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Assessing the knowledge and practices regarding eye care and complications of diabetes among diabetic patients 18 years and older, attending a tertiary diabetic clinic in Kampala, Uganda.

BY

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Outline

Assessing the knowledge and practices regarding eye care and complications of diabetes among diabetic patients 18 years and older, attending a diabetic clinic in Kampala, Uganda

This research was done for Master of Public Health (MPH) dissertation, analysed to assess knowledge and practices regarding eye care and eye complications of diabetes among diabetic patients 18 years and older, attending a tertiary diabetic clinic in Kampala, Uganda.

Part A presents the research protocol. It states the study background and the research process. The study was cross-sectional and primary data was collected from a diabetic clinic in a Ugandan tertiary hospital.

Part B presents the reviewed literature of articles that have been published, summaries and reports on eye care and diabetes complications in diabetic patients.

Part C presents the research project format that is suitable for journal submission. The background of the research is summarised, results presented and discussed.

PART A: PROTOCOL

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List of Abbreviations

KP Knowledge and Practices

MPH Master of Public Health

DM Diabetes Mellitus

WESDR Wisconsin Epidemiological study of Diabetic Retinopathy

DR Diabetic Retinopathy

AAO American Academy of Ophthalmologist

IDF International Diabetes Federation

UKPDS United Kingdom Prospective Diabetes Study

PDR Proliferative Diabetic Retinopathy

ETDRS Early Treatment of Diabetic Retinopathy Study

VEGFs Vascular endothelial growth factors

DRVS Diabetic Retinopathy Vitrectomy Study

WHO World Health Organization

PIL Patient Information Leaflet

Purpose of the study

The aim of this study is to audit the knowledge and practices regarding eye care and eye complications of diabetes among diabetic patients 18 years and above in Kampala, Uganda.

Specific objectives

1. To determine the level of awareness about eye care and eye complications of diabetes among diabetic patients aged 18 years and older.
2. To determine the level of eye care health seeking behaviour among diabetic patients aged 18 years and older.
3. To ascertain the factors that affect knowledge and eye care health seeking behaviours of diabetic patients.

Definition of terms

Eye complications of diabetes: Diabetic retinopathy (damage to the retina at the back of the eye due to diabetes).

Eye care: Regular eye check-up for diabetic retinopathy as recommended by World Health Organization (WHO).

Knowledge: Patients' awareness of ocular effects of diabetes, as pertaining to the questions in the patient information leaflet (PIL).

Practice: How the patient uses the available eye care services to care for self, as pertaining to the questions in the PIL.

2.0 Background

2.1 Diabetes mellitus and its associated eye complications

2.1.1 Diabetes mellitus

Diabetes mellitus (DM) is a condition that occurs when the body is unable to control the glucose levels due to reduced insulin production or failure to use the insulin that has been produced or both¹. Insulin refers to a hormone that controls blood glucose². DM is mainly manifested by increased blood sugar (hyperglycaemia) resulting from failure of insulin to change carbohydrates, fats and proteins into the energy required by the body, namely glucose. Persistent hyperglycaemia is associated with various complications including renal, cardiovascular, ocular and neural complications¹. The World Health Organization (WHO) standard for diagnosis of diabetes mellitus is fasting plasma glucose levels that are equal to or less than 7.0mmol/l (126mg/dl) or 2 hour plasma glucose levels equal to or less than 11.1mmol/l(200mg/dl)³. Diabetes mellitus symptoms include polyuria, loss of weight, polydipsia, occasionally with visual disturbances and polyphagia¹.

Diabetes mellitus is classified into two main types, diabetes mellitus type 1 and diabetes mellitus type 2. Type 1 DM, also known as “insulin dependent DM” occurs due to autoimmune destruction of Beta cells which produce insulin and as a result there is absolute deficiency of insulin and in these individuals. Exogenous insulin is required and the age of onset is normally before 30 years¹.

Type 2 DM also known as adult on-set DM or non-insulin dependent DM results from the failure of the body to utilize the secreted insulin (insulin resistance) and in this category individuals have relative insulin deficiency and do not depend on insulin for survival¹. The other type of DM is known as gestational diabetes that occurs during pregnancy.

2.1.2 Diabetic eye complication (Diabetic Retinopathy)

One of the eye complications resulting from DM is diabetic retinopathy (DR) and it has been reported as one of the major causes of blindness among patients with DM⁴. Diabetic retinopathy is a visual threatening eye condition arising from changes in the retina microvasculature as a result of persistent hyperglycaemia and other associated conditions like high blood pressure⁵. It is a common eye complication among type 1 and type 2 diabetic patients⁶.

2.2 Diabetes mellitus and diabetic eye complication (Diabetic Retinopathy) epidemiology

2.2.1 Epidemiology of diabetes

Globally the prevalence of diabetes mellitus (DM) has become a public health concern⁷. In 2015, it was estimated that DM affects 415 million adults aged between 20 and 79 years and this number is predicted to increase to 615 million in 2040 if not stopped⁸. About 80% of all the patients living with DM are found in middle and low- income countries, with urban areas harbouring 69% of the diabetic population.

In the African region 19.8 million adults have been estimated to have DM⁹, of which the largest proportion of undiagnosed individuals are found in Africa at 69%. Recent studies done in Uganda indicate that DM has also become an important public health concern and the overall national prevalence was estimated at 2.0%. This figure varies in different regions with some areas reaching 9.0%¹⁰. One hospital based study done in Western Uganda reported the prevalence of DM at 2.5%¹¹. The population of individuals living with DM in Uganda has significantly risen from approximately 98000 people in the year 2000 to about 1.5 million people in the year 2010 out of a population of 30 million individuals¹².

2.2.2 Epidemiology of diabetic retinopathy

Diabetic retinopathy, a common complication of diabetes mellitus is responsible for 1.8 million (4.8%) cases of blindness out of 37 million cases in the world⁷. The overall global prevalence of DR amongst those with DM is reported at 36.4% affecting 93 million individuals⁷.

The duration of disease among the diabetic population is associated with micro-vascular complications as demonstrated by the Wisconsin Epidemiological Study¹³. Both type 1 and type 2 diabetic mellitus patients experience diabetic retinopathy. Over 97 % of all of type 1 DM, and 77.8% of type 2 DM patients progress to some level of retinopathy after having lived with DM for 15 years¹. In Africa, the prevalence of diabetic retinopathy in people with DM has been reported between 30.2 to 31.6% by a systematic review of population-based studies conducted in 21 African countries. However, the four studies done in a clinical setting, the prevalence ranged between 7.0 to 62.6%¹⁴. In a hospital based study done in Western Uganda, the prevalence of diabetic retinopathy was reported at 12.5%¹⁵ and an earlier study in Mulago hospital had identified 9 out of 105 patients with diabetes mellitus as having diabetic retinopathy¹⁶.

As diabetic retinopathy is a condition that develops slowly and saliently, early recognition and timely intervening are crucial in its management. Diabetic patients should therefore be screened to prevent needless visual loss². In diabetic individuals, to prevent development and complications associated with DR, regular eye check-ups are required in addition to regular measurement and regulation of their blood glucose levels, lipid levels and hypertension⁶.

2.3 Risk factors for diabetic retinopathy in diabetes mellitus

2.3.1 Disease duration.

Several studies have indicated that diabetes mellitus duration is a major predictor for developing retinopathy among patients of both type 1 and type 2 DM. Before the age of 30 years, the prevalence of any type of retinopathy after 2 years was 8%, after 5 years 25%, after 10 years 75%, and after 15 years 97.5%, as reported by the Wisconsin Epidemiological study of Diabetic Retinopathy (WESDR). In patients with retinopathy at a young age, Proliferative Diabetic Retinopathy (PDR) manifested in 1.2% of those who had DM for less than 10 years and this increased to 67% in patients who had the disease for over 35 years¹⁷.

2.3.2 Use of Insulin

Dependency on insulin has been reported as a significant factor in predicting the course of retinopathy. In a meta-analysis of seven cohort studies, there was significant association between insulin use and the risk of developing DR among type 2 diabetic patients¹⁸.

2.3.3 Glycaemic control

Hyperglycaemia is strongly associated with the risk of developing retinopathy in diabetic patients. The Diabetes Control and Complications Trial¹⁹, showed a reduction in the incidence of developing retinopathy by 76% among type 1 DM taking insulin and 54% reduction among the patients on routine treatment. In another study WESDR, persistent high levels of glycosylated haemoglobin (HbA1c) was linked to development of PDR²⁰. HbA1c is a component of haemoglobin to which glucose binds and acts as a marker of prolonged level of blood glucose. Reducing HbA1c from 8 to 7% reduces the risk of micro vascular damage by 35% and HbA1c of more than 8% is related to severe retinopathy²¹.

2.3.4 Blood pressure

There is evidence from several studies showing that controlled blood pressure reduces vascular complications among DM patients. The WESDR study found a strong link between high systolic pressure and developing retinopathy among the individuals who have had diabetes mellitus for more than 15 years¹⁷. The United Kingdom Proliferative Diabetic Study (UKPDS) also found that tight control of blood pressure (<150/85mmHg) reduced visual acuity deterioration by 47% and reduction in developing retinopathy by 34% among type 2 DM patients²².

2.3.5 Pregnancy

In the WESDR study, it was revealed that Type 1 diabetic pregnant women had two times the risk of developing PDR compared to those that were not pregnant. Insulin dependent women in a study in Saudi

Arabia, 24% of the pregnant women showed development of retinopathy. Other factors that were indicated to increase the risk of progression to retinopathy among pregnant women were duration of >15years, high blood pressure and bad control of blood sugar²³.

2.4 Diabetic retinopathy natural history

Diabetic retinopathy is a progressive condition that presents in stages. An individual may have no signs of DR, but as micro-vascular changes start to occur in the retina, the signs become apparent. Diabetic retinopathy begins to manifest initially with mild non-proliferative diabetic retinopathy (NPDR), progresses to moderate and severe form of NPDR, and later to proliferative diabetic retinopathy (PDR)²⁴. Mild NPDR occurs in the early stages of the disease and increased permeability in the micro-vasculature of the retina is a major characteristic. Moderate and severe NPDR present with micro-vascular closure of the retina. Macula involvement can occur at any stage during progression of DR²⁴. It presents with oedema, retinal thickening as a result of leaking blood vessels and finally macula ischemia occurs. In PDR there is worsening ischemia with development of new abnormal vessels on the retina and posterior vitreous surface²⁴.

Loss of vision in diabetic retinopathy arises from different mechanisms. The main cause is ischaemia of the macula, haemorrhage of the vitreous and retina and retinal detachment that occurs when there is contraction of the fibrous tissue that has been formed together with the new vessels²⁴.

2.5 Screening and prevention of diabetic retinopathy

In diabetic individuals, to prevent development and complications associated with DR, regular eye check-up (screening) for diabetic retinopathy is required in addition to regular measurement and regulation of their blood glucose levels, lipid levels and hypertension²⁵. The American Academy of Ophthalmologists²⁶ has provided guidelines on screening for diabetic retinopathy. Type 1 DM patients are required to screen annually for diabetic retinopathy starting five years when the diagnosis of the disease has been made while the type 2 DM patients are supposed to have an eye examination at diagnosis and thereafter have yearly eye examinations²⁶.

2.5.1 Primary prevention and early detection of diabetic retinopathy

A healthy lifestyle is vital in moderating diabetes mellitus and visual complications associated with it. In individuals who have developed visual complications, it is more cost effective to treat DR compared to the direct costs that come with visual loss³. Hence the need to educate both the physicians and patients about the importance and indication for referral.

Amongst the various methods to help prevent and manage DR, positive awareness of the condition among the diabetic patients can help to improve on timely, early identification and management of the condition

with prevention of late complications²⁷. Studies have indicated that knowledge of risk factors and prevention of eye complications is essential in prevention of visual loss amongst diabetic patients. Despite the substantial number of individuals having awareness of eye care / screening and eye complications resulting from diabetes mellitus, the utilization of the eye care services has not been at the desirable levels, hence the need for improvement²⁷. Evidence from two trials indicates that treating diabetic retinopathy may provide 90% effectiveness in prevention of severe visual loss through use of available treatment²⁸. Despite availability of treatment, few diabetic patients have been given information and referred to the ophthalmologist by the primary physicians as required by the American Academy of ophthalmology and the American Diabetes Association guidelines²⁹. Therefore, there is need to educate both the physicians and patients about the importance and indication for referral to the ophthalmologist²⁹. Data from two studies done at population level, between 43% and 64% of diabetic participants had not had an eye exam at the time of enrolment into the study³⁰.

The gold standard for detecting DR is by use of stereoscopic colour 30 degrees fundus photographs in 7 fields that are standard³¹. Ophthalmoscopy (direct/indirect) is the common method used to screen for DR. Dilated ophthalmoscopy has a sensitivity ranging from 45% to 98% and specificity of 62% to 100%³². Diabetic patients having NPDR and macular oedema must be given a referral to the eye specialist for further management.

2.5.2 Secondary Prevention.

The recommendation for proper glycaemic control among diabetic patients is HBA1c of 7.0% or less.

2.6 Treatment of diabetic retinopathy

The first and most important step in the management of diabetic retinopathy remains lifestyle changes and diet. However other effective treatment modalities have been used to preserve vision and dramatically reduce the risk of vision loss. These treatments include the following:

2.6.1 Laser

This is the major form of treatment for diabetic retinopathy that is visually threatening. Severe visual loss from PDR was reduced at least by 50% in a study of diabetic retinopathy among diabetic mellitus patients. Macular laser reduced the rate of visual loss to half in patients with macular oedema in the study that looked at Early Treatment Diabetic Retinopathy³³. In another study, pan-retinal laser in PDR patients reduced visual loss rate by 60% while focal laser was found to reduce Macula oedema by 50%³⁴. Therefore, laser treatment can prevent visual loss among individuals with sight-threatening macula oedema and proliferative diabetic retinopathy. While laser is useful in preventing visual loss, it cannot restore vision that has been lost.

2.6.2 Vitrectomy

Vitrectomy is used to treat advanced PDR in which vitreous haemorrhage and retinal detachment are observed. Vitrectomy therapy removes both vitreous haemorrhage as well as prevention and relief of retinal traction in patients with advanced PDR. In the Diabetic Retinopathy Vitrectomy Study (DRVS), type 1 diabetic patients with severe PDR who received early Vitrectomy within three months, 25% of them achieved a visual acuity of $\geq 6/12$ when followed up at 4 four years³⁵.

2.6.3 Vascular endothelial growth factors (VEGFs)

The development of new retinal vessels is initiated by VEGFs. This causes increased permeability with resultant neovascularization and reduced macular oedema. The introduction of anti-VEGF specific drugs like ranibizumab (Lucentis) and bevacizumab (Avastin) in managing macular oedema in diabetic patients has been useful. When ranibizumab was compared to pan-retinal photocoagulation, the standard treatment for PDR, there was reduced possibility of developing diabetic macular oedema, reduced peripheral visual field loss and decreased need for Vitrectomy³⁶.

2.7 Justification of the study

Diabetic retinopathy is a significant cause of visual impairment and blindness among patients with diabetes mellitus if not detected early. For effective formulation and implementation of convincing approach of health awareness, reference data on knowledge and practices among diabetic individuals on eye care and associated eye complications is important²⁷

Research studies to evaluate knowledge and practices and others on attitudes amongst individuals with diabetes mellitus have been done previously in Saudi Arabia²⁵, Bangladesh³⁷, India³⁸, Oman³⁹ and Nigeria⁴⁰ amongst other countries. The desire for improved awareness on control of risk factors, prevention, diagnosis and management of diabetic retinopathy has been stated in most of these studies.

Improved awareness among diabetic patients about DR has been reported by different studies to improve early detection, prevention and reversal of visual impairment associated with it. However, many other studies conducted in different regions have indicated limited knowledge about DR and use of eye care services among patients with diabetes mellitus, hence the severe eye complications seen among these individuals^{41,42}. This could be a similar situation among the diabetic patients in Uganda.

To date no study in Uganda has been conducted to assess the awareness and practice of diabetic patients regarding eye care and associated eye complications. Therefore, it was necessary that a study be conducted

to collect information that would help to design health awareness and self-care prevention strategies for the diabetic patients in Uganda. The data collected would also help to improve the management of diabetic patients as well as inform policy in terms of allocating resources for prevention of eye conditions among individuals living with diabetes mellitus in Uganda.

3.0 Methods

3.1 Study

A cross-sectional study was done to collect data on the demographics, level of awareness and practices of the participants regarding eye care and diabetes eye complications.

Data was collected for a period of two months (August and September 2018), on every day of the week that the clinic was conducted. The participants were selected from patients attending the diabetic clinic using a random systematic sampling and every n th patient was included as per the register. In a situation where the patient declined participation in the study or was not eligible, then the next one was picked. This was done until the required sample size was obtained.

The medical outpatients register made by the nurse in charge on each clinic day was used as a sampling frame for this study. The participants were briefed by the nurse in charge regarding the study purposes.

3.2 Study setting

The study was conducted at Mulago National Referral Hospital in Kampala, the capital city of Uganda. It is the National referral health care unit of the country. It conducts an outpatient's diabetic clinic one time a week, in addition to full-time patient services. Health care services including consultations, investigations and medicines, and are provided free for both inpatients and outpatients. Therefore, this makes this hospital a good setting for undertaking the study since it receives individuals from all parts of the country (Appendix IV).

3.3 Sample size

The sample size for the study was calculated with the formula adopted from Kasiulevicius et al⁴³ for calculating sample size for prevalence studies and is stated as: $n = Z^2 P (1-P)/d^2$, Where:

p is the anticipated population/prevalence

d is the required precision on the either side of the proportion

n represent the required sample size

Z2 = 1.96 (the cut-off value of the Normal distribution at the 95% confidence level)

In a study done in Nigeria, a low-middle income country like Uganda, the level of knowledge regarding diabetes mellitus, complications associated with it and eye care among diabetic patients was documented at 40.77% and their practice was reported at 31%⁴⁴. Basing on the above-mentioned statistics, a sample size of 371 was required to estimate the proportion of participants demonstrating good awareness and a sample size of 329 participants was required to assess the proportion of participants demonstrating good eye care practice. Using the significance level (type I error) of 5% (at 95% level of confidence) and permissible error (precision) of 5%, the sample sizes were estimated as below:

Sample size for assessing level of awareness $n = 1.962 \times 40.77(100-40.77)/5^2$

=371 participants

Level of health seeking behaviour (Practice)

$n = 1.962 \times 31(100-31)/5^2$

=329 participants

The final sample size to estimate both level of awareness on diabetes mellitus, its associated eye complications and the level of eye care health seeking behaviour was selected by taking the largest estimated sample size from above (371 participants). Accounting for the anticipated non-response rate of 10%, the final sample size was 409 participants.

3.4 Characteristics of study population

The population of the study comprised of individuals with diabetes mellitus who were 18 years and over selected from the diabetic clinic at Mulago referral hospital, Kampala.

3.4.1 Inclusion criteria

All individuals with diabetes mellitus attending a diabetic clinic at Mulago hospital aged 18 years and older and had ability to give informed consent

3.4.2 Exclusion criteria

All individuals who were unable to respond to the questionnaire like those with hearing impairment, unable to comprehend the information, and the vulnerable individuals like prisoners, and those with mental disorders like Bipolar and depression

3.5 Recruitment and enrolment

Following the procedure for sampling, the investigator recruited and enrolled the participants. Participants were identified as they waited to see the clinicians after registering with the nurse in-charge. The participants were clearly informed about the purpose of the study, benefits and risks involved.

3.6 Research procedures and Data collection methods

The participants who were interested in participating in the study were then offered an informed consent form to sign before enrolment.

This study utilized interviewer administered questionnaire to obtain data from participants and the questionnaire was in English. To ensure that data collected was uniform, the questionnaire was administered by the investigator who was fluent in both English and the Local language (Luganda) that is used in the region. A validated questionnaire that was already used in a previous study done in India was used⁴⁴ and most questions in the knowledge and practice sections were open ended to minimize the bias that could arise due to questions that are leading.

The questionnaire consisted of three sections, with 8 questions assessing the demographic characteristics of the participants, 13 questions to assess knowledge of the participants, including general knowledge of DM and its complications, risk factors for complications in DM, screening and options for managing diabetic retinopathy. The third section had 15 questions that assessed participant practices, including control and treatment of DM and its complications. The questionnaire was pre-tested on 10 individuals with DM to help assess if information meant to be collected by the tool was what was being collected. The responses to the questions were scored and the total score attained by the participant in each section was calculated. Based on the number of correct responses to 'must know' questions in the knowledge section of the questionnaire and 'must do' questions in the practice section, each patient in the study was categorized as having 'good' or 'poor' knowledge, and 'good' or 'poor' practice pattern.

3.7 Data management and analysis

Data was captured in EPIDATA version 3.1¹ for proper data management from where it was exported to STATA version 15.0² for analysis. We used mean (for normally distributed continuous variables), medians (for non-normally distributed continuous variables), frequencies, percentages and graphs to describe patient characteristics. Study objectives one and two were analysed by computing the number and proportion of participants demonstrating good awareness and good practice. Fishers and Pearson chi- square, T-test and Rank sum tests were used to test for associations between participants' characteristics and practice. To identify factors that influence participants' practice, a logistic regression model was used and variables with a p value of the unadjusted odds ratio that is <0.2 were taken to multivariable analysis to identify factors that significantly predicted participants' practice at a 95% confidence interval.

3.8 Ethical Consideration:

Ethical approval was obtained from the University of Cape Town Faculty of Health Science Research Ethics Committee (UCT-REC). Ethical clearance was also attained from the Mulago Research Ethics Committee (MREC) prior to study commencement.

3.9 Risk and benefit description

3.9.1 Risks

There was minimal risk or discomfort anticipated for an individual participating in this study. They could be asked some questions about their life that were personal and could cause discomfort. They could also be delayed in being seen by the physician or miss their place in the queue while taking the interview. No blood or any other sample was taken from the participants in this study.

3.9.2 Benefits

Findings from the study could offer valuable information to health workers in improving the quality of services for diabetic patients with emphasis on eye care. In addition, the participants received information on how to prevent eye complications of diabetes mellitus. If they had not had their eyes checked or had missed their appointment, they were appropriately referred to the recommended facilities to receive the service. The participants' routine medical care was not altered in any way, regardless of whether they decided to participate in this study or not. A patient information leaflet (PIL) (Appendix III) on how to care for the eyes

¹ EpiData Software - <http://www.epidata.dk>.

² StataCorp. 2017. Stata Statistical Software: Release 15. College Station, TX: StataCorp LLC.

was available in the clinic. The PIL had been translated into the local language (Luganda) for participants who were unable to read English (appendix IV)

3.10 Informed consent process

All participants were asked to complete an informed consent (Appendix II) before participation. The informed consent form (Appendix III) was translated into the local language (Luganda) for participant unable to read English. Participants that were eligible to take part in the study were asked to read or had the information in the consent form read to them in the language they best understood and comprehended. Thereafter the concerns that they had were addressed. They were told that participating in the research was entirely voluntary and that they could opt out of the study at any time and stage of the study. The informed consent form provided information on the purpose, and content of the study to the individuals who were eligible to take part in the study. Furthermore, the consent form was to inform participants about the study benefits and risks as well as the study procedures. The researcher ensured that all the information in the consent form was well understood by going through it with the participant before commencement of data collection. Each participant who agreed to take part in the study went ahead and signed the informed consent form to show their willingness to participate. In this study no type of reimbursement was given to participants during the study period. At the end of the consenting process the participant was provided with a copy of the consent form that had been signed.

3.11 Privacy and Confidentiality

The interviews were conducted in a private room. All answers were treated confidentially. Complete anonymity using coded identification numbers was ensured. Completed questionnaires were protected and stored under double-lock conditions after data capture. The principle researcher was in custody of the key. Access to the electronic data was restricted to the principle investigator. The participants were briefed that information obtained from them could be published in a journal that is peer reviewed. However, no participant information would be identifiable should the findings of the study be published.

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APPENDICES

Appendix I

Questionnaire Key

1. The questionnaire will be administered to the participant by the investigator and it will not be shown to the participant. The patient will not be given the answer options or prompted regarding the options.
2. Correct answers in knowledge and practice sections are highlighted in purple
3. The scores for each section are highlighted green.
4. Some questions in knowledge and practice sections may have more than one correct answer.
5. Each correct response is given a score of one.
6. Some questions do not have a right answer and hence, are left unmarked.

Identification

Interviewer's initials.....

Date..... study number.....

Part 1

Questions on demographic characteristics

1. What is your gender?

1. Male
2. Female
3. Others (Specify).....

2. How old are you? (In years)

.....

3. What is your religious affiliation?

1. Christian
2. Islam
3. Others (specify).....

4. What is your marital/relationship status?

1. Single

2. Married
3. Divorced
4. Widowed
5. Cohabiting

5. What is your level of education?

1. Primary
2. Secondary
3. University/Tertiary institution
4. Never been to school

6. What is your current employment status?

1. Employed
2. Unemployed

If answer is "Unemployed" in question 6 above skip to question 8

7. What is the level of your income? (Per month)

1. Low income <100,000 shillings
2. Middle income 100,000-500,000 shillings
3. High income >500,000 shillings

8. How long have you had diabetes?

1. ≤1 year
2. 1≤2years
3. 2≤5 years
4. 5≤10 years
5. >10 years

Part 2

Knowledge

Preliminary statement: You will be asked a few questions to test your knowledge about diabetes and its complications. These questions are asked purely to test your knowledge about diabetes. They are not aimed at finding out what you actually practice. (Do not mention anything about diabetic retinopathy at this point.)

1. What are the tests done to diagnose diabetes (to find out if a person is diabetic)?

1. Blood tests
2. Urine tests
3. Any other (specify)

2. How can you keep diabetes under control?

1. Medication
2. Diet
3. Exercise
4. Weight reduction
5. Going for regular check up
6. Do not know
7. Any other (specify)

3. Once diabetes is diagnosed, how long should diet control/ treatment be continued?

1. Till the sugar levels get under control
2. Lifelong
3. Any other (specify)

4. Which parts of the body are affected by diabetes?

1. Kidney
2. Feet
3. Eyes
4. Nerves
5. Heart
6. Do not know
7. Any other (specify)

If option 3 in Question 4 has been circled (diabetes can affect the eyes), proceed to question 5; if not, skip to Practice section.

5. What problems can patients with diabetes have in the eye?

1. Cataract
2. Retinopathy (damage to retina/nerve at the back of the eye due to diabetes)
3. Infections in the eye
4. Defective vision

5. Do not know

6. Any other (specify)

Total score for knowledge regarding diabetes: 17

Good knowledge: score of 9 and above

Poor knowledge: score of less than 9

If option 2 in Question 5 has been circled (patients with diabetes can have retinopathy, i.e., damage to retina/nerve at the back of the eye due to diabetes), proceed to question 6; if not, skip to Practice section.

6. How did you first find out that diabetes can cause retinopathy (damage to the retina/ nerve at the back of the eye due to diabetes)?

1. Informed by physician at local hospital
2. Informed by ophthalmologist at local hospital
3. Informed by optometrist at local optical dispensary
4. Informed by physician at the diabetic clinic
5. Informed by ophthalmologist at Eye hospital
6. Got information from media, books (specify)
7. Got information from family/ friends
8. Any other (specify)

7. How many years after diagnosis of diabetes did you find out that diabetes can cause retinopathy?

1. At the time of diagnosis
2. Any other (specify time interval in years since diagnosis of diabetes)

8. Can diabetic retinopathy (damage to the retina/ nerve at the back of the eye due to diabetes) cause blindness?

1. Yes
2. No
3. Do not know

9. What are the factors that cause progression/worsening of diabetic retinopathy (damage to the retina/ nerve at the back of the eye due to diabetes)?

1. Poor control of diabetes
2. Hypertension

3. Nephropathy
4. Anaemia
5. Do not know
6. Any other (specify)

10. What are the treatment options available for diabetic retinopathy (damage to the retina/ nerve at the back of the eye due to diabetes)?

1. Spectacles
2. Laser
3. Surgery
4. Injection into the eye
5. Do not know
6. Any other (specify)

11. Can a person with diabetic retinopathy (damage to the retina/ nerve at the back of the eye due to diabetes) have normal vision?

1. Yes
2. No
3. Do not know

12. Should patients with diabetes have a periodic/regular dilated eye check up to look for diabetic retinopathy (examination of the back of the eye after instilling dilating eye drops to look for changes in the retina due to diabetes)?

1. Yes > proceed to Question 13
2. No > skip to practice section
3. Do not know > skip to practice section

13. How often should patients with diabetes who have no diabetic retinopathy (damage to the retina/ nerve at the back of the eye due to diabetes) have a dilated eye check-up?

1. Once in 6 months
2. Once a year
3. Once in 2 years
4. Once in 5 years
5. Do not know

6. Any other (specify)

Total score for knowledge regarding diabetic retinopathy: 11

Good knowledge: score of 5 and above

Poor knowledge: score of less than 5

Practice

Preliminary statement: You will be asked a few questions to find out what you actually do regarding treatment and control of diabetes and its complications.

1. Do you take medicines for diabetes as advised by the physician?

1. Yes

2. No

2. Do you follow the diet schedule as advised by the physician?

1. Yes

2. No

3. Do you take regular exercise?

1. Yes (specify type: walking/ jogging/ cycling/ work out in gym/ any other; duration per day; how often in a week)

Recommended exercise regime: Regular moderate-intensity physical activity;

30- 60 min daily, 5-7 days/week

2. No

4. Is your diabetes under control at present? (Verify later with the most recent HbA1C levels done)

3. Yes

4. No

5. Do not know

5. Do you go for regular follow up as advised by your physician?

1. Yes > skip to Question 7

2. No > proceed to Question 6

6. Why do you not go for regular follow up as advised by your physician?

1. Cannot afford

2. No family support

3. Do not think it is important
4. Did not find time
5. Checking sugar levels with glucometer at home is sufficient
6. Did not know that regular follow up is necessary
7. Any other (specify)

Total score for patient's practice pattern regarding diabetes: 5

Good practice pattern: score of 4 and above

Poor practice pattern: score of less than 4

7. Has anyone told you that you need to go for a periodic/regular eye check-up?

1. Yes (specify when: time interval in years since diagnosis of diabetes, and who, and where)
2. No

8. Do you have a periodic/ regular eye check-up?

1. Yes > proceed to Question 9
2. No > skip to Question 13

9. To whom do you go for your periodic/ regular eye check-up?

1. Physician at local hospital
2. Optometrist at local optical dispensary
3. Ophthalmologist at local hospital
4. Ophthalmologist at Eye hospital
5. Eye camps
6. Any other (specify)

10. Why do you go for a periodic/regular eye check-up?

1. Follow up/treatment of diabetic retinopathy
2. To check power of glasses
3. Been instructed to have periodic eye check-up, but do not know reason
4. Any other (specify)

11. How often do you go for a dilated eye check-up?

(Key: correct option will depend on presence and level of diabetic retinopathy (damage to the retina/ nerve at the back of the eye due to diabetes) and treatment regime followed)

1. Once in 3 months
2. Once in 6 months
3. Once a year
4. As advised by ophthalmologist (specify) 5. Any other (specify) **Score of 1 for correct answer**

12. To whom do you go for your dilated eye check-up?

1. Physician at local hospital
2. Optometrist at local optical dispensary
3. Ophthalmologist at local hospital
4. Ophthalmologist at Eye hospital
5. Screening by dilated fundus photography
6. Any other (specify)

(Options 3 or 4 or 5 may be circled; **score of 1 for correct practice**)

13. Why have you not gone for a periodic/ regular eye check-up?

1. Do not trust the local doctor
2. Poor family support
3. Long distance from hospital (in hours of travel by the means of transport usually utilized by the patient)
4. Financial problems
5. Physically unwell (specify details of physical ailment)
6. Did not know that periodic eye check-up should be done
7. Had good vision; so did not feel need for check-up
8. Any other (specify)

14. How long after diagnosis of diabetes did you have your first dilated eye check-up?

1. Within 3 months of diagnosis of diabetes
2. >3 months to 1 year after diagnosis of diabetes
3. >1 year to 5 years after diagnosis of diabetes
4. >5 years to 10 years after diagnosis of diabetes
5. >10 years to 15 years after diagnosis of diabetes
6. > 15 years to 20 years after diagnosis of diabetes
7. > 20 years after diagnosis of diabetes (specify number of years)

15. Why did you go for your first dilated eye check-up?

- 1. Was referred by physician at local hospital (specify reason for referral)**
- 2. Was referred by optometrist at local optical dispensary (specify reason for referral)**
- 3. Was referred by physician at the diabetic clinic (specify reason for referral)**
- 4. Was referred from eye camp**
- 5. Went on my own because I knew that diabetes can cause retinopathy (damage to the retina/ nerve at the back of the eye due to diabetes)?**
- 6. Went on my own because I had problems in the eye (specify nature of problem)**
- 7. Any other (specify)**

Total score for patient's practice pattern regarding diabetic retinopathy: 5

Good practice pattern: score of 4 and above

Poor practice pattern: score of less than 4

End

Appendix II

Informed consent form

My name is Mackline Hope, a Master of Public Health student at the University of Cape Town. I am conducting a study as a requirement for completion of my Masters Degree and I am kindly requesting for your participation.

The study title

Assessing the Knowledge and Practices regarding eye care and complications of diabetes among diabetic patients 18 years and older, attending a tertiary diabetic clinic in Kampala, Uganda.

The purpose of this study

The purpose of this study is to collect information about what knowledge and practices the diabetic patients have on eye care and eye complications in diabetes. You are required to respond to questions in the questionnaire which includes sections on, your personal details, knowledge and practices. Before you decide to take part in this interview; I would like to explain to you the purpose of the interview, the risks and benefits, and what would be expected of you if you agree to participate in the interview. If you decide to participate in the discussion, you will be asked to sign a consent form that will acknowledge your willingness to participate in the study. It is your right to ask whatever is on the consent form that you may not understand.

Study procedures

The principle investigator will administer a questionnaire to the participant in the language they best understand. The questionnaire has three sections, including the demographics section that collects personal information, a section that collects data on your knowledge regarding diabetes and its complications and a section on what you do regarding treatment and control of diabetes and its complications. This interview will take about 30 minutes of your time.

Risks and discomforts

Risks

I anticipate minimal risk to you when you participate in this research study. You may be asked some questions about your life that are personal and may cause discomfort. You may also delay in being seen by

the physician or miss your place in the queue while taking the interview. No blood or any other sample will be removed from you in this study.

Benefits

Findings from the study may offer valuable information to health care providers to improve quality of eye care services for diabetic patients. In addition, you will receive information on how to prevent eye complications of diabetes. If you have not had your eyes checked or have missed your appointment, you will be appropriately referred to the recommended facilities to receive the service. Any questions that you may have regarding Diabetes and its complication will be addressed. A flyer with information on how to care for your eyes is available at your clinic.

Payment for participation

There is no cost to you for participating in this study apart your time. You will receive a light refreshment after your interview as a compensation for your participation in this study.

Alternatives

Your routine medical care will not be affected in any way whether or not you decide to participate in this study.

Confidentiality of information and privacy

The interviews will be conducted in a private room. All answers will be confidential. Complete anonymity using coded identification numbers will be ensured. Completed questionnaires will be safely protected and stored under double lock conditions. The principle researcher will be in custody of the key. Access to the electronic data will be restricted to the principle investigator. The information obtained from you may be published in a journal that is peer reviewed, however no participant will be identified during the publication of the findings from the study without seeking permission from them.

Your Participation is voluntary

It is important that you know the following:

- You do not have to be in this study if you do not want to.
- You may decide to not take part in the study.
- You may stop being in the study at any time.

- You will be given a copy of this form, and the other copy will be kept in a secure and confidential place. You are free to choose to answer all or only some of the questions.

Any questions or concerns regarding this study, please contact the researcher using the telephone or email address below.

Dr. Mackline Hope: Tel: +256772659941: Email: drmackline@gmail.com

If you have concerns regarding your rights or wellbeing with respect to participation in this study; can direct them to the chairman of the Mulago Research Ethics Committee Dr. Frederic Nakwagala on this number +2562325869

Consent Declaration

I -----have read/been read the above information and clearly

Understand the explanation. I accept to voluntarily participate in the study of Assessing the Knowledge and Practices regarding eye care and complication of Diabetic Patients

18 years and older, attending a tertiary Diabetic Clinic in Kampala, Uganda

Signature/Thumbprint of the Subject-----

Date-----

For illiterate participants: I attest that the information contained in this written consent has been read and explained to the participant. To the best of my knowledge, the information provided was complete and accurate. The participant appears to understand the purpose, methods, risks and benefits of taking part in this study. He/she willingly agrees to his/her taking part in the study and has placed his/her thumbprint on this consent of his/her own free will.

Name of witness----- Signature of witness-----Date-----

Appendix III

Informed consent form (Luganda Version)

Ekiwandiiko kyokukkiriza okwetaba mu kunoonyereza

Erinya lyange nze Mackline Hope, omuyizi ku ddaala elyokubili mu 'Public Health' mu setendekero ya University of Cape Town. Nkola okunoonyereza ng'ekyetaago kyokumaliliza diguli yange eyokubili era nkusaba weetabe mu kunoonyereza kuno.

Omutwe gwokunoonyereza

"Okupima omumanya wamu nenkola ezekuusa ku kulabilira amaaso nebizibu byabalwadde ba ssukaali abalina emyaka kkumi namunaana (18) nokudda waggulu, abajanjabibwa ku kilinika yabassukaali mu Kampala, Uganda"

Ekigendererwa kyokunoonyereza kuno

Ekigendererwa kyokunoonyereza kuno kwekukungaanya obubaka obukwata ku magezi nenkola abalwadde ba sukaali gyebalina ku maaso wamu nebizibu byamaaso. Weetagibwa okwanukula ebibuuzo ebili mu kiwandiiko kyebibuuzo omuli ebitundu ku, ebikukwatako gwe ngomuntu, amagezi wamu nenkola. Nga tonnaba kusalawo kwetaba mu bibuuzo bino, njagala okukunyonyola omugaso gwebibuuzo, obulabe n'emiganyuro nabiki ebyandikusubidwamu singa okkiriza okwetaba mu bibuuzo bino. Bwosalawo okwetabamu, ojja kusabibwa okuteeka omukono ku kiwandiiko kyebibuuzo ekijja okukakasa okweyagalirakwo okwetaba mu kunoonyereza. Ddembelyo okubuuza buli kimu ekili ku kiwandiiko kyokukkiriza kyoyinza obutategeera.

Emitendera gyokunoonyereza

Akulira okunoonyereza ajja kugaba ekiwandiiko ky'ebibuuzo eri eyetabyemu mu lulimi lwebategeera obulungi. Ekiwandiiko ky'ebibuuzo kilina ebitundu bisatu, omuli ekitundu kyebikukwatako ekikungaanya obubaka bwomuntu sekinnomu, ekitundu ekikungaanya obubaka obukwata ku kumanyakwo ku bulwadde bwa ssukaali wamu nebizibu byabwo nekitundu ekikwata ku kiki kyokolera ddala ekikwata ku bujanjabi nokuziyiza obulwadde bwa sukaali nebizibu. Ebibuuzo bino bijja kutwala eddakiika amakumi asatu agobuddebwo.

Obuzibu nebitali bilungi

Ebizibu

Nteebeleza obuzibu butono eri gwe bwewetaba mu kunoonyereza kuno. Oyinza okubuuzibwayo ebibuuzo ebikwata ku bulamubwo ebyobuntu era biyinza okuleetawo obutawulira bulungi. Era oyinza okulwawo okulabibwa omusawo, oba okusubwa ekifokyo mu lunyilili ngebibuuzo bibuuzibwa. Tewali musaayi oba sampo ndala enakujjibwako mu kunoonyereza kuno.

Emiganyuro

Ebizuulidwa okuva mu kunoonyereza kuno biyinza okuwa obubaka obwomugaso eri abagabi bobujanjabi okuteleeza omutindo gwobujanjabi bwamaaso kulwabalwadde ba ssukaali. Okwongerako, ojja kufuna obubaka kungeri yokuziyizaamu ebizibu byamaaso mu bulwadde bwa ssukaali. Bwoba tonnaba kukeberwa maasogo oba ng'osubidwa okulabwa, ojja kuweelezebwa ku malwaliro agalagirwa okusobola okufuna obujanjabi. Obujanjabibwo obwabulijjo, tebujja kukosebwa mungeri yonna oba osalawo okwetaba mu kunoonyereza oba nedda. Ebibuuzo byonna byoyinza okubeela nabyo ebyekuusa ku bulwadde bwa ssukali nebizibu byabwo bijja kugonjoorwa. Ekipande ekiliko obubaka ku ngeri yokulabilira amaasogo wekili ku kilinikayo.

Okusasulira okwetaba mu kunoonyereza

Tewaliiwo bisale byonna gyoli kulwokwetaba mu kunoonyereza kuno okujjako kulwobuddebwo. Ojja kufuna ekyokunywa ekiweweewu oluvanyuma lwokubuuzibwa ebibuuzo ng'okuddizibwa kulwokwetabakwo mu kunoonyereza kuno.

Obuyinza bwo

Bwosalowo obutetaba mukunoonyereza kuno tekija kutabula bujjanjabi bwolina kufuna mu kilinika eno

Obwekusifu bwobubaka wamu

Ebibuuzo bijja kubuuzibwa mu kisenge ekyekyama. Okwanukurwa kwonna kujja kubeera kwakyama. Obwekusifu nga tukozesa namba ezilaga bujja kukakasibwa. Ebiwandiiko ebiwedde bijja kutelekebwa bulungi era bikuumibwe awantu awasibidwa emilundi ebili. Anoonnyereza ajja kukuuma ekisumuluzo. Okulaba ebiwandiiko ebili ku kompyuta bijja kulabibwako akulira okunoonyereza kwokka. Obubaka obukujjibwako buyinza okufulumizibwa mu biwandiiko ebisomedwamu, wabula, tewali yetabyemu ajja kulagibwa mu biseera byokufulumya ebiwandiiko ebizuulidwa okuva mu kunoonyereza nga tosabye lukusa okuva gyebali.

Okwetabamu kwa kyeyagalire

Kyamugaso nti omanyanya bino wammanga:

- Toteekedwa kubeera mu kunoonyereza bwoba toyagala.
- Oyinza okusalawo obuteetaba mu kunoonyereza.
- Oyinza okukoma okubeera mu kunoonyereza akadde konna.
- Ojja kuweebwa kkopi yekiwandiiko kino, wamu nekkopi endala ejja kutelekebwa mu kifo ekyekusifu. Oli waddembe okulondawo okwanukula ebibuuzo byonna oba ebimu.

Ebibuuzo byonna oba ensonga ezekuusa ku kunoonyereza, bambi tuukilira anoonyereza ng'okozesa enamba yessimu oba omutimbagano gwa yintaneti wammanga.

Musawo Mackline Hope: Esimu: +256772659941:
Omutimbagano: drmackline@gmail.com

Bwoba n'ebibuuzo ebikwata ku ddembe lyo mukunoonyereza kuno laba sentebbe

Mulago Research Ethics Committee Dr. Dr. Frederic Nakwagala ku simu +256772325869

Webale.

Okukkiriza

Nze-----nsomye/nsomedwa obubaka obuli waggulu era ntegedde bulungi okunyonyorwa. Nzikiriza okweyagalira okwetaba mu kunoonyereza ku "Okupima omumanya wamu nenkola ezekuusa ku kulabilira amaaso nebizibu byabalwadde ba ssukaali abalina emyaka kkumi namunaana (18) nokudda waggulu, abajanjabibwa ku kilinika yabassukaali mu Kampala, Uganda.

Omukono -----

Enaku zomwezi-----

Kulwabetabyemu abatamanyi kusoma nakuwandiika: Nkakasa nti obubaka obuli mu kiwandiiko kino busomedwa era nebunyonyonyorwa eyetabyemu. Okusenziira ku kutegeera kwange, obubaka obuweeledwa bubadde bujuvu era nga bumala. Eyetabyemu alabika okutegeera ekigendererwa, enkola, obulabe wamu nemiganyuro ejili mu kwetaba mu kunoonyereza kuno. Yeyagalira okukkiriza okwetaba mu kunoonyereza era atadde ekinkumukye ku kiwandiiko kino nga yeyagalidde.

Erinya lyomujulizi----- Omukono gw'omujulizi-----

Ennaku zomwezi.....

Appendix IV

Information leaflet on diabetes and diabetic retinopathy (English Version)

DIABETES AND THE EYES

Diabetes is a problem with your body that causes blood glucose (sugar) to rise higher than normal. You may have heard that diabetes causes eye problems and may lead to blindness. People with diabetes do have a higher risk of blindness than people without diabetes. But most people who have diabetes have nothing more than minor eye disorders. With regular check-ups, you can keep minor problems minor. And if you do develop a major problem, there are treatments that often work well if you begin them right away.

EYE CARE

There are steps you can take to avoid eye problems.

FIRST AND MOST IMPORTANT, keep your blood sugar levels under tight control.

SECOND bring high blood pressure under control. High blood pressure can make eye problems worse.

THIRD, quit smoking.

FOURTH, we generally recommend that you see your eye care professional at least once a year. Having your regular doctor look at your eyes is not enough. Nor is having your eyeglass prescription tested by an optician. Only an eye care professional can detect the signs of damage to your eyes and provide the right treatment.

FIFTH, see your eye care professional if:

- your vision becomes blurry
- you have trouble reading signs or books
- you see double
- one or both of your eyes hurt
- your eyes get red and stay that way
- you feel pressure in your eye
- you see spots
- straight lines do not look straight
- you can't see things at the side as you used to.

Appendix V

Information leaflet on diabetes and diabetic retinopathy (Luganda Version)

OBULWADDE BWA SSUKAALI N'AMAASO

Obulwadde bwa ssukaali kye kizibu kyomubiri ekireeta ssukaali okweyongera okusukka kuwa bulijjo. Oyinza okuba wawulirako nti ssukaali areeta ebizibu ku maaso nga kiyinza okugaleetera okuziba. Abantu abalina obulwadde bwa ssukaari babeera mu katyabaga kanene ako kuziba amaaso okusinga abatamulina. Naye abantu abasinga tebalina nyo kyamanyi okuggako okutawanyizibwa amaaso ekitonotono. N'okujjumbiranga okwekebeza kukendeeza ku buzibu obutonoto. Bwoba ofunye obuzibu obwa maanyi, waliyo eddagala erikola obulungi bw'oba olitandikiddewo.

OKULABIRIRA AMAASO

Eriyo emitendera gyosobola okugoberera okuziyiza ebizibu by'amaaso.

EKISOOKEERA DDALA OBUKULU, Fuba okulaba nti ssukaali tarinnya

EKYOKUBIRI, Fuba okulaba nti pressure yo terinnya. Presssure okulinywa kiyinza okwongera obuzibu ku maaso

EKYOKUSAATU, Vva ku kunywa ssigala

EKYOKUNA, Okutwaliza awamu tubakubiriza okulaba omusawo wo omukugu ow'amaaso wakiri omulundi gumu mu mwaka. Omusawo owa bulijjo okutunulila amaasogo kyokka, oba okufuna ekipimo kyagalubundi ebikebeddwa okuva eri omusawo owa amaaso tekimala. Omusawo omukugu ow'ebyamaaso yekka y'asobola okuzuula obubonero obw'obuvune ku maaso go n'akuwa obujjanjabi obutuufu.

EKYOKUTAANO, Laaba omusawo omukugu ow'ebya amaaso singa:

- Ofuna ekifu ku maaso (ngatolaba bulungi)
- Ofuna obuzibu mu kusoma ebubonera oba ebitabo
- Ekintu ekimu okirabamu ebintu bibiri
- Eriiso lyo erimu oba gombi nga kaluma
- Amaaso gamyuka okumala ebanga
- Owulila nga amaaso gatujja
- Olaba ebbala ku liiso
- Emisitale emitereevu nga gikyamyeye
- Tokyasobola kulaba ebintu kumabali nga bwe wakolanga

Appendix VI
Eligibility checklist for study participants

Eligibility Criteria			
	Inclusion Criteria	Include	Exclude(If any is ticked)
1	Diabetic	<input type="checkbox"/> YES	<input type="checkbox"/> NO
2	Aged ≥18	<input type="checkbox"/> YES	<input type="checkbox"/> NO
3	Able and willing to give written informed consent	<input type="checkbox"/> YES	<input type="checkbox"/> NO
4	Attending a diabetic clinic at Mulago Hospital	<input type="checkbox"/> YES	<input type="checkbox"/> NO
	Exclusion criteria	YES	NO
1	Hearing impairment	<input type="checkbox"/>	<input type="checkbox"/>
2	Prisoners	<input type="checkbox"/>	<input type="checkbox"/>
3	Mental disorder	<input type="checkbox"/>	<input type="checkbox"/>
4	Unable to comprehend		
	All inclusion criteria met and no exclusion	<input type="checkbox"/>	<input type="checkbox"/>
	If yes, assign study id.		

Appendix VII

Proposed study Budget for 2 months' duration of the study

Item	Justification	Unit cost (UGX)	Number of units	Amount (UGX)
Paper Reams	Print CRFs & consents	20,000	10	200,000
Printing & photocopying	Print study documents	300,000	1	300,000
Filing cabinet	Store study documents	200,000	1	200,000
Box files	Filing	15,000	10	150,000
Punching machine	Filing	20,000	1	20,000
Ink pad	Consenting	10,000	1	10,000
Pens	Data collection	500	10	5,000
Flash disk	Data collection	50,000	1	50,000
Statistician	Data analysis	1,200,000	1	1,200,000
Total				2,135,000

Appendix VIII

Uganda Map



22 June 2018

HREC REF: 193/2018

Prof C Cook
Ophthalmology
H53, OMB

Dear Prof Cook

PROJECT TITLE: ASSESSING THE KNOWLEDGE AND PRACTICES REGARDING EYE CARE AND COMPLICATIONS OF DIABETES AMONG DIABETIC PATIENTS 18 YEARS AND OLDER, ATTENDING A TERTIARY DIABETIC CLINIC IN KAMPALA, UGANDA (Masters candidate- Dr Mackline Hope)

Thank you for submitting your response to the Faculty of Health Sciences Human Research Ethics Committee dated 11 June 2018.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

1. The HREC are concerned that 409 seems like a large sample for one person to interview singlehandedly.
2. Is this practical and/or feasible given timelines and expected attendance numbers at the clinic?

Approval is granted for one year until the 30 June 2019.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

The HREC acknowledge that the student, Dr Hope Mackline will also be involved in this study.

Yours sincerely

Signature Removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

HREC 193/2018

Federal Wide Assurance Number: FWA00001637.

Institutional Review Board (IRB) number: IRB00001938

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines.

The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

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MULAGO NATIONAL REFERRAL HOSPITAL
P.O. Box 7051
KAMPALA, UGANDA

IN ANY CORRESPONDENCE ON THIS
SUBJECT PLEASE QUOTE NO...

THE REPUBLIC OF UGANDA

23rd July, 2018

Dr. Hope Mackline
Principal Investigator
School of Public Health
University of Cape Town.

Dear Mackline,

Re: Approval of Protocol MHREC 1457: "Assessing the Knowledge and Practices Regarding Eye Care and Complications of Diabetes among Diabetic Patients 18 Years and Older, Attending a Tertiary Diabetic Clinic in Kampala, Uganda".

The Mulago Hospital Research and Ethics Committee reviewed your proposal referenced above and granted approval on 19th July, 2018. The conduct of this study will therefore run for a period of one (1) year from 19th July, 2018 to 18th July, 2019.

This approval covers the protocol and the accompanying documents listed below;

- Eligibility checklist for study participants
- Informed consent form
- Questionnaire

This approval is subjected to the following conditions:

1. That the study site may be monitored by the Mulago Hospital Research and Ethics Committee at any time.
2. That you will abide by the regulations governing research in the country as set by the Ugandan National Council for Science and Technology including abiding to all reporting requirements for serious adverse events, unanticipated events and protocol violations.
3. That no changes to the protocol and study documents will be implemented until they are reviewed and approved by the Mulago Hospital Research and Ethics Committee.
4. That you provide quarterly progressive reports and request for renewal of approval at least 60 days before expiry of the current approval.
5. That you provide an end of study report upon completion of the study including a summary of the results and any publications.
6. That you will include Mulago Hospital in your acknowledgements in all your publications.

I wish you the best in this Endeavour.

Signature Removed

DR. NAKWAGALA FREDERICK NELSON
CHAIRMAN- MULAGO HOSPITAL RESEARCH & ETHICS COMMITTEE.
Vision: "To be the leading centre of Health Care Services"



PART B

LITERATURE REVIEW

Search Strategy

Using the PRISMA method, I searched and reviewed published articles, dissertations and online reports that were pertinent to the topic assessing the knowledge and practices regarding eye care and complications of diabetes among diabetic patients.

Keywords/Terms

Diabetes, Diabetic retinopathy, diabetic eye disease, Eye check-up, Eye-care-seeking behaviour, ocular knowledge and practice.

Inclusion

Hospital and population based cross sectional studies, reports, summaries, ophthalmology articles, and articles reporting on eye care and diabetes mellitus complications in diabetic patients.

Databases

Article identification was done through PubMed, web of science, science digest and grey literature (WHO website, Google and Google Scholar).

Exclusion

Articles not written in English and abstracts lacking full texts

Age limit: Articles that had individuals with ages less than 18 years

Results: A total of 37 articles specific to diabetic eye care, knowledge and practice among diabetic patients were identified and used in reviewing the literature.

Introduction

Diabetic retinopathy (DR) is a complication common among diabetes mellitus (DM) patients and causes 1.8 million (4.8%) cases of blindness out of 37 million cases in the world¹. Globally the overall prevalence of DR is reported at 36.4% affecting 93 million individuals².

The duration of disease among the diabetic population is associated with micro-vascular complications as demonstrated by the Wisconsin Epidemiological Study. Both type 1 and type 2 diabetic mellitus patients experience Diabetic retinopathy. After having, diabetes mellitus for over 15 years about 97.5% of all type 1 DM patients and 77.8% of all type 2 DM patients start developing diabetic eye complications³. Diabetic retinopathy prevalence in Africa ranged from 30.2% to 31.6% as reported by a systematic review of population-based studies conducted in 21 African countries. However, four studies done in a clinical setting, the prevalence ranged between 7.0 to 62.6%⁴. In a study done in Western Uganda, among diabetic patients in a hospital, diabetic retinopathy prevalence was reported at 12.5%⁵ and an earlier study in Mulago hospital had identified 9 out of 105 patients with diabetes as having diabetic retinopathy⁶.

Diabetic retinopathy is a condition that develops slowly and saliently, early recognition and timely intervening are crucial in its management. Therefore, diabetic patients should be screened so as to prevent visual loss⁷. In diabetic individuals, to prevent development and complications associated with DR, regular eye check-ups are required in addition to regular measurement and regulation of their blood glucose levels, lipid levels and hypertension⁸.

Knowledge and practice on diabetes mellitus, eye care and diabetic retinopathy

Knowledge and practice descriptive studies are aimed at collecting information on a particular topic of interest. Avoiding visual loss among diabetic patients is affected by the knowledge of the individual on the disease process, associated complications, and the required regular check-ups. Assessing the level of knowledge and practice regarding eye care and DM complications may help the health care service providers to focus their care on the needs of the communities they serve. Awareness of eye care and complication of DM generally differs across different communities. There are also statistical differences between population and hospital studies.

Knowledge on diabetes mellitus, diabetic retinopathy and eye care

Literature on knowledge of diabetic retinopathy and eye care in diabetic patients is limited. The rates of awareness between patients living with diabetes mellitus and individuals in the community population may differ. Knowledge levels are likely to be lesser in the general population⁹.

A south- Indian study done among DM type II patients presenting at a diabetic clinic, revealed that, among the 200 patients interviewed, a significant proportion (72.5%) were aware that DM causes eye damage. Out of the 200 patients, 52.5% knew that DM could decrease vision while 32.5% stated that DM could lead to total blindness. The level of knowledge on risk factors and modalities of treatment were found to be low, as 29% of the patients cited poorly controlled blood sugar being a risk factor while 54% of the patients knew that diabetic retinopathy can be treated ¹⁰.

High level of knowledge among diabetic patients, regarding effects of DM on eyes has been stated by several studies^{11,12}. The study done in Kenya revealed that 95% of the participants were aware that DM affects the eyes, while the one done in Malaysia showed that 86% of the diabetics had knowledge about eye effects of DM. The level of knowledge among the Jeddah diabetic patients was adequate at 92.4%; but a small proportion of 10.5% of the respondents were aware of the recommended visits for eye check-ups. Significant association between good levels of awareness with good level of education, frequency of follow up visits and patient source of information were reported.

In another study done in India, of the 288 patients interviewed, 42% were reported as having good awareness on DM, however only 4.5% had good awareness regarding diabetic retinopathy. A substantial association between good level of awareness and good levels of practice was reported. A significant proportion of 61.1% of the respondents never went for a regular eye examination and 38.5% of patients stated lack of awareness about the need for this as the major reason¹³.

A study done in Nigeria, Kano among diabetic patients, the knowledge rate was very high (84.3%)¹⁴. These results compare with findings from Myanmar diabetic patients where 86.0% of the respondents attending an outpatient unit were aware of diabetic retinopathy¹⁵. Contrary to the above two studies, one of the studies done in Kenya, a significant proportion of patients (69%) were not aware what DR was and only 69% of the patients could cite inadequate blood glucose control being a risk factor in diabetic retinopathy¹⁶. In the above study done in Nigeria, the patients mentioned hospital staff and fellow patients as the major source of information on diabetic retinopathy while other sources like internet and mass media seemed not to play a big role.

Results from a population-based study conducted in India, a significant proportion (37.1%) of the participants had good levels of knowledge on DR and more evidently higher among the individuals of high socioeconomic class, when they were compared with those of low socioeconomic status (OR=1.85; 95% CI: 1.32-2.58)⁹. In the same study, individuals who had good knowledge on DM were also more aware of the various treatment

modalities. When compared with another study done in Karachi Gaddap town (Pakistan), the level of knowledge about DR was found to be very low at 17.5% among the 527 participants that were interviewed¹⁷.

In an Indian study done to assess the DM prevalence and its correlates, awareness of DM was compared between the rural and urban population. The results reported that 43.2% of the total study population had heard about DM. The rates of awareness in the urban residents was higher at 58.4% and lower among the rural residents at 36.8%. Residents in the urbanized areas were more knowledgeable on DM complications and the factors that increase the risk of DR. Individuals in this study who knew that DM had effects on different organs in the body, a significant proportion of 54% mentioned the feet as being affected followed by 52.3% stating that the eyes were affected as well. The difference realized between the urban and rural population was attributed to the level of education. Knowledge was found to be low among those with no formal schooling (23.7%), reporting having heard about diabetes mellitus when compared with a higher proportion of 52.2% among those with primary education and above¹⁸. In this same study, the knowledge among participants was higher in the diabetic individuals compared to the general population.

In another study done in Pakistan Karachi, there was a substantial statistical variance observed among the diabetic and non-diabetic population. Among the diabetic population the knowledge of DM and DR was 41% compared to 35% among the non-diabetic individuals. The diabetic individuals (42%) also showed improved practice scores than non-diabetic individuals (36%). This study indicated that the likely explanation for this outcome was that, the diabetic individuals were taking precautions so to prevent diabetes complications⁹.

The level of education has been identified by several studies as a major feature in knowledge of DM and the complications associated with it. A hospital-based study conducted in Kenya among diabetic patients, the level of awareness of DR was reported to be 10% in those with no formal education. Participants who had attained secondary and tertiary levels education, the level of knowledge was 39%. In the same study high monthly income was significantly related to good knowledge levels¹⁶.

In a rural Indian population-based study, comparable results were attained. After conducting awareness meetings with the study population, only 19% of the individuals with none to primary school education level had knowledge on DM while the proportion of those with knowledge on diabetic retinopathy was even reduced to 13%. Amongst those with secondary and tertiary education 61% were aware of DM while 42% had knowledge about diabetic retinopathy. There was higher knowledge about DR among individuals of high socio-economic status and those that were older (40-49 years). Individuals who had awareness about DR also had more knowledge on different methods of treating DR.

In another study done in Tamil Nadu India, the awareness of diabetic individuals regarding systemic effects of DM was high (74.3%), however majority of the participants (87.2%) had low knowledge on particular eye effects and the importance of regular eye check-up among the study participants¹⁹. Increased awareness on eye examination was significantly associated with post-secondary and above level of education. In contrast the awareness on eye effects of DM was low where only 3.8% of the patients mentioned refraction effects while none stated cataract or diabetic retinopathy in a study done in Ghana²⁰.

Eye care knowledge

A study done in urban Indonesia among diabetic patients reported that only 49.4% of the study participants testified to having been informed about the need for having their eyes examined by the specialist²¹. Almost a similar result was reported in a Turkish study among diabetic patients where 41.9% of the individuals knew that yearly eye check-ups were a necessity for DM patients²².

In another study done among Hispanic diabetic patients, the rate of knowledge on eye care was found to be even lower among the diabetic Hispanic patients. Among the patients who had had DM for more than a year prior to the study, 34% were aware that strict control of blood sugar could prevent eye problems, compared to only 13% among the newly diagnosed diabetic patients. This probably indicates that duration of the disease affects the patient's knowledge²³.

Contrary to the above two studies, the knowledge that eyes could be damaged by diabetes was reported to be high among the participants in a CoDiab-VD cohort²⁴ and in the study done among Oman diabetic patients²⁵. The majority also knew the significance of glycaemic regulation and periodic eye check-up in prevention of eye diseases.

Practice towards diabetes and diabetic retinopathy

Different studies done on knowledge and practice have shown that having knowledge does not always equal to good practice. A Nigerian study reported that, of the 185 individuals with DM, 84.3% were knowledgeable on diabetic retinopathy however their awareness on the DR risk factors was limited¹⁴. There was also very low practice towards diabetic retinopathy since 15.7% of the patients reported having had diabetic retinopathy screening. In another study done in South Africa among diabetic patients, findings that were relatively similar to the Nigerian study were obtained. The diabetic patients who had good knowledge revealed poor practice regarding diabetic retinopathy. This study indicated that 97.3% knew that that DM had effects on the eyes

and 73% understood the importance of having a regular eye examination even when their DM is under control. Nevertheless, the diabetic patients who had actually had their annual eye exam were only 37%²⁶.

Interesting findings from a study in Nepal indicated that participants who had high knowledge on DR, only 7.7% had adequate practice. A remarkable finding from this study was that as knowledge increased, the level of practice reduced. The authors' possible explanation for this finding was that these individuals may be lacking the motivation to relate awareness to practice and being over confident²⁷.

However, several other studies have come out to demonstrate what clearly affects the practice towards eye health seeking behaviour. A study done in Kenya¹⁶ indicated that there was a substantial association between increased knowledge on DR and eye check-up practices. Being married was positively associated with improved DR practice. In another study done in rural India comparing two groups, those with and those without knowledge about diabetic retinopathy revealed a statistical significant difference in terms of accepting the right practices relating to DR⁹. Amongst individuals with knowledge on DR, 93% approved that all DM patients must have eye examinations. Of the individuals that had knowledge about DR, 66.5% mentioned that even with good sugar control, diabetics must have eye check-ups regularly compared to only 44.5% of the individuals in the group that had no knowledge.

Other studies have shown that having the disease longer and other members of the family having DM positively influence practice. In a study done in Nepal, individuals who had had diabetes for >5-10 years showed a high level of practice about DM²⁸. Regarding practice towards DM, the females had a higher practice compared to men in this study.

Different studies have demonstrated low level practice on diabetic retinopathy. A study done in Kenya stated that 63% of the study participants agreed that a pregnant woman who is diabetic should be seen by an eye care specialist. However only 7.1% of the pregnant diabetic women had actually gone to see an eye specialist for an eye exam¹⁶. It associates the reduced level of practice on low level economic status, low level of education and lower rates of referral by physicians. Some studies have indicated that the major source of knowledge for the patients are health professionals/doctors, fellow diabetic patients and mass media²⁷.

In the Nigerian study, while 80.5% knew diabetic retinopathy could result into blindness, screening for diabetic retinopathy had been only done by 15.7% of the participants. There was reduced knowledge on the need for early detection of DR through screening among the participants. Hence, there is necessity to increase on the level of awareness and making retinopathy screening services accessible to the patients as the authors recommended in this study.

Eye care practice

In diabetic individuals, to prevent development and complications associated with diabetic retinopathy (DR), regular eye check-up (screening) for diabetic retinopathy is required in addition to regular measurement and regulation of blood glucose levels, lipid levels and hypertension²⁸.

The American Academy of Ophthalmologists²⁹ has provided guidelines on screening for DR. Individuals with DM type 1 are required to annually screen for DR starting five years after diagnosis of the disease while the type 2 diabetic patients are supposed to have an eye examination at diagnosis and thereafter have yearly eye examinations²⁹

Studies done in Iceland have indicated that the prevalence of blindness is low among diabetic patients who get involved in eye screening programs at 1% and 1.6% in type 1 and type 2 DM patients respectively ^{30,31}. Low prevalence rates of blindness among diabetic patients who undergo routine eye screening were also reported by different studies^{32,33,34,35}. Therefore, having regular screening and timely laser treatment in diabetic patients is very important in preventing visual loss³⁶

In a study done among United States DM patients, high socioeconomic position, older age and high education level were associated with going for annual eye check-up³⁷. In an Australian study, nearly 71% of the individuals with DM reported having their eyes examined with in a period of 2 years and a substantial proportion (18%) of the DM patients had never had their eyes examined.

In summary, from the literature above the level of awareness and practice is seen to be affected by the setting where the study is conducted. High knowledge level is seen among the studies done in hospital settings compared to studies done in the general population. The other key factors that significantly influence the level of knowledge and practice are level of education and social economic status of the participants^{9,16}. These findings could also explain the difference seen between developing and developed countries regarding knowledge and practices. Screening for diabetic eye complications is important in preventing visual loss among diabetic patient.

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Part C

Journal ready Manuscript

Assessing the knowledge and practices regarding eye care and complications of diabetes among diabetic patients 18 years and older, attending a tertiary diabetic clinic in Kampala, Uganda.

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This manuscript has been prepared in accordance with the South African Ophthalmic Journal guidelines. The journal requires the tables and illustrations to be submitted in the dpi jpeg format. However, for the purposes of submission of this thesis for marking to the University of Cape Town(UCT), the tables and illustrations have been presented in their original format.

Declaration of interests.

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Abstract

Purpose

The aim of this study was to audit the knowledge and practices regarding eye care and eye complications of diabetes mellitus (DM) among diabetic patients 18 years and above in Kampala, Uganda.

Methods.

A cross-sectional study was done to collect data on the demographics, level of awareness and practices of the 409 diabetic patients regarding eye care and eye complications of DM. Data collected was captured in EPIDATA version 3.1, exported to STATA version 15.0 for further management and analysis. Participants characteristics were summarised using summary statistics and graphs. Using a standard questionnaire, scores for knowledge and practice for diabetes; knowledge and practice on diabetic retinopathy were generated and in all the four scores aforesaid, participants were classified as having good or poor knowledge and practice¹. Proportions of participants demonstrating good awareness and good practice were reported. Fishers and Pearson chi-square tests were used to test for associations between patient's characteristics and knowledge and practice on DM. Bivariable and logistic regression analysis was performed and variables with a p-value of <0.2 of the unadjusted odds ratio were further analysed at multivariate logistic regression analysis to find out factors that significantly predict patient's knowledge and practice on diabetes mellitus.

Results.

A total of 409 participants were interviewed in the study, majority were females 293 (71.6%) and mean age (SD) was 50 (12) years. A high proportion of participants 314 (76.9%) was aware that DM could affect the eyes but only 24 (5.9%) stated diabetic retinopathy as an eye complication in diabetic patients. Good knowledge about diabetes mellitus was demonstrated by 178 (43.5%) of the study participants. However, only 33.3% had good knowledge on eye care and diabetic retinopathy. It was determined that female diabetic patients and those who stayed with DM for 10 years and beyond were less likely to have good practice on DM compared to male patients and those who had been with DM for less than five years (OR, 95% CI: 0.58, 0.36-0.95, P=0.029; OR, 95% CI: 0.53, 0.32-0.87, P=0.011). It was also found that diabetic patients with good knowledge of DM were at least three times more likely to have good practice compared to those with the poor knowledge (OR, 95% CI: 3.2, 2.1 -4.8, P<0.001).

Conclusion

Lack of knowledge regarding the importance and need for periodic eye check-up for diabetic retinopathy was a significant finding in his study. Good knowledge on diabetes, gender and duration of DM had significant association with the patients practice patterns.

Key words

Diabetes, Diabetic retinopathy, diabetic eye disease, Eye check-up, ocular knowledge and practices.

Background

Globally the prevalence of diabetes mellitus (DM) has become a public health concern². In 2015, it was globally estimated that DM affects 415 million adults aged between 20 and 79 years and this number is predicted to increase to 615 million in 2040 if not stopped³. The prevalence of DM in Africa was reported at 13.7% in a systematic review⁴. Recent studies done in Uganda indicate that DM has also become an important public health concern and the overall national prevalence was estimated at 2.0% but this figure varies in different regions with some areas reaching 9.0%⁵. One hospital based study done in Western Uganda reported the prevalence of DM at 2.5%⁶. The population of individuals living with DM in Uganda has significantly risen from approximately 98000 people in the 2000 to about 1.5 million people in the year 2010 with in a population of 30 million individuals⁷.

Diabetes mellitus has been associated with various complications including renal, cardiovascular, ocular and neural complications due to its chronicity⁸. One of the eye complications resulting from is diabetic retinopathy (DR) and it has been reported as one of the major causes of blindness among patients with diabetes mellitus⁹. Globally blindness due to diabetic retinopathy has been reported to be at 4.8% and different studies have indicated that individuals who have had diabetes mellitus for over 20 years, 75% of them are likely to develop diabetic retinopathy and 2% of these become blind after a period of 15 years of having diabetes mellitus². One study done in a hospital in Western Uganda reported the prevalence diabetic retinopathy at 12.5%¹⁰ and an earlier study in Mulago Hospital had identified 9 out of 105 patients with diabetes mellitus as having diabetic retinopathy¹¹.

Diabetic retinopathy is a condition that develops slowly and saliently, therefore early recognition and timely intervening are crucial in its management. In diabetic individuals, to prevent development and complications associated with DR, regular eye check-ups are required in addition to regular measurement and regulation of blood glucose levels, lipid levels and hypertension¹².

Amongst the various methods to help prevent and manage DR, positive awareness of the condition among the diabetic patients can help to improve on timely, early identification and management of the condition with prevention of late complications⁸.

Studies have indicated that knowledge on risk factors and prevention of eye complications is essential in prevention of visual loss amongst diabetic patients. Despite the substantial number of individuals having awareness on eye care/screening and complications resulting from DM, the utilization of the eye care services has not been at the desirable levels, hence the need for improvement⁸. For effective formulation and implementation of convincing approach of health awareness methods regarding DM, reference information on knowledge and practices among diabetic individuals on eye care and associated complications is

important⁸. Research studies to evaluate knowledge and practices and others on attitudes amongst individuals with DM have been done previously in other countries like Saudi Arabia¹³, Bangladesh¹⁴, India¹⁵, Oman¹⁶ and Nigeria¹⁷ among others. The desire for improved awareness on control of risk factors, prevention, diagnosis and management of DM has been stated in most of these studies.

Justification of the study

Diabetic retinopathy is an important cause of blindness among diabetic patients if not detected early. Improved awareness among diabetic patients about DR has been reported by different studies to improve on early detection, prevention and reversal of visual impairment associated with it. However, many other studies conducted in different regions have indicated limited knowledge and utilization of eye care services among diabetic patients. This could be a similar situation among the diabetic patients in Uganda.

Furthermore, no study in Uganda has been conducted to assess the awareness and practice of diabetic patients regarding eye care and associated eye complications. Therefore, it is against this background that a study was conducted to collect information that would help to design health awareness and self-care prevention strategies for the diabetic patients in Uganda. The data collected could also help to improve the management of diabetic patients as well as inform policy in terms of allocating resources for prevention of eye conditions associated with diabetes mellitus among individuals living with diabetes mellitus in Uganda.

Methods.

A cross-sectional study was done to collect data among 409 diabetic mellitus patients. Data was captured in EPIDATA version 3.1 for proper data management from where it was exported to STATA version 15.0 for analysis. We used mean (for normally distributed continuous variables), medians (for non-normally distributed continuous variables), frequencies, percentages and graphs to describe patient characteristics. Study objectives one and two were analysed by computing the number and proportion of participants demonstrating good awareness and good practice¹. A fishers and Pearson chi-square, T-test and Rank sum testes was used to test for associations between patient's characteristics and practice. To find out factors that determine patients' practice, a logistic regression model was used and variables with a p value of the unadjusted odds ratio that is <0.2 were taken to multivariable analysis to find out factors that significantly predict patients practice at a 95% confidence interval.

Results

Four hundred nine (409) diabetic mellitus patients participated in the study. Majority were females 71.6%, Christians 74.6% and mean age of the participants was 50 years (SD 12). A significant number of participants was married and cohabiting 228 (55.8%) and attained primary level of education. A good number of participants were employed 211 (51.6%) and in the middle-income level 127 (60.5%). **Table I** demonstrates the demographic characteristics of the study population.

Table I: Participants characteristics

Participants characteristics	Frequency	Percentage(%)
Gender		
Male	116	28.4
Female	293	71.6
Age (years), mean (SD)	50(12)	
Religion		
Christian	305	74.6
Moslem	100	24.5
Others	4	1.0
Marital status		
Single	30	7.3
Married	126	30.8
Divorced	56	13.7
Widowed	68	16.6
Cohabiting	102	24.9
Separated	27	6.6
Education level		
Never been to school	200	49
Primary	144	35
Secondary	43	11
University/Tertiary institution	22	5
Employment status		
Employed	211	51.6
Unemployed	198	48.4
Level of income		
No Income	199	48.7
Low-income <100,000 shillings	52	12.7
Middle-income 100, 000-500,000 shillings	127	31.1
High-income >500,000 shillings	31	7.6
Duration of diabetes		
<1 year	35	8.6
1 to <2 years	46	11.3
2 to <5 years	95	23.2
5 to <10 years	100	24.5
≥10 years	133	32.5

The majority of the respondents 233(56.9%) had had diabetes mellitus for more than 5 years.

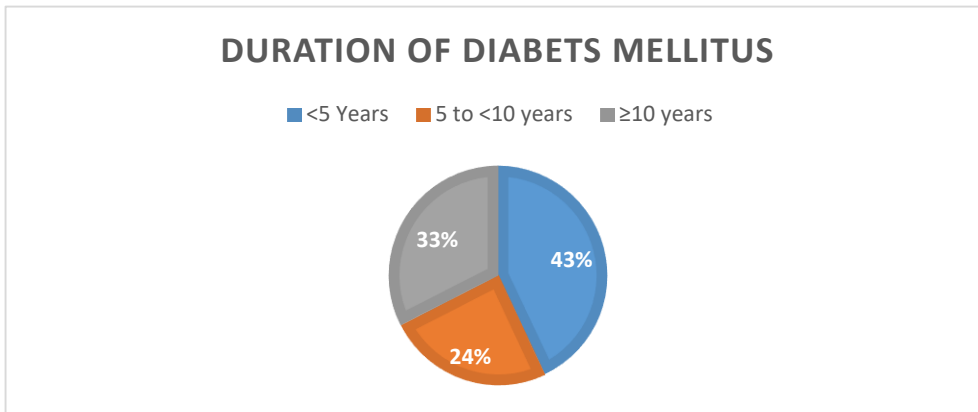


Figure 1: Pie chart showing duration of diabetes mellitus

Out of the 409 study participants, 178 (43.5%) demonstrated good knowledge on DM and 176 (43.0%) demonstrated poor practice regarding DM.

Figure 2 demonstrates knowledge and practice on diabetes mellitus

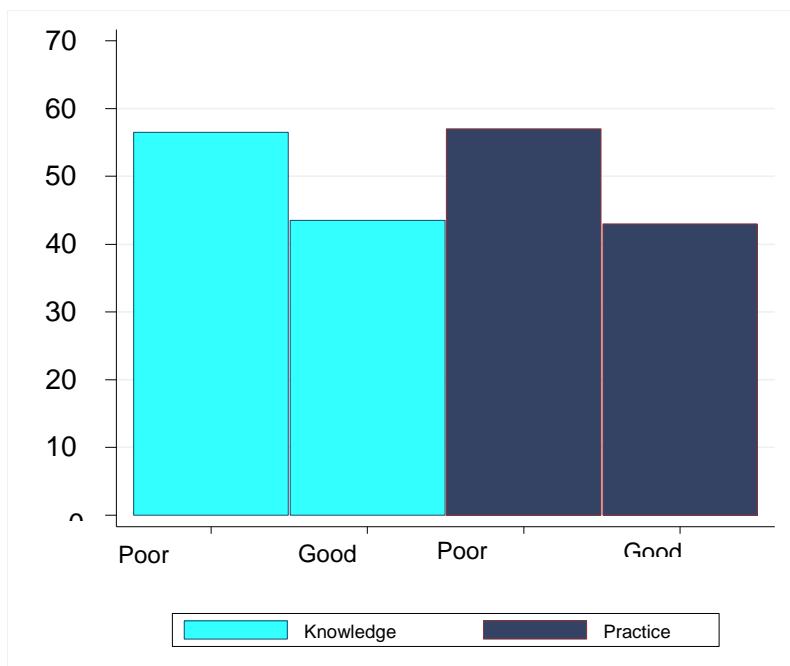


Figure 2: Knowledge and practice on diabetes

A high proportion of participants 314 (76.9%) were aware that DM could affect the eyes but only 24(7.7%) could state diabetic retinopathy as an eye complication in diabetic patients. Majority 46.7% had obtained their information from Physicians at the local diabetic clinic. Questions on knowledge regarding eye care and

diabetic retinopathy were administered to only 24 participants who mentioned diabetic retinopathy as an eye complication.

Figure 3 demonstrates knowledge on diabetic retinopathy and eye care.

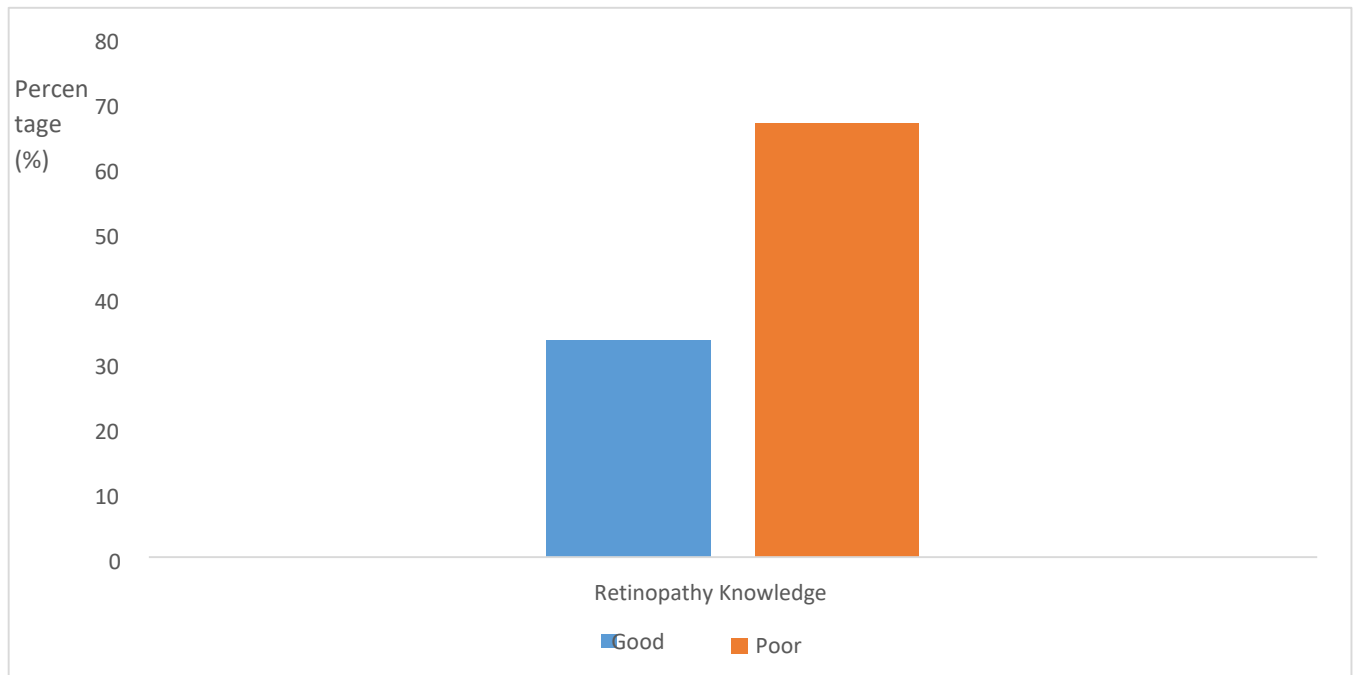
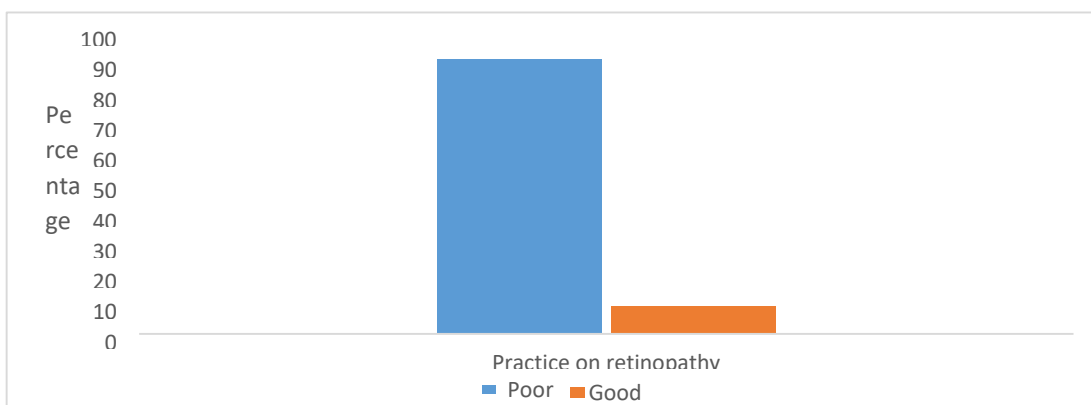


Figure 3: Knowledge on diabetic retinopathy and eye check-up (n=24)

Of the 24 participants who mentioned DR as an eye complication, 95.8% knew that a periodic check-up to screen for diabetic retinopathy among DM patients was important. Among those who knew the importance of a periodic eye check for diabetic patients, majority (58.3%) did not know that eye check-up should be done once a year among the diabetic patients with no diabetic retinopathy. Questions regarding practice patterns on Diabetes mellitus were administered to all the study participants.

Poor practice of eye care and diabetic retinopathy was demonstrated in a large proportion of the participants 91.0% practice patterns respectively. **Figure 4** represents practice on diabetic retinopathy and eye care.

Figure 4 Practice on diabetic retinopathy and eye check-up (n=145)



Majority of the participants followed their regular clinic visits as advised by their physicians. For those who never followed the scheduled visits stated their reasons as presented in **Table II below**.

Table II: Barriers to regular follow up clinic visits

	Frequency	%
Do you go for regular follow up as advised by your physician?		
Yes	371	90.9
No	37	9.1
Barriers to regular check up		
Cannot afford	11	39.1
No family support	1	3.6
Do not think it is important	1	3.6
Did not find time	9	7.1
Checking sugar levels with glucometer at home	1	3.6
Did not know that regular follow up is necessary	2	7.1
Any other	3	10.7

Most of the participants 212(51.9%) in this study had been informed about the need to go for a regular eye check-up. However, more than half 260 (64.2%) did not have a regular eye check- up and of those who had had a regular check-up, the majority, 66.4% went for reasons other than screening or treatment of DR. The commonest reason for not attending a regular eye check-up was that patients did not know that periodic eye check-up should be done (64.2%). The reasons given for not having a periodic eye check-up are given in the **table III below**.

Table III: Barriers to periodic regular eye check-up

	Frequency	Percentage(%)
Do you have a periodic regular eye check?		
Yes	145	35.8
No	260	64.2
Barriers to regular check up		
Do not trust the local doctor	0	0.0
Poor family support	0	0.0
Long distance from the hospital	4	1.5
Financial problems	37	14.2
Physically unwell	1	0.4
Do not know that periodic eye check- up should be done	159	61.2
Had good vision, so did not need check-up	58	22.4
Any other	16	6.2

Factors associated with good practice on diabetes

To determine the factors associated with good practice among DM patients, a logistic regression model was used to find out factors that significantly determined good practice on DM among diabetic patients. Variables whose p-value of the un adjusted Odds ratio (OR) (Bivariable level) was less than 0.2 were considered at multivariable analysis to find out factors that significantly determine practice on diabetes mellitus. **Table IV** below presents factors associated with good practice on diabetes

Table IV: Factors associated with good Practice on diabetes

Participants characteristics	Poor practice 233(57.0%)	Good practice 176(43.0%)	Un adjusted OR (95% CI)	P value	Adjusted OR (95% CI)	P value
Gender						
Male	57(49.1)	59(50.9)	1.00		1.00	
Female	176(60.1)	117(39.9)	0.64(0.42-0.98)	0.045	0.58(0.36-0.95)	0.029
Age(years)						
<45	74(57.8)	54(42.2)	1.00		-	
45+	158(56.4)	122(43.6)	1.05(0.69-1.62)	0.793		
Religion						
Christian	175(57.4)	130(42.6)	1.00		-	
Non-Christian	58(55.8)	46(44.2)	1.07(0.68-1.67)	0.775		
Education level						
No formal education	8(36.4)	14(63.6)	1.00		1.00	
Formal education	225(58.1)	162(41.9)	0.41(0.17-1.00)	0.051	0.39(0.15-1.01)	0.051
Employment status						
Employed	118(55.9)	93(44.1)	1.00		-	
Not employed	115(58.1)	83(41.9)	0.92(0.62-1.36)	0.660		
Duration of diabetes						
<5 years	94(53.4)	82(45.6)	1.00		1.00	
5 to <10 years	53(53.0)	47(47.0)	1.02(0.62-1.66)	0.948	0.89(0.52-1.50)	0.659
≥10 years	86(64.7)	47(35.3)	0.62(0.39-0.99)	0.048	0.53(0.32-0.87)	0.011
Knowledge on diabetes						
No	158(68.4)	73(31.6)	1.00		1.00	
Yes	75(42.1)	103(57.9)	2.97(1.98-4.46)	<0.001	3.2(2.1-4.8)	<0.001
Marital status						
Single	21(70.0)	9(30.0)	1.00		1.00	
Married	125(54.8)	103(45.2)	1.92(0.84-4.38)	0.120	1.62(0.68-3.86)	0.273
Divorced/widowed/separated	87(57.6)	64(42.4)	1.72(0.74-4.00)	0.210	1.74(0.71-4.23)	0.224

Income						
No income		116(58.3)	83(41.7)	1.00		
Low income(<100000)		30(57.7)	22(42.3)	1.03(0.55-1.90)	0.938	-
Middle/high income		87(55.1)	71(44.9)	1.14(0.75-1.74)	0.541	

From the results in table 4, it was found out that gender strongly determines good Practice on diabetes mellitus (Odds ratio (OR), 95% Confidence interval (CI): 0.58, 0.36-0.95, P- Value (P) =0.029). Female diabetic patients were less likely to have good practice on DM compared to male patients, where females had 0.58 times the odds of having good Practice on diabetes mellitus compared to the male patients. Duration of diabetes mellitus was a significant factor in determining good practice. Patients who had stayed with DM for 10 years and beyond had 0.53 times the odds of good practice on diabetes mellitus compared to those who had been with DM for less than five years (OR, 95% CI): 0.53, 0.32-0.87, P=0.011). In addition, knowledge of DM significantly determined practice on DM (OR, 95% CI: 3.2, 2.1 -4.8, P<0.001). This implies that patients who had good knowledge of DM had at least 3 times the odds of having hood practice compared to those who had poor knowledge on DM. However, education, age, occupation and marital status did not significantly determine good practice (p>0.05).

DISCUSSION

This study enrolled and interviewed 409 participants with majority being females. A cross-sectional hospital-based study aimed at assessing knowledge and practices of diabetic patients regarding diabetes eye complications and eye care. The majority were females and the mean age of the participants was 50 (SD=12) and had had diabetes for > 5 years. Similar trends were reported by studies done in Kenya and Ethiopia among diabetic patients^{18,19}.

Out of the 409 study participants, 178 (43.5%) demonstrated good knowledge on diabetes mellitus (DM). Other studies done in India have demonstrated good levels of knowledge on DM among 40.9% and 49.7% of their participants respectively^{20,21}. On the other hand, lower levels of knowledge were reported in a study done in India where only 28% of the study population had awareness on DM¹. In this study 314(76.9%) of the participants were aware that DM could affect the eyes. This result is close to findings from other studies done among DM patients in Oman 72.9%,²² Malaysia 87.2%²³, in Karachi 70.0%²⁴ and in Nepal²⁵. The awareness level found in this study that DM affects the eyes also compares to the study done in south India 71.9%¹ and in Kano Nigeria 80.5%²⁶. However, this was much less, than the 95% observed in the study done in Kenya.

Out of the 314 patients that knew DM could affect the eyes, only 24 (7.7%) were able to state diabetic retinopathy as an ocular complication of DM. Similarly, some studies done have indicated low levels of knowledge on Diabetic retinopathy 7.0%²⁷ and 17.0%¹ among their study participants. On the other hand, some studies have reported slightly higher proportions of participants being aware of diabetic retinopathy as an ocular complication of DM, 36.3% in the south Indian study²⁸ and 30.9% in the north India²⁹ study and 22.8% in the Ethiopian study³⁰.

In this study, only 8 out of the 24 (33.3%) participants who had awareness of diabetic retinopathy (DR) demonstrated good knowledge of diabetic retinopathy and this represented only 1.9% of the total study participants.

A similar finding among DM patients was reported in a study done in eastern India¹. Results that contrast the above findings, were reported by a study done in India which reported the level of knowledge on diabetic retinopathy among the study participants at 37.1%²¹.

Among the patients who demonstrated good knowledge about diabetes, 92.3% were not aware of diabetic retinopathy despite it being a serious cause of visual impairment and blindness among diabetic patients.

The findings above show the need for patient education on diabetic retinopathy, since a large proportion of the participants were not able to state diabetic retinopathy as an ocular complication of DM. Measures to improve patients' knowledge on DM and its associated eye complication among diabetic patients should be put in place at all levels of interaction with the health workers in the health care system. Community sensitization programmes should also be put in place since some community-based studies have showed even a lesser awareness level of DM complications within the community. With more than half of the study participants not being aware of the most severe and potential blinding eye condition indicates insufficient education regarding eye care and possible eye complications in DM patients.

Programmes to improve patient awareness about DM and its associated eye effects should be emphasized at all levels of the health care system where the patients get in contact with health workers. This could be at primary, secondary and tertiary levels of healthcare where awareness messages could be easily relayed to DM patients.

Health education programmes on DM and its associated complications can be conveyed through patient education leaflets, pamphlets, posters, mass media, and during DR screening camps. Special days like the World Sight Day and World Diabetes Day can be used to deliver awareness messages to the diabetic patients, health workers and the community.

Good knowledge levels on DM were significantly associated with good practice towards DM (OR, 95% CI: 0.58, 0.36-0.95, P=0.029) after adjusting for age, gender, employment status and education status. Patients who had good knowledge of DM had at least 3 times the odds of having good practice compared to those who had poor knowledge on DM. This finding is an indication that, the awareness an individual has about their disease determines their practice. Therefore, improving patient's knowledge is important as this determines how the patient follows the appropriate guidelines and follow up visits as required.

Despite knowledge influencing practice as seen in our study, there are other several factors that affect the patient's decision to have a periodic check-up. In this study most of the participants 212 (51.9%) had been informed about the need to go for a regular eye check-up, however more than half 260 (64.2%) did not have a periodic regular eye check-up and of those who had had a regular check-up went for other reasons not

screening for diabetic retinopathy. A study done in India³¹ revealed same results where diabetic patients did not go for eye check-ups despite having knowledge on the eye effects of DM.

The commonly mentioned barrier to the regular eye check-up was that the patients were not aware that they should have a periodic regular eye check-up. The same finding was reported in a study done in India¹. This further shows a gap in the way information is delivered to patients regarding importance of screening for diabetic retinopathy. In our study, the majority of the participants attended their regular clinic visits but lacked awareness of the need to have periodic eye checks to screen for diabetic retinopathy. Diabetic retinopathy being a silent blinding condition with symptoms appearing late, regular screening to look for early retinal changes should be emphasized.

In our study majority of the patients 41.7%, who knew diabetic retinopathy as an ocular complication of DM had obtained the information from the diabetic clinic by physicians and nurses. The media, books and internet seemed to play a small part in informing the participants. This result is similar to the findings obtained from study done, in south India, where 71.4% of the participants obtained their information from the diabetic clinic¹. The above proportion (41.7%) of patients in this study shows that there is still a gap in information delivery to the diabetic patients.

Health care workers/physicians and eye care consultants need to lay clear strategies on how to best deliver health messages regarding complications of DM and its potential blinding effects among diabetic patients.

The healthcare workers should emphasize the importance of having a periodic regular screening for diabetic retinopathy when giving information to diabetic patients. The risk factors for diabetic retinopathy should also be addressed to prevent development or worsening of retinopathy.

The level of awareness of risk factors of diabetic retinopathy was poor among the respondents in this study. Majority of the participants were not aware that uncontrolled blood pressure (91.3%) is one of the risk factors for developing and worsening diabetic retinopathy. These results compare with those from a study done in Kenya¹⁸ and another done in India¹ in which the participants from both studies showed low level awareness on diabetic retinopathy risk factors

Gender strongly determined good practice on DM (OR, 95% CI: 0.58, 0.36-0.95, P=0.029). Female diabetic patients were less likely to have good practice on DM compared to male patients, where females had 0.58 times the odds of having good practice on DM compared to the male patients. This could probably be explained by the fact that males have enough money to travel for clinic appointments and they may be better educated especially in our setting.

Duration of diabetes mellitus was a significant factor in determining good practice of DM and eye care. Patients who had stayed with DM for 10 years and beyond had 0.53 times the odds of good practice on DM compared to those who had been with DM for less than five years (OR, 95% CI: 0.53, 0.32-0.87, P=0.011). This could be explained that patients who have had the disease for long, have attended the diabetic clinic many times and they have been probably exposed to information on DM and its complications. Similar findings were obtained in a study done in Malaysia²³ where duration of disease was significantly associated with practice among the study participants.

Education, age, occupation and marital status did not significantly determine good practice ($p>0.05$). This contrasts findings from studies done Kenya^{18,19} where the above demographics were significantly associated with good practice.

Limitation

1. Some scientific terms were difficult to explain to the patients like “Damage to the back of the eye” being used to mean diabetic retinopathy
2. The associations between patient characteristics and diabetic retinopathy practice were not statistically significant. This could have been due to the low power, 24 participants out of the 409 study participants who were aware of diabetic retinopathy. used in making the associations

Conclusion

1. A large proportion (92.3%) of study participants were unaware that diabetes mellitus causes diabetic retinopathy.
2. There was poor knowledge and practice regarding eye care and diabetic retinopathy among the study participants.
3. Lack of awareness that regular eye check-up among diabetic patient was the most stated reason for not having a periodic eye check-up amongst the study participants.
4. Gender and duration of diabetes mellitus were strongly associated with good practice of diabetes while age sex and marital status had no effect on practice.

Recommendations

1. Lack of knowledge regarding the importance and need for periodic eye check-up for diabetic retinopathy was a significant finding in his study. Good knowledge on DM had significant association with the patients practice patterns. Therefore, diabetic patients should be educated about the importance of regular eye screening to prevent visual impairment and blindness which are preventable if diabetic retinopathy is detected and treated early.
2. A study should be done to assess the prevalence of diabetic retinopathy among the diabetic patients.

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The American Academy of Ophthalmologists (AAO) guidelines on screening for diabetic retinopathy

Screening for Diabetic Retinopathy - 2014

AAO Quality of Care Secretariat, Hoskins Center for Quality Eye Care

Summary

The American Academy of Ophthalmology recognizes that screening for diabetic retinopathy using validated digital imaging can be a sensitive and effective detection method. Such technology has not been demonstrated to be as effective, however, at detecting and quantifying the spectrum of other ophthalmic pathology that can accompany diabetic retinopathy, including cataract and glaucoma, which are more prevalent in patients with diabetes mellitus. Imaging technology also does not mitigate the need for periodic comprehensive ophthalmic examinations.

Background

The Preferred Practice Pattern on Diabetic Retinopathy states¹:

Diabetic retinopathy is a leading cause of visual impairment in working-age adults. While defects in neurosensory function have been demonstrated in patients with diabetes mellitus prior to the onset of vascular lesions, the most common early clinically visible manifestations of diabetic retinopathy would include microaneurysm formation and intraretinal hemorrhages. Microvascular damage leads to retinal capillary nonperfusion, cotton wool spots, increased numbers of hemorrhages, venous abnormalities, and intraretinal microvascular abnormalities (IRMA). During this stage, increased vasopermeability can result in retinal thickening (edema) and/or exudates that may lead to a loss in central visual acuity. The proliferative stage results from closure of arterioles and venules with secondary proliferation of new vessels on the disc, retina, iris, and in the filtration angle. These new vessels then lead to traction retinal detachments and neovascular glaucoma respectively. Vision can be lost in this stage from capillary nonperfusion or edema in the macula, vitreous hemorrhage, and distortion or traction retinal detachment.

Diabetic retinopathy can occur at any age. The primary prevention and screening process for diabetic retinopathy varies according to the age of disease onset. Several forms of retinal screening with standard fundus photography or digital imaging, with and without dilation, are under investigation as a means of detecting retinopathy. Appropriately validated digital imaging technology can be a sensitive and effective screening tool to identify patients with diabetic retinopathy for referral for ophthalmic evaluation and management.² Some studies have found that photography is more sensitive in identifying sight-threatening retinopathy than clinical examination with ophthalmoscopy.^{3, 4, 5, 6} Digital cameras with stereoscopic capabilities are useful for identifying subtle neovascularization and macular edema.^{7, 8} At this time, it is not clear that photographic screening programs achieve a greater reduction in vision loss than does routine

community care in areas where access to ophthalmologists is straightforward. Studies have found a positive association between participating in a photographic screening program and subsequent adherence to receiving recommended comprehensive dilated eye examinations by a clinician.^{9, 10} Of course, such screening programs have great value in circumstances in which access to ophthalmic care is limited.^{11, 12, 13, 14} Future research should also include establishing standardized protocols and satisfactory performance standards for diabetic retinopathy screening programs.

At this time, these technologies are not considered a replacement for a comprehensive eye evaluation by an ophthalmologist experienced in managing diabetic retinopathy.

Recommendations for Care

Early detection of retinopathy depends on educating patients with diabetes as well as their families, friends, and health care providers about the importance of regular eye examination even though the patient may be asymptomatic. Patients must be informed that they may have good vision and no ocular symptoms, yet may still have significant disease that needs treatment, which depends on timely intervention.

The care process for diabetic retinopathy includes a medical history, an ophthalmic examination and screening of high resolution retinal photographs of patients who have not had previous treatment for diabetic retinopathy, and vigilant follow-up. An effective screening program can determine who needs referral to an ophthalmologist for close follow-up and possible treatment, and who simply requires annual screening. People with Type 1 diabetes should have annual examinations for diabetic retinopathy beginning five years after the onset of their disease, while those with Type 2 diabetes should have a prompt examination at the time of diagnosis, then at least yearly examinations thereafter. Women who develop gestational diabetes do not require an eye examination during pregnancy, and do not appear to be at increased risk for developing diabetic retinopathy during pregnancy. However, diabetics who become pregnant should be examined soon after conception and early in the first trimester of the pregnancy. The recommended follow-up is every 3-12 months for no retinopathy or moderate non-proliferative diabetic retinopathy (NPDR), or every 1-3 months for severe NPDR.

Ophthalmologists can play an important role in the total care of the patient with diabetes. At the time of the eye examination, patients can be counseled about the importance of maintaining near-normal blood glucose and blood pressure and monitoring serum glycosylated hemoglobin levels, which may lessen the risk of retinopathy developing and progressing. It is recommended that an HbA1c of 7.0% or lower is the target for glycemic control in most patients while in selected patients there may be benefit to setting a target of 6.5%. Aspirin may be used without concern for worsening diabetic retinopathy by patients with diabetes who require aspirin for other medical indications and have no contraindications. Intravitreal injections of anti-vascular

endothelial growth factor (VEGF) agents have been shown to be an effective treatment for center-involving diabetic macular edema. Treating physicians should note that the use of betadine antiseptic drops is recommended during intravitreal injections. At this time, laser photocoagulation remains the preferred treatment for non-center-involving diabetic macular edema.

Physicians that care for patients with diabetes, and patients themselves, need to be educated about indications for ophthalmologic referral. Referral to an ophthalmologist is required when there is any non-proliferative diabetic retinopathy, proliferative diabetic retinopathy (PDR), or macular edema. Ophthalmologists should communicate the ophthalmologic findings and level of retinopathy with the primary care physician as well as the need for optimizing metabolic control. It is reasonable to encourage patients with diabetes to be as compliant as possible with therapy of all medical aspects of their disease.

Imaging

The Ophthalmic Technology Assessment on Single Field Fundus Photography for Diabetic Retinopathy Screening states¹⁵:

A variety of techniques can be used to detect and classify diabetic retinopathy, including direct and indirect ophthalmoscopy, stereoscopic color film fundus photography, fluorescein angiography, and mydriatic or nonmydriatic digital color or monochromatic photography.¹⁶ Ophthalmoscopy is the most commonly used technique to screen for diabetic retinopathy. However, un-dilated ophthalmoscopy, especially that done by non-ophthalmologists, has poor sensitivity relative to 7-field stereoscopic color photography. Under typical clinical conditions, direct ophthalmoscopy done by non-ophthalmologists has a sensitivity of approximately 50% for the detection of proliferative retinopathy.¹⁷ The gold standard for the detection and classification of diabetic retinopathy is stereoscopic color fundus photographs in 7 standard fields, as defined by the Early Treatment Diabetic Retinopathy Study (ETDRS) group.¹⁸ Although this technique is accurate and reproducible, it is labor intensive and requires skilled photographers; skilled photograph readers; and sophisticated photography equipment, film processing, and archiving. The turnaround time from acquisition of the data to interpretation can take weeks in clinical trials. Finally, from the patient's perspective, it can be time consuming and uncomfortable. In short, 7-field stereoscopic fundus photography is not an ideal screening technique, but it can serve as the standard with which to compare other screening technologies.

There is level I evidence that single-field fundus photography with interpretation by trained readers can serve as a screening tool to identify patients with diabetic retinopathy for referral for ophthalmic evaluation and management, but it is not a substitute for a comprehensive ophthalmic examination. The advantages of single-field fundus photography interpreted by trained readers are ease of use (only one photograph is required), convenience, and ability to detect retinopathy. The disadvantage is that reported sensitivity values are less

than ideal when compared with 7–standard field photography. When compared with ophthalmoscopy, however, single-field fundus photography has the potential to improve the quality of the evaluation and the numbers of patients evaluated. The use of nonmydriatic fundus photography systems represents a compromise. Although it is apparent that mydriasis improves image quality and sensitivity, particularly in older patients, it is uncertain whether this is outweighed by the disadvantage of dilation related to patient compliance. In other words, the diminished sensitivity of a nonmydriatic photograph may be acceptable if more patients complete the process.

Whether any of the systems discussed can accommodate the tens of thousands of photographs necessary to appreciably improve detection rates for diabetic retinopathy in the general population is unknown. Caution should be exercised in strictly applying the test characteristics from the reported studies; most tests perform less well in the real-world setting. Further studies will be required to assess the implementation of programs that are based on single-field fundus photography in a real clinical setting to confirm the clinical effectiveness and cost-effectiveness of these techniques in improving population visual outcomes. Future research also should include establishing standardized protocols and satisfactory performance standards for diabetic retinopathy screening programs.

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Approvals

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