

Diabetic 
RetinaScreen

An Clár Náisiúnta Scagthástála Reitíní do Dhiabéitigh
The National Diabetic Retinal Screening Programme

Standards for Quality Assurance in Diabetic Retinopathy Screening

First edition
Revision 5

Contents

Foreword	2
Preface	3
Members, authors and contributors	4
1. Introduction	6
2. Background to diabetic retinopathy screening in Ireland	8
3. Principles of the National Diabetic Retinal Screening Programme	9
4. Standards development and monitoring	11
5. Quality assurance objectives and standards	12
6. References	25
7. Definitions	26
Appendix 1 Non-diabetic retinopathy eye disease	27

Foreword

Diabetes is a serious life-long disorder. As with other chronic disorders it cannot be cured, only controlled. Control of the complications of diabetes is essential to the quality of life of those affected. The health service in Ireland spends large amounts of funding on diabetes care, particularly on treating complications. Better management and control of diabetes, together with early detection and treatment will reduce complications, benefitting both the individual and health services.

Retinopathy is one of the most common serious complications of diabetes. This sight-threatening condition is preventable by early detection, through population screening and treatment.

The National Screening Service (NSS) is responsible for the development and implementation of Diabetic RetinaScreen – The National Diabetic Retinal Screening Programme. The NSS is part of the Health Service Executive National Cancer Control Programme (NCCP) and has gained significant expertise over many years in planning, implementing and managing effective population-based call, re-call screening programmes in Ireland. The NSS governs BreastCheck – The National Breast Screening Programme, CervicalCheck – The National Cervical Screening Programme and the recently introduced BowelScreen – The National Bowel Screening Programme.

Diabetic retinopathy is the leading cause of new cases of preventable blindness in the working age population (20-75) in developed nations¹⁻³. No screening test is 100 percent accurate. Therefore, to achieve maximum public health benefit from a population-based diabetic retinopathy screening programme, every aspect of the service must be fully quality assured. It is incumbent upon the NSS to ensure that the quality assurance standards are met, and where possible, exceeded. It is these standards that will allow each person who participates in the programme to have undoubted confidence in its ability to deliver. This confidence in the programme will allow it to reach its ultimate goal of reducing the incidence of preventable blindness among the screened population.

I would like to thank all those involved for committing both their time and expertise in developing a set of standards that will ensure a screening service that operates in line with the highest achievable standards.

Ms Majella Byrne
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Preface

The primary goal of Diabetic RetinaScreen – The National Diabetic Retinal Screening Programme is to reduce the risk of sight loss among people with diabetes by the early detection and treatment of sight-threatening retinopathy.

Eye screening can detect diabetic retinopathy at an early stage when it is easier to treat and treatment is more successful. The experience of other international diabetic retinopathy screening programmes has shown that of the population screened and treated, six per cent are prevented from going blind within a year of treatment and 34 per cent within 10 years of treatment⁶.

The eligible population that will be invited for screening are aged 12 and older, diagnosed with diabetes and excluding those who do not have perception of light in both eyes.

There are a number of steps that make up the complex process that is diabetic retinopathy screening. Each aspect of the screening process must be fully quality assured. Quality assurance is process-driven, and specific steps help define and achieve screening goals.

To ensure continual adherence to quality assurance across every aspect of the National Diabetic Retinal Screening programme, a set of written and auditable quality assurance (QA) standards needed to be developed. The performance of the programme will be monitored and measured against these standards.

The National Screening Service (NSS) Quality Assurance Committee for Diabetic Retinopathy Screening was established in December 2011 to develop quality assurance standards, based on the NHS Scotland (National Diabetes Retinopathy Screening), NHS England standards and the HSE Framework Document for a population-based diabetic retinopathy screening programme in Ireland. The standards were also developed to take into consideration the existing screening programmes in Ireland and recognised international best practice.

At the time of publishing, the NSS was not responsible for the treatment aspect of the programme. Governance of treatment has since come under the remit of the NSS and accordingly, standards for treatment are being developed with the relevant Diabetic RetinaScreen Clinical Advisory Group.

This first edition of Standards for Quality Assurance in Diabetic Retinopathy Screening represents best practice. Rigorous adherence to best practice will ensure that the screening programme has a significant impact on reducing the incidence of blindness in those with diabetes in Ireland.

Mr Simon Kelly
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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) in developed nations¹⁻³.

Diabetes mellitus

Diabetes mellitus, or simply diabetes, is a group of metabolic diseases in which a person has high blood sugar, either because the body does not produce enough insulin, or because cells do not respond to the insulin that is produced. This high blood sugar produces the classical symptoms of polyuria (frequent urination), polydipsia (increased thirst) and polyphagia (increased hunger).

There are three main types of DM. Type 1 DM results from the body's failure to produce insulin, and presently requires the person to inject insulin or wear an insulin pump. This form was previously referred to as 'insulin-dependent diabetes mellitus' (IDDM) or 'juvenile diabetes'. Type 2 DM results from insulin resistance, a condition in which cells fail to use insulin properly, sometimes combined with an absolute insulin deficiency. This form was previously referred to

as non insulin-dependent diabetes mellitus (NIDDM) or 'adult-onset diabetes'. The third main form, gestational diabetes, occurs when pregnant women without a previous diagnosis of diabetes develop a high blood glucose level. It may precede development of Type 2 DM.

Diabetic retinopathy

Diabetic retinopathy is a microvascular complication associated with diabetes.

Over time, diabetes affects the circulatory system of the retina. The earliest phase of the disease is known as 'background diabetic retinopathy'. In this phase, the arteries in the retina become weakened and leak, forming small, dot-like hemorrhages. These leaking vessels often lead to swelling or edema in the retina and decreased vision.

The next stage is known as 'proliferative diabetic retinopathy'. In this stage, circulation problems cause areas of the retina to become oxygen-deprived or ischemic. New, fragile vessels develop as the circulatory system attempts to maintain adequate oxygen levels within the retina. This is called neovascularization. Unfortunately, these delicate vessels hemorrhage easily. Blood may leak into the retina and vitreous, causing spots or floaters, along with decreased vision.

In the later phases of the disease, continued abnormal vessel growth and scar tissue may cause serious problems such as retinal detachment and glaucoma.

The duration of diabetes is a major risk factor for the development of retinopathy. Research has shown that retinopathy develops within five years of diagnosis in 25 per cent of people with Type 1 diabetes, 40 per cent of people with Type 2 diabetes taking insulin and 24 per cent of people with Type 2 diabetes who are not taking insulin⁴.

Timely and appropriate care for people with diabetes can significantly reduce visual loss over time, improve patients' quality of life, and reduce the financial burden associated with the complications of visual impairment. Screening, followed by treatment of sight-threatening retinopathy, has been shown to be effective.

Diabetic retinopathy screening

Retinopathy is a treatable condition with optimal medical management as a first line defense, where early detection through retinopathy screening facilitates timely treatment in the event of diabetic eye disease developing. The potential benefits of screening include⁵:

- Early detection and treatment of sight threatening diabetic retinopathy.
- Enhanced length and/or quality of life which might result from a delay in onset of the disease or in the severity of retinopathy.
- Saving of healthcare resources as a result of reduced levels of care required for diabetes complications (reduced hospital admissions, cost acquired from blindness etc.).

The experience of other international diabetic retinopathy screening programmes has shown that of the population screened and treated, six per cent are prevented from going blind within a year of treatment and 34 per cent within 10 years of treatment⁶. In addition, the costs of preventing blindness through screening for retinopathy are much lower than those for treatment of advanced lesions.

Background to diabetic retinopathy screening in Ireland

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 2006 the Department of Health and Children made a number of policy guidance recommendations on the model of care and services for people with diabetes. They recommended a structured diabetic retinopathy screening programme as a priority.

In Ireland, early detection through a structured national diabetic retinal screening (DRS) programme was identified as a priority by the Expert Advisory Group for Diabetes in 2008⁷. This priority was subsequently adopted by the HSE National Diabetes Programme, and the national screening programme was scheduled for introduction in 2011.

In 2011 the HSE National Diabetes Programme tasked the National Screening Service (NSS) with the development and implementation of the National Diabetic Retinal Screening Programme.

The NSS, which is part of the Health Service Executive National Cancer Control Programme (NCCP), has gained significant expertise in implementing and managing successful population based call, recall screening programmes in Ireland. The NSS governs BreastCheck – The National Breast Screening Programme, CervicalCheck – The National Cervical Screening Programme and BowelScreen, the recently introduced National Bowel Screening Programme.

Diabetic RetinaScreen – The National Diabetic Retinal Screening Programme commenced in the first quarter of 2013.

Principles of the National Diabetic Retinal Screening Programme

The National Diabetic Retinal Screening Programme will set standards, monitor the programme and carry out quality assurance audits.

The following are the principles of the National Diabetic Retinal Screening Programme, which is a population-based, call, re-call programme with an annual screening interval:

- Eligible patients will include all those with diagnosed diabetes, aged 12 and over and who are not excluded*.
- The screening service will be accessible to all eligible patients.
- Screening will be carried out using digital retinal photography.
- A register of eligible people with diagnosed diabetes will be established and maintained by the programme office.
- Designated and approved grading centres will grade the images.
- There will be timely referral, assessment and treatment of abnormalities discovered.
- There will be timely feedback to the screening programme of the result of screening events and of referrals.
- There will be a robust system of clinical governance and quality assurance.

- All aspects of the diabetic retinopathy screening programme will be quality assured to ensure a positive screening pathway and experience for the client.

* The only exclusion category will be those who 'have no perception of light in both eyes' (NPL).

Eligible population

Screening will be offered to people with diagnosed diabetes, aged 12 and over, registered with the programme. All international evidence and research shows that there is no advantage to screening for retinopathy before the age of 12. This is due to the link between retinopathy and puberty.

Cohort

The eligible population is an estimated 190,000+ people and continues to expand. This is based upon 5.6 per cent of the adult population (from the age of 20+) and one per cent of the child population (aged 12-19) diagnosed with diabetes.

Programme overview

The National Diabetic Retinal Screening Programme has an initial register of people diagnosed with diabetes. The register is compiled from information received from national health schemes including the Medical Card Scheme, Drugs Payment Scheme and Long Term Illness Scheme. General practitioners (GPs) will also have the opportunity to register those diagnosed with diabetes. This register will be used to invite people to participate in the programme.

Each person on the register will be sent an invitation letter inviting them to consent to participation in the programme. Once the programme has received verbal consent in addition to nominated GP details, an appointment will be scheduled by the programme. A parent or guardian must provide consent on behalf of those aged under 16.

Screening will take place at a number of locations at either a fixed or mobile unit.

Screening will be carried out using digital photography. In certain cases, where digital photography is not possible, a slit lamp examination may be offered.

Results will be sent by post within three weeks of having the screening test. The nominated GP will also receive a copy of the result and any associated management recommendation.

Management recommendations:

- A. Return to annual routine screening.
- B. Referral to a designated ophthalmology clinic for further assessment. This service is free of charge.
- C. Additional screening using slit lamp technology, or further digital photography.

The programme will establish and manage a pathway for each of the above.

It is envisaged that approximately 25 per cent of individuals screened will require further assessment at an ophthalmology clinic. Eighteen per cent of referrals will be due to the detection of diabetic retinopathy and seven per cent of referrals will be as a result of non-diabetic eye disease.

Other eye changes detected, that are not due to diabetes (e.g. glaucoma or cataract) will be reported. In such cases, a referral will be made by the programme to an ophthalmology clinic.

The ophthalmology clinic will provide any necessary treatment and follow-up. This service is free of charge. The GP will be sent a copy of all correspondence relating to attendance, diagnosis, treatment and discharge.

Standards development and monitoring

Quality assurance (QA) standards are a vital component of a quality management system. In order to ensure the safety and effectiveness of a national screening programme, QA standards should be clearly linked to programme objectives and must be measurable, evidence-based and provide comparable information over time.

Each quality standard has a description (or criteria) and target associated with it. Standards must be measurable (quantitative) and the criteria chosen should be valid, reliable and feasible.

The QA standards are:

- Focused on clinical issues and non-clinical factors that impact on the quality of care provided throughout the screening process
- Written in simple language
- Based on evidence and best practice
- Take account of other relevant recognised standards and clinical guidelines
- Clear and measurable
- Reviewed and revised at appropriate intervals
- Are written in terms of business days which are defined as Monday to Saturday inclusive i.e. 6 business days per week

Quality assurance objectives and standards

Objective 1:

Identification of cohort: To ensure the register of eligible population is complete

Standard	Criteria	Minimum	Achievable
1	Single collated list (register) of all people with diabetes and systematic call, re-call from a single management system.	To be present	To be present
2	Acquire and maintain demographic details for eligible persons aged ≥ 12 years who have been diagnosed with diabetes.	Annual	Annual
3	Proportion of GPs participating in the National Diabetic Retinal Screening Programme.	$\geq 95\%$	100%
4	Each person listed on the register should have a unique identifier number.	100%	100%
5	There must be processes in place to identify clients with more than one record on the diabetic screening register and to merge the records into a single record.	Min: < 5%	< 1% of records at any one time
6	Regular register cleansing using national standard operating procedure (SOP).	6 monthly	Monthly
7	Regular back-ups and secure storage of the personal health information and related data held on the register.	Nightly back-up	Nightly back-up
8	All personal health information transferred between the Diabetic Retinopathy Screening Programme register and third party service providers must use Virtual Private Networks (VPNs) or secure email systems and must be encrypted to an accepted standard or protocol.	To be present	To be present

KPI -1(2) Numerator = total number of eligible people on register at final day of reporting period.
Denominator = number of eligible people (as defined by CSO multiplied by rate of diabetes) at final day of reporting period.

KPI -1(3) Numerator = number of GPs participating in the DR National Programme at final day of reporting period.
Denominator = number of GPs registered in the country (Irish Medical Council) at final day of reporting period.

KPI -1(5) Numerator (%) Numerator = number of new eligible clients merged (duplicate) within the reporting period.
Denominator Denominator = total number of new eligible clients identified within the reporting period.

Objective 2:

Call/re-call process: To invite all eligible persons (where the programme has been informed of them having diabetes) to participate in the programme and attend for the diabetic retinopathy screening test

Standard	Criteria	Minimum	Achievable
1	All eligible people (where the programme has been informed of a diagnosis of diabetes) will receive a written invitation to attend for screening at least once every year, unless a current screening result is already on the call, re-call module.	≥95%	100%
2	All new clients will be invited to participate in the screening programme within 1 month of the programme being notified of eligibility.	≥95%	100%
3	All new clients who have consented will be offered a first screening appointment within 2 months of the date of the provider receiving client details.	≥90%	100%

KPI -2(1) Numerator = number of people invited during the report period plus number of suspensions*.
Denominator = eligible population.

*Suspensions – those marked inactive due to being under the care of an ophthalmologist for the treatment/follow-up of diabetic retinopathy (DR) or of an eye condition other than DR at final day of report period.

Patients who are not invited to be screened because of other factors, e.g. terminal illnesses, physical or intellectual disability may still be eligible but will be made inactive for an agreed period of time. Patients who choose not to participate in the screening programme will be 'deconsented' from the diabetic retinopathy screening programme.

The exclusion category 'having no perception of light in both eyes' (NPL) will be distinguished from all other categories. The exclusion category 'having no perception of light in both eyes' (NPL) will be removed from the denominator, where this information is available. No other category will be removed from the denominator.

KPI -2(2) Numerator = number of new unique eligible clients notified to the programme (during a reporting period) who were offered an invitation to participate in screening within one month of the programme being notified of their eligibility.
Denominator = number of new unique eligible clients notified to the programme (during a reporting period).

KPI -2(3) Numerator = number of eligible clients who consented to the programme (during a reporting period) who were offered a screening appointment within 2 months (52 business days) of the date of the provider receiving client details.
Denominator = number of eligible clients who consented to the programme (during a reporting period).

Objective 3:

To maximise uptake: To maximise the number of invited persons receiving the test

Standard	Criteria	Minimum	Achievable
1	The proportion of those invited to screening who attend and have a satisfactory outcome*.	≥70%	≥ 80%

KPI -3(1) Numerator = number of unique eligible clients invited for screening during the reporting period who attended an appointment and had a satisfactory outcome*.
Denominator = the number of unique eligible people with diabetes invited for screening within the reporting period.

*Outcome = satisfactory by digital photography or slit lamp biomicroscopy (i.e. gradable with result).

Objective 4:

To maximise performance of screening test: To ensure photographs are of adequate quality

Standard	Criteria	Minimum	Achievable
1	Percentage of clients where a gradable digital image cannot be obtained.	Less than 7% total ungradable*	Programme should have between 2.5 and 6.3% total ungradable*

KPI -4(1) Numerator = number of unique clients screened** within the reporting period who had an outcome of ungradable, unobtainable or unassessable.

Denominator = total number of unique clients screened** within the reporting period.

*Ungradable – any image that does not have a RxMx grade.

**Based on date of last screening in the period if >1 screening event took place in the reporting period.

Objective 5:

To maximise performance of screening test: To ensure grading is accurate

Standard	Criteria	Minimum	Achievable
1	Every registered grader to participate in ongoing training.	80% of grading staff are compliant	100% of grading staff are compliant
2	Evidence of clinical lead (or nominated senior grader) providing outcomes of the ongoing training to grading staff on a regular basis.	Completed 6-monthly	Completed 6-monthly
3	Second full disease grading for images with diabetic retinopathy or other non-diabetic eye disease outcome on first grading.	100%	100%
4	Normal images with no diabetic retinopathy which are re-graded independently as part of quality assurance.	10% of normal images re-graded	10% of normal images re-graded
5	Arbitration grading of all image sets where there is disagreement as to the grade between the first full disease grading and the second full disease grading.	100%	100%
6	Referral outcome regrading of all image sets that are deemed referable to ophthalmology clinic.	100%	100%

- KPI-5(1) Numerator = number of registered graders participating in ongoing training in a defined period.
Denominator = total number of graders registered.
- KPI-5(3) Numerator = number of image sets with diabetic retinopathy or non-diabetic eye disease in a time period where second full disease grading took place.
Denominator = total number of image sets with diabetic retinopathy or non-diabetic eye disease at first full disease grading in the same time period.
- KPI-5(4) Numerator = number of images sets with no diabetic retinopathy after first full disease grading in a time period that are re-graded.
Denominator = total number of image sets with no diabetic retinopathy after first full disease grading in the same time period.
- KPI-5(5) Numerator = number of image sets where arbitration grading was carried out in a time period.
Denominator = total number of images that required arbitration grading in the same time period.
- KPI-5(6) Numerator = number of image sets where referral outcome grading was carried out in a time period.
Denominator = total number of image sets that are deemed referable to ophthalmology clinic following first full disease, second full disease or arbitration grading in the same time period.

Objective 6:

To minimise harm: To ensure GP and client are informed of all test results

Standard	Criteria	Minimum	Achievable
1	Time between screening visit and issuing of result letters to GP to be a maximum of 12 business days or less.	95% ≤ 12 business days	100% ≤ 12 business days
2	Time between screening visit and issuing of result letter to client to be 15 business days or less.	95% ≤ 15 business days	100% ≤ 15 business days

KPI -6(1): Numerator = number of unique clients attending a screening appointment within the reporting period* for whom a screening result letter was issued to the GP within 12 business days of the screening visit.
Denominator = number of unique clients attending a screening appointment within the reporting period*.

KPI -6(2) Numerator = number of unique clients attending a screening appointment within the reporting period* to whom a screening result letter was issued within 15 business days of the screening visit.
Denominator = number of unique clients attending a screening appointment within the reporting period*.

*Where >1 screening visit occurs in the reporting period the last shall be used.

Objective 7:

To minimise harm: Ensure timely referral of all clients with screening results

Standard	Criteria	Minimum	Achievable
1	Time between final outcome and issue of referral request (letter) for all referrals to be a maximum of 12 business days.	95% referred in ≤ 12 business days.	100% referred in ≤ 12 business days.

KPI -7(1): Numerator = number of clients attending a screening visit that required a referral request for whom a referral request letter was issued to the ophthalmology clinic within 12 business days of the screening visit.
Denominator = number of clients having attended a screening visit within the reporting period that required a referral request.

Objective 8:

To minimise harm: To ensure timely consultation for all screen-positive clients (those with referable retinopathy)

Standard	Criteria	Minimum	Achievable
1	Time between notification of positive test and consultation.		
	1. Urgent (R3aM0, R3aM1, R3sM0, R3sM1, Age-related Macular Degeneration*).	1a. 60% ≤ 12 business days 1b. 95% ≤ 24 business days	1. 95% ≤ 12 business days
	2. Routine (R2M0, R2M1, R1M1, Incomplete Examination (I), Ungradable Image (U), non-diabetic eye disease*).	2a. 70% ≤ 78 business days 2b. 95% ≤ 108 business days	2. 95% ≤ 78 business days

* See Appendix

KPI-8(1₁) Numerator = number of clients attending a screening visit within the reporting period whose final grading outcome was R3aM0, R3aM1, R3sM0, R3sM1 or Age-related Macular Degeneration receiving consultation within 12 or 24 business days of notification of positive test.

Denominator = number of clients attending a screening visit within the reporting period whose final grading outcome was R3aM0, R3aM1, R3sM0, R3sM1 or Age-related Macular Degeneration and who were referred to an ophthalmology clinic.

KPI-8(1₂) Numerator = number of clients attending a screening visit within the reporting period whose final grading outcome was R2M0, R2M1, R1M1, Incomplete Examination (I), Ungradable Image (U) or non-diabetic eye disease receiving consultation within 78 or 108 business days of notification of positive test.

Denominator = number of clients attending a screening visit within the reporting period whose final grading outcome was R2M0, R2M1, R1M1, Incomplete Examination (I), Ungradable Image (U) or non-diabetic eye disease (and who were referred to an ophthalmology clinic).

Objective 9:

To minimise harm: To follow-up screen positive clients (those with referable retinopathy) (failsafe)

Standard	Criteria	Minimum	Achievable
1	All screen positive clients (those with referable retinopathy) who do not attend for further assessment/treatment are contacted by the programme and an outcome recorded for each.	100%	100%

KPI-9(1) Numerator = number of clients attending for screening with a screen positive result that are followed-up as they have not attended for further treatment/assessment (within a time period).

Denominator = total number of clients with a screen positive result that require follow-up where a notification of assessment/treatment has not been received for ophthalmology within a time period.

Objective 10:

To minimise harm: To ensure timely slit lamp biomicroscopy assessment of clients recorded as ungradable

Standard	Criteria	Minimum	Achievable
1	Maximum time between digital screening visit and assessment by follow-up slit lamp biomicroscopy to be scheduled to occur within 42 business days of the client's digital screening visit.	80% ≤ 42 business days	90% < 42 business days

KPI-10(1) *Numerator = number of clients attending for screening, to whom a referral to slit lamp biomicroscopy was recommended, to be scheduled to occur within 42 business days of the client's digital screening visit*
Denominator = number of clients attending for screening to whom a referral to slit lamp was recommended.

Objective 11:

Treatment: To ensure timely treatment of those requiring referral to ophthalmology

Standard	Criteria	Minimum	Achievable
1	Ensure timely treatment of those requiring referral for treatment. Calculated based on time between listing and first treatment following screening. 1. Urgent (R3aM0, R3aM1, R3sM1, R3sM0). 2. Routine (R2M0, R2M1, R1M1, Incomplete Examination (I), Ungradable Image (U))	1. 90% ≤ 12 business days 2. 70% ≤ 60 business days	1. 95% ≤ 12 business days 2. 95% ≤ 60 business days

KPI-11(1,) Numerator = number of clients with referral reason R3aM0, R3aM1, R3sM1, R3sM0 attending for treatment in the reporting period who are listed at first consultation and where date of treatment minus the date of listing ≤ 12 business days.
 Denominator = number of clients with referral reason R3aM0, R3aM1, R3sM1, R3sM0 attending for treatment in the reporting period who are listed at first consultation.

KPI-11 (1₂) Numerator = number of clients with referral reason R2M0, R2M1, R1M1, Incomplete Examination (I) or Ungradable Image (I) attending for treatment in the reporting period who are listed at first consultation and where date of treatment minus the date of listing ≤ 60 business days.
 Denominator = number of clients with referral reason R2M0, R2M1, R1M1, Incomplete Examination (I) or Ungradable Image (U) attending for treatment in the reporting period who are listed at first consultation.

The criteria of 'listed at first visit' has been added to this objective. Programmes are now only required to track those patients who are listed for treatment at their first consultation with an ophthalmologist following referral from screening. Programmes are not required to track those patients that the ophthalmologist does not list for treatment at the first consultation and instead chooses to monitor for a period of time before listing for treatment.

This does not preclude failsafe tracking arrangements of patients who are not listed for laser at their first assessment, but these patients no longer form part of this objective.

Objective 12:

Treatment: To minimise time between screening event and first treatment

Standard	Criteria	Minimum	Achievable
1	<p>Minimise time between screening event and first treatment. Calculated based on time between screening visit and first treatment. Time does not exceed:</p> <p>1. Urgent (referred as R3aM0, R3aM1, R3sM1, R3sM0).</p> <p>2. Routine (referred as R2M1, R2M0, R1M1, Incomplete Examination (I), Ungradable Image (U)).</p>	<p>1. 70% ≤ 36 business days</p> <p>2.a. 70% ≤ 90 business days</p> <p>2.b. 95% ≤ 108 business days</p>	<p>1. 95% ≤ 36 business days</p> <p>2. 95% ≤ 90 business days</p>

KPI-12(1_a) Numerator = number of clients with outcome R3aM0, R3aM1, R3sM1, R3sM0 attending for treatment within the reporting period for whom the time between the screening visit and first treatment was ≤ 36 business days.
Denominator = number of unique clients with outcome R3aM0, R3aM1, R3sM1, R3sM0 attending for treatment within the reporting period.

KPI-12 (1_{2a}) Numerator = number of clients with outcome R2M1, R1M1, R2M0, Incomplete Examination (I) or Ungradable Image (U) attending for treatment within the reporting period for whom the time between the screening visit and first treatment was ≤ 90 business days.
Denominator = number of unique clients with outcome R2M1, R1M1, R2M0, Incomplete Examination (I) or Ungradable Image (U) attending for treatment within the reporting period.

KPI-12 (1_{2b}) Numerator = number of clients with outcome R2M1, R1M1, R2M0, Incomplete Examination (I) or Ungradable Image (U) attending for treatment within the reporting period for whom the time between the screening visit and first treatment was ≤ 108 business days.
Denominator = number of unique clients with outcome R2M1, R1M1, R2M0, Incomplete Examination (I) or Ungradable Image (U) attending for treatment within the reporting period.

Objective 13:

Outcome: To ensure regular collection of data indicating levels of new blindness due to diabetic retinopathy

Standard	Criteria	Minimum	Achievable
1	On an ongoing basis it is the responsibility of the photography and grading service and the ophthalmology clinics to electronically return data to the programme through established interfaces.	To be present	

Objective 14:

Workforce training: To ensure that all photography and grading staff involved in the delivery of the programme are appropriately trained, competent and accredited by a recognised and approved educational body agreed by NSS.

Standard	Criteria	Minimum	Achievable
1	Ensure that all administrative staff are appropriately trained and follow local procedures/protocols. Evidence of same should be available to the NSS/programme as requested.	To be present	To be present
2	Ensure that staff classified as graders of retinal images are fully trained and qualified in accordance with a recognized and approved educational body agreed by NSS. A record of same should be maintained and be retrievable for quality control purposes/audit/inspection. Evidence should be available to the NSS/programme as requested.	100%	100%
3	Ensure that screening staff (staff taking retinal images) are fully trained and qualified in accordance with a recognized and approved educational body agreed by NSS. A record of same should be maintained and be retrievable for quality control purposes/audit/inspection. Evidence should be available to the NSS/programme as requested.	100%	100%
4	Diabetic retinopathy screening service providers must have a system in place to ensure that the competency of individual graders is assessed by ongoing quality assurance. A record of same should be maintained and be retrievable for quality control purposes/audit/inspection. Evidence should be available to the NSS/programme as requested.	To be present	To be present
5	Case review and audit must be undertaken by the service provider to facilitate continuing improvement. A record of same should be maintained and be retrievable for quality control purposes/audit/inspection. Evidence should be available to the NSS/programme as requested.	To be present	To be present
6	Evidence of external quality assurance (EQA) should be maintained and available for quality control purposes/audit/inspection. Evidence should be available to the NSS/programme as requested.	To be present	To be present

KPI-14(2) Numerator = number of staff classified as graders of retinal images are fully trained and qualified in accordance with a recognized and approved educational body agreed by NSS.
Denominator = total number of staff classified as graders.

KPI-14(3) Numerator = number of staff classified as screening staff (staff taking retinal images) are fully trained and qualified in accordance with a recognized and approved educational body agreed by NSS.
Denominator = total number of staff classified screening staff (staff taking retinal images).

Objective 15:

Workforce: To ensure optimum workload for all graders in order to maintain expertise

Standard	Criteria	Minimum	Achievable
1	To ensure optimum workload for all graders in order to maintain expertise.	95% of staff recorded on grading system.	100% of staff recorded on grading system.
	<p>Graders who do not hold additional roles as either an optometrist or an ophthalmologist must grade a minimum of 1,000 client image sets per annum.</p> <p>Graders who are also qualified optometrists and undertake this role and do not grade 1,000 image sets must grade a minimum of 500 image sets and then supplement this number with test image sets: 500 – 699 min – 9 test sets pa 700 – 899 min – 8 test sets pa 900 – 999 min – 7 test sets pa</p> <p>Ophthalmologists who are clinical leads and are medical retina specialists who are registered on the system as graders are not required to grade a minimum number of image sets.</p> <p>Ophthalmologists who are clinical leads and are not medical retina specialists and are grading on the system are required to achieve a minimum number of 500 grades per annum.</p>		
	Graders who grade in more than one screening programme should achieve a minimum of 1,000 grades per annum across all programmes.		
	A record of the above should be maintained and be retrievable for quality control purposes/audit/inspection. Evidence of same should be available to the NSS/programme as requested.	To be present	To be present

Objective 16:

Commissioning – screening interval: To ensure that the screening interval is annual

Standard	Criteria	Minimum	Achievable
1	All eligible people with diabetes known to the programme are invited for screening at least once every 11-13 months.	90%	100%

KPI-16(1): Numerator = number of unique eligible clients on the programme register who are waiting between 11 and 13 months for an invitation on the last day of the reporting period.
Denominator = number of unique eligible clients on the register on last day of reporting period.

Note: This looks at the 'round slippage' i.e. proportion of eligible clients not receiving invitation for screening within 11-13 months of becoming eligible*.

*Clients become eligible when they are uploaded to DRS register or when they are discharged back to routine recall from assessment/treatment.

Objective 17:

Governance – quality assurance: To ensure the service participates in quality assurance

Standard	Criteria	Minimum	Achievable
1	An external quality assurance process is required to ensure the service is quality assured and is assessed against the standards (participation in a peer/audit review process as deemed appropriate by the NSS/programme).	Three Years	Three Years
2	Multidisciplinary Team (MDT) meetings are essential in the delivery of a quality assured service. Key service providers who are involved in the delivery of the screening service must attend these meetings on a regular basis (as defined by the NSS/programme).	Periodic meetings as defined by NSS/programme	Periodic meetings as defined by NSS/programme

Objective 18:

Outcome: To monitor inappropriate referrals following screening

Standard	Criteria	Minimum	Achievable
1	Monitor inappropriate referrals following screening as follows: 1. False positive rate of diabetic retinopathy test (neither further photograph or clinical examination warranted referral).	≤ 15% of patients referred	≤ 10% of patients referred

KPI-18(1) Numerator = number of clients screened within the reporting period who were referred to ophthalmology and who were returned to routine re-call following assessment.
Denominator = number of clients screened within the reporting period who were referred to ophthalmology.

Objective 19:

Facilities – access area

	Standard	Criteria	Minimum	Achievable
Access area	1	There should be adequate waiting area for clients.	100%	100%
	2	There should be adequate reception area for clients.	100%	100%

Objective 20:

Facilities – administrative area

Standard	Criteria	Minimum	Achievable
1	There should be adequate office space to house the administrative support for the service ensuring compliance with health and safety guidelines.	100%	100%
2	There should be adequate space for secure storage of the programme clinical records of all current clients within this administrative area.	100%	100%
3	There should be a provision to enter data into the programme computerised management system from this administrative space.	100%	100%
4	Computer and printer hardware as well as dedicated telephone and fax facilities should be available in this administrative space.	100%	100%

Objective 21:

Data protection and confidentiality

Standard	Criteria	Minimum	Achievable
1	The contracted service providers will be registered with the Data Protection Commissioner and will comply with directives regarding the use and security of personal information, subject to the provisions of the Data Protection Act 1988 and the Data Protection (Amendment) Act 2003.	Service providers registered	Service providers registered

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Definitions

Term	Criteria
Consultation	Attendance at a hospital eye clinic for assessment of retinopathy
First treatment	The date at which treatment for diabetic retinopathy was first carried out following listing
First visit	An appointment with a specialist directly resulting from a referral from a screening service
Issuing	The production of result notification, e.g. printing of notification letters
Listing	The date at which a decision to treat by laser was recorded by the specialist
Notification	The issuing of a result letter
Referred	An appropriate referral request was made
Referred as	With a final grading outcome as specified
Result letters	An appropriate indication to an entitled party of: a) the date at which the patient attended the screening encounter b) the final outcome of grading the patient image sets c) the action recommended
Screening encounter	Date of patient attendance for a screening event: photography where assessable images obtained, or otherwise date of slit-lamp biomicroscopy

Appendix

Non-diabetic retinopathy eye disease

Description	Context / explanation	Conditions for Referral	Requires Referral
BRVO	Clinical finding of Branch Retinal Vein Occlusion of the eye	As defined	Y
CRVO	Clinical finding of Central Retinal Vein Occlusion of the eye	As defined	Y
BRAO	Clinical finding of Branch Retinal Arterial Occlusion of the eye	As defined	Y
CRAO	Clinical finding of Central Retinal Arterial Occlusion of the eye	As defined	Y
Arterial emboli	Retinal arterial emboli of the eye	As defined	Y
Retinitis	Inflammatory disorder of the retina of the eye	As defined	Y
Cataract	An opacity of the crystalline lens of the eye	May only be observed during slit lamp	Y
Glaucoma	A progressive optic neuropathy characterised by a particular pattern of optic nerve and visual field damage	REFER IF CUP DISC RATIO ≥ 0.8 OR IF ASYMMETRY >0.3	Y
Age-related Macular Degeneration	Clinical finding of Age Related Macular Degeneration	REFER IF SUBRETINAL / INTRARETINAL HAEMORRHAGE +/- EXUDATE	Y
Amybyopia	Reduced vision in one or both eyes caused by visula deprivation in childhood	First diagnosis of this condition requires referral WITH DR CHANGES	Y
Pigmented Retinal Lesion	Clinical Finding of Pigmented Retinal Lesion	REFER LESIONS > 3 DISC AREAS OR PIGMENTED LESION WITH OVERLYING LIPOFUSCIN (ORANGE PIGMENT)	Y
Haemorrhage Exudate	Clinical finding of Haemorrhage Exudate	SEE AGE RELATED MACULAR DEGENERATION	Y



An tSeirbhís Náisiúnta Scaghástála
National Screening Service

The National Screening Service is part of the Health Service Executive National Cancer Control Programme. It encompasses BreastCheck – The National Breast Screening Programme and CervicalCheck – The National Cervical Screening Programme, BowelScreen – The National Bowel Screening Programme and Diabetic RetinaScreen – The National Diabetic Retinal Screening Programme.

ISBN 978-1-907487-11-8



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DR/PUB/Q-1 Revision 5.0
ISBN 978-1-907487-11-8