Diabetic RetinaScreen

An Clár Náisiúnta Scagthástála Reitiní do Dhiaibéitigh
The National Diabetic Retinal Screening Programme

Standards for **Quality Assurance in Diabetic Retinopathy Screening**

Revision 6.1

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Foreword

Diabetes is a serious life-long, condition. Management of diabetes and its associated complications is essential to the quality of life of people with diabetes. Diabetes can be treated and its consequences avoided or delayed with diet, physical activity, medication and regular screening and treatment for complications benefitting both people with diabetes and the health services that support them.

Eye screening is a critical part of a person's overall diabetic management and care. Retinopathy is one of the most common and serious complications of diabetes. It can cause blindness if left undiagnosed and untreated. Diabetic retinopathy is the leading cause of new cases of preventable blindness in the working age population (20-75) in developed nations[1-3]. Screening can prevent or reduce damage to the eyesight when retinopathy is detected early.

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 National Screening Service (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.

Quality Assurance

It is crucial that screening programmes operate in accordance with rigorous standards. Quality assurance is the process of checking that standards are met, and ensuring continuous improvement is encouraged. Diabetic RetinaScreen regularly measures itself against these standards to make sure we are meeting our purpose. Assuring and improving the quality of services is essential if population screening is to achieve its intended benefits to population health, while minimising unintended but known harms to those taking part.

Appreciation

Diabetic RetinaScreen, the national diabetic retinal screening programme, is providing an essential service to the Irish public. This could not be achieved without the dedication and professionalism of the individuals who work to ensure that services are delivered to high standards, and the active participation of the thousands of people we invite to choose screening every year.

Quality assurance is at the heart of the Diabetic RetinaScreen programme and dictates every aspect of the screening journey. The Quality Assurance Committee for Diabetic RetinaScreen monitors standards for each part of the programme, and I thank them for their ongoing work and support for the programme.

The Diabetic RetinaScreen Clinical Advisory Group (CAG) sets quality standards and advises the Diabetic RetinaScreen Executive Management Team on clinical aspects of the programme. I thank past and present members of these groups for their ongoing professional dedication, input, and support. The review of these standards was conducted in line with the NSS QA Policy Framework: Standard Setting & Revision Procedure (NSS/S&F-6). I am grateful also to the international members of CAG who reviewed these standards.

I would like to acknowledge the work of all colleagues who contributed to the development of this sixth revision. In particular, thank you to the Diabetic RetinaScreen Programme Manager, Clinical Director and the Diabetic RetinaScreen team, and those who provide leadership and advice in the Executive Management Team meetings.

Fiona Murphy

Chief Executive
National Screening Service

Preface

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 a leading cause of preventable vision impairment and blindness in the European Region[4]. The aim of Diabetic RetinaScreen - the National Diabetic Retinal Screening Programme - is to reduce the risk of sight loss among people with diabetes through the early detection and treatment of retinopathy. Eye screening can detect diabetic retinopathy at an early stage when it is easier to treat, and treatment is more successful.

Diabetic RetinaScreen is for people aged 12 and older, who have been diagnosed with diabetes (Type 1 and Type 2).

There are a number of steps that make up the complex process of diabetic retinopathy screening. Each aspect of the screening process is fully quality assured.

Quality assurance is process-driven, and specific steps help define and achieve screening goals. This edition of Standards for Quality Assurance in Diabetic Retinopathy Screening sets out the specific quality standards, quality requirements and Key Performance Indicators (KPIs) for the programme.

A significant aspect of this quality assured Diabetic RetinaScreen programme is the role of the Diabetic RetinaScreen Clinical Advisory Group (CAG). The primary remit of the CAG is to set quality standards and make recommendations to the Diabetic RetinaScreen Executive Management Team on clinical pathways and protocols in the programme. These standards have been set by the CAG. Ongoing monitoring of the programme's performance against the standards is the remit of the Quality Assurance Committee.

I wish to thank the members of the CAG for bringing their acknowledged expertise and giving of their time to developing this edition.

Prof David Keegan Clinical Advisory Group for Diabetic Retinopathy Screening

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1. Introduction

Each part of the screening process must be fully quality assured and monitored to ensure it adheres to standards and gives rise to the best possible outcomes. Diabetic RetinaScreen measures performance of screening activity against Quality Assurance (QA) standards, providing regular reports for review and consideration, as well as conducting formal service provider audits. One of the aims of this review was to develop a framework whereby data is reviewed regularly at both programme and individual service level.

QA is an integral component of any population screening programme. In the HSE's National Screening Service (NSS), the QA Policy Framework (1) outlines our approach to QA to safeguard and improve outcomes for participants in our four population screening programmes - BowelScreen, BreastCheck, CervicalCheck and Diabetic RetinaScreen. This overarching policy framework supports the NSS commitment to quality by ensuring that the range of standards outlined by programmes are comprehensive, fit for purpose and informed by high quality evidence and best practice. We consistently assess the validity of our standards, working with all relevant stakeholders to support this work.

There is a suite of supporting documentation arising from the QA Policy Framework (2), (3), (4). They support the programme specific Standards for Quality Assurance, which set out the specific quality standards, quality requirements and Key Performance Indicators (KPIs) for each programme. The NSS QA Manual (5) sets out the generic HSE NSS QA structures and processes, which support the delivery of quality assured population screening programmes and should be read in conjunction with the programme-specific Standards for Quality Assurance.

1. Quality Assurance Policy Framework for NSS (NSS/S&F-1)
2. QA Policy Framework: Standard Setting & Revision Procedure (NSS/S&F-6)
3. QA Policy Framework: Governance (under development) (NSS/S&F-7)
4. QA Policy Framework: Standardised Language Procedure (under development) (NSS/S&F-8)
5. QA Policy Framework: QA Manual (NSS/S&F-9)

Diabetic RetinaScreen Quality Assurance (QA) Standards Review Process

A process has been developed whereby all Diabetic RetinaScreen QA standards are published and subject to formal review. One of the purposes of the Diabetic RetinaScreen Clinical Advisory Group is to recommend best practice, and to ensure that standards are appropriate and drive quality improvement. The standards are kept under review and revised as necessary, as further evidence or data becomes available.

The review's preparatory work involved the members independently reviewing and assessing the existing Diabetic RetinaScreen standards and identifying any potential gaps where a QA standard may need to be developed. During the review some QA standards were archived and/or replaced with new standards. Decisions for update included significant change to clinical practice, standards that did not have any outcome measures, and publication of new evidence. Where a current QA standard has been archived, but remains clinically relevant, data will continue to be collected to allow future analysis as required. Where there was no clear evidence, the agreed QA standards are derived from the opinion of the Diabetic RetinaScreen Clinical Advisory Group

New QA Standards

Any new QA standards will be developed in line with the following criteria:

- Overall importance – does the indicator address an area within the screening pathway that would significantly impact on the quality and outcome of service delivered?
- Evidence based – is the indicator based on high quality evidence, where this evidence exists?
- Measurability – is the indicator measurable? Are the required data items accessible and available for collection?

Quality Assurance - requirements and standards

Ensuring quality assurance in service delivery comprises compliance with both quality requirements and quality standards.

Quality requirements are stated as a description. There is no target associated with a requirement as service providers must fulfil the requirement. For many requirements, we propose that evidence to demonstrate that a requirement has been met will consist of a stated policy, indicating that the requirement has been incorporated into local practice, supported by results of periodic survey / audit activities to show that policy has been followed.

Quality standards are stated as a description of an activity with a measurable level of performance, with an associated performance threshold for achievement.

2. Quality Assurance Objectives and Standards

Objective 1 Identification of cohort: To ensure the register of eligible participants is complete.

1.1	QA Requirement – Acquisition and update of demographic details	Example of evidence achievement	Reporting Period
	Processes shall be in place to acquire, maintain and update the demographic details of participants with diabetes who have consented to participate in the programme	Copy of Register Office SOP	Assessed through IQA

1.2	QA Requirement – Registration of new participants	Example of evidence achievement	Reporting Period
	DRS Programme to ensure equity of access for participants to register with the programme	Copy of Register Office SOP	Assessed through IQA

1.3	QA Requirement – Register Accuracy	Example of evidence achievement	Reporting Period
	There must be processes in place to identify participants with more than one record on the diabetic screening register and register cleansing processes to which includes processes such as merging of records	Copy of Register Office SOP	Assessed through IQA

Objective 2: Screening pathway Call/ re-call process

QA Standard 2.1.1

Name	Completeness of offer for routine digital screening
Description	All eligible consented participants (where the programme has been informed of a diagnosis of diabetes) on the routine digital screening pathway will receive an appointment to attend for screening at least once every year
Rationale	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
Definition: Numerator and Denominator	Numerator = number of participants on the routine digital screening pathway offered an appointment during the reporting period plus number of suspensions*. Denominator = eligible population.
Performance Thresholds	Minimum ≥95%, Achievable 100%
Caveats	*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. The exclusion category 'having no perception of light in both eyes' (NPL) will be distinguished from all other categories and will be removed from the denominator where this information is available.
Data Collection	Data Source is from Optomize Service Objectives Report
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.
Review dates	Standard introduced as part of Rev 1 04/06/2013

QA Standard 2.1.2

Name	Completeness of offer for two yearly screening pathway
Description	All eligible participants on the two-yearly screening pathway will receive an appointment to attend for screening at least once every two years
Rationale	Standard introduced to specifically monitor participants in the two-yearly screening pathway.
Definition: Numerator and Denominator	Numerator = number of participants on the two-yearly screening pathway offered an appointment during the reporting period Denominator = Number of participants on the two-yearly screening pathway
Performance Thresholds	Minimum ≥95%, in 24 months, Achievable 100% in 23-25 months
Caveats	None
Data Collection	Data Source is from Optomize Service Objectives Report
Reporting period	Quarterly, rolling 24-month data reported 3 months in arrears.
Review dates	Standard introduced as part of Rev 6

QA Standard 2.1.3

Name	Completeness of offer for digital surveillance pathway
Description	All eligible participants on digital surveillance pathway will receive an appointment to attend for digital surveillance at least once a year
Rationale	Standard introduced to specifically monitor participants in the digital surveillance pathway.
Definition: Numerator and Denominator	Numerator = number of participants on the digital surveillance pathway offered an appointment during the reporting period Denominator = Number of participants on the digital surveillance pathway
Performance Thresholds	Minimum ≥95% Achievable 100%
Caveats	None
Data Collection	Data Source is from Optomize Service Objective Report
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.
Review dates	Standard introduced as part of Rev 6

QA Standard 2.1.4

Name	Completeness of offer for Slit Lamp Biomicroscopy (SLB) pathway
Description	All eligible people on SLB annual recall pathway will receive an appointment to attend for screening at least once every year, unless a current screening result is already on the call, re-call module.
Rationale	New standard introduced to specifically monitor participants in the SLB pathway.
Definition: Numerator and Denominator	Numerator = number of participants on the SLB pathway offered an appointment during the reporting period Denominator = Number of participants on the SLB pathway
Performance Thresholds	Minimum ≥95% Achievable 100%
Caveats	None
Data Collection	Data Source is from Optomize Service Objective Report
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.
Review dates	Standard introduced as part of Rev 6

2.2	QA Requirement – Invitation to participate	Example of evidence achievement	Reporting Period
	All new participants registered for the programme by their healthcare professional will be invited to participate in the screening programme within 1 month of the programme being notified of eligibility.	Copy of Register Office SOP	Assessed through IQA

QA Standard 2.3

Name	Timely offer for first routine digital screening appointment
Description	All new participants who have consented will be offered a first screening appointment within 2 months of the date of the provider receiving the participant's details.
Rationale	To ensure that screening is performed as soon as possible after diagnosis to assess whether retinopathy is present.
Definition: Numerator and Denominator	Numerator = number of eligible participants who consented to the programme (during a reporting period) who were offered a screening appointment within 2 months of the date of the provider receiving the participant's details. Denominator = number of eligible participants who consented to the programme (during a reporting period).
Performance Thresholds	Minimum ≥90%, Achievable 100%
Caveats	None
Data Collection	Data Source is from Optomize Service Objective Report
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.
Review dates	Standard introduced as part of Rev 1 04/06/2013

QA Standard 2.4

Name	Timely offer for first appointment on the pregnancy pathway
Description	Proportion of pregnant women with diabetes offered their first appointment on the pregnancy pathway at 10 (+/-2) weeks gestation.
Rationale	Pregnant women with diabetes have clear guidelines for the management of their diabetes To ensure screening is performed as soon as possible after referral to the pathway.
Definition: Numerator and Denominator	Numerator: number of pregnant women with diabetes notified to the programme who are offered their first appointment on the pregnancy pathway at 10 weeks gestation +/- 2weeks. Denominator: number of notifications of women with diabetes who are pregnant received by programme within the reporting period.
Performance Thresholds	Minimum ≥70%, Achievable ≥90%
Caveats	**Excluded are:** • women diagnosed with gestational diabetes are not eligible for the preg nancy pathway. • women already under the care of ophthalmology for diabetic retinopathy as they will remain under the care of their Ophthalmologist for the duration of their pregnancy • women who were screened 3 months before the date of notification (this includes women who notify the programme of their pregnancy on the day of their annual screen) • women where the notification of pregnancy is received by the programme after 10 weeks gestation. Women with diabetes who are on the pregnancy pathway but who are no longer pregnant before attending their routine digital screening appointment can be exception reported.
Data Collection	Data Source is from Optomize Service Objective Report
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.
Review dates	New Standard introduced in this review

QA Standard 2.5

Name	Commissioning – screening interval
Description	All eligible consented participants on the RDS or SLB Pathway are offered a screening appointment at least once every 11-13 months
Rationale	This standard looks at the round slippage. If the screening interval is not maintained, people with diabetes may not be seen often enough and detection of disease may be delayed.
Definition: Numerator and Denominator	Numerator = number of unique eligible consented participants on the RDS and SLB pathway who are offered a screening appointment between 11 and 13 months on the last day of the reporting period. Denominator = number of unique eligible consented participants on the register on last day of reporting period.
Performance Thresholds	Minimum 90%, Achievable 100%
Caveats	Exclusions: Participants under the care of Ophthalmology Participants become eligible from the date the provider receives the participant's details or when they are discharged to annual recall from assessment/treatment
Data Collection	Data Source is from Optomize Service Objective Report
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.
Review dates	Standard introduced as part of Rev 1 04/06/2013

QA Standard 2.6

Name	Commissioning – screening interval – two yearly screening
Description	All eligible participants on the Two-Yearly Screening Pathway are invited for screening at least once every 23-25 months
Rationale	This standard looks at the round slippage for participants on the two-yearly screening pathway
Definition: Numerator and Denominator	Numerator = number of unique eligible participants on the programme's two-yearly screening pathway who are waiting between 23 and 25 months for an invitation on the last day of the reporting period. Denominator = number of unique eligible participants on the programme's two-yearly screening pathway on the last day of reporting period.
Performance Thresholds	Minimum 90%, Achievable 100%
Caveats	Participants become eligible when they move to the two-yearly screening pathway from RDS assessment.
Data Collection	Data Source is from Optomize Service Objective Report
Reporting period	Quarterly, rolling 24-month data reported 3 months in arrears.
Review dates	Standard introduced as part of Rev 6

QA Standard 2.7

Name	Timely appointment offer for participants referred to digital surveillance
Description	Proportion of participants with a worst grade R1M1 referred to DS from screening to be offered an appointment 1 month from date final graded in RDS .
Rationale	To ensure timely digital surveillance assessment of participants referred from screening and minimise time between screening event and digital surveillance.
Definition: Numerator and Denominator	Numerator = number of participants attending for screening with a worst grade R1M1 to whom a referral to digital surveillance was recommended, where the appointment offered date is within one month of the client's digital screening visit Denominator = number of participants attending for screening with a worst grade R1M1 to whom a referral to digital surveillance was recommended.
Performance Thresholds	Minimum 90%, Achievable 100%
Caveats	Calculated based on time between screening visit and digital surveillance appointment date
Data Collection	Data Source is from Optomize Service Objective Report
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.
Review dates	Standard introduced as part of Rev 6

QA Standard 2.8

Name	Timely recall for digital surveillance
Description	Proportion of participants on the DS screening pathway who are graded to 6 months recall to DS to be offered a timely recall appointment.
Rationale	People with diabetes moved onto the digital surveillance pathway need to be seen on a regular basis and it is important that they attend their follow-up appointments in a timely manner. If the follow-up period is not maintained, people with diabetes may be seen too frequently or not often enough and detection of disease may be delayed.
Definition: Numerator and Denominator	Numerator = number of participants attending for digital surveillance with a worst grade R1M1 to whom a 6 month recall to digital surveillance was recommended, to be scheduled to occur within 6 months +/- three weeks of the client's digital surveillance visit Denominator = number of participants attending for digital surveillance with a worst grade R1M1 to whom a 6 month recall to digital surveillance was recommended
Performance Thresholds	Minimum 90%, Achievable 100%
Caveats	
Data Collection	Data Source is from Optomize Service Objective Report
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.
Review dates	Standard introduced as part of Rev 6

Objective 3: To maximise uptake: to maximise the number of invited participants receiving the test

QA Standard 3.1

Name	Uptake: to maximise the number of invited persons receiving the test
Description	The proportion of those invited to screening who attend and have a satisfactory outcome
Rationale	To maximise uptake: To maximise the number of invited persons receiving the test
Definition: Numerator and Denominator	Numerator = number of unique eligible participants 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.
Performance Thresholds	Minimum ≥70%, Achievable ≥80%
Caveats	*Outcome = satisfactory by digital photography or slit lamp biomicroscopy (i.e. gradable with result). This standard applies to participants on all pathways in the programme who have been offered an appointment for screening.
Data Collection	Data Source is from Optomize Service Objective Report
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.
Review dates	Standard introduced as part of Rev 1 04/06/2013

QA Standard 3.2

Name	Uptake: repeat non-attenders
Description	The proportion of eligible people with diabetes who have not attended for Routine Digital Screening in the previous 3 years.
Rationale	This standard identifies people with diabetes who do not regularly attend RDS appointments. This will enable the programme to identify and implement interventions to increase participation in this cohort.
Definition: Numerator and Denominator	Numerator = number of unique eligible participants invited for routine digital screening who have not attended for screening within the previous 3 years and have been on the register for at least 3 years. Denominator = the number of unique eligible participants who have been on the register for at least 3 years
Performance Thresholds	Minimum ≤8%, Achievable ≤5%
Caveats	Participants on two yearly screening and digital surveillance pathways are not included in this standard.
Data Collection	Data Source is from Optomize Service Objective Report
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.
Review dates	Standard introduced as part of Rev 6

3.3	QA Requirement – Identify participants who repeatedly postpone	Example of evidence achievement	Reporting Period
	There must be a process in place to identify participants who repeatedly postpone their appointments pushing them outside of recommended screening intervals.	SOP on monitoring of participants in postponed and excluded states	Assessed through IQA

Objective 4: To maximise the performance of the screening test: To ensure photographs are of adequate quality

QA Standard 4.1

Name	Test: ungradable images RDS pathway
Description	Percentage of participants where a gradable digital image cannot be obtained.
Rationale	To maximise performance of screening test: To ensure photographs are of adequate quality
Definition: Numerator and Denominator	Numerator = number of unique participants screened within the reporting period who had an outcome of ungradable, unobtainable, or unassessable. Denominator = total number of unique participants screened within the reporting period.
Performance Thresholds	Minimum ≤7%, Achievable between 2.5 and 6.3% total ungradable
Caveats	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.
Data Collection	Data Source is from Optomize Service Objective Report
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.
Review dates	Standard introduced as part of Rev 6

QA Standard 4.2

Name	Test: ungradable images DS pathway
Description	Percentage of participants where a gradable digital image cannot be obtained.
Rationale	Percentage of participants where a gradable digital image cannot be obtained.
Definition: Numerator and Denominator	Numerator = Number of unique participants screened in a digital surveillance encounter within the reporting period who had an outcome of ungradable, unobtainable or unassessable Denominator = total number of unique participants screened in a digital surveillance encounter within the reporting period.
Performance Thresholds	Minimum ≤3%, Achievable ≤1% total ungradable
Caveats	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.
Data Collection	Data Source is from Optomize Service Objective Report
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.
Review dates	Standard introduced as part of Rev 6

Objective 5: To maximise the performance of the screening test: To ensure grading is accurate

	QA Requirement - Training of Graders	Example of evidence achievement	Reporting Period
5.1	Every grader active with the programme to participate in training, assessment and retraining, if the assessment is not passed.	The pass mark is set at 80%, if not passed graders must retake the test, if graders fail twice their grading must undergo 100% QA. Test and training results documentation to be submitted annually.	Report to be submitted annually and additionally assessed through Service Provider Audit
5.2	Evidence of clinical lead (or nominated senior grader) review of the outcomes of the ongoing training for grading staff on a regular basis.	Documentation to be submitted as part of the service provider audit.	Assessed through the Service Provider Audit

QA Standard 5.3

Name	Second full disease grading
Description	Second full disease grading for images with diabetic retinopathy or other non-diabetic eye disease outcome on first grading in the RDS pathway.
Rationale	To maximise performance of screening test: to ensure grading is accurate.
Definition: Numerator and Denominator	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.
Performance Thresholds	100%
Caveats	Non-diabetic eye disease as defined in Appendix 1
Data Collection	Data Source is from Optomize Service Objective Report
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.
Review dates	Standard introduced as part of Rev 1 04/06/2013

QA Standard 5.4

Name	Regrading of normal images
Description	Normal images with no diabetic retinopathy which are re-graded independently as part of quality assurance.
Rationale	To maximise performance of screening test: to ensure grading is accurate.
Definition: Numerator and Denominator	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.
Performance Thresholds	10% of normal images re-graded
Caveats	None
Data Collection	Data Source is from Optomize Service Objective Report
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.
Review dates	Standard introduced as part of Rev 1 04/06/2013

QA Standard 5.5

Name	Arbitration grading
Description	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.
Rationale	To maximise performance of screening test: to ensure grading is accurate.
Definition: Numerator and Denominator	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.
Performance Thresholds	100%
Caveats	None
Data Collection	Data Source is from Optomize Service Objective Report
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.
Review dates	Standard introduced as part of Rev 1 04/06/2013

QA Standard 5.6

Name	Inter-grader agreement
Description	Inter-grader agreement levels for images where second full disease grading takes place
Rationale	To maximise performance of screening test: to ensure grading is accurate.
Definition: Numerator and Denominator	Numerator = The number of primary grades that equal the final grade and secondary grades that equal the final grade in the reporting period. Denominator = The number of primary grades and secondary grades in the reporting period.
Performance Thresholds	≥90% Intergrader agreement
Caveats	As only 10% of R0M0 grades are regraded, the 90% of R0M0 grades go through only primary grading are excluded from this standard
Data Collection	Data Source is from Optomize Service Objective Report
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.
Review dates	Standard introduced as part of Rev6

Objective 6- 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

	QA Requirement	Example of evidence achievement	Reporting Period
6.1	Ensure that all administrative staff are appropriately trained and follow local procedures/ protocols.	Copy of administration manual and evidence of staff training to be submitted as evidence	Assessed through Service Provider Audit
6.2	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.	Assessed through Service Provider Audit
6.3	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.	Assessed through Service Provider Audit
6.4	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.	Assessed through Service Provider Audit
6.5	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.	Assessed through Service Provider Audit
6.6	Evidence of participation by the screening service provider in an external quality assurance (EQA) scheme, approved by the NSS should be maintained and available for quality control purposes/audit/ inspection.	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.	Assessed through Service Provider Audit

Objective 7: Workforce: To ensure optimum workloads for all graders in order to maintain expertise

	QA Requirement	Example of evidence achievement	Reporting Period
7.1	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. 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 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. 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. 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.	Assessed through Service Provider Audit

Objective 8: To minimise harm: To ensure GP and participant are informed of all test results

QA Standard 8.1

Name	Result letter to GP
Description	Time between screening visit and issuing of result letters to GP to be a maximum of 12 business days or less.
Rationale	To minimise harm: To ensure the GP is informed of all test results
Definition: Numerator and Denominator	Numerator = number of unique participants 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 participants attending a screening appointment within the reporting period.
Performance Thresholds	Minimum = 95% in ≤12 business days Achievable = 100% in ≤12 business days
Caveats	Where >1 screening visit occurs in the reporting period the last shall be used.
Data Collection	Data Source is from Optomize Service Objective Report
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.
Review dates	Standard introduced as part of Rev 1 04/06/2013

QA Standard 8.2

Name	Result letter to participant
Description	Time between screening visit and issuing of result letter to the participant to be 15 business days or less.
Rationale	To minimise harm: in order to reduce anxiety for people with diabetes it is important for them to receive their results in a timely manner. The distinction in performance thresholds between QA standard 8.1 and 8.2 is to ensure sufficient time for the letter to the GP to be received and reviewed, if participants contact the GP to discuss the result.
Definition: Numerator and Denominator	Numerator = number of unique participants 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 participants attending a screening appointment within the reporting period.
Performance Thresholds	Minimum = 95% in ≤15 business days Achievable = 100% in ≤15 business days
Caveats	Where >1 screening visit occurs in the reporting period the last shall be used.
Data Collection	Data Source is from Optomize Service Objective Report
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.
Review dates	Standard introduced as part of Rev 1 04/06/2013

Objective 9: To minimise harm: Ensure timely referral of all participants with screening results

QA Standard 9.1

Name	Timely Referral of participants
Description	Time between final outcome and issue of referral request (letter) for all referrals to be a maximum of 12 business days.
Rationale	To minimise harm: Ensure timely referral of all participants with screening results
Definition: Numerator and Denominator	Numerator = number of participants 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 participants having attended a screening visit within the reporting period that required a referral request.
Performance Thresholds	Minimum = 95% in ≤12 business days Achievable = 100% in ≤ 12 business days
Caveats	As the process of sending the referral to the treatment centre is an automated one once the grading is complete, the service providers must have a failsafe in place to ensure there are no errors in the process
Data Collection	Data Source is from Optomize Service Objective Report
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.
Review dates	Standard introduced as part of Rev 1 04/06/2013

Objective 10: To minimise harm: To ensure timely slit lamp biomicroscopy assessment of participants recorded as ungradable

QA Standard 10.1

Name	Referral from RDS to SLB
Description	Maximum time between digital screening visit and assessment by follow-up slit lamp biomicroscopy to be offered within 42 business days of the client's digital screening visit
Rationale	To minimise harm: To ensure timely slit lamp biomicroscopy assessment of participants recorded as ungradable
Definition: Numerator and Denominator	Numerator = number of participants to whom a referral to slit lamp biomicroscopy was recommended, to be offered an appointment within 42 business days of the client's digital screening visit Denominator = number of participants attending for screening to whom a referral to slit lamp was recommended.
Performance Thresholds	Minimum = 80% in ≤42 business days Achievable = 90% in ≤ 42 business days
Caveats	The date of the SLB appointment offered to be within 42 business days, if participants DNA or postpone an appointment offer within the timeframe, the standard will be deemed as met. Participants who are on the annual recall SLB pathway are not included in the count for this standard.
Data Collection	Data Source is from Optomize Service Objective Report
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.
Review dates	Standard introduced as part of Rev 1 04/06/2013

QA Standard 10.2

Name	Referral from DS to SLB
Description	Maximum time between digital surveillance encounter and assessment by follow-up slit lamp biomicroscopy to be scheduled to occur within 42 business days of the client's digital surveillance visit
Rationale	To minimise harm: To ensure timely slit lamp biomicroscopy assessment of participants recorded as ungradable following a digital surveillance screening.
Definition: Numerator and Denominator	Numerator = number of participants attending for digital surveillance visit, to whom a referral to slit lamp biomicroscopy was recommended, to be scheduled to occur within 42 business days of the client's digital surveillance visit Denominator = number of participants attending for a digital surveillance visit to whom a referral to slit lamp was recommended
Performance Thresholds	Minimum = 80% in ≤42 business days Achievable = 90% in ≤ 42 business days
Caveats	The date of the SLB appointment offered to be within 42 business days, if participants DNA or postpone an appointment offer within the timeframe, the standard will be deemed as met. Participants who are on the annual recall SLB pathway are not included in the count for this standard.
Data Collection	Data Source is from Optomize Service Objective Report
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.
Review dates	Standard introduced as part of Rev 6

Objective 11: To minimise harm; To ensure timely consultation for all screen positive clients (those with referable retinopathy)

QA Standard 11.1

Name	Urgent Referrals: Time to Consultation
Description	Time between notification of positive test and consultation, for Urgent referrals*
Rationale	To minimise harm: To ensure timely consultation for all screen-positive participants (those with referable retinopathy)
Definition: Numerator and Denominator	Numerator = number of participants attending a screening visit within the reporting period whose final grading outcome was an urgent referral whose consultation took place within 12 or 24 business days of notification of positive test. Denominator = number of participants attending a screening visit within the reporting period whose final grading outcome was an urgent referral and who were referred to an ophthalmology clinic.
Performance Thresholds	Minimum = 1a. 60% ≤ 12 business days 1b. 95% ≤ 24 business days Achievable = 95% ≤ 12 business days
Caveats	*Urgent referrals on the programme are those with a DR grade R3aM0, R3aM1, R3sM0, R3sM1, urgent referrals include those on the pregnancy pathway with a retinopathy grade of R1M1 or worse and the NDED condition Wet-Age-related Macular Degeneration
Data Collection	Data Source is from Optomize Service Objective Report
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.
Review dates	Standard introduced as part of Rev 1 04/06/2013

QA Standard 11.2

Name	Routine Referrals: Time to consultation
Description	Time between notification of positive test and consultation, for Routine referrals*
Rationale	To minimise harm: To ensure timely consultation for all screen-positive participants (those with referable retinopathy)
Definition: Numerator and Denominator	Numerator = number of participants attending a screening visit within the reporting period whose final grading outcome was a routine whose consultation within 78 or 108 business days of notification of positive test. Denominator = number of participants attending a screening visit within the reporting period whose final grading outcome was a routine referral and who were referred to an ophthalmology clinic
Performance Thresholds	Minimum = 2a. 70% ≤ 78 business days 2b. 95%≤ 108 business days Achievable = 95% ≤ 78 business days
Caveats	Routine referrals on the programme are those with a DR grade R2M0, R2M1, R1M1, Incomplete Examination (I), Ungradable Image (U) or non-diabetic eye disease – see Appendix for the list of NDEDs
Data Collection	Data Source is from Optomize Service Objective Report
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.
Review dates	Standard introduced as part of Rev 1 04/06/2013

Objective 12: To minimise harm: To follow-up screen positive participants (those with referable retinopathy) (failsafe)

	QA Requirement management of DNAs in the Treatment Centres	Example of evidence achievement	Reporting Period
12	All screen positive participants (those with referable retinopathy) who do not attend for further assessment/ treatment are contacted by the programme and an outcome recorded for each.	To be assessed through monthly returns report from the treatment centres.	Assessed through treatment centre service reviews

Objective 13: Treatment: To ensure timely treatment of those requiring referral to Ophthalmology

QA Standard 13.1

Name	Time between first consultation and first treatment (urgent referrals)
Description	The time between recorded first treatment decision (in clinic) and date offered appointment for urgent patients (R3aM0, R3aM1).
Rationale	Treatment: To ensure timely treatment of those requiring referral to ophthalmology
Definition: Numerator and Denominator	Numerator = number of participants with referral reason R3aM0, R3aM1, attending for treatment in the reporting period who are listed at first consultation and where date of treatment minus the date of listing is ≤ 12 business days. Denominator = number of participants with referral reason R3aM0, R3aM1, attending for treatment in the reporting period who are listed at first consultation.
Performance Thresholds	Minimum = 90% in ≤12 business days Achievable = 95% in ≤ 12 business days
Caveats	This standard only looks at patients who are listed for treatment at their first consultation.
Data Collection	Data Source is from Optomize Service Objective Report
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.
Review dates	Standard introduced as part of Rev 1 04/06/2013

QA Standard 13.2

Name	Time between first consultation and first treatment (routine referrals)
Description	The time between recorded first treatment decision (in clinic) and date offered appointment for routine patients.
Rationale	Treatment: To ensure timely treatment of those requiring referral to ophthalmology
Definition: Numerator and Denominator	Numerator = number of participants with referral reason R2M1, R1M1 attending for treatment in the reporting period who are listed at first consultation and where date of treatment minus the date of listing is ≤ 60 business days. Denominator = number of participants with referral reason R2M1, R1M1 attending for treatment in the reporting period who are listed at first consultation.
Performance Thresholds	Minimum = 70% in ≤60 business days Achievable = 95% in ≤ 60 business days
Caveats	This standard only looks at patients who are listed for treatment at their first consultation.
Data Collection	Data Source is from Optomize Service Objective Report
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.
Review dates	Standard introduced as part of Rev 1 04/06/2013

Objective 14: Governance – quality assurance: To ensure the service participates in quality assurance

	QA Requirement - Clinical Governance	Example of evidence achievement	Reporting Period
14	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 quarterly basis.	A record of the MDT meetings should be maintained and be retrievable for quality control purposes/audit/ inspection. Evidence should be available to the NSS/programme as requested.	Assessed through Service Provider Audit

Objective 15: To monitor inappropriate referrals following screening

QA Standard 15.1

Name	False positive referral rate
Description	False positive rate of diabetic retinopathy test (neither further photograph or clinical examination warranted referral).
Rationale	To monitor inappropriate referrals following screening
Definition: Numerator and Denominator	Numerator = number of participants screened within the reporting period who were referred to ophthalmology and who were returned to routine re-call following their first assessment. Denominator = number of participants screened within the reporting period who were referred to ophthalmology.
Performance Thresholds	Minimum = ≤ 15% of patients referred Achievable = ≤ 10% of patients referred
Caveats	The false positive rate is based on the screening photo image and not the image taken in the treatment centre. Data from this standard will be used to develop a new QI process to monitor false positive rates.
Data Collection	Data Source is from Optomize Service Objective Report
Reporting period	Quarterly, rolling 12-month data reported 3 months in arrears.
Review dates	Standard introduced as part of Rev 1 04/06/2013

Review and development of the Standards for Quality Assurance in Diabetic RetinaScreen Rev 6

Multi-stakeholder involvement is a key requirement for the effective review and development of quality assurance standards. The stakeholders involved in the development of this document are outlined in the Authors & Contributors on page 7. The steps involved in the review and development of this document are outlined below in the Diabetic RetinaScreen QA standards review and process section.

Budget and Resource Implication

This revision of the standards document considered feedback and change requests and any new screening guidance issued since the last revision of the standards. No new technologies have been recommended in this revision. To monitor compliance to these standards and requirements, additional resources in the form of QA visit teams and enhanced data provision are required. These costs and resources are incorporated into the strategic planning projects for Diabetic RetinaScreen. Stakeholder Resourcing is their responsibility and is defined within the terms of Memorandums of Understanding (MOUs), Service Level Agreements (SLA), and contracts with stakeholders.

Implementation plan

Stakeholders are notified and are provided with the new revision of the standards when they are published. Stakeholders are required by contract or MOU to ensure that their staff are aware of and trained on implementing the standards and requirements relevant to their area of practice. On-going assistance is provided by the programme, treatment centre and quality assurance coordinators in Diabetic RetinaScreen. In general, a lead in period of three months is provided before monitoring commences against new or amended standards. To assist with implementation a summary of the changes made to this revision will be shared with the relevant stakeholders.

Communication and Dissemination

Internal to NSS:
This document is a controlled document and dissemination internally is managed via the distribution list assigned on the NSS Quality Management Information system (Q pulse). The system will automatically email each person on the distribution list, and they must acknowledge they have read and understood the document.

External to NSS:
The NSS communications team will update the website with the new revision. Stakeholders are provided with a copy of the revised standards once approved for implementation within the NSS, initially via soft copy and then in hard copy once printed.

Governance and approval

Each chapter of the document was revised in line with documented governance arrangements as outlined in the Diabetic RetinaScreen QA standards review and development process below.

Monitoring, Evaluation and Audit

This document outlines the standards and requirements for the Diabetic RetinaScreen programme, a schedule of both internal and service provider audits against the standards are planned and organised on a rolling basis. The frequency of audits conducted are in line with the NSS QA Policy Framework: QA Manual (NSS/S&F-9), and NSS Audit SOPs.

Review and Update

A formal review will be carried out at in line with the NSS QA Policy Framework: Standard Setting & Revision Procedure (NSS/S&F-6) within a minimum of 5 years unless there is a change informed by legislation, best practice, the Regulator, or EU Directives etc., which would identify the need to update the standards sooner.
Internally within the NSS, an alert is sent to the document owner when a review is due via NSS Quality Management Information system (Q pulse). The standards will be kept under review and comments and feedback are welcome to inform this process. Any change requests raised against the document throughout the period of each revision is stored on NSS Quality Management Information system (Q pulse).

Diabetic Retina Screen QA standards review and development process

Step 1. Review of the latest version of appropriate literature and guidance documents available

Step 2. Gap analysis, amendment of existing content and incorporation additional Guidance

Step 3. Review, amendment, and approval of content by CAG, which includes international experts. Final draft prepared

Step 4. Review, amendment, and approval of content by Diabetic Retina Screen Executive Management Team (EMT)

Step 5. Approved document submitted to Diabetic RetinaScreen QA Committee for assurance regarding the process for the review

Step 6. Approved document submitted to Q-Pulse QMS for approval, communication and dissemination

Step 7. Approved document published online and circulated to the relevant Stakeholders.

References

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2. Ciulla TA, Amador AG, Zinman B. Diabetic retinopathy and diabetic macular edema. Diabetes Care. 2003;26(9):2653.

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4. Bourne RRA, Jonas JB, Bron AM, Cicinelli MV, Das A, Flaxman SR, et al. Prevalence and causes of vision loss in high income countries and in Eastern and Central Europe in 2015: magnitude, temporal trends and projections. Br J Ophthalmol.2018;102:575–85.

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, in Routine Digital Screening or Digital Surveillance, or otherwise date of slit-lamp biomicrosopy

Appendix 1

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
BRVO	Clinical finding of Branch Retinal Arterial Occlusion of the eye	As defined	Y
CRVO	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 De-generation	Clinical finding of Age Related Macular Degeneration	REFER IF SUBRETINAL / INTRARETINAL HAEMORRHAGE +/- EXUDATE	Y
Ambylopia	Reduced vision in one or both eyes caused by visual 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 Pigmented Retinal Lesion	SEE AGE RELATED MACULAR DEGENERATION	Y

An tSeirbhís Náisiúnta Scagthástála
National Screening Service

Diabetic RetinaScreen
An Clár Náisiúnta Scagthástála Reitiní do Dhiaibéitigh
The National Diabetic Retinal Screening Programme