VISION 2020 LINKS

Diabetic Retinopathy Network
DR-NET

Toolkit

2021

INTERNATIONAL CENTRE FOR EYE HEALTH

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

THE QUEEN ELIZABETH DIAMOND JUBILEE TRUST

VISION 2020 THE RIGHT TO SIGHT

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Foreword

This document was first compiled by the VISION 2020 LINKS Team at the International Centre for Eye Health, London School of Hygiene & Tropical Medicine, for the DR-NET workshop of LINKS partners as part of the Commonwealth Eye Health Consortium programme funded by the Queen Elizabeth Diamond Jubilee Trust.

This edition has been reviewed and updated in 2021

Contributors included (alphabetically): Nick Astbury, Cova Bascaran, Mike Eckstein, Allen Foster, Zhara Gregory, Amanda Huang, Greer Iton, Denise Mabey, Geeta Menon, Tunde Peto, Heiko Philippin, Adeline Pinnock, Caroline Styles, Claire Walker, David Yorston, Marcia Zondervan

The document is a working draft which will be updated as required.

Glossary

BDR	Background diabetic retinopathy
CMO	Central macular oedema
CSMO	Clinically significant macular oedema
DM	Diabetes mellitus
DMO	Diabetic macular oedema
DR	Diabetic retinopathy
IOP	Intraocular pressure
iTAT	international Test and Training
LMIC	Lower Middle Income Country
MoH	Ministry of Health
NPDR	Non-Proliferative diabetic retinopathy
NPL	No perception of light
OCT	Optical coherence tomography
PDR	Proliferative diabetic retinopathy
PRP	Pan-retinal photocoagulation
VA	Visual acuity
VEGF	Vascular endothelial growth factor
VR	Vitreo-retinal
VTDR	Visually threatening diabetic retinopathy

1. Purpose

The purpose of this DR-NET Toolkit is to:

- assist participating countries and partners in developing a **National Framework** for the Management of Diabetic Retinopathy
- promote the development of **Good Practice Guidelines** for Diabetic Retinopathy
- provide **Guidance for Planning and the Implementation of** Diabetic Retinopathy services

Audience

The toolkit is primarily developed to assist:

- Eye Care Managers;
- Eye Health Professionals;
- Health workers managing patients with diabetes;
- Ministry of Health policy makers.

Content

The content includes sections on:

2. National Framework of Standards

Diabetes is becoming a more common condition worldwide.
It can affect anyone in any population.
Diabetes can have a major impact on the wellbeing of an individual.
It can lead to complications which reduce life span and increase morbidity.
There is evidence that:

- the onset of Type 2 diabetes can be prevented or delayed;
- good management increases life expectancy and reduces morbidity;
- patient knowledge and self-management are important in diabetes care.

The Standards for **Health Care** for people with Diabetes Mellitus are as follows:

Standard 1: **Prevention of Type 2 diabetes**	**1.** The Ministry of Health will promote strategies to reduce the risk of developing Type 2 diabetes in the population, including a healthy lifestyle, prevention of smoking and reduction in obesity.
Standard 2: **Identification of people with diabetes**	**2.** The Ministry of Health will develop and implement strategies to identify people with diabetes in the population who do not know they have diabetes.
Standard 3: **Empowering people with diabetes**	**3.** All children, young people and adults with diabetes will receive a service which encourages good knowledge of their health condition, good management of their diabetes, and promotes a healthy lifestyle.
Standard 4: **Clinical care of people with diabetes mellitus**	**4.** All children, young people, pregnant women and adults with diabetes will receive good quality care, including: • rapid and effective treatment of diabetic emergencies; • appropriate management during pregnancy; • support to optimise control of their blood glucose; • support to manage high blood pressure and other risk factors for developing the complications of diabetes.

The Standards for **Eye Health Care** for people with Diabetes Mellitus are:

Standard 5 **Examination of the retina**	**5.** The MoH will promote and develop services so that all people with diabetes will receive an eye examination of the retina at least every two years to check for diabetic retinopathy.
Standard 6 **Clinical care by an eye specialist for people with diabetic retinopathy**	**6.** The MoH will promote and develop services so that all people with high risk diabetic retinopathy will receive ongoing care from an eye specialist.
Standard 7 **Treatment for vision threatening diabetic retinopathy**	**7.** The MoH will promote and develop protocols / systems of care to ensure that all people who develop sight-threatening diabetic retinopathy receive appropriate and effective care to reduce their risk of visual loss.

3. Assessment of Need

In assessing:

- the number of people in a country with diabetes mellitus (DM), who need regular eye examination,
- the number with diabetic retinopathy (DR) at risk of visual loss, and
- the number with vision threatening diabetic retinopathy (VTDR) who require treatment to prevent visual loss from DR, the following information is required:

STEP 1 – calculate the number of people with Diabetes Mellitus (DM)
From population data (https://population.un.org/wpp/DataQuery/) find the total population (P) and the percentage aged over 20 years (A%)
From International Diabetes Federation data find the prevalence of diabetes in the population aged over 20 years (B%)
The number of people with diabetes (DM) is calculated from the formula:

$$DM = P \times \frac{A}{100} \times \frac{B}{100}$$

This is the number of people in the population who require an eye examination at least every two years and more frequently if they already have retinopathy.

STEP 2 - calculate the number of people in the population with Diabetic Retinopathy (DR) and Vision Threatening Diabetic Retinopathy (VTDR)
The proportion of people with diabetes with retinopathy is usually estimated to be **35%** of those with DM
Number of people in the population with diabetic retinopathy (DR) = $\frac{DM \times 35}{100}$

The proportion of people with diabetes with vision threatening diabetic retinopathy (VTDR) is usually estimated at **10%** of those with DM
Number of people in the population with VTDR = $\frac{DM \times 10}{100}$

STEP 3 - calculate the number of people per million population with Diabetes Mellitus (DM) and Vision Threatening Diabetic Retinopathy (VTDR)
Lastly, if the total number of people in the population with Diabetes Mellitus (DM), and with Vision Threatening Diabetic Retinopathy (VTDR), is divided by the population in millions, then
NUMBER PER MILLION POPULATION with diabetes who require an annual eye examination = DM/P (in millions)
NUMBER PER MILLION POPULATION with VTDR who require treatment to prevent visual loss and four-monthly screening = VTDR/P (in millions)

See country charts on next page

DR-NET: POPULATION ASSESSMENT OF DIABETIC RETINOPATHY

Country	Population	% pop aged 20+	Pop aged 20+	% with DM	Number with DM	% with DR	Number with DR	% with VTDR	Number with VTDR	Number with DM / m total pop	Number with VTDR /mill total pop
Botswana	2,350,000	57%	1,339,500	5.5	73,672	35%	25,785	10%	7,367	31,349	3,134
Ghana	31,070,000	53%	16,467,100	1.8	296,407	35%	103,742	10%	29,640	9,539	956
Kenya	53,770,000	50%	26,885,273	2.2	591,476	35%	207,016	10%	59,147	11,000	1,101
Malawi	9,130,000	46%	8,799,800	3.0	263,994	35%	97,398	10%	263,99	11,534	2,891
Nigeria	206,140,000	46%	94,824,400	3.0	2,844,720	35%	995,652	10%	284,472	8,412	1,380
Tanzania	9,730,000	46%	27,475,800	3.7	1,016,604	35%	355,811	10%	101,660	15,015	10,448 …
Uganda	45,740,000	43%	19,668,200	1.6	314,691	35%	110,141	10%	31,469	10,015	688
Zambia	18,380,000	44%	8,087,200	3.4	274,964	35%	96,237	10%	27,496	13,145	1,502
From above, African countries cited have a PREVALENCE of DM of about 10,000-20,000 people / million total pop											
From above, African countries cited have a PREVALENCE of VTDR of about 1,000-2,000 people / million total pop											
Fiji	896,440	63%	564,757	15.1	85,278	35%	29,847	10%	85,27	95,133	9,516
Vanuatu	307,140	52%	159,715	10.8	17,249	35%	6,037	10%	17,24	56,185	5,615
Solomon	686,880	50%	343,440	14.6	50,142	35%	17,549	10%	50,14	73,093	7,309
Jamaica	2,960,000	69%	2,042,400	11.7	238,960	35%	83,636	10%	238,90	80,729	8,070
From above, Pacific / Caribbean countries cited have a PREVALENCE of DM of about 70,000-90,000 people / million total pop											
From above, Pacific / Caribbean countries cited have a PREVALENCE of VTDR of about 7,000-9,000 people / million total pop											

4a. Screening patients with Diabetes for Retinopathy: Visual Acuity Measurement, Dilation and Retinal Examination

Pathway for screening people with diabetes for retinopathy.

1. Screening programmes must be accessible and affordable to ensure that all people with diabetes have equal opportunities to be screened.
2. A mechanism should be in place to identify people with diabetes and invite them for a regular retinal examination.
3. The minimum examination components to assure appropriate referral should include a visual acuity and retinal examination adequate for DR classification. Ideally this would be retinal imaging but can include direct or indirect ophthalmoscopy or slit lamp bio-microscopic examination of the retina.
4. There should be a written grading scheme and referral criteria based on the method of screening. The frequency of screening will depend on the presence of any DR or VTDR.
5. After screening ensure that a record including VA, retinal findings (where relevant) and outcome of screening are available for staff involved in diabetes care.
6. There must be an efficient referral mechanism to the eye department including a fast-track process for urgent referrals to ensure patients receive timely treatment. This should include pathways for non-diabetic eye disease such as cataract and glaucoma.
7. There should also be a mechanism to identify patients who do not attend and to follow them up, as this group is at risk of vision loss.
8. Administrative support for the screening / grading service is required to manage appointments, support audit and clinical governance.

Staff, Training and Service Development

1. 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 workers can perform ophthalmoscopy (fundoscopy) and retinal photography for assessment of DR. A non-ophthalmic technician can also be trained to perform retinal photography. Regular training and feedback for all screeners/graders is required to maintain expertise.
2. Training in screening for DR should be provided for health care workers in both diabetes clinics and eye clinics to improve screening uptake. Healthcare workers involved in screening should be able to provide people with diabetes, adequate and appropriate education and support for self-management, which together with regular eye screening and timely treatment, are central to slow down the progression of sight-threatening retinopathy.

3. To ensure quality assurance, audit of screeners' and graders' referrals and false positives is recommended. The hospital staff should be responsible for feedback to screeners/graders by providing regular communication.

Required Equipment

1. Visual acuity chart (at correct distance, in a suitable room)
2. Occluder
3. Mydriatic drops: Pupils must be dilated with Tropicamide 1.0% or Phenylephrine 2.5% if using direct, indirect or slit lamp biomicroscopy
4. Equipment for screening. Functioning slit lamps, ophthalmoscopes and fundus camera (NB maintenance contracts are extremely important)
5. Access to medical care records and patient contact details
6. Patient counselling information such as leaflets, eye models etc.
7. Suitable disinfectants for equipment and the retinal camera.

4b. Grading Retinal Images for Diabetic Retinopathy

Grading Classifications

Approximate equivalence of alternative classification systems for DR

Early Treatment DR Study	**UK National DR Screening Committee (based on retinal photography**	**Scottish DR Grading Scheme (based on retinal photography**	**American Academy of Ophthalmology (based on retinal examination)**
10 None	R0 none	R0 None	No apparent retinopathy
20 Microaneurysms only	R1 Background	R1 Mild background	Mild NPDR
35 Mild NPDR			Mod NPDR
43 Moderate NPDR	R2 Pre-proliferative	R2 Moderate BDR	
47 Moderately severe NPDR			
53A-D Severe NPDR		R3 Severe BDR	Severe NPDR
53E Very severe NPDR			

61 Mild PDR	R3 Proliferative diabetic retinopathy (PDR)	R4 PDR	PDR	
65 Moderate PDR				
71, 75 High risk PDR				
81, 85 Advanced PDR				

NPDR = non-proliferative diabetic retinopathy
BDR = background diabetic retinopathy
PDR = proliferative diabetic retinopathy

Practical grading and referral criteria

Diabetic retinopathy	Findings Observable on Dilated Ophthalmoscopy	Referral
No apparent retinopathy	No abnormalities	Review in 1 year
Mild non-proliferative	Microaneurysms only	Review in 1 year
Moderate non-proliferative diabetic retinopathy	More than just microaneurysms, but less than severe non-proliferative DR	Review in 1 year
Severe non-proliferative DR	Any of the following: • Intraretinal haemorrhages (≥20 in each quadrant) • Definite venous beading (in 2 quadrants) • Intraretinal microvascular abnormalities (in 1 quadrant) • and **no** signs of proliferative retinopathy	Refer to ophthalmologist
Proliferative DR	• Neovascularization • Vitreous/preretinal haemorrhage	Urgent referral to ophthalmologist

Chart adapted from ICO Guidelines for Diabetic Eye Care, 2017

Retinal images

1. All the retinal images of the patient must be available for grading.
2. The image manipulation tools which assist review are: red-free, zoom, contrast, brightness and drag.
3. Images should be assigned to patients, not just episodes, to ensure previous visits can be accessed.
4. The Grade should be stored with each image set to build up the patient file and track progression / regression of disease.
5. Feedback for photographers / screeners should be given, particularly if images are ungradable.

Pathway for grading retinal images of patients for retinopathy

1. A written protocol on how to do grading - including urgent referral pathway, how to deal with ungradable images etc. – should be available to all staff.
2. A pathway to identify and refer those patients needing urgent clinical attention must be in place.
3. There must be an efficient referral mechanism to the eye department designed to minimise gender, economic and literacy barriers to participation to ensure that routinely referred patients receive a timely appointment.
4. The retinal image database must be updated after each patient is screened.
5. A feedback report from the hospital eye services to the grading service is important to ensure each patient is followed up and evaluation takes place.

Staff, training and service development

1. A minimum workload should be set and monitored for each grader.
2. Regular training in grading for all graders are required to maintain expertise.
3. A monthly feedback meeting of all screening, grading, treatment staff are required to discuss referrals, outcome and any issues in the service.
4. The international Test and Training (iTAT) for DR grading provides a mechanism for quality assurance and continued professional development
5. All grading staff should be doing or aiming to do the International Certificate of Higher Education in Diabetic Retinopathy Screening. (see https://www.drscollege.org/UserFiles/File/Course)
6. Administrative support for the screening / grading service is required.

Required equipment

1. A personal computer or high-end laptop with grading-quality monitor is required and the screen used should be calibrated to a matching resolution
2. Access to medical care records and patients' contact details
3. A database containing all the patients previous and current retinal images
4. A room which can be darkened is required
5. A 'comments' function that can be accessed by other graders / clinical lead
6. A back-up facility to preserve the retinal image bank is important.

4c i. Laser Treatment for Proliferative Diabetic Retinopathy

Different types of laser

Most lasers in industrialised countries use green light, at approximately 510nm wavelength. This is absorbed in the outer retina and retinal pigment epithelium.

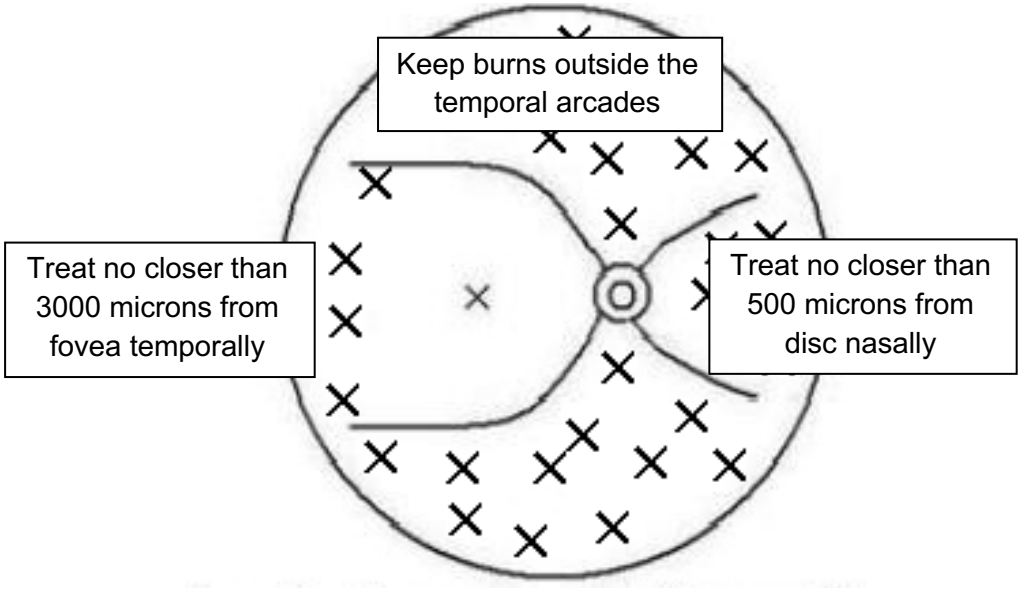
In LMICs, some clinics use a diode laser that produces infrared light at 810nm. This is absorbed in the retinal pigment epithelium and choroid. As the choroid is sensitive to pain, diode laser treatment is more uncomfortable for the patient, and a local anaesthetic block should be considered.

Before giving the laser treatment

1. Consider risk factors: is the blood glucose and blood pressure control optimum?
2. Document the corrected visual acuity.
3. Dilate the eye to be treated.
4. Obtain informed consent for pan-retinal photocoagulation (PRP)
   - Benefits: prevent visual loss
   - Risks:
     - reduced visual field which might affect driving regulations,
     - impaired night vision,
     - temporary visual reduction secondary to macular oedema,
     - failure of treatment.
5. Explain to the patient the importance of not looking at the laser beam during treatment.

Performing the laser treatment

1. Use topical anaesthesia and a contact lens.
   Alternatively, if you are going to treat the entire retina, it may be better to give sub-Tenon's local anaesthesia and if appropriate use an indirect laser.
2. Set the spot size to 200 microns (or 500 microns with three-mirror contact lens).
3. Set exposure time to 0.1 seconds (multispot laser 0.01-0.02s). Shorter duration can be less painful for the patient.
4. Increase the power until a mild white burn is visible.
5. Treat the inferior retina first, placing the burns one burn width apart, and continue until the entire lower half is treated.
   If you are confident the patient will return, wait 2-4 weeks before treating the superior retina. If the patient is unlikely to return, treat the entire retina in one sitting.


Keep burns outside the temporal arcades
Treat no closer than 3000 microns from fovea temporally
Treat no closer than 500 microns from disc nasally

4c ii. Laser Treatment for Diabetic Maculopathy

Macular laser treatment is for Clinically Significant Macular Oedema (CSMO). This is a clinical definition and does not require a fluorescein angiogram.
CSMO is defined as:

1. Hard exudates at or within 500μm of the fovea, if associated with thickening of the adjacent retina,
   or
2. Retinal thickening at or within 500μm of the fovea,
   or
3. Retinal thickening of one optic disc area or any larger which is within one disc diameter of the centre of the macula.

Before giving the laser treatment

1. Consider risk factors: is blood glucose and blood pressure control optimum?
2. Document the corrected visual acuity.
3. Dilate the eye to be treated.
4. Obtain informed consent detailing the potential benefits and risks as:
   - Benefits: prevent further visual loss (note that the vision rarely improves)
   - Risks:
     - failure of treatment,
     - re-treatment required,
     - loss of vision due to foveal burn,
     - paracentral scotomas which usually fade but may persist
5. Explain to the patient the importance of not looking at the laser beam during treatment.

Performing the laser treatment

1. Use topical anaesthesia and a contact lens.
2. Set the spot size at 50-100 micron. A small area of thickening close to fixation can be treated with 50-micron spot size.
3. Start at a low power (e.g. 70 milliwatts) and a short duration (e.g. 0.05 seconds). Increase the duration to 0.1s before increasing the power. Remember that the burn will get more intense in less oedematous areas and also closer to the fovea.
4. Directly treat microaneurysms in areas of retinal thickening. A mild grey burn should be evident beneath the microaneurysm.
5. Place burns two burn widths apart in areas of thickening not associated with microaneurysms.

Only treat areas of retinal thickening between 500 and 3000 microns from the fovea at the first session (see diagram on p15). Consider treating to within 300 microns of the fovea if initial session does not resolve oedema.

4c iii. Intra-Vitreal Therapy for Diabetic Macular Oedema (DMO)

Developments

Until recently, focal and focal/grid laser photocoagulation have been the mainstay of treatment for diabetic macular oedema (DMO) and the benchmark by which treatments were evaluated.

There is growing evidence that intra-vitreal VEGF inhibitors (with or without laser photocoagulation) provide a better visual outcome.

In many countries anti-VEGF injections are now considered standard therapy for eyes with centre-involving macular oedema and reduced vision.

Proposed Treatment Protocol

The general indication for treatment is recently reduced visual acuity with central macular oedema in a patient with diabetes.

A proposed treatment protocol for anti-VEGF treatment is as follows:

- Monthly injections for 4-6 months, followed by a phase of treatment as required (PRN) until the macula is dry or until there is no further improvement.
- 4-8 weekly follow-up of patients undergoing anti-VEGF treatment visual acuity assessment with examination of the macula, and if available, OCT scan to decide if re-treatment is required.
- In year two, if the patient is stable without treatment for several monthly assessments the frequency of follow-up appointments may be reduced gradually to 3-4 times / year.

Informed consent, benefits and risks of injection

Discuss the indications, risks, benefits and alternatives with patients.

Obtain informed consent.

The **RISKS** of intra-vitreal injections include:

- Pain
- Bleeding (sub-conjunctival, vitreous haemorrhage)
- Retinal tear / detachment
- Cataract (from inadvertently hitting the lens)
- Infection (endophthalmitis)
- Loss of vision (from any of above)
- Need for multiple injections in the future (patients need to understand this)

Medications

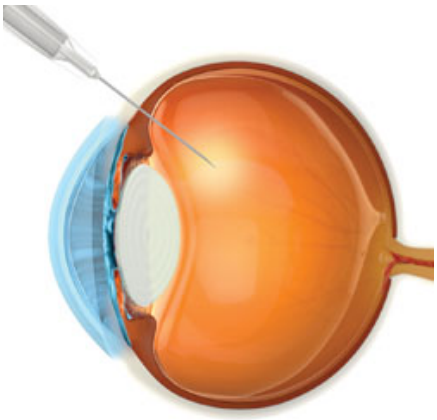
- Intravitreal Bevacizumab (Avastin) 1.25mg/0.05ml
- Intravitreal Ranibizumab (Lucentis) 0.5mg/0.05ml
- Intravitreal Aflibercept (Eylea) 2.0mg/0.05ml

Technique

Performing an intra-vitreal injection involves the following steps:

1. Establish an accurate diagnosis and develop a clear treatment plan.
2. Explain the diagnosis and treatment plan to the patient and obtain informed patient consent.
3. Place the patient in the supine position if possible.
4. Confirm the eye to be injected.
5. Apply topical proparacaine and wait at least 10 seconds.
6. Apply 5% povidone iodine to the conjunctival surface, eyelids, and lashes and leave for 60 seconds.
7. Apply drape, sterile lid speculum.
8. Have the patient look 180 degrees away from the injection site. For example, if injecting the right eye in the infero-temporal quadrant, ask the patient to look up and to the left.
9. Check the correct dose of medication is being given and make sure the needle tip (which is usually a short 27-30g) is always kept absolutely sterile.
10. Insert the needle at the marked site in a smooth and single motion, aiming for the mid-vitreous cavity. The injection is placed 3.5-4.0mm posterior to the limbus. Injection in the infero-temporal quadrant is common, although any quadrant may be used.
11. After the sclera is penetrated, the needle is advanced toward the centre of the globe and the solution is gently injected into the mid-vitreous cavity.
12. The needle is removed, and a sterile cotton swab is immediately placed over the injection site to prevent reflux.

Example video: https://www.youtube.com/watch?v=HRM9LaPnbUw



Immediate post-injection care:

1. Check and ensure there is good optic nerve perfusion i.e. the patient can see your hand moving. Central retinal artery occlusion is indicated by the absence of light perception. In this case, paracentesis is indicated in an attempt to restore central retinal artery perfusion immediately.
2. Reassure patients that they may see floaters which can be an air bubble, or medication.
3. Transient, mild elevations of IOP are common, although IOP usually drops below 30mmHg 15 to 20 minutes after injection.
4. Endophthalmitis is the most feared complication of intra-vitreal injection. All patients should be provided with information regarding the signs and symptoms of complications, such as eye pain or discomfort, redness, photophobia and diminished vision. Patients should be instructed to return immediately if these signs or symptoms develop.

Follow–up

At follow–up, determine the need for further therapy by measuring visual function and review the results of ocular imaging studies. Also check the status of the fellow eye.

4c iv. Vitreo-Retinal Surgery

Modern vitrectomy surgery can be a useful intervention in advanced diabetic retinopathy. It requires sub-specialty trained ophthalmologists and expensive equipment that needs to be maintained. It uses disposables such as gas and oil that have a limited shelf life. A unit needs to perform at least 250 cases a year (five/week) and should cover a population of about five million people to make it economically viable. Setting up a fully functional vitrectomy unit will cost at least US$200,000. Each vitrectomy case will cost between $400 and $1000 depending on the complexity and consumables required.

Generally the need for a vitrectomy for advanced diabetic retinopathy is a sign that other treatment has failed either because it was inadequate or more likely that patients did not attend for screening and treatment in a timely fashion. There are several indications for vitrectomy. The benefits, outcomes and risks of surgery differ significantly according to the indication. Vitrectomy should only be considered if the visual function after surgery is likely to be significantly better than not intervening.

Despite the complexity and cost, diabetic vitrectomy has an important role in a diabetic retinopathy programme, as these patients usually have severe disease in both eyes, and this surgery can prevent or cure blindness.

Indications

Vitreous haemorrhage: The outcome of vitrectomy for vitreous haemorrhage depends on the state of the underlying retina. In an eye with haemorrhage in the vitreous cavity but little other pathology apart from retinal neovascularization and no fibrovascular membranes, then vitrectomy and intra-operative laser is likely to improve the vision. This is a cost-effective treatment.

The timing of the surgery depends on what is happening to the underlying retina. If the retina has already had adequate pan-retinal laser and the retinopathy is regressing then waiting six months for the blood to clear is reasonable. However, if the retina has not had previous laser, or the retinopathy is still active, urgent surgical intervention within two months is necessary. An ultrasound B-Scan can be useful to help monitor the retina while waiting for surgery. In patients with poor vision in their other eye, earlier surgery should be considered.

Fibro-vascular membranes with retinal/macular traction: the surgery is complex, time-consuming and expensive. Outcomes are not as good as for simple vitreous haemorrhages and complications such as retinal detachment are not uncommon. Close follow-up is required, which may require inpatient facilities and multiple outpatient visits as well as multiple surgical procedures. Pre-operative intravitreal anti-VEGF may be required.

Assessment and Surgery

Patients need careful pre-operative assessment by the operating surgeon. Surgery can be done under local anaesthesia and as a day case if patients can safely return home. Once the vitrectomy is completed, patients are likely to need close follow-up and multiple clinic visits.

Training Requirements

A vitreo-retinal surgeon will require at least one year of specialist surgical training after completing basic ophthalmology training. Once trained, they are in demand and retention can be an issue.

4d. Patient Counselling

What is patient counselling?

Patient counselling offers the opportunity to elicit necessary information from your patient so as to offer correct advice, and guidance in their care.

It is a 'bottom up' approach where the health professional is the facilitator, and the patient needs are the primary focus. They give relevant advice and guidance on managing the health condition to optimise quality of life.

Who is it given to?

The patient living with diabetes or at high risk of diabetes, and / or the patient's immediate relatives or carers.

Who gives the counselling?

Health workers who have been trained in counselling patients with diabetes, as well as health workers with a knowledge of diabetes and diabetic retinopathy, who are caring for the patients.

When is counselling given?

- At first diagnosis.
- Any time the patient has questions.
- During or after a retinal screening episode
- When there is evidence of poor disease management or development of diabetic complications.
- Before, during or after treatment e.g., laser appointments
- Often counselling can be given by staff whilst performing other duties and speaking to the patients and their carers.

Why is counselling given?

Once diagnosed, diabetes requires life-long management; it therefore requires good patient compliance and good medical care.

There is evidence that good control of blood glucose, blood lipids and blood pressure is important in minimising the risk of developing complications of diabetes including visually threatening retinopathy.

Patient Counselling is a person-centred approach and includes the patient's needs when managing their health condition. Counselling provides an opportunity for the health professional to give individualised care and support

When facilitated by a health professional, patient counselling can:

- empower the patient to make better health choices
- dispel myths regarding their health condition
- acquires skills to manage their condition
- motivate them to attend future appointments
- build trust with their patients
- provide evidence-based strategies to help the patient succeed

How is formal counselling done?

It is important to be friendly, positive and encouraging. Nagging and creating fear should be avoided to prevent using a 'victim blaming' approach.

1. Explain who you are and the purpose of the meeting
2. Ask for consent to carry out a counselling session
3. Start discussion using a 'patient centered 'approach'

(A patient centred approach involves the patient in the decision making regarding their care.) As health professionals:

- Make the patient feel at ease
- Focus on the root problem/cause not just the diagnosis
- Be empathetic
- Use two-way communication at all times
- Use active listening skills
- Take into account their social and practical needs
- Provide realistic strategies that the patient can achieve
- Treat patients with dignity and respect
- Provide non-judgemental, unbiased advice and guidance
- Identify the patient's questions and needs - what do they already know?
- Give the patient chance to repeat back the information you have given
- Give the patient time and opportunity to ask questions.

4. Assist the patient to develop and reach SMART goal(s)
5. Signpost the patient to other agencies if needed
6. Assess the patient's capabilities and skills to achieve their goal
7. Use simple language and provide appropriate advice and information in easy-to-understand formats.
8. Let the patient lead conversations while you facilitate and guide those discussions

What are the key messages for patients?

Discuss these key messages using a 'patient-centred approach'.

Take your medication: Patients should be encouraged to take their medication. If they are not, we need to find out why and give advice.
Attend all your clinic appointments!
Stop smoking as smoking aggravates the blockage of small blood vessels caused by diabetes.
Take daily exercise which will help you lose weight, lower blood pressure, control blood sugar and lower blood lipid levels. 30 minutes walk per day is recommended, but anything is better than nothing.
Eat a healthy balanced diet by eating regular meals with plenty of fruit and vegetables. Eat less saturated fat, sugar and salt.
Blood pressure needs to be measured and treated if high. Salt can increase the blood pressure, therefore less than 1.5 teaspoons a day is recommended.
Monitor your blood glucose which should be between 4-7 mmol/L between meals, and no more than 10 mmol/L two hours after food.
Watch your weight as being overweight makes the diabetes worse. If you are overweight seek advice about an appropriate diet.
Type 1 people with diabetes need specialist advice on insulin dosage to manage their blood glucose levels.

4e. Community Health Promotion and Education

What is Health Promotion?

Providing relevant up-to-date information or resources a person needs to improve their health. It also involves improving people's skills and capabilities and changing the social and environmental conditions and systems that affect health and well-being.

Who are the Stakeholders?

- Policy makers, Programme Managers, Health Professionals
- Health authorities, health organisations, private health sector
- People with DM / DR, and their relatives and carers
- General population

What are the Roles / Responsibilities?

Policy makers

- Ensure that diabetic eye disease is included in the National Framework for Diabetes and integrated into the primary health programme.
- Include policies that addresses health inequity and health inequality for diabetic patients
- Ensure sufficient funding and resources are allocated.
- Ensure those resources cater for different communities

Programme Managers

- Be responsible for a training programme for health professionals
- Monitor availability and quality of health promotion /education
- Support the implementation of health education in the field
- Ensure vulnerable groups are included
- Take into consideration accessibility (knowledge of community and media)

Health Professionals

- Disseminate the health promotion message using a variety of media: social media, campaigns, counselling, policies, posters, peer education
- Build links with local diabetes professionals and other key stakeholders
- Build on or create patient groups
- Initiate peer-to-peer groups to improve health behaviour
- Set an example themselves
- Keep up to date with relevant training in public health promotion

People with DM / DR and their relatives and carers

- Take responsibility for their own health
- Take responsibility for self-management of their condition
- Manage their condition by taking appropriate education classes on diabetes and DR

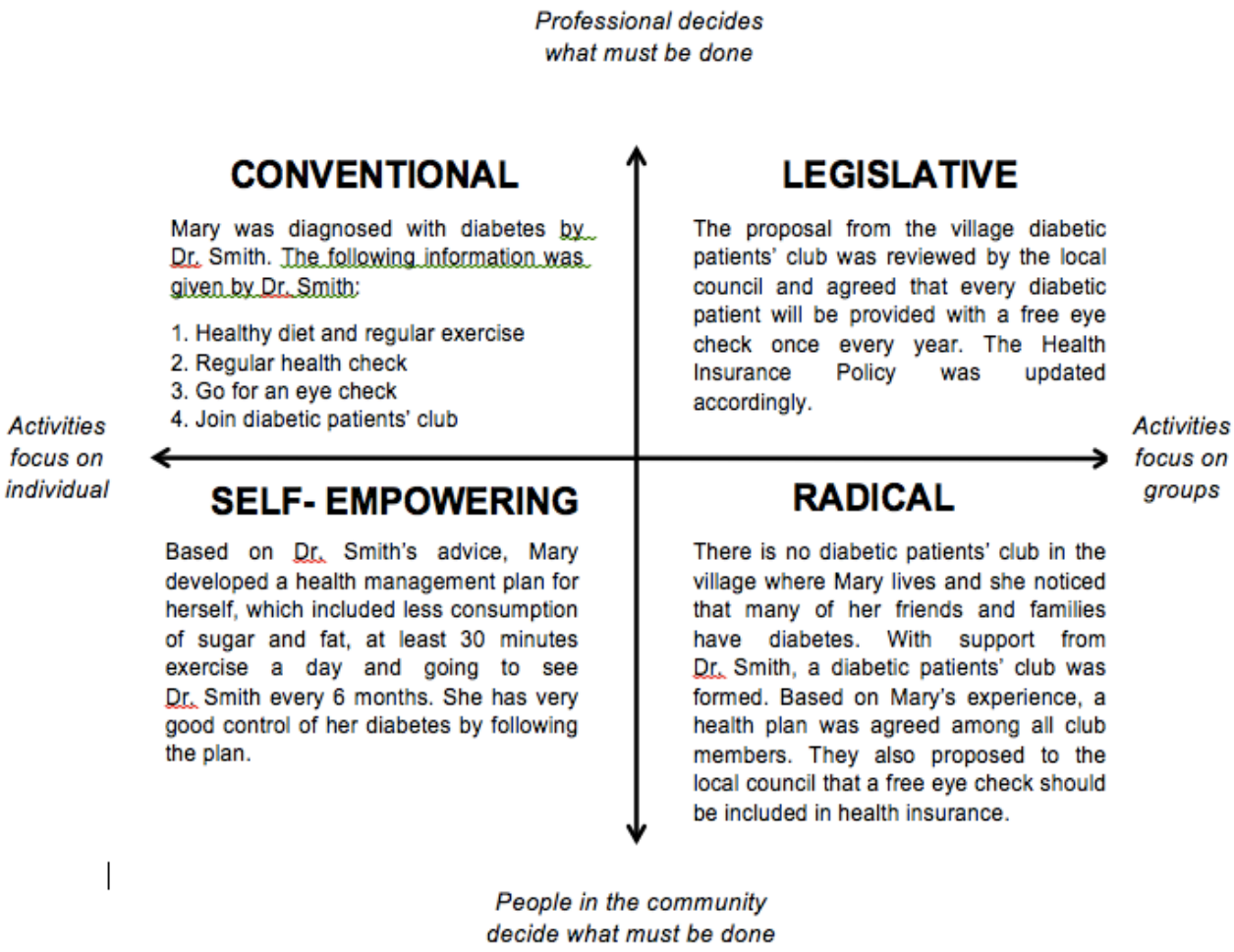
What the population needs to know about diabetes

What is Diabetes?	What are the consequences?	What is the impact on life?	How to reduce the risk?
• Raised blood sugar • Thirst • Weight loss • Fatigue • Frequency	• Heart attack • Stroke • Blindness • Kidney damage • Loss of toes / feet / leg	• Financial burden • Loss of income • Independence loss • Disability • Early death	• Regular health checks • Quit smoking • Regular exercise • Healthy diet • Control of blood pressure • Control of blood glucose

Example

An example of Health Education and Promotion based on Beattie's[1] Model. It shows the type of interventions that could be used to enable a patient to receive care, advice and support with regard to diabetes and DR.

Mary: a diabetic patient and Dr. Smith: an endocrinologist



The aim should be that **all quadrants** are factored in when delivering a health promotion strategy for a diabetes eye screening programme.

1. Beattie, A. (1991) Knowledge and control in health promotion: a test case for social policy and theory. In: Gabe, J., Calnan, M., Bury, M. (eds) The Sociology of the Health Service. London: Routledge/ Taylor and Francis.

5. Assessing Human Resources Required for DR

Tasks to be considered

- Counselling the patient with diabetes
- Examining the retina
- Grading the retina
- Deciding if treatment is required
- Performing treatment
- Post treatment assessment
- Regular recall and monitoring
- Database management

Workforce skills needed

Task	How?	Who?
Counselling the patient	Communicate information and answer questions about diabetes and diabetic retinopathy	Person trained in counselling diabetic patients
Examining the retina	Fundus camera	Trained technician
	Ophthalmoscope	Diabetologist and / or trained Eye Specialist
	Slit lamp microscope + lens	Trained Eye Specialist
Grading the retina	From digital retinal image using standard grading criteria	Technician or doctor trained in retinal image grading.
Deciding if treatment is required	Based on standard recommendations and clinical experience	Eye specialist with training and experience in treating DR
Performing treatment	Laser - PRP	Eye specialist with training and experience in treating DR. Injections may be given by non-doctors after training
	Laser - macular grid	
	Anti-VEGF injections	
	VR surgery	Eye specialist with VR training
Post-treatment assessment	Assess outcome of treatment	Eye specialist who is the person providing treatment
Database management	Set up and support screening database. Manage patient appointments.	IT technician Clerical officer

Numbers needing screening and treatment (see page 8 on assessing need).

Screening

In Africa for every 1 million total population an estimated 10,000 – 20,000 patients have DM and require screening every one-two years. Of these, an estimated 1,000 – 2,000 have visually-threatening retinopathy and require screening every four months.

If they are all diagnosed and identified for screening that is 220 - 440 people with diabetes per week per million population requiring examination.

The numbers in other parts of the world where diabetes is more common are likely to be several times higher.

Treatment

In Africa for every 1 million total population an estimated 1,000 – 2,000 patients need treatment.

If they all attend for treatment that is 20-40 new patients per week requiring treatment, but many require repeated treatments.

This is a prevalence figure, so once the backlog is managed the incidence of new cases will be lower.

The numbers in other parts of the world where diabetes is more common are likely to be several times higher.

How many people are needed to screen and treat / million pop?

The human resources required need to be sufficient for current demand for services, while planning for the future needs to consider an increase in demand as the service develops. See section on assessing need.

6. Equipment Required

Retinal image screening

1. Visual acuity chart (at correct distance, in a suitable room)
2. Occluder
3. Mydriatic drops: Tropicamide 1.0% or Phenylephrine 2.5% recommended.
4. Functioning fundus camera (with maintenance contract) + backup camera
5. Access to medical care records and patient contact details
6. Patient counselling information such as leaflets, eye models etc.
7. Suitable disinfectants for equipment and the camera

Retinal image grading

1. A personal computer or high-end laptop with grading quality monitor is required and the screen used should be calibrated to a matching resolution
2. Access to medical care records and patient contact details
3. A database containing all the patient's previous and current retinal images
4. A room which can be darkened is required
5. Comments function that can be accessed by other graders / clinical lead
6. A back-up facility to preserve the retinal image bank is important

Injections

1. A clean room, of similar standard to a room suitable for cataract surgery
2. Couch for patient to lie on, at a height comfortable for injector
3. Sterile drapes
4. Sterile gloves for injector
5. Topical anaesthetic and antiseptic
6. Lid speculum and measuring device for ensuring injection is 3.5-4mm behind limbus
7. Anti-VEGF drugs
8. 27g needles and 1ml syringe

Laser treatment

1. Topical anaesthesia
2. Suitable laser (see IAPB standard list)
3. Contact lens

Vitreo-retinal surgery

1. Capital costs
    - Operating Microscope $100,000
    - Indirect viewing system (e.g. Biom, Resight) $7,000-$10,000
    - Suitable Laser $20,000
    - Vitrectomy machine $60,000
    - Cryotherapy machine and probes $15,000

2. Consumables for each case
   - VR pack for each case (including light and cutter) $250

   Other equipment may be required depending on the complexity; e.g.
   - Silicone oil $90 per case
   - Perfluoron $80 per case
   - Sutures $12 per case
   - Dual blue dye $30 per case
   - Laser probe $70 per case
   - Diathermy $20 per case
   - Forceps $70 (disposable but could be used multiple times)
   - Delamination scissors $100 (disposable but could be used multiple times).

7. Training Required

For each cadre of staff involved in the diagnosis and management of a patient with diabetes and diabetic retinopathy appropriate training is required.

Principles
Certain principles are useful to remember:
The patient should be kept at the centre of everything that is planned, including the training of staff.
Training should be orientated to the safe and effective accomplishment of tasks.
These can be summarised as follows:

Tasks
1. Patient history taking
2. Patient counselling
3. Visual acuity assessment
4. Complete examination of the eye
5. Retinal image taking
6. Retinal image grading
7. Clinical decision making on management
8. Giving an intra-vitreal injection
9. Applying laser for macular oedema (CSMO)
10. Applying laser for proliferative diabetic retinopathy (PDR)
11. Vitrectomy
12. Complex VR surgery
13. IT database management
14. Clerical support of patient records

For each task the staff member requires:

1. Relevant knowledge
2. Training in the skill
3. Appropriate attitude and care

It is not possible to go into the training details required for each task in this Toolkit.

Competency assessments for a few of the specific and important tasks relevant to the management of a patient with diabetic retinopathy are given in the pages that follow as examples.

Competency Assessment Record for Intra-Vitreal Injections

Action	Rationale	Poor	OK	Good	Explain
Rationale and Assessment					
Maintains a professional approach and attitude throughout the whole procedure.	Professional responsibility, gaining trust of the patient.				
Confirms that patient is aware of procedure and correct eye to be injected.	To promote patient choice and ensure informed consent.				
Correct explanation of procedure given to patient.	To allay patient's fears and gain their confidence.				
Preparation and Procedure					
Correct identification of the patient and correct eye for injection.	To avoid identification errors.				
Demonstrates appropriate hand washing technique and donning of gloves and that patient has received anaesthetic drops and povidone iodine	To prevent contamination and reduce risk of cross infection and ensure patient comfort				
Demonstrates appropriate technique for drawing up injection solution and checks volume to be administered	To prevent contamination and reduce injection of bubbles and excess volume into the eye.				
Correct selection and preparation of aseptic field and equipment (dressing trolley)	To prevent contamination and reduce risk of cross infection.				
Correct preparation of the patient	For patient comfort and to facilitate access for injections.				
Carries out the injection using appropriate technique	For patient safety and efficacy				
Checks visual acuity	To ensure patient has at least count fingers vision and exclude NPL in case of central retinal artery compromise.				

Completion/Decontamination					
Injection/Procedure Correct technique/ demonstrating practical ability and dexterity throughout the procedure	To minimise patient discomfort during the procedure				
The practitioner responds appropriately to deal with any difficulties experienced during the procedure.	The injections are uncomfortable for the patient, the patient may require additional support during the procedure				
Correct disposal of sharps and waste in accordance with local sharps disposal policy.	To prevent sharps injury. To prevent contamination and reduce risk of cross infection.				
Correct decontamination of asepsis field and self, post-procedure	To prevent contamination and reduce risk of cross infection.				
Accurate documentation in patient's health records of any complications and/or difficulties encountered during this procedure.	To provide an accurate record of interventions undertaken.				
Name of assessor	Signature				
Name of assessed					

Competency Assessment Record for Laser Treatment

Action	Rationale	Poor	OK	Good	Explain
Rationale and Assessment					
Maintains a professional approach and attitude throughout the whole procedure	Professional responsibility, gaining trust of the patient				
Confirms that patient is aware of procedure and correct eye to be lasered. Assesses visual acuity appropriately	To promote patient choice and ensure informed consent To ensure baseline vision level is noted				
Correct explanation of procedure given to patient	To allay patient's fears and gain their confidence				
Discusses relevance of diabetic control, hypertension, smoking	To assist patient understanding of disease				
Preparation and Procedure					
Correct identification of the patient and correct eye for laser treatment.	To avoid identification errors				
Demonstrates appropriate hand washing technique and that patient has received anaesthetic drops	To prevent infection and ensure patient comfort				
Demonstrates adherence to laser safety protocol, ensuring protection of patient and any observers	To prevent accidental laser injuries				
Demonstrates appropriate knowledge for adjusting the laser settings	To ensure optimal effect of laser without complications				

Applies laser contact lens and positions patient correctly	For patient comfort and to facilitate good view for lasering.				
Applies laser treatment competently	For optimal management				
Completion					
The practitioner responds appropriately to deal with any difficulties experienced by the patient during the procedure	Laser treatment is uncomfortable for the patient, the patient may require encouragement and support during the procedure				
Correct lens cleansing technique at the end of the procedure	To prevent contamination and reduce risk of cross infection				
Accurate documentation in patient's health records including any complications and/or difficulties encountered during this procedure	To provide an accurate record of interventions undertaken				
Name of assessor	Signature				
Name of assessed					

8. Financial Planning

The costs which have to be covered can be usefully divided into:

- Capital, occasional one-time costs
- Running, regular ongoing costs

Capital, occasional one-time costs
The main categories to be considered are:

- Equipment costs (see equipment section)
- Costs for staff to attend one-time specific training courses
- Purchase of vehicles if outreach is part of the service
- Buildings e.g. conversion of an ordinary room into a clean room for intravitreal injections

Running, regular ongoing costs
The main categories to be considered are:

- Salaries of staff
- Consumable costs for medicines / items required for screening & treatment
- Servicing and maintenance of equipment
- Utility costs – rent, water, electricity etc.
- Transport costs – fuel, if outreach is part of the service

Steps to be considered in Financial Planning

1. Cost containment
   First, an estimate should be made of the monthly running costs and consideration be given to how these can best be contained. Only purchase essentials; try to buy in bulk; buy generics whenever possible.

2. Income Generation
   Second, consideration should be given as to how income can be obtained to cover these running costs.
   Sources of income may be government support (e.g. salaries and utilities); income from direct patient fees or medical insurance systems.

   To be financially sustainable the monthly income has to be at least as much as the monthly expenditure.

3. Capital costs
   Capital costs for equipment and training courses are occasional one-time costs. These can be requested from government, non-govt. organisations, local philanthropy, service organisations etc.

9. Monitoring

Monitoring of Diabetic Retinopathy Screening Programmes

Areas of Monitoring

- Screening appointments: do patients come back for their (annual) screening?
- Treatment appointments: do patients arrive at the referral hospital for further diagnostics and treatment?
- Grading of DR images (if applicable) or staging of DR by screening staff. About 10% of images/gradings should be verified by a consultant
- Treatment outcome: visual acuity and DR/Maculopathy – are they stable?

Implementation of Monitoring

A database system which can automate all monitoring requirements is recommended. In principle it can be done on paper but this is more tedious and might result in erratic implementation of monitoring.
In order to create the respective monitoring reports the following data is necessary to be collected in the database **for each visit**:

- Date of visit
- Type of visit (screening, diagnostics, treatment, follow-up etc)
- Date of planned next visit
- Type of planned next visit (same categories as above)
- Grading results in each eye
- Treatment given in each eye
- Visual acuity in each eye for each visit
- Other routine examinations which are done during the visit, e.g. blood glucose, blood pressure, height, weight, abdominal circumference etc.

Example

An example of a database for Monitoring a Diabetic Retinopathy Programme is shown on the next page.

10. Example of a Diabetic Retinopathy Patient Database

Key elements of the database are two tables:
1 A table containing information about the patient (gender, date of birth…)
2 A table with information about all visits of a patient.
These two tables are linked with each other through an unique patient identifier.
The figures below show examples for the important elements of the two tables.

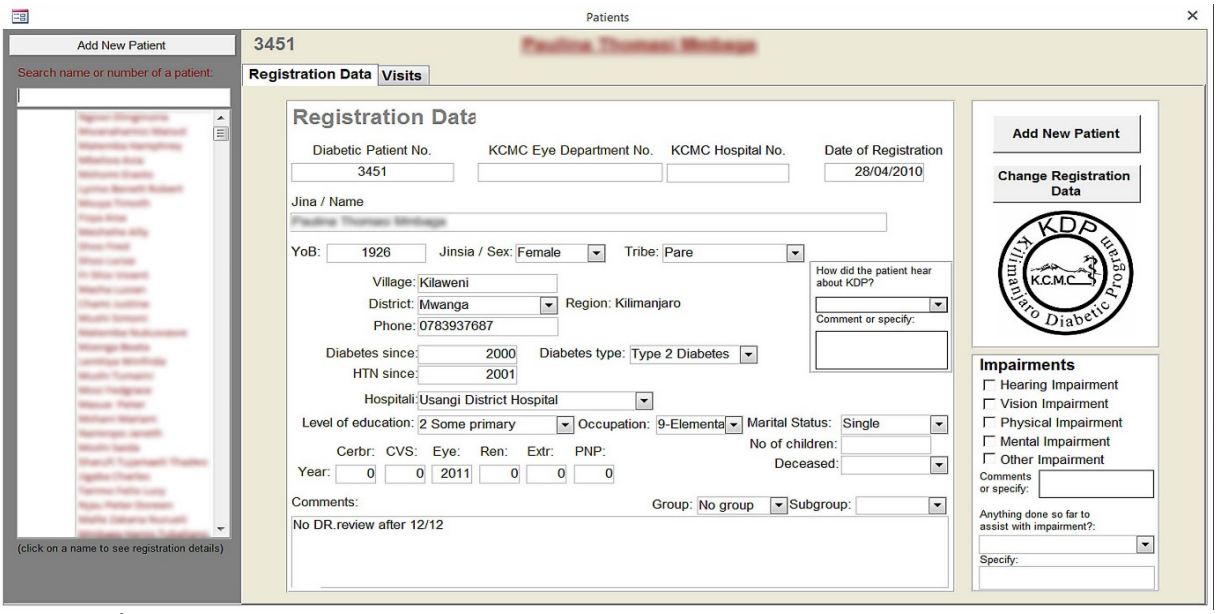


Figure Above:
Information about a patient for a diabetic patient register. This form captures information on a patient which rarely changes over time. The left column allows one to search and select patients. This sample database was done in MS Access.

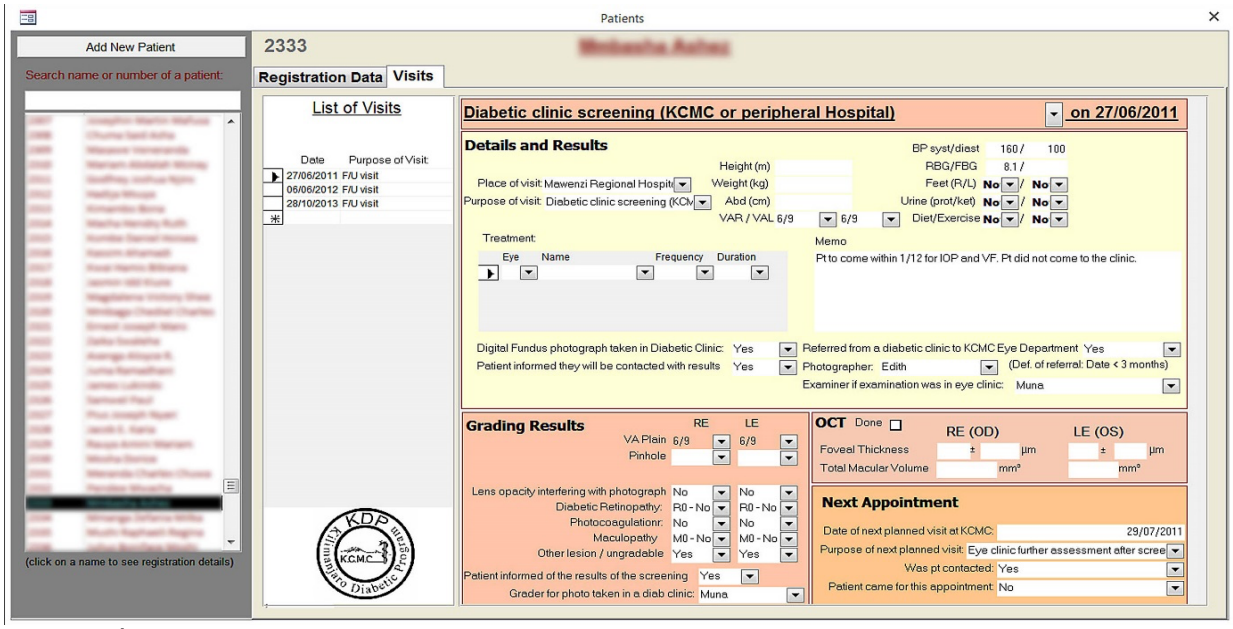


Figure above:
This form shows all information from different visits made by the patient. For each selected patient a variable number of visits are stored and listed in the second column from left.

11. Templates for Planning Services

Template Tables to Plan a Programme to Prevent Visual Loss from Diabetic Retinopathy

A. Situational Analysis

A1. What is the Need?

POPULATION AT RISK	
Place	
Total Population	
Population to be covered (consider age groups)	
DIABETES MELLITUS	
Prevalence of DM	
Number of people with DM (needing examination of retina every 1-2 yrs.)	
DIABETIC RETINOPATHY	
Proportion of people with diabetes (%) who have Diabetic Retinopathy	
Number of people with Diabetic Retinopathy	
VISION THREATENING DR (VTDR)	
Proportion (%) of people with diabetics who have VTDR	
Number of people with VTDR (needing treatment)	

KEY INDICATORS OF NEED	
CASE DETECTION - How many need an eye examination every 1-2 yrs?	
TREATMENT - How many need treatment (per year)?	

A2. What is being done today?

KEY INDICATORS OF SERVICE PROVISION	
CASE DETECTION - How many people with diabetes had a retina exam in 2015?	
TREATMENT - How many **people/eyes** were treated for DR in 2020? • Laser for PDR (people and eyes) • Laser for CMO (people and eyes) • Anti-VEGF injections (people and eyes)	

Describe the stage of the DR Programme Development using this table

Activity	Does this happen at your local level?	Does this happen at National level?
1. Do you diagnose and treat DR cases attending the eye clinic (with or without outreach clinics)	**YES / NO**	**YES / NO**
2. Do you do outreach clinics to identify and diagnose DM patients?	**YES / NO**	**YES / NO**
3. Examine all diabetes patients for DR at hospital diabetes clinic (with / without outreach clinics)	**YES / NO**	**YES / NO**
4. Create a register of all known people with diabetes mellitus register and call people for eye exam	**YES / NO**	**YES / NO**

Cross cutting activities

5. Are you doing training in DR for health professionals	**YES / NO**	**YES / NO**
6. Are you providing health education about DM and the eye to diabetics in the community	**YES / NO**	**YES / NO**

A3. What are the Available Resources?

Resource	Available	Comment
What Health staff are available?		
What Equipment for diagnosis is available?		
What Equipment for treatment is available?		
Do you have any Management protocols?		
Do you have a patient database and /or electronic patient records?		
What is the source of funding?		
Who provides Leadership for the service?		
What Records & Statistics are kept and analysed?		
Is there any Patient Information literature?		
Who are involved from? • **Government** • **Non- govt.** • **Community**		

B. Setting Priorities

What are the priorities to prevent visual loss from DR?	What are the major constraints?	What are the solutions to these constraints?	What can be done in the next 2 years?
1			
2			
3			
4			

C. Draft Activity plan for next 24 months:
Complete only where relevant to the identified priorities

Action	When	Who	Cost	Is this activity? ➢ MUST DO NOW ➢ EASY TO DO ➢ FOR LATER
Diagnosis and Case Detection				
Treatment				
Practice guidelines and protocols				
Human resource development				
Leadership and planning				
Community awareness				
Financing the programme				
Evidence, Statistics and Information System				
Advocacy and policy				
Education of health professionals				

12. DR-NET website address (includes useful resources):

https://sites.google.com/site/drnetcomm/home

VISION 2020 LINKS Diabetic Retinopathy Network (DR-NET) Toolkit 2021

Notes