

Public health functions to be exercised by the NHS Commissioning Board

Service specification No.22

NHS Diabetic Eye Screening Programme

November 2012



Policy	Clinical	Estates	
HR / Workforce	Commissioner Development	IM & T	
Management	Provider Development	Finance	
Planning / Performance	Improvement and Efficiency	Social Care / Partnership Working	
Document Purpose	Policy		
Gateway Reference	18376		
Title	Public health functions to be exercised by the NHS Commissioning Board, Service specification No.22, NHS Diabetic Eye Screening Programme		
Author	Department of Health		
Publication Date	15 November 2012		
Target Audience	PCT Cluster CEs, NHS Trust CI Foundation Trust CEs , Director	Es, SHA Cluster CEs, Care Trust CEs, s of PH	
Circulation List	Directors of Adult SSs		
Description	This specification is part of an agreement made under section 7A of the National Health Service Act 2006. It sets out requirements for and evidence underpinning a service to be commissioned by the NHS Commissioning Board for the financial year 2013-14. It may be updated in accordance with the agreement.		
Cross Ref	N/A		
Superseded Docs	N/A		
Action Required	N/A		
Timing	N/A		
Contact Details	Miss Josephine Taylor Screening Team Quarry House, Quarry Hill Leeds LS2 7UE 0113 2545971		
For Recipient's Use			

You may re-use the text of this document (not including logos) free of charge in any format or medium, under the terms of the Open Government Licence. To view this licence, visit www.nationalarchives.gov.uk/doc/open-government-licence/

© Crown copyright 2012 First published November 2012 Published to DH website, in electronic PDF format only. www.dh.gov.uk/publications

Public health functions to be exercised by the NHS Commissioning Board

Service specification No.22

NHS Diabetic Eye Screening Programme

Contents

Public health functions to be exercised by the NHS Commissioning Board	
Contents	4
Service specification No.22	5
Section 1: Purpose of Screening Programme	6
Section 2: Scope of Screening Programme	9
Section 3: Delivery of Screening Programme	15
Section 4: Service Standards, Risks and Quality Assurance	28
Section 5: Data and Monitoring	31

Service specification No.22

This is a service specification within Part C of the agreement "Public health functions to be exercised by the NHS Commissioning Board" dated November 2012 (the "2013-14 agreement").

The 2013-14 agreement is made between the Secretary of State for Health and the National Health Service Commissioning Board ("NHS CB") under section 7A of the National Health Service Act 2006 ("the 2006 Act") as amended by the Health and Social Care Act 2012.

This service specification is to be applied by the NHS CB in accordance with the 2013-14 agreement. An update to this service specification may take effect on an agreed date as a variation made in accordance with the 2013-14 agreement.

This service specification is not intended to replicate, duplicate or supersede any other legislative provisions that may apply.

The 2013-14 agreement including all service specifications within Part C is available at <u>www.dh.gov.uk/publications</u>

Section 1: Purpose of Screening Programme

1.1 Purpose of the Specification

To ensure a consistent and equitable approach across England a common national service specification must be used to govern the provision and monitoring of NHS Diabetic Eye Screening Services (DESP).

The purpose of the service specification for the NHS DESP is to outline the service and quality indicators expected by the NHS Commissioning Board (NHS CB) for the NHS CB's responsible population.

The NHS DESP is in a development phase and the national service specification represents the service that should be provided when the development phase is complete. Local services will be in different stages of development and Local Area Team NHS CB commissioners should agree a pace of change with providers to deliver a service that meets the national service specification.

The service specification is not designed to replicate, duplicate or supersede any relevant legislative provisions which may apply, e.g. the Health and Social Care Act 2008 or the work undertaken by the Care Quality Commission. The specification will be reviewed and amended in line with any new guidance as quickly as possible.

This service specification needs to be read in conjunction with the current NHS DESP guidance and recommendations. These can be found on the NHS DESP website: http://diabeticeye.screening.nhs.uk/

NHS DESP Programme Standards:

http://diabeticeye.screening.nhs.uk/standards#fileid10982

Guidance and updates on KPIs: http://www.screening.nhs.uk/kpi

NHS DESP Guidance on Exclusions, Suspensions and Management of Ungradables

Guidance on Failsafe & Guidance on Managing serious incidents: <u>http://diabeticeye.screening.nhs.uk/quality#fileid11292</u>

UK National Screening Committee Guidance, Managing Serious Incidents in the English NHS National Screening Programmes

http://www.screening.nhs.uk/quality-assurance#fileid9902

1.2 Aim

The aim of the NHS DESP is to reduce the risk of sight loss amongst people with diabetes by the prompt identification and effective treatment if necessary of sight threatening diabetic retinopathy, at the appropriate stage during the disease process.

1.3 Objectives

This will be achieved by delivering evidence-based, population-based screening programmes that:

- identify the eligible population and ensure effective delivery with maximum coverage.
- are safe, effective, of a high quality, externally and independently monitored, and quality assured.
- lead to earlier detection, appropriate referral, effective treatment and improved outcomes.
- are delivered and supported by suitably trained, competent, and qualified, clinical and non-clinical staff who, where relevant, participate in recognised ongoing CME, Continuous Professional Development (CPD), and External Quality Assurance (EQA) schemes.
- have audit embedded in the service.

1.4 Health outcomes

There are around 2.5m people with diabetes in England. Diabetic retinopathy is a complication of diabetes and is the leading cause of blindness in the working population in the developed world. Diabetic retinopathy, if left untreated, can lead to sight loss which can have a devastating effect on the individual and their families. By promptly identifying and treating the disease, these effects can be reduced or avoided completely.

As diabetic eye screening is just one component of diabetes care, the screening programme should be integrated with routine diabetes care

The NHS DESP contributes to the Public Health Outcomes Framework (DH, 2012) which aims:

"to improve and protect the nation's health and wellbeing and to improve the health of the poorest, fastest."

Specifically diabetic eye screening contributes to:

- Domain 4: "Healthcare Public Health and Preventing Premature Mortality"
- Reduced numbers of people living with preventable ill health and people dying prematurely, while reducing the gap between communities.
- Preventable Sight Loss

1.5 Principles

• All individuals will be treated with courtesy, respect and an understanding of their needs,

- All those participating in the NHS DESP will have adequate information on the benefits and risks to allow an informed decision to be made before participating,
- Access to screening is matched to the needs of the target population in terms of availability, accessibility and location
- Screening will be effectively integrated across a pathway including between the different providers, screening centres, primary care and secondary care.

Section 2: Scope of Screening Programme

2.1 Description of screening programme

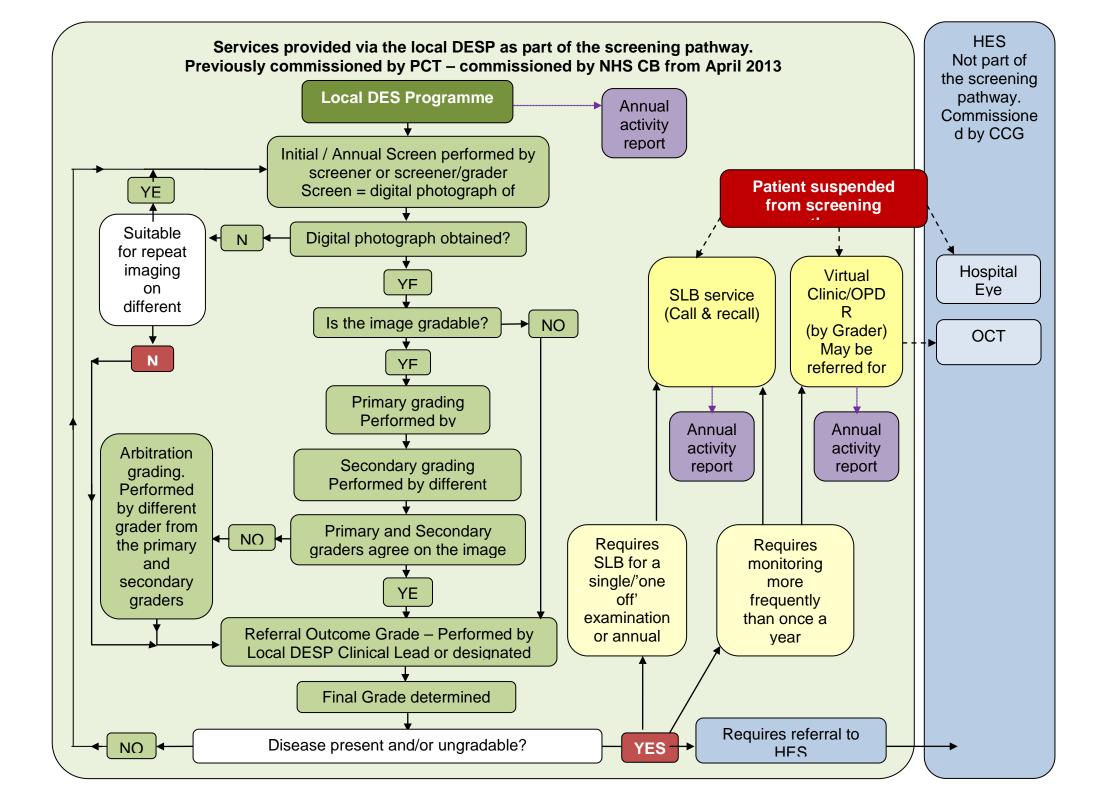
The Programme comprises a number of elements which the provider is expected to achieve:

- identifying and inviting all eligible people for screening at regular intervals (i.e. call/recall);
- taking digital images of service user's eyes;
- grading the digital images of service user's eyes;
- providing surveillance clinics with slit lamp bio-microscopy assessments
- providing surveillance clinics using virtual photographic clinics
- Ensuring services users with referable eye disease are referred to appropriate Hospital Eye Services
- Undertaking internal Quality Assurance (QA)
- Providing clinical oversight and governance for the Programme

In accordance with UK National Screening Committee (UK NSC) standards and protocols the provider is expected to fulfil the following

- Work to nationally agreed NHS DESP standards, guidance, policies and pathway.
- Implement and support national IT developments
- Use National Screening Programme materials and protocols for their use
- Provide timely and accurate performance data
- Be required to respond to national action/lessons such as change of software, supplier, techniques
- Work with the NHS CB in reporting on and resolving incidents and serious incidents
- Report against standard Key Performance Indicators (KPIs) and quality indicators as required
- Take part in QA processes
- Implement failsafe procedures according to national guidance and continuously ensure quality
- Ensure that there is sufficient resource to provide routine (currently annual) digital screening to the defined population
- Work with the local public health team to ensure uptake is maximised and there is equity of access to the service for all patients.

The programme interfaces with and is supported by a number of other services (e.g. primary care, diabetology, hospital eye services and IT support). In order to ensure that the programme delivers a co-ordinated and seamless service in a multi-provider environment, the screening provider must work with any providers that support or deliver other elements of the complete pathway or provide interfacing services and must work to common standards, policies and protocols.



2.2 Description of the Screening Pathway

The NHS DESP is based on the policies developed by the UK NSC. The screening procedure is divided into the following stages:

- Identification,
- Invitation,
- Inform,
- Test,
- Diagnose,
- Treatment/ intervention,
- Surveillance,
- Monitor outcomes.

In accordance with UK NSC standards and protocols the provider shall follow the care pathway for diabetic eye screening. Regardless of the model of delivery e.g. technician /optometry based/ fixed camera/ mobile camera the pathway as specified must be followed.

The population eligible for screening is: All persons diagnosed with diabetes aged 12 or over who have light perception or better in at least one eye.

Screening should be offered to the eligible population unless they have been excluded or suspended according to national guidance – *NHS DESP: Exclusions, Suspensions and Management of Ungradables*

Screening ends when a service user is screened and the result is:

- Screen negative i.e. No DR or non referable DR and re-invited in one year
- Screen positive i.e. Referable DR and referred to the hospital eye service (HES)
- Assessed as medically unfit for screening and or treatment and excluded from the programme
- Other eye pathology and is referred to the GP according to local protocol

Surveillance will be provided when a service user has an:

- Ungradable image and requires slit lamp bio-microscopy
- Referable grade and clinical lead assess against best evidence that patient can be monitored through a virtual digital photography clinic

2.3 Failsafe

In accordance with UK NSC standards and protocols the provider shall comply with the NHS DESP guidance on failsafe. It should ensure that it establishes, maintains and follows quality assurance and failsafe processes.

The Provider will:

- Undertake systematic validation and cleansing of both data received from General Practices and data relating to service users excluded and suspended from screening;
- Ensure that results have been sent to General Practices, service users and other appropriate clinicians by agreement by NHS CB
- Referrals have been processed appropriately;
- Track each subjects progress along the screening Pathway using the Programme's management software according to national guidance.
- Ensure safe systems are in place for referring subjects into and out of the Programme (e.g. to/from the HES)
- Ensure safe systems are in place between different elements of the Programme (e.g.to/from surveillance clinics).

2.4 Key Roles and Responsibilities

In accordance with UK NSC standards and protocols the provider will ensure that the following roles are fulfilled:

- Clinical Lead
- Programme Manager

Clinical Lead

The Provider is responsible for providing Clinical Leadership, The Clinical Lead has overall clinical responsibility and accountability for the Programme.

The Clinical Lead will either be a Consultant (or very senior associate) Ophthalmologist who is a medical retina specialist or a Consultant Diabetologist.

The detailed responsibilities of the Clinical Lead are set out in section 3.4 below.

Programme Manager

The Provider is responsible for providing Programme Management. The programme manager is responsible for coordination of the Programme and its quality assurance processes, and to implement continuous improvement strategies. The detailed responsibilities of the Programme Manager are set out in section 3.4 below.

Lead Ophthalmologist

Where the Clinical Lead is a Consultant Diabetologist there will be a lead ophthalmologist to advise on grading and medical retina issues.

2.5 Commissioning Arrangements

The commissioning of the NHS DESP pathway involves commissioning at different levels, as set out below.

The provider will provide the screening programme to the registered and resident population within the geographical boundaries that is served by named General Practices. This will include any institutions, prisons and mental health hospitals.

In order that populations are safely managed, the provider should not offer a service to populations smaller than a single general practice. Populations should be managed according to NHS DESP Guidance.

NHS diabetic eye screening services will be commissioned by the NHS CB alongside specialised services where appropriate.

2.6 National commissioning through the NHS Commissioning Board

The NHS CB has responsibility to ensure that the Diabetic Eye Screening pathway is seamless from entry in primary care through to integration with NHS management, treatment and care including liaison with Acute Trusts/ Hospital Eye Services.

Elements of the NHS DESP to be commissioned include:

- Working with GP practices to create, validate and maintain on at least a quarterly basis (using nationally recommended IT packages such as GP2DRS) a register of all people with diabetes age 12 and over who are eligible to be invited for screening
- A provider to deliver the NHS DESP in an accessible, high quality and safe manner.
- Ensuring appropriate levels of governance and accountability by supporting a Programme Board
- Ensure that there are safe referral mechanisms to transfer patients from the screening programme to the Hospital Eye Service
- Ensure that any changes to provision of Hospital Eye Services that might affect screening services are assessed to ensure the safety of the interface between services
- Ensure that information transfer between services is effective
- Ensuring good relationships and communication between users, screening services, specialist services and primary care services to drive up quality of care provided by the screening programme for people with diabetes.
- Working with National Screening Programme and suppliers of national IT systems to ensure safe and effective screening programme that meets national guidance.

Section 3: Delivery of Screening Programme

3.1 Service model summary

This service can be delivered by different models in a number of ways eg technician screeners/Optometric based or fixed/mobile. The provider will operate a model that will maximise the informed uptake of the screening offer in a safe and cost- effective manner.

The screening programme will operate an annual screening interval for all patients invited for routine screening according to NHS DESP Guidance, unless advised to alter by the National Screening programme.

Any patient requiring more frequent screening (3 or 6 monthly assessment) should be seen in surveillance clinics.

Pregnant women requiring more frequent screening should be seen within surveillance clinics.

Programmes should not operate 3 or 6 monthly recall intervals as part of the routine screening programme.

The Programme includes the following elements:

- Programme Management
- Clinical Leadership
- Administration of the Programme
 - o Identify the cohort
 - o Inform subjects
 - o Invite subjects
 - Screening Test (Digital Image Capture)
- Grading of Digital Images
- Surveillance
 - Slit lamp Bio-microscopy screening
 - Virtual digital photographic clinic
- Ophthalmology Referral (*Diagnose, treat, intervene, outcome*)
- Failsafe
- Internal QA

These elements are set out under their respective headings below (sections 3.4 to3.11). The Provider must perform each of these elements

3.2 **Population coverage**

In line with national guidance, the NHS CB and service providers will work together, and with the local Departments of Public Health, and Health and Wellbeing Boards to:

- optimise coverage and uptake across their catchment area.
- co-operate with regular analysis of screening coverage to identify groups who either access screening at lower levels, or do not access services at all.
- ensure that the participation rates are optimal.

3.3 **Programme Coordination**

In accordance with UK NSC standards and protocols the provider will be responsible for ensuring that the part of the programme they deliver is coordinated. Where collaboration is necessary, one part of the programme should interface seamlessly with others, particularly in the areas of timeliness and data sharing. This will ensure that the aims and objectives of the NHS DESP are met.

In circumstances where different organisations other than 'The Provider' deliver different parts of the pathway eg Grading or Administration, these relationships must be covered by appropriate SLAs and contracts however the provider must:

- provide clinical oversight and accountability for all aspects of the service,
- be responsible for meeting standards
- be responsible for meeting KPIs and performance targets
- be the lead organisation in the case of Serious Incidents.

3.4 **Programme Management**

The Provider should appoint the Programme Manager, who shall be responsible to the Clinical Lead, who can delegate the task of the day-to-day running of the screening programme to the Programme Manager.

The Programme Manager is responsible for:

- safe running of call/recall, management of exclusions & suspensions, administration, failsafe
- smooth running of screening sessions
- ensuring screening and grading capacity
- compliance of workforce with education and training requirements
- compliance with internal QA requirements
- monitoring the local programme's performance against NHS DESP Standards

The role of the Programme Manager is specified in detail in NHS DESP guidance.

3.5 Clinical and Corporate Governance

In accordance with UK NSC standards and protocols the provider shall be responsible for ensuring that the part of the programme they deliver is coordinated and interfaces with other parts of the programme with which they collaborate, in relation to timeliness and data sharing.

Each provider will ensure that there is an appropriate level of dedicated DES co-ordinator time with appropriate administrative support to be responsible for the operational coordination of the screen, to contribute to strategic development, to ensure timely reporting and to respond to requests for information. Where there is only one named coordinator, the provider will ensure that there are adequate cover arrangements in place to ensure sustainability and consistency of programme.

The provider is responsible for delivering Clinical Leadership for the programme.

Clinical Lead

The Provider shall appoint the Clinical Lead who will be clinically responsible and have accountability for the Programme.

The Clinical Lead will be a Consultant (or very senior associate) Ophthalmologist with medical retina experience or Consultant Diabetologist, who will:

- Be professionally accountable for their local diabetic eye screening programme
- Be responsible for the overall running of the local programme
- Provide strategic leadership for the programme
- Provide clinical support for their Programme Manager
- Ensure all grading is undertaken according to NHS DESP grading criteria
- Provide clinical supervision for screening and grading staff
- Provide clinical supervision for staff operating surveillance clinics
- Be responsible for maintaining the quality of grading through regular monitoring of grading staff performance and the provision of ongoing education and training.
- Lead a regular Multi-Disciplinary Team (MDT) meeting to review cases and provide CPD for staff
- Be responsible for making clinical decisions related to screening subjects up to the point where a referral has been made into the Hospital Eye services.

The role of the Clinical Lead is specified in detail in NHS DESP guidance.

Governance

In accordance with UK NSC standards and protocols the provider shall:

- ensure that responsibility for the screening programme lies at Executive-level,
- ensure that there is appropriate internal clinical oversight of the programme and have its own management and internal governance of the services provided with the appointment of a Clinical Lead, a Programme Manager.
- Ensure representation on the multidisciplinary Programme Board established by the NHS CB and key stakeholders as a minimum,
- ensure that there is regular monitoring and audit of the screening programme, and that, as part of organisation's Clinical Governance arrangements, the Provider organisation's Trust Board is assured of the quality of the screening programme
- comply with the UK NSC guidance 'Managing Serious Incidents in the English NHS National Screening Programme' (or updated version).
- have appropriate and timely arrangements in place for referral into treatment services that meet programme standards found on the National Screening programme Website <u>http://diabeticeye.screening.nhs.uk/</u>
- Provide documented evidence of clinical governance and effectiveness arrangements on request
- Ensure that an annual report of screening services is produced which is signed off by the organisation's Board.
- have a sound governance framework in place covering the following areas:
 - information governance/records management
 - equality and diversity
 - user involvement, experience and complaints
 - failsafe procedures

3.6 Administration of the Programme

The Provider is responsible for delivering administration of the programme This includes:

- Identification of the eligible population
- Maintaining an accurate database of the eligible population. This should include where the Provider is made aware (other than from a General Practice update) that subject details have changed, the Provider shall record this fact and shall provide regular and frequent updates detailing such changes to the General Practices of such subjects. Where this can be achieved through the NHS DESP's 'GP2DRS solution', the Provider shall use such 'GP2DRS solution'.
- Identification of the eligible population who are either excluded or suspended

- Undertaking regular audits of excluded/suspended patients to ensure accurate records
- Inviting for screening the eligible population who are neither excluded or suspended

3.7 Management of excluded & suspended subjects

The provider will make every effort to maximize the offer and uptake of screening in vulnerable/ hard-to-reach populations (including those who are not registered with a GP), within the resources available.

The provider shall manage subjects excluded or suspended from the Programme in accordance with the NHS DESP Guidance: *'Exclusions, Suspensions and Management of Ungradables' March.*

3.8 Operation of call/recall service & safe appointment booking system for annual screening

In accordance with UK NSC standards and protocols the provider shall

- operate a central call/recall service from a single centre to invite each subject in the Cohort to attend screening appointments, unless that subject has been excluded or suspended from screening (in accordance with the NHS DESP Guidance).
- ensure that the Programme operates safe appointment booking systems in accordance with NHS DESP Guidance and timescales.
- unless required otherwise by the NHS DESP Guidance, invite (by post) all such subjects to attend screening on an annual basis by sending out initial invitations to subjects inviting them to attend a Digital Image Capture session within 3 months of their initial diagnosis of diabetes and thereafter by sending invitations every 12 months following each subject's last Digital Image Capture session
- use an appropriate booking model for inviting subjects for Annual Screening, that meets national guidance of the NHS DESP.
- maintain up to date records of all screening locations (including accessibility) and screening dates and times.
- provide subjects with information about their appointment, together with any other information required by the NHS DESP Guidance.
- ensure that all subject invitation letters conform to current national templates
- ensure that subjects are given all the information that they need to make informed choices about their participation in the Programme and the transfer of their data to those involved in the different elements of the Programme with the use of nationally agreed information leaflets including patient information for non-English speakers and access to appropriate interpreting.

 ensuring programmes obtain consent in accordance with NHS DESP guidance.

3.9 Reporting screening results

The Provider shall:

• Report the results to the subject and to the subject's primary care professional in accordance with NHS DESP Guidance and timescales.

3.10 Analysis of non-responding subjects and DNAs

The Provider shall:

• Undertake an analysis of non-responding subjects and DNAs on a six monthly basis and take appropriate action to address issues of non-attendance.

3.11 Subject Participation

The Provider shall

- monitor the Programme and engage with subjects by conducting subject satisfaction surveys and processing survey results.
- provide a satisfaction survey on an annual basis and include the summary in the annual report

3.12 Screening test (Digital Image Capture)

The Provider shall:

• be responsible for delivering the screening test (Digital Image Capture) in line with NHS DESP Guidance

3.13 Maintenance and implementation of protocols & policies

The Provider shall:

 ensure that it documents, maintains and implements protocols across the Digital Image Capture elements of the Programme, in line with NHS DESP Guidance

3.14 Booking screening appointments

The Provider shall

• promptly book screening appointments for its screening locations on the Programme's management software.

3.15 **Procuring & maintaining equipment**

The Provider shall:

- procure, maintain and refresh the equipment it requires (e.g. nationally-approved digital cameras and monitors) to enable it to carry out the Service.
- ensure that all equipment it uses to provide the Service continues to meet the NHS DESP Guidance.
- ensure that each camera that it uses to provide the service is configured to use the single, same resolution as every other camera used in the Programme and that such resolution is sufficiently high to enable the accurate grading of digital images, in line with NHS DESP Guidance.

3.16 Conducting screening sessions

The Provider shall:

- undertake digital image capture screening in accordance with NHS DESP Guidance for each subject who has an appointment and attends for screening.
- ensure that this includes (unless otherwise updated by the NHS DESP Guidance):
 - Preparing the patient, providing information about the test, obtaining informed consent, measuring Visual Acuity and undertaking mydriasis,
 - Taking 2 digital colour photographs

3.17 Following screening

The Provider shall ensure that each subject is processed into the correct grading and referral pathway and all urgent referrals are flagged in accordance with the Programme's protocols.

3.18 Grading of Digital Images

The Provider is responsible for delivering the 'Grading of Digital Images'

The Provider will:

• Ensure that there is adequate grading capacity at all points in the grading pathway so that results are available within national recommended timescales.

•

3.18.1 Grading Pathway

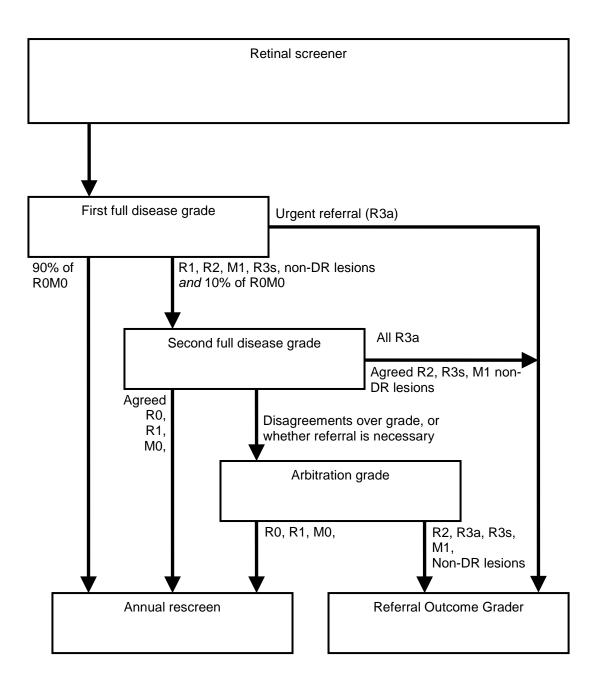
The Provider shall provide primary, secondary and arbitration grading according to NHS DESP Grading Pathway below. Any person found to have a referable disease will have their image graded by the clinical lead (or a clinician designated and supervised by the clinical lead). This grade is referred to as the 'Referral Outcome Grade'.

3.18.2 Grading Definitions

The Provider shall:

- grade images in accordance with NHS DESP Guidance: *Revised Grading Definitions March*
- Use features based grading

Grading Pathway



3.18.1 Maintenance and implementation of protocols & policies

The Provider shall:

- ensure that it documents, maintains and implements protocols for grading pathway of the Programme, in line with NHS DESP Guidance.
- establish and maintain quality assurance & failsafe processes as required by the NHS CB, and/or the NHS DESP Guidance for the grading pathway
- ensure grading complies with the NHS DESP Retinopathy Grading Definitions;
- ensuring staff participate in regular quality assurance of the accuracy of the outcome grading, overseen by the Clinical Lead;
- ensure that designated staff are trained in the use of grading protocols.

3.19 Surveillance Clinics

The Provider shall:

- Operate surveillance clinics
 - using digital photography
 - using slit lamp bio-microscopy
- Operate an administration function to provide call/recall, appointments and failsafe for surveillance clinics
- Use programme management software surveillance module to make appointments, and record results for this service
- Refer patients to surveillance clinics using appropriate technology that, in the opinion of the Clinical Lead need more frequent review and do not require referral to the HES. This should be done against local protocols based on best evidence and NHS DESP guidance. Surveillance clinics will include digital photography and slit lamp bio-microscopy. Surveillance clinics may interface with OCT assessment where this has been agreed with commissioners of Hospital Eye Services.
- Refer patients to slit lamp bio-microscopy surveillance clinics with ungradable images
- Record surveillance activity separately to screening service activity
- Report the results of the surveillance to the subject and to the subject's primary care professional in accordance with NHS DESP Guidance and timescales.

3.19.1 Maintenance and implementation of protocols & policies

The Provider shall:

- ensure that it documents, maintains and implements protocols for Slit Lamp Biomicroscopy (SLB) and digital photography surveillance clinics
- establish and maintain quality assurance & failsafe processes

- record SLB and digital photography outcomes according to local protocols based on best evidence and NHS DESP guidance
- ensure all staff undertaking SLB participate in regular quality assurance of the accuracy of SLB Surveillance, overseen by the Clinical Lead;
- ensure that all staff are trained in the use of local protocols.

3.19.2 Procuring & maintaining equipment

The Provider shall procure, maintain and refresh the equipment it requires to enable it to carry out the Service. The Provider shall ensure that all equipment it uses to provide the Service continues to meet the NHS DESP Guidance.

3.19.3 Conducting assessments

The Provider shall:

- undertake slit lamp biomicroscopy grading in accordance with NHS DESP Guidance,
- ensure the person carrying out the test should meet national standards and guidance.

3.19.4 Following assessments

The Provider shall:

- ensure that it records all results accurately using the Programme's management software and in accordance with NHS DESP Grading Definitions.
- ensure that each subject is processed into the correct referral pathway according to national timelines, so that it is referred in accordance with the Care Pathway.

3.20 Failsafe

The Provider shall:

- ensure safe systems are in place for referring subjects into and out of the Programme (eg to/from the HES) and between different elements of the Programme (eg to/from surveillance)
- monitor every patient who is suspended from annual screening to ensure they are safely entered into the correct care pathway according to national timescales.
- ensure that patients who no longer require follow up at a hospital eye service return to routine annual screening or surveillance according to NHS DESP guidance.
- ensure that patients who no longer require surveillance are returned to routine annual screening according to NHS DESP guidance.
- Regularly audit patients who are excluded to ensure they meet NHS DESP criteria for exclusions.

3.21 Internal QA

The Provider will undertake internal QA activities in accordance with NHS DESP guidance.

The Clinical Lead is responsible for implementing internal quality assurance and taking action for continual service improvement. This will include as a minimum:

- Regular review of data of grading quality
- Provision of a multidisciplinary team meeting at regular intervals
- Regular audits of patients presenting with disease to symptomatic services in line with NHS DESP Standards and guidelines.

3.22 Location(s) of programme delivery

The Provider shall:

- identify and secure the usage of venues which are suitable for the delivery of the Service.
- meet the costs of using such venues, ensuring they are fit for purpose according to national guidance
- ensure that their venues are readily accessible and appropriate for the service users, including:
 - geographically accessible for clients arriving by public transport, by car and on foot
 - structurally and physically accessible, including meeting the needs of any disabled or partially sighted service users and fulfils the Disability Discrimination Act legislation
 - providing facilities which are suitable for the delivery of the Services.

3.23 Days/Hours of operation

The days and hours of service operation will be based on the need of the target population with the aim of maximizing the uptake of the screening offer.

3.24 Entry into the screening programme

The referral route is defined by the Care Pathway and is detailed in the sections above.

3.25 Working across interfaces

There must be accurate and timely communication and handover across interfaces of the screening pathway.

The Programme interfaces with professional's responsible for primary care including local GPs, and GPs providing services for prison populations and

Armed Forces personnel (They involve the communication of information in order to ensure that:

- the service user register is maintained up to date;
- Primary Care is made aware of a service user's failure to attend appointments;
- Primary Care is made aware of a service user's screening results in order to ensure integration with the overall diabetes care of that service user and
- the service user has a local point of contact to discuss any aspect of the delivery and outcomes from the screening programme

The Programme interfaces with the region's hospital eye services. The interfaces which involve the referral of service users to the HES are shown in the Care Pathway. In addition, the Programme must deliver failsafes in accordance with national guidance in order to ensure safe and appropriate transfer of the service user to the care of the HES has been completed.

3.26 Transfer of and Discharge from Care Obligations

Screening ends when a service user is screened and the result is:

- Screen negative i.e. No DR or non referable DR and re-invited in one year
- Screen positive i.e. Referable DR and referred to the hospital eye service
- Assessed as medically unfit and excluded from the programme
- Other eye pathology and is referred to the GP according to local protocol

Surveillance will be provided when a service user has:

- An ungradable image and requires slit lamp bio-microscopy
- A referable grade and the clinical lead assess against best evidence that patient can be monitored through either a digital photograph and/or a slit lamp bio-microscopy

The end of the pathway for screening is defined in national guidance.

3.27 Exclusion criteria

The Provider shall manage subjects excluded or suspended from the Programme in accordance with the NHS DESP Guidance.

3.28 Staffing

The Provider will have adequate numbers of appropriately trained staff in place to deliver the screening programme in accordance with national guidance and NHS DESP standards and will include induction training for all new staff and regular update training for existing staff including safe-guarding policies.

Competencies & On-Going Training

The Provider will only use trained, qualified and competent staff to deliver the Service and will put in place a regime of continuing professional development for its staff. The Provider will maintain records of staff competency and shall ensure staff undertake at least the minimum volumes of work required to maintain their competency, as set out in the NHS DESP Standards.

The Provider will support the expeditious attainment and maintenance of staff competency through City and Guilds certificates and diplomas and through on-going training, as set out in the NHS DESP Guidance.

The Provider will ensure all its grading staff participates in the Test and Training set according national guidance.

Providers should maintain and provide a register of all staff who grade within the programme including their qualifications, the frequency of undertaking Test and Training and their pin number. This should be made available to NHS CB on request.

3.29 IT

The Provider will:

- Ensure that the programme management software that is in use is the most up to date version available and meets NHS DESP guidance
- Ensure that the software is configured to meet NHS DESP guidance
- Ensure that there is a disaster recovery plan in place
- Ensure that there is adequate server capacity for safe programme operation.

3.30 User involvement

Provider(s) will be required to:

- Have a written plan that demonstrates that they regularly and routinely collect (or have plans in place to collect) the views of service users, families and others in respect of the services they provide
- Demonstrate how those views will influence service delivery for the purposes of raising standards
- Show that all users and their families are given information about how to provide feedback about services they receive, including about the complaints procedure.

The results of user involvement will be made available to the NHS CB on request.

Section 4: Service Standards, Risks and Quality Assurance

4.1 Key criteria and standards

The provider will comply with the NHS DESP Programme Quality Assurance Standards (<u>http://diabeticeye.screening.nhs.uk/standards</u>)

4.2 Risk assessment of the pathway

Providers are expected to have an internal quality assurance process that assures NHS CB of its ability to manage the risks of running a screening programme. Providers may use the Failures Modes and Effects Analysis (FMEA) method which is recommended by the NHS National Patient Safety Agency's risk assessment programme. Risks will be defined in the standard NHS format (*likelihood and severity multiplied to give a RAG score*)

Providers are expected to maintain a register of risks and work with the NHS CB and QA staff to identify key areas of risk in the screening pathway to ensure that these points are reviewed in contracting and peer review processes. On a quarterly basis high scoring risks will be identified and agreed between the provider and the NHS CB, and plans put in place to mitigate against them.

4.3 Quality assurance

The NHS CB will suspend a service on recommendation from QA.

The Provider will:

- conduct internal quality assurance processes against NHS DESP standards outlined by the National Screening programme.
- carry out regular internal quality assurance of grading following national guidance (<u>http://diabeticeye.screening.nhs.uk/EQA</u>) which will include as a minimum monitoring its own levels of inter-grader agreement to measure the consistency of its grading, and shall investigate and resolve any instances of low levels of inter-grader agreement.
- cooperate with the National Quality Assurance Team in undertaking ad hoc audits and reviews of grading to ensure grading quality
- will take action to improve grading quality where it is shown not to meet national standards
- meet national programme QA standards, or have plans in place to meet them where this is not the case.
- participate fully in national Quality Assurance processes and respond in a timely manner to recommendations made.

 collect and submit minimum data sets as required to assure the NHS CB and the Quality Assurance Team in Public Health England of the safety and quality of the services provided.

4.4 Serious incidents

Providers should follow and adhere to the national guidance in dealing with an SI, as defined in the Guidance on managing serious incidents.

The Clinical Lead has a professional responsibility to investigate, report and contribute to any potential or actual SIs. The Clinical Lead has the responsibility to maintain an incident log and bring to the attention of all relevant bodies any systematic failures within the programme.

The provider organisation for a screening programme has the responsibility to document and report any incidents that could have a bearing on national policy or national delivery of the programme to inform lessons learned.

Where there is an incident or SI the provider is obliged to share data in a timely manner with Quality Assurance Teams or the NHS CB in order to mitigate risk and deal with their SI

The provider will comply with the latest UK NSC guidance on SIs and the guidance produced by the NHS DESP.

In the event of a serious incident the provider shall inform the NHS CB/public health lead within 24 hours of the circumstances and provide all reasonable assistance to the NHS CB in investigating and dealing with the incident.

The Provider is expected to undertake the following with respect to risk management:

Comply with appropriate statutory regulations (e.g. Data Protection Act, COSHH Regulations etc) to ensure a safe working environment.

- Have a critical/serious incident policy in place and make sure all staff are aware of it and of their responsibilities within it.
- Have a robust system in place whereby users, their families, other professionals and the public can raise concerns about the quality of care and where there are adequate arrangements for the investigation of such concerns.

4.5 **Procedures and protocols**

The provider will be able to demonstrate that written procedures and protocols are in place to ensure best practice is consistently applied for all elements of the screening programme (these must be consistent with National Screening programme requirements). This will include policy based on best practice for the care of service users who have declined to take part in the screening programme. Where the provider undertakes screening on more than one site, they will ensure consistency of procedures and protocols across all sites, including policies for onward referral to, for example, counselling or appropriate clinical services.

4.6 Continual service improvement

Where national recommendations and core and/or developmental standards are not currently fully implemented the provider will be expected to indicate in service plans what changes and improvements will be made over the course of the contract period.

The Provider shall develop a CSIP (continual service improvement plan) in line with the KPIs and the results of internal and external quality assurance checks. The CSIP will respond and any performance issues highlighted by the the NHS CB, having regard to any concerns raised via any service user feedback. The CSIP will contain action plans with defined timescales and responsibilities, and will be agreed with the NHS CB.

The Clinical Lead and Programme Manager will be expected to participate in regional and national events to ensure they remain up to date with national guidance.

4.7 Teaching and Training

The Provider shall ensure that:

- education, training and staff development are an integral part of the service and complies with the requirements of the NHS DESP.
- it keeps up to date with clinical advances,
- it contributes to education and training of other relevant professionals where appropriate.

It should also aspire to:

participate in properly conducted quality research where possible (with appropriate ethical approval).

Section 5: Data and Monitoring

5.1 Key performance indicators

The provider shall adhere to the requirements specified in the document Key Performance Indicators for Screening. The National Screening programme website must be checked for the latest version http://diabeticeye.screening.nhs.uk/kpis

5.2 Data collection, monitoring and reporting

The Provider shall continually monitor and collect data regarding its delivery of the Service and shall also provide reports to the NHS DESP

The Provider will comply with the **timely** data requirements of the National Screening programme. The most up to data Diabetic Eye Screening Dataset can be accessed from the National Screening programme Website.

Data requirements include the production of quarterly KPI reports and annual data returns as per the deadlines specified nationally

The Provider shall provide assurance to the Director of Public Health and the Local Authority Health and Well Being Board as outlined in Section 3.2.

5.3 Data reporting

The Provider will promptly provide both KPI and the Annual Report data to the NHS DESP, as required by the NHS DESP Guidance.

Annually reported figures will be reported to allow the NHS CB to make informed decisions about the programme provision for the population that they are responsible for. Providers should supply reasonable ad hoc requests for activity data to support service delivery, improvement and planning.

The provider will supply identifiable information regarding screening to the NHS CB in the event that a Serious Incident occurs relating to the programme, for the investigation of a complaint, for a specified quality assurance exercise or for any other reason that the NHS CB would reasonably require this information.

Activity and performance data will be shared with the NHS CB to allow benchmarking between areas within the eligible screening programme population.