Retinal photographic screening in a diabetic clinic versus ophthalmologist screening in an eye clinic; Task-sharing to increase diabetic retinopathy screening in Tanzania

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ABSTRACT

Background: We compared two methods of screening for diabetic retinopathy in a diabetic clinic by a technician using a digital retinal camera, and in an eye clinic by an ophthalmologist.
Objective: To find out if task-sharing might result in more screening uptake.
Methods: The study site was a tertiary referral hospital in North Tanzania. All patients aged 18 years and above attending the adult diabetic clinic during this period, living in Kilimanjaro Region and diagnosed with type-2 diabetes were invited to participate. After attending their regular diabetes check-ups, the participants in the study either remained in the diabetic clinic to be screened by a technician using the retinal camera or moved through a fast-track system and were screened for diabetic retinopathy in the eye clinic by an ophthalmologist. One hundred and thirty six participants were screened in the diabetic clinic group and 137 in the eye clinic group.
Results: Diabetic retinopathy was detected at 52.4% in the diabetic clinic, with 3.2% requiring treatment. In the eye clinic detection was 36.9% with 4.1% requiring treatment.
Conclusion: Diabetic retinopathy screening with a retinal camera operated by a trained technician is an effective and efficient method of diabetic retinopathy screening, to detect diabetic retinopathy and maculopathy, and a good use of task-sharing. This research suggests the implementation of comprehensive community-based programmes with the aim of providing knowledge-based teaching, clinical support, resources and action plans that health care workers can use to empower people with diabetes to be healthy living with diabetes and be proactive in preventing the complications of diabetes.

Key words: Retinal photographic screening, Task-sharing, Diabetic retinopathy

INTRODUCTION

Diabetic Retinopathy (DR) is the most common microvascular complication and the leading cause of preventable adult blindness[1,2]. When the capillaries of the retina are exposed to high and sustained glucose levels, they become damaged. Subsequent leaking and closure of these capillaries causes retinal oedema and ischaemia with loss of function, especially with central retinal or macular involvement[3]. Ischaemia causes production of vascular endothelial growth factor stimulating production of new blood vessels leading to proliferative diabetic retinopathy[1].

Worldwide the number of People with Diabetes (PWD) is increasing[2-4]. There are 19 million people in Africa (20-79 years) with diabetes, more than half undiagnosed[5]. In sub-Saharan Africa; the number of adults living with the disease will be 23.9 million by 2030[2,5,6], with an increase amongst poorer rural populations[7]. Diabetic Retinopathy (DR) is a microvascular complication[3], and if left untreated may lead to irreversible loss of vision, frequently among those of working age[4]. Vision Threatening Diabetic Retinopathy (VTDR) can significantly affect a person's psychosocial functioning and ability to manage their diabetes[5-7].

DR-screening meets the WHO-criteria for screening and blindness prevention[8]. Early diagnosis and treatment are both effective and efficient in preventing vision loss and blindness[9]. DR-screening should be initiated at diagnosis for people with type-2 diabetes, and in certain contexts repeated annually even when the person remains asymptomatic so that if VTDR is detected it can be successfully treated[9].

In resource-poor areas of sub-Saharan Africa access to care is difficult, and socioeconomic factors hinder optimal prevention of visual loss from DR[10]. Despite eye care services supporting diabetic clinics, late presentation for screening and treatment are common[11-13]. Task-sharing has been highlighted as an important strategy in the management of care in understaffed and resource-poor health systems[14]. A previous study in Kilimanjaro demonstrated that free referral for DR-screening from the diabetic clinic to the eye clinic (<100 meters away) only increased uptake by 36%; 71% had not had a dilated eye examination in the past year[13].

Knowledge that diabetes damages the eyes and the need for screening, do not translate into action[15-17]. Additional efforts are needed[18,19]. Poor health literacy is a worldwide issue facing health educators and carers[20]. The International Council of Ophthalmology emphasises the need that PWD are well informed by HCWs about their diabetes condition, self-care, how diabetes affects their eyesight and the need to receive prompt treatment before loss of vison[21].

The rational for this study was to establish if the target population would accept screening by a technician versus an ophthalmologist to promote task sharing prior to the roll out of the rural screening program, and the efficacy of Diabetic Retinopathy (DR)-screening using the digital diabetic retinopathy screening and grading of the images. We compared two methods of DR-screening: (i) in a diabetic clinic by a technician using a digital retinal camera, and (ii) in an eye clinic by an ophthalmologist; to find out if task-sharing might result in more screening uptake. The Intervention Mapping (IM) protocol was the basis of the intervention program[16,22]. IM is comprised of six iterative steps with discrete tasks, supported with theoretical and empirical evidence[16].

This study built on a previous tertiary hospital study, to test more pro-active ways to encourage utilization of free DR-screening services at the hospital by task-sharing[13], using IM to determine if DR-screening in the diabetic clinic with a digital retinal camera operated by a technician, would lead to higher uptake of screening compared to screening in the eye clinic by an ophthalmologist[23,24]. The comparison also aimed to identify if task-sharing, i.e., DR-screening with a technician, was as effective and efficient in detecting diabetic retinopathy; measured by recording the findings on the dilated eye screening form and comparing the findings of patients screening by the technician or by the ophthalmologist.

MATERIALS AND METHODS

Study design: A randomised prospective comparison of two screening methods.

Study setting: The study site was a tertiary referral hospital in the Northern Region of Tanzania. The Eye Department provides a full range of ophthalmic services, while the diabetic clinic (headed by a specialist endocrinologist) holds clinics twice a week for People with Diabetes (PWD). The uptake of screening compared (i) DR-screening in the diabetic clinic with a digital retinal camera (TOPCON-NW8) operated by a technician and (ii) DR-screening in the eye clinic <100 metres away by an ophthalmologist, who was a registrar-in-training. A four-day pilot was followed by the comparison, which ran for a two-month period (16 days).

Participants: The sample size was calculated based on the estimated difference in proportion between P1 (current use of service = 30%) and P2 (anticipated use of service after intervention = 50%) as 20 with a significance level of $\alpha = 0.05$ (two-sided) and power of $1-\beta = 0.2$. To detect a difference, 103 patients were needed in each group. In the final analysis n=124 in the diabetic clinic and n=122 in the eye clinic, were adequate numbers of participants to be analysed for the study.

Inclusion criteria and consent: All patients aged over 18 years attending the adult diabetic clinic during this period, living in Kilimanjaro Region and diagnosed with type-2 diabetes were invited to participate in the comparison by a research assistant. Patients who did not meet these criteria were excluded, but still received free DR-screening. Reasons for non-inclusion in the comparison: being too ill (having a blood sugar level requiring urgent hospital admission), having type-1 diabetes, and living outside of Kilimanjaro Region. Consenting participants had a leaflet explaining the study read to them. Each participant gave written consent before participation. Confidentiality and continued quality of care were assured, and participants were informed they could withdraw from the study at any time. The study adhered to the World Medical Association Guidelines for Screenings outlined at the 1964 Declaration of Helsinki[25]. A questionnaire regarding participants' eye health behaviour in terms of knowledge of DR and previous screening for DR was completed with assistance of diabetic clinic staff.

Randomisation and masking: On entry participants were given an envelope by the primary investigator allocating them to the eye clinic or the diabetic clinic from a random numbers table. Once the participants had been reviewed by the diabetic clinic doctors and nurses, they were moved on to where they had been allocated for DR-screening. Not all participants chose to be screened on the same day; some chose to come back on another day.

Procedure: In the eye clinic a fast-track system enabled PWD presenting for DR-screening to bypass waiting lines for general ophthalmology patients. In the diabetic clinic PWD were screened consecutively as they presented to the technician. Participants were administered pupil-dilating eye drops before DR-

screening was conducted by the technician who used a TOPCON-NW8 camera to take retinal photographs and entered data onto the Dilated Eye Screening Form (Figure 1). The demographic data, images and results of DR-screening where later entered onto the program's database and participants were appropriately informed of the results, either by short messaging service (SMS/ text) or phone call.

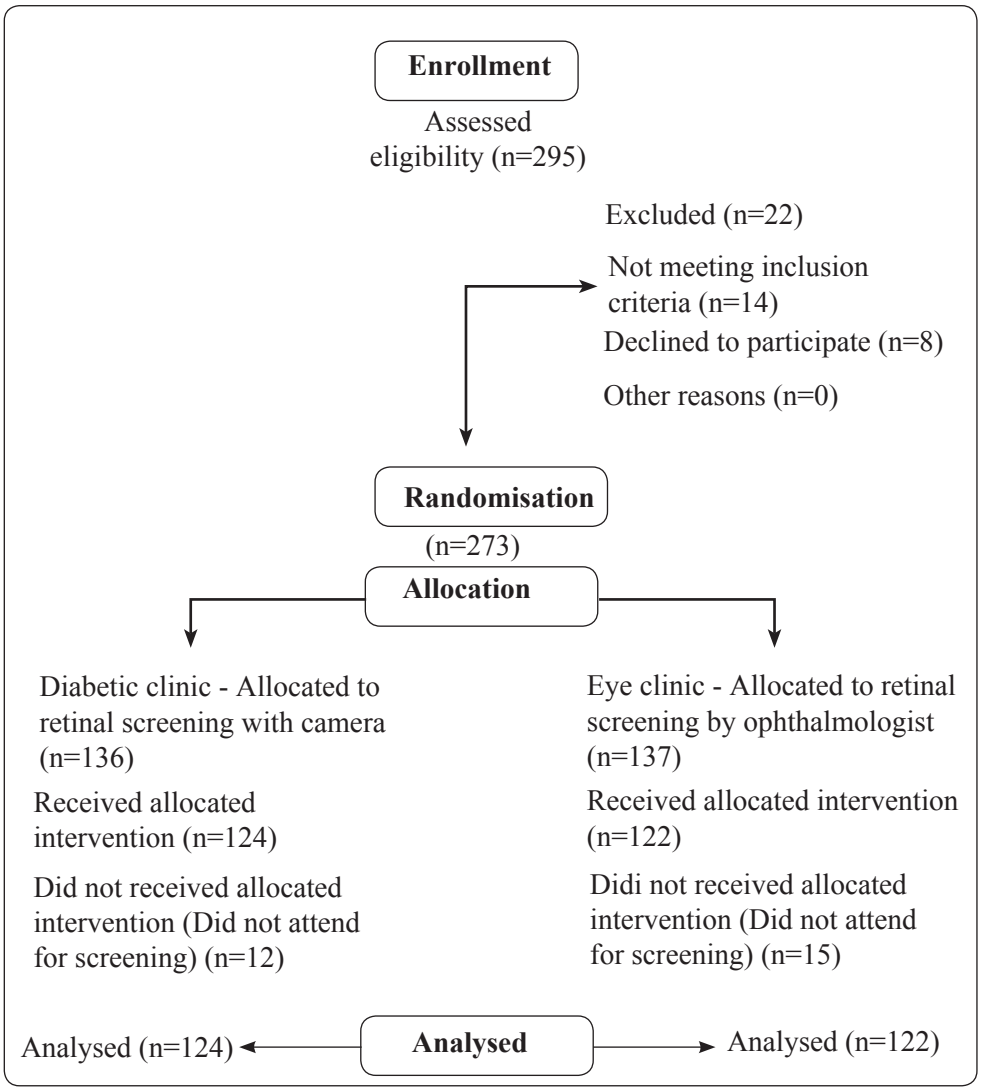
Figure 1: Diabetic retinopathy screening

The standard criteria for detection of DR were developed in 1991 by the Early Treatment Diabetic Retinopathy Study, with classification of DR and capture of fundus images using 30-degree stereoscopic photographs with 7 standard fields on colour slide film[13]. These guidelines require the support of trained graders with costly equipment and is both labour intensive and time consuming[14].

In the United Kingdom national screening programs have been adopted using digital photography with central reading centres[15], whereas elsewhere digital fundus photography is becoming more common if the guidelines set out in 2013 by the International Council of Ophthalmology (ICO) are followed[14,16]. The most important being that any DR-screening program is coupled with timely and adequate referral and access to ophthalmic consultation for care to ensure that the screening is beneficial.

Various studies of digital photography validation have shown it as an effective and efficient method to accurately identify and appropriately determine the severity of DR, compared to slit lamp biomicroscopic examination by a trained ophthalmologist[12,14]. Digital fundus photography has several notable advantages; it is less distressing to the patient, less time consuming, can be performed by trained technicians (as opposed to ophthalmologists) and taken into areas where access to eye health is limited, and allows for storage of retinal images for analysis, review, and epidemiological study[17]. Mydriasis (pupil dilation) for photography increases specificity and sensitivity of screening[18,19,] whilst a collateral benefit of digital screening is the high detection of other eye conditions[20].

Figure 2: Flow of participants through the trial consort diagram



On completion of the DR-screening the technician gave the participant written information on how they would be informed of the outcome of the findings. Grading of photographs was done by the consultant ophthalmologists; results were entered onto the Dilated Eye Screening Form and then entered with the digital fundus photographs into the program's database for future follow-up or treatment. We based our grading on the international classification of diabetic retinopathy and diabetic macular oedema. Diabetic macular oedema was graded as: M0 no macular findings, M1 hard exudates within one to 2 disc diameters of the fovea and M2 haemorrhage or exudates within one disk diameter of the fovea. If no VTDR was detected, participants were informed by SMS/text message and would receive a further SMS reminder for repeat DR-screening in one year. If VTDR was detected for participants attending the diabetic clinic, they were phoned with a date for follow-up assessment at the hospital's eye clinic. If VTDR was detected in participants attending the eye clinic, they were offered treatment on the same day. Results from both clinics were entered onto the program's electronic database and into the participants' diabetic diary.

In the Eye Clinic, participants were registered at a special (fast-track) counter. There was no charge for registering at the eye clinic or for DR retinopathy screening. Pupil-dilating eye drops were administered, and a dilated fundus examination was conducted using an indirect ophthalmoscope and slit lamp biomicroscopy by an attending ophthalmologist. The fundus findings were recorded on the Dilated Eye Screening Form (Figure 3) and the participant was immediately informed of the results.

Figure 3: Dilated eye screening form (for completion by the technician)

Diabetic No: ..... Mobile No: .....

Hospital No: ..... E/Clinic No: ..... Age Sex: Male ☐ Female ☐

Name of patient: .....

From patient's KDP diabetic diary: Date ..... R/E: ☐ L/E: ☐

Blood pressure: ☐ RBS: ☐ PH R/E ☐ PH L/E ☐

Digital fundus photograph taken: Y/N patient informed they will be contacted with results: Y/N

Name of photographer : ..... Duration of diabetes .....

Outcomes: The outcome of interest was attendance or non-attendance for screening for DR. Odds Ratios (OR) and 95% Confidence Intervals (CI) were calculated to test associations with screening acceptance. The standard intervention of screening with ophthalmologists was compared with the new intervention of screening with retinal imaging.

The screening was conducted by ophthalmologists working in the eye clinic, replicating real life working conditions. As the primary goal was not to establish presence of diabetic retinopathy but to compare the two interventions, the interobserver variability in grading of diabetic retinopathy is irrelevant. The technician was highly trained in taking retinal photographs.

Ethics approval was granted by Tumaini University Ethics committee, Clearance Certificate Number 241, Research Proposal Number 273. The hospital administration approved the study.

RESULTS

Of the 295 people assessed for eligibility, 22 did not meet the enrolment criteria and 8 declined to take part in the study. Among the 273 patients enrolled, 80 females and 44 males were randomized to the diabetic clinic group. Average ages were 57.02 years and 60.63 years respectively. There were 74 females and 48 males to the eye clinic group. Average ages were 56.72 years and 67.75 years respectively. There were no major differences in demographic or clinical factors between the sexes. Female participants were slightly younger. Females were 2.42 times (95%CI 1.47-3.98) more likely to have no or primary education. Female participants were 9.3 times (95% CI 2.8-31.2) more likely to be unmarried. In the diabetic clinic the mean duration of diabetes for males was 10.9 years, for females 9.5 years. In the eye clinic the mean duration of diabetes for males was 9.51 years, for females was 6.86 years. The Eye-Health Questionnaire results are presented in Table 1.

Table 1: Eye health questionnaire results

Variable	Diabetic clinic		Eye clinic	
Gender	Male (n=49) No. (%)	Female (n=87) No. (%)	Male (n=57) No. (%)	Female (n=80) No. (%)
Knowledge that diabetes damages the eye				
Yes				
No	38 (77.6)	70 (80.5)	41 (71.9)	53 (66.3)
	11 (22.4)	17 (19.5)	16 (28.1)	27 (33.7)
Previous dilated eye examination for DR*				
Yes				
No	30 (61.2)	43 (49.4)	29 (50.9)	37 (46.3)
	19 (38.8)	44 (50.6)	28 (49.1)	43 (53.7)
Knowledge that dilated eye examination should be yearly				
Yes	19 (38.8)	40 (46.0)	16 (28.1)	29 (36.3)
No	30 (61.2)	47 (54.0)	41 (71.9)	51 (63.7)

Of the participants 54% had not previously had a dilated eye examination for DR. The reasons included having no problem with their eyes (n=51), being unaware of the need (n= 14), and difficult access to a clinic (n=24). Only one participant mentioned cost.

The outcomes of the study's Diabetic Retinopathy Screening are presented in Table 2. There was no difference between the two allocation groups in uptake of screening; 124 (91.1%) patients were screened in the diabetic clinic and 122 (89.1%) in the eye clinic (Figure 4). In the diabetic clinic findings for any diabetic retinopathy (R1-R3) were 70 (52.4%), in the eye clinic 35 (36.9%) (Table 2). Diabetic retinopathy requiring treatment were 4 (3.2%) and 5 (4.1%). The most significant difference was between levels of referable maculopathy (M1) detected in the diabetic clinic 31 (25.0%) versus in the eye clinic 16 (13.11) (Table 3).

Table 2: Clinical trial diabetic retinopathy screening results

Variable	Diabetic clinic (n= 124) No. (%)	Eye clinic (n=122) No. (%)
No diabetic eye disease (either eye)	54 (43.5%)	72 (59.0%)
Background DR (R1)	49 (39.5%)	29 (23.8%)
Pre-proliferative DR (R2)	12 (9.7%)	11 (9.0%)
Proliferative DR (R3)	4 (3.2%)	5 (4.1%)
No maculopathy (M0)	89 (71.8%)	90 (73.8%)
Maculopathy Not Referable (MNR)	3 (2.4%)	12 (9.8%)
Referable maculopathy (M1)	31 (25.0%)	16 (13.1%)

Figure 4: Dilated Eye Screening Form (for completion by ophthalmologist)

Diabetic No: ..... Mobile No: .....

Hospital No: ..... E/Clinic No: ..... Age Sex: Male ☐ Female ☐

Name of patient: .....

From patient's KDP diabetic diary: Date ..... R/E: ☐ L/E: ☐

Blood pressure: ☐ RBS: ☐ PH R/E ☐ PH L/E ☐

Digital fundus photograph taken: Y/N Patient informed they will be contacted with results: Y/N

Name of photographer : ..... Duration of diabetes .....

Lens Opacity R/E: No Lens opacity interfering with photo Yes ☐ Referred to KCMC E/Dept ☐

L/E: No ☐ Lens opacity interfering with photograph Yes ☐

Diabetic Retinopathy R/E: R0 = No DR ☐ M0 = No Mac ☐

R1 = DBR ☐ MNR = Mac not referable ☐

R2 = Pre=proliferative DR ☐ M1 = referable maculopathy ☐

R3 = Proliferative DR ☐

P= Photocoagulation ☐ OL/UG = other lesion/ ungradable ☐

L/E: R0 = No DR ☐ M0 = No Mac ☐

L/E: R0 = No DR ☐ M0 = No Mac ☐

R1 = BDR ☐ MNR = Mac not referable ☐

R2 = Pre=proliferative DR ☐ M1 = referable maculopathy ☐

DISCUSSION

The researchers had anticipated that if participants accepted screening with the retinal camera there would be a greater uptake of participants in the diabetic clinic over the eye clinic. The equal uptake of screening in both clinics was a surprise finding. The fast-track service in the eye clinic is thought to have removed the barrier of waiting for screening in this clinic.

There was good detection of diabetic retinopathy in both clinics. The difference in the detection of significant maculopathy in the diabetic clinic can be explained by the fact that the reading and grading of retinal photographs was supervised by the senior (consultant) ophthalmologists with a final grading decision approved by a consultant. The DR-screening in the eye clinic was conducted by a registrar who was not as experienced as the ophthalmologists. This demonstrates the value of retinal photography and task-sharing in DR-screening by technicians.

The study found no difference in screening uptake between the diabetic clinic and the eye clinic. The high level of participation by both groups made it impossible to assess factors associated with DR-screening uptake. Findings of the earlier hospital study suggested that fewer patients would attend the eye clinic due to longer waiting times[26]: Eighteen percent of patients left while their eyes were dilating, and before the fundus examination was completed[26]. The high uptake in both groups was likely due to a motivated team in the diabetic clinic, who provided education on the need for DR-screening, and that the fast-track systems reduced waiting times. Unlike the previous study no patients were observed leaving either clinic whilst waiting for their eyes to dilate prior to DR-screening[13]. The task-sharing undertaken by the staff involved educating the participants about the need for

DR-screening, handing out the DR-information leaflets (comic strips)[20]. The fast-track services in both clinics appear to have removed a key barrier to uptake of DR-screening.

The advantage of digital fundus photography is that each participant had their fundus photographs stored on the program's database for future reference. With task-sharing a technician can conduct a significant number of DR-screenings with a digital fundus camera freeing up the ophthalmologist for clinical work. Another advantage is that a technician can conduct screening in remote locations[26,27]. This task-sharing reduces the need for lengthy, remote travel by trained ophthalmologists. Uptake of DR-screening depends on knowledge that DM damages the eye, need for DR-screening, knowledge of options and the benefits of screening, and access to ophthalmic services. In this population, although females had lower levels of education and were more likely to be unmarried, their level of knowledge regarding DR-screening and the possibility of vision loss due to DR were similar to the levels reported by males. The most common reason for not attending for screening was not perceiving a problem with the eyes. This suggests the need for PWD to understand that routine DR-screening is important in diagnosing sight threating DR that can be effectively treated before visual symptoms occur[21,24,26]. Other researchers support these findings[28,29].

CONCLUSION

DR-screening with a retinal camera operated by a trained technician is an effective and efficient method of DR-screening, to detect diabetic retinopathy and maculopathy, and a good use of task-sharing. Retinal fundus screening was acceptable to the target audience.

Strengths and limitations of the study

The study showed that both modes were an effective and efficient method of DR-screening. Firstly, indicated by high uptake with those accepting free screening with the technician in the diabetic clinic and those accepting free screening with an ophthalmologist using the fast track in the eye clinic. Secondly, by the acceptance of DR-screening using a retinal camera with a technician, and the great value of task-sharing in the context of the target audience. The researchers had been unsure if this method would be acceptable to participants. Thirdly, the use of the retinal camera allowed the researcher to trial the program's database to store demographic data and digital fundal images prior to the roll-out of the proposed regional rural DR-screening program.

Selection bias was a major limitation of the study as the participants were regular attenders of the hospital's diabetic clinic. An attempt was made to interview those who agreed to take part and then failed to attend for screening; an inadequate number agreed to be interviewed.

Relevance of the study for clinicians and policy makers

The study shows that with a motivated team providing clear explanations of the need for and access to DR-screening, uptake can be increased. By providing PWD with information about DR that explains the condition, the rational of screening and why early intervention while asymptomatic is important to preserve sight, it is possible to prevent avoidable blindness from diabetic retinopathy by early diagnosis.

Further research

Researchers should pay careful attention to the barriers identified for DR-screening uptake and treatment[26,28]. PWD need to understand how to access eye health services, the hidden and transparent costs, treatment options and outcome expectations. PWD must understand what being screened for DR means and the disease process. The greatest challenge to researchers is to address the social and cultural barriers to uptake of screening for DR and treatment. Ultimately, we must understand the individual's concerns and fears and personalise care[22,26,29,35,36].

CONCLUSION

The comparison of uptake of DR-screening in the diabetic clinic using a digital retinal camera versus screening in an eye clinic by ophthalmologists demonstrated no significant difference in uptake between the two methods. This unexpected finding was likely influenced by the introduction of a DR-screening service that provided good advice and information about the need for screening, a personal diabetic diary, and the support of a motivated team during the duration of the study. At the same time, the previous barriers to uptake of screening were removed and participants were fast-tracked through the DR-screening service.

The introduction of fast-track systems and DR-screening options in the diabetic clinic and eye clinics which remained after the completion of the study were instrumental in allowing better allocation of ophthalmologist resources. This shows the success of task-sharing which is essential where time and resources are limited. The success of technician operated digital fundus cameras as a method of DR-screening assisted in providing an evidence base for the development of transportable diabetic eye services, to provide care for rurally remote communities. Most importantly the future would be a comprehensive community-based approach with the aim of providing knowledge-based teaching,

clinical support, resources and action plans that HCWs could use to empower PWD to be healthy living with diabetes and avoid the complications of diabetes[22].

Declaration

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Availability of data and materials: All data and materials can be provided by the first author.

Competing interests: The authors declare that they have no competing interests.

Authors' contributions: CH designed the Training Workshop. CH and AH planned the execution and the evaluation study. JM contributed to the implementation. GK helped supervise the project and CH took the lead in writing the manuscript. All authors discussed the results and contributed to the final manuscript.

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