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Regional Diabetic Retinopathy Programme

Eastern Mediterranean Region



REGIONAL DIABETIC RETINOPATHY PROGRAMME

CBM EASTERN MEDITERRANEAN REGION (EMR)

Developed in collaboration with the International Council of Ophthalmology (ICO)

INTRODUCTION

In 2013/2014, the International Council of Ophthalmology (ICO) developed detailed guidelines for diabetic eye care¹. This was updated in 2016. CBM's regional programme aims to translate these guidelines into practice, applying it to the context of the Eastern Mediterranean Region. The programme can of course be modified and applied to different contexts as appropriate.

WHAT IS DIABETES

Diabetes is a chronic, debilitating lifelong disease that occurs either when the pancreas does not produce enough insulin (type 1) or when the body cannot effectively use the insulin it produces (type 2). Insulin is a hormone that regulates blood sugar by enabling the glucose from food to enter the body cells and be used as a source of energy. Hyperglycaemia, or raised blood sugar, is a common effect of uncontrolled diabetes and over time leads to serious damage to many of the body's systems, especially the nerves and blood vessels.

THE BURDEN OF DIABETES

347 million people worldwide have diabetes and more than 80% of them live in low and middle income countries. The burden of diabetes is increasing globally, particularly in developing countries. The World Health Organisation (WHO) projects that diabetes deaths will double between 2005 and 2030 and that diabetes will be the 7th leading cause of death in 2030.

DIABETES AND ITS MANY COMPLICATIONS

Long-term complications of diabetes develop gradually. The longer the duration of diabetes — and the less or poorly controlled the blood sugar — the higher the risk of complications. Eventually, diabetes complications may become disabling or even life-threatening. The following complications are among the most serious:

¹ The guidelines are available here: <http://www.icoph.org/taskforce-documents/diabetic-retinopathy-guidelines.html>

- **Blood vessel (vascular disease) damage:** Diabetes dramatically increases the risk of various cardiovascular problems, including hypertension, heart attack, and stroke.
- **Nerve damage (neuropathy) and foot damage:** Excess sugar can injure the walls of the tiny blood vessels (capillaries) that nourish the nerves, especially in the legs. Left untreated, this could lead to loss of all sense of feeling in the affected limbs, foot ulcers and limb amputation.
- **Kidney damage (nephropathy):** The kidneys contain millions of tiny blood vessel clusters (glomeruli) that filter waste from the blood. Diabetes can damage this delicate filtering system. Severe damage can lead to kidney failure or irreversible end-stage kidney disease, which may require dialysis or a kidney transplant.
- **Eye damage (retinopathy):** Diabetes can damage the blood vessels of the retina (diabetic retinopathy), potentially leading to blindness. It also increases the risk of other serious vision conditions, such as cataracts and glaucoma.

DIABETIC RETINOPATHY

Diabetic Retinopathy (DR) is the most common and most damaging form of diabetic eye disease. It is seen in both type 1 and type 2 diabetes (earlier in type 1 than in type 2) and like in other end organs, is the result of vascular changes and micro-circulation in the retina of individuals who have had diabetes for several years.

There are two types of diabetic retinopathy:

- **Early diabetic retinopathy**

In this form, also known as non-proliferative diabetic retinopathy (**NPDR**), blood vessel walls weaken, bulge and may leak fluid and blood into the retina. At the macula, the central part of the retina, this could result in diabetic macular edema (**DME**), a condition that progressively interferes with central vision and requires expert (laser, injection of medications, or surgery) treatment.

- **Advanced, vision-threatening diabetic retinopathy**

This is a more severe form of diabetic retinopathy, and is also known as proliferative diabetic retinopathy (**PDR**). It is characterized by the growth of fibro-vascular tissue due to chronic, poorly controlled diabetes. It includes pre-retinal neovascularization which may ultimately lead to vitreous hemorrhage and various forms of retinal detachment.

Note: In the management of diabetes in general, and of DR in particular, every effort must be made to help patients never to reach this advanced stage, as, by

then, full sight recovery may no longer be possible and even the best treatment may still leave many severely visually impaired. This is why close collaboration with Low Vision and Community Based Rehabilitation (CBR) services must be established at the outset.

GLOBAL EPIDEMIOLOGICAL DATA ON BLINDNESS & DR

According to the WHO, 285 million people worldwide are currently visually impaired and 39 million of them are blind. Up to 80% of these cases are avoidable or treatable. In 2002, DR accounted for about 5% of world blindness, representing almost 5 million blind². However, based on all the evidence available to date and the projected dramatic increase in the incidence of diabetes (e.g. 98% in Sub-Saharan Africa) over the next 20 years, it is likely that many more individuals will suffer from eye complications which, if not properly managed, may lead to permanent eye damage. This explains why DR management is now on the list of priority interventions. We must also keep in mind that management of DR needs to be integrated into diabetes management services (control of sugar levels, control of hypertension and lipids).

Also based on available evidence³, the following broad guidelines can be used to quickly estimate the burden of DR and the planning of DR services:

- **1 in 3** diabetic patients have DR, or will develop it in the span of their disease
- **1 in 10** diabetic patients have or will develop advanced, vision threatening DR in the span of their disease.

When applied to population size, this formula gives the following numbers of corresponding diabetes/DR cases (Table 1)*:

Table 1: Estimate of needs for planning & provision of DR services

	1 Mio Pop.	500.000 Pop.	100.000 Pop.
Diabetes Patients	50.000	25.000	5.000
DR Patients	17.000	8.500	1.700
In Need of Treatment (Laser, Injection of anti-VGEF agents, Retinal Surgery)	5.000	2.500	500

² <http://www.who.int/blindness/causes/priority/en/index5.html>

³ Ruta et al. Prevalence of diabetic retinopathy I Type 2 diabetes in developing and developed countries: <http://www.ncbi.nlm.nih.gov/pubmed/23331210>

* Corresponding data or dynamic equivalent for different regions may be used here, as appropriate.

CBM & DR

Up till now, CBM has addressed DR in a non-specific manner, and only as part of its comprehensive approach to preventing avoidable blindness. Interested or involved local partners were supported in their individual efforts to provide whatever DR services they could afford or had competence for. However, until now, DR has not been a major focus of CBM's work. With the rapid rise of diabetes globally and in the Eastern Mediterranean Region, and with DR having been identified as a priority in the recent WHO Global Action Plan, CBM has decided to develop a programmatic approach and standards to effectively address DR [in the Eastern Mediterranean Region], starting on a pilot basis in a few carefully selected partners' projects.

This Regional Diabetic Retinopathy Programme Manual is CBM's second Eye Health Programme Manual initiated by the EMR Regional Office. It comes after the 'Regional Cataract Programme EMR Manual', introduced in 2012/2013 to ensure quality, cost-efficiency and effectiveness, patient satisfaction and sustainability, in keeping with global benchmarks. It is a direct outcome of CBM EMR's co-operation with the ICO and key global and regional experts on Diabetic Retinopathy.

In order to make the manual relevant to different settings within EMR and ultimately to other regions, and prior to starting planning and implementing any new DR project, a detailed situation analysis will be required, to help understand the specifics of each location (magnitude, needs, key stakeholders, available resources and competencies, etc.) and adjust the strategy accordingly.

It is hoped that thanks to its underlying implementation framework and the lessons learned through its implementation, this manual could also be relevant to governments and other local service providers.

DEVELOPMENT OF A REGIONAL PROGRAMME MANUAL

CBM's Programme Manual has been developed based on the following facts:

- Optimal management of DR requires a 2 pronged strategy (see table 2), a level of resources and a range of skills and expertise that are beyond the remit of any single player, including CBM.

Table 2: Requirements for an integrated & optimal management of DR

Medical	Ophthalmic
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<ul style="list-style-type: none"> • Better glycaemia control, including as appropriate, quarterly testing of HA1c • Optimized control of Blood Pressure (BP) • Nutrition counselling and education, customized for various regions • Better foot and dental care • Education on living with diabetes • Timely referral of patients needing ophthalmic assessment & management <p>And, when everything else has failed,</p> <ul style="list-style-type: none"> • Referral of those with diabetes associated disabilities (blindness, stroke) to Low Vision and CBR services 	<ul style="list-style-type: none"> • Regular screening for, and monitoring of DR • Timely referral of patients needing further expert assessment, or medical and/or surgical treatment of DR • Timely laser treatment • Anti-VGEF or corticosteroid treatments, as and where appropriate • Timely VR surgery where needed <p>And, when everything else has failed,</p> <ul style="list-style-type: none"> • Referral of those with diabetes associated disabilities (blindness, stroke) to Low Vision and CBR services
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- Close cooperation with other key players at national, regional & district levels (National Diabetic Associations, diabetic centres, national lead diabetologists, endocrinologists and internists with vast experience in the management of diabetes) is not just good and helpful but essential to the successful implementation of the programme.
- A matrix like the one suggested in Table 3 below, complemented where appropriate by a check list, can be used to map the resources available at primary, secondary and tertiary levels, including **staff** and **equipment** likely to be needed for the delivery of DR services (i.e. for detecting, referring, treating, monitoring & reporting). The WHO Tool for Assessing Diabetes and Diabetic Retinopathy Systems (TADDS) can also be used for the assessment of Diabetes Mellitus and Diabetic Retinopathy services at the country level.

Table 3: Matrix for the rapid assessment of DR services in a region

Primary Level (Target population?)	Role & Responsibility in Diabetes Management	Role & Responsibility in DR Management	Priority Changes to be made & Additional Needs
<ul style="list-style-type: none"> • Level of services • Available personnel (type & number) and key partners* • Available infrastructure & equipment, including consumables (list) • Inclusion***? Who? How? • Use of educational materials & guidelines 			

• Current funding? By whom?			
Secondary Level (Target population?)	Role & Responsibility in Diabetes Management	Role & Responsibility in DR Management	Priority Changes to be made & Additional Needs
<ul style="list-style-type: none"> • Level of services • Available personnel (type & number) and key partners* • Available infrastructure & equipment, including consumables (list) • Inclusion**? Who? How? • Training capacity & resources • Production/use of educational materials & guidelines • Current funding? By whom? 			
Tertiary Level	Role & Responsibility in Diabetes Management	Role & Responsibility in DR Management	Priority Changes to be made & Additional Needs
<ul style="list-style-type: none"> • Level of services • Available personnel (type & number) and key partners* • Available infrastructure & equipment, including consumables (list) • Inclusion**? Who? How? • Training capacity & resources • Production of educational materials & guidelines • Current funding? By whom? 			

*These could include NGOs, government, Disabled People's Organisations (DPOs), etc.

**Inclusion of neglected populations (poor, people with disabilities, women)

- This matrix can also be used to determine:
 - the gaps in knowledge, skills and competencies among available personnel;
 - the gaps in appropriate and functional equipment, consumables and supplies needed for the effective delivery of DR services;
 - the current nature and extent of inclusive services;
 - whether guidelines or algorithms for the management of DR exist;
 - the current level of funding, if any, that is available for DR services (where, who, how?) and the potential for additional funding.
- Finally, such a matrix could also be very useful in helping determine the nature and extent of collaborative partnerships likely to be needed with other structures managing diabetic patients, especially non-ophthalmic ones.

Against that backdrop and building on its own as well as global experience and partnerships, CBM hopes to inspire others to support the development of DR management

- by strengthening its partners and by developing cost effective model DR programmes within health systems which can lead to the scaling up of services;

- by making the most of the existing medical and eye care infrastructure involved in the prevention and management of diabetes in the region.

In addition, CBM will ensure that all partners participating in the programme will adhere to accessibility guidelines so that DR programmes are inclusive of people from all disability groups, including vision impairment, and other marginalised people, and that people with permanent vision impairment as a result of DR access their right to wider opportunities.

OBJECTIVE OF THE EMR DR PROGRAMME

To reduce the burden of avoidable blindness and visual impairment, and more specifically, that of visual impairment caused by Diabetic Retinopathy in the Eastern Mediterranean Region.

EXPECTED OUTCOMES OF THE EMR DR PROGRAMME

1. Strengthened medical and surgical infrastructure, resulting in early detection, referral, treatment and monitoring of sight threatening complications related to DR and, ultimately, a reduction in the prevalence of visual impairment caused by DR
2. All involved personnel at all levels of the health pyramid are fully trained in DR management, including, where appropriate, in surgery
3. Fully inclusive DR services and greatly improved access to the programme by poor and underserved populations, e.g. people with disabilities
4. Establishment of a model for DR detection, referral and treatment from primary all the way through to tertiary level, with a clear, easy to implement and reliable referral system and the establishment of high quality DR surgical units at the tertiary level
5. Establishment of a clear collaborative framework for the integrated management of diabetes (medical and ophthalmic)
6. Availability of data on DR prevalence and services (quality and gaps in terms of accessibility, affordability, availability) at all levels
7. Establishment of a reliable data management system to collect evidence for monitoring, advocacy and sustainability purposes
8. Setting up of a centralised management system to ensure a more effective coordination of human resource training, provision of equipment and consumables and cost-efficient supplies

PARTICIPATING PARTNERS

Any CBM partner organisation in the EMR Region or any new organisation that is not currently a CBM partner organisation but demonstrates a high potential to initiate, strengthen or expand a DR programme, can apply for support. The strength of their potential will be assessed based on the following criteria (the more, the better; see also the assessment matrix in Table 2):

- ✓ has the required capacity (trained human resources, functional and appropriate equipment and adequate supplies) to offer the whole range of DR treatments, including laser and VR surgery⁴
- ✓ has a track record for quality ophthalmic services, preferably including DR services
- ✓ commits to meeting agreed quality benchmarks
- ✓ agrees to implement measures to make their eye care services and activities fully inclusive
- ✓ is willing to meet CBM's accountability requirements
- ✓ is willing to contribute to knowledge management, learning, data collection, and advocacy

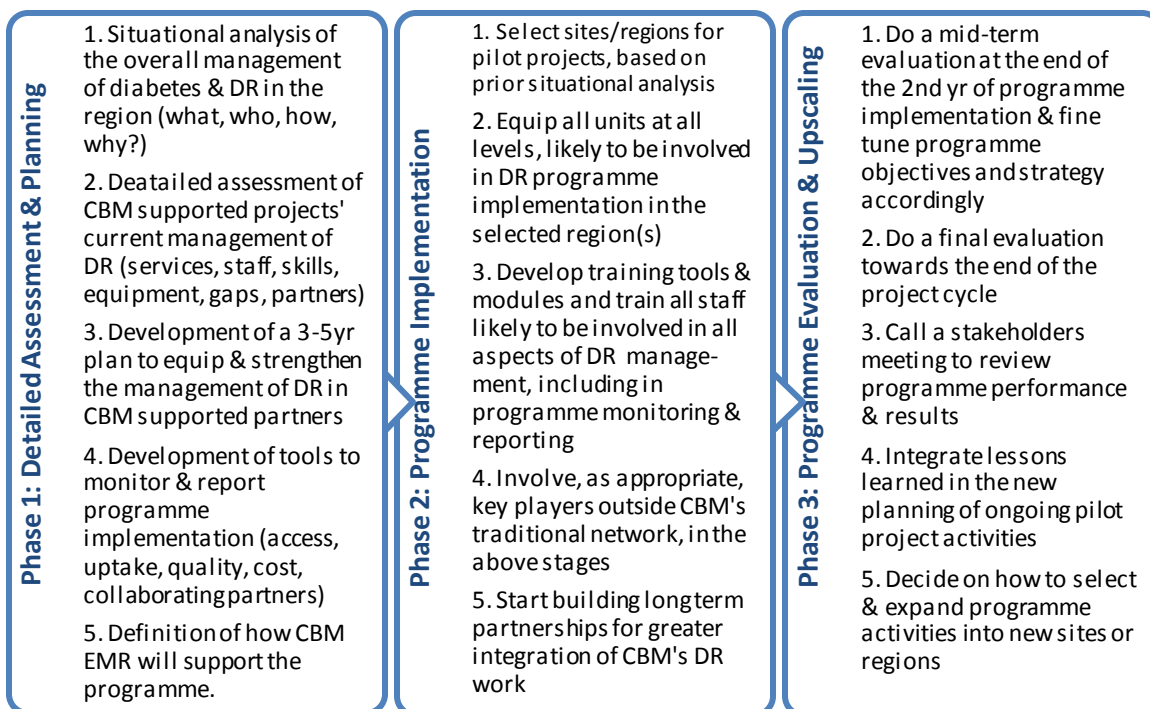
IMPLEMENTATION METHODOLOGY

Because few implementation templates exist, particularly in regions with resource constraints, CBM EMR will carry out the implementation of its DR programme in a cautious, stepwise manner, as detailed in Table 4.

- Phase 1: Detailed situational analysis and project planning
- Phase 2: DR programme implementation, monitoring & reporting
- Phase 3: DR programme evaluation and upscaling

Table 4: Stepwise implementation of DR programme

⁴ If the above cannot be met, or where skills are in short supply, it could be considered to set up a tri-partite network of collaborating eye units i) early screening & referrals; ii) assessment of referrals & routine laser treatment; iii) advanced laser & VR surgery. In that case, **start with (i) & (ii) first**, while preparing for (iii)



PROGRAMME IMPLEMENTATION AND SUPPORT

1. Eligible partners (based on the above criteria) sign up to the DR programme, thereby agreeing to programme benchmarks and accountability standards.
2. CBM provides them with the necessary resources as per the results of the needs assessment, either to get started immediately or to rapidly build their basic DR infrastructure first. The latter scenario could include resources and other support for the technical and managerial training of the local teams that may be required initially. This will be particularly important in those areas where a full medical and surgical DR programme cannot be initiated immediately due to limited available local skills.
3. A procurement system is set up by CBM, run via key partners in each country, to provide quality equipment and consumables, in keeping with the range of skills locally available as well as other country specific requirements.
4. For those partners which are ready to start immediately, consumables and other essential supplies, including anti-VEGF (anti vascular endothelial growth factor), are provided on a 6 months basis, and/or can be purchased at benchmarked negotiated prices, as appropriate.
5. A certain percentage per surgery and per laser session will be agreed to cover partners' overheads. Partners will utilise these resources to carry out agreed laser treatments and/or DR surgeries and report back on agreed indicators, using CBM's standard format for the regional DR programme.

MONITORING FRAMEWORK

All partners are responsible for monitoring progress and success of DR activities at their level. CBM's EMR Regional Office will monitor projects periodically, consolidate and analyse programme data and give recommendations and

feedback. Regional data and lessons learnt will be made available to the CBM family and can be used for advocacy purposes. The following 4 sets of indicators (*process, quantitative, quality & qualitative*) are recommended:

1. Process Indicators (most important during phase 1 of the implementation matrix)
 - Completion of situational analysis and need assessment (date)
 - Prevalence of Diabetic Retinopathy (can be obtained through RAAB)
 - List of priority training needs, by level (primary, secondary, tertiary) and type (new, refresher) (number)
 - Number of education materials produced (number)
2. Quantitative Indicators
 - Total number of DR patients seen
 - Number/% of "walk in" DR patients
 - Number/% of referred DR patients from other services
 - Number/% of patients with disabilities
 - Total number of laser treatment sessions provided
 - Number of Anti-VEGFs injection given
 - Number of surgeries performed for DR
 - Cost per anti-VEGF treatment (Cost Per Session)
 - Cost per laser treatment (Cost Per Session)
 - Cost per VR surgery for DR
3. Quality Indicators
 - Number of patients with surgical complications
 - Visual acuity on discharge, at 4 and 12 weeks, then quarterly
 - Blood pressure control (OK, Fair or Poor), as reported by attending Medical Officer
 - Quarterly Glycated Haemoglobin (HAc1), where possible
4. Qualitative Indicators
 - Overall patient satisfaction with DR services provided
 - Number of hours spent by walk-in patients before being attended to (1/4hr, 1/2hr, 3/4hr, 1hr, etc.)
 - Number of hours spent by referred patients before being attended to (1/4hr, 1/2hr, 3/4hr, 1hr, etc.)

MONITORING AND REPORTING OF DR ACTIVITIES

• Monitoring tools & instructions

- Patient records
- Visual outcomes (measured as levels of Visual Acuity)
- Follow up assessments
- Unit cost calculation

- Output tables and/or Tally Sheets, specifically adapted for this purpose

- **Monitoring & Reporting format**

In general, vision improvement, even after successful DR treatment (laser and surgical) is rather slow. As a result and unless there are specific reasons to do so (e.g. for research), it is not useful to monitor and report DR activities more frequently than quarterly. Hence the following recommendations for the frequency of patient follow up:

- On discharge, then at 4 and 12 weeks, then quarterly following laser or surgical treatment (include data on visual outcomes)
- Quarterly for all other cases
- Quarterly/six monthly for case studies
- Special reports on special events, outreach activities, M&E activities, as appropriate

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CBM in partnership with ICO



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