UK National Screening Committee

NHS Screening Programmes

Diabetic Eye

Interim Quality Assurance Standards

Interim quality standards and performance objectives for Diabetic Eye Screening Programmes pending a full standards review

Version 1.11 / 22 August 2014

About the NHS Diabetic Eye Screening Programme

The NHS Diabetic Eye Screening Programme aims to reduce the risk of sight loss among people with diabetes by the early detection and treatment, if needed, of diabetic retinopathy. Screening using digital photography is offered every year to all eligible people with diabetes aged 12 and over.

The UK National Screening Committee and NHS Screening Programmes are part of Public Health England (PHE), an executive agency of the Department of Health. PHE was established on 1 April 2013 to bring together public health specialists from more than 70 organisations into a single public health service.

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Review / approval

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Contents

About the NHS Diabetic Eye Screening Programme 2

About this publication 3

Contents 5

Executive summary 6

Objective 1 7
Objective 2 8
Objective 3 8
Objective 4 9
Objective 5 9
Objective 6 10
Objective 7 10
Objective 8 10
Objective 9 11
Objective 10 11
Objective 11 11
Objective 12 12
Objective 13 12
Objective 14 13
Objective 15 14
Objective 16 16
Objective 17 16
Objective 18 16
Objective 19 17

NHS Diabetic Eye Screening Programme Definitions 17

Appendix 1 – National SOP for database cleansing 18

Appendix 2 – Guidance for the collection of evidence for the review of certification of sight impairment 21

Appendix 3 – Summary of key changes in interim standards 23

Executive summary

The most recent Diabetic Eye Screening (DES) Quality Assurance Standards are no longer fit for purpose. This is due to changes in organisational structure across the NHS, or the use of terminology which is no longer valid and does not match definitions used for other purposes within DES, for example in KPIs. There is a full review of Quality Assurance Standards for all the non-cancer screening programmes taking place later this year but NDESP felt that some interim guidance was required immediately.

We have therefore revisited the previously published QA standards and made only those changes we felt were required to reflect organisational change or invalid terminology. The review of standards across all areas of the programme will be undertaken at the full standards review.

Whilst revisiting the standards, we have taken the opportunity to include the standards guidance within the standards document rather than having two separate documents to refer to. The interim standards therefore replace the DES Quality Assurance Standards version 1.5 published 18 October 2012 and the DES Quality Assurance Standards Guidance Document version 1.6 published 23 January 2012.

A summary of key changes can be found at Appendix 3.

THEME: IDENTIFICATION OF COHORT			
Objective 1	Criteria	Minimum standard	Achievable standard
To ensure database is accurate	1. Single collated list of all people with diabetes and systematic call recall from a single management system	1. To be present	
	2. Comparison of DESP database programme size with CQRS (Care Quality Reporting Service) diabetic population	2. 6 monthly comparison	2. Quarterly comparison
	3. Proportion of GP practices participating	3. 100%	
	4. Regular database cleansing using national standard operating procedure (SOP)	4. 6 monthly	4. Monthly
	Criteria 1, 2 and 4 – evidence to be assessed at QA visit		
Additional Guidance	Criteria 2 – The comparison of the DES database against the number of people with diabetes reported by GPs via CQRS is intended to be a comparison of programme size and not of demographic data such as names and addresses. The DES database should be equal to or greater in size than the CQRS population as the CQRS data only includes those with diabetes aged 17+. For programmes that are not able to access this information via HSCIC or their Area Team, a statement should be issued to this effect and agreed by the Area Team. NDESP is working with HSCIC and Area Teams to resolve this difficulty. Criteria 3 – It is best practice for a general practice only to be counted if all registered patients at that GP practice are referred into a **single** programme. Criteria 4 – Please refer to Appendix 1 for national Standard Operating Procedure (SOP) for database cleansing. Programmes and commissioners should agree the frequency of database cleansing. This will be influenced by factors such as the mobility of their diabetic population.		

THEME: TO INFORM/INVITE			
Objective 2	Criteria	Minimum standard	Achievable standard
To invite all eligible persons with known diabetes to attend for the DR screening test	1. Percentage of the eligible population invited to screening **Eligible population**: the number of people a) 12 years and older; b) With diabetes; and c) Excluding those who do not have perception of light in both eyes. **Numerator** – number of people invited for routine digital screening (RDS) during the report period plus number of suspensions and exclusions. **Denominator** – eligible population (includes suspensions and exclusions) 2. All newly diagnosed patients must be offered first screening within three months of the programme being notified of their diagnosis	1. To be set following analysis of current information – minimum standard to be set at lower quartile value 2. Policy endorsed by Programme Board and recorded in Programme Board minutes	1. To be set following analysis of current information – achievable standard to be set at upper quartile value 2. Policy endorsed by Programme Board and recorded in Programme Board minutes
	Criterion 2 – Evidence to be assessed at QA visits.		
Additional Guidance	Criteria 1 – Please note that the numerator needs to be extracted for a 12 month period as the denominator (eligible population) will always be the number of eligible people on the programme register at the last day of the reporting period selected ie it will be the cohort for the year.		

THEME:TO MAXIMISE UPTAKE			
Objective 3	Criteria	Minimum standard	Achievable standard
To maximise the number of invited persons receiving the test	The proportion of those offered routine digital screening (RDS) who attend a digital screening event. (Subjects attending a routine digital screening event/ subjects offered screening expressed as a percentage)	=/>70%	=/>80%

THEME:TO MAXIMISE PERFORMANCE OF SCREENING TEST			
Objective 4	Criteria	Minimum standard	Achievable standard
To ensure photographs are of adequate quality	Percentage of patients where a digital image has been obtained but final grading outcome is ungradable	To be set following analysis of current information – minimum standard to be set at lower quartile value	To be set following analysis of current information – achievable standard to be set at upper quartile value

THEME:TO MAXIMISE PERFORMANCE OF SCREENING TEST			
Objective 5	Criteria	Minimum standard	Achievable standard
To ensure grading is accurate	1. Every grader registered on the software as a grader to participate in the online test and training scheme. All graders should achieve compliance with the participation policy for the online test and training scheme. 2. Evidence of clinical lead or nominated senior grader feeding outcomes of the online test and training set back to grading staff on a regular basis.	1. 80% of grading staff are compliant.	1. 100% of grading staff are compliant.
	Criteria *1 and 2 – Evidence to be assessed at QA visits*		
Additional Guidance	Criteria 1 – Participation policy from 1 April 2014: 10 test and training sets in a rolling 12 month period. Criteria 2 – Evidence that will be reviewed at QA visits will include: • That the clinical lead has reviewed test results of all graders and has taken appropriate action where necessary. This should be carried out on a quarterly basis as a minimum and a record of this should be maintained for inspection. • Individual graders should receive feedback from either the clinical lead or a senior grader after each completed test set and a record of this should be maintained for inspection. Best practice should also include group teaching sessions based around the results of the on-line test and training set.		

THEME:TO MINIMISE HARM			
Objective 6	Criteria	Minimum standard	Achievable standard
To ensure GP and patient are informed of all test results	Time between screening event and issuing of result letters to GP and patient.	70% <3 weeks 99% <6 weeks	95% <3 weeks
Additional Guidance	The minimum standard is set at 99% (rather than 100%) to allow for patients' deaths that take place before the result letter is generated (and therefore counted) by the screening management software.		

THEME: TO MINIMISE HARM			
Objective 7	Criteria	Minimum standard	Achievable standard
Ensure timely referral of patients with R3A screening results	Time between screening event and issue of referral request	95% referred within 2 calendar weeks	98% referred within 2 calendar weeks

THEME: TO MINIMISE HARM			
Objective 8	Criteria	Minimum standard	Achievable standard
To ensure timely consultation for all screen-positive patients	Time between notification of positive test and consultation: 1.Urgent (R3AM0 R3AM1) 2.Routine (R2M0, R2M1, R1M1)	 1.a. 60% <2 weeks 1.b. 80%<4 weeks 2.a. 70% <13 weeks 2.b. 95% <18 weeks	 1. 95% <2 weeks 2. 95% <13 weeks

THEME:TO MINIMISE HARM			
Objective 9	Criteria	Minimum standard	Achievable standard
To follow up screen-positive patients (those with referable retinopathy) (failsafe)	Timeline tracking undertaken to agreed national template	6 monthly feedback report to the Programme Board of the results of timeline tracking.	Quarterly feedback report to the Programme Board of the results of timeline tracking.
	Evidence to be assessed at QA visit		

THEME:TO MINIMISE HARM			
Objective 10	Criteria	Minimum standard	Achievable standard
To ensure timely biomicroscopy assessment of patients recorded as ungradeable	Maximum time between routine digital screening event and attendance for assessment by slit lamp biomicroscopy to be no more than 14 weeks	Quarterly review of the results of timeline tracking, reported to the Programme Board.	Monthly review of the results of timeline tracking, reported to the Programme Board.
	Evidence to be assessed at QA visit		

THEME:INTERVENTION/ TREATMENT			
Objective 11	Criteria	Minimum standard	Achievable standard
To ensure timely treatment of those listed by ophthalmologist	Time between listing and first treatment, following screening, if listed at first visit: *1. Urgent (R3M0, R3M1)* 2. Routine (R2M1, R1M1)	*1. 90% <2 weeks* 2. 70% <10 weeks	1. 95% <2 weeks 2. 95% <10 weeks

THEME:INTERVENTION/ TREATMENT			
Objective 12	Criteria	Minimum standard	Achievable standard
To minimise overall delay between screening event and first treatment	Time between screening encounter and first treatment, if listed at first visit to hospital eye service following screening, does not exceed: 1. Urgent (referred as R3M0/R3M1) 2. Routine (referred as R2M1, R1M1)	*1. 70% <6 weeks* 2.a 70% <15 weeks *2.b. 95% <18 weeks*	1. 95% <6 weeks 2. 95% <15 weeks

THEME:OUTCOME			
Objective 13	Criteria	Minimum standard	Achievable standard
To ensure regular collection of data indicating levels of new visual impairment due to diabetic retinopathy	Audit of severely sight impaired (SSI)/sight impaired (SI) certifications of visual impairment (CVIs) predominantly due to diabetic retinopathy Audit of incident visual acuity of 6/60 or worse in the better seeing eye. [LogMAR equivalent +1.0] which is predominantly due to diabetic retinopathy It is the responsibility of Ophthalmology in Hospital Eye Services to return data to the screening programme.	An annual report submitted to the Programme Board; to include the results of the audit of all incident cases of certifications of SSI/SI and VA data using national template.	An annual report submitted to the Programme Board; to include the results of the audit and case reviews of all incident cases of certifications of SSI/SI and VA data using national template.
	Evidence to be assessed at QA visit		
Additional Guidance	Please refer to Appendix 2 Guidance for the collection of evidence for the review of certification of sight impairment		

THEME: WORKFORCE AND I.T.			
Objective 14	Criteria	Minimum standard	Achievable standard
To ensure that screening and grading of retinal images are provided by a trained and competent workforce	Screening and grading staff to be appropriately qualified in accordance with national standards	100% of staff classified as graders (group a) to achieve qualification in accordance with national standards 100% of staff taking images (group b) to achieve qualification in accordance with national standards	100% of all staff groups (groups a-e) to achieve qualification in accordance with national standards
Additional Guidance	This Quality Assurance Standard applies to all staff working in the following job roles in a Diabetic Eye Screening Programme that is commissioned as part of the NHS DESP: a. Grader – any individual logged on the software system as a grader, who does not hold a specialist medical qualification in ophthalmology or diabetology. This includes individuals whose primary qualification is as an optometrist. b. Screener – any individual logged on the software system as a screener, who does not hold a specialist medical qualification in ophthalmology or diabetology. This includes individuals whose primary qualification is as an optometrist. c. DESP Administrator – any individual conducting administrative duties for a programme affecting the patient pathway or who supervises appointment booking activities. Staff solely providing appointment bookings, whilst working to a fixed protocol under the supervision of a person who is qualified, are not included. d. Programme Manager e. Administrative Manager Standards that state "non-grading" staff apply to groups b. c. d. e. as described above. 1. All new graders and those currently in training must pass the online component of Units 7 & 8 of the Diabetic Retinopathy Screening (DRS) City and Guilds Qualification before being signed off as competent to grade unsupervised in a local Diabetic Eye Screening Programme and should obtain the complete DRS Qualification through City and Guilds within two years of appointment. 2. Graders who do not obtain their qualification by the timescales described in the National Standard, must be 100% supervised. This means that **all** images they grade must be graded by another grader who is qualified 3. All non-grading staff should obtain the appropriate DRS Qualification for their role in the programme through City		

	and Guilds within two years of appointment. 4. Staff who take images and do not obtain their qualification by the timescales described in the National Standard, must be supervised. This means that another qualified member of staff must be physically available to supervise the unqualified member of staff and must regularly check on their performance during each image taking session. **Evidence that will be assessed to measure whether or not Standard has been achieved:** Submissions for the annual report will continue. Currently programmes are required to state whether or not each of their screening and grading staff are registered with City and Guilds or have achieved modules or the full certificate in their annual report Programme Boards should receive quarterly reports regarding the qualifications of all staff. Minutes of Programme Boards will be reviewed at QA visits

THEME: WORKFORCE AND I.T.			
Objective 15	Criteria	Minimum standard	Achievable standard
To ensure optimum workload for all graders in order to maintain expertise	Graders who do not hold additional job roles as either an optometrist or an ophthalmologist must grade a minimum of 1000 patient image sets per annum. Graders who also are qualified optometrists and undertake this job role and do not grade 1000 image sets must grade a minimum of 500 image sets and then supplement this number with 10 image sets from the online test and training set If an Optometrist grader does not grade the minimum number of image sets, then evidence of participation in the online test and training set should be provided. 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.	95% of staff recorded on grading system meet minimum requirements.	100% of staff recorded on grading system meet minimum requirements.

	Diabetologists who are clinical leads and registered on the system as graders must grade a minimum of 500 patient image sets per annum.		
Additional Guidance	This is irrespective of the number of weekly working hours of the graders. To ensure regular grading activity, Programmes will be required to audit all grading numbers per grader on a quarterly basis. The minimum individual grader figures per quarter should reflect a level of activity which will ensure that the whole year target can be achieved. Graders who have not been in post for a full year should have their image set requirement calculated on a pro rata basis, based on number of complete months worked. Surveillance grades can be included in the minimum numbers for all graders. Graders who grade in more than one screening programme should achieve a minimum of 1000 grades per annum across all programmes. In order to demonstrate this, a grader should elect a main programme and the main programme should seek verification from other (secondary) programmes that the grader has worked in to confirm the number graded in secondary programmes. It is the responsibility of the main programme to ensure that the grader achieves minimum numbers graded.		

THEME: COMMISSIONING			
Objective 16	Criteria	Minimum standard	Achievable standard
To optimise programme efficiency and ensure ability to assure quality of service	Minimum programme size.	Greater than 12000 people diagnosed with diabetes on programme register	

THEME: COMMISSIONING			
Objective 17	Criteria	Minimum standard	Achievable standard
To ensure that the screening interval is annual.	Programme operates an annual screening interval for routine digital screening	Policy endorsed by Programme Board stating annual screening interval and recorded in Programme Board minutes.	
	Evidence to be assessed at QA visits.		

THEME: GOVERNANCE			
Objective 18	Criteria	Minimum standard	Achievable standard
To ensure the public and health care professionals are informed of performance of the screening programme at regular intervals	1. Production of nationally specified reports 2. Production of KPI data	1. Submission of reports according to nationally specified timetable. 2. Quarterly submission of KPI data as required.	

THEME: GOVERNANCE			
Objective 19	Criteria	Minimum standard	Achievable standard
To ensure the service participates in quality assurance	External quality assurance	Participation in peer-review visit programme.	

NHS Diabetic Eye Screening Programme Definitions
Link to NDESP programme definitions: **Operational guidance**

Appendix 1 – National SOP for database cleansing

Standard Operating Procedure to ensure database accuracy within Local Diabetic Eye Screening Programmes

Introduction

As part of systematic diabetic eye screening , local screening programmes should offer central call/recall for the eligible population within the boundaries of the screening programme, regardless of what model the programme operates. It is not acceptable that GPs or optometric practices undertake call/recall.

A secure and systematic screening programme requires that a central list of patients (the programme register) is collated and managed effectively, with efficient processes for regular update of patient details. The data comprises patient identifiable information including name, date of birth, contact details, NHS number and the patient's registered GP Practice name and contact details.

The central administration team will need to develop efficient data exchange with GP practices, usually a manual paper retrieval exercise, in order to maintain and update the central collated list, until the national standard for cohort identification is available.

The status of patients (ie eligible, suspended, excluded, ineligible and off-register) must meet the criteria described in national guidance.

The National SOP identifies key areas where local programmes should be checking their database. The National SOP should be supported by local protocols.

National Database cleansing standard operating procedure (SOP)	
Area	**Action**
Check the DES database list size against the GP practice register list size(s).	Run DES database list size report on a regular basis*. For each GP practice, compare the number of people with diabetes reported by the GP practice against the number held for the practice in the DES Programme. Investigate variation. Compare list size by GP against list size in DES. Investigate variation. *Frequency will depend on local circumstances. In programme areas with highly mobile populations this will need to be done frequently eg monthly. Quarterly or six-monthly may be adequate in areas where there is a stable population.
Transfer of patient identifiable data from GP to DES database	Programmes to have access to Open Exeter / Clinical Care Record (NHS Spine). In cases of manual transfer of patient information by fax or posted paper reports, local protocol in place to: • Check patient not already known • If not known, add details to database • Issue first appointment within 3 months • If patient already known, check details • If patient known check that changes represent most current data In cases of electronic extraction, including GP2DRS, run checks as above. Maintain audit trail where change has occurred to patients records
Data validation checks on DES database	Request Miquest data reports from GP Practices/PCT Informatics Dept on a regular basis* • Check that people no longer listed at practice are ceased if known to have moved or died • Check that changes represent most current data *Frequency will depend on local circumstances. In programme areas with highly mobile populations this will need to be done frequently eg monthly. Quarterly may be adequate in areas where there is a stable population. If recall is organised around GP practices then validation checks should precede calling of patients for each practice.

Post office returns	On receipt of post office returns, check against Open Exeter/Spine and/or contact GP practice to determine whether patient has moved or died.
Deceased patients	Information can be received that patient has died from multiple sources. Check that data is correct on Open Exeter or by contacting GP Practice before marking as deceased and moving 'Off Register'
Excluded patients (Opt out / Medically Unfit)	Review details of all patients that are excluded quarterly • Check % excluded per GP practice – investigate any significant variation from programme average • Check each exclusion has appropriate reason and this is supported by correct paperwork • Check patients marked as opt out have not exceeded maximum period of opt out
Not diabetic	Information can be received that a patient is not diabetic. Check that information is correct by contacting registered GP Practice. Check whether patient should still continue to be screened according to national guidance (eg pancreatic transplant, bariatric surgery) Mark Off-Register 'not diabetic' only in the case of coding / diagnosis errors.
Patient seen in another programme	Patients can be marked as Off Register 'Seen in another programme' due to patient choice or serving a prison sentence. An annual audit of these patients should be carried out. See Patient Choice and Transfer across Programme Boundaries available at: http://diabeticeye.screening.nhs.uk/operational-guidance for further information
Under 12	Check that any under 12's held 'Off register' are made eligible when they reach age 12 and their parent/guardian receives an invitation to screening.
Refused demographic transfer but known to DESP	Patients can be marked as Off Register and in this status if they have previously been known to the DESP, but have subsequently decided they do not wish to be included in an automatic transfer of cohort information system implemented by the DESP . These patients will therefore not be invited for screening. If the patient wishes to change this they must inform their GP. An annual audit of patients in this category should be undertaken to check with the GP the patient is still objecting to electronic data transfer.

Appendix 2 – Guidance for the collection of evidence for the review of certification of sight impairment

Background

A review of cases of sight impairment is a key element of internal QA. Analysis of why sight impairment occurred in patients with diabetes can help identify system errors in screening pathways and enable programmes to strengthen failsafe mechanisms. It will also ensure subsequent care pathways for each patient.

Process

Arrangements for the collection of sight impairment data should be part of SLAs between all the relevant organisations involved in the screening and treatment pathways. Programmes should be able to produce a protocol for the collection of this data at QA visits.

Programmes should record all new cases of severe sight impairment/sight impairment and reduction in VA to 6/60 predominantly due to diabetic retinopathy which have occurred during the reporting period. Data should be regularly collected, reviewed quarterly and presented annually to the Local Diabetic Eye Screening Programme Board. The Programme Board should record any action taken by the Programme as a result of case reviews. The data set to be considered for review should be as follows:

Minimum standard; audit should include the following fields:	
Pseudonymised ID	**Link to screening database**
Date of Birth	**Date**
Sex	**M/F**
Date of Diagnosis	**Date/Unknown**
Date of registration SI	**Date/Not Regd**
Best corrected VA R/L at reg SI	**VA R/L**
Date of registration SSI	**Date/Not Regd**
Best corrected VA R/L reg SSI	**VA R/L**
Date first registered in screening database	**Date / Not Regd/Null**
Date of last screen prior to registration	**Date / Not screened/Null**
Best corrected VA R/L at last screen before registration	**VA R/L**
RxMxPx Grade R/L at last screen before registration	**RxMxPx / RxMxPx**
Achievable standard: case reviews should include the following analysis:	

Screening history timeline	Description
Treatment history timeline	**Description**
In the opinion of the clinical lead:	
Were any failures or delays in notification of the patient to the programme likely to have contributed to or hastened loss of sight?	**N or Y and brief description**
Were any failures within the screening pathway likely to have contributed to or hastened loss of sight?	**N or Y and brief description**
Were any failures within the referral and treatment pathway likely to have contributed to or hastened loss of sight?	**N or Y and brief description**
Has this case been reviewed through the programmes incident management process with Regional QA team at any time?	**N or Y and brief description**
Describe any changes made to programme policies or procedures as a result of this case	**Description**
Do any failures described above have a possible impact beyond the local programme?	**N or Y and brief description**
If the answer to the previous question is yes, have NDESP or Commissioners been notified via the QA team?	**Y/N/Null**

Evidence to be presented and reviewed at QA visit

The clinical lead should be able to demonstrate the collection, analysis and any resultant action from the review of cases of sight impairment. There should be evidence that an annual summary has been discussed and considered at the Local Diabetic Eye Screening Programme Board. Suitable evidence could be Programme Board minutes, a report, e-mails or presentation and associated collections of individual data in spreadsheets, printed pro forma or in a database.

Appendix 3 – Summary of key changes in interim standards

The following table summarises the key changes in the interim standards from those in the Quality Assurance Standards v1.5 18 October 2012 and the Guidance on Standards v1.6, 23 January 2012.

Item	Section	Original	Amendment
Objective 1	Criteria 2.	QMAS	CQRS
Objective 1	Additional Guidance	n/a	New: guidance if cannot access CQRS
Objective 2	Criteria 1.	Numerator	Amended to match KPI for consistency
Objective 2		Denominator	Amended to match KPI for consistency
Objective 2	Additional Guidance	n/a	New: added for clarification
Objective 3	Criteria	'a digital screening event'	'a *routine* digital screening event'
Objective 4	Criteria		wording amended to clarify
Objective 6	Criteria	'encounter;	'event' for consistency
Objective 7	Criteria	encounter	'event' for consistency
Objective 8	Criteria	R3	R3A (new grading definition)
Objective 10	Criteria	'… between digital screening encounter'	'… between *routine* digital screening *event'*
Objective 13	Additional Guidance	Appendix 2	Updated appendix 2
Objective 14	Additional Guidance	Interim measures guidance	Section removed as no longer applicable
Objective 15	Criteria	Number of test sets	Updated to 10 sets to reflect current Test and Training participation requirements
Objective 17	Criteria		'for *routine* digital screening' to clarify
Objective 18	Criteria	Annual reports	'nationally specified reports' to reflect new reporting policy
Objective 18	Minimum Standard	1.Submission of Annual report by 31 October 2.KPI data to the NSC	1.Submission of reports according to nationally agreed timetable 2. KPI data as required To reflect new reporting policy
Appendix 1			Updated
Appendix 2			Updated
Appendix 3			Additional