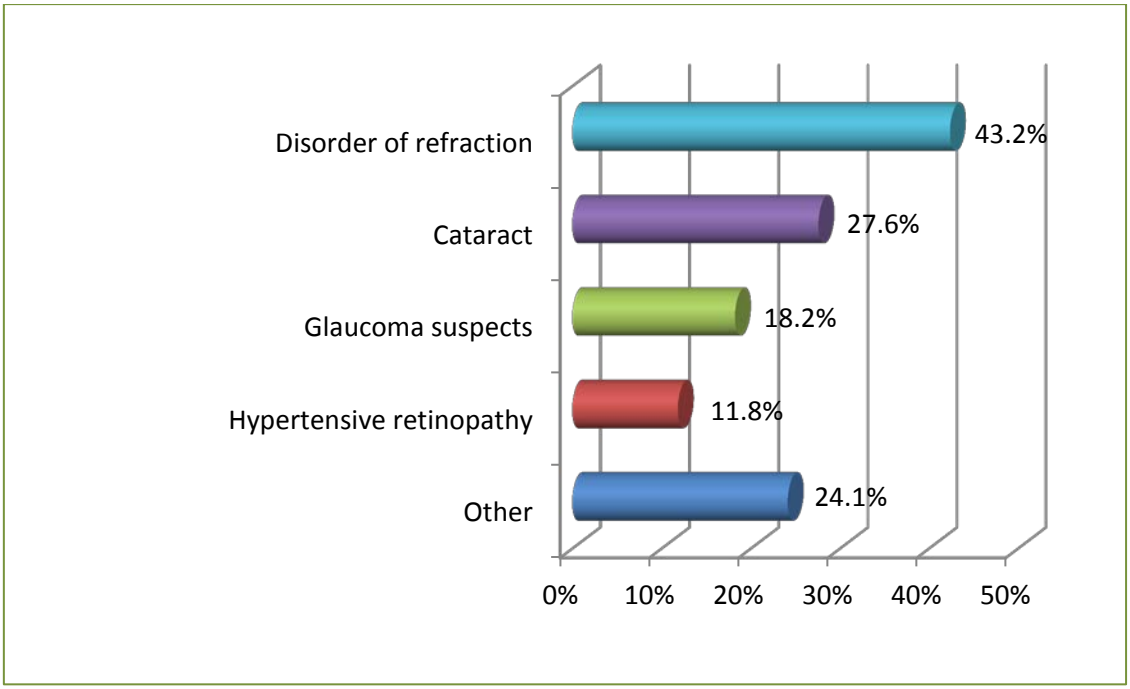

Figure 6. Other eye pathology (n=203)

3.3 Diabetic control measure (Blood HbA_{1c} levels)

From the 203 patients in this study, results of only 195 patients were found, as shown in table 9. According to the SEMDSA guidelines, in the majority of patients an HbA_{1c} level < 7% is considered reasonable. The mean HbA_{1c} level was 8.4%, the lowest level was 5.4% and the highest level 13.1%. A total of 68.7% (134/195) patients' HbA_{1c} results were higher than 7% and only 31.3% (61/195) were less than 7%.

No correlation was found between patient HbA_{1c} levels and the degree of diabetic retinopathy in this sample.

Table 8. Patient HbA1c levels (%) (n=195)

n	Mean	Median	SD	Min	Max
195	8.4	8.0	2.0	5.4	13.1

3.4 Patient referral

Of the 203 patients screened, 42.9% (87/203) were referred to Optometry for a refractive disorder and 47.8% (97/203) were referred to Ophthalmology for other ocular pathology. Of the patients referred, one patient could be referred for more than one ocular disease.

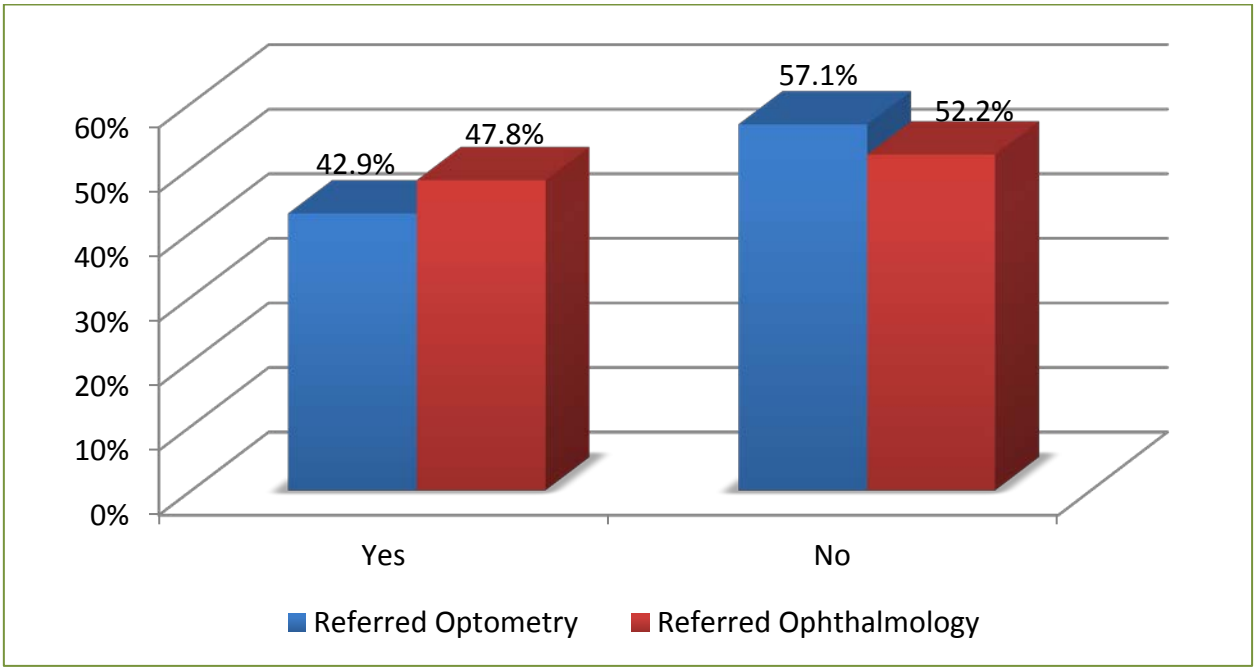

Figure 7. Patient referral for eye pathology

Not all ocular pathology identified required referral to Ophthalmology. Reasons for referral to Ophthalmology as shown in figure 8 was for glaucoma suspects in 18.2% (37/203) of patients, cataracts in 14.8% (30/203) and diabetic retinopathy in 10.8% (22/203). Other ocular diseases in 11.3% (23/203) of patients included macular hole, chorioretinal disorders in diseases classified elsewhere, disorders of vitreous body, age-related macular degeneration, macular scar, other disorders of lens and asteroid hyalosis.

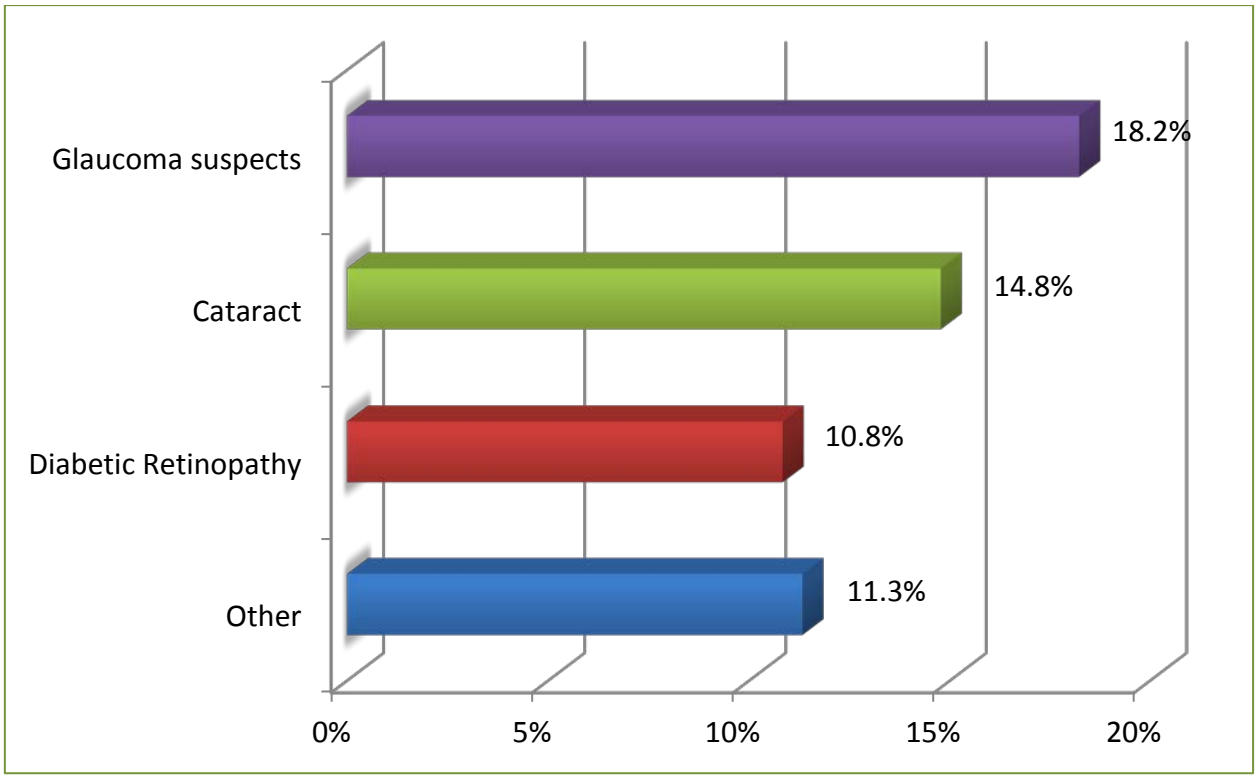

Figure 8. Ocular pathology referred to Ophthalmology (n=203)

3.5 Patient appointment date for Ophthalmology and Optometry clinics

As shown in figure 9, from the 203 patients only 48.8% (99/203) patients were given appointment dates. Almost 50% of the patients were given appointment dates within three months of referral. Patients who did not receive appointment dates were contacted by the Optometry Clinic at the end of 2014 to arrange dates. Patients who did not receive appointment dates for 2014 or early 2015 were contacted in 2015 by the Ophthalmology Clinic to arrange dates.

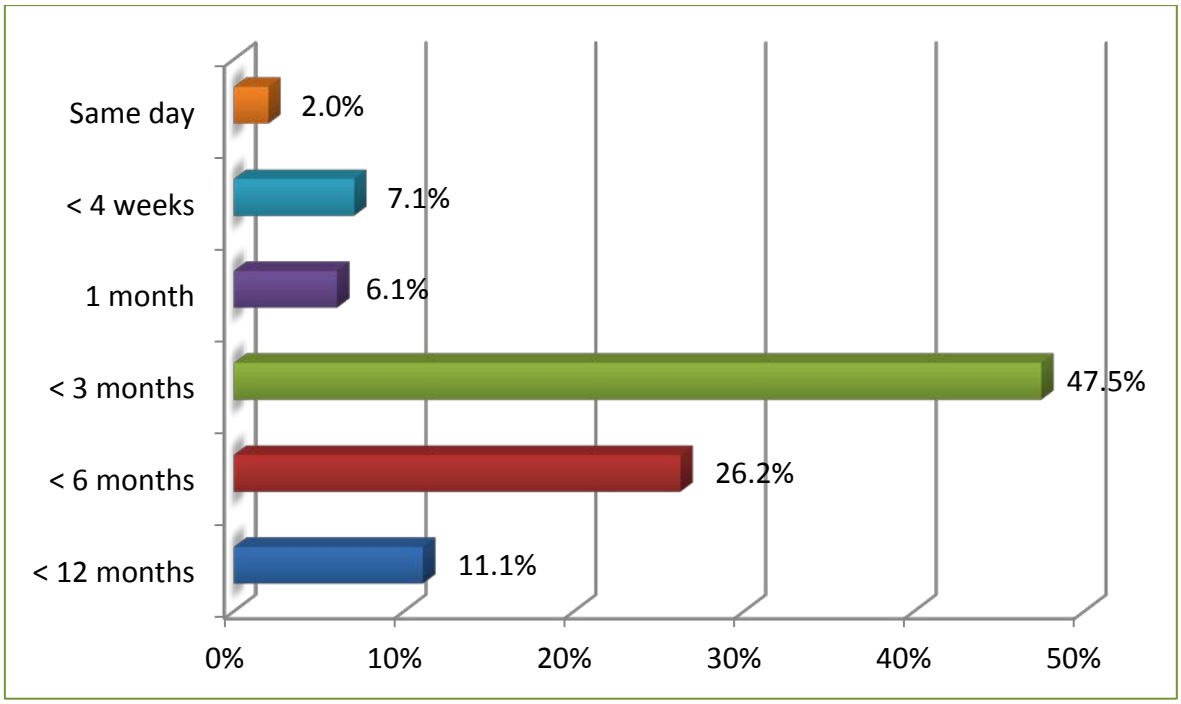

Figure 9. Patients referral timeline (n=99)

CHAPTER 4: DISCUSSION

This is the first study done at primary healthcare level where diabetic retinopathy screening was performed in Bloemfontein. The study clearly demonstrates that NDH Outpatients' Department is falling short of the current recommended annual diabetic retinopathy screening protocol as recommended by SEMDSA and OSSA.[13, 15] It shows similar results where patients stated that primary care providers did not communicate information about eyesight and were not performing basic eye screening.[17]

Similar demographics in South African studies showed participants were predominantly females with 77.0% female patients in Cape Town [19], Mopani District 71.6% [26] and in this study 72.7%. Considering the mean age of patients in this study was 57 years, in Mopani District it was 61.5. It could suggest that the prevalence of diabetes mellitus is higher in older patients. Middle-aged females are often not employed as they are usually housewives and therefore able to attend appointments at the clinic. Male persons could be working and would probably be able to afford appointments at private general practitioners. Older patients access the public health service due to financial constraints.

Doctors at NDH have been attending to diabetic clinic patients, but in more than 80% of patients over the last year no enquiries about visual disturbances or assessment of vision had been performed. Snellen charts and ophthalmoscopes are available at the clinic. The majority of patients were aware that diabetes could adversely affect their vision; however only 15.5% of patients had ever been referred for diabetic retinopathy screening since they were diagnosed with diabetes.

In a similar study participants reported that primary care providers did not communicate information about eye care and failed to perform basic eye screening.[18] This suggests that patients had not been educated that annual eye examination is required in all diabetics. It also demonstrates the need to educate

healthcare professionals and diabetic patients about diabetic retinopathy, glaucoma and cataracts which commonly leads to visual impairment in diabetics.

The 2002 SA National Prevention of Blindness Programme guidelines on the definition of blindness and visual impairment was used for this study (Table 1). These guidelines are echoed by the 2012 WHO definition of blindness and visual impairment. Refractive disorders requiring referral were found in 42.9% of right eyes and 47.8% of left eyes. The reason for the higher prevalence could be that visual acuity lower than 6/12 was considered to be abnormal in this study. Refractive disorder was respectively found in a similar study on male patients to be 62.0% in right eyes and 52.8% in left eyes.[26] Where visual acuity in patients does not improve with spectacles or pinhole, the underlying pathology is less likely a refractive disorder. In this study approximately a third of right eyes and a third of left eyes had significant visual impairment that would affect the ability to obtain/retain a driver's licence for a standard motor vehicle.[25] Similarly in Cape Town reduced visual acuity and reduced red reflex was the highest in 84% of patients.[19]

With the use of an ophthalmoscope an opacification of the lens, identified by absent or reduced red reflex, was easily identified in almost a third (27.6%) of patients. Just over half of those patients needed referral to an ophthalmologist for cataracts.

In Mopani district cataracts were more prevalent in left eyes of males (52.8%) and right eyes (39.3%) of female patients, with visual impairment.[26] Patients with cataracts in the Cape Town study accounted for 35%.[19] The eclipse test is performed to assess for a shallow anterior chamber of an eye. This test determines whether pharmacological dilation of a pupil can safely be performed without the risk of precipitating acute closed angle glaucoma. Almost all of the patients in this study had a negative eclipse test. This highlights that dilation of pupils can be safely done in most patients at primary healthcare level where diabetic retinopathy screening is performed.

Screening for raised intraocular pressure (IOP), an indication of possible glaucoma, was easily performed in less than a minute for each patient with an iCare tonometer, with results available immediately. As diabetics have a higher risk for glaucoma, it was useful to add this to the eye screening of patients. After a refractive disorder, glaucoma/glaucoma suspects was the second most prevalent eye disease (18.2%) identified in patients of this study. The highest IOP recorded was 68 mmHg in the right eye and 60 mmHg in the left eye of the same patient who was immediately referred to Ophthalmology. Mopani District glaucoma prevalence was much lower at 3.6%.[26] In this study an Icare tonometer, fundus photography and the assistance of an Ophthalmology registrar was used to diagnose glaucoma suspects with possibly a higher accuracy than in Mopani District.

Using non-mydriatic fundus photography as a screening tool was much easier than having to pharmacologically dilate and use an ophthalmoscope as a screening instrument. The fundus camera is also very easy to use by any healthcare worker with patient cooperation. Minimal discomfort was caused to patients in this study. This has also been done in a past study in South Africa at primary healthcare level, where a mobile fundus camera was used.[19] Another benefit of this study was that images were saved on the computer and at future eye screening, the current and previous images can be compared to assess if there had been progression of diabetic retinopathy in patients. Over 90% of the fundus and macula images obtained were of sufficient quality to be graded by the ophthalmologist. Also patients were shown their eye images and educated on why diabetes causes visual impairment and why glucose control is important. Patients could better understand why they had visual impairment when an image with their diabetic retinopathy was compared to an image where there was no diabetic retinopathy. Patients who had no evidence of diabetic retinopathy and who had a visual acuity of 6/12 or better were also shown their eye images and educated that they had done well by controlling their diabetes as proved by the absence of any eye disease, and encouraged to continue their present treatment plan. This had a positive impact on patients' perceptions about why diabetes control is important. General practitioners used eye images to give immediate

feedback to their patients and reinforce the message about the importance of glycaemic control.[17] It also reduced the workload of an overburdened Eye Clinic that is unable to cope with seeing all the diabetic patients for diabetic eye screening.

Compared to Malawi (n=249), the prevalence of proliferative diabetic retinopathy was 4.8% in type 2 and much higher at 12.5% in type 1 diabetic patients. Sight threatening maculopathy was found in 14.5% of types 2 diabetics and 18.8% of type 1 diabetic patients. [27.] A similar study in Cape Town at primary healthcare level (n=400) found proliferative diabetic retinopathy at 6.1% and maculopathy 15.2% respectively.[19] With this study the prevalence of proliferative diabetic retinopathy was also lower at 2.7% of right eyes and 3.4% of left eyes. The prevalence of referrable maculopathy was also lower respectively at 6.8% of right eyes and 5.3% of left eyes.

As stated by the WHO[1], the three main causes for blindness in diabetics are cataracts, glaucoma and diabetic retinopathy. The findings of this study are in accordance with the above. Preventing and treating visual impairment in patients have a significant impact on the quality of their life. It is known that diabetics have a higher risk for the development of glaucoma and cataracts. The statistics of this study is in line with the three main causes of blindness in South Africa, which are cataracts, glaucoma and diabetic retinopathy. Screening for diabetic retinopathy in this study was possible at primary healthcare level due to the availability of a fundus camera.

It should be highlighted that HbA_{1c} levels only reflect the last three months of diabetic control, where diabetic retinopathy develops over years of uncontrolled diabetes. In 68.7% of patients their diabetes was not well controlled according to the SEMDSA guidelines, with HbA_{1c} levels higher than 7%. This could suggest that insufficient attempts at diabetic control could lead to micro- and macro-vascular complications when diabetes is uncontrolled.

4.1 Limitations of the study

Potential limitations may include the examination skills of the researcher to screen for diabetic retinopathy and other ocular pathology. This was reduced by correlating the findings with digital fundus images stored on a computer and discussing the findings of each patient with a registrar from the Department of Ophthalmology. This helped to improve the reliability and the validity of the study results. Tight blood pressure and lipid control also influence the development of diabetic retinopathy. The researcher did not include these variables for this study. Sampling bias might be present with selection of the sample; it might not represent the study population fairly.

CHAPTER 5: CONCLUSION

This study indicated that the prevalence of eye pathology was high in this group of diabetic patients, although the prevalence of diabetic retinopathy was low. The other main causes for visual impairment (refractive disorders, cataracts and glaucoma suspects) in diabetic patients can also be screened for at primary healthcare level.

Early detection and early referral to appropriate services (Ophthalmology and Optometry clinics) are possible at primary healthcare level.

The study demonstrates that the Outpatient Department at National District Hospital is falling short of the current recommended annual diabetic retinopathy screening protocol as recommended by OSSA and SEMDSA. Another concern was that almost 80% of patients had never been referred to an ophthalmologist for diabetic retinopathy screening. The need to educate both the general public and healthcare professionals about eye diseases and conditions such as glaucoma, diabetic eye disease, age-related macular degeneration and low vision was determined. The WHO highlights that more than 80% of worldwide visual impairment is treatable and preventable, but due to the deficiency in eye care delivery/provision people are still at risk of visual loss. There is definite potential for improvement of primary health eye care provision at the Outpatient Department of the National District Hospital.

No correlation between the control of diabetes (HbA_{1c} levels) and the degree of diabetic retinopathy was established.

5.1 Recommendations

The researcher recommends to the Management team of National District Hospital to continue eye screening of all diabetic clinic patients as part of routine care with

the non-mydriatic fundus camera. A collaborative practice model with Optometry and Ophthalmology departments can be developed to ensure long-term eye screening of patients. This will reduce the burden at the tertiary level Ophthalmology Clinic, where many patients have waiting times of more than twelve months. Patients arrive at the Ophthalmology clinic with significant visual impairment that could have been prevented or mitigated, had it been diagnosed earlier.

It is also recommended to increase the awareness of doctors and nursing staff attending to Outpatients to enquire and examine diabetic patients for visual complaints. National or local initiatives of health promotion activities to increase patient awareness that uncontrolled diabetes can lead to visual impairment can be conducted by any healthcare worker or community healthcare worker.

It is suggested to the Free State Department of Health (FS DoH) that within each district, at a primary healthcare facility or district hospital, a trained ophthalmic nurse / medical officer (can include a community service medical officer) or both be placed and an iCare tonometer and a non-mydriatic fundus camera made available to screen patients in that specific district. As further steps telephonic consultations and referrals to the Ophthalmology Clinic can be arranged. The aforementioned healthcare workers should also be able to perform minor surgeries and administer basic medical treatment.

Greater priority should be given to the control of diabetic patients, with HbA_{1c} levels checked as per protocol. Medication review, patient education and referral to a dietician should be ensured and monitored. Treatment guidelines should be followed at primary healthcare level and where needed diabetic patients should be referred to the next level of care.

The WHO and the SA National Prevention of Blindness Programme aim to eliminate avoidable causes of blindness by 2020 through the use of primary healthcare and community-based interventions. This study has confirmed that it is possible to bring eye screening services to primary healthcare diabetic patients,

where significant incidents of eye pathology can be identified earlier and many cases of resultant blindness prevented.

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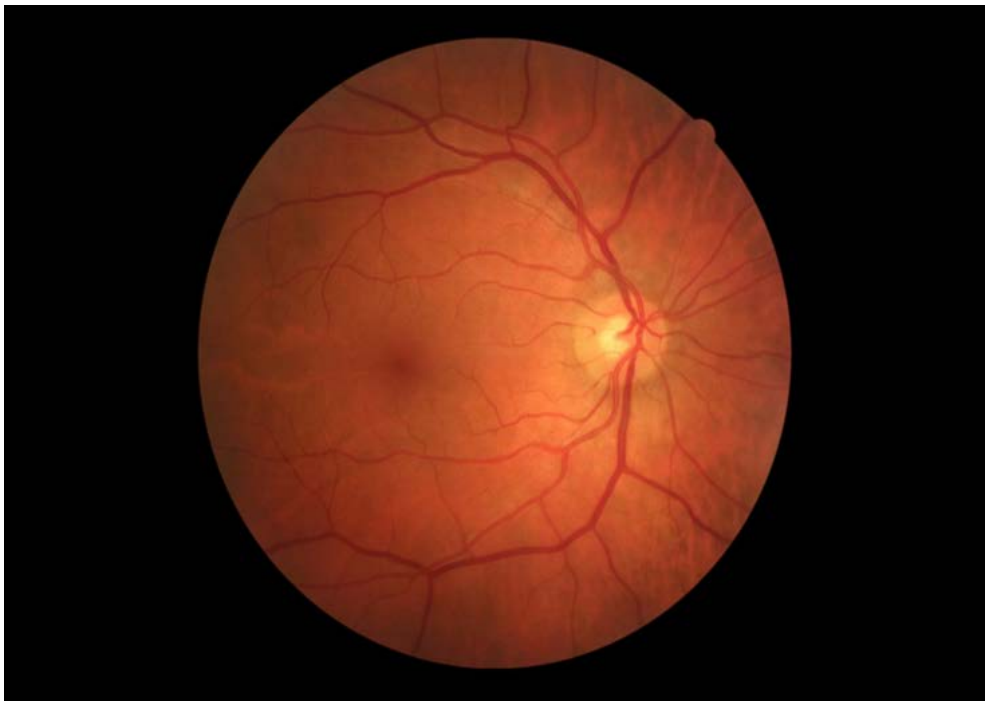
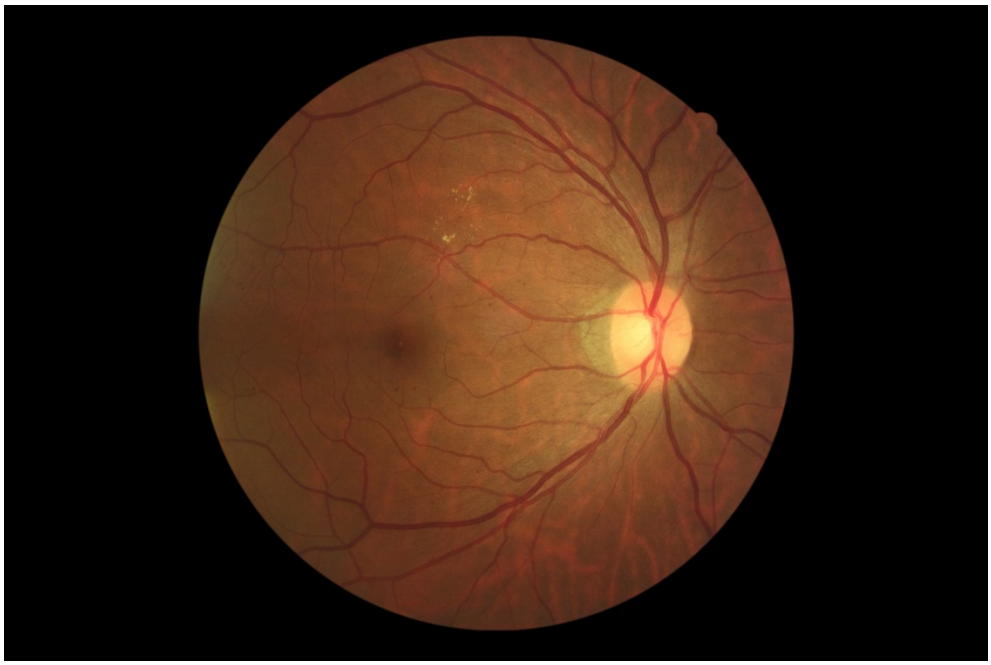
Appendices

Appendix 1. Additional photographs

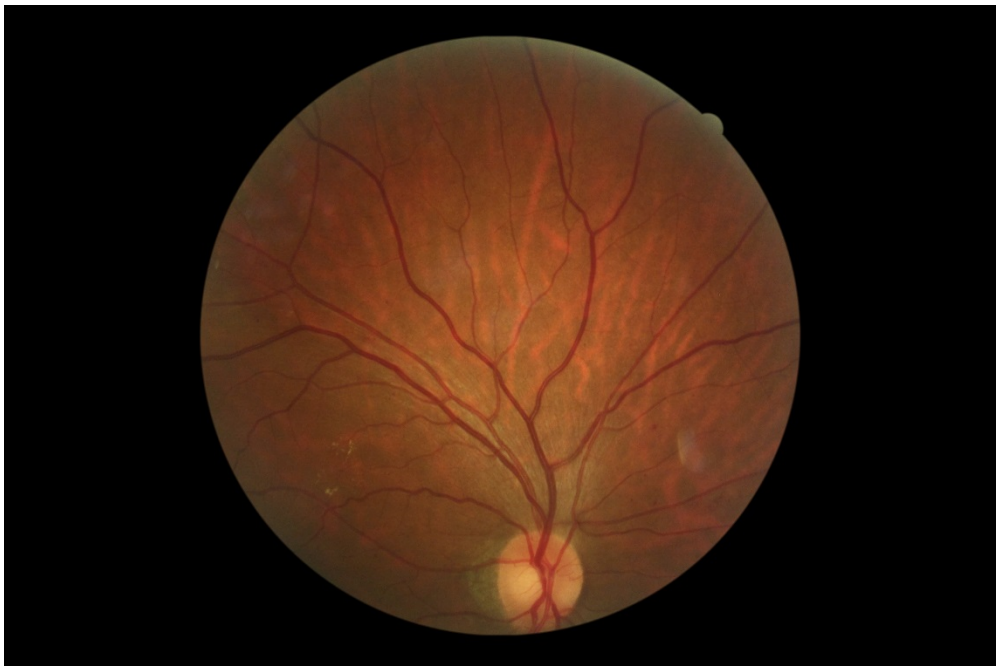
Fundus photos of patients in this study (eyes were not dilated)



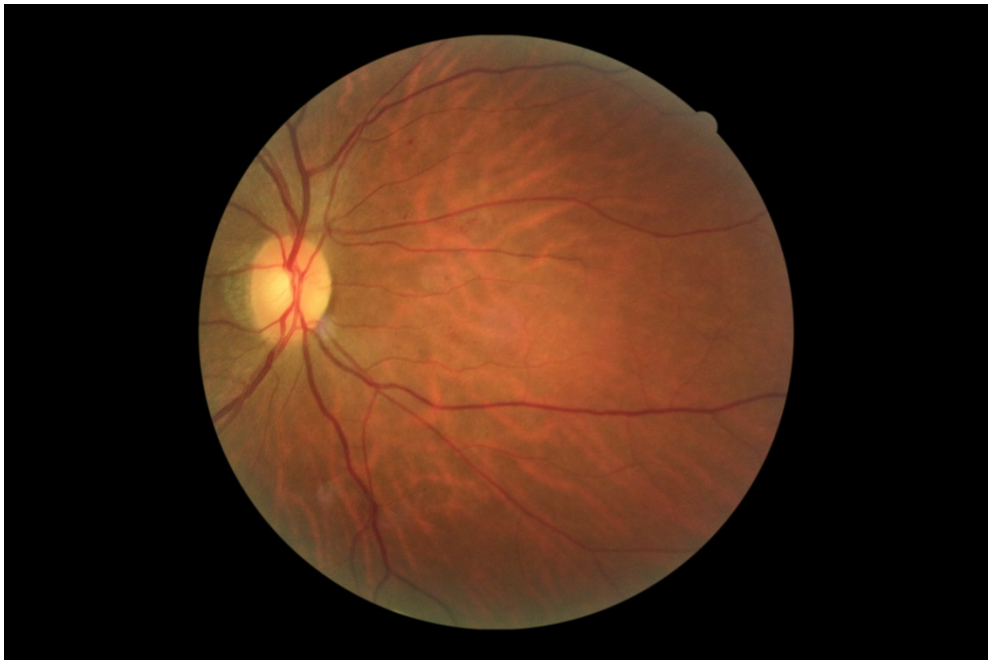
Patient 1: Normal eye (no evidence of ocular pathology)



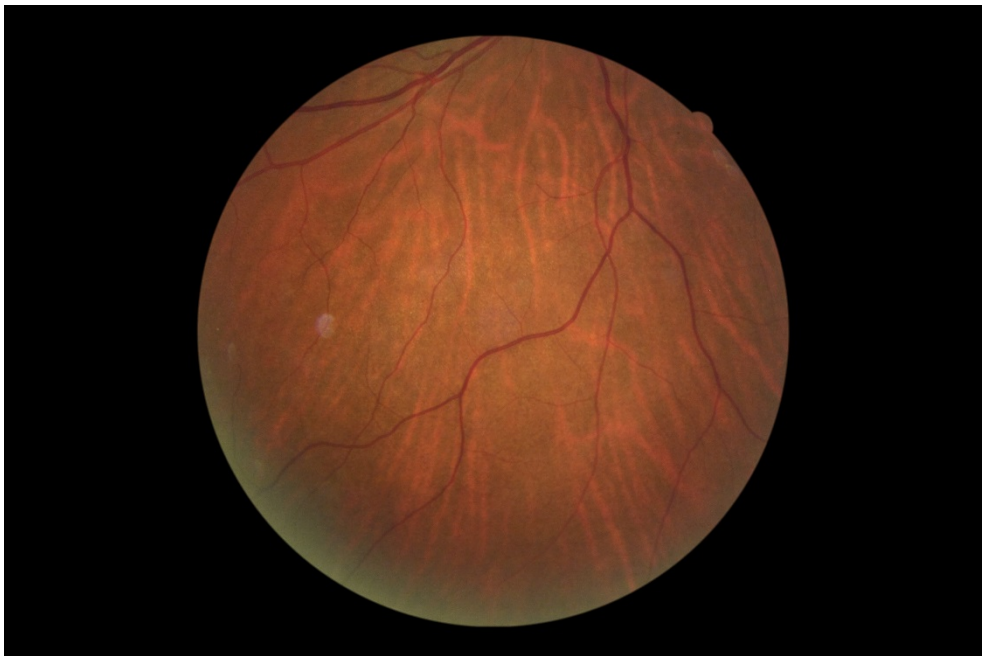
Patient 2: Mild background diabetic retinopathy and referable maculopathy of right eye



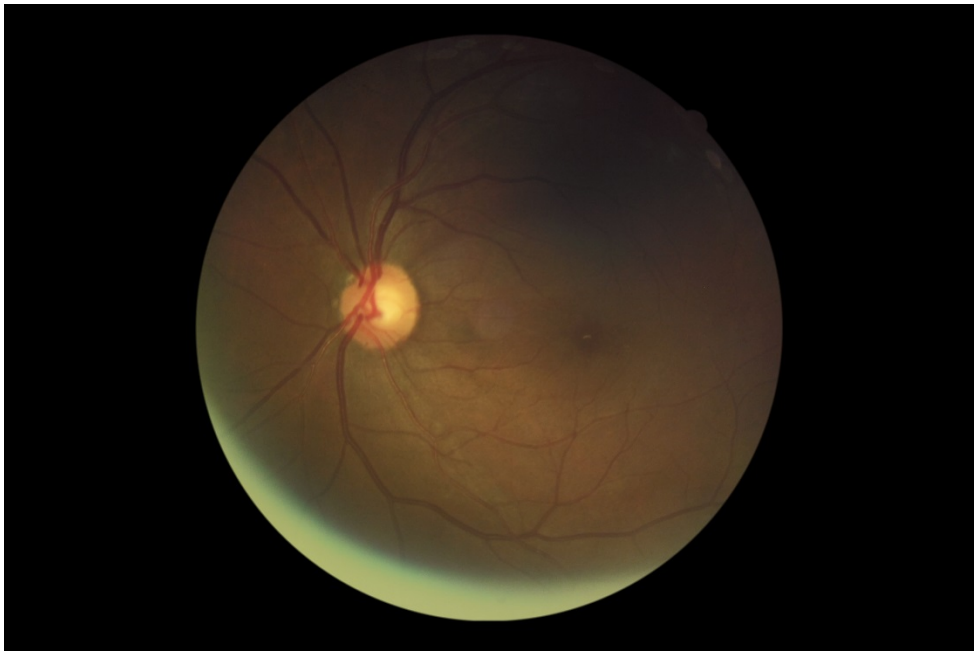
Patient 2: Looking downwards (improved view of periphery)



Patient 2: Looking sideways (improved view of periphery)



Patient 2: Looking upwards (improved view of periphery)



Patient 3: Left eye glaucomatous disc changes with normal intraocular pressure of 14mmHg (Icare tonometer used)

Appendix 2. Certificate of Language Editing

Dr Annemie Grobler

PhD (English), APEd (SATI) member 1003103

Language practitioner - translation, text editing and proofreading

anyaproofreading@gmail.com

PO Box 35002

Faunasig

9325

Cell nr 0845102706

This is to certify that the following document has been professionally language edited:

PREVALENCE OF DIABETIC RETINOSCOPY IN A GROUP OF DIABETIC CLINIC PATIENTS AT NATIONAL DISTRICT HOSPITAL, BLOEMFONTEIN

Author: Dr Joleen Patricia Cairncross

Nature of document: Mini-dissertation

Date of this statement: 29 October 2016

AM Grobler

Appendix 3. Patient Information Sheet

INFORMATION DOCUMENT

Study title: Prevalence of diabetic retinopathy in a group of diabetic clinic patients at National District Hospital, Bloemfontein

Dear Sir/Madam

I, Dr JP Cairncross am doing research on diabetic retinopathy. Research is just the process to learn the answer to a question. In this study I want to learn how many diabetic patients attending National District Outpatients have diabetic retinopathy. Diabetic retinopathy is an eye disease caused by uncontrolled diabetes mellitus and affects the vision. I am going to examine the eyes of patients coming for diabetic disease follow up, to look for possible eye diseases resulting from diabetes. Patients suffering from diabetes eye complication or other eye disease will be referred to the Department of Ophthalmology. Where the eye disease can be corrected with spectacles, patients will be referred to the Department of Optometry. Also to improve medical treatment of diabetes, should this be needed, by the doctors at National Hospital Outpatients. I hope to raise awareness to patients on the importance of diabetic control and reducing diabetic retinopathy.

I am inviting you to participate in this research study.

The study will involve eye examination of each participant. Visual acuity will be checked with a Snellen chart. Intra-ocular pressure will be checked with Icare tonometer. This instrument will gently touch the outer surface of the eye and measure the pressure. It is painless and takes a few seconds. The pupils of both eyes will be dilated medically, with tropicaimide 1% eye drops for improved view of the retina (where diabetic retinopathy changes can be seen). Participants will be instructed to look down and 1-2 drops will be inserted. Participants will be asked to apply gentle pressure to corner of the eye (close to the nose) for 2 minutes. This will reduce absorption into the blood stream. This will be repeated on the other eye. After 20 minutes pupils will be adequately dilated for the fundus photographs to be taken. This will make it easier to view the retina, posterior segment of the eye, where the diabetic eye disease can occur. Blood $HbA1_C$ levels within last three months will be checked in participant's notes. If not available, the blood sample will be repeated. $HbA1_C$ level is a marker used to assess the control of diabetes. All these investigations will be done on the same day where possible. Alternatively patients will be given a date to return. The researcher will discuss each participant with the Department of Ophthalmology and review management plan of diabetic retinopathy. Approximately 300 patients will participate in the study. This will only be done in Bloemfontein, South Africa.

Risks involved would be after dilation of eyes. Your vision will be blurred. This usually lasts 4 to 6 hours. However it might last up to 24 hours in some patients. The researcher recommends participants not to drive a car until the vision is normal. Please have someone drive you home. After instillation of the eye drops your eyes may sting, be a bit red and be sensitive to light. Very rarely an allergic reaction may occur with swelling(in or around the eyes, the face, tongue and throat), severe dizziness and trouble breathing. Seek medical attention if this should occur. Also rarely the pressure in your eyes may increase. If you have severe eye ache please seek medical attention. If any of these effects persist or worsen, the participant should inform their nearest healthcare worker that they are part of a study and should be referred immediately to National Hospital Casualty department. Please show this Patient Information leaflet to the healthcare worker. Or patients can contact the researcher directly telephonically. Most people using this medication do not have serious side effects.

Being part of this study you will have the benefit of routine diabetic eye screening, with the added benefit of other eye diseases, if present, being diagnosed and treated. The researcher work in partnership with the Departments of Ophthalmology and Optometry and will arrange further appointments and treatments. The researcher will contact you telephonically to make arrangements.

Participation is voluntary, and refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled; the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Efforts will be made to keep personal information confidential. Absolute confidentiality cannot be guaranteed. Personal information may only be disclosed if required by law. Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the Ethics Committee for Medical Research and the Medicines Control Council (where appropriate)
If results are published, this may lead to cohort identification. No personal identity data will be published.

Please contact me for further information/reporting of study-related adverse events
Dr Joleen Cairncross
0848901001
jo77c@doctors.org.uk

Contact details of REC Secretariat and Chair- for reporting of complaints and problems.
Mrs. Henriette Strauss or Mrs. Jemmima Du Plessis. Contact no: 051 405 2821/12

Appendix 4. Patient Information Sheet (Afrikaans)

Inligtingsstuk:

Titel van die studie: Prevalensie van Diabetiese Retinopatie in ‘n groep diabetiese kliniek pasiente by Nasionaal Streekshospitaal, Bloemfontein.

Geagte Mnr/Mev

Ek, dr. JP Cairncross, doen navorsing oor diabetiese retinopatie. Navorsing is die proses om ‘n antwoord te kry op ‘n vooraf opgestelde vraag. In hierdie studie wil ek vasstel hoeveel pasiënte met diabetes wat by Nasionaal Buitepasiënte Kliniek opvolg, diabetiese retinopatie het. Diabetiese retinopatie is ‘n oogsiekte wat visie affekteer en veroorsaak word deur ongekontrolleerde diabetes mellitus. Ek gaan pasiënte, met diabetes, se oë ondersoek by hul opvolg besoeke om sodoende moontlike oogsiektes te diagnoseer. Pasiënte wat aan enige oogsiekte of oogsiekte as gevolg van diabetes ly, sal verwys word na Departement van Oftalmologie. Indien die probleem slegs met die dra van ‘n bril gekorrekteer kan word, sal pasiënte na Departement Optometrie verwys word. Ek hoop om hierdeur bewustheid te kweek oor die belangrikheid van optimale glukose beheer in pasiënte met diabetes en sodoende diabetiese retinopatie te verminder.

Ek nooi u uit om deel te neem aan hierdie studie.

Die studie sluit ‘n oogtoets van elke deelnemer in. ‘n Snellen kaart sal gebruik word om visuele gesigskerpte te bepaal. Intra-okulêre druk sal gemeet word deur ‘n Icare tonometer. Hierdie instrument meet die druk van die oog deur liggies and die buitenste oppervlak van die oog te raak. Geen pyn word ervaar deur hierdie prosedure nie en dit neem slegs ‘n paar sekondes. Tropicaimide 1% oogdruppels sal gebruik word om die pupille van beide oë te dilateer. Hierdeur word ‘n beter aansig van die retina geopenbaar om enige veranderinge, wat deur diabetes veroorsaak word, waar te neem. Deelnemers sal gevra word om af te kyk terwyl 1-2 druppels in die oog geplaas word en daarna vir 2 minute druk toe te pas aan die binnekant van die ooghoek, by die neusbrug. Dit verminder absorpsie van die druppels in die bloedstroom. Dit word dan herhaal in die ander oog. Na 20 minute sal die pupille genoegsaam gedilateer wees om foto’s te neem van die retina, posterior segment van die oog, waar diabetiese oogsiekte plaasvind.

Bloed HbA1c waardes wat binne die laaste 3 maande geneem is, sal gebruik word. Indien daar geen onlangse HbA1c in die leêr is nie, sal ‘n nuwe monster geneem word. HbA1c is ‘n waarde wat die kontrole van diabetes in die bloed aandui. Al die bogenoemde prosedures sal op dieselfde dag geskied, indien moontlik. Indien nie, sal die pasiënte ‘n opvolgdatum kry.

Die navorser sal elke deelnemer met Departement Oftalmologie bespreek en ‘n verdere behandelingsplan sal vasgestel word. Hierdie studie sal slegs in Bloemfontein uitgevoer word met ongeveer 300 deelnemende pasiënte.

Newe –effekte met betrekking tot toediening van oogdruppels en dilatasie van oë:

- Versteurde visie. Dit duur ongeveer 4 tot 6 ure, alhoewel dit tot 24 uur kan duur in sommige pasiënte. Die navorser beveel aan dat deelnemers nie self moet bestuur totdat visie terugkeer na normaal nie.
- ‘n Brandgevoel in die oë, oë wat rooi word en sensitief is vir lig.
- ‘n Allergiese reaksie wat swelling van die oë en lugweg, lughoofdigheid en asemnood teweeg bring, is skaars.
- Erge oogpyn.

Indien enige van bogenoemde newe-effekte vererger of nie opklaar nie, moet u dadelik verwys word na Nasionaal Ongevalle Departement. Wys asseblief hierdie inligtingsstuk vir die mediese praktisyn aan diens. U kan ook die navorser telefonies kontak.

Deur u deelname aan die studie, word u oë nie slegs getoets vir diabetiese oogsiektes nie, maar vir enige ander oogsiekte teenwoordig. Dit word dan gediagnoseer en verder behandel. Die navorser reël verdere afsprake met Departement Oftalmologie en Optometrie. Die navorser sal u persoonlik kontak in verband met die reëlings.

Deelname is vrywillig. Deelnemers kan in enige stadium van die studie besluit om te onttrek en sal nie gepenaliseer word daarvoor nie.

Persoonlike inligting sal sover moontlik konfidensieël gehou word aangesien absolute konfidensialiteit nie gewaarborg kan word nie. Persoonlike inligting mag bekend gemaak word as vereis word deur die wet. Organisasies wat die navorsing kan naslaan vir gehalteversekering en data-analise, sluit groepe in soos die *Ethics Committee for Medical Research* and the *Medicines Control Council.* Resultate wat gepubliseer word maak deel uit van ‘n kohort studie, dus sal geen persoonlike data gepubliseer word nie.

Vir enige verdere inligting of studie-verwante newe-effekte, kontak
Dr Joleen Cairncross
0848901001
E-pos adres: jo77c@doctors.org.uk

Kontakbesonderhede van REC Sekretaris – Mev. Henriette Strauss of Mev. Jemmina Du Plessis: 051 – 4052821/12.

Appendix 5. Patient Consent Form

PATIENT CONSENT TO PARTICIPATE IN RESEARCH:

Dear Sir/Madam

You have been asked to participate in this research.

PREVALENCE OF DIABETIC RETINOPATHY IN GROUP OF DIABETIC CLINIC PATIENTS AT NATIONAL DISTRICT HOSPITAL, BLOEMFONTEIN

You have been informed about the study by Dr Joleen Cairncross

You have been informed about the procedures involved, the possible risks and further management related to this study. You have received a patient information leaflet explaining the aforementioned. The patient information leaflet also include the contact details of the researcher and the Secretariat of the Ethics Committee of the Faculty of Health Sciences.

Your participation in this research is voluntarily and you will not be penalized nor lose benefits if you refuse to participate or decide to terminate participation. The benefits of participating in this study will be having eye screening added to your routine diabetic follow up visit.

If you agree to participate in the research you will be given a signed copy of this document as well at the participant information leaflet, which is a written summary of the research.
To complete everything will take approximately 30 minutes.

The research study, including the above information has been verbally described to me. I understand what my involvement in the study means and I voluntarily agree to participate.

I, the undersigned……(full name and surname) from……
(address) File no…….. Date of birth……..
Contact numbers……../……
Hereby authorize Dr Joleen Cairncross to include me as a participant in this study.

..... ……..
Signature of participant Date

..... .……..
Signature of researcher Date

Appendix 6. Patient Consent Form (Afrikaans)

Pasiënt toestemming tot deelname aan navorsingsstudie:

Geagte Mnr/Mev

U is gevra om deel te neem aan die volgende navorsingsstudie.

PREVALENSIE VAN DIABETIESE RETINOPATIE IN ‘n GROEP DIABETIESE KLINIEK PASIëNTE BY NASIONAAL STREEKSHOSPITAAL, BLOEMFONTEIN.

Dr. Joleen Cairncross het u ingelig oor hierdie studie.

U is verder ook ingelig oor die prosedures, die moontlike risiko’s en die verdere hantering met betrekking tot die studie. Jy het ‘n inligtingsstuk ontvang wat die bogenoemde verduidelik. Die inligtingsstuk bevat ook die kontakbesonderhede van die navorser, sowel as die sekretaris van die Etiekkomitee van die Fakulteit Gesondheidswetenskappe.

U deelname aan hierdie studie is vrywillig en u sal nie nadelig beïnvloed word indien u besluit om te onttrek of nie deel te neem aan die studie nie. Die voordele met betrekking tot deelname aan die studie is ‘n oogtoets tydens u diabetiese opvolg besoek.

Indien u bereid is om deel te neem aan die studie sal u ‘n ingligtingsstuk met ‘n opsomming van die navorsing, sowel as ‘n getekende kopie van hierdie dokument ontvang. Dit sal ongeveer 30 minute van u tyd neem om alles te voltooi.

Die navorsingsstudie, sowel as die bogenoemde inligting is verbaal aan my verduidelik. Hiermee gee ek vrywilliglik toestemming om deel te neem aan die studie en verstaan my betrokkenheid in hierdie verband.

Ek, die deelnemer ……..(volle naam en van)
van……..(adres)
Leer no.....Geboorte datum.....
Kontak nommer...../.....
Hiermee gee ek toestemming aan Dr Joleen Cairncross vir deelname aan hierdie studie.

.....	.....
Handtekening van deelnemer	Datum
.....	.....
Handtekening van navorser	Datum

Appendix 7. Patient Data Sheet

A4

Prevalence of diabetic retinopathy in a group of diabetic clinic patients at National District Hospital, Bloemfontein

Participant number: .....

For office use only

A) Visual acuity — Right | Left — R 1-2, L 3-4

1: No light perception
2: Light perception
3: Finger counting
4: Hand movement
5: 6/60
6: 6/36
7: 6/24
8: 6/18
9: 6/12
10: 6/9
11: 6/6

B) Visual acuity (specticles/pinhole) — Right | Left — R 5-6, L 7-8

1: No light perception
2: Light perception
3: Finger counting
4: Hand movement
5: 6/60
6: 6/36
7: 6/24
8: 6/18
9: 6/12
10: 6/9
11: 6/6

C) Pupil reflexes — Right | Left — R 9, L 10

1: RAPD present
2: absent

D) Appearance of red reflex — Right | Left — R 11, L 12

1: Absent
2: Present

E) Intra-occular pressure (mmHg) — Right | Left — R 13-14, L 15-16

Participant number: .....

	Right	Left	For office use only
F) Eclipse test			
1: Positive			17
2: Negative			18
G) Fundus examination	**Right**	**Left**	
Retina:			
1: No diabetic retinopathy anywhere			R 19
2: Mild backgroun D.R - at least one dot haemorrhage or microaneurysm, with or without hard exudates			L 20
3: Observable background D,R - four or more blot haemorrhages, in one hemi-field only			
4: Referable backgroun D.R - four or more blot haemorrhages, in both inferior and superior hemi-fields			
5: Proliferative PDR - active new vessels, vitreous haemorrhages			
6: Inadequate - not adequately visualised			
Macula:			
1: Observable maculopathy - lesions in a radius of >1 but <2 disc diameters of centre of fovea, hard exudates			R 21
2: Referable maculopathy - lesions in a radius of <1 disc diameter of centre of fovea, blot haemorrhages, hard exudates			L 22
H) Blood HbA1C level within 3 months			. 23-26
I) Incidental Findings			
.....			27-28
.....			29-30
.....			31-32
.....			33-34
.....			35-36
J) Outcome			
Referred to Ophthalmology			37
1: Yes			
2: No			
Referred to Optometry			38
1: Yes			
2: No			

Paricipant number: .....

Follow up at Ophthalmology ☐ 39
1: Same day
2: < 4 weeks
3: 1 month
4: 3 months
5: 6 months
6: 12 months

Reason for referral to Ophthalmology
..... ☐☐ 40-41
..... ☐☐ 42-43
..... ☐☐ 44-45
..... ☐☐ 46-47
..... ☐☐ 48-49

Known to Ophthalmology?
1: Yes ☐ 50
2: No ☐ 51

Participant referred back to NDH OPD for DM control?
1: Yes ☐ 52
2: No ☐ 53

Appendix 8. Patient Questionnaire

A3

Prevalence of diabetic retinopathy in a group of patients attending the diabetic clinic at National District Hospital, Bloemfontein

		For office use only
1) Date:	...../...../.....	1-6
2) Participant number	.....	7-9
3) Age	.....	10-12
4) Gender	1 Male 2 Female	13
5) Home language	1 Afrikaans 2 English 3 Sotho 4 Other, specify.....	14
6) How long have you been on treatment for diabetes?	Years: ..... Months:	15-16 17-18
7) How long have you been attending National Outpatients for diabetes?	Years: ..... Months:	19-20 21-22
8) How many times per year do you have a routine visit to see the Dr for your diabetes?	.....	23-24
9) In the last year, at a routine visit has the Dr asked about your vision?	1 Yes 2 No 3 Not sure	25
10) In the last year, at a routine visit has the Dr checked your vision with a Snellen chart	1 Yes 2 No 3 Not sure	26
11) In the last year, at a routine visit has the Dr checked your eyes with an ophthalmoscope?	1 Yes 2 No 3 Not sure	27
12) In the last year, at a routine visit have you ever mentioned to your Dr that your vision is deteriorating?	1 Yes 2 No 3 Not sure	28

Participant number .....

		For office use only
13) In you opinion, can diabetes worsen your vision?	1 Yes 2 No 3 Not sure	29
14) Have you been referred to Ophthalmology since you've been diagnosed with Diabetes Mellitus?	1 Yes 2 No 3 Not sure	30