



Clinical Practice Guidelines for Treatment Clinics

First edition

Contents

Foreword	1
1. Introduction	2
1.1 Purpose and scope	2
2. Treatment clinic guidelines	3
2.1 Facilities and access	3
2.2 Administration room	3
2.3 Information technology	3
2.4 Clinical room	4
2.5 Equipment	4
2.6 Surveillance clinic (if present)	5
2.7 Intravitreal injection room	5
2.8 Staffing	5
3. Management of new referrals	6
3.1 Administration	6
4. Management of treatment clinics	6
4.1 Administration	6
5. Clinical guidelines	7
5.1 Management of referrals for proliferative diabetic retinopathy	7
5.2 Management of stable treated proliferative diabetic retinopathy	8
5.3 Management of referrals for preproliferative diabetic retinopathy	9
5.4 Management of referrals for diabetic macular oedema (DMO)	10
5.5 General assessment and treatment guidelines	12
5.6 Management of non-diabetic eye disease referrals	12
5.7 Communication of results	12
6. Management of attendance	13
7. Governance	13
8. References	13

Foreword

The National Screening Service (NSS), part of the Health Service Executive (HSE), has significant expertise in developing, implementing and delivering organised population-based screening programmes. The NSS encompasses BreastCheck – The National Breast Screening Programme, CervicalCheck – The National Cervical Screening Programme, BowelScreen – The National Bowel Screening Programme and Diabetic RetinaScreen – The National Diabetic Retinal Screening Programme.

Since its introduction in 2013, Diabetic RetinaScreen has been providing regular, free diabetic retinopathy screening and treatment to those with diabetes aged 12 and over. This document provides guidelines for treatment centres providing support to the Diabetic RetinaScreen programme. These updated guidelines are a culmination of the work of the Clinical Advisory Group, under the guidance of the National Screening Service.

Contributions have been made from its diverse membership. The members are Ms Colette Murphy, Programme Manager, Diabetic RetinaScreen; Dr Margaret Morgan, Medical Ophthalmologist; Prof Sean Dineen, National Clinical Lead for HSE Diabetes Programme, Consultant Endocrinologist; Chríossa O'Connor, Optometrist; Dr Mark James, Medical Ophthalmologist, Cork University Hospital; Ms Deirdre Townley, Consultant Ophthalmologist, University Hospital Galway; Helen Kavanagh, Deputy Programme Manager, Diabetic RetinaScreen. Mr Donal Donnelly, Treatment Centre Co-ordinator, Diabetic RetinaScreen; and Prof David Keegan, National Clinical Lead for Diabetic RetinaScreen, Consultant Ophthalmologist.

These guidelines serve as a support for the treatment centres in the administration of the treatment arm of the national screening and treatment programme. They are evidence-based and adhere to best international practice. The guidelines form part of the National Clinical Programme for Ophthalmology and form an important bridge between the two programmes.

The committee recognises that there is constant evolution of care in this field and the need for ongoing development of these guidelines.

Professor David Keegan
Chair, Clinical Advisory Group
Diabetic RetinaScreen

1. Introduction

Diabetes mellitus (DM) is associated with the development of a number of complications. One of these is the development of diabetic retinopathy, potentially resulting in blindness. Diabetic retinopathy is the leading cause of new cases of preventable blindness in the working age population (20-75 years) in developed nations¹.

Retinopathy screening for patients with diabetes is an internationally accepted standard of diabetes care, and the development of population-based screening programmes has been prioritised by national and international policy makers.

In 2011 the Health Service Executive (HSE) National Diabetes Programme tasked the National Screening Service (NSS) with the development and implementation of a national diabetic retinal screening programme. The NSS has extensive experience of developing and implementing population-based screening programmes and is responsible for BreastCheck – The National Breast Screening Programme, CervicalCheck – The National Cervical Screening Programme and BowelScreen – The National Bowel Screening Programme.

Diabetic RetinaScreen – The National Diabetic Retinal Screening Programme became available in early 2013. It is underpinned by quality assured standards which were developed to take into consideration existing successful screening programmes in Ireland and recognised international best practice. The programme which is Government-funded, offers free access to annual screening for people with diabetes, aged 12 and over. Diabetic RetinaScreen uses specialised digital photography to look for changes that could affect the eyesight. Any follow-up, further assessment or treatment of diabetic retinopathy that is recommended as part of the screening programme is free of charge.

1.1 Purpose and scope

This document specifies how treatment clinics will deliver services as part of the Diabetic RetinaScreen programme and sets out the administrative and clinical supports required by the programme.

Our aim is to provide all those who require further investigation or treatment with the highest possible standard of care, and to ensure that each person is offered comprehensive information in relation to their diagnosis which is clear, objective and readily available.

2. Treatment clinic guidelines

2.1 Facilities and access

All Diabetic RetinaScreen treatment clinics are located in a dedicated outpatient facility and provide the following:

- Clear signage from the hospital entrance to the Diabetic RetinaScreen treatment clinic
- An appropriate reception area
- An appropriate waiting area
- Adequate restroom facilities

2.2 Administration room

Administrative support should be provided with:

- Dedicated office space for administrative support
- Appropriate computer and printer hardware
- Telephone and fax facilities
- Space for medical record storage
- A facility to update the OptoMize system

2.3 Information technology

Diabetic RetinaScreen uses a systematic screening package called OptoMize. The OptoMize system must be accessible to relevant staff, including administrative and clinical staff members. Training is required for all OptoMize users with unique log-in credentials assigned to each. Details of all clinical encounters for assessment and treatment are recorded on the OptoMize system.

2.4 Clinical room

The clinical room should provide:

- A dedicated area for visual acuity measurement
- The potential to record LogMAR visual acuity
- A facility to enter the results of the clinical assessment/procedures performed on OptoMize system
- Adequate size with good ventilation
- A secure space

2.5 Equipment

Each clinic room must be equipped with the following:

- Access to a LogMAR chart
- Snellen chart
- Adjustable patient chair
- Examination couch
- Slit lamp
- Indirect ophthalmoscope
- Lenses for slit lamp and indirect fundoscopy
- Laser lens for macular and panretinal laser
- Tonometer
- Disposable tonometer prisms
- Computer and IT networks

There should be access to:

- Fundus Camera and Fluorescein Camera
- Optical coherence tomography (OCT)

2.6 Surveillance clinic (if present)

A dedicated area for visual acuity measurement requires the following:

- LogMAR chart
- Snellen chart
- Adjustable patient chair
- Fundus camera
- Optical coherence tomography (OCT)

2.7 Intravitreal injection room

The intravitreal injection rooms must comply with standards as outlined in the Royal College of Ophthalmologists (2018) Guidance on Intravitreal Injection Therapy².

2.8 Staffing

The Diabetic RetinaScreen treatment clinic requires the following resources:

- Lead clinician, with sessional support in their absence
- Dedicated nurse assigned to the clinic
- Administrative support
- Ophthalmologist trained in the delivery of laser treatment
- Ophthalmologist trained in the delivery of intravitreal injections
- Appropriate medical staff

Where there is a surveillance clinic in place there should be an ophthalmologist assigned with clinical responsibility for the delivery and quality assurance of this service.

3. Management of new referrals

3.1 Administration

All new referrals will be in a pending queue on the OptoMize system for administration staff to print and process. Urgent new referrals are offered an appointment within 12-24 business days after notification of screening result, as outlined in the 'Standards for Quality Assurance in Diabetic Retinopathy Screening'.³ Non-urgent new referrals are offered an appointment within 78-108 business days after notification of screening result.³ All new referrals received are reviewed by a clinician. A dedicated telephone number and email address must be provided to clients for appointment scheduling.

4. Management of treatment clinics

4.1 Administration

- Where a client has previously attended an eye clinic in the treatment clinic, access to their clinical records is to be provided to the treating clinician.
- A dedicated telephone contact number must be provided to patients following treatment.
- Any change to demographic details while the client is in treatment should be sent to the photography and grading provider and to the Diabetic RetinaScreen programme to ensure accuracy.
- The hospital will send information to the programme if a patient advises they are being treated privately.
- The hospital will operate a clear policy on management of patient complaints and concerns in compliance with HSE complaints policy.
- The hospital will manage DNAs in accordance with their local hospital DNA policy.

5. Clinical guidelines

5.1 Management of referrals for proliferative diabetic retinopathy

The following steps must be adhered to for effective management of referrals for proliferative diabetic retinopathy.

5.1.1 Initial assessment

12-24 business days after notification of screening result³

5.1.2 History

Review and document history with specific emphasis on and consideration given to:

- Control of blood glucose and blood pressure

5.1.3 Examination

- Visual acuity
- Slit lamp assessment
- Gonioscopy in presence of neovascularisation (NVI)

5.1.4 Imaging

- OCT in presence of coexisting diabetic macular oedema (DMO)
- Fundus Fluorescein Angiography (FFA) if indicated to assess extent of ischaemia

5.1.5 Management

- Address control of systemic risk factors, namely:
 - Blood glucose
 - Hypertension

5.1.6 Photocoagulation

- Treatment to commence within 12 business days after initial assessment, to comply with the 'Standards for Quality Assurance in Diabetic Retinopathy Screening'³. Treatment may include the following:
 - Neovascularisation of the disc (NVD) – pan-retinal photocoagulation (PRP)
 - Neovascularisation of the retina elsewhere (NVE) – PRP
 - 300-400µm burns, 10-50 ms duration spaced 1-1.5 burn widths apart over 1-3 sessions
Primary PRP 1200-1800 burns with further laser dictated by level of activity of neovascularisation. More spots (~3000) will need to be applied if using a multi-spot laser.
 - Extensive neovascularisation, vitreous/preretinal haemorrhage, tractional retinal detachment increase number of burns up to 3000 for primary PRP (5000 if multi-spot).
 - Neovascularisation of iris (NVI) no NVA or NVG – PRP
 - NVI + NVA/NVG consider intravitreal anti-VEGF agent soon after diagnosis in addition to PRP

5.1.7 Review post completion of pan-retinal photocoagulation (PRP)

- 8-12 weeks, dependent on severity at presentation

5.1.8 Indications for referral for assessment for vitrectomy

- Non resolving vitreous haemorrhage
- Tractional retinal detachment
- Rhegmatogenous retinal detachment
- Symptomatic epiretinal membrane
- Non resolving DMO with vitreo-macular traction

5.2 Management of stable treated proliferative diabetic retinopathy

Record as R3 on OptoMize and select stable treated retinopathy in advanced eye disease option. Annual review if no DMO or nondiabetic eye disease present; requiring more frequent review if significant systemic risk factors present.

5.3 Management of referrals for pre-proliferative diabetic retinopathy

Initial assessment should take place within 78-108 business days after notification of screening result.³

5.3.1 History

Review and document history with specific emphasis on and consideration given to:

- Control of blood glucose and blood pressure.
- Preproliferative diabetic retinopathy in pregnancy should be referred to the eye clinic for urgent assessment and ongoing management.

5.3.2 Examination

- Visual acuity (preferably LogMAR)
- Slit-lamp assessment

5.3.3 Imaging

- OCT in presence of coexisting DMO
- FFA if indicated to assess extent of ischaemia

5.3.4 Management

- Address control of systemic risk factors:
 - Blood glucose
 - Hypertension

5.3.5 Follow-up

Consider ocular and systemic risk factors when scheduling follow-up appointment, which should be made at a time appropriate to ETDRS grade.

5.3.6 Photocoagulation

- Consider in the following situations:
 - Where there is a history of poor clinic attendance
 - At the clinician's discretion in exceptional cases deemed to be at high risk of progression to PDR, particularly if an eye has been lost as result of PDR

5.4 Management of referrals for diabetic macular oedema (DMO)

Maculopathy referrals from Diabetic RetinaScreen are deemed non-urgent and should be seen within 78-108 business days of notification.³

5.4.1 History

Review and document history with specific emphasis on and consideration given to:

- Control of blood glucose and blood pressure.

5.4.2 Examination

- Visual acuity (preferably LogMAR)
- Slitlamp assessment

If any one or more of the four criteria listed below is present in an eye on clinical examination, maculopathy level on the OptoMize clinical system must be entered as M1 to assess the appropriateness of the screening programme referral.

- The presence of exudate within a radius of 1 disc diameter of the center of the fovea.
- The presence of a group of exudates within the macula.
- The presence of any microaneurysm or haemorrhage within a radius of 1 disc diameter of the centre of the fovea, only if associated with a visual acuity (VA) of $\leq 6/12$.
- Retinal thickening within 1 disc diameter of the centre of the fovea.

5.4.3 Investigations

OCT (Optical coherence tomography)

- Colour photography with an appropriate camera. Avoid use of pseudo colour.
- Fundus Fluorescein Angiography if indicated ahead of focal laser treatment.

5.4.4 Management

- Address control of systemic risk factors, namely:
 - Blood glucose
 - Hypertension

5.4.5 Photocoagulation

- Treatment to commence within 60 days of initial assessment.
 - Non centre involving CSMO (clinically significant macular oedema) regardless of the visual acuity level – Modified ETDRS focal/grid laser.
 - Centre involving CSMO and visual acuity >20/32 (6/9.5) – Modified ETDRS focal/grid laser may be applied. In cases where there is centre involving CSMO and visual acuity >20/32 (6/9.5) with no defined source of leakage observation is indicated.
- Review is required three to four months after the laser treatment has been performed.

5.4.6 Injection schedule

Indication for intraocular injection:

- Centre involving CSMO with Visual Acuity $\leq 20/32$ (6/9.5)

5.4.6.1 Treatment Naïve Patients

Six initial injections should be given at four week intervals followed by review. Injections should be continued at four week intervals while visual acuity continues to improve until visual acuity is stable over three consecutive visits, regardless of persistent thickening⁴. The addition of laser should also be considered in patients receiving treatment with intravitreal anti-VEGF agents⁴

5.4.6.2 Previously Treated Patients

Three initial injections should be given at four week intervals followed by review. Injections should be continued at four week intervals while visual acuity continues to improve until visual acuity is stable over three consecutive visits, regardless of persistent thickening⁴.

The addition of laser should also be considered in patients receiving treatment with intravitreal anti-VEGF agents.

5.4.6.3 Switching treatment in “non-responders”:

Non Responder (define at 6 months treatment after 4 weekly injection schedule applied)

- Vision gain ≤ 5 Letters
- OCT change $< 50\mu\text{m}$

All second line agent use cases to be discussed with Treatment Centre Clinical Lead

- NO Ranibizumab or Aflibercept if HbA1C level $\geq 12\%$ / 107 MMOL.
- NO Ranibizumab or Aflibercept if vision $\leq 3/60$ and fibrosis / Disorganisation of retinal inner layers (DRIL) on OCT.

5.5 General assessment and treatment guidelines

- There should be information leaflets available detailing the procedure and associated risks and benefits. Leaflets are available to order free of charge at www.healthbrochures.ie.
- For all procedures performed there must be informed consent obtained and recorded from the patient.
- All planned procedures must be recorded on the OptoMize system.
- All procedures performed must be recorded on the OptoMize system.
- Where there is no option in the 'drop down menu' for a specific procedure, the procedure must be recorded as 'other procedure' with details recorded in the comment field.

5.6 Management of non-diabetic eye disease referrals

Clinician review will determine those that may require a more timely assessment.

All referrals found to have non-diabetic eye disease at screening are deemed to require further assessment.

Following confirmation of the diagnosis, each centre should check if patient is under the care of another ophthalmologist.

- If so, refer back to that ophthalmologist for ongoing care and discharge patient back to screening for annual recall with discharge images entered on OptoMize.
- If patient is not under the care of another ophthalmologist, book care plan as per local standard e.g. to cataract clinic or glaucoma clinic in the patient's immediate catchment area and discharge patient back to screening for annual recall with discharge images entered on Optomize.

5.7 Communication of results

It is the responsibility of the treatment clinic to communicate the result of the examination and all treatments performed to:

- Relative diabetes care clinicians in primary and secondary care.
- Current ophthalmologist if recorded by patient.

6. Management of attendance

There should be a departmental attendance policy to include a 'did not attend' (DNA) /cancellation policy. The programme recommends following up-to-date HSE guidelines in the management of DNA cases.

Medical records of patients who DNA or cancel appointments, should be reviewed by a clinician, to decide on the timing of future appointments.

7. Governance

The management of Diabetic RetinaScreen requires regular operational meetings between hospital administration, clinic nursing staff and clinical leads. Regular management reports include waiting times, capacity of the service, management of DNAs in addition to reports on administrative workloads, including backlogs or as required by the programme.

Quarterly multi-disciplinary team (MDT) meetings are required. These can take place virtually between the treatment center clinicians and Diabetic RetinaScreen to review referrals and the failsafe process.

8. References

- ¹ (KemptJH, O'Colmain B, Leaske M, Haffner S, Klein, Moss S. et al. The prevalence of diabetic retinopathy among adults in the United States. Archives of ophthalmology. 2004;122(4:552.3)
- ² Royal College of Ophthalmologists (2009) Guidance on Intravitreal Injection Therapy. Accessible at <https://www.rcophth.ac.uk/wp-content/uploads/2018/02/Intravitreal-Injection-Therapy-August-2018-2.pdf>
- ³ Standards for Quality Assurance in Diabetic Retinopathy Screening, First edition <https://www.diabeticretinascreen.ie/fileupload/Documents/DR-PUB-Q-1%20Rev%204%20Standards%20for%20Quality%20Assurance%20in%20Diabetic%20Retinopathy%20Screening.pdf>
- ⁴ Diabetic Retinopathy Clinical Research Network (DRCnet).

Notes

