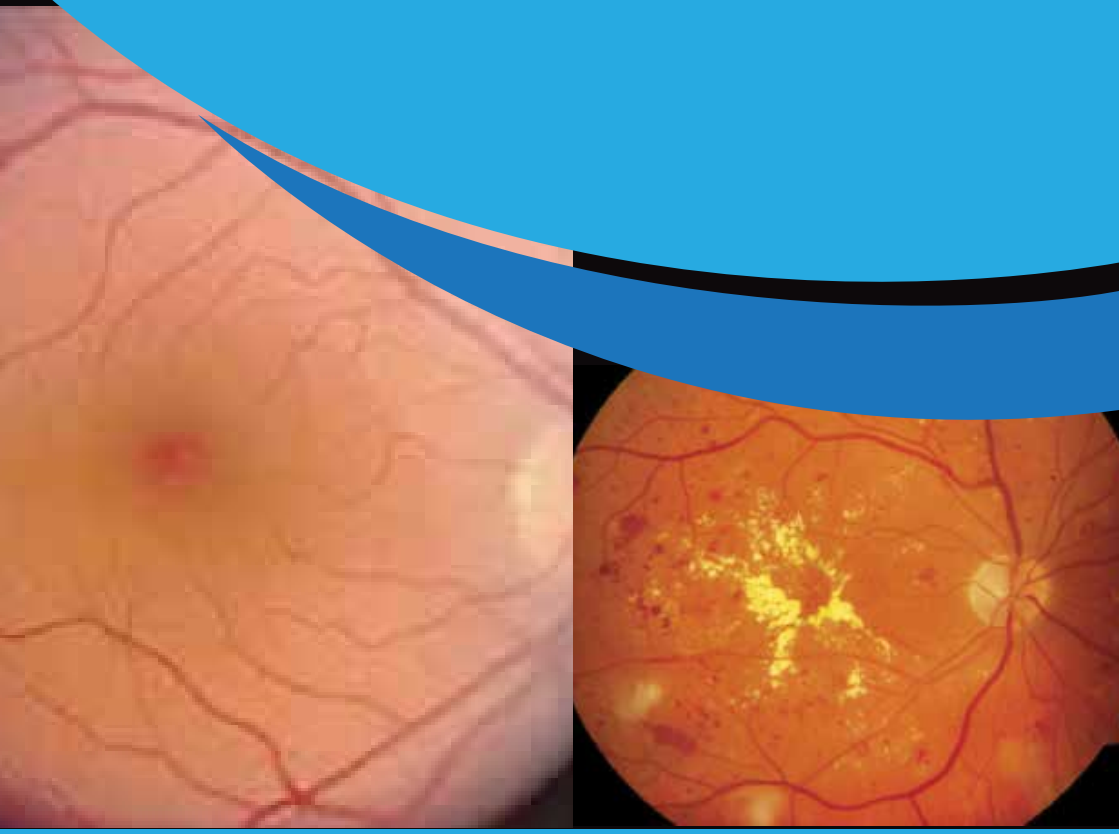
REPUBLIC OF KENYA

MINISTRY OF HEALTH



Guidelines for Screening and Management of Diabetic Retinopathy

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These Guidelines for the screening and management of diabetic retinopathy in Kenya 2017 edition (also referred to as **Clinical Practice Guidelines for Diabetic Retinopathy in Kenya** within this document**)** contain relevant information required by health care providers in prevention and management of **diabetic retinopathy** as of the date of issue. All reasonable precautions have been taken by Ministry of Health to verify the information contained in this document.

To obtain clarifications and provide feedback on the usability of the guidelines, contact:
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FOREWORD

Diabetes mellitus (DM) is a global epidemic with significant morbidity. Diabetic retinopathy (DR) is the specific micro vascular complication of Diabetes mellitus (DM) that affects over a third of persons with Diabetes mellitus. Diabetic retinopathy is a growing cause of vision loss in Kenya, yet this vision loss can be delayed or prevented if Diabetic retinopathy is detected and treated early.

The aim of these guidelines is to provide evidence-based, clinical guidance for screening and management of diabetic retinopathy. The foundations of the guidelines are based on evidence taken from literature and published clinical trials as well as current standard practice. The scope of the guidelines is largely on management of diabetic retinopathy, although screening for DR also enables identification of other components of diabetic eye disease. These guidelines are prepared primarily for eye care and diabetes care providers. They are however relevant to other healthcare professionals in primary, secondary and tertiary health care levels.

The guidelines are advisory and are not intended as a set of rigid rules, since patients require tailored treatment for their particular extent of disease, comorbidities and personal circumstances. However, it is anticipated that adherence to the guidelines will be beneficial and will lead to a uniformly high standard of care for patients with diabetic retinopathy.

A lot of effort has been put in the development of these guidelines. I therefore urge all the stakeholders to utilize them in order to improve the clinical practice in screening and management of diabetic retinopathy in Kenya.

JULIUS KORIR., *CBS*
PRINCIPAL SECRETARY

PREFACE

The Ministry of Health and partners have developed these guidelines to provide guidance for ophthalmic and non-ophthalmic health care providers in the country. They are intended to improve the quality of eye care for patients with diabetes. In particular, the guidelines demonstrate the need for close linkage between diabetes services and ophthalmic services in primary, secondary and tertiary care.

Diabetes and diabetic retinopathy are linked in many public health aspects. They are rapidly increasing public health problems both in Kenya and worldwide, and their management begins in primary health care. They are chronic and initially asymptomatic conditions for which screening is a suitable intervention. They share modifiable risk factors, hence some of the prevention strategies are shared. In addition, everyone with diabetes is at risk of diabetic retinopathy and other diabetes related eye conditions.

I am glad to note that the guidelines encourage a collaborative approach between diabetes and eye care services, and a multidisciplinary team approach in the provision of care. Screening for diabetic retinopathy has in the past been a missing link in routine diabetes services, and these guidelines form an integral step towards realising comprehensive diabetes services and strengthening referral mechanisms between the two services.

The Division of Non-Communicable Diseases, the Ophthalmic Services Unit and other stakeholders need to work closely to make this a reality, and thus reduce the incidence of blindness from diabetes.

DR JACKSON KIOKO K., *OGW*
DIRECTOR OF MEDICAL SERVICES

ACKNOWLEDGEMENT

The development of these clinical practice guidelines for diabetic retinopathy has been possible through extensive consultation with relevant players in diabetes care. It also involved extensive literature search for local and global evidence of the problem and current best practice. The Ministry of Health acknowledges and expresses sincere gratitude to the Technical Working Group (TWG) (annexed) who worked hard to develop this document, taking into account our local context.

The efforts from the different technical units of the ministry including, the Division of Non-Communicable Diseases and the Ophthalmic Services Unit have been substantial and are well acknowledged. A number of people provided constructive input on several draft of the guidelines in their technical expertise such as nutrition, health promotion, pharmacy and others. This input effort is recognised as it ensured that the recommendations are appropriate, relevant and realistic.

We can never forget our patients and members of the public who accepted to give relevant data and input required to generate the evidence.

Special thanks goes to Dr Nyawira Mwangi, of the Kenya Medical Training College (KMTC), who took the lead, and ensured that every step as stated in 'AGREE framework' are followed as per international standards.

We are most grateful to the overall guidance on the process provided by the department of standards, regulation and quality assurance to meet the required standards.

We acknowledge our partners, The Fred Hollows Foundation for mobilising the required financial resources through the Excellence in Ophthalmology and Vision Award (XOVA) grant, which financed the whole process of guidelines development. We also thank BAYER East Africa Ltd for facilitating and financing the printing of this document.

These clinical practice guidelines have been written in simple and understandable language. They will be made available widely for use at all levels of care to ensure a high quality of diabetes care and that no one goes blind from diabetic eye diseases.

Thank You,

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HEAD, OPHTHALMIC SERVICES UNIT

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NON-COMMUNICABLE DISEASES

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

Abbreviations and Acronyms

AGREE	Appraisal of Guidelines for Research and Evaluation
CPG	Clinical Practice Guidelines
DED	Diabetic Eye Disease
DM	Diabetes Mellitus
DME	Diabetic Macula Edema
DR	Diabetic Retinopathy
ETDRS	Early Treatment Diabetic Retinopathy Study
FFA	Fluorescein Angiography
HbA_{1c}	Glycated haemoglobin
HCW	Health Care Worker
HMIS	Health Management and Information System
ICO	International Council of Ophthalmology
IDF	International Diabetes Federation
ILM	Internal Limiting Membrane
IOP	Intra-Ocular Pressure
KNH	Kenyatta National Hospital
MoH	Ministry of Health
NCD	Non-Communicable Diseases
NPDR	Non-Proliferative Diabetic Retinopathy
OCT	Optical Coherence Tomography

OSU	Ophthalmic Services Unit
PGEAC	Practice Guidelines Evaluation and Adaptation Cycle
PDR	Proliferative Diabetic Retinopathy
PLWD	Persons Living With Diabetes
QA	Quality Assurance
RAAB	Rapid Assessment of Avoidable Blindness
RAAB+DR	Rapid Assessment of Avoidable Blindness, which includes a DR component
RAS	Renin Angiotensin System
ToT	Training of Trainers
VEGF	Vascular Endothelial Growth Factor
VTDR	Vision Threatening Diabetic Retinopathy
WDF	World Diabetes Federation
WHO	World Health Organization

Executive Summary

Diabetic Retinopathy is a major complication of diabetes, where damage to the retina is provoked by micro-vascular damage to retinal vessels. If untreated, diabetic retinopathy leads to progressive vision loss and may eventually blindness. Diabetes also increases a person's risk for other eye complications, including cataract and glaucoma, all of which are referred to as diabetic eye disease (DED). The risk of DED is proportional to the duration of diabetes and persistently high levels of blood glucose.

A global concern

As the global prevalence of diabetes continues to increase, so does the number of people with diabetic retinopathy. According to the International Diabetes Federation (IDF) 2015 estimates, 415 million people are living with diabetes worldwide(1). Approximately one third of these have, or will develop, some form of diabetes-related retinopathy. More than 93 million people suffer some form of diabetes-related eye damage, making diabetic retinopathy the leading cause of new blindness in 25- to 74-year-olds globally. Of the one in 10 adults with diabetes globally, three quarters are living in low- and middle-income countries, where healthcare resources are already severely challenged.

In terms of the burden of dependence associated with this epidemic, the potential loss of earning capacity, the need for greater social support, the personal and social costs of severe visual impairment threaten to overwhelm health and social care systems. Diabetes and DED can destabilise economies worldwide and impede sustainable development. In addition to placing a large financial burden on individuals and their families due to the cost of insulin and other essential medicines, substantial economic implications arise from increased use of health services, loss of productivity and the long-term support needed for people with visual loss.

Kenyan Situation

The International Diabetes Federation estimates the prevalence of diabetes in Kenya in 2015 to be 2-5%(1), and over 50% of cases are undiagnosed. The country is experiencing a rise in diabetes owing to demographic, nutritional and social changes such as urbanization. As the prevalence rises, patients face an even greater threat from the long-term complications, including eye complications. Owing to poor glycaemic control, majority of the patients end up at the tertiary facilities for treatment of end organ damage.

The Kenya STEPwise survey for non-communicable diseases risk factors in 2015 found that 88% of Kenyans aged 18-69 years had never had a blood sugar measurement in their lifetime (2). The survey found the prevalence of diabetes to be 2%. Only 40% of those known to have diabetes were on treatment for diabetes.

One in every three people with diabetics develop diabetic retinopathy. A study in Kenya found a prevalence of 35.9% (26).

Reducing the risks

The risk of vision loss in people with diabetes is up to 25 times greater than in people who do not have diabetes. People with diabetes whose disease is poorly controlled are more likely to develop all systemic complications, including retinopathy. It is imperative that the prevention, early detection and treatment of diabetic eye disease be integrated into comprehensive diabetes management to reduce the risk of blindness. The main interventions are good metabolic control and regular eye examination.

Good long-term diabetes management is essential to prevent or delay the progression of eye complications. The recommendations that focus on the prevention of the modifiable risk factors for diabetic eye disease are: effective individual support for adoption of healthy diet, reduce body weight, increase physical activity, cessation of smoking, use of medication as required to optimise glycaemic control. Improved serum lipid and blood pressure control can also slow the progression of retinopathy, especially when initiated soon after the diagnosis of diabetes. Supportive group care sessions have been shown to improve health behaviour, quality of life, and blood glucose levels. Psychosocial support and family involvement help to empower patients for self-management, thus these are also recommended.

Early diagnosis and timely treatment

Loss of vision from diabetic retinopathy can be prevented or minimised through better control of blood sugar, early diagnosis and treatment of retinopathy. Periodic retinal examinations (even when there are no symptoms) are therefore a key to preventing diabetes related vision loss. This examination is done through a dilated pupil or through retinal photography to detect sight-threatening retinal changes. It is recommended that all people with diabetes should have a retinal examination at diagnosis of diabetes or soon after, and then annually or as recommended by the eye doctor.

The decision to commence treatment should be discussed between the person with diabetes and the health professional, as this enhances compliance, adherence and achievement of treatment goals. The treatment options include laser photocoagulation, intravitreal Injections of anti-Vascular Endothelial Growth Factor (anti-VEGF) or steroids, vitrectomy/membrane peeling or a combination of these treatments.

Implications for policy

Reducing the burden of disease from DR will require the development of strong screening programs, with strong health information systems, referral mechanisms, and education of patients and care providers. People with diabetes

should have access to regular biochemical tests (fasting blood sugar, HbA_{1c}, lipid profile, urine micro-albumin), blood pressure and eye examinations.

Implications for research

Health services and systems research will be required to provide evidence on various aspects of epidemiology, prevention and management of diabetic eye disease, particularly access to care, quality of care and financing for screening programs in Kenya. We have limited data from population-based studies on the distribution of diabetes and diabetic eye disease in different regions of the country.

Scope, Context and Rationale

Clinical practice guidelines ('guidelines') are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances(3). The **clinical practice guidelines for Diabetic retinopathy (DR)** address the spectrum of clinical care for diabetic retinopathy (prevention, screening, diagnosis, referral, treatment and follow-up). The guidelines will apply to all persons living with diabetes (PLWD) who are seen at any level of the health care system (without exclusion), for they are all at risk of diabetic retinopathy.

These guidelines have been developed for use by health care workers at all levels of the health care system, and in both medical clinics and eye clinics. *They should also be used by:* policy makers to inform policy decisions for health services, by educators for supporting training and by health care managers to guide resource allocation for service delivery.

The need to develop the guidelines has arisen from the growing dual public health problem of diabetes and diabetic retinopathy in Kenya. These national guidelines have been developed using existing international guidelines for the management of DR, particularly the International Council of Ophthalmology (ICO) guidelines(4) for diabetic eye care (updated 2016). Care has also been taken to ensure harmonization with other guidelines such as the International Diabetes Federation diabetes eye health guidelines(5) and Kenya national strategy for prevention and control of Non-Communicable diseases (NCDs) (6). The guidelines are consistent with research evidence from recognized studies on DR interventions.

The anticipated outcome of the use of the guidelines is improved quality of care for diabetic retinopathy through early detection and timely treatment. This outcome will be monitored using process and outcome indicators that are specified in this document. Enabling factors for this outcome include the priority accorded to Non-Communicable diseases in the country, the existence of a coherent eye care system and the presence of public-private partnerships for eye health in various counties. Potential barriers to this outcome include logistical challenges

in dissemination of guidelines, and low utilization of guidelines by health workers (7), which will be mitigated against by active advocacy, stakeholder involvement, training of target users and patient empowerment. The guidelines will be reviewed within 5 years.

Methodology for guideline development

These clinical practice guidelines have been developed through a consultative step-by-step process involving multiple stakeholders and coordinated by a steering group. The guidelines have been adapted from existing international evidence-based clinical guidelines using the overlapping ADAPTE and PGEAC methodologies and toolkits (8-11), as well as the guidelines of the World Health Organization (12). The guidelines were identified through a literature search on various databases. The methodological quality of the guidelines was assessed in accordance to the AGREE II instrument (13). Fig 1 shows the steps that have been followed in this process that has taken several years.

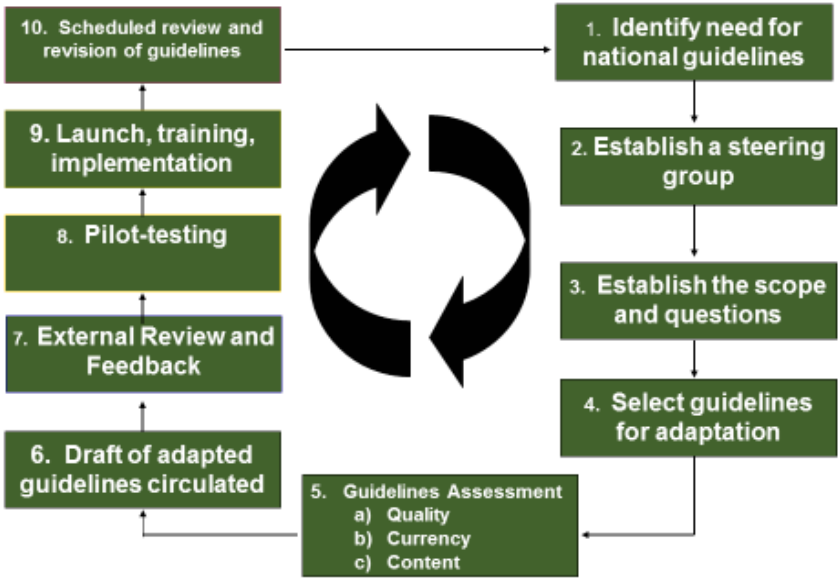

Figure 1: Steps followed in development of national DR guidelines

The three main areas of focus regarding screening and management of DR were identified as patient education; provider and practice performance; resources and infrastructure. Table 1 shows the **P**opulation, **I**ntervention, **P**rofession, **O**utcomes and **H**ealth Care setting (PIPOH) of interest for the DR services in Kenya while Table 2 summarizes the principles that guided the guidelines development.

Table 1: PIPOH summary for Kenya DR clinical practice guidelines

PIPOH Parameter	Description
Population of interest	All patients' with diabetes mellitus who are aged ≥ 12 years
Intervention	Screening, diagnosis and management of diabetic retinopathy
Profession (target users)	Primary care workers, diabetes care providers, eye care workers, administrators, policy-makers
Outcome of interest	All persons living with diabetes are screened for DR at least annually and blindness from DR is prevented
Health care setting	Primary, Secondary and Tertiary level health care settings

Table 2: Guiding principles for development of DR guidelines

Guiding Principles
1. **Respect for evidence-based principles in the development of guidelines** 2. **Ensure the quality of guidelines is high** 3. **Participation of key stakeholders to foster acceptance and ownership of the adapted guideline and ultimately promote its use** 4. **Consideration of context during adaptation to ensure relevance for local practice and policy** 5. **Transparency to promote confidence in the process** 6. **Flexible format to accommodate specific needs and circumstances** 7. **Respect for and acknowledgement of guideline materials used as sources**

Introduction to diabetes and diabetic eye disease

Globally the number of people that develop and live with is increasing every year. In 2015, 415 million people worldwide were living with diabetes, which is equivalent to one in 10 adults. Three quarters of these people live in low- and middle-income countries. If the current trend continues, by the year 2040 one in 10 adults (642 million people) will be living with diabetes(1). About 12% of the global health expenditure is on diabetes and its complications. In Kenya the International Diabetes Federation (IDF) estimates the prevalence of diabetes in 2015 to be 2-5%(1). The Kenya National STEPwise survey on non-communicable diseases 2015 found the prevalence to be 2% for the age group 18-69 years(2).

The dramatic increases in the prevalence of diabetes and the growing problem of diabetic eye disease, particularly diabetic retinopathy (DR) are intrinsically linked, and threaten to overwhelm health systems worldwide. Everyone with diabetes is at risk of developing eye disease. The risk of vision loss in people with diabetes is up to 25 times greater than in people who do not have diabetes(14). Approximately one-third of people with diabetes have diabetes-related eye disease, and the risk increases with the duration of diabetes(15). DR is currently the leading cause of vision loss in working age adults. It is predicted to become one of the leading causes of blindness globally within the next 20 years(1).

DR has a negative impact on the quality of life. People with severe vision loss require additional health resources and endure reduced levels of physical, emotional and social well-being(16, 17). Although diabetes is a complex and lifelong disease, adequate and appropriate education, self-management, psychosocial support, metabolic control, regular eye screening and timely treatment can slow the progression of sight-threatening retinopathy. Persons with diabetes should undergo a comprehensive eye examination at diagnosis of diabetes or soon after diagnosis together with any other ophthalmological investigations recommended by the eye doctor.

The management of diabetes and diabetic eye disease requires integrated health systems and supportive policies. The aim of these guidelines is to provide guidance to incorporate the prevention, screening and treatment of DR into clinical diabetes management in primary, secondary and tertiary care settings. It highlights the importance of multidisciplinary support and integrated co-operative care among health disciplines, and of the central role of people with diabetes in managing their disease (Fig 2). There is need for effective communication and professional interaction between these different and related health care disciplines involved in the management of diabetes.

The patient should be taken as an active and central participant in their own care and not just a recipient. Adequate and appropriate education and support for self-management, together with regular eye screening and timely treatment are central to slow down the progression of sight-threatening retinopathy. Increased *physical activity*, *healthy diet*, and improved *patient understanding of the relationship between food and blood glucose levels* can enhance metabolic control.

At primary health care level, all persons with diabetes should receive appropriate assessment of diabetes, health education, counselling and treatment to achieve metabolic control of blood glucose, blood pressure and cholesterol. They should have blood glucose tests and eye examinations, with at least one retinal examination annually, or more frequently if recommended by the eye specialist. **Recommendation:** Health workers in primary care should raise awareness on diabetic retinopathy, and support people with diabetes to access eye health examinations. They should also be referred for ophthalmic evaluations by an eye care worker at secondary level at least once a year or as recommended by the eye care worker.

At the secondary and tertiary health care level, screening for diabetic retinopathy should be carried out through a dilated pupil using a direct or indirect ophthalmoscope, or other instruments that the eye care worker has at his/her disposal, such as slit-lamp biomicroscopy or retinal photography. Pupil dilatation is not necessary where a non-mydriatic fundus camera is available for fundus photography. Pupil dilation may however improve the sensitivity and image quality, especially when the ocular media is not clear due to cataract.

The use of the fundus camera is not complicated and its operators do not require advanced training. The process of fundus photography is quick and non-invasive, hence patients would find it preferable. The images can be read and graded locally by the ophthalmologist or sent electronically to a facility for reading using appropriate software. The grading identifies the persons who already have diabetic retinopathy that require interventions to prevent loss of vision. These patients need to be referred for treatment of DR, which is often at the tertiary level. **Recommendation:** There is need to develop strong links between existing diabetes services and eye care services at primary, secondary and tertiary levels. If the facility has the requisite skilled workforce, equipment and drugs, intravitreal injections and laser treatment should be offered to patients that require the treatment.

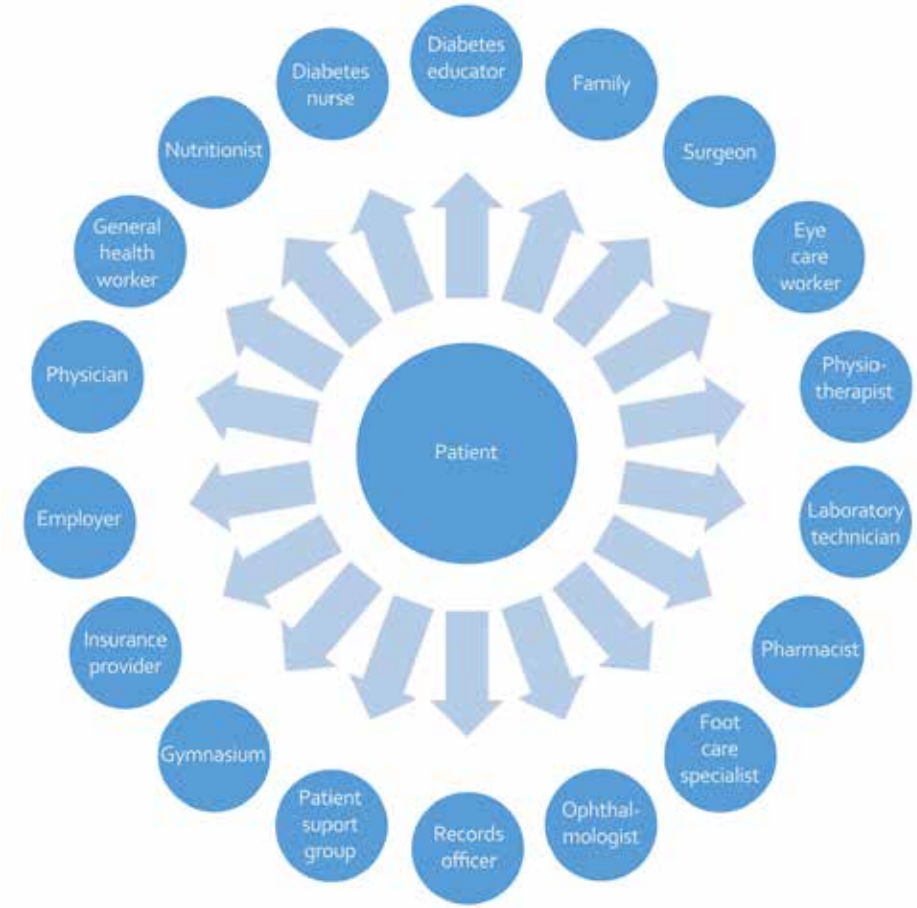

Figure 2: The relationship between the patient and other people who are important in diabetes care to prevent diabetic retinopathy

Diabetic eye disease is a common complication of uncontrolled diabetes. Good management of diabetes is essential to prevent or delay the onset of diabetic eye diseases, particularly DR. These complications can be prevented by good control of blood glucose levels, as well as good control of blood pressure and cholesterol levels. Education of diabetic patient is very important to enable them manage their condition. Access to diabetic education, necessary medicines (insulin and oral glucose lowering agents and anti-hypertensives, lipid lowering agents), regular blood glucose monitoring and exercise are very important.
Recommendation: People with diabetes should ensure they have optimal sugar, BP and cholesterol control in addition to at least once annual eye / retinal examination.

Communication with patients

The main focus should be on optimising glycaemic control by adopting a healthy diet, physical activity, self-monitoring, and adherence to treatment. Achieving and maintaining behaviour change can be difficult, especially in low-resource settings. The most effective interventions have been found to be those that include information in the language of the patient, provide information on consequences and involve individualised setting of specific goals (18). **Recommendation:** Verbal and written information should be provided to patients. Patient education materials such as posters, leaflets and flyers on DR should be available.

Peer support

Peer-to-peer group care sessions have been demonstrated to improve healthy behaviour and quality of life while lowering HbA_{1c} and fasting glucose levels (19). **Recommendation:** Patients should be encouraged to participate in diabetes patient support groups.

Family support

Adding a family-based psychological component to care may help to improve diabetes management, especially for people with poorly controlled diabetes. For example, involving the family in meal planning can improve self-management of the diabetic patient (20). **Recommendation:** Diabetes support and education for families should be provided.

Lifestyle changes

Healthy eating and an improved understanding of the relationship between food and blood glucose levels can lead to improved metabolic control in people with diabetes. Weight loss in obese patients and increased physical activity as well as cessation of smoking and consumption of alcohol are other important life style measures (21, 22). **Recommendations:** All patients should receive regular, individualised support for self-management. This includes a healthy diet, increased physical activity and weight reduction for the obese. All smokers should be encouraged to quit smoking.

Glycaemic control

Overall improved glycaemic control can slow the progression of DR, especially when initiated soon after the diagnosis of diabetes. Good glycaemic control early in the course of diabetes has an important impact on long-term outcome of retinopathy. However good glycaemic control is beneficial at any stage of DR (21, 23). PLWD should have regular monitoring of fasting and post-pradial blood sugar, HbA_{1c}, lipid profile and urine micro-albumin. **Recommendation:** Encourage regular monitoring of blood sugar at home. Aim for a target blood

glycosylated haemoglobin (HbA_{1c}) of < 7%. A comprehensive biochemical profile should be done at least annually (fasting lipids profile, HbA_{1c}, urine for microalbuminuria and other tests).

Control of blood pressure

Hypertension in diabetes is associated with development of diabetic retinopathy. Blood pressure monitoring and control are thus important. Appropriate management of hypertension combined with lifestyle change and glycaemic control will slow the progression of DR. Recommendation: Encourage regular monitoring of blood pressure in a health care setting and at home if possible. Target blood pressure of 140/90 mmHg. Drugs blocking the renin-angiotensin system (RAS) may have additional benefits, particularly for mild retinopathy, but should be discontinued during pregnancy.

Control of lipidaemia

Lipid-lowering has been shown to reduce the risk of progression of diabetic retinopathy, particularly macula oedema and exudation. **Recommendation:** Serum fasting lipids profile should be assessed at diagnosis and annually. Consider statins in primary and secondary prevention of DR but discontinue statins in pregnancy.

Pregnancy

Progression of retinopathy is a significant but relatively low risk in pregnancy. A retinal assessment before, during and after pregnancy is therefore particularly helpful in patients' known to have retinopathy. **Recommendations:** Patients should be assessed for diabetic retinopathy before pregnancy, at least once every trimester of pregnancy, as well as within 6 months after delivery or more frequently if recommended by the eye specialist. Statins and angiotensin inhibitors should be discontinued in patients who are planning for pregnancy.

Early screening and regular check-ups

Although diabetic retinopathy can permanently damage the retina and lead to blindness, it is possible to prevent further loss of vision with a timely diagnosis of the early stages of non-proliferative DR. Periodic eye examinations are therefore essential for the prevention of DR-related vision loss. Adherence to this recommendation can be improved by: informing people with diabetes that eye screening is important even if their vision is not impaired, placing reminders on a calendar or medical record, and acknowledging fear of blindness (24). **Recommendation:** Annual dilated eye examination of all patients with diabetes, starting at the time of diagnosis of diabetes mellitus, unless the eye specialist recommends different frequency. A service charter for diabetes clinics and eye clinics should be available to inform patients of the minimum care they should expect and to highlight the importance of yearly risk assessment such as eye

screening. Eye examination for type 1 DM should be at diagnosis and then after five years, and yearly thereafter.

Timely treatment

Timely treatment can prevent vision loss in many people with diabetic retinopathy. The decision to undergo treatment should be made in cooperation between the person with diabetes and the health professional. When discussing treatment with the patient, health professionals should explain: the costs and benefits of treatment, what to expect during and after treatment, the importance of continued follow up examinations after treatment.

Strengthening services using evidence

There is need to collect, analyse and use local data to improve diabetes and diabetic retinopathy services. **Recommendation:** Data will be systematically collected in both diabetes clinics and eye clinics. The Ophthalmic Services Unit will coordinate the use of this data to inform decisions on service improvement strategies.

Screening for diabetic retinopathy

What is screening?

Screening is a population-based approach to reduce risk from a particular condition within an identified population. Its purpose is to identify asymptomatic disease, or risk factors for disease, and to subsequently provide an effective treatment, which will lead to beneficial patient outcomes. Screening helps to reduce population risk for blinding DR too. Both Diabetes and Diabetic Retinopathy meet the Wilson and Jungner (1968) criteria for screening.

Why is screening for DR necessary?

The prevalence of DR among patients attending Kenyatta National Hospital (KNH) diabetes clinic was 31.9% in 2011 (25).A population based study in Nakuru also found the prevalence of any DR to be 35.9% in 2014.(26). This prevalence has progressively increased from 22.6% at KNH diabetes clinic in a study done in 2007 (27). Systematic screening for DR among people with diabetes is therefore warranted. Active screening for DR identifies patients who require treatment in order to prevent or delay diabetes-related loss of vision.

Who should screen for DR?

The screening examination for DR should be performed by trained personnel (health care worker, eye care workers or technicians) and *should consist of a minimum of:*

1. A retinal examination appropriate for DR will include direct or indirect ophthalmoscopy, slit lamp bio-microscopic examination of the retina or retinal photography.
2. Visual acuity test using distant and near charts. If the visual acuity is reduced, then pin hole test is also performed.

The practice of using ophthalmologists or retinal specialists to screen every person with diabetes is an inefficient use of resources, even if sufficient ophthalmologists are available. Suitably trained mid-level eye care worker can perform ophthalmoscopy (funduscopy) and retinal photography for assessment of DR.(4) A non-ophthalmic technician can also be trained to do retinal photography. Training in screening for DR will be provided for health care workers in both diabetes clinics and eye clinics.

The screener should determine whether the retina is normal or abnormal. Patients who have retinopathy are then referred to an eye care worker who should then conduct a comprehensive examination and grade the retinopathy. Thus screening is not an ophthalmologist-dependent intervention.

Recommendation: All health workers have a role in ensuring patients undergo screening. All health workers should also document and collect data on screening activities, as the data is useful for planning and monitoring services. Physicians and ophthalmologists will be responsible for screening, training of health workers and data management. The liaison nurse in the diabetes clinic and eye clinic will forward the captured data to the designated records officer for reporting.

Training health workers to implement the DR guidelines

A manual for training will be provided. A regular program for training of trainers (ToT) and training of screeners will be implemented. Participants will be health workers working in diabetes clinics, outpatient clinics and eye clinics. Medical records officers and equipment technicians will also be trained. *They will be trained on:*

- How to carry out screening using the resources at the facility
- How to take verbal consent
- Distinguishing a normal/abnormal retinal
- Referral procedure: who, where, when and how to refer
- Data collection and data management
- Process indicators for the DR service

Referral pathway

Once a decision for referral or treatment has been made, it should be carried out as soon as possible. The nearest health facility offering DR services will be identified, and patients will be referred to reach the facility *on designated days when comprehensive eye examination can be conducted*. A mapping of the referral facilities in the country will have identified these days in advance, so that screeners are aware of them. *Ideally the referral eye centres: eye clinic and ophthalmologist should be staffed with:*

- 1 vitreoretinal surgeon per 8-10 million population
- 1 medical retina specialist at each level 5 facility (and 2 at Kenyatta National Hospital)
- 1 surgical retina specialist at each level 5 facility (and 2 at Kenyatta National Hospital)

How will clinical governance for DR services be carried out?

The Ophthalmologist and the physician / diabetologist will provide clinical governance as the team leads at health facility level. *The clinical governance team will also include:*

- Liaison diabetes nurse (from the diabetes clinic)
- Liaison ophthalmic nurse (from the eye clinic)
- Designated medical records officer
- Biomedical / equipment maintenance technician

The Ophthalmic Services Unit (OSU) will be responsible for clinical governance at national level.

What challenges may be experienced in screening for DR?

Cataract

Cataract is often encountered during screening for DR. Cataract causes haziness of the ocular media, and may also make it more difficult to identify DR, and DR progresses faster after cataract surgery, therefore the patient requires a more detailed evaluation.

Vitreous haemorrhage

Vitreous haemorrhage interferes with clarity of the ocular media, obstructing examination of the fundus. It may occur as a complication of Diabetic Retinopathy, and requires treatment.

Glaucoma

A screening program for DR is expected to pick up glaucoma. These patients require additional tests besides fundoscopy (including tonometry, and perimetry) and long-term medical/surgical treatment by an ophthalmologist. Intravitreal steroids should be avoided unless absolutely necessary in patients with glaucoma.

False positives

False positives for DR overload the health system. Clinical audit is required to monitor the frequency of false positives. Retraining of screeners will be necessary to correct this problem.

Recommendations:

1. Fundus photographers should be trained to identify cataract, other causes of media haziness and glaucoma on the images.
2. Patients who have these pathologies SHOULD be referred to an ophthalmologist.
3. Ultrasonography may be useful in assessing the posterior segment in the presence of cataract or vitreous haemorrhage.
4. Regular retraining in form of short courses (either online courses or standard contact courses) should be provided for screeners.

What are the methods available for screening for DR?

a. Check list

At each health care level, the health worker will use a checklist to identify whether the patient has had a retinal examination in the preceding 12 months. Any patient who has not had the retinal examination in the preceding 12 months will be referred to the nearest eye health specialist for a retinal examination (see appendix for checklist).

b. Clinical examination

A retinal examination using any of the methods described below will be used to screen for DR. The advantages and disadvantages of each method are stated. Verbal consent will be taken from the patients before the procedure. Screening should identify true positives (patients with DR). For this to be achieved, it is important to use the correct equipment, adhere to the standards of practice, make correct diagnosis and have a quality assurance mechanism. The guidelines for quality assurance are provided as an addendum to this document.

Refer to the ophthalmologist:

a. Any patient with ocular symptoms
b. Visual acuity worse than 6/12
c. Where retinal findings are unclear
d. Where the retinal examination cannot be done

Methods of retinal examination

Slit Lamp Biomicroscopy

- Used in routine clinical practice
- Pupils must be dilated for fundus examination
- Evaluation of the anterior and posterior segment with contact/non-contact lenses
  (+78 D or +90 D)

Direct Ophthalmoscopy

- Pupils must be dilated

Binocular indirect ophthalmoscopy

- Pupils must be dilated
- Large field of view
- Complementary to slit-lamp examination with lenses for peripheral retinal lesions

Mydriatic retinal photography (conventional fundus camera)

- Pupils must be dilated
- Permanent record
- High sensitivity
- Can be reported using telemedicine

Non-mydriatic retinal photography

- Recommended for screening
- Permanent record
- Dilated pupils may improve sensitivity and image quality (but the photo can be taken without dilating the pupils)
- Can be reported using telemedicine
- May be accompanied by optical coherence tomography scanning or fundus fluorescein angiography
- Can be used for personalised patient education, therefore the patient should be shown the photo by the photographer and given information on the changes noted, so as to encourage future attendance to retinal screening and good glycaemic control

Recommendation: Screening programs can utilise whatever screening method is available. Pupil dilation is recommended. Visual acuity should be assessed before pupil dilation. Ideally, the fundus camera should be located in the diabetes clinic.

How can the role of patients and patient education in screening be strengthened?

The health worker or eye care worker should:

- Discuss results and implications with the patient
- Encourage regular eye examination/screening
- Inform the patient that timely treatment for diabetic eye disease is most effective
- Provide education on the importance of controlling blood glucose, blood pressure and lipid levels (refer to appendix 4)
- Refer the patient for counselling, rehabilitation or to social services as appropriate
- Refer the patient to an ophthalmologist for further assessment and treatment as appropriate
- Encourage patients to ask the educator questions
- Advise patient to seek medical attention urgently if they notice any unusual eye symptoms e.g. changes in vision, cloudy vision or floaters

What is the evidence from Cochrane systematic reviews for interventions used to treat diabetic retinopathy?

Laser photocoagulation is beneficial in reducing the risk of severe visual loss and the risk of progression 12 months after treatment in patients with proliferative diabetic retinopathy compared to no treatment or deferred treatment. However most trials here are old and the quality of evidence is judged as low.(28)

There is very low or low quality evidence from randomized controlled trials that anti-VEGF injections are effective in patients with proliferative diabetic retinopathy but they prevent intraocular bleeding.(29)
There is high quality evidence that anti-VEGF injections are effective in preserving and improving vision in patients with diabetic macula oedema compared to grid laser.(30)

Intravitreal steroids delivered either by injection or implants may improve visual outcomes in patients with persistent or refractory diabetic macula oedema but it is unclear whether they are beneficial in other earlier stages.(31)

Diagnostic evaluation of patients at the eye clinic

Once the person with diabetes has been referred to an eye specialist, he or she should undergo a complete ophthalmic assessment. This should include taking medical history, assessing visual acuity, and identifying and grading DR or diabetic macula oedema (DME), as guided below. Assessment for glaucoma and cataract should be done using additional examination and investigations. The final diagnosis is to be made by the ophthalmologist.

Table 3: Components of a comprehensive ophthalmic assessment

Assessment	Content
Medical history	• Duration of diabetes • Systemic history (e.g., renal disease, systemic hypertension, hyperlipidaemia, pregnancy, heart disease, depression). **Co-morbidities are very common in diabetes.** • Ocular history or symptoms • Past glycaemic control, (haemoglobin A_{1c}), current blood sugar • Medications (insulin, oral hypoglycaemics, anti-hypertensives, and lipid-lowering drugs)
Initial Physical Exam	• Best corrected visual acuity (BCVA): a. For Distance b. For Near Vision. • Measurement of intraocular pressure (IOP) • Gonioscopy when indicated (e.g., when neovascularization of the iris is seen or in eyes with increased IOP) • Slit-lamp biomicroscopy with pupil dilatation, check anterior and posterior segments

Fundus Examination Assessment	Retinal photography and slit-lamp biomicroscopy through dilated pupils have high sensitivity in the hands of trained eye health professionals. Optical Coherence Tomography and Fluorescence Angiography may also be useful.

Table 4: Early Treatment Diabetic Retinopathy Study (ETDRS) classification of diabetic retinopathy: Non-proliferative Diabetic Retinopathy (Annex 4)

Non-proliferative Diabetic Retinopathy		
Category/ Description	**Management**	**Referral to Ophthalmologist**
No DR	Review in 12-24 months	Referral not required
Very mild NPDR ***(****Microaneurysms only)*	Review in 12-24 months	Referral not required
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	Review range 6–12 months, depending on severity of signs, stability, systemic factors, and patient's personal circumstances	Referral not required
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	Review in approximately 6 months *Note:* PDR in up to 26% and high-risk PDR in up to 8% within a year	Referral required

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	Review in 4 months *Note:* PDR in up to 50% and high-risk PDR in up to 15% within a year	Referral required
Very Severe NPDR *Two or more of the criteria for severe NPDR*	• Review in 2–3 months • High-risk PDR in up to 45% within a year • Panretinal photocoagulation • Intravitreal anti-vascular endothelial growth factor (anti-VEGF)	Referral required

Table 5: Early Treatment Diabetic Retinopathy Study (ETDRS) classification of diabetic retinopathy: Proliferative Diabetic Retinopathy (PDR) (Annex 4)

Proliferative Diabetic Retinopathy (PDR)		
Category/ Description	**Management**	**Referral to ophthalmologist**
Mild-Moderate PDR *New vessels on the disc (NVD) or new vessels elsewhere (NVE), but extent insufficient to meet the high-risk criteria*	Treatment considered according to severity of signs, stability, systemic factors, and patient's personal circumstances such as reliability of attendance for review. If not treated, review in up to 2 months • Panretinal photocoagulation • Intravitreal anti-vascular endothelial growth factor (anti-VEGF)	<1 month

High Risk PDR *New vessels on the disc (NVD) greater than ETDRS standard photograph 10A (about 1/3 disc area)* *Any NVD with vitreous haemorrhage* *NVE greater than ½ disc area with vitreous haemorrhage*	Treatment advised – Should be performed immediately when possible, and certainly same day if symptomatic presentation with good retinal view • Panretinal photocoagulation • Intravitreal anti-vascular endothelial growth factor (anti-VEGF)	<1 month
Advanced Diabetic Eye Disease • *Subhyaloid haemorrhage* • *Vitreous haemorrhage* • *Neovascularization of the iris (NVI)* • *Tractional retinal detachment* • *Neovascular Glaucoma*	• Panretinal photocoagulation • Anti-VEGF • Parsplana vitrectomy • Shunt surgery (For NVI with Neovascular glaucoma)	<1 month

Table 6: Early Treatment Diabetic Retinopathy Study (ETDRS) classification of diabetic retinopathy: Diabetic Maculopathy (Annex 4)

Diabetic Maculopathy (ETDRS)		
Category/ Description	**Management**	**Referral to ophthalmologist**
Non-Clinically Significant Macular Oedema	Observe	<3 months
Clinically Significant Macular Oedema *Retinal thickening within 500 µm of the centre of the macula and or exudates within 500 µm of the centre of the macula, if associated with retinal thickening; the thickening itself may be outside the 500 µm*	• Central laser • Diffuse oedema: Grid laser • Focal oedema: Focal laser • Micropulse laser • Parsplana vitrectomy (If associated with traction from a taut posterior hyaloid)	<1 month
Retinal thickening one disc area (1500 µm) or larger, any part of which is within one disc diameter of the centre of the macula	• Anti-VEGF • Intravitreal steroids	
Ischaemic Maculopathy • *Dull foveal reflex* • *Enlarged FAZ on FA*	No effective specific treatment	1 month

Table 7: International Council of Ophthalmology (ICO): Diabetic Maculopathy Classification. Re-examination and Referral Recommendations Based on Simplified Classification of Diabetic Retinopathy* and Diabetic Macular Edema for Low-/ Intermediate Resource Settings

Diabetic Maculopathy (ICO Classification)		
Category/ Description	**Management**	**Referral to ophthalmologist**
Non-centre involving	• Central laser • Diffuse oedema: Grid laser • Focal oedema: Focal laser • Micropulse laser • Parsplana vitrectomy (If associated with traction from a taut posterior hyaloid)	3 months
Centre involving	• Anti-VEGF • Intravitreal steroids • Micropulse laser • Parsplana vitrectomy (If associated with traction from a taut posterior hyaloid)	1 month
Diabetic macular ischaemia	No effective specific treatment	1 month

Follow up of patients after initial assessment
All patients will require follow up. The frequency of follow-up depends on the clinical findings.

Table 8: Follow-up schedule

Assessment Findings	Follow up schedule
No DR	*Repeat examination annually*
Mild or moderate non-proliferative DR	*Repeat examination annually*
Severe non-proliferative or proliferative DR	*Pan-retinal photocoagulation (see below)*
Diabetic macular oedema	*Central (Focal/grid/micropulse laser), intravitreal injections of anti-VEGF (see below)*

Treatment for diabetic retinopathy / macula oedema

What key studies have investigated the treatment options?

The evidence for optimal management for DR has been generated from large randomised clinical trials conducted between 1972 and 2014, and involving more than 5,000 people with diabetes, as summarised below.

Table 9: Summary of key studies on treatment options for DR

	Study	Findings / Recommendations
1	**Diabetes Control and Complications Trial (32)**	Intensive therapy with accurate glycaemic control was found to slow the progression of DR.
2	**Early Treatment Diabetic Retinopathy Study (33)**	Careful follow-up, timely laser treatment and vitrectomy when necessary was found to reduce the risk of blindness for people with proliferative DR.
3	**Diabetic Retinopathy Study (34)**	Laser (photocoagulation) treatment was found to be effective in reducing the risk of severe visual loss in people with advanced diabetic retinopathy.

4	**Diabetic Retinopathy Vitrectomy Study (35)**	Vitrectomy in people with vision loss from non-clearing vitreous haemorrhage and severe proliferative DR was found to increase the chance of restoring or maintaining good vision.

Treatment interventions

The final diagnosis and the type of treatment that a patient should receive: should be made by the ophthalmologist. There is evidence from Cochrane systematic reviews to support the use of laser photocoagulation in proliferative diabetic retinopathy(28), anti-VEGF injections in diabetic macula oedema(30), and intravitreal steroids in refractory diabetic macula oedema(31).

Laser or intravitreal injections can be administered by the ophthalmologist at secondary level, while surgical intervention will be provided by the vitreo-retinal surgeon at tertiary level. A treatment protocol or standard operating procedure for administering this treatment will be provided as an annex to these guidelines.

Intravitreal steroids

Table 10: Use of intravitreal steroids

Indication	Diabetic Macula oedema
Mechanism of Action	Reduces oedema, inhibits fibrin deposition, capillary dilation, leukocyte migration, capillary proliferation, fibroblast proliferation, deposition of collagen and inflammation
Procedure	• *Requirements:* Intravitreal steroids are administered in a sterile environment (theatre) by an ophthalmologist or other eye care provider in presence of an ophthalmologist. • *Drugs used:* Intravitreal Triamcinolone or Dexamethasone Intravitreal Implant. • *Procedure:* Pars plana intravitreal injection, 4 mm behind the limbus in the infero-temporal quadrant under topical anaesthesia using a sterile technique. • Following the intravitreal injection, patients should be monitored for elevation in intraocular pressure and for endophthalmitis within the first 2 weeks.
Possible Complications	• Development of cataract in phakic patients • Increases in intraocular pressure and glaucoma • Endophthalmitis • Retinal detachment
Contraindication	Ocular or peri-ocular infections, Glaucoma, steroid responders
Patient assessment should include	Blood glucose/Blood pressure
Follow Up	Regular monitoring with slit-lamp fundus examination, binocular indirect fundoscopy or optical coherence tomography

Intravitreal anti-VEGF

Table 11: Use of anti-VEGF

Indication	Diabetic Macula oedema
Mechanism of Action	Blocks the effect of vascular endothelial growth factor (VEGF) and slows vessel leakage
Procedure	• Injections are given 4 mm behind the limbus in the infero-temporal quadrant under topical anaesthesia using a sterile technique by an ophthalmologist or other eye care provider supervised by an ophthalmologist. • *Dose:* For Severe DME: Ranibizumab 0.5mg, Bevacizumab 1.25mg, or Aflibercept 2mg administered monthly for 3 months and then monitor. Response should be monitored monthly using clinical examination and OCT, which will also guide the need for further treatment. • For persistent retinal thickening and leaking points: consider laser treatment (if prior laser treatment not done) or intravitreal triamcinolone, especially in pseudophakic eyes. • If there is DME associated with PDR, consider combining with laser treatment.
Possible Complications	• Sub-Conjunctival haemorrhage • Raised intraocular pressures • Endophthalmitis • Retinal detachment
Contraindication	Ocular or peri-ocular infections, Traction retinal detachment or active fibro-vascular membranes

Patient assessment should include	Blood glucose / Blood pressure
Follow Up	Regular monitoring through clinical examination and optical coherence tomography (OCT)

Laser photocoagulation

Table 12: Laser treatments

	Laser photocoagulation
Indications	Proliferative DR (PDR) and some cases of severe non-proliferative DR (NPDR): *Pan-retinal laser treatment* Diabetic Macula oedema: *Focal/ grid treatment and newer laser delivery systems such as Micro pulse Laser have clinical utility in the treatment of selected cases of diabetic macula oedema*
Mechanism of Action	Ablates ischaemic retina and induces regression of the new vessels and therefore prevents or stops bleeding on the retina
Procedure	• Conducted by an ophthalmologist or equally trained eye care workers in presence of an ophthalmologist in an out-patient setting under topical anaesthesia (or retrobulbar or subtenon's anaesthesia), and dilated pupil. Laser beam is guided precisely using a slit lamp or indirect ophthalmoscope using special contact lenses loupes respectively. The procedure may also be done in theatre. • Treatment is administered in one or more sittings depending on the person's condition.
Possible Complications	Loss of peripheral vision/visual field loss, reduced night vision, foveal burn, choroidal neovascularization (CNV), subretinal fibrosis,epiretinal membranes. In view of these side effects, particularly with grid laser, the current recommendation is to use less intense laser delivery, and grid laser has limited indications.
Patient assessment should include	Blood glucose/Blood pressure

Follow Up	Multiple follow-up examinations, to timely identify any disease progression
Requirements	Lockable dark room, laser machine, lenses, protective goggles, stable power supply, training for service providers

Vitrectomy / Internal limiting membrane (ILM) peeling

Table 13: Surgical interventions for DR

Indication	• Severe vitreous haemorrhage of 1-3 months that does not clear spontaneously • Advanced active proliferative DR that persists despite laser treatment • Traction retinal detachment involving/threatening the macula • Combined traction-rhegmatogenous retinal detachment • Traction macular oedema or epiretinal membrane involving the macula
Mechanism of Action	Removal of the vitreous gel, fibrous proliferations. Enhanced oxygen circulation Concurrent laser treatment is also done intraoperatively
Procedure	Performed under local or general anaesthesia by a vitreo-retinal surgeon. Surgeon inserts instruments into the eye and removes vitreous gel, fibrous tissue; flattens retina and repairs retinal tears if any

Possible Complications	• Retinal breaks and detachment, Vitreous Haemorhage • High intraocular pressure • Cataract
Follow Up	1 week, 1 month, 3 months and every 6 months thereafter (or as recommended by attending surgeon),
Requirements	Theatre space, vitrectomy machine, surgical instruments (vitrectomy set), laser machine, tamponade agents (gas, silicone oil), consumables

Integrating diabetes service and eye care service

Blindness from DR is avoidable, but only if there is close collaboration between diabetes care givers and eye health professionals at each level of the health system (36). *This can be achieved by:*

- Ensuring patients with diabetes who present with diabetic retinopathy are also being appropriately monitored by a primary care or specialist diabetes physician
- Building links with local diabetes professionals to develop reliable referral pathways for patients from the diabetes clinic to the eye clinic
- Setting up a screening (fundus) camera in the diabetes clinics, so that it is easily accessed by the target population
- Organising joint training programs for diabetes and eye health workers
- Prioritising DR as a diabetes issue rather than principally an eye issue
- Empowering patients to demand for an eye examination from the care provider
- Encouraging all primary health care workers to recommend all patients to have an annual retinal check
- Increasing involvement in advocacy for patients with diabetes and diabetic retinopathy

Monitoring and Evaluation of the DR services

Diabetic Retinopathy is a growing cause of preventable blindness in Kenya.
The clinical practice guidelines (CPGs) adhere to the basic principles for the screening of a disease at population level, and will guide screening for patients with diabetes who are 12 years of age and older by health care workers (HCWs) at health facilities. The CPGs include provisions for referral of patients from frontline HCWs to eye care workers and specialists, and for comprehensive DR screening and management in the DR referral/treatment centres.
The Monitoring & Evaluation framework provides a systematic approach for the MoH to track the processes and quality of these services.

Monitoring of DR Screening Program

The monitoring process will track indicators based on routinely collected data, via the HMIS at various levels of the health care system, other institutional data systems and other MoH routine data tracking systems. The Ophthalmic Services Unit will coordinate the collection of data.

Process Indicators:

Table 14: Process Indicators

Facility:_____ **County:**_____ **Reporting Period/Month:**_____		
Process Indicators		**No.**
Screening (Diabetes Clinic)	Number of patients with DM (Diabetes Clinic)	
	Number of DM patients screened for diabetic retinopathy	
	Numbers of referral to the eye care specialist/ ophthalmologist	
Diagnosis of DR (Eye Clinic)	Number of patients with diabetic retinopathy	
	Number of patients with Vision threatening diabetic retinopathy(VTDR)	
Treatment of DR (Eye Clinic)	Number of people treated for DR with Intravitreal Injections	
	Number of people treated for DR with Laser	
	Number of people treated for DR with surgery	
Training of health workers in Eye and Diabetes Clinics)	Trainings on DM and DR	
	No. of Patients Group Trainings	
	No of HCWs trainings**	

***** Training of health workers in medical/diabetes clinic and eye clinics will be conducted jointly***

Outcome Indicators:

- No of people diagnosed with (Vision Threatening Diabetic Retinopathy (VTDR) in each quarter, monitored for trends over successive years
- Visual outcomes after treatment
- Incidence of blindness due to VTDR (Number of patients identified with VTDR who progress to blindness)

Evaluation of the DR Screening Program

Planned DR evaluation activities on annual basis or periodic basis (in case of RAAB+DR) will measure the delivery of the DR screening program against international standards.

Annual analysis of the HMIS data by the MoH will report on the following indicators:

- Number of DM patients(Diabetes Clinic)
- Number of DM patients screened for diabetic retinopathy.
- Number of patients with diabetic retinopathy
- Number of patients with Vision threatening diabetic retinopathy(VTDR)
- Number of people treated for DR (laser/intravitreal injections)
- Number of people treated with surgery(Vitrectomy) for DR

Periodic eye health RAAB surveys by the MoH and eye health partners, should include DR component (RAAB+DR), this will allow reporting on the following in persons aged 50 years and above:

- Prevalence of DM
- Prevalence of DR and diabetic eye diseases
- Prevalence of Vision Threatening Diabetic Retinopathy (VTDR)
- The proportion of people with known diabetes who have had a previous retinal examination
- Estimated proportion of people with known diabetes with adequate glycaemic control
- Prevalence of blindness due to VTDR (Number Identified with VTDR who proceeded to be blind)

Cost of implementing the DR guidelines

Patients' with diabetes require screening for DR at least annually over the entire life course. This has significant cost implications for the patient and also for the health system. A recent study by the Division of Non-Communicable Diseases has evaluated the cost of diabetes services to the patient, including DR services. However there is need to identify the cost at each level of the health system: community, primary health facilities, secondary health facilities, tertiary health facilities and rehabilitation services.

Community level: Cost would entail health promotion, and recommendation to go for screening. (Workforce and materials)

Primary health facilities: Administering a risk assessment tool/ questionnaire, and testing for blood sugar, and possibly refer (workforce, materials/papers/pens, and laboratory facilities)

Secondary health facilities: Reconfirming diagnosis of diabetes, and screening for diabetic retinopathy (as recommended in the guidelines) (workforce, materials/papers/pens, laboratory facilities, equipment). If treatment facilities are available at this level (intravitreal injection and/or laser where appropriate, add injectable drugs (Anti-Vascular Endothelial Growth Factor, VEGF).

Tertiary facilities: Would entail the above requirements plus the cost of endo-laser (the additional cost is the high skilled workforce, vitrectors and endo-laser).

Conclusion: The Ophthalmic Services Unit will endeavour to evaluate the costs, and the cost-effectiveness of the DR services, which will be included in the next revision.

Implementation of the Guidelines

The Ophthalmic Services Unit is responsible for implementation of the guidelines, which will be through:

a. Dissemination of outputs at the point of use: electronic and print copies of the guidelines, posters and checklists in diabetes and eye clinics
b. Seminars, conferences and other professional meetings
c. Training forums on use of guidelines
d. Support supervision
e. Other forums that the stakeholders and users may find appropriate

Revision of the guidelines

The revision is scheduled at 5 year intervals, and this will be guided by the Ophthalmic Services Unit and the Division of Non-Communicable Diseases.

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APPENDICES

Appendix 1: Checklist for screening for DR

Patient's name:.....

Date of birth:.....

Date of screening:.....

Duration of diabetes:.....

Have you ever had an examination of the back of the eye *(either a photograph was taken or drops were instilled into the eye before examination)?*

a. YES b. NO

How long ago was the last examination of the back of the eye?

a. < 12 months

b. ≥ 12 months

Where was the eye examination done? .....(facility)

Recommendation: Have an eye check: *as soon as possible / in the next ……months at _____ health facility*

Appendix 2: Key messages for patients

DID YOU KNOW THAT DIABETES AFFECTS THE EYES?

What can you do to prevent blindness?

1. Diabetes is characterized by high sugar levels in blood
2. High blood sugar destroys small blood vessels in the body including those at the back of the eyes, leading to a condition called diabetic retinopathy.
3. Damage to the eyes is slow, painless, and progressive and can finally leads to blindness.
4. The damage to the eyes needs to be detected early, before irreversible damage occurs.
5. An eye check by an eye specialist can detect damage to the eyes before symptoms develop. During the examination, the eye specialist will check vision, and instil an eye drop to assess the damage in the eye.
6. For treatment of diabetic retinopathy, the eye specialist may advise on sugar, blood pressure, and lipid control.
7. For treatment of diabetic retinopathy, the eye specialist may perform laser or administer injections in the eye or perform eye surgery.
8. All persons with diabetes should have their eyes checked once every year by an eye specialist, even before any symptoms or poor vision develops OR AS RECOMMENDED BY THE DOCTOR.
9. A child with diabetes should have their eyes checked annually from the age of 12 years, or more frequently if recommended by the specialist.
10. A pregnant mother with diabetes should undergo an eye check by an eye specialist at least once every trimester, and soon after delivery, or as frequently as recommended by the eye specialist.
11. If eyes are found to be normal at your eye check by an eye specialist, please continue with an eye check annually. If you notice any abnormality with your eyes, visit the eye specialist as soon as possible.

Appendix 3: Key messages for health workers

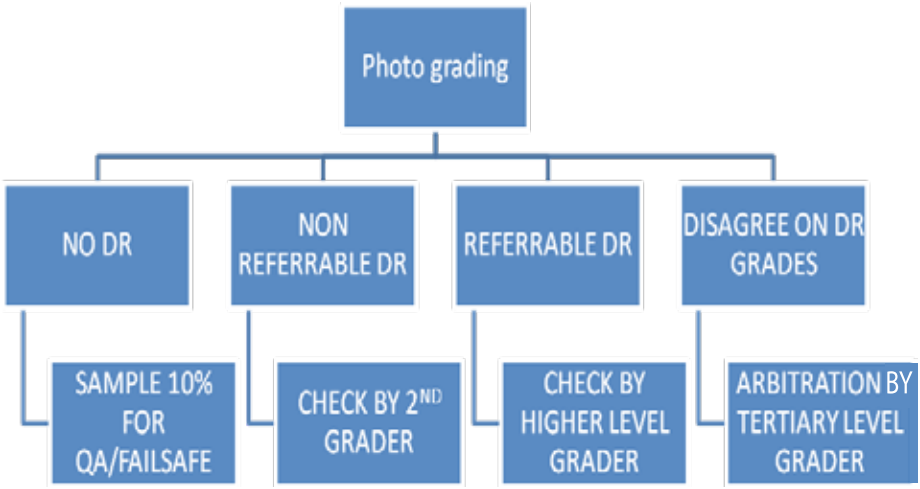
1 in 3 of patients' with diabetes has diabetic retinopathy. Act to save their vision today!

1. Send all NEWLY diagnosed patients with diabetes for a retinal examination.
2. Ensure ALL patients with diabetes have an annual retinal examination.
3. REFER any patient with diabetes who has poor vision or eye symptoms to an eye specialist URGENTLY.
4. DO NOT WAIT for visual loss to refer patients with diabetes to an eye specialist- '*prevention is better than cure'.*
5. Glycated haemoglobin (HbA_{1c}) is a good indicator for long-term sugar control and should be done at least annually for all patients. Glycaemic control prevents or delays diabetic retinopathy.
6. Assess for other end organ damage- Diabetic foot, neuropathy, renal and cardiac function at least annually.
7. Assess for hypertension, hyperlipidaemia and other co-morbidities as these may impact negatively on diabetes and diabetic retinopathy.
8. Send all pregnant patients with diabetes for a retinal examination at least each trimester and post-delivery, or more frequently if recommended by the eye specialist.

Appendix 4: Diabetic Retinopathy: Quality controls for photo grading, where retinal imaging is used for screening

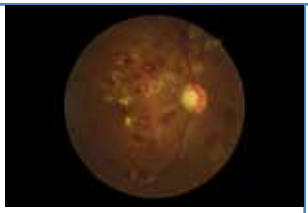
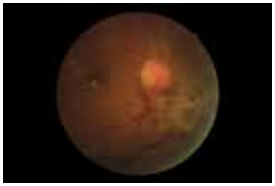
1. To Assure Quality of Fundus Photography the following are necessary:
   - Images are taken and reviewed by appropriately qualified staff
   - Skilled Staff have sufficient exposure and regular training
   - Dark room
   - Pupil Dilated (if possible)

2. To do this:
   - If no retinopathy is identified, in the images assessed by a primary grader, a sample 10% of these are checked again for QA and failsafe purposes.
   - If non referable retinopathy is present in the images seen by primary grader, they are also checked again by a secondary grader.
   - If referable retinopathy is present, images are checked and confirmed by a third higher level grader (tertiary grader, optometrist or ophthalmologist).
   - If there are any disagreements between grades by different graders, then images are reviewed by the tertiary level grader, which include Ophthalmologists specialised with medical retina subspecialist.

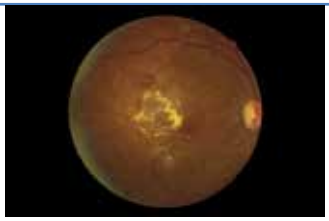
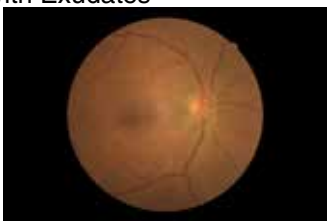


Appendix 5: Grading of Diabetic Retinopathy

Diabetic Retinopathy GRADE	TYPICAL IMAGE (A guide typical picture)	Findings observable on dilated ophthalmoscopy/ Fundus Photography
No apparent Diabetic Retinopathy		No abnormalities
Mild Non-proliferative Diabetic Retinopathy	 	Micro-aneurysms only
Moderate non-proliferative DR		1-3 quadrants of micro-aneurysims Not more than 1 quadrant of venous beading Cotton wool spots

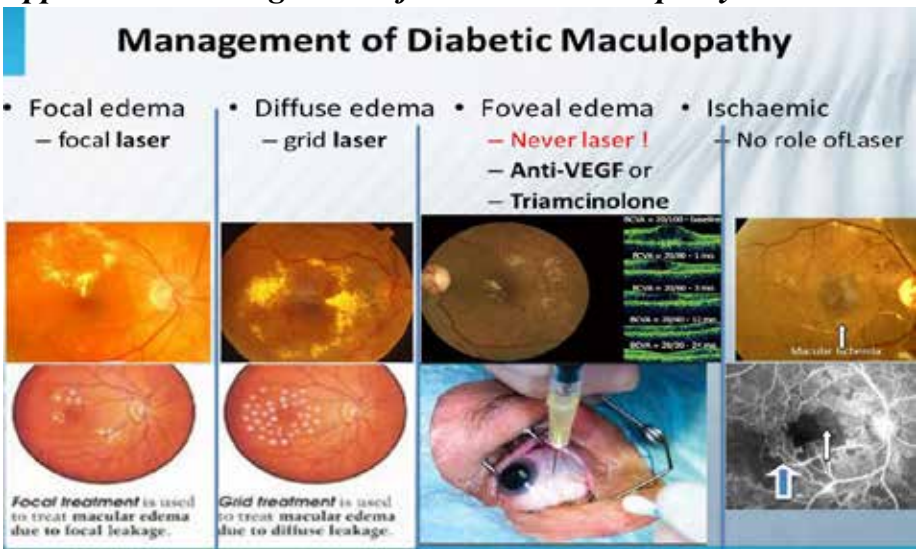
Severe non-proliferativ		*Any of the following:* • Intraretinal haemorrhages (≥20 in each (4)quadrant) • Definite venous beading (in two quadrants) • Intra-retinal microvascular abnormalities (in one quadrant) • No signs of proliferative DR
Proliferative DR	 	*Severe non-proliferative DR and one or more of the following:* • Neovascularisation (new vessels at the Disc NVD or else where NVE) • Vitreous/pre-retinal haemorrhage Neovascularisation Vitreous haemorrhage

Appendix 6: Grading of Diabetic Macular Edema

Diabetic Retinopathy	TYPICAL IMAGE (A guide typical picture)	Findings observable on dilated ophthalmoscopy*
DME absent		No retinal thickening or hard exudates in posterior pole
DME present		Retinal thickening or hard exudates in posterior pole
Mild DME		Retinal thickening or hard exudates in posterior pole but outside central subfield of the macula (diameter 1000 µm)
Moderate DME		Retinal thickening or hard exudates within the central subfield of the macula but not involving the centre point – also known as 'centre-threatening DME'
Severe DME	 With Exudates  Without Exudates	Retinal thickening or hard exudates involving the centre of the macula – also known as 'DME with centre involvement' or 'centre-involved DME'

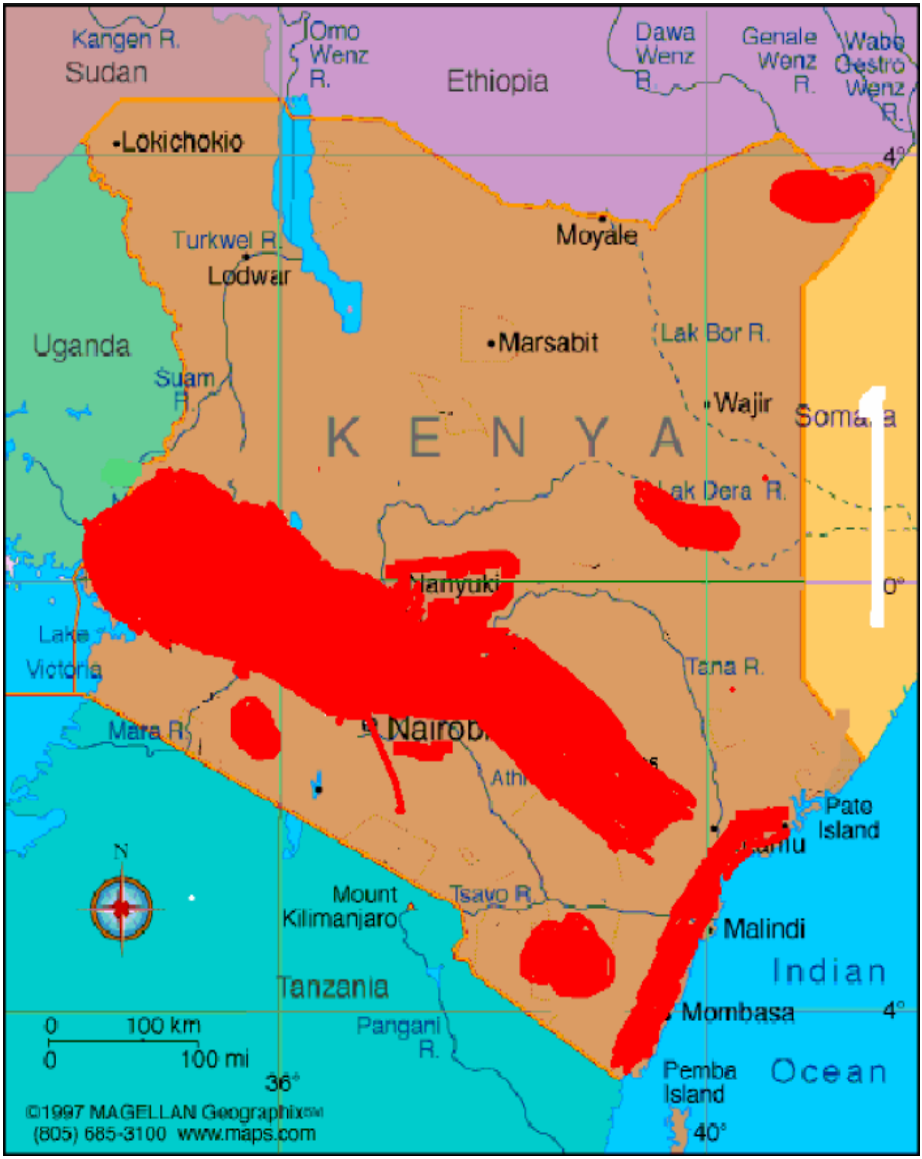
*Hard exudates are a sign of current or previous macular edema. DME is defined as retinal thickening; this requires a three-dimensional assessment that is best performed by a dilated examination using slit-lamp biomicroscopy and/or stereo fundus photography. Optical coherence tomography is the most sensitive method to identify the sites and severity of DME.

Appendix 7: Management of Diabetic Maculopathy



Appendix 8: Diabetes Map of Kenya

The Diabetes Map of Kenya



Source: *Diabetes Management & Information Centre Nairobi Kenya (DMI Centre)*

Appendix 9: Mapping of DR services in Kenya

	County	Referral centres	DR Services available			
			Dilated Eye Examination	Laser	Intravitreal injections	Vitrectomy
1.	Baringo	County Referral Hospital	■			
2.	Bomet	County referral hospital	■			
		Tenwek Mission Hospital	■	■	■	■
3.	Bungoma	County Referral Hospital	■			
4.	Busia	County Referral Hospital	■			
5.	Elgeyo-Marakwet	County Referral Hospital	■			
6.	Embu	County Referral Hospital	■			
7.	Garissa	County Referral Hospital	■			
8.	Homa Bay	County Referral Hospital	■			
9.	Isiolo	County Referral Hospital	■			
10.	Kajiado	County Referral Hospital	■			
11.	Kakamega	County Referral Hospital	■			
12.	Kericho	County Referral Hospital	■			
13.	Kiambu	County Referral Hospital	■			
		Thika Level 5 hospital	■			
		PCEA Kikuyu Eye Hospital	■	■	■	■
14.	Kilifi	County Referral Hospital	■			
15.	Kirinyaga	County Referral Hospital	■			
16.	Kisii	County Referral Hospital	■			
		Kisii Eye Institute (Innovation eye Centre)	■	■	■	
17.	Kisumu	County Referral Hospital	■			
		Jaramogi Oginga Odinga Teaching and Referral	■	■		
18.	Kitui	County Referral Hospital	■			
19.	Kwale	County Referral Hospital	■			
		Kwale Eye Centre	■			
20.	Laikipia	County Referral Hospital	■			
		Nyahururu Hospital	■			
21.	Lamu	County Referral Hospital	■			
22.	Machakos	County Referral Hospital	■	■		
23.	Makueni	County Referral Hospital	■			
24.	Mandera	County Referral Hospital	■			
25.	Marsabit	County Referral Hospital	■			
26.	Meru	County Referral Hospital	■			

		Maua Methodist Hospital				
27.	Migori	County Referral Hospital				
28.	Mombasa	County Referral Hospital				
29.	Muranga	County Referral Hospital				
		Kenneth Matiba Eye Centre				
30.	Nairobi	Kenyatta National Hospital				
		Mbagathi Hospital				
		Mama Lucy Hospital				
		City Eye Hospital/Upper Hill eye and Laser Centre				
		St Mary's Mission Hospital				
		Lions Eye Hospital-LORESHO				
		MP Shah Hospital				
		Agha khan Hospital				
31.	Nakuru	County Referral Hospital				
32.	Nandi	County Referral Hospital				
33.	Narok	County Referral Hospital				
34.	Nyamira	County Referral Hospital				
35.	Nyandarua	County Referral Hospital				
36.	Nyeri	County Referral Hospital				
		Tumutumu Mission Hospital				
		Mathari Mission Hospital				
37.	Samburu	County Referral Hospital				
38.	Siaya	County Referral Hospital				
39.	Taveta	County Referral Hospital				
40.	Tana River	County Referral Hospital				
41.	Tharaka Nthi	County Referral Hospital				
		Chogoria Hospital				
42.	Trans-Nzoia	County Referral Hospital				
43.	Turkana	County Referral Hospital				
44.	Uasin Gishu	County Referral Hospital-HURUMA				
		Moi Teaching and Referral Hospital				
45.	Vihiga	County Referral Hospital				
		Sabatia Eye Hospital				
46.	Wajir	County Referral Hospital				
47.	West Pokot	County Referral Hospital				

Appendix 10: Technical Working Group and Reviewers

	Name	Technical Competence	Affiliated Institution
1.	Ms Atieno Jalangó	Diabetic Educator	Kabarak University
2.	Prof Jefitha Karimurio	Public Eye Health Specialist	University of Nairobi
3.	Dr Joseph Nyamori	Vitreo Retinal Surgeon	University of Nairobi
4.	Mr James Ngigi	Special Procedures	Kenyatta National Hospital
5.	Dr Kibata Githeko	Vitreo Retinal Surgeon	City Eye Hospital
6.	Dr Lena Matata	Public Health Specialist	Fred Hollows Foundation
7.	Dr Michael Gichangi	Public Eye Health Specialist	Ministry of Health/Head, Ophthalmic Services Unit
8.	Dr Muchai Gachago	Vitreo Retinal Surgeon	University of Nairobi
9.	Dr Nyawira Mwangi	Eye Health System/Public Eye Health Specialist	Kenya Medical Training College
10.	Dr Patrick Nyaga	Vitreo Retinal Surgeon	Kenyatta National Hospital
11.	Dr Nancy N. Ngugi	Diabetologist	Kenyatta National Hospital
12.	Dr Stephen Gichuhi	Ophthalmologist/ Epidemiologist	University of Nairobi
13.	Dr Monicah Bitok	Ophthalmologist/Clinical Auditor	Head, Quality Assurance Ophthalmic Services Unit
14.	Mr George Ohito	Cataract Surgeon/Senior Clinician	St Marys Hospital Nairobi
15.	Alain Nazaire MBongo Zindamoyen	Vitreo Retinal surgeon	PCEA Kikuyu Hospital

Other Reviewers

16.	Dr Njeri Mucheru	Pharmacist	Pharmacy Services Unit
17.	Dr Annah W.Wamae	Paediatrician	Head: Division of Clinical Practice, MoH
18.	Dr Susan A. Nyawande	Nutritionist and Researcher	Health Promotion Unit
19.	Dr Mukiri Mukuria	Ophthalmologist	University of Nairobi
20.	Mr Muriithi Nguuri	Diabetic eye field worker	City Eye Hospital
21.	Ms Lindsay Hampton (Hampejsková)	Research consultant	College of Ophthalmology of Eastern, Central and Southern Africa
22.	Sarah Gathu	Research Assistant	Fred Hollows Foundation

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