

Clinical guidelines for diabetic retinopathy in Kenya: an executive summary of the recommendations

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ABSTRACT

All persons living with Diabetes Mellitus (DM) have a lifetime risk of developing Diabetic Retinopathy (DR), a potentially blinding microvascular complication of DM. The risk increases with the duration of diabetes. The onset and progression of DR can be delayed through optimization of control of blood glucose, blood pressure and lipids. The risk of blindness from DR can be reduced through cost-effective interventions such as screening for DR and treatment of sight-threatening DR with laser photocoagulation and anti-VEGF medications.

Several factors make it important to provide guidance to clinicians who provide services for diabetes and diabetic retinopathy in Kenya. First, the magnitude of both DM and DR is expected to increase over the next decade. Secondly, as the retina is easily accessible for examination, the early signs of retinopathy may provide clinicians with the first evidence of microvascular damage from diabetes. This information can be used to guide subsequent management of both DM and DR. Thirdly, there are notable gaps in service delivery for the detection, treatment and follow-up of patients with DR, and the services are inequitable. Strengthening of service delivery will require close collaboration between diabetes services and eye care services.

Following a systematic and collaborative process of guideline development, the first published national guidelines for the management of diabetic retinopathy have been developed. The purpose of this paper is to highlight the recommendations in the guidelines, and to facilitate their adoption and implementation.

Key words: Clinical practice guidelines, Diabetic retinopathy, Kenya

INTRODUCTION

Diabetes Mellitus (DM) is a priority non-communicable disease that requires multidisciplinary care and continuity of care. Its prevalence and incidence is increasing in every country. According to the STEPwise survey¹ for risk factors of non-communicable diseases in 2015, DM affects an estimated 2% of the Kenyan population aged 18-69 years with the highest proportion (5%) being in the 45-59 years age group. Every patient with diabetes is at risk of potentially blinding ocular complications, particularly Diabetic Retinopathy (DR). In turn, visual loss from diabetic retinopathy is associated with additional morbidity, such as falls, fractures and difficulties with seeing and taking medications. Both DM and DR are silent diseases that patients may be unaware of until they

cause complications. Clinicians attending to patients with these conditions have a role to reduce the associated morbidity, disability and mortality.

Diabetic Retinopathy (DR) is the leading cause of blindness in diabetes, and for this reason it warrants specific attention. It is estimated that a third of the people with diabetes have diabetic retinopathy, and one third of the latter (or 10% of those with diabetes) have vision threatening DR². Early signs of retinopathy or maculopathy in a patient with diabetes, identified on retinal examination, may be the first evidence of generalised microvascular damage from poor control of diabetes. This information would be very useful in planning subsequent holistic management of the patient. There is therefore need to strengthen links between eye care services and diabetes services.

The risk factors for DR include both modifiable and non-modifiable factors. Epidemiologic studies have identified the non-modifiable risk factors to include increasing duration of diabetes and genetic factors^{2,3}. The leading modifiable risk factors include poor control of blood sugar, poor control of blood pressure and dyslipidaemia^{2,4-6}. Service providers need to pay attention to these factors, as well as to other lifestyle factors associated with diabetes in order to delay onset or progression of DR. These are interventions for primary prevention of blindness from DR.

Stronger service delivery for DR is required within the existing health system⁷⁻⁹. Currently there are notable gaps in the screening, diagnosis, referral, treatment and follow-up. Although screening for DR and laser treatment are cost-effective interventions for prevention of blindness from DR¹⁰, there are inequities in access to them. Some of the services are underutilised and of insufficient quality. DR guidelines and use of clinical guidelines is an important step towards ensuring that all people with diabetes have access to quality DR services.

The purpose of these clinical practice guidelines is to give guidance regarding screening and diagnosis of DR, management of diabetes as it pertains specifically to DR, and treatment of DR. These guidelines apply to all patients with type 1 or type 2 diabetes who are at least 12 years old, who receive care at the primary, secondary or tertiary level of the health system. They should be used by health workers providing diabetes services and eye care services, as well as by administrators and policy-makers who plan for the resources for these services.

METHODOLOGY FOR GUIDELINES DEVELOPMENT

The development of these guidelines was a systematic, widely consultative process guided by an expert technical group over a lengthy period and involving many stakeholders. The process was guided by the use of several toolkits and guidelines which include: ADAPTE toolkit¹¹, PGEAC framework¹², AGREE 11 instrument¹³ and WHO handbook for guidelines development¹⁴.

The guidelines were adapted from existing relevant standards and guidelines, particularly the American Diabetes Association standards for medical care in diabetes¹⁵ International Council of Ophthalmology guidelines for diabetic eye care¹⁶ Canadian Diabetes Association's retinopathy guidelines¹⁷ and the Royal College of Ophthalmologists' diabetic retinopathy guidelines¹⁸. The following guidelines were also reviewed, and the recommendations are in line with their provisions: Kenya national guidelines for management of diabetes¹⁹, Kenya national strategy for the prevention and control of non-communicable diseases²⁰, and International Diabetes Federation's diabetes eye health guide for health professionals²¹. The adaptation strategy

was chosen instead of de novo development in order to avoid duplication of effort, to use the available resources cost-effectively and to facilitate customization of the guidelines to reflect local context. These guidelines were identified through a literature search followed by application of the AGREE 11 instrument to evaluate the quality of the guidelines. Previous drafts of local DR guidelines were also reviewed. Care was taken to ensure that the guidelines are evidence-based, locally applicable, of high quality, and that the process of adaptation was consultative. The guidelines were subjected to external review by a multidisciplinary team as well as pilot-testing in various health facilities.

The process of guideline development is discussed in detail in a separate paper.

Key messages

1. Stronger service delivery is needed for People Living with Diabetes (PLWD) in Kenya in relation to DR. There is need to develop strong links between diabetes services and eye care services within the existing health system.
2. Blindness from DR is avoidable, but only if diabetes care givers and eye health professionals perform their roles in ensuring early detection and treatment of DR.
3. Screening is important for early detection of treatable diabetic retinopathy. It is also a cost-effective intervention for reducing blindness from DR. All patients with diabetes aged 12 years and above should have a retinal examination (usually a dilated eye examination or a retinal photograph) once a year or more frequently if recommended by the eye specialist.
4. Consistent and appropriate metabolic control reduces the onset and progression of sight-threatening diabetic retinopathy.
5. Laser photocoagulation therapy, local intraocular pharmacological therapy and surgery reduce the risk of significant visual loss.

Recommendations

Domain: Strengthening links between diabetes services and eye care services at primary, secondary and tertiary level of care

1. All health workers providing diabetes services should raise awareness of PLWD on diabetic retinopathy and support them to access eye examination (Panel 1).
2. The health worker attending to a PLWD at any health care level should use a checklist (Panel 2) to identify whether the patient has had a retinal examination in the preceding 12 months. Any patient who has not should be referred to the nearest facility for screening for DR.

3. 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:
 - a. A retinal examination appropriate for DR, which would include dilated direct or indirect ophthalmoscopy, slit lamp bio-microscopic examination of the retina or retinal photography
 - b. Visual acuity test using distant and near charts. If the visual acuity is reduced, then pin hole test is also performed.”
4. All PLWD require follow up, therefore service providers in both eye clinics and diabetes clinics should encourage compliance with follow-up.
5. A service charter for diabetes services and eye care services should be available in all clinics offering these services to inform PLWD of the minimum care they should expect and to highlight the importance of yearly comprehensive risk assessment including dilated eye examination.
6. The ophthalmologist and the physician/diabetologist/endocrinologist will provide clinical governance as the team leads for diabetes services and eye care services. The clinical governance team would also include: (a) liaison diabetes nurse (from the diabetes clinic), (b) liaison ophthalmic nurse (from the eye clinic), (c) designated medical records officer and (d) a biomedical / equipment maintenance technician.
7. The physician/diabetologist/endocrinologist and the ophthalmologist would be responsible for oversight on the screening for DR, training of health workers and data management.
8. The Ophthalmic Services Unit would be responsible for clinical governance for DR services at national level.
9. Data would be systematically collected in both diabetes clinics and eye clinics. The liaison nurse in the diabetic clinic and eye clinic would forward the captured data to the designated records officer for reporting.
10. The Ophthalmic Services Unit would coordinate the use of this data to inform decisions on service improvement strategies.

Panel 1: Key messages for health workers attending to PLWD

**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 baseline retinal examination.
2	Ensure all patients with diabetes have an annual retinal examination.
3	Refer any patient with diabetes who has poor vision 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 hemoglobin (HbA1c) is a good indicator for long-term sugar control and should be done at least annually for all patients. Good glycemic control prevents or delays diabetic retinopathy.
6	Assess for other end organ damage- oral examination, diabetic foot review, renal and cardiac function, tests for neuropathy at least annually
7	Assess for hypertension, hyperlipidemia 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.

Panel 2: Checklist for screening for DR

Patients 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

Domain: Eye examination for DR

Annual dilated and comprehensive eye examination is recommended for all patients with diabetes, aged 12 years and above, starting at the time of diagnosis of diabetes mellitus, unless the eye specialist recommends a different frequency. For type 1 diabetes, an eye exam should be done at diagnosis, at 5 years of diagnosis and annually thereafter.

Domain: Patient-centred care

1. Health workers should provide verbal and written information on diabetes, diabetic retinopathy, and on the health care that is needed, including self-management.
2. All PLWD should receive regular and individualised self-management support on healthy diet, appropriate physical activity and weight reduction if they are overweight. All smokers should be encouraged to quit smoking.
3. Patient education materials such as posters, leaflets, booklets and flyers on DR should be available (Panel 3) to patients and to peer support groups.
4. Diabetes support and structured self-management education should also be provided to family members of PLWD.
5. PLWD should be treated with dignity and involved in decision-making for their care. The results of their examination and the implications should be explained to them, and they should be encouraged to ask questions. The presence of co-morbidities should be taken into consideration in the care of each patient.

*Panel 3: Key messages for patients***DID YOU KNOW THAT DIABETES AFFECTS THE EYES?**

What can you do to prevent blindness?

1	Diabetes mellitus is marked by high sugar levels in blood. 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.
2	Damage to the eyes is slow, painless, gets worse with time and finally leads to blindness if not treated in good time.
3	The damage to the eyes needs to be detected early, before permanent damage occurs.
4	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. Both eyes need to be examined.
5	For prevention and treatment of diabetic retinopathy, the eye specialist may advise on sugar, blood pressure, and lipid control.
6	For treatment of diabetic retinopathy, the eye specialist may perform laser or administer injections in the eye or perform eye surgery.
7	All persons with diabetes should have their eyes checked once every year by an eye specialist, even before any symptoms or poor vision develop or as frequently as recommended by the eye specialist.

8	A child with diabetes should have the eyes checked annually from the age of 12 years, or more frequently if recommended by the specialist.
9	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.
10	If the 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.

Domain: Metabolic control

1. All PLWD should be asked about the level of control of glucose, blood pressure and lipids.
2. To prevent the onset and delay the progression of diabetic retinopathy, people with diabetes should be treated to achieve optimal control of blood glucose.
3. Regular monitoring of blood sugar at home should be encouraged.
4. Regular monitoring of blood pressure in a health care setting or at home should be encouraged. Target blood pressure is 140/90 mmHg. Drugs blocking the Renin-Angiotensin System (RAS) may have benefits, particularly for mild retinopathy, but should be discontinued during pregnancy.
5. A comprehensive biochemical profile (risk assessment) should be done at least annually, and include fasting lipid profile, HbA_{1c}, urine microalbumin among other tests.
6. Aim for a target glycosylated haemoglobin (HbA_{1c}) of <7%.
7. Serum fasting lipid profile should be assessed at diagnosis and annually. Consider statins in primary and secondary prevention of DR but discontinue statins in pregnancy.

Domain: Pregnancy

1. All female PLWD of reproductive age should be asked if they are pregnant.
2. 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.
3. Statins and angiotensin inhibitors should be discontinued in patients who are planning for pregnancy.
4. All women of child-bearing age who have diabetes should be educated that pregnancies should be planned.

Domain: Screening programs for DR

1. All PLWD should be screened for DR at least once a year, irrespective of whether they have ocular symptoms or not.
2. Screening programs can utilise whatever screening method is available (ophthalmoscopy, slit-lamp biomicroscopy and retinal photography), and should be conducted by a suitably trained person. Pupil dilation is recommended. Visual acuity should be assessed before pupil dilation.
3. Photography based screening
 - a. Where a fundus camera is available, ideally the fundus camera should be located in the diabetes clinic.
 - b. Fundus photographers should be trained to identify cataract, other causes of media haziness and glaucoma on the images. Patients who have these pathologies should be referred to an ophthalmologist. Ultrasonography may be useful in assessing the posterior segment in the presence of cataract or vitreous haemorrhage.
 - c. Regular retraining in form of short courses (either online courses or standard contact courses) should be provided for screeners.
4. The following patients should be referred to an ophthalmologist:
 - a. Where the screening examination is unsuccessful, or the results of the visual acuity test or retinal examination are unclear
 - b. Where the retinal examination is unsuccessful, for example due to additional pathologies
 - c. Any grade of retinopathy, except mild non-proliferative retinopathy
 - d. Visual acuity worse than 6/12 and all patients with ocular symptoms
5. 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 the guidelines.
6. 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. Health workers at each health facility will collect this data using standard monthly data collection forms. The Ophthalmic Services Unit in the Ministry of Health will coordinate the collection of data.

Domain: 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. Ophthalmic evaluation by an eye care worker is available at the secondary level of the health system. This should include taking medical history, assessing visual acuity, and identifying and grading DR or Diabetic Macula Oedema (DME), using standard procedures described in the guidelines.

Domain: Referral pathway

Once a decision for referral for evaluation or treatment has been made, it should be carried out as soon as possible. The nearest health facility offering DR services will be identified (mapping of services has been conducted, and this information is provided as an addendum to the guidelines), and patients will be referred to reach the facility on the designated days that the services can be provided.

Domain: Treatment interventions

The ophthalmologist will make the final diagnosis and the decision on the treatment that the patient should receive. There is evidence from Cochrane systematic reviews included in Panel 4 to support the use of laser photocoagulation in proliferative diabetic retinopathy²² anti-VEGF injections in diabetic macula oedema²³ and intravitreal steroids in refractory diabetic macula oedema²⁴. Laser or intravitreal injections can be administered by the ophthalmologist at secondary level. Surgical interventions for DR will be provided by the vitreo-retinal surgeon at tertiary level. Practical information on these procedures is provided in the guidelines.

Panel 4. 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 low²².

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 bleeding²⁵.

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 laser²³.

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 stages²⁴.

Domain: Follow up

All PLWD screened for DR will require follow up. The frequency of follow-up depends on the clinical findings, and the grading/severity of DR, as described in the guidelines.

Domain: Patients with low vision

Refer the patient with low vision (best corrected visual acuity of <6/18) for rehabilitation. PLWD who would benefit from counselling and social services should be referred as appropriate.

Domain: Monitoring DR services

Specific process and outcome indicators will be used to monitor services on a quarterly basis at each level of service delivery, using the hospital health management and information system. Health workers at each health facility will therefore collect this data using standard monthly data collection forms. The Ophthalmic Services Unit will coordinate the collection of data. The indicators of interest are listed in the guidelines.

CONCLUSIONS

Patients with diabetes require specific care relevant to diabetic retinopathy, which includes patient education, screening, referral, treatment and follow-up. These are the first published national clinical practice guidelines for the screening and management of diabetic retinopathy. Their goal is to ensure best practice throughout the whole pathway from primary care to tertiary care. Implementation of the guidelines has potential to reduce blindness from DR.

The Working Group welcomes feedback from all users of these guidelines. In particular, data on the enablers and challenges experienced in the use of the guidelines would be very useful in informing revisions on the guidelines. Please email feedback to the Ophthalmic Services Unit, Ministry of Health, through ophthalmicserviceske@gmail.com.

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