

NHS public health functions agreement 2016-17

Service specification no.22

NHS Diabetic Eye Screening Programme

Prepared by Public Health England

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Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

NHS public health functions agreement 2016-17

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Prepared by –

Public Health England

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Service specification No.22

This is a service specification to accompany the 'NHS public health functions agreement 2016-17 (the '2016-17 agreement') published in December 2015.

This service specification is to be applied by NHS England in accordance with the 2016-17 agreement. This service specification is not intended to replicate, duplicate or supersede any other legislative provisions that may apply.

Where a specification refers to any other published document or standard, it refers to the document or standard as it existed at the date when the 2016-17 agreement was made between the Secretary of State and NHS England Board, unless otherwise specified. Any changes in other published documents or standards may have effect for the purposes of the 2016-17 agreement in accordance with the procedures described in Chapter 3 of the 2016-17 agreement

Service specifications should be downloaded in order to ensure that commissioners and providers refer to the latest document that is in effect.

The 2016-17 agreement is available at www.gov.uk (search for 'commissioning public health').

All current service specifications are available at www.england.nhs.uk (search for 'commissioning public health').

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 Programmes (NDESP).

The purpose of the service specification for the NDESP is to outline the service and quality indicators expected by NHS England (NHSE) for NHS England's responsible population.

The NDESP was in a development phase during the implementation of the common pathway and that development is now complete. Local providers should now be delivering a service that meets the national service specification. Further developments of the service may commence during 2016/17 relating to the implementation of extended screening intervals. The national service specification reflects requirements for any early implementers of that potential development.

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 NDESP guidance and recommendations. These can be found on the NDESP website:

<https://www.gov.uk/topic/population-screening-programmes/diabetic-eye>

NHS DESP Programme Standards:

<https://www.gov.uk/government/publications/diabetic-eye-screening-standards-and-performance-objectives>

Guidance and updates on KPIs:

<https://www.gov.uk/government/publications/young-person-and-adult-screening-submit-key-performance-indicator-data>

NDESP Operational Guidance:

<https://www.gov.uk/government/collections/diabetic-eye-screening-commission-and-provide>

Guidance on Failsafe:

<https://www.gov.uk/government/publications/diabetic-eye-screening-programme-failsafe-procedures>

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

<https://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes>

1.2 Aim

The aim of the NDESP 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 Quality Assurance (QA) schemes
- have audit embedded in the service

1.4 Health outcomes

There are around 2.9m people with diabetes mellitus in England. Diabetic retinopathy is a complication of diabetes and is one of the leading causes 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 individuals 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 NDESP 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 NDESP 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

1.6 Equality

The objectives of the screening programme should include:

Help reduce health inequalities through the delivery of the programme

Key deliverables:

- Screening should be delivered in a way which addresses local health inequalities, tailoring and targeting interventions when necessary
- A Health Equity Impact Assessment should be undertaken as part of both the commissioning and review of this screening programme, including equality characteristics, socio-economic factors and local vulnerable populations
- The service should be delivered in a culturally sensitive way to meet the needs of local diverse populations
- User involvement should include representation from service users with

- equality characteristics reflecting the local community including those with protected characteristics
- Providers should exercise high levels of diligence when considering excluding people with protected characteristics in their population from the programme and follow both equality, health inequality and screening guidance when making such decisions

The provider will be able to demonstrate what systems are in place to address health inequalities and ensure equity of access to screening, subsequent diagnostic testing and outcomes. This will include, for example, how the services are designed to ensure that there are no obstacles to access on the grounds of the nine protected characteristics as defined in the Equality Act 2010.

The provider will have procedures in place to identify and support those persons who are considered vulnerable/ hard-to-reach, including but not exclusive to, those who are not registered with a GP; homeless people and rough sleepers, asylum seekers, gypsy traveller groups and sex workers; those in prison; those with mental health problems; those with drug or alcohol harm issues; those with learning disabilities, physical disabilities or communications difficulties. The provider will comply with safeguarding policies and good practice recommendations for such persons.

Providers are expected to meet the public sector Equality Duty which means that public bodies have to consider all individuals when carrying out their day-to-day work – in shaping policy, in delivering services and in relation to their own employees

<https://www.gov.uk/equality-act-2010-guidance>

It also requires that public bodies:

- have due regard to the need to eliminate discrimination
- advance equality of opportunity
- foster good relations between different people when carrying out their activities

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 with diabetes for screening at regular intervals (i.e. call/recall)
- taking digital images of the eyes of the person with diabetes
- grading the digital images of the eyes of the person with diabetes
- providing surveillance clinics with slit lamp biomicroscopy assessments
- providing surveillance clinics using digital imaging
- ensuring people with diabetes with referable eye disease are referred to appropriate Hospital Eye Services/Treatment Services
- undertaking internal Quality Assurance (QA)
- providing clinical oversight and governance for the Programme

In accordance with NHS Screening Programmes' standards and protocols the provider is expected to fulfil the following

- work to nationally agreed NDESP standards, guidance, policies and pathway
- implement and support national IT developments
- use NHS Screening Programme materials and the protocols for their use
- provide timely and accurate performance data
- respond to national action/lessons such as change of software, supplier, techniques
- work with NHS England and NHS Screening Programmes QA team 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 commissioners to ensure uptake is maximised and there is equity of access to the service for all people with diabetes.
- ensure the workforce is qualified and meeting all NDESP standards

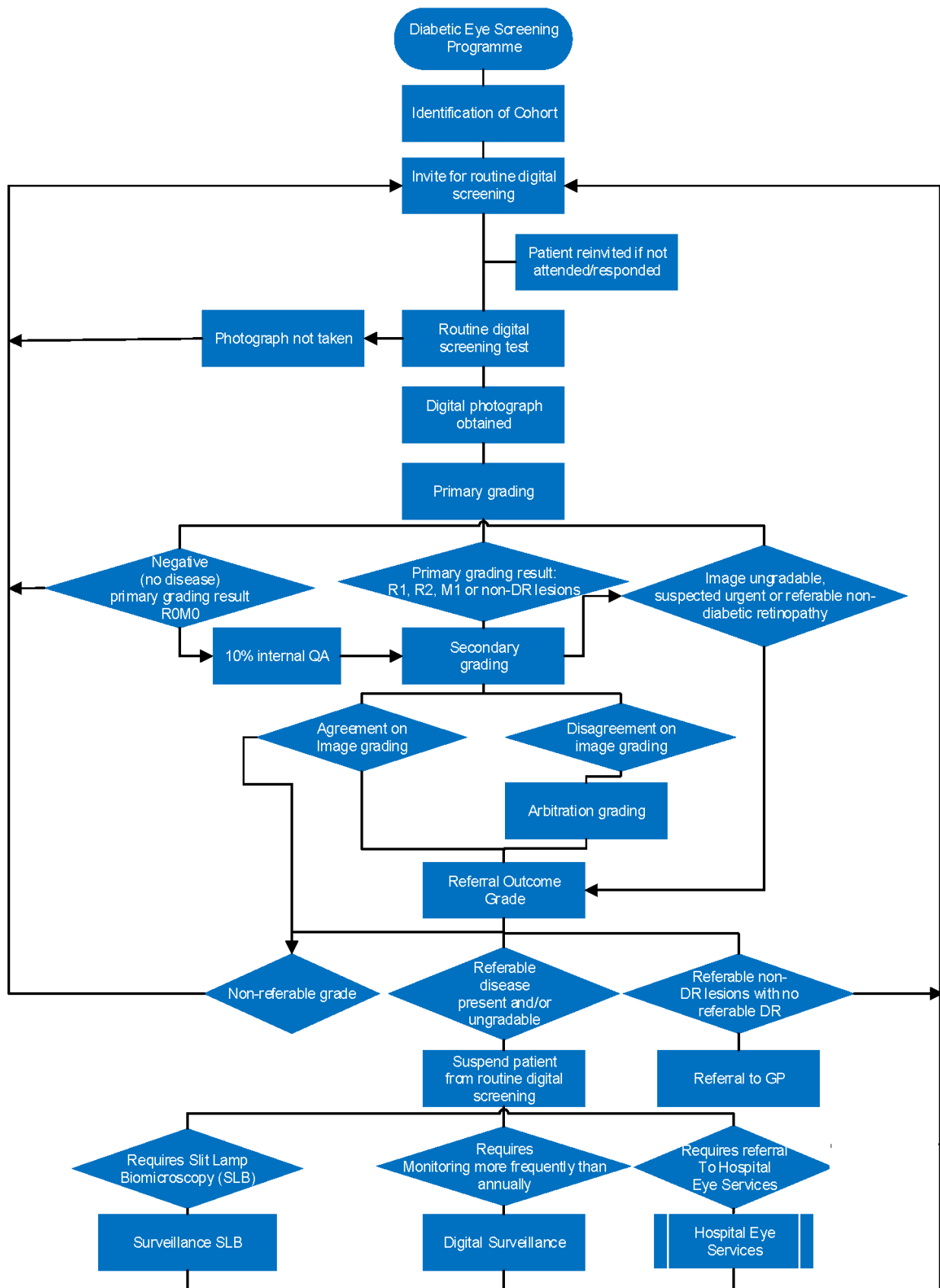
The programme interfaces with and is supported by a number of other services (e.g. primary care, diabetology, hospital eye services and IT support).

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 Care Pathway

A new screening pathway diagram will be here based on the Map of Medicine pathway – link below.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/440075/Diabetic_eye_screening.pdf



Version 1.0/08-2015

2.3 Description of the Screening Pathway

The NDESP is based on the policies developed by the NHS Screening Programmes. The screening procedure is divided into the following stages:

- Identification
- Invitation
- Inform
- Test
- Diagnose
- Referral for treatment/ intervention
- Surveillance
- Monitor outcomes

In accordance with NHS Screening Programmes' 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 mellitus (excluding gestational 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 – *NDESP: Exclusions, Suspensions and Management of Ungradables*

<https://www.gov.uk/government/publications/diabetic-eye-screening-screening-exclusions-and-suspensions-and-managing-ungradable-images>

2.4 Failsafe

In accordance with NHS Screening Programmes' standards and protocols the provider shall comply with the NDESP 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 people with diabetes excluded and suspended from screening
- Ensure that results have been sent to people who have attended screening, General Practices and other appropriate clinicians for example paediatrician, obstetrician, diabetologist
- Ensure referrals have been processed appropriately
- Track the progress of each person with diabetes along the screening pathway using the Programme's management software according to national guidance.

- Ensure safe systems are in place for referrals referring 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).

2.5 Key Roles and Responsibilities

In accordance with NHS Screening Programmes' standards and protocols the provider will ensure that the following roles are fulfilled:

- Clinical Lead
- Programme Manager
- Senior Screener/Grader
- Screener/Grader
- Failsafe Officer
- Administrator

Clinical Lead

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

The Clinical Lead (CLDESP) will either be a consultant (or senior specialty doctor) ophthalmologist with medical retina experience or a consultant diabetologist. In many programmes, the CLDESP is also the ophthalmology lead for DR at one of the HES/treatment centres but this is not a requirement. If the CLDESP is a consultant diabetologist then a consultant or senior specialty doctor grade ophthalmologist with medical retina experience should be appointed to provide dedicated support to the programme.

The detailed responsibilities of the Clinical Lead are set out in section 3.5 below.

Programme Manager

The Provider is responsible for providing Programme Management. The programme manager has overall responsibility for the operational running of all aspects of the programme including its quality assurance processes and for implementing continuous improvement strategies. The detailed responsibilities of the Programme Manager are set out in section 3.4 below.

Senior Screener/Grader

The Provider is responsible for providing a senior screener/grader. The senior screener/grader will be clinically responsible to the clinical lead. The senior

screeener/grader will be an experienced grader who supervises and provides training and feedback to the programme's team of screeners and graders and ensures that all members of the screening and grading team meet national standards. This role may be undertaken by the clinical lead or be delegated to the programme manager or an accredited screener/grader.

Screeners/Graders

The Provider is responsible for providing an appropriate number of screeners and graders to ensure that all eligible people with diabetes in its cohort can be screened and graded according to national standards. Grading must be provided at primary, secondary, arbitration and referral outcome grade levels. The responsibilities of the screener include: explaining the test procedure to the person with diabetes and obtaining consent; undertaking visual acuity checks, instilling eye drops, taking digital images. The responsibilities of the grader include: grading each digital image according to national standards.

Failsafe Officer

The Provider is responsible for providing failsafe of all stages of the screening pathway. This role may be undertaken by one designated person or may be a clearly defined shared responsibility amongst two or more members of the team, each undertaking failsafe for a particular aspect of the care pathway from cohort identification through to referral and follow up. Failsafe should be undertaken at each stage of the care pathway according to national guidelines.

Administrator

The Provider is responsible for providing an appropriate number of administrators for the programme in order to ensure the timely provision of the following services to people with diabetes : identification of cohort; invitation, reminder, appointment booking; despatch of results, responding to telephone enquiries.

2.6 Commissioning Arrangements

The commissioning of the NDESP pathway involves commissioning at different levels which may include NHS England, CCGs.

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 NDESP Guidance.

With a 5% growth per annum in the number of people diagnosed with diabetes the delivery of DES is being put under significant pressure. A strategic approach to commissioning in DES is recommended to realise benefits to people with diabetes and to the NHS in terms of quality and cost effectiveness. Guidance for commissioners can be found at:
<https://www.gov.uk/government/publications/diabetic-eye-screening-guidance-for-commissioners>

2.7 National commissioning through NHS England

NHS England 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 NDESP 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 mellitus (excluding gestational diabetes) age 12 and over who are eligible to be invited for screening
- a provider to deliver the NDESP in an accessible, high quality and safe manner
- ensuring appropriate levels of governance and accountability by supporting a Programme Board
- ensuring that there are safe referral mechanisms to transfer people with referable diabetic retinopathy from the screening programme to the Hospital Eye Service including the acknowledgment of referrals and acceptance of responsibility for those who are screen positive
- ensuring 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
- ensuring that information transfer between services is effective
- ensuring good relationships and communication between people with diabetes, screening services, specialist services and primary care services to drive up quality of care provided by the screening programme
- working with National Screening Programme and suppliers of national IT systems to ensure a safe and effective screening programme that meets national guidance

Elements of the pathway, e.g. call/recall; screening/grading; can be commissioned separately however all elements must be linked and working effectively across the pathway to ensure robustness of delivery, robust and

sustainable governance and the safety of people with diabetes. This includes the exchange of information and outcomes.

2.8 Links between screening programme and national programme centre expertise

PHE, through the NHS screening programmes, is responsible for leading high-quality, uniform screening, providing accessible information to both the public and health care professionals, and developing and monitoring standards. It is also responsible for the delivery of national quality assurance, based at regional level, and for ensuring training and education for all those providing screening is developed, commissioned and delivered through appropriate partner organisations.

Section 3: Delivery of Screening Programme

3.1 Service model summary

This service can be delivered by different models in a number of ways e.g. 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 a 12 month screening interval for all people with diabetes invited for routine digital screening according to NDESP Guidance, unless advised to alter by the NHS Screening programmes.

Anyone requiring more frequent screening (for example 3 or 6 monthly assessment) should be seen in digital surveillance clinics. Programmes should not operate recall intervals of less than 12 months as part of the routine screening programme.

Pregnant women require more frequent screening and should be seen within surveillance clinics at intervals that meet NICE guidelines.

The Programme includes the following elements:

- Programme Management
- Clinical Leadership
- Administration of the Programme
 - *Identify the cohort*
 - *Inform*
 - *Invite*
 - *Report outcome*
- Screening Test (Digital Image Capture)
- Grading of Digital Images
- Surveillance
 - Slit lamp Biomicroscopy surveillance screening
 - Digital image surveillance
- Ophthalmology Referral (*Diagnose, treat, intervene, outcome*)
- Failsafe
- Internal QA

These elements are set out under their respective headings below (sections 3.4 to 3.11). The Provider must perform each of these elements

3.2 Population coverage

In line with national guidance, NHS England 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 NHS Screening Programmes' standards and protocols the provider will be responsible for ensuring that the part of the programme they deliver is co-ordinated. 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 NDESP are met.

In circumstances where different organisations other than 'The Provider' deliver different parts of the pathway for example 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
- manage risks and mitigation plans

3.4 Programme Management

The Provider should ensure the appointment of 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 NDESP Standards

3.5 Clinical and Corporate Governance

In accordance with NHS Screening Programmes' 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 manager 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 person named, the provider will ensure that there are adequate cover arrangements in place to ensure sustainability and consistency of programme management.

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 professional accountability for the Programme.

The Clinical Lead will either be a consultant (or senior specialty doctor) ophthalmologist with medical retina experience or a 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 NDESP 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 people with diabetes up to the point where a referral has been made into the Hospital Eye services
- ensure failsafe processes are working effectively

In many programmes, the CLDESP is also the ophthalmology lead for DR at one of the HES treatment centres but this is not a requirement.

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

<https://www.gov.uk/government/publications/diabetic-eye-screening-roles-of-clinical-leads>

Governance

In accordance with NHS Screening Programmes' 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 and a Programme Manager.
- Ensure representation of key stakeholders on the multidisciplinary Programme Board established by NHS England
- ensure that there is regular monitoring and audit of the screening programme and that as part of the organisation's Clinical Governance arrangements, the Provider organisation's Trust Board is assured of the quality of the screening programme
- comply with the NHS Screening Programmes' guidance 'Managing Serious Incidents in the English NHS National Screening Programmes' (or updated version) and NHS England serious incident documentation
- have appropriate and timely arrangements in place for referral into treatment services that meet programme standards found on the National Screening programme website
<https://www.gov.uk/government/collections/nhs-population-screening-programme-standards>
- provide documented evidence of clinical governance and effectiveness arrangements on request
- ensure that regular reports of screening services are produced to meet national guidelines which are 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
 - involvement, experience and complaints from people with diabetes
 - 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 in a single collated list. This should include where the Provider is made aware (other than from a General Practice update) that details of a person with diabetes have changed, the Provider shall record this fact and shall provide regular and frequent updates detailing such changes to the General Practices of those people. Where this can be achieved through the NDESP's 'GP2DRS solution', the Provider shall use such 'GP2DRS solution'
- undertake at a minimum quarterly updates of lists of people with diabetes from GP practices
- providing systematic call/recall of the eligible population for routine digital screening, slit lamp biomicroscopy and digital surveillance
- identification of the eligible population who are either excluded or suspended
- undertaking regular audits of those people with diabetes excluded/suspended to ensure accurate records
- inviting for screening the eligible population who are neither excluded nor suspended
- providing results from routine digital screening, slit lamp biomicroscopy and digital surveillance to people who have been screened and their clinicians

3.7 Management of people with diabetes excluded & suspended

The provider will make every effort to maximise 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 people with diabetes excluded or suspended from the Programme in accordance with the NDESP Guidance: '*Exclusions, Suspensions and Management of Ungradables*'.

<https://www.gov.uk/government/publications/diabetic-eye-screening-screening-exclusions-and-suspensions-and-managing-ungradable-images>

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

In accordance with NHS Screening Programmes' standards and protocols the provider shall

- operate a central call/recall service from a single centre to invite each person with diabetes in the Cohort to attend screening appointments, unless that person with diabetes has been excluded or suspended from screening (in accordance with the NDESP Guidance)
- invite (by post) all people with diabetes to attend screening by sending out initial invitations inviting them to attend a routine digital image capture session within 3 months of their being notified to the screening programme and thereafter by sending invitations every 12 months

following each person's last digital image capture session, unless required otherwise by the NDESP Guidance

- ensure that the Programme operates safe appointment booking systems in accordance with NDESP Guidance and timescales
- use an appropriate booking model for inviting people with diabetes for screening, that meets national guidance of the NDESP
- maintain up to date records of all screening locations (including accessibility) and screening dates and times
- provide people with diabetes with information about their appointment, together with any other information required by the NDESP Guidance
- ensure that all invitation letters conform to current national templates
- ensure that all people with diabetes 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 information for non-English speakers and access to appropriate interpreting
- ensuring programmes obtain consent in accordance with NDESP guidance
- Providers must always use the patient information leaflets from PHE Screening at all stages of the screening pathway to ensure accurate messages about the risks and benefits of screening and any subsequent surveillance or treatment are provided. PHE Screening should be consulted and involved before developing any other supporting materials.
- Providers must involve PHE Screening and PHE Communications in the development of local publicity campaigns to ensure accurate and consistent messaging, particularly around informed choice, and to access nationally-developed resources. For local awareness campaigns, local contact details must be used.
- Providers must not develop their own information about screening for local NHS websites but should always link through to the national information on NHS Choices (<http://www.nhs.uk/Livewell/Screening/Pages/screening.aspx> or the relevant programme page) and GOV.UK (<https://www.gov.uk/topic/population-screening-programmes> or the relevant programme page).
- To support PHE Screening to carry out regular reviews of the national screening public information leaflets and online content, providers are encouraged to send PHE Screening the results of any local patient surveys which contain feedback on these national resources.

3.9 Reporting screening results

The Provider shall:

- report the results to the person with diabetes and to their primary care professional and consultant diabetologist, paediatrician and obstetrician (where relevant) in accordance with NDESP Guidance and timescales

3.10 Analysis of non-responders-and DNAs

The Provider shall:

- undertake an analysis of non-responders-and DNAs on a six monthly basis at a minimum and take appropriate action to address issues of non-attendance

3.11 Participation

The Provider shall

- monitor the Programme and engage with people with diabetes by conducting satisfaction surveys and processing survey results.
- provide a satisfaction survey on an annual basis and report the summary outcome to the programme board

3.12 Screening test (Digital Image Capture)

The Provider shall:

- be responsible for delivering the screening test (digital image capture) in line with NDESP 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 NDESP 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 NDESP Guidance

- ensure that each camera that it uses to provide the service is set at the same or similar settings as every other camera used in the Programme, within the limitations of the resolution settings available for each camera. The resolution must be sufficiently high to enable the accurate grading of digital images, in line with NDESP Guidance

3.16 Conducting screening sessions

The Provider shall:

- undertake digital image capture screening in accordance with NDESP Guidance for each person with diabetes who has an appointment and attends for screening
- ensure that this includes (unless otherwise updated by the NDESP Guidance):
 - Preparing the person with diabetes, providing information about the test, obtaining informed consent, measuring Visual Acuity and undertaking mydriasis
 - Taking 2 digital colour images of each retina

3.17 Following screening

The Provider shall ensure that each person with diabetes 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 the NDESP grading pathway overview.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/403074/Pathway_Diagrams_V1_2_29Oct12_SSG_1_.pdf

Any person found to have referable disease will have their images graded by the clinical lead (or a senior accredited grader 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 NDESP Guidance: *Revised Grading Definitions*
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/402294/Revised_Grading_Definitions_V1_3_1No_v12_SSG.pdf
- Use features based grading

3.18.3 Maintenance and implementation of protocols & policies

The Provider shall:

- ensure that it documents, maintains and implements protocols for the grading pathway of the Programme, in line with NDESP Guidance
- establish and maintain quality assurance & failsafe processes as required by NHS England, and/or the NDESP Guidance for the grading pathway
- ensure grading complies with the NDESP Retinopathy Grading Definitions
- ensure 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 imaging
 - using slit lamp biomicroscopy
- operate an administration function to provide call/recall, appointments and failsafe for surveillance clinics
- use the programme management software surveillance module to make appointments and record results for this service
- work towards recording all surveillance clinic screening events directly on the screening management software, irrespective of where the clinics take place
- refer people with diabetes to digital surveillance clinics 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 NDESP guidance, using appropriate technology. Surveillance clinics may interface with OCT assessment where this has been agreed with commissioners of Hospital Eye Services.

- refer people with diabetes with ungradable images to slit lamp biomicroscopy surveillance clinics
- record surveillance activity separately to screening service activity
- report the results of the surveillance to the person screened and to their primary care professional and consultant diabetologist, paediatrician and obstetrician (where relevant) in accordance with NDESP 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 imaging surveillance clinics
- establish and maintain quality assurance & failsafe processes
- record SLB and digital imaging outcomes according to local protocols based on best evidence and NDESP 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 NDESP Guidance.

3.19.3 Conducting assessments

The Provider shall:

- undertake slit lamp biomicroscopy grading in accordance with NDESP Guidance,
- ensure the person carrying out the test meets 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 NDESP Grading Definitions
- ensure that each person screened is processed into the correct referral pathway according to national guidelines, 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 people with diabetes into and out of the Programme (eg to/from the HES) and between different elements of the Programme (eg to/from surveillance)
- monitor every person with diabetes who is suspended from ~~annual~~ routine screening to ensure they are safely entered into the correct care pathway according to national timescales
- ensure that people with diabetes who no longer require follow up at a hospital eye service return to routine annual screening or surveillance according to NDESP guidance
- ensure that people with diabetes who no longer require surveillance are returned to routine annual screening according to NDESP guidance
- Regularly audit people with diabetes who are excluded to ensure they meet NDESP criteria for exclusions

3.21 Internal QA

The Provider will undertake internal QA activities in accordance with NDESP 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 people with diabetes presenting with disease to symptomatic services in line with NDESP Standards and guidelines
- Following guidelines according to the 'Managing Grading Quality' and 'Participation in Test and Training' documents.
<https://www.gov.uk/government/collections/diabetic-eye-screening-commission-and-provide>

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 people with diabetes including:
 - geographically accessible for people arriving by public transport, by car and on foot
 - structurally and physically accessible, including meeting the needs of any disabled or partially sighted people with diabetes 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 shall be based on the needs and wants of the target population with the aim of maximising the uptake of the screening offer and in consultation with the Commissioner. Consideration of the move to 7 day services should be made, building the local evidence base, acknowledging that this will be based on local population needs

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 professionals 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 register of people with diabetes is maintained up to date
- primary care is made aware of any failure to attend appointments
- primary care is made aware of screening results in order to ensure integration with the overall diabetes care of that person with diabetes
- the person with diabetes 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 people with diabetes to the HES are shown in the Care Pathway. In addition, the Programme must deliver failsafe in accordance with national guidance in order to ensure safe and appropriate

transfer of the person with diabetes to the care of the HES has been completed.

3.26 Transfer of and Discharge from Care Obligations

Screening ends when a person with diabetes is screened and the result is:

- screen negative i.e. No referable DR and to be re-invited for routine digital screening in 12 months or according to national guidance
- screen positive i.e. referable DR and referred to the hospital eye service and suspended from routine digital screening
- assessed as medically unfit and excluded from the programme
- other eye pathology and is referred to the GP or directly to the hospital eye service according to local protocol but remains eligible for routine digital screening

Surveillance will be provided when a person with diabetes has:

- An ungradable image and requires slit lamp biomicroscopy
- A referable grade and the clinical lead assesses against best evidence that the person with diabetes can be monitored at a digital surveillance clinic.

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

3.27 Exclusion criteria

The Provider shall manage people with diabetes excluded or suspended from the Programme in accordance with the NDESP Guidance.

<https://www.gov.uk/government/publications/diabetic-eye-screening-screening-exclusions-and-suspensions-and-managing-ungradable-images>

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 NDESP standards. The Provider should undertake contingency planning to ensure the programme's resilience. The Provider will include induction training for all new staff and regular update training for existing staff including safe-guarding policies.

3.29 Competencies & On-Going Training

Providers are responsible for funding minimum training requirements to maintain an effective screening workforce including CPD where necessary. Training requirements are detailed at <http://cpd.screening.nhs.uk/diabeticeye> and must meet with NDESP Pathway Standards

<https://www.gov.uk/government/publications/diabetic-eye-screening-standards-and-performance-objectives>

Providers should ensure training has been completed satisfactorily and recorded and that there is a system in place to assess on-going competency.

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

<https://www.gov.uk/government/publications/diabetic-eye-screening-test-and-training-participation>

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 when this is issued. This should be made available to NHS England on request.

The provider will ensure that the clinical lead and programme manager attend one NDESP educational event each year as a minimum .

3.30 IT

The Provider will:

- ensure that the programme management software that is in use is the most up to date version available and meets NDESP guidance
- ensure that the software is configured to meet NDESP guidance
- ensure that there is a disaster recovery plan in place
- ensure that there is adequate server capacity for safe programme operation
- ensure senior level IT support to oversee software upgrades/changes
- be able to quantify spend on IT system and support and provide on request

3.31 Involvement of people with diabetes

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 people with diabetes, families and others in respect of the services they provide
- demonstrate how those views have influenced service delivery for the purposes of raising standards
- show that all people with diabetes and their families are given information about how to provide feedback about services they receive, including about the complaints procedure.

The results of involvement of people with diabetes will be made available to NHS England on request.

3.32 Safety & Safeguarding

The provider should refer to and comply with the safety and safeguarding requirements as set out in the NHS Standard Contract. As an example, please see link below for 2013/14 NHS Standard Contract:

<http://www.england.nhs.uk/wp-content/uploads/2013/03/contract-service.pdf>

Section 4: Service Standards, Risks and Quality Assurance

4.1 Key criteria and standards

Programme standards are available on the programme website (<https://www.gov.uk/topic/population-screening-programmes>). Providers will meet the acceptable and work towards the achievable programme standards. A number of resources to support providers are available on the programme website.

4.2 Risk assessment of the screening pathway

Providers are required to have an internal quality assurance and risk management process that assures the commissioners of its ability to manage the risks of running a screening programme.

Providers will:

- ensure that mechanisms are in place to regularly audit implementation of risk reduction measures and report incidents
- ensure that risks are reported through internal governance arrangements, such as risk registers
- review and risk assess local screening pathways in the light of guidance offered by Quality Assurance processes or the National Screening programme
- work with the Commissioner and Screening Quality Assurance Service (SQAS) teams to develop, implement, and maintain appropriate risk reduction measures

High scoring risks will be identified and agreed between the provider and the commissioners and plans put in place to mitigate against them. The provider will identify risks with high scores. The provider and commissioner will agree plans to mitigate risks.

4.3 Quality assurance

Providers will participate fully in national Quality Assurance processes, cooperate in undertaking ad-hoc audits and reviews as requested by SQAS teams and respond in a timely manner to their recommendations. This will include the submission to SQAS teams and commissioners of:

- Agreed data and reports from external quality assurance schemes
- minimum data sets as required .
- self-assessment questionnaires / tools and associated evidence

All providers should operate failsafe systems that can identify, as early as possible, people with diabetes that may have been missed or where screening results are incomplete.

Providers will respond to SQAS recommendations within agreed timescales. They will produce with agreement of commissioners of the service an action plan to address areas for improvement that have been identified in recommendations. Where SQAS believe there is a significant risk of harm to the population, they can recommend to commissioners to suspend a service.

Section 4.4 Safety concerns, safety incidents and serious incidents

Providers will comply with the national guidance for the management of safety concerns and incidents in screening programmes and NHS England guidance for the management of serious incidents

(<https://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes>).

Section 4.5 Procedure and protocols

The provider will be able to demonstrate that they have audited procedures, policies and protocols in place to ensure best practice is consistently applied for all elements of the screening programme.

Section 4.6 Service improvement

Where national recommendations and acceptable/achievable 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 to any performance issues highlighted by the commissioners, 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 commissioners.

4.7 Teaching & Training

Providers must facilitate screener training in line with programme requirements/standards as detailed in each NHS screening programme specification. Providers should ensure training has been completed

satisfactorily and recorded and that they have a system in place to assess on-going competency.

Providers must allow appropriate annual CPD in line with programme and requirements, for example a screening study day or completion of national NHS Screening Programme e-learning.

Providers 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 / Public Health Outcomes Framework

The provider shall adhere to the requirements specified in the document 'Key Performance Indicators for Screening'. Please refer to <https://www.gov.uk/government/collections/nhs-screening-programmes-national-data-reporting> for further details, guidance and updates on these indicators

Public Health Outcomes Framework Indicator

2.21vii: The percentage of those offered screening for diabetic eye screening who attend a digital screening event

Key Deliverable: The acceptable level should be achieved as a minimum by all programmes

Acceptable $\geq 70.0\%$

Achievable $\geq 80\%$

5.2 Data collection monitoring

Providers should ensure that appropriate systems are in place to support programme delivery including audit and monitoring functions.

The Provider shall continually monitor and collect data regarding its delivery of the Service

The Provider will comply with the timely data requirements of the National Screening programmes and regional Quality Assurance teams. This will include the production of Annual Reports. The most up to date Dataset can be accessed from the National Screening programme website

5.3 Data reporting

The Provider will promptly provide both KPI and the Annual Report data to the NDESP, as required by the NDESP Guidance. This data is reported against the minimum data set relating to the standards.

- Activity and performance data will be shared with the screening coordinator of the Area Team of NHS England to allow benchmarking between areas within the eligible screening programme population.
- Annually reported figures will be reported to allow NHS England 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 to their local area team.

More details of routine reporting are found on the NDESP website.