REPORT OF THE KITALE DIABETIC RETINOPATHY STUDY

Assessment of the magnitude, risk factors and capacity to manage diabetic retinopathy (DR) at Kitale Level 5 Hospital in Kenya

Study conducted by the Ministry of Health in collaboration with:

1. Operation Eyesight Universal
2. University of Nairobi

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1 Executive summary

Diabetes is an emerging major cause of blindness in the world. In 2016, Kenya launched an ambitious project to screen all diabetic patients attended at referral hospitals for DR using retina cameras and treat those in need. Scientific data is needed to inform creation the hospital-based screening projects and this was the first study to provide such evidence. The study was conducted between March and April 2018 at diabetic medical clinic of Kitale level 5 Hospital in Trans-Nzoia County. It was funded by Seeing is Believing through the Operation Eyesight Universal. The objectives were to measure prevalence of DR in patients 18+ years old, assess accuracy of the made diagnosis using retina photographs, estimate prevalence of known risk factors and audit resources and services for DR.

This was a cross-sectional study approved by the Institutional Research and Ethics Committee of Moi University and management of Kitale hospital. Informed consent was taken followed by: visual acuity, dilatation of pupils, taking of retina photos by a validated technician, clinical examination by a validated eye doctor and review of patient`s files for risk factors. Retina photos were further assessed by a retina specialist. Audit of resources and services was done through interviews with hospital workers. Data was managed and analysed by an epidemiologist.

All the 256 diabetic patients who attended Kitale diabetic medical during the study period participated in the study but 3 were excluded from analysis (1 was under age and 2 lacked data on age). Out of the remaining 253 patients, 155(61.3%) were women. Median age was 58 and the peak age group 50-59 years. Sixteen point seven 16.7% out of 151 patients had never attended school and women had lower level of education than men. About a half of the patients were unemployed and less than a half did not have hospital insurance cards.

There were 76.9%, 70.0%, and 32.6% patients with high blood pressure, high body mass index and poorly controlled random blood sugar respectively. The period they had lived with diabetes ranged from 1 year to 45 year with a medium duration of 6 years.

Eye sight was checked in 251 patients and 86.4% had normal vision. The prevalence of blindness from all likely causes was 3.2%(95%CI: 1.0%-5.4%). Out of 250 patients 59(23.6%, 95%CI: 18.3%-28.9%) cataracts and 1 had corneal scar. Retina photographs of 234, 18 and 1 patients were gradable, ungradable and missing respectively. Fourteen out of the 18 patients with ungradable

photos had cataracts. The other 45 patients with cataracts had gradable photos as the cataracts were not dens enough to obstruct viewing of the retina. The prevalence of DR estimated by the grader was 24.8%(95%CI:19.3%-30.3%). Photos of 244 patients were reported by a retina specialist and 216 patients had gradable photos. The technician had the advantage of viewing the retina directly using the camera. The prevalence of DR estimated by the specialist using the retina photos was 15.3%(95%CI:10.6%-20.0%%). The ophthalmologist provided the clinical findings of 251 patients and a prevalence of estimate of 16.3% (95%CI:11.8%-20.8%). The prevalence of DR in women (18.7%, 95%CI: 12.6%-24.8%) was higher than in men (12.5%, 95%CI: 5.8%-19.2%) but this difference was not statistically significant (p= 0.20).

Assessment of the accuracy of diagnosis made by grader (screening test) compared with clinical diagnosis by eye doctor (gold standard) revealed sensitivity of 32/35 x 100 = 91.4%(95%CI:76.9% - 98.2%) and specificity of 172/198 x 100 = 86.9%(95%CI:81.4% - 91.2%).

DR services at Kitale were funded by the County Government with support from Operation Eyesight Universal and Seeing is Believing. The hospital did not have an organised DR screening project. Prior to this study, an average of 1 patient per week was screened for DR at the eye clinic. During this study screening was based at the medical clinic and an average of 86 patients were screened per week. If this trend continues and medical clinic is open 40 weeks in a year, 86 patients x 40 weeks = 3,440 diabetic patients will be screened in a year. If we apply the prevalence estimate of 24.8%(95%CI:19.3%-30.3%) by the grader, then the number of patients likely to be referred to the eye clinic from medical clinic will be (3,440 x 24.8)/100 = 853 (95%CI: 664 – 1,042) in a year.

Kitale hospital had resources for treatment of diabetes and screening for DR but had a shortage of resources for treatment of DR. Patients with DR were referred to Eldoret and Sabatia Hospitals.

It was concluded that: 16% of diabetic patients at the hospital had DR and about 1,000 patients will be referred to eye clinic annually when the screening project starts; photographs are accurate in screening for DR; known risk factors of DR were prevalent among the diabetic patients; the hospital had resources for screening but lacked resources for treatment of DR.

It was recommended that the hospital should strengthen services for management of both diabetes and DR and conduct a qualitative study to establish barriers to delivery of DR services.

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2 List of abbreviations

BMI	Body Mass Index
BP	Blood Pressure
DR	Diabetic Retinopathy
NPDR	Non-proliferative Diabetic Retinopathy
FGD	Focus Group Discussion
HbA1C	Glycated haemoglobin
HMIS	Health Management Information System
KPP	Knowledge, Perceptions and Practices
MOH	Ministry of Health, Kenya
MPH	Master of Public Health
NGO	Non-Governmental Organization
OCT	Optical Coherent Tomography
OEU	Operation Eyesight Universal
OSU	Ophthalmic Services Unit (of the Ministry of Health)
UON	University of Nairobi
WHO	World Health Organization

3 Acknowledgements

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1. Standard Chartered Bank for sponsoring the study through the Seeing is Believing Project
2. Staff and management of Kitale hospital for supporting all the stages of this study from proposal writing, application for ethical approval, data collection to reporting of findings
3. Staff at the diabetic retinopathy clinic of Kenyatta National Hospital who trained and validated the team for this study

4 Introduction

Diabetes is an emerging major cause of blindness in the world and in Kenya. A study across a number of communities in Kenya in 2009 showed that the overall age-standardized prevalence of diabetes mellitus was 4.2%.(1) The Stepwise study conducted in 2015 by the Ministry of Health revealed that 3.1% and 1.9% of adults aged 18-69 years had impaired fasting glycaemia and raised blood glucose respectively.(2)

The most common type of diabetes is type 2, usually found in adults. After many years (usually 20), diabetes mellitus type 2 seems to cause diabetic retinopathy which in turn leads to loss of vision from bleeding, retinal scars and macular oedema. Type 1 occurs in younger ages and causes diabetic retinopathy earlier and more frequently than type 2. There appears to be no primary prevention of diabetic retinopathy so far. Early detection is therefore very important.

Recent studies show the following risk factors of diabetic retinopathy.

Study reference	Country	Risk factor	adjOR (95%CI)
Lima 2016(3)	Brazil	Poor glycaemic control (HbA1c ≥7.0%)	3.83 (1.57–9.37)
		Duration of DM	
		- 11–15 years	7.52 (3.03–18.68)
		- >15 years	9.01 (3.58–22.66)
		Co-morbidities	
		- diabetic nephropathy	3.32 (1.62–6.79)
Krishnaiah 2007(4)	India	Increasing age (≥50years)	4.04 (1.88–8.68)
		Urban residents (vs rural)	6.07 (2.84–12.98)
		Middle and upper socioeconomic status	2.34 (1.16–4.73)
		Hypertension (BP ≥140/90mmHg)	3.48 (1.50–8.11)
		Duration of diabetes ≥15 years	8.62 (2.63–28.29)

Footnote: BP=blood pressure

The retinopathy is broadly classified as non-proliferative and proliferative. A population based DR study conducted by Mathenge et al in Nakuru revealed a prevalence of DR 35.9% (95%CI 29.7-42.6) in persons aged 50+ years.(5) Diabetics may also develop visual impairment due to macular

oedema with or without DR. The prevalence of clinically significant macula oedema in a Kenyan study was reported to be 8.7% in newly diagnosed diabetics at the Kenyatta National Hospital.(6)

Screening has been shown to be effective in detecting early diabetic eye disease.(7) Screening for DR involves examination of the retina either using clinical methods or taking retina photographs of diabetics. Photographs may be reported on site or remotely via telemedicine by an eye specialist. In Kenya, a DR screening project was launched in 2016. The first two fundus cameras were installed at the diabetes medical clinic at Kenyatta National Hospital in March 2016 and at Nakuru Level 5 hospital in October 2016. Diabetic patients had their retina photographs taken and graded by validated technicians. Patients with DR were referred to the eye clinics.

In 2017 and 2018, the Kenya Ministry of Health developed National guidelines for management of DR and a protocol for assessment of the magnitude of DR at referral hospitals. The guidelines recommend one vitreoretinal surgeon per 8-10 million population and one medical retina specialist at each level 5 facility like Kitale. A medical retina specialist is an ophthalmologist who provides all DR treatments except vitreoretinal surgery.

A Knowledge Attitudes and Practice study of diabetes care givers conducted at the Kenyatta National Hospital in 2009 revealed that most respondents (n=42, 91%) saw diabetes mellitus and diabetic retinopathy as urgent health problems and regular ophthalmic screening of all diabetic patients was universally recommended.(8) Suboptimal communication among hospital departments (internal medicine and ophthalmology) was pointed out as a barrier together with lack of laser equipment and costs.

A fundus camera was installed at eye clinic of Kitale level 5 hospital in 2015. A technician who had worked in a prior large diabetic retinopathy research study in Nakuru takes retina photographs only for the patient who are referred to the eye clinic (about 20 diabetic patients per day).

4.1 Justification for the Study

Before this study, there was no data to inform establishment of a hospital-based screening project at Kitale Level 5 Hospital. Moreover, compliance with screening guidelines and treatment of DR may be influenced by Knowledge, Perceptions and Practices (KPP) of medical staff and patients.

4.2 Research questions

The research questions for this study were:

1. What is the magnitude of DR in diabetic patients attending diabetic medical clinic at the Kitale Level 5 Hospital?
2. Is screening for DR by examining retina photographs of diabetic patients accurate?
3. What is the prevalence of selected known risk factors of DR in patients attending diabetic medical clinic at the Kitale Level 5 Hospital?
4. Does Kitale Level 5 Hospital have adequate capacity to treat DR patients?

4.3 Objectives

The general objective of this study is to assess the magnitude, risk factors and capacity to manage DR patients at the Kitale Level 5 hospital.

The specific objectives were to:

1. Measure prevalence of DR by examining retina photographs taken from diabetic patients using a fundus camera
2. Assess the accuracy of diagnosing DR using retina photographs (screening test)
3. Determine prevalence of selected known risk factors of DR
4. Assess available resources and services for management of DR

The activities in the table below were undertaken to fulfil the objectives were as shown below:

Objectives	Activities/indicators
a. Measure prevalence DR	- Validated DR grader (technician) took the retina photos and report whether each of the study patient has DR or not
b. Assess accuracy of diagnosing DR using retina photos	- An ophthalmologist (who had not seen the retina photos and report from the grader) conducted clinical examination and reported whether each of the patients had DR or not
	- Comparison of the diagnosis by grader and ophthalmologist to assess the difference between the two methods
	- A retina specialist also examined the photos and comparison made with the findings of grader and ophthalmologist
c. Determine the prevalence of risk factors	- Taking of clinical history and review of medical records to extract information on smoking, drinking of alcohol and pregnancy, blood sugar control, hypertension, cholesterol level and renal function
d. Assess available resources for management of DR	- Number/category of staff, space, equipment, medicines/consumables, availability/sources of funding, types of DR services rendered, availability/type of Health Information System used and referral system (internal and external)

5 Methods

5.1 Study site and period

Data for this study was collected at the Kitale Level 5 Hospital between March and April 2018. Kitale is an agricultural town located in northern rift valley in Kenya 382 Kilometres North-west of Nairobi City (map in Annex1).

5.2 Study populations

All diabetic patients attending the medical clinic at Kitale Level Hospital were eligible to participate in this study.

5.3 Inclusion criteria

Diabetic patients aged 18+ years who consent to participate in the study were included. DR is very rare in children and it takes about 20 years for a diabetic patient to develop DR.

5.4 Exclusion criteria

The following individuals/eyes were excluded:

- Patient who are too sick to undergo retina photography/eye examination

5.5 Estimation of the minimum sample size for the prevalence study

The minimum number of diabetic patients selected at medical diabetic clinic was computed using the following equation(9):

$$\text{Minimum sample size} = e\frac{d^2 b(1-b)}{c^2}$$

Where: b= expected prevalence; c = desired precision of the estimate; d = 95% confidence level (z score 1.96) and e= expected design effect.

The parameters used were: expected prevalence of diabetic retinopathy in diabetes clinic = 30%(5), absolute precision 6% (ideally 20% of p)(9-11), design effect = 1 since we do not expect any clustering when individuals are sampled(11). Therefore, the minimum sample = 224. If we add 10% for likely non-response, the sample = 224+23 = 247.

5.6 Estimation of minimum sample size for the assessment of diagnostic test

Estimation of the minimum sample needed to assess the accuracy of screening for DR using a fundus camera was done using the following formula:

$$TP+FN = z^2 \times \frac{Sen(1-Sen)}{W^2}$$

$$N(sN) = \frac{TP+FN}{P}$$

Where TP=true positive, FN=false negative, z=confidence interval normal distribution value ie for 95%, z=1.96, P=prevalence of disease in the test population, w=accuracy, N(sN)=sample size powered for sensitivity.

A systematic review found the sensitivity of fundus cameras in detection of DR was above 80%.(12). A study examining non-mydriatic single-field photography found a sensitivity of 86%.(13) A study in Kenya found a prevalence of DR of 35.9% of diabetics.(5) Using the formula above assuming a sensitivity of 85%, prevalence of 35.9% and assuming that a measure within 10% would be suitable enough (so w=0.10) gives a sample size of 136.

5.7 Selection of patients for quantitative study

All patients attending the diabetic medical clinic during the study period were recruited for the prevalence, risk factors and diagnostic test studies.

5.8 Examination methods

The following examination were conducted on all the selected patients:

- A certified technician/grader took retina photograph with eyes dilated using a fundus camera and reported whether each of the photos indicates patient has DR or no DR. All photos were examined by a retina specialist to confirm the findings
- Clinical examination of the retina was done by an eye specialist to confirm presence or absence of DR and grade the retina changes.
- Taking history of eye complaints and risk factors for DR by an eye care worker
- Testing of visual acuity using Snellen Charts by an eye care worker
- Review of patient's medical clinic files for information on DR risk factors such as blood sugar control, HbA1c, blood pressure, cholesterol, renal function

5.9 Grading of retina changes

The following retina changes were documented by a retina specialist: micro aneurysms, hard exudates, soft exudates (cotton wool spots), intra-retinal hemorrhages, venous beading, intraretinal microvascular abnormalities (IRMA), macular oedema and neovascularisation. The changes will be graded according to the Early Treatment Diabetic Retinopathy Study (ETDRS) classification system(14) summarized in Annex 2.

5.10 Data management

Data arising from the study was recorded on the devices acquiring the specified data (e.g. camera for retina photos) and on paper forms (questionnaire data). The questionnaires are in Annex 3-4. A trained data entry clerk transcribed paper-based data into electronic format. The study epidemiologist designed the databases, ensure integrity and security of stored data and exported data for analysis. Stata version 14 (StataCorp, College Station, Texas, USA) was used to analyse the data. The data from the pilot study was used to test-run the electronic data capture tools.

Data accruing from this study was owned by the Kitale Eye unit and will be freely shared with the sponsors and study team.

5.11 Data analysis

To measure the prevalence, the total number of patients found to have any diabetic retinopathy (DR) was divided by the total number of diabetics examined (sample size n=250) and the proportion reported as a percentage and its 95% confidence interval (CI).

To determine the risk factors for DR, we compared the diabetic patients with DR with diabetics who did not have DR. Initially univariable analysis was conducted. The proportion exposed to various risk factors in the two groups was compared using the chi-square t-test. Continuous variables (such as duration since diagnosis of diabetes mellitus) was compared using the t-test or the Wilcoxon-Mann-Whitney U test depending on their distribution. Associations between exposures and DR was determined using multivariable regression analysis to estimate the OR and 95%CI controlling for confounding by age, sex etc. The likelihood ratio test was used to assess statistical significance of associations. Variables that were associated with the DR on univariable analyses at a level of $p<0.05$ were included in the multivariable analysis and then those with $p<0.2$ were retained in the final regression model.

The diagnostic accuracy of screening by camera (herein called the screening test) compared to clinical examination was performed at two levels. One, comparing the rate of detection of various clinical features of DR by both methods and secondly by comparing the overall assessment of the technician with the ophthalmologist. To compare the rate of detection of clinical features, for each participant, the presence or absence of clinical features such as microaneurysms, hard exudates, cotton wool spots and others were recorded by both camera and read by an independent ophthalmologist different from the one who performed the clinical examination of the patients. The kappa statistic and its 95%CI were computed to estimate the level of agreement between the two methods. Similarly, the overall assessment of the status of the participant (a dichotomous classification as DR or no DR) by both the technician and the ophthalmologist were compared. We used the clinical examination by the ophthalmologist as the gold standard. The predictive values, sensitivity and specificity of the screening test will be calculated. The kappa statistic and its 95%CI for agreement between the technician and ophthalmologist on this overall assessment were also computed.

Data was entered from the paper questionnaires into Excel spreadsheets and transferred to Stata version 14.1 (StataCorp, College Station, Texas, USA) for statistical analysis.

5.12 Study team and allocation of duties

The study team comprised of the following personnel:

1. Principal investigator and co-investigators
2. Epidemiologist
3. Retina specialist
4. Technician/grader
5. Enumerators (eye care workers/post-graduate doctors)
6. Data entry clerk
7. Local eye care worker (from eye clinic)
8. Local health care worker (from medical clinic)

5.13 Ethical Considerations

Informed consent

The informed consent documents in Appendices 6-8 were used. The document for patients was translated into Kiswahili (Annex 8). Written information about the study was provided to potential participants. Study participants were informed that they had the freedom to withdraw from the study at any time without having to explain why they opted to do so.

Minimisation of risk

There was minimal discomfort to the patient during examination and taking of retina photographs. The study participants were examined by qualified eye care workers.

Confidentiality

Participant identifiable information was not shared in any way that is not necessary for the day-to-day administration of the study. Participant identifiable information were not published. All data collection activities were carried out taking into account patient´s privacy, dignity and confidentiality.

Compensation and reimbursement

The compensation for participants was in form of free eye examination. The study participants were screened for DR at the diabetic medical clinic and those found to have DR referred to the eye clinic within the same hospital for further examination and treatment.

5.14 Dissemination of test results

Examination results with clinical implications were fed back to participants as soon as they were out in keeping with standard clinical protocol. Existing eye care facilities and personnel of the Ministry of Health at Kitale Level 5 were engaged to treat participants with eye problems.

5.15 Feedback

Overall study results will be fed back to the local communities using the existing eye/health care systems.

5.16 Expected Application of the Results

Results of the research will be presented to the Ministry of Health, health management teams and partners. Aggregated data and manuscripts accruing from the project will be freely shared with those seeking it having obtained necessary regulatory approval.

Study results will be published in scientific journals.

6 Results

6.1 Study population

All the 256 patients who attended the Diabetic Medical Clinic at Kitale Level 5 during the study period were screened. However, the following 3 patients were excluded from analysis: study numbers 98 and 127 whose ages were not recorded and number 247 who was aged 16 years. The 253 studied patients and the dates they were examined are shown in Table 1.

Table 1: Study population and data collection period

Date	Number of diabetic patients screened for DR	%
19.03.2018	8	3.2
20.03.2018	11	4.3
21.03.2018	60	23.7
22.03.2018	4	1.6
23.03.2018	13	5.1
03.04.2018	42	16.6
04.04.2018	70	27.7
05.04.2018	17	6.7
06.04.2018	28	11.1
Total	253	100

The distribution of the patients by sex (Figure 1) was 98 males and 155 females (61.3%) and the male to female ratio was 1:1.6.

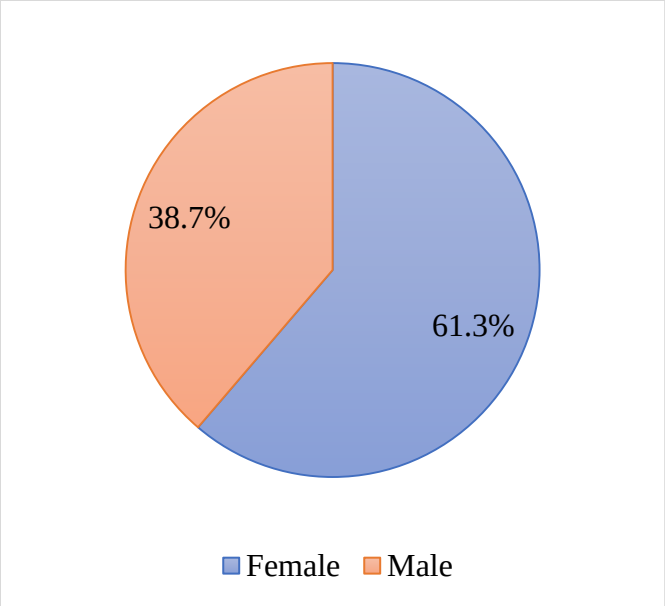

Figure 1: Distribution of the screened patients by sex

Distribution of the 253 patients by age groups is in Figure 2. The youngest was 18 years and the oldest 90 years. The mean age was 57.8 years and standard deviation 12.7 years. The median and mode were both 58.0 years.

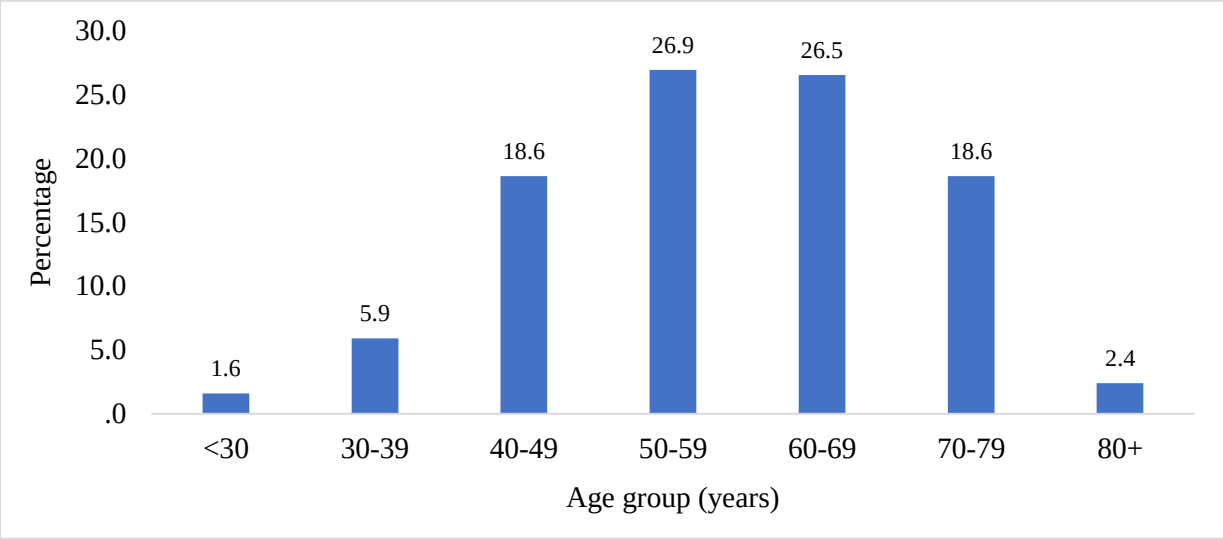

Figure 2: Distribution by age

Most of the patients (58.9%) had not attended school beyond primary school. Women were significantly more likely to have a lower level of education than men. There were 109 (70.3%) women with no more than primary school education compared to 39 (40.6%) men (p<0.001).

Table 2: Level of education

Sex	Highest level of education attained				
	Never attended school	Primary school	Secondary school	College	Total
Male	5(5.2%)	34(35.4%)	34(35.4%)	23(24.0%)	96
Female	37(23.9%)	72(46.5%)	34(21.9%)	12(7.7%)	155
Total	42(16.7%)	106(42.2%)	68(27.1%)	35(13.9%)	251

The marital status of 219 patients (86.6%) was recorded as shown in Table 3 and most of them (93.6%) were married.

Table 3: Marital status

sex	Marital status				
	Single	Married	Divorced	Widowed	Total
Male	1(1.2%)	78(96.3%)	0(0.0%)	2(2.5%)	81(100%)
Female	3(2.2%)	127(92.0%)	3(2.2%)	5(3.6%)	138(100%)
Total	4(1.8%)	205(93.6%)	3(1.4%)	7(3.2%)	219(100%)

Two hundred and thirteen patients answered the question on whether they had an active National Hospital Insurance Fund (NHIF) card and 92(43.2%) said they had the card (Table 4).

Table 4: Patients with active NHIF cards

Do you have an active NHIF card?	Number of patients	%
No	121	56.8
Yes	92	43.2
Total	213	100

One hundred and sixteen (52%) out of 223 patients said they were working (employed) while 222 specified the type of employment and about a half (48.2%) were unemployed (Figure 3).

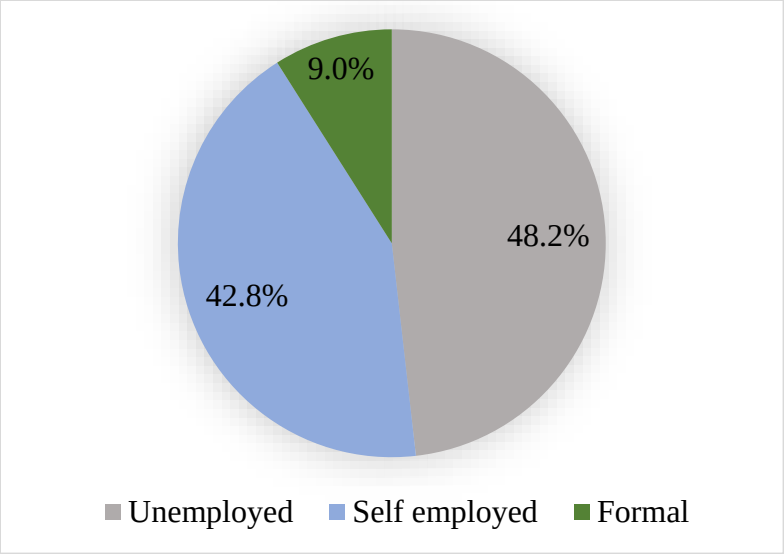

Figure 3: Employment status

Table 5 shows that formal employees had NHIF card coverage. However, most of the cards (75, 83.3%) were held by patients who were either self-employed or unemployed.

Table 5: Type of employment and NHIF card coverage

Type of employment	Does the patient have an active NHIF card?			
	Yes	No	Total	% with card
Formal	15	2	17	88.2
Self employed	39	50	89	43.8
Unemployed	36	68	104	34.6
Total	90	120	210	42.9

Two hundred and fifty of the patients had duration they had lived with diabetes reported in years (Figure 3). The minimum duration was 1 year with 28(11.2%) patients and maximum 45 years. The median duration was 6 years.

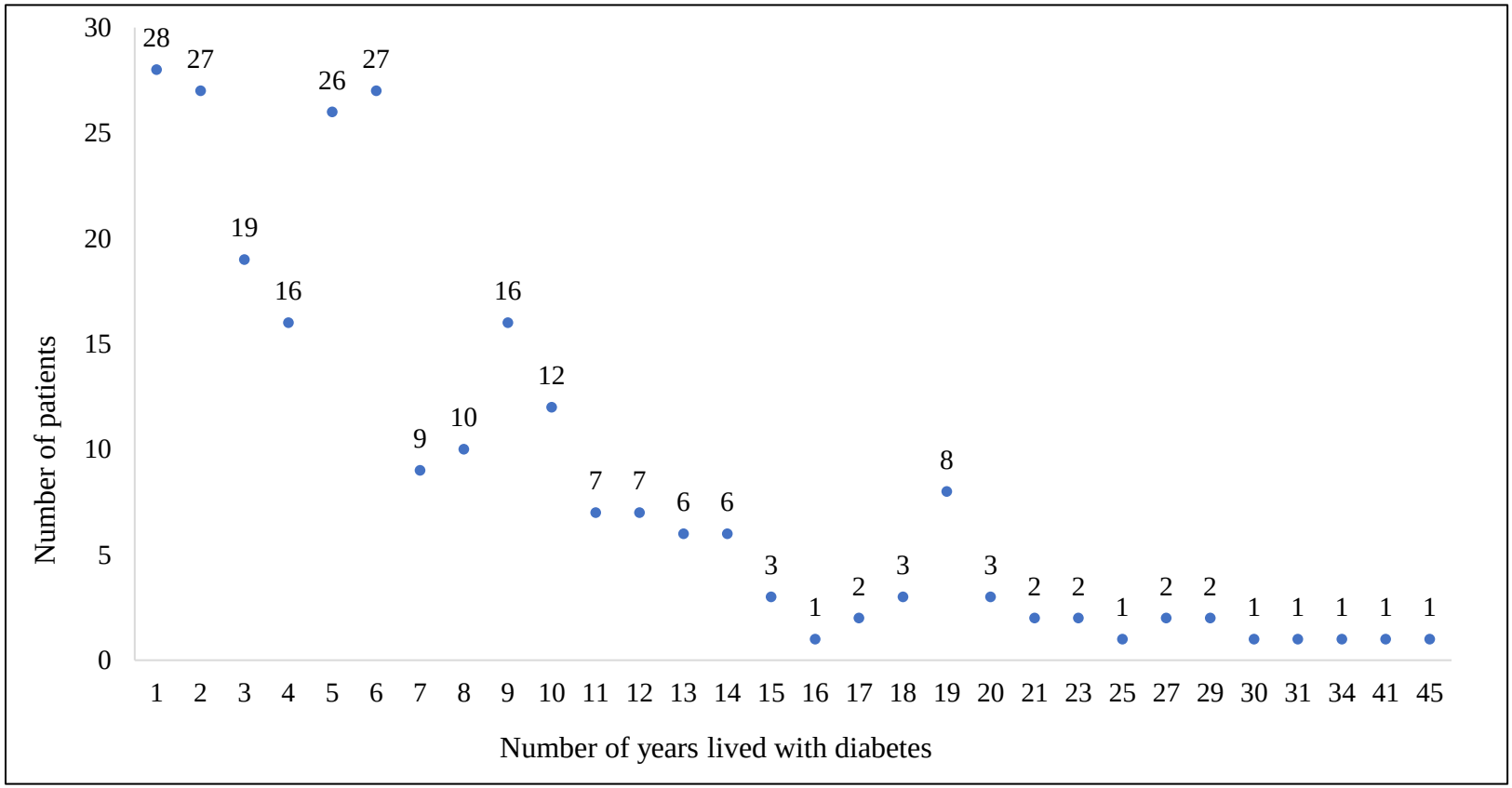

Figure 4: Number of calendar years the patient had lived with diabetes

6.2 Visual status

Presenting vision in the better eye is shown in Table 6. Most (86.4%) of the patients had normal vision. The prevalence of blindness from all likely causes was 3.2%(95%CI: 1.0%-5.4%).

Table 6: Visual status of diabetic patients of diabetic patients at Kitale Hospital

WHO grading	Number of patients (%)
Normal vision (6/6-6/18)	217(86.4%)
Visual Impairment (<6/18-6/60)	22(8.8%)
Severe Visual Impairment (<6/60-3/60)	4(1.6%)
Blind (<3/60)	8(3.2%)
Total	251(100%)

6.3 Anterior segment examination

Examination of the cornea revealed that 3 out of 250 patients had corneal scars and 1 had scars in both eyes. The prevalence of corneal scars was 1.2%(95%CI: 0.0%-3.1%).

Examination of the lens (Table 7) revealed that 23.6%(95%CI: 18.3%-28.9%) of the patients had cataracts.

Table 7: Cataract in diabetic patients at Kitale Hospital

Diagnosis	Number of patients (%)
No cataract	191(76.4%)
Cataract in both eyes	49(19.6%)
Cataract in one eye	10(4.0%)
Total	250(100%)

6.4 Examination of retina for DR

The grader took and reported retina photos of 252 patients with dilated pupils but report of 1 patient was missing. Of the 252 patients, 234 (92.9%) had gradable (Table 8) and 18(7.1%) had ungradable photos.

The prevalence of DR estimated by the grader was 24.8%(95%CI:19.3%-30.3%).

Table 8: Identification of patients DR by the retina photo grader

Diagnosis	Number of patients	%
No DR	176	75.2
DR	58	24.8
Total	234	100

Fourteen out of the 18 of the patients with ungradable photos had cataracts (Table 9). The other 45 patients with cataracts had gradable photos.

Table 9: Grading of the retina photos and lens changes

Diagnosis by grader	Clinical examination		Total
	Patient has cataracts	Patient does not have cataracts	
Patient has no DR	32	143	175
Patient has DR	13	43	56
Ungradable photos	14	4	18
Total	59	190	249

Photos of 244 (96.4%) patients sent to the University of Nairobi for reporting by a retina specialist. Out the 244 patients, 216 had gradable photos (Table 10) and 28(11.5%) had ungradable photos. Ten of the photos the specialist reported to be ungradable had been reported as gradable by the screener/grader. Thirty three out of 216 photos had signs of DR and prevalence of DR estimated by the retina specialist was 15.3%(95%CI:10.6%-20.0%%).

Table 10: Diagnosis of DR by retina specialist using retina photos

Diagnosis	Number of patients	%
No DR	183	84.7
Mild NPDR	11	5.1
Moderate NPDR	16	7.4
Severe NPDR	4	1.9
PDR	2	0.9
Total	216	100

The ophthalmologist at Kitale Hospital examined 252(99.6%) of the screened patients (Table 11) but data for 1 patient was missing. Forty-one patients had DR and the prevalence by clinical grading was 16.3% (95%CI:11.8%-20.8%).

Table 11: Clinical diagnosis by ophthalmologist

Clinical diagnosis	Number of patients	%
No DR	210	83.7
Mild NPDR	31	12.3
Moderate NPDR	8	3.2
Severe NPDR	1	0.4
PDR	1	0.4
Total	251	100

The distribution of DR by sex is shown in Table 12. The difference between the prevalence of DR in women and men was not statistically significant (p= 0.20).

Table 12: Distribution of DR by sex

Sex	Number of patients			% with DR(95%CI)	Odds Ratio(95%CI)
	Without DR	With DR	Total		
Male	84	12	96	12.5(5.8-19.2)	1.6 (0.8-3.3)
Female	126	29	155	18.7(12.6-24.8)	
Total	210	41	251	16.3 (11.8-20.8)	

6.5 Association of DR with DME

Clinical diagnosis for DME by the ophthalmologist is shown in Table 13 and the prevalence of DME was 5.2%(95%CI: 2.4%-7.9%). Data for 1 patient was missing. All patients with DME had DR.

Table 13: Clinical diagnosis of DME

Diagnosis	Number of patients	%
Patient has no DME	239	94.8
Patient has DME	13	5.2
Total*	252	100

Diagnosis of DME by retina specialist using photos is shown in Table 14. The prevalence of DME was 9.3%(95%CI: 5.4%-13.2%). All photos with DME changes had DR changes.

Table 14: Diagnosis of DME using photos

Diagnosis	Number of patients	%
No DME	196	90.7
Has DME	20	9.3
Total	216	100

6.6 Other retina findings

Other retina findings included:

- 17 patients (6.7%) had cup disc ratio of >0.5
- 3 patients aged 47, 57 and 58 years had drusen
- 1 patient had retina scar

6.7 Assessment of the screening process

The comparison of the diagnosis made by the grader using retina photos and clinical diagnosis by a validated ophthalmologist at Kitale Hospital (gold standard) is displayed in Table 15.

Table 15: Evaluation of the screening process

Identification of DR by the screener (photo grading)	Confirmation of DR by ophthalmologist (clinical diagnosis)		
	Patient has DR	Patient does not have DR	Total
Patient has DR	32	26	58
Patient does not have DR	3	172	175
Total	35	198	233
Assessment of the screening			
1. Sensitivity = 32/35 x 100 = **91.4%(**95%CI:76.9% - 98.2%)			
2. Specificity = 172/198 x 100 = **86.9%(**95%CI:81.4% - 91.2%)			
3. Positive predictive value = 32/58 x100 = **55.2%**(95%CI:41.5%-68.3%)			
4. Negative predictive value = 172/175 x100= **98.3%**(95%CI:95.1%-99.6%)			
5. Yield = 253 /35 = 7 diabetic patients screened for every 1 confirmed case of DR			

6.8 Prevalence of selected known risk factors

The prevalence of reported risk factors is shown in Table 16.

Table 16: Prevalence of selected known risk factors of DR the in diabetic patients

Risk factor	Number of patients examined		% with specified risk factor(95%CI)
	Total	With risk factor	
Systolic BP >120mmHg	229	176	76.9(71.4 -82.4)
Body Mass Index (BMI) ≥25	220	154	70.0(63.9-76.1)
Diastolic BP >80mmHg	229	129	56.3(49.8-62.8)
Random blood sugar >11.1mmol/L	227	74	32.6(26.5-38.7)
Over10 years with diabetes	250	60	24.0(18.7-29.3)
Patient smokes (current or past)	253	28	11.1(7.2-15.0)
Patient takes alcohol	251	10	4.0(1.7-6.4)
History of renal disease	248	8	3.3(1.1-5.6)
HbA1c levels ≥7.0%	6	6	100%

6.9 Association between the risk factors and DR

The association between the above risk factors with DR is shown in Table 17. The years lived with Diabetes mellitus was the only risk factor for diabetic retinopathy (DR). Those who had DR had lived with DM longer than those without (11.7yrs vs 7.1yrs). Those who had lived with DM>10 years were 4.7 times more likely to have DR than those who had lived with DM for 10 years or less. There was no statistically significant difference for all the other risk factors.

Table 17: Asociation of the risk factors with DR

Exposure factor	All N=251	Diabetic retinopathy N=41 n(%)	No diabetic retinopathy N=210 n(%)	OR (95%CI)	p-value
Years lived with diabetes Mean(SD)	7.8 (6.8)	11.7 (7.2)	7.1 (6.5)	-	<0.01[a]
Diabetes >10 years			59 (22.5)	21 (51.2) 38 (18.4)	4.7 (2.2-9.8) <0.01
High blood sugar	74 (32.9)	15 (39.5)	59 (31.6)	1.4 (0.7-2.9)	0.34
Hypertension	174 (76.7)	31 (83.8)	143 (75.3)	1.7 (0.7-4.3)	0.26
BMI	152 (69.7)	25 (67.6)	127 (70.2)	0.9 (0.4-1.9)	0.75
Cigarette smoking (ever smoked)	30 (12.0)	5 (12.2)	25 (11.9)	1.1 (0.4-2.9)	0.96
Alcohol[b]	9 (3.6)	1 (2.6)	8 (3.8)	0.7 (0.1-5.5)	0.70
Pregnancy[b]	1 (0.7)	-	1 (0.8)	-	-
Renal disease[b]	8 (3.3)	2 (5.0)	6 (2.9)	1.7 (0.3-9.0)	0.50

FOOTNOTE: This analysis excludes 1 ungradable patient. Proportions may vary depending on how many participants had data for each variable. BMI-body mass index; [a] t-test; [b] very low numbers so analysis inconclusive.

6.10 Assessment of facilities for screening and management of DR

The resources for DR screening and treatment at the Kitale Level 5 hospital are in Annexes 13-21 and are summarised in Table 18.

Table 18: Resources for DR screening and treatment at Kitale Hospital

Clinic	Available resources	Interpretation/comment
Medical Outpatient Clinic (MOPC)	• Has a diabetes medical clinic open 5 days/week • No space and equipment for DR screening • Diabetologist = 0, Physician = 1, Medical Officers = 2 and Clinical Officers = 3 • Nutritionist = 1 • Nurse = 2 • Counsellors = 1	• The MOPC has space and staff to manage Diabetes mellitus • Has no space and resources for DR screening
Eye Clinic	• General eye clinic open 5 days/week • Retina clinic open 1 day/week • Eye theatre open 3 days/week • Fundus camera = 1 • Indirect fundoscopy sets = 2 • Slit lamps = 2 (+2 non-functional) • No laser, vitrectomy, OCT and angiography sets • Operating microscopes = 1 (+2 non-functional) • Repairs equipment. Spare parts not available • Has diagnostic eye drops. No intravitreal injections • Retina specialist = 0, Ophthalmologist = 1, Ophthalmic clinical officers = 3 • Ophthalmic nurses = 6 • Technicians = 0 • Manager for DR services = 1	• The eye clinic has resources for general ophthalmology and for DR screening • Has space for medical retina • Has space for surgical retina • Has limited staff and equipment for medical retina • No staff and equipment for surgical retina • No system for supply of spares parts. Spare parts not available locally

6.11 DR Services and referral

DR services at Kitale are funded by the County Government with support from Operation Eyesight Universal and Seeing is Believing. The hospital did not have an organised DR screening project.

The number of patients attended at the diabetes and eye clinics in 2016 is shown in Table 19 and 185/1,017 x 100 = 18.2% of the diabetic patients were screened for DR. In 2017, services at all public hospitals in Kenya were grossly disrupted by multiple strikes by health care workers.

Table 19: Number of patients seen at diabetic and eye clinics in 2016

Clinic	Number of patients attended		
	Male	Female	Total
Diabetic Clinic	383	634	1,017
Eye Clinic	9,553	10,259	19,812
Screened DR	85	99	185

In the 11 weeks period (January and March 2018) prior to this study, only 12 walk-in patients were screened for DR at the Eye Clinic. During the study, screening was done at diabetic medical clinic and 256 diabetics were screened within 3 weeks. About 1 patient/week was screened when screening was based at eye clinic and 86 patients/week when based at medical clinic.

If we assume that MOPC is operational for 40 weeks in a year, then 86 patients x 40 weeks = 3,440 patients in a year. At this rate and 24.8%(95%CI:19.3%-30.3%) prevalence of DR the number of patients likely to be referred to eye clinic = (3,440 x 24.8)/100 = 853 (95%CI: 664 – 1,042) patients per year. Most (96.4%) of these patients will require repeat retina photos once a year since they had either no DR or mild NPDR on clinical examination.

Patients who required laser treatment, intravitreal injection, OCT, Fluorescein angiography and retina specialist opinion were referred to either the Moi Teaching and Referral Hospital or Sabatia Eye Hospital. The two hospitals do not have VR surgeons.

Patient records and Health Management Information System were not computerised.

7 Discussion

This study generated the baseline data needed to plan hospital-based DR screening and treatment services at Kitale Level 5 Hospital in Kenya. It was confirmed that retina photographs could be used to accurately estimate the prevalence of DR. The study had adequate power to estimate the prevalence of DR since the predetermined minimum sample size was achieved.

The proportion of female diabetics in this study (61.3%; 95%CI ,55.2%-67.4%) was significantly more than males. Other studies show generally equal proportions of males and females.(15-17) There was an earlier global estimate in 1998 that showed diabetes mellitus to be commoner in females in developing countries but equal to males in developed countries.(18) Although the proportion of females with DR (19%) was higher than males (13%) the difference did not reach statistical significance. Most studies on DR prevalence in Kenya have demonstrated similar results. Females consisted 52% in Nakuru (Mathenge); 63% in KNH (Mutinda) and 54% in KNH (Nkumbe)(6); and 46% in Chogoria, Tumu Tumu and Nyeri (Githeko)(19).

Patients in this study were aged between 18 and 90 years. However, most prevalence studies of diabetes mellitus have focused on adults aged 50 years and above as type 2 diabetes mellitus is a disease of older people. The peak age-group of the diabetics in this study was 50-69 years (median 58 years) which was similar to other population-based studies in Africa. In a Nairobi slums study enrolling adults 18+ years the peak occurrence was 65 years and above(15), in a Ghana study of adults 50+ years the peak was 60-69 years(16) and in a Nigeria population survey of people aged 40+ years the peak was 80+ years(17), Global estimates suggest that in low and middle-income countries peak age-group is 70-74 years, but it must be remembered that these were estimates.(20)

The level of education of the target population informs the type of health education and promotion materials to be developed. In this study, 16.4% of the participants had never attended school and over a half had not attended school beyond secondary school. Women were significantly more likely to have a lower level of education than men. Most of published reports indicate that in Kenya the proportion of women with formal education is lower than of men. The 2014 Kenya Health and Demographic Survey(21) reported that 89.7% of men and 85.5% of women aged 15-49 years Trans Nzoia were literate while 38.8% men and 35.2% women had secondary school level education or higher. The 2009 Kenya Population and Housing Census(22) indicated that about 18.6% of

Kenyans aged 3years and older had never attended school (men 16.7%, women 20.5%). It further indicated that 5.7% and 6.8% of similar population in Trans Nzoia West and East had never attended school. In Kenya, literacy levels are expected to increase with time because of the recently introduced free primary education policy.

Almost all patients in this study were married and this is an indication were likely to have strong social support, which is important especially for diabetic patients with impaired eye sight. However, about a half of the patients were unemployed and more than a half did not have active hospital insurance cards. These findings imply that most of the patients were of low social economic status and they were paying out-of-pocket for health services. Health is one of the key pillars of the "big four" Government of Kenya agenda for the period 2018-2022. Increase of National Hospital Insurance Fund (NHIF) coverage is one the strategies being used to meet the goal of Universal Health Coverage. As a result, the hospital should actively sensitize all diabetic patients on the need to acquire NHIF cards to provide financial protection by reduction of out-of-pocket payments.

Most (86.4%) of the patients in this study had normal vision but the prevalence of blindness from all likely causes was higher than in the general population. The Ministry of Health estimates that the prevalence of blindness in Kenya is 0.7%(23) compared to 3.2% in this study.

The proportion of retinal images that is ungradable in this study was low (6.8%) compared to a previous teleophthalmology study in Murang'a, Kenya among diabetics where the proportion of ungradable images was 24%.(24) Our results compare well with a review of teleophthalmology studies for diabetic retinopathy which found the proportion of ungradable photos to be about 3.1% - 10.6%.(25) In this study, mydriatic drops were applied to dilate the pupils when taking photographs and conducting examination. Mydriasis has been reported to reduce technical failure rates(26).

Media opacities due to conditions such as cataract and corneal scaring are among the reason why retina images may not be gradable. In this study 23.6%(95%CI: 18.3%-28.9%) and 1.2%(95%CI: 0.0%-3.1%) patients had cataracts and corneal scars respectively. Most (77.8%) of the patients with ungradable photos had cataracts. However, majority (76.3%) of the patients with cataracts had gradable photos as the cataracts were not dense enough to obstruct the view of retina.

The prevalence of DR in our study by clinical method was 16.3% (95%CI:11.8%-20.8%) and it was consistent with what other hospital-based studies show in the region. A recent review found the prevalence of DR among diabetics in Eastern Africa to range between 10% and 47%.(27) Population-based studies show a higher prevalence of about 35%.(27) The prevalence we found using the camera was 24.8% (95%CI; 19.3%-30.3%) which is somewhat similar to a Nakuru population- based study that used cameras. The prevalence of any DR diagnosed by retinal images among diabetics in the Nakuru, Kenya study was 35.9% (95% CI, 29.7–42.6%).(28) The two confidence intervals overlap.

The grades according to the ETDRS in this study were different from other studies in Kenya. The proportion of mild or moderate non-proliferative DR (NPDR) in our study was 12.4% vs 22.1% in the Nakuru study, while severe NPDR and PDR were in this study 2.8% vs 13.9% in Nakuru.(28) It is unclear why this is so but it is possible that differences in the study population (hospital-based versus population-based) and socio-economic or genetic differences in susceptibility may play a role. Kitale also referred patients with DR to other hospitals and this could lower the prevalence.

The prevalence of clinically diagnosed diabetics is macula oedema (DME) in this study was 5.2%(95%CI: 2.4%-7.9%). However, the diagnosis of DME this study was only indicative and not confirmatory because we did not use optical coherent tomography (OCT) which is the gold standard.(29, 30) All the patents with DME in this study had DR and hence they were referred for further investigation and management. Also, there was a likelihood that clinical features of DME could be confounded by those of other maculopathies such as hypertension and AMD. The prevalence of clinically significant macula oedema was reported to be 8.7% in newly diagnosed diabetics at the Kenyatta National Hospital.(31)

The British Diabetic Association standards propose a screening test for diabetic retinopathy should have a minimum sensitivity of 80% and a specificity of 95%(32). The sensitivity in this study was 91.4%(95%CI:76.9% - 98.2%) and specificity 86.9%(95%CI:81.4% - 91.2%). It is anticipated that with time that the specificity will improve as the staff gain experience.

In this study, the most prevalent known risk factors of DR were uncontrolled blood pressure (76.9%), high body mass index (70.0%), poor blood sugar control (32.6%) and being diabetic for many years (24.0%). However, apart from the years lived with DM that was an important risk factor for DR in this study, the other expected risk factors including high body mass index, high

blood sugar, high blood pressure, renal disease and pregnancy, were not significantly associated with DR in this study. This was a cross-sectional study powered for the prevalence of diabetic retinopathy, not to determine the risk factors of diabetic retinopathy. In addition, few people were exposed to factors like renal disease, cigarette smoking and pregnancy.

The Kenya national guidelines for screening and management of patients with DR (also referred to as Clinical Practice Guidelines) specify that a Level 5 hospital like Kitale should have a medical retina specialist to offer DR services. However, the findings of this study revealed that Kitale hospital had resources for screening but lacked experts and equipment to treat DR. The Hospital referred all patients with DR services to Eldoret and Sabatia Hospitals. Eldoret hospital is the regional referral hospital but it neither had a vitreoretinal surgeon nor a medical retina specialist. That means diabetics with DR had to travel to far-way hospital for treatment. The number of patients who were treated for diabetes and DR at Kitale in 2017 were very few because there were multiple national strikes by health workers. During this study, the number of patients screened for DR increased from approximately 1 patient to 86 patients per week, meaning that previously, very few diabetics had their eyes checked for DR. If the trend set during this study is maintained, it is anticipated that about 3,440 patients will be screened and 1,000 patients sent for treatment of DR at Kitale within a period of year. Such number of patients will require the hospital to scale-up DR services. An evaluation of the Kenyatta National Hospital diabetic retinopathy screening program revealed that after the screening project was established the number of diabetic patients referred for further evaluation at the eye clinic doubled and number who received eye treatments tripled(33).

It was proposed a further qualitative study is needed to establish the level Knowledge, Perceptions and Practices (KPP) among the medical staff and patients at Kitale hospital and barriers to delivery of DR services. Such barriers may have a negative impact on compliance with national screening and treatment guidelines.

8 Conclusions and recommendations

The following conclusions were made from the findings of this study:

- The prevalence of clinically diagnosed DR at Kitale hospital 16% diabetic
- About 1,000 patients will be referred to eye clinic from the screening project in a year
- Diagnosis of made using retina photographs is accurate in screening for DR
- Known risk factors of DR were prevalent in the diabetic patients at the hospital
- The hospital had resources for screening but lacked resources for treatment of DR
- About half of the patients were unemployed and majority had no hospital insurance cards

It was recommended that the hospital should:

- Sale-up screening for DR
- Train at least one medical retina specialist
- Strengthen health education and services for control of diabetes and DR
- Sensitise all patients on the need to have hospital insurance cards
- Conduct a qualitative study to establish barriers to delivery of DR services

9 References

1. Christensen DL, Friis H, Mwaniki DL, Kilonzo B, Tetens I, Boit MK, et al. Prevalence of glucose intolerance and associated risk factors in rural and urban populations of different ethnic groups in Kenya. Diabetes Res Clin Pract 2009;84(3):303-10.
2. Ministry of Health. Kenya STEPwise survey for non communicable diseases risk factors 2015 report. In; 2015.
3. Lima VC, Cavalieri GC, Lima MC, Nazario NO, Lima GC. Risk factors for diabetic retinopathy: a case–control study. International Journal of Retina and Vitreous 2016;2(1):21.
4. Krishnaiah S, Das T, Nirmalan PK, Shamanna BR, Nutheti R, Rao GN, et al. Risk factors for diabetic retinopathy: Findings from The Andhra Pradesh Eye Disease Study. Clinical ophthalmology (Auckland, N.Z.) 2007;1(4):475-482.
5. Mathenge W, Bastawrous A, Peto T, Leung E, Yorston D, Foster A. Prevalence and Correlates of Diabetic Retinopathy in a Population-based Survey of Older People in Nakuru, Kenya. Ophthalmic Epidemiol 2014;21(3):169-77.
6. Nkumbe H, Kollmann K, Gaeckle H. Assessment of diabetic retinopathy in newly diagnosed black Kenyan type 2 diabetics. East Afr Med J 2010;87(3):109-14.
7. Ting DS, Cheung GC, Wong TY. Diabetic retinopathy: global prevalence, major risk factors, screening practices and public health challenges: a review. Clin Experiment Ophthalmol 2016;44(4):260-77.
8. Kupitz DG, Fenwick E, Kollmann KH, Holz FG, Finger RP. Diabetes and Diabetic Retinopathy Management in East Africa: Knowledge, Attitudes, and Practices of Hospital Staff in Kenya. Asia Pac J Ophthalmol (Phila) 2014;3(5):271-6.
9. Solomon AW, Zondervan M, Kuper H, Buchan J, Mabey D, Foster A. Trachoma control - A guide for programme managers. Geneva: World Health Organization 2006.
10. World Health Organization. Trachoma epidemiologic survey protocol. Geneva 1993;WHO/PBL/93.33.
11. Minassian D. Epidemiology in practice: Sample size calculation for eye surveys: a simple method. J Comm Eye Health 1997;10(23):42-44.
12. Shi L, Wu H, Dong J, Jiang K, Lu X, Shi J. Telemedicine for detecting diabetic retinopathy: a systematic review and meta-analysis. British Journal of Ophthalmology 2015;99(6):823-831.
13. Scanlon PH, Malhotra R, Thomas G, Foy C, Kirkpatrick JN, Lewis-Barned N, et al. The effectiveness of screening for diabetic retinopathy by digital imaging photography and technician ophthalmoscopy. Diabet Med 2003;20(6):467-74.
14. Early Treatment Diabetic Retinopathy Study Research Group. ETDRS report number 10. Ophthalmology 1991;98:786-806.
15. Ayah R, Joshi MD, Wanjiru R, Njau EK, Otieno CF, Njeru EK, et al. A population-based survey of prevalence of diabetes and correlates in an urban slum community in Nairobi, Kenya. BMC Public Health 2013;13:371.
16. Gatimu SM, Milimo BW, Sebastian MS. Prevalence and determinants of diabetes among older adults in Ghana. BMC Public Health 2016;16(1):1174.
17. Kyari F, Tafida A, Sivasubramaniam S, Murthy GV, Peto T, Gilbert CE. Prevalence and risk factors for diabetes and diabetic retinopathy: results from the Nigeria national blindness and visual impairment survey. BMC Public Health 2014;14:1299.
18. King H, Aubert RE, Herman WH. Global burden of diabetes, 1995-2025: prevalence, numerical estimates, and projections. Diabetes Care 1998;21(9):1414-31.

19. Githeko A, Kollmann K, Adala H. The prevalence, pattern and risk factors of diabetic retinopathy among diabetic patients attending peripheral health institutions in Central Kenya. M.Med Dissertation, University of Nairobi 2001.
20. Guariguata L, Whiting DR, Hambleton I, Beagley J, Linnenkamp U, Shaw JE. Global estimates of diabetes prevalence for 2013 and projections for 2035. Diabetes Res Clin Pract 2014;103(2):137-49.
21. Kenya National Bureau of Statistics. Kenya Demographic and Health Survey; 2014.
22. Kenya National Bureau of Statistics. Kenya Population and Housing Census. Nairobi: Government of Kenya; 2009.
23. Ministry of Health. National Strategic Plan for Eye Health and Blindness Prevention 2012-18; 2011.
24. Kiage D, Kherani IN, Gichuhi S, Damji KF, Nyenze M. The Muranga Teleophthalmology Study: Comparison of Virtual (Teleglaucoma) with in-Person Clinical Assessment to Diagnose Glaucoma. Middle East Afr J Ophthalmol 2013;20(2):150-7.
25. Salongcay RP, Silva PS. The Role of Teleophthalmology in the Management of Diabetic Retinopathy. Asia Pac J Ophthalmol (Phila) 2018;7(1):17-21.
26. Murgatroyd H, Ellingford A, Cox A, Binnie M, Ellis I, MacEwen C, et al. Effect of mydriasis and different field strategies on digital image screening of diabetic eye disease. Br J Ophthalmol 2004;88:920-24.
27. Burgess PI, MacCormick IJ, Harding SP, Bastawrous A, Beare NA, Garner P. Epidemiology of diabetic retinopathy and maculopathy in Africa: a systematic review. Diabet Med 2013;30(4):399-412.
28. Mathenge W, Bastawrous A, Peto T, Leung I, Yorston D, Foster A, et al. Prevalence and correlates of diabetic retinopathy in a population-based survey of older people in Nakuru, Kenya. Ophthalmic Epidemiol 2014;21(3):169-77.
29. Mookiah MR, Acharya UR, Fujita H, Tan JH, Chua CK, Bhandary SV, et al. Application of different imaging modalities for diagnosis of Diabetic Macular Edema: A review. Comput Biol Med 2015;66:295-315.
30. Virgili G, Menchini F, Murro V, Peluso E, Rosa F, Casazza G. Optical coherence tomography (OCT) for detection of macular oedema in patients with diabetic retinopathy. Cochrane Database Syst Rev 2011(7):Cd008081.
31. Nkumbe HE, Kollmann KH, Gaeckle HC. Assessment of diabetic retinopathy in newly diagnosed black Kenyan type 2 diabetics. East Afr Med J 2010;87(3):109-14.
32. Scanlon P. The English National Screening Programme for diabetic retinopathy 2003–2016. Acta Diabetol 2017;54:515-25.
33. Gichuhi S, Gichangi M, Nyamori J, Gachago M, Nyenze M, Nyaga P, et al. Evaluation of the Kenyatta National Hospital diabetic retinopathy screening program 2015-2016. J Ophthalmol East Cent & S Afr 2017;21(2):40-5.

10 Annexes

Annex 1: Investigators, Qualification and Institutional Affiliations

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4. **Dr. Joseph Nyamori**
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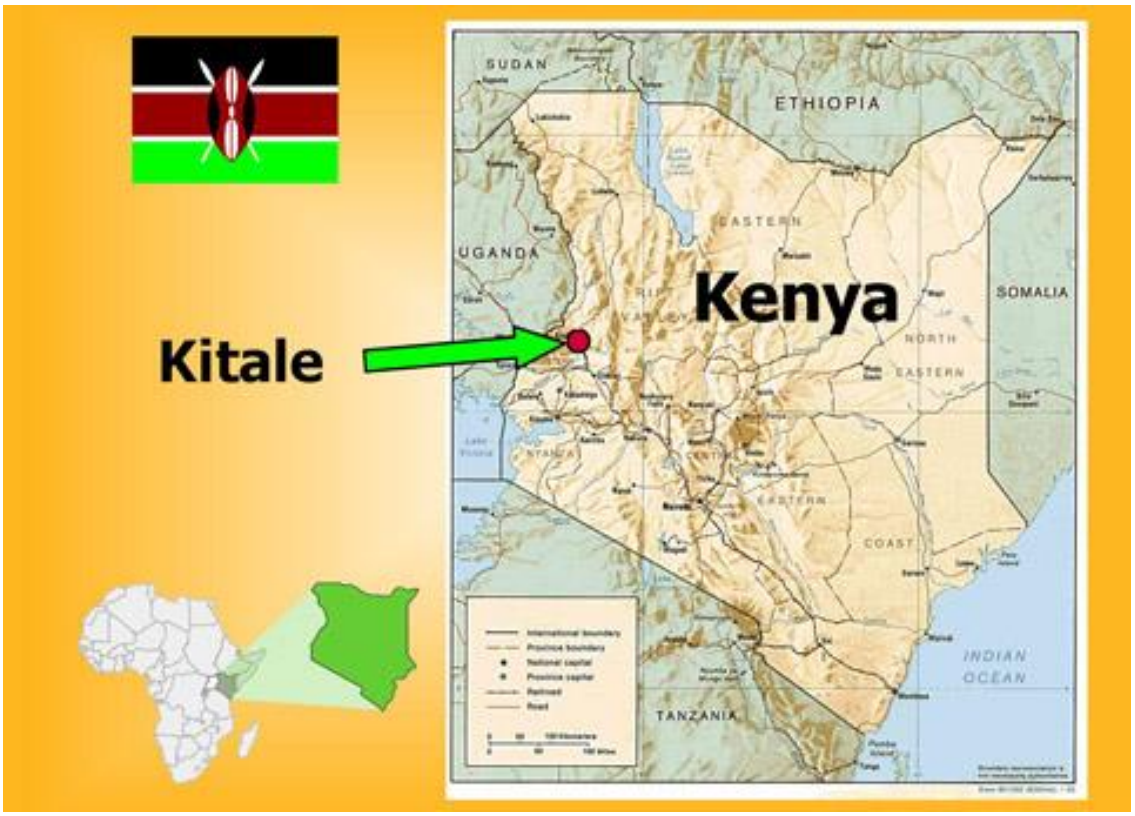
Conflict of interest: None of the above researchers have any conflict of interest to declare.

Annex 2: Map of Kenya showing the location of Kitale



Annex 3: Data collection tool for Prevalence, risk factors

PERSONAL DATA

Name: _____

Age (years): _____

Sex: Male ☐ Female ☐

Highest education level:

Never been to school ☐ Primary ☐ Secondary ☐ College ☐

Year when diagnosed to be diabetic: _____/_____/____

Duration of diabetes (years): _____

Date of interview: _____/_____/_____

Findings on Fundus camera (nonmydriatic)

Microaneurysms ☐ Haemorrhages ☐ Exudates ☐ Cotton wool spots ☐

Tortuous vessels ☐ NVD ☐ NVE ☐ Rubeosis iridis☐

Vitreous haemorrhage☐ Subhyaloid haemorrhage ☐

Neoascular glaucoma ☐ Macular thickening ☐

Other (specify): _____

Grading on fundus camera (ETDRS)

Retina

No DR ☐ Mild NPDR ☐ Moderate NPDR ☐ Severe NPDR ☐

Very severe NPDR ☐ PDR ☐

Advanced Diabetic Eye Disease ☐ Ungradable photo ☐

Macula

No DME`☐ Non-clinically significant DME ☐ CSME ☐

Ungradable photo ☐

Slit lamp examination

Media opacity

Corneal scar ☐ Microcystic oedema ☐ Cataract ☐

Other (specify) _____

Clinical findings on Fundoscopy (Dilated)

Microaneurysms ☐ Haemorrhages ☐ Exudates ☐ Cotton wool spots ☐

Tortuous vessels ☐ NVD ☐ NVE ☐ Rubeosis iridis☐

Vitreous haemorrhage☐ Subhyaloid haemorrhage ☐

Neoascular glaucoma ☐ Macular thickeing ☐ No fundus view ☐

Other (specify): _____

_____

Grading on fundoscopy (ETDRS)

Retina

No DR ☐ Mild NPDR ☐ Moderate NPDR ☐ Severe NPDR ☐

Very severe NPDR ☐ PDR ☐

Advanced Diabetic Eye Disease ☐ Ungradable ☐

Macula

No DME`☐ Non-clinically significant DME ☐ CSME ☐

Ungradable ☐

Risk factors

1. BP: _____mmHg
2. Weight: _____Kg Height:_____Metres BMI: _____
3. RBS/FBS: _____mmol/L
4. HbA1c: _____%
5. Cholesterol/Lipogram: _____
6. Current Smoker Yes ☐ No☐ (If no, go to Q. 7)
7. Never smoked ☐ Past smoker ☐
8. Alcohol: Yes ☐ No☐
9. Pregnant: Yes ☐ No☐
10. Renal disease: Yes ☐ No☐

Annex 4: Abbreviated early treatment diabetic retinopathy study (ETDRS) classification

a) Non-proliferative Diabetic Retinopathy

Category	*Description*
No DR	*No signs of DR*
Very mild NPDR	*Microaneurysms only*
Mild NPDR	*Any or all of: Microaneurysms, retinal haemorrhages, exudates, cotton wool spots, up to the level of moderate NPDR.* *No IRMA or significant beading*
Moderate NPDR	*Severe retinal haemorrhages (more than ETDRS standard photograph 2A: about 20 medium–large per quadrant) in 1–3 quadrants or mild IRMA* *Significant venous beading can be present in no more than 1 quadrant* *Cotton wool spots commonly present*
Severe NPDR	*The 4–2–1 rule: One or more of:* *Severe haemorrhages in all 4 quadrants* *Significant venous beading in 2 or more quadrants* *Moderate IRMA in 1 or more quadrants*
Very severe NPDR	*Two or more of the criteria for severe NPDR*

a) Proliferative Diabetic Retinopathy (PDR)

Category	*Description*
Mild-moderate PDR	*New vessels on the disc (NVD) or new vessels elsewhere (NVE), but extent insufficient to meet the high-risk criteria*
High risk PDR	*New vessels on the disc (NVD) greater than ETDRS standard photograph 10A (about 1/3 disc area)* *Or*

	Any NVD with vitreous haemorrhage *Or* *NVE greater than ½ disc area with vitreous haemorrhage*
Advanced diabetic eye disease	*Subhyaloid haemorrhage* *Vitreous haemorrhage* *Neovascularization of the iris (NVI)* *Tractional retinal detachment*

a) Diabetic Maculopathy

Category	*Description*
Non-clinically significant macular oedema	*No macula oedema*
Clinically significant macular oedema	*Retinal thickening within 500 μm of the centre of the macula* *Or* *Exudates within 500 μm of the centre of the macula, if associated with retinal thickening; the thickening itself may be outside the 500μm* *Or* *Retinal thickening one disc area (1500 μm) or larger, any part of which is within one disc diameter of the centre of the macula*
Ischaemic maculopathy	*Dull foveal reflex* *Enlarged FAZ on FA*

Annex 5: Tool for assessment of facilities and services for DR

Name of the Hospital:	
Name of town:	
Name of County:	
Date of the visit:	
Name of enumerator:	
Name(s) of respondent(s):	

A. HUMAN RESOURCES

Diabetic MOPC team	*Number available*	*Comment*
Diabetologists		
Physicians		
Medical officers		
Nutritionists		
Nurses		
Counsellors		
Others (specify)		
1		
2		
Diabetic retinopathy team		
Retina specialists		
Ophthalmologist		
Ophthalmic clinical officers		
Ophthalmic nurses		
Technicians		
Manager/coordinator for DR services		
Others (specify)		
1		
2		

B. FACILITIES/STRUCTURES

Type of facility	*Available (yes/no)*	*Adequate (yes/no)*	*Number of days open/week*	*Comments*
DR screening room at Diabetic MOPC				
General eye clinic				
Diabetic/retina eye clinic				
Eye theatre				

C. EQUIPMENT

Medical clinic	*Number functional*	*Number non-functional*
Fundus camera		
Direct ophthalmoscope		
Others (specify)		
1		
2		
Eye clinic		
Fundus camera		
Indirect fundoscopy sets		
Slit lamps		
Laser sets		
Vitrectomy sets		
OCT		
Operating microscopes		
Retina angiography sets		
Others (specify)		
1		
2		

D. SUPPLIES

Type of supply	*Available (yes/no)*	*Adequate (yes/no)*	*Comments*
Diagnostic eye drops			
Intravitreal injection			
Spare parts for equipment			

E. STAKEHOLDERS FOR MANGEMENT OF DR

Active	*Support provided*	*Anticipated support*	*Duration of support (years)*
1. Operation Eyesight Universal			
2. SiB			
3			
4			
Potential			
1. County Government			
2			
3			

F. DR SERVICES PROVIDED IN THE PAST 1 YEAR (2016)

Type of service	*Available (yes/no)*	*Number of patients*	*Comment*
Diabetics screened for DR at MOPC			
MOPC refers DR patients to eye clinic for screening			
Diabetics seen first at eye clinic (walk in)			
Patients with DR treated			
Intravitreal injections			
Laser treatments			

Diabetic vitrectomy			
Equipment maintenance			

G. HMIS (2016)

Information system	*Yes*	*No*	*Comment*
Manual patients´ records used			
Computerised patient records used			
Partially computerised records			
All DR data transmitted electronically			
Data analysed and used for planning			

H. REFFERAL NETWORK

Service requiring referral	*Yes/No*	*Referred to*	*Comment*
Retina specialist opinion			
Laser			
Surgery			
Intravitreal injections			
OCT			
Fluorescein angiography			
Others (specify)			
1			
2			

Annex 6: Budget estimates for the 2017 Kitale diabetic retinopathy study

FTE = Full time Equivalent (equivalent of one full day of consultancy services)

ACTIVITIES	***UNITS***	***RATE (Shillings)***	***TOTAL COST (Shillings)***	***TOTAL US$ ($1 = 100 Shillings)***
1. Preparation meetings				
Planning meetings	1 day	30,000	30,000	300
Sub-total			***30,000***	300
2. Development of research protocol				
Proposal development	6 FTE	30,000	180,000	1,800
Application for ethical approval	1 application	50,000	50,000	500
Sub-total			***230,000***	2,300
3.Training technician of grader				
Transport/refunds	1 participants	3,000	3,000	30
Per diem (accommodation & subsistence)	1 graders x 5 days	7,000	35,000	350
Training consultant	3 FTE	30,000	90,000	900
Sub-total			***128,000***	1,280
4. Stationery				
Pencils	12	30	360	4
Erasers	10	30	300	3
Pencils sharpeners	10	30	300	3
Field notebooks	12	50	600	6
Ball pens	10	10	100	1
Photocopy papers (reams)	10	500	5,000	50
Felt pens (sets, assorted)	2	500	1,000	10
Flip chart paper (rims)	1	1000	1,000	10
Masking tape	2	80	160	2
Stapler	3	800	2,400	24

Staples (packets)	6	200	1,200	12
Pocket folders	30	200	6,000	60
Gloves size 7/8 (dozens, some for survey)	30	100	3,000	30
Mobile telephone calls (graders/supervisors)	10	500	5,000	50
Printing/photocopy of questionnaires		50,000	50,000	500
Sub-total			***76,420***	764
5. Equipment and drugs				
Fudus (retina) camera		Available	-	
Accessories (computer and printer)		Available	-	
Diagnostic drugs	10	300	3,000	30
Gloves size 7/8	400	30	12,000	120
Sub-total			***15,000***	150
6. Data collection and management				
6.1. Data collection				
Honoraria grader (technician) lunches	1 person x 15 days	2,000	30,000	300
Honoraria for eye clinic worker	1 person x 15 days	2,000	30,000	300
Honoraria for medical clinic worker	1 person x 15 days	2,000	30,000	300
Per diem for research assistant (diagnostic test)	10 days	7,000	70,000	700
Per diem for In-depth interviews research assistant	7 days	7,000	49000	490
Per diem for research assistant to review medical records	1 person x 5 day	7,000	35000	350
Supervision of data collection by consultants	3 FTE	30,000	90,000	900
Sub-total			***334,000***	3,340
6.2 Data management				
Data entry clerk for quantitative data	1 clerk x 10 days	7,000	70,000	700

Data entry of qualitative data	1 clerk x 10 days	7,000	35,000	350
Supervision of data management	3 FTE	30,000	90,000	900
Sub-total			***195,000***	1,950
7.0 Report writing and debriefing				
Report writing	3 FTE	30,000	90,000	900
Debriefing	1 FTE	30,000	30,000	300
Sub-total			**120,000**	1,200
TOTAL (BUDGET ESTIMATE)			**1,128,420**	11,284
10. Contingencies			***71,580***	716
AVAILABLE BUDGET			**1,200,000**	12,000

Annex 7: Informed consent form for diabetic patients

You are invited to take part in a research study to determine the prevalence, risk factors and barriers to delivery of diabetic retinopathy (DR) services at the Kitale Level 5 Hospital in Kenya.

Participation in this study is voluntary and the information gathered will be used solely for academic and intended purposes such as inform policy at the government level. If you choose to be in the study you can withdraw at any time without consequences of any kind. Refusal to participate in the study will not lead to you not receiving quality healthcare.

You do not have to write your name or identify yourself in any way in any of the questionnaires.

As part of the study you will be asked a few questions regarding your health, you will have an eye examination on a slit lamp biomicroscope after dilation of your pupils and have photos taken of your retina by a fundus camera. Pupil dilation will lead to blurring of vision for about 3 hours after which normal vision will resume.

Thank you for your kind participation in this study.

_____ _____

Participant's Signature Date

Annex 8: Informed consent form for diabetic patients (Kiswahili)

CHETI CHA IDHINI CHA WAGONJWA

Unakaribishwa kushiriki kwenya utafiti wa kuzindua kiwango, vihatarishi na vikwazo vya kutoa huduma za kutibu maadhara ya ugonjwa wa kisukari kwenye macho katika hospital kuu ya Kitale level 5 hapa Kenya.

Kuhusika kwenye utafiti huu ni kwa hiari yako na habari zitakazokusanywa zitatumika tu kwa masomo na kujulisha sera za serikali. Ukikubali kujiunga na utafiti unaweza kutoka wakati wowote bila kugandamizwa kwa njia yeyote. Kukataa kujuhusisha hakutasababisha unyimwe huduma za afya za hali ya juu.

Sio lazima jina lako liandikwe kwenye dodoso.

Kama sehemu ya utafiti utaulizwa maswali kuhusu afya yako, utapimwa macho kwenye taa watakata yenye hadubini baada ya kutiwa dawa ya kupanua mboni ya jicho na baadaye kupigwa picha picha ya retina katika sehemu ya nyuma ya jicho. Kupanua mboni ya jicho kutasababisha ukungu wa kuona kwa kama masaa matatu halafu baadaye utaweza kuona kawaida yako.

Asante kwa kuhusika na utafiti huu.

_____ _____

Sahihi ya muhusika Tarehe

Annex 9: Data

Hospital and respondent's findings

Name of the Hospital:	KITALE COUNTY REFERAL HOSPITAL
Name of town:	KITALE
Name of County:	TRANS-NZOIA
Date of the visit:	04/04/2018
Name of researcher:	DR. HILLARY RONO
Name(s) of respondent(s):	GRACE WACHIRA HILLARY RONO MARGARET OPAA

Human resources for management of DR findings

Diabetic MOPC team	***Number available***	***Comment***
Diabetologists	None	
Physicians	1	
Medical officers	2	Assisted by clinical officers
Nutritionists	1	
Nurses	2	
Counsellors	1	
Others (specify)	None	
1		
2		
Diabetic retinopathy team		
Retina specialists	0	
Ophthalmologist	1	
Ophthalmic clinical officers	3	
Ophthalmic nurses	6	
Technicians	0	
Manager/coordinator for DR services	1	
Others (specify)		
1	2 MOs, 3 COs, 2 nurses in the MOPC diabetic clinic 1 physician comes 1&week to assist	
2		

***Facilities for DR* findings**

Type of facility	***Available*** *(tick correct response)*	***Adequate*** *(tick correct response)*	***Number of days open/week***	***Comments***
DR screening room at Diabetic MOPC	***Yes*** ***No*** ✓	***Yes*** ***No***	5	
General eye clinic	***Yes*** ✓ ***No***	***Yes*** ✓ ***No***	5	
Diabetic/retina eye clinic	***Yes*** ✓ ***No***	***Yes*** ***No*** ✓	1	Every Wednesday
Eye theatre	***Yes*** ✓ ***No***	***Yes*** ✓ ***No***	3	Every Tuesday, Wednesday & Thursdays

***Equipment for DR* findings**

Medical clinic	***Number functional***	***Number non-functional***
Fundus camera	None	
Direct ophthalmoscope	None	
Others (specify)		
1		
2		
Eye clinic		
Fundus camera	1	
Indirect fundoscopy sets	1	
Slit lamps	2	2
Laser sets	None	
Vitrectomy sets	None	
OCT	None	
Operating microscopes	1	2
Retina angiography sets	None	
Others (specify)		
1		
2		

***Supplies* findings**

Type of supply	***Available*** *(tick correct response)*	***Adequate*** *(tick correct response)*	***Comments***
Diagnostic eye drops	***Yes*** ✓ ***No***	***Yes*** ✓ ***No***	
Intravitreal injection	***Yes*** ***No*** ✓	***Yes*** ***No***	
Spare parts for equipment	***Yes*** ***No*** ✓	***Yes*** ***No*** ✓	- No proper system of supplies - Not available locally

***Stakeholders for management of DR* findings**

Active	***Support provided***	***Anticipated support***	***Duration of support (years)***
1. Operation Eyesight Universal			
2. SiB			
3			
4			
Potential			
1. County Government		✓	
2			
3			

***DR services provided in the past 1-year* findings**

Type of service	***Available (yes/no)***	***Number of patients***	***Comment***
Diabetics screened for DR at MOPC	No	*Table below*	
MOPC refers DR patients to eye clinic for screening	Occasionally		
Diabetics seen first at eye clinic (walk in)	None		
Patients with DR treated	12		From Jan 2018 to March 2018
Intravitreal injections	None		
Laser treatments	None		
Diabetic vitrectomy	None		
Equipment maintenance	Yes		

Data	*2016*			*2017*		
	Male	*Female*	*Total*	*Male*	*Female*	*Total*
Diabetes MOPC attendance	*383*	*634*	*1017*	*324*	*402*	*726*
Eye CLINIC attendance	*9,553*	*10259*	*19,812*	*3,429*	*3,842*	*7,271*
Patients screened for DR	*69*	*80*		*20*	*25*	
Patients with DR	*16*	*19*		*6*	*3*	*9*

***HMIS (2016)* findings**

Type of Information system	***Tick what is used***	***Comment***
Manual patients´ records used	✓	
Computerised patient records used		
Partially computerised records	✓	
All DR data transmitted electronically		
Data analysed and used for planning		

***Referral of DR patients to other hospitals* findings**

Service that require patient to be referred to other hospitals	***Tick against the correct option***	***Name of the hospital they are referred to***	***Comment***
Retina (VR) specialist opinion	✓	• Moi Teaching & Referral Hospital • Sabatia Eye Hospital	
Laser	✓	• *MTRH* • *Sabatia Eye Hospital* • *Tenwek*	
Surgery			
Intravitreal injections	✓	*Sabatia Eye Hospital*	
OCT	✓		
Fluorescein angiography	✓		
Others (specify)			
1			
2			

Annex 10: Photos of Kitale DR study

Photo 1: Checking of Visual Acuity

Photo 2: Checking of Visual Acuity using a pinhole

Photo 3: Instillation of eye drops to dilate the pupils

Photo 4: Taking of retina photos using a fundus camera

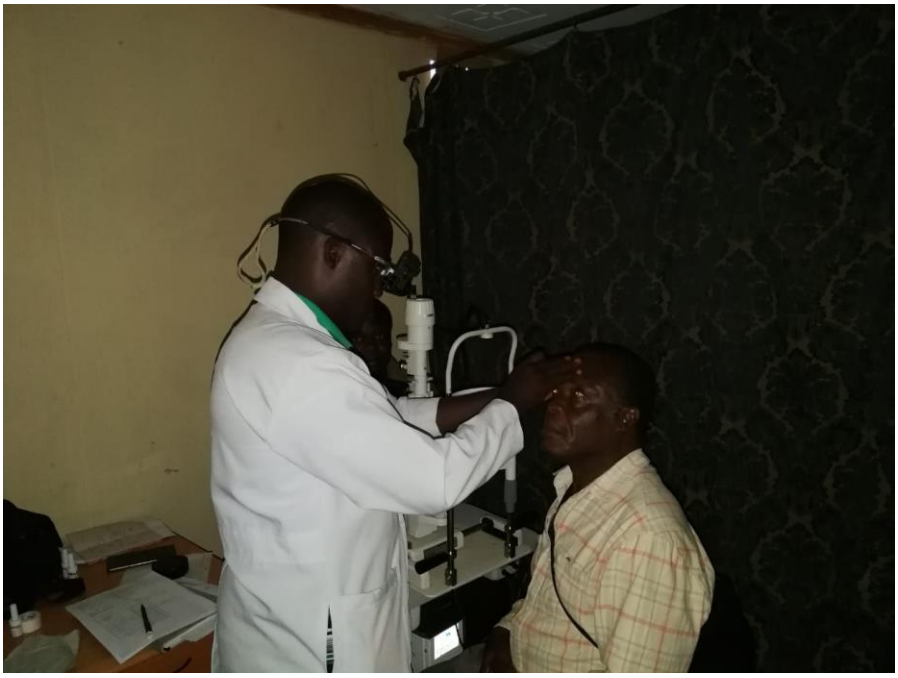


Photo 5: Clinical examination by the eye doctor

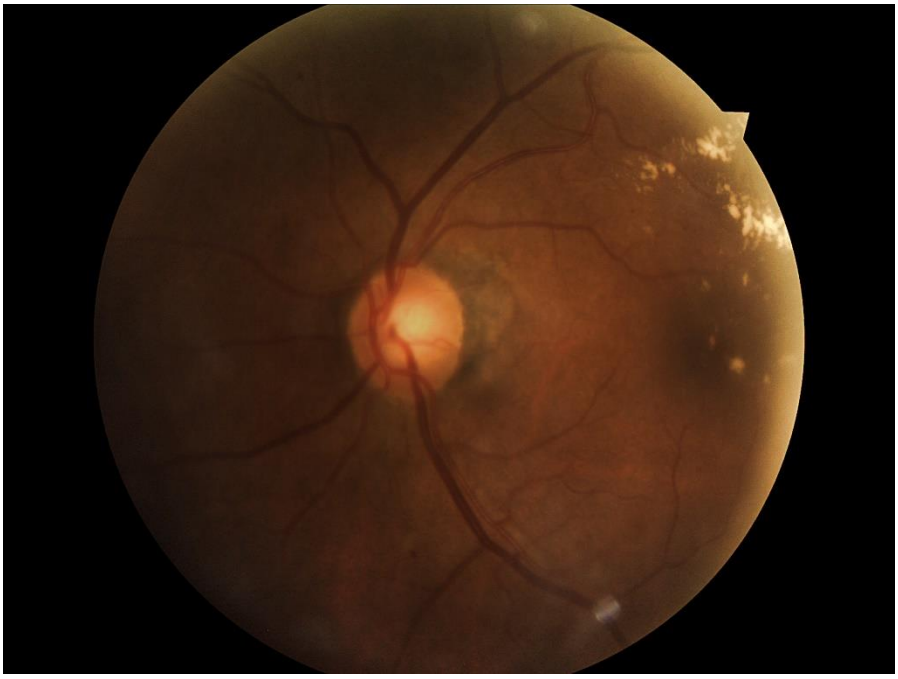


Photo 6: Retina photo of a patient with diabetic changes

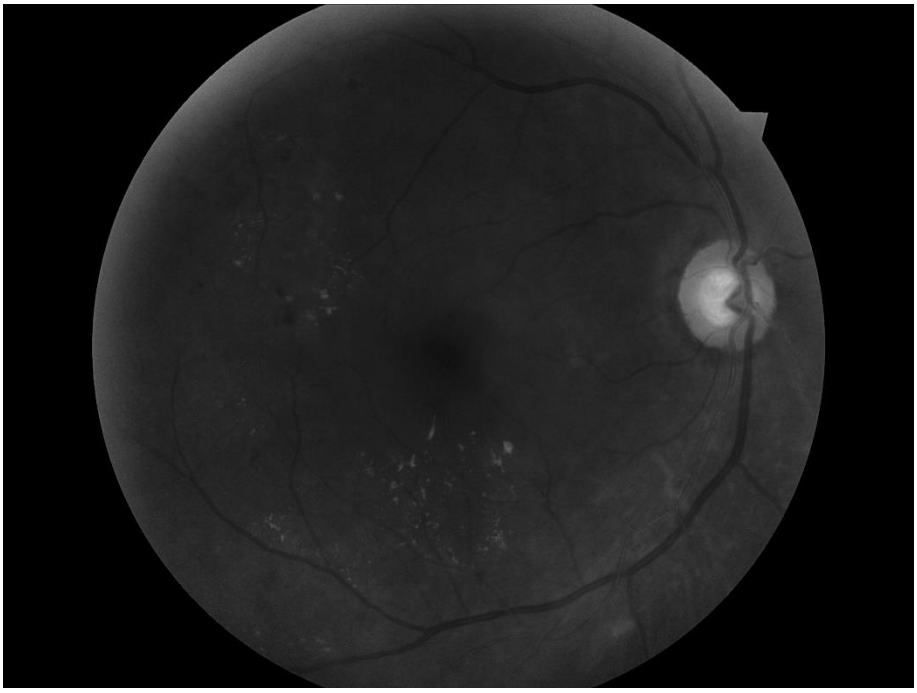


Photo 7: Black and white retina photo of a patient with diabetic changes