

UK NATIONAL SCREENING COMMITTEE

Essential Elements in Developing a Diabetic Retinopathy Screening Programme

**This Workbook is designed to inform and assist SHAs and PCTs
integrate current or planned diabetic retinopathy screening programmes
with the Diabetic Retinopathy Screening Programme in England**

Workbook 4

August 2007

Addenda

The following documents have been published or updated since the initial release of Workbook 4 in January 2007, and affect the advice and guidance in this workbook. All documents are available from the National Programme website at <http://www.nsretinopathy.org.uk>,

[Advice on administering eyedrops](#), updated 29/01/2007

This workbook contains three interdependent sections, all of which will need careful consideration by those involved in planning and setting up a diabetic retinopathy screening programme:

Section 1 details the necessary elements of a programme

Section 2 explains the quality assurance standards against which programmes will be evaluated

Section 3 details various IT considerations to be made when setting up and managing a programme

It is vital to understand that these sections should be considered together: for example, the way that a programme is administered will be affected by a sound understanding of the quality assurance standards. It will also be affected by the model or combination of models used. Costing and pricing of the model is underpinned by the procurement and maintenance of appropriate cameras, software and support. These considerations together will determine whether one screening model should be selected over another.

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Introduction to the Programme Management Workbook

We have received many phone calls from clinicians, managers and public health professionals asking how problems are being tackled in other services. We have also been in touch with many services during the course of the work of the Steering Group and its sub-committees, and are in the position to summarise the experience from the field and make it available more generally.

These issues are largely concerned with the management of the programme, and the services that compose it.

This is the fourth edition of the Programme Management Workbook. The latest version of the workbook is always available from the National Screening Programme website at <http://www.nscoretinopathy.org.uk>, and is distributed through links with the National Clinical Director for Diabetes (Dr Sue Roberts) and links with the Public Health Network.

Changes made since the preceding edition are highlighted in blue and marked with a line in the margin so that the reader knows what is new and what is constant.

Programme management

The policy for screening for diabetic retinopathy was clearly set out in the National Service Framework for Diabetes, which is being led by Dr Sue Roberts. The National Screening Committee has set up a Programme Centre based in Cheltenham led by Dr Peter Scanlon to support the Diabetic Retinopathy Screening Programme.

Locally policy will be implemented by screening programmes, each covering a defined population with a common set of objectives and a single programme manager. Screening will be commissioned by primary care trusts.

The first step for any programme to take is to be absolutely clear about the population it covers. This can be done on the basis of primary care trusts and, for fine detail, by primary care teams, because the borders of primary care trusts do not match perfectly with hospital catchment areas.

The first step in management is to identify responsibility for commissioning the programme by one PCT taking lead responsibility. In parallel each programme needs to identify its programme manager. It is not expected that the programme manager will be a public health professional, unless that public health professional is employed by the trust delivering ophthalmology services and has been given specific responsibility for programme management. Each programme manager must then be clear about which primary care trusts they will cover in whole or in part, and set up a working relationship with those trusts.

Sir Muir Gray, Director, UK National Screening Committee

Section 1: Essential elements of the screening process

The following list details essential elements of any local screening programme, drawing on all of these sections.

- Clearly identify the boundaries of the screening programme and the population to which screening will be offered in relation to neighbouring programmes.
- Assess current screening practice within the locality and involve the key stakeholders in planning the development of systematic screening (e.g. Commissioners, Ophthalmologists, Diabetologists, Optometrists, Nurses, IT representatives) and ensure that each programme is based around at least 12,000 people with diabetes / 500,000 population base.
- Appoint a **programme manager** with responsibility for leading the diabetic retinopathy programme, and a **clinical lead with overall clinical responsibility for its secure operation**.
- **Select a delivery model appropriate to local circumstances, taking into account existing screening arrangements where these can securely be extended as part of a systematic, quality assured programme**
- Consider IT requirements and costs (number of users, number of sites, server capacity, software for managing the programme, existing and required network infrastructure, backup, maintenance and support).
- Set up a central administration structure for the service including establishing and maintaining a single collated list of **all people with diabetes in the area covered by the programme**.
- Determine who is going to screen people with diabetes for retinopathy (two digital colour photographs of each eye by a trained and accredited screener, after mydriasis), at what location, and what to do with patients who have poor quality images.
- Set up a grading centre for grading of images and for quality assurance purposes.
- Organise arbitration level grading so that an ophthalmologist or other health professional experienced in this field can quality assure second full grading, and preferably so that an ophthalmologist can assess images considered to be referable before a referral is made.
- At the hospital eye clinic, set up measures to monitor referrals from the screening programme, including the identification of false positives, data collection for standards relating to clinic appointments and treatment, and feedback to the screening programme of any assessment of the level of diabetic retinopathy, whether following referral from the screening programme or not.

- Consider local training requirements for the workforce in parallel with national initiatives.
- Have a policy to involve people with diabetes and create public information and awareness.
- The SHA should take an active interest in the PCT commissioning process to assess whether the essential elements contained in this document are addressed. It should ensure that what is included in the Local Development Plan (LDP) adequately provides for both capital purchases such as cameras, software, trolleys and transport as well as revenue workforce expenditures. [Discussions are underway with the Department of Health regarding the funding of external national quality assurance. Meanwhile it is sensible to allocate £8000 per annum for each PCT for the cost of setting up and running external Quality Assurance nationally.](#)
- **NSF targets specify that 80% of patients on the single collated list should have been offered screening appointments by the end of March 2006, and 100% of eligible patients should have been offered screening appointments between 1 January 2007 and 31 December 2007.**

1.1 Leadership of the programme

[The first step in establishing a diabetic retinopathy screening programme is to appoint a programme manager with responsibility for leading the diabetic retinopathy programme, and a clinical lead with overall clinical responsibility for its secure operation.](#)

Screening services that have successfully developed in England have all had enthusiastic individuals to champion the service. Such individuals, working with an appropriate multi-disciplinary team, may come from various disciplines or levels of seniority, but are essential for the development of a successful service.

1.2 Programme size

It is important that all screening programmes cover **at least** 12,000 people with diabetes. This key requirement may require PCTs to band together to form programmes. Programmes must be sufficiently large:

- a) to enable meaningful management data to be collected and analysed, in order to reveal significant statistical trends;
- b) for graders to encounter sufficient examples of the various clinical indicators of diabetic retinopathy to be experienced in disease identification; and
- [c\) to allow secure and efficient administration.](#)

It is generally recommended to arrange screening programmes around the treatment centres into which cases of sight-threatening diabetic retinopathy will be referred. It can cause administrative difficulty in the eye clinic if it has to return data to more than one programme. It can also cause quality assurance problems for a programme if two or more programmes are served by the same clinic because, for instance, one

programme may over-refer patients thus causing treatment delays for other programmes served by the centre.

For further details, please refer to NDST Factsheet 4 at http://www.cgsupport.nhs.uk/downloads/NDST/Factsheet_screening_size.pdf.

1.3 Public and patient involvement

Informing and involving people with diabetes in all aspects of their care is a central part of the Diabetes NSF. It has been essential to involve people with diabetes in deciding how national and local services will be provided and how care pathways can be developed and implemented. Screening for diabetic retinopathy can form a key part of care plans for people with diabetes and it is vital that they and their carers understand why it is being done and the risks associated with failing to be screened.

Public education about the aim of the diabetic screening programme, which is to detect sight threatening diabetic retinopathy, has been undertaken. The general public should be made aware of the limitations of the programme as well as the advantages because, as with all screening programmes, 100% of persons with sight threatening retinopathy will not be detected.

Three patient information leaflets have been completed, and are available on the English national 'Patient and Public involvement part of the website at <http://www.nscaretinopathy.org.uk>.

“Eye screening for people with diabetes – the facts”

This leaflet explains why screening is undertaken and what the patient should expect to happen at the screening visit. It also contains information from PIAG on handling of information about the patient and opting out procedures.

“Diabetic retinopathy – the facts.”

This leaflet describes the features of and risk factors for diabetic retinopathy. It is designed to be an adjunct to discussion with the patient when diabetic retinopathy is detected.

“Preparing for laser treatment for diabetic retinopathy and maculopathy.”

This leaflet explains why and how laser treatment is given, and discusses the risks and benefits. It is designed to be read by the patient prior to their appointment for laser treatment as an aid to discussion in an informed consent process.

1.4 Administration

The administration of the programme should centre on the delivery of the Service Objectives and Quality Assurance Standards, listed at Appendix 2.

All people with diabetes aged 12 years and older should be offered screening for sight-threatening diabetic retinopathy using digital photography for quality assurance purposes, but special consideration needs to be given to the housebound, those in

nursing homes and in prisons.

Highly organised and systematic administration will reduce the risk of disease progressing unavoidably. Administration centres should maintain a folder containing the processes and protocols for every aspect of programme administration and co-ordinate the processes and protocols for all other aspects of the screening programme.

The administration of the programme needs to consider the following:

- The creation and regular maintenance of a full and accurate database, which securely identifies every person with diabetes aged 12 years or over (the **single collated list**). This is the foundation stone of systematic screening. Care needs to be taken to 'weed out' very regularly those who have died or moved. It is as important to monitor those who have not been invited to screening as those that have, as the former are in a high risk group. For that reason, and because it is essential that consistent up-to-date data be collated, it is **not** recommended that the management of the call/recall process be carried out by GP surgeries. See 'Importance of central call/recall' at <http://www.nscretinopathy.org.uk>.
- The administration of the programme, including the issuing of **all** invitations for screening and the tracking of patient activity, should be carried out from a **single centre** to reduce the risk of error and to ensure: a) consistency of management and information provision is maintained; and b) that clear lines of responsibility and accountability for this key function are facilitated in practice.
- The full list should be subdivided to distinguish between those people who must be invited for screening (who will appear on the **active list**) and who should not be invited (who will appear on the **inactive list**). The latter group, which should be very small in number, should be sub-divided into those who are *temporarily inactive* and those who are *permanently inactive*, and that list must be managed and monitored carefully and regularly following the principles laid down in the 'exclusions paper', *Excluding patients from the NHS Diabetic Retinopathy Screening Programme temporarily or permanently*, available from the national programme website at <http://www.nscretinopathy.org.uk/exclusions.html>.
- Exclusion of people with diabetes from screening, including those excluded by GPs, needs to be handled very carefully and systematically. It is expected that these should form a very low proportion of the single collated list. This group of people are likely to be most vulnerable to developing diabetic retinopathy that will lead to loss of sight simply because they are not being screened.
- People should **not** be automatically excluded because they are under the care of an ophthalmologist. Assessment in the hospital eye clinic may not involve a regular examination of the retina; the ophthalmologist may not be a medical retina specialist, or may not know that the patient has diabetes. Those who are **housebound** or in **nursing homes** should also be managed according to the principles in the exclusions paper.

- Ensure that patients are given all the information that they need to make informed choices about their participation in screening and the transfer of their data to those involved in the screening and treatment process. This information should also include the effects and risks of mydriatic eyedrops: see *Transfer and management of patient information in diabetic retinopathy screening programmes* [<http://www.nscretinopathy.org.uk/patient-data.html>], and the leaflet *Eye screening for people with diabetes - the facts* [<http://www.nscretinopathy.org.uk/leaflets.html>].
- Organisation of screening appointments including follow up of non-attenders, linkage with those under ophthalmological review both for diabetes-related and non-diabetic problems.
- Annual reporting of the outcomes of screening for those patients under the care of an ophthalmologist should be in a form consistent with the English Retinopathy Minimum Grading Classifications of retinal status and make clear whether the patient is being referred back to the screening programme or the date that he or she will next be reviewed in ophthalmology.
- Formal annual audit of screening uptake / coverage. Uptake is the measure of response to an invitation to attend for screening. Coverage is the proportion of those eligible who have had a completed screen in the last year, so requires data from slit lamp biomicroscopy and hospital eye clinics. Coverage is also dependent on the progress of issuing invitations and appointments each year.
- Retinal screeners (see section 1.5.1) will need to be accredited in current competence and to demonstrate evidence of continuing medical education.
- Quality assurance system to review a number of screen negative cases with formal reporting system and feedback to screeners.
- System for recall of positive cases with evidence of capacity to manage increase in referrals to ophthalmology services.
- Laser photocoagulation – evidence of increase in capacity to undertake laser treatment for patients with sight threatening diabetic retinopathy.
- Link with diabetes services for all cases with evidence of diabetic retinopathy to optimise glycaemic control and hypertension (if present) and link with screening for other complications / risk factors for macrovascular disease.
- Collection of data relating to partial and full registration of blindness (and visual acuity measurements) secondary to diabetic retinopathy covering the whole population at risk. It should be understood that some patients that are registered blind **do** have residual vision and it is very important that care is taken to assess all registered blind patients. A patient should only be excluded from the invitation list if (s)he has been assessed in a formal screening environment as being a person who will not benefit from treatment or if there is a report from an ophthalmologist to that effect.

- Collation of all screening information to produce annual report including screening coverage, referral rates, false positives, any false negatives identified, outcome of laser treatment and **instance of loss of visual acuity**. The template for the current version of the annual report is available on the NSC website at <http://www.nscretinopathy.org.uk/ga.html>. This should be completed by 31 October each year dealing with activity during the preceding 1 April to 31 March. A copy of the report should be forwarded to reports@nscretinopathy.org.uk.
- NSF targets specify that 80% of patients on the single collated list should have been offered screening appointments by the end of March 2006, and 100% of eligible patients should have been offered screening appointments between 1 January 2007 and 31 December 2007.

1.4.1 Prisoners

People with diabetes who are prisoners are clearly eligible for screening. It is recognised that there are competing claims on NHS resources between ease of service delivery, staff security, the cost of transporting prisoners to hospitals and the risks of bringing a prisoner into an insecure environment with other potentially vulnerable patients present.

Factors that should be taken into account include the diabetic population of a particular prison, the criminal and social history and the resulting security assessment of the prisoner, the cost to the NHS set against the cost to the prison service and the availability of resources within the screening area.

For instance, some prisons are small and have a very high turnover of short-stay prisoners and this will probably make it impractical for the programme to provide screening in the prison. Other prisons have a large and stable long-term stay population and it is likely that it will be practical and economic for the programme to carry out screening in the prison. These factors will determine whether the programme will pay an annual or bi-annual visit to the prison or whether the prison will have to bring the prisoner to one of the programme's screening venues.

Providing the prison with a standard form may help you ensure a) that you have accurate records of those with diabetes who are in prison in your area and b) that you have some key information that will facilitate accurate identification of those who are being screened. A template is available from <http://www.nscretinopathy.org.uk/prison-form.html>. It is likely that activity will need to be coordinated with the programme that usually manages the prisoner's care to ensure that he or she is not avoidably screened twice in any screening period, and to ensure that outcomes follow the prisoner.

1.4.2 Standards relating directly to the administration of screening

The following 7 service objectives / quality assurance standards relate directly to the administration of a screening programme:

Standard 1: Objective - to reduce new blindness due to diabetic retinopathy.

Standard 2: Objective - to identify and invite all eligible persons with known diabetes to attend for the DR screening test.

Standard 3: Objective - to ensure database is accurate.

Standard 4: Objective - to maximise the number of invited persons accepting the test.

Standard 15: Objective - to ensure timely rescreening.

Standard 16: Objective - to ensure the public and health care professionals are informed at regular intervals.

Standard 18: Objective - to optimize programme efficiency and ensure ability to assure quality of service.

Standard 1. Objective - to reduce new blindness due to diabetic retinopathy.

Measure:

Annual blind and partially sighted registration rates predominantly due to diabetes, compared to 1990/1 rates of 9.5 & 9.3 respectively per million per year (national data).

Minimum standard: 10% reduction within 5 years

Achievable standard: 40% reduction within 5 years

Local identification of visual impairment due to diabetes:-

VA 6/60 or worse in the better seeing eye.

(LogMar equivalent +1.0)

VA 6/18 or worse in the better seeing eye

(Logmar equivalent +0.5)

Minimum standard: 10% reduction within 5 years.

Achievable standard: 40% reduction within 5 years.

Comment – it is unlikely that any screening programme will have sufficient numbers to accurately measure meaningful changes but it is important to collect these data to establish a baseline and for national comparisons in combination with other information.

Standard 2. Objective - to identify and invite all eligible persons with known diabetes to attend for the DR screening test.

Minimum standard (completeness of database):

a) Proportion of GPs participating - 90%.

b) Proportion of known people with diabetes on register – 90%.

- c) Single collated list of all people with diabetes
- d) Systematic call/ recall from a single centre of all people eligible for screening on the collated list

Achievable standard (completeness of database):

- a) Proportion of GPs participating - 98%.
- b) Proportion of known people with diabetes on register – 98%.
- c) Single collated list of all people with diabetes
- d) Systematic call/ recall from a single centre of all people eligible for screening on the collated list.

Standard 3. Objective - to ensure database is accurate.

Minimum standard: Accuracy of addresses on database of persons aged 12 or more, as determined by Post Office returns - 95%.

Achievable standard: Accuracy of addresses on database of persons aged 12 or more, as determined by Post Office returns - 98%.

Standard 4. Objective - to maximise the number of invited persons accepting the test.

Minimum standard:

1. Initial screen - 70% eligible persons accepting the test
2. Repeat screen - 80% eligible persons accepting the test

Achievable standard:

1. Initial screen - 90% eligible persons accepting the test
2. Repeat screen - 95% eligible persons accepting the test

Standard 15. Objective - to ensure timely rescreening.

Minimum standard: 70% of patients rescreened within 12 months of the previous screening encounter or 95% rescreened within 15 months of the previous screening encounter.

Standard 16. Objective - to ensure the public and health care professionals are informed at regular intervals.

Measure and standard: Timely production of annual report.

Standard 18. Objective – to optimize programme efficiency and ensure ability to assure quality of service.

Minimum programme size of 12,000 people diagnosed with diabetes on the current patient list.

Achievable standard: 15,000 people diagnosed with diabetes on the current patient list.

1.5 Workforce, training and education

1.4.3 National Occupational Standards

The National Service Framework for Diabetes stipulates:

People with diabetes should be confident that the member of staff they see:

- is properly trained and up-to date;
- provides high quality care underpinned by clinical and service protocols and audit; and
- has the interpersonal skills to communicate effectively with them.

Competences covering all the tasks involved in the identification of sight threatening diabetic retinopathy were developed with Skills for Health as part of the overall Diabetes Competence Framework. The retinopathy competences completed Four Nations collaboration and were approved as National Occupational Standards in February 2005. They can be accessed from the English National Screening website <http://www.nscretinopathy.org.uk> or from the Skills for Health website using the following link http://www.skillsforhealth.org.uk/view_framework.php?id=75.

1.4.4 Accreditation of competence

An accreditation qualification based on the National Occupational Standards was originally developed in conjunction with NHSU and their awarding consortium of City & Guilds and the National Open College Network. Following dissolution of NHSU, City & Guilds are now the awarding body. The pilot phase of the accreditation process commenced in November 2005 and was completed in May 2006.

A *Level 3 Certificate* in Diabetic Retinopathy Screening has been developed as an accreditation of the minimum level of competence required by ALL personnel involved in the identification of sight-threatening diabetic retinopathy in the English National Screening Programme.

Accreditation is a one-off measure of current competence. It recognises that the learner has been assessed against the standards set for the profession and has achieved the required standard. Principally it is designed to protect the patient but also protects the worker and employer. It is *not* a measure of continuing competence. Continuing competence is achieved through Continuing Professional Development and is measured by Performance Indicators (internal and external quality assurance) in the National Screening Programme and appraisal.

1.4.5 Learning units

Unit 1: National Screening Programmes, Principles, Processes and Protocols

Unit 2: Diabetes and its Relevance to Retinopathy Screening

Unit 3: Anatomy, Physiology and Pathology of the Eye and its Clinical Relevance

Unit 4: Preparing the Patient for Retinopathy Screening

Unit 5: Measuring Visual Acuity and Performing Pharmacological Dilatation

Unit 6: Imaging the Eye for the Detection of Diabetic Retinopathy

Unit 7: Detecting Retinal Disease

Unit 8: Classifying Diabetic Retinopathy**Unit 9: Administration and Management Systems in a Retinopathy Screening Programme**

Optometrists will not be required to complete assignments for the following units on production of appropriate evidence of Acquired Prior Experiential Learning:

Unit 3: Anatomy, Physiology and Pathology of the Eye and its Clinical Relevance

Unit 4: Preparing the patient for Retinal Screening

Unit 5: Measuring Visual Acuity and Performing Pharmacological Dilatation

They should contact the awarding centre for details.

Each unit can be individually certificated or a candidate can enrol for the whole award. The whole award (Level 3 Certificate in Diabetic Retinopathy) is made up of the 3 mandatory units and 3 optional units. The units chosen by a candidate must be agreed with their screening programme and should match their job role. Recommended units according to job role can be found in the Centre Resource Pack using the following link:

http://www.cityandguilds.com/documents/ind_healthsocial_health/7359-vqhandbook_v1.1_oct06.pdf.

Additional units must be taken by candidates if their job role extends beyond the 6 units in the award.

The following units are the minimum recommended for the various job roles in a screening programme for diabetic retinopathy:-

Measurement of visual acuity and drop instillation: Units 1, 2, 4 and 5

Imaging the eye: Units 1, 2, 3, 4, 5 and 6

Grading diabetic retinopathy (disease / no disease only): Units 1, 2, 3 and 7

Grading diabetic retinopathy (full disease grading): Units 1, 2, 3, 7 and 8

Screening Centre Managers and Administrators: Units 1, 2, 4 and 9

A Frequently Asked Questions document about the Certificate in Diabetic Retinopathy Screening can be obtained from the English National Screening Programme website <http://www.nscretinopathy.org.uk>, from the award website <http://www.drscertificate.org> or by contacting an administrator at the awarding centre using the following email address: drsadministrator@glos.nhs.uk.

1.4.6 Training

There is no formal national training programme. Programmes are advised to set up local training programmes. However a list of training resources for the award is being developed.

Screening staff should recognise that going on a training course does not assure competence. Only completion of the accreditation units assures competence.

1.5 Screening programme models

There are four main models of screening programme:

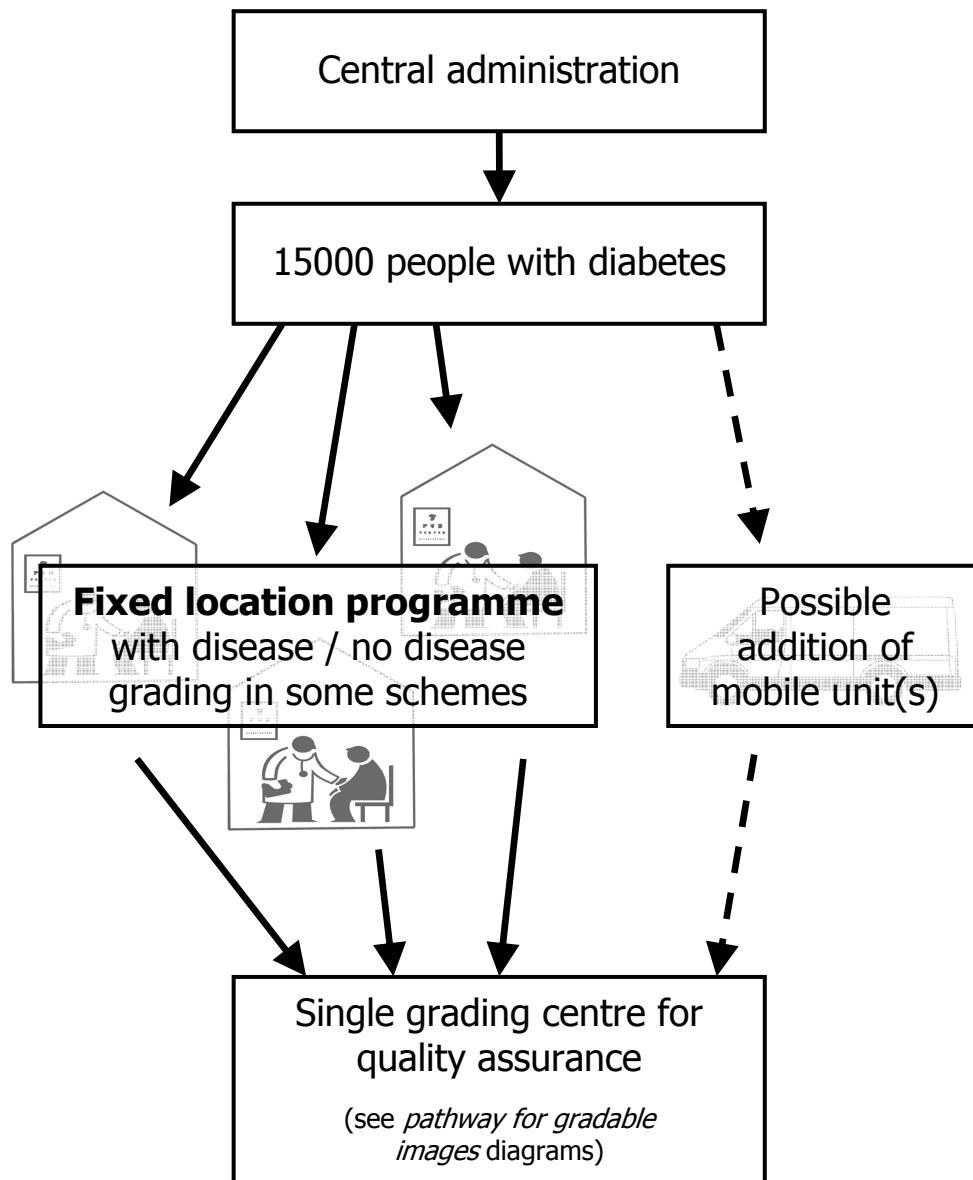
- a) Fixed location screening services where the service is supplied through one or more static units, such as cameras in a hospital or diabetes centre;
- b) Mobile screening services where the service is provided at a range of locations, such as GP surgeries or from a mobile screening van;
- c) Optometry-based services where the central administration of the programme directs patients to accredited optometrists; and
- d) Mixed services which may involve any or all of the above or other external agencies.

When planning which model to use, the relative costs of each should be carefully compared: see Linda Garvican's 2004 costings at <http://www.nscretinopathy.org.uk>, though note that these do not include certain capital expenditure including hardware and software costs, nor the depreciation costs in relation to hardware (capital charges). Software costs will depend upon many factors including the number of users / sites, the complexity of the model (including customisations to take into account local working arrangements) and the likely support burden, and this will be a significant factor in selecting a cost-effective screening model.

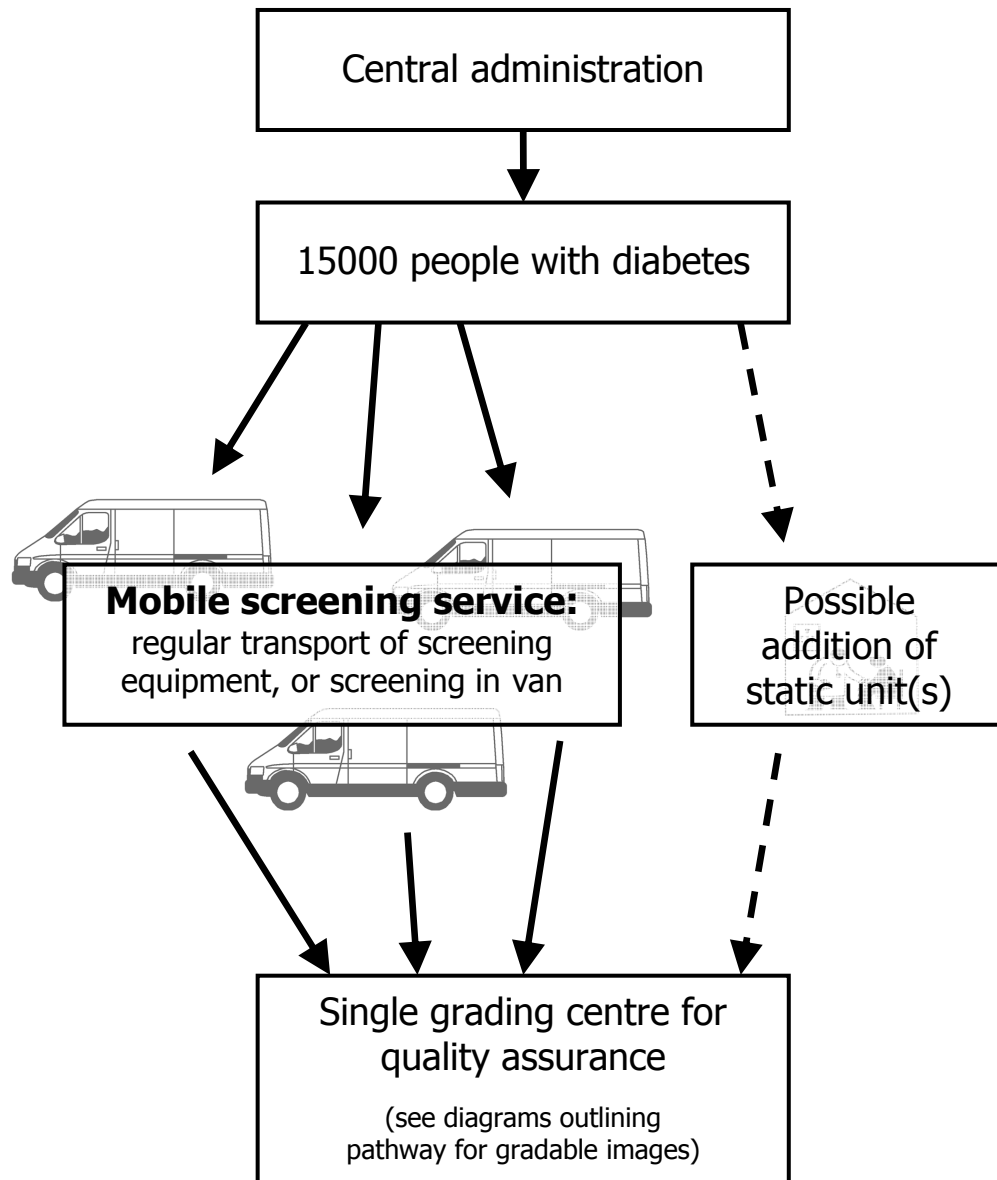
Account should also be taken of the running of dedicated slit-lamp biomicroscopy clinics to review those people who resulted in ungradable images.

The following diagrams illustrate the various models of screening:

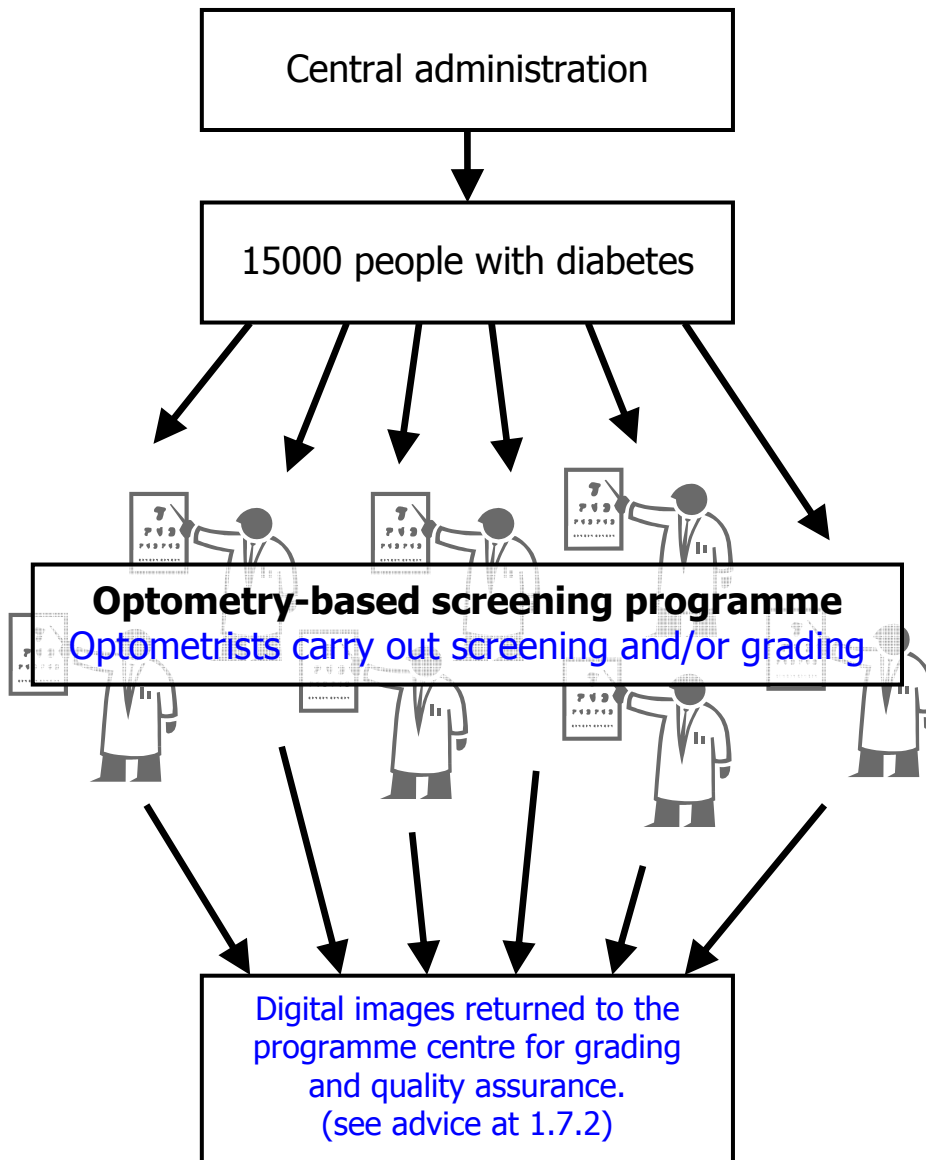
1.5.1 Fixed location screening services



1.5.2 Mobile screening services



1.5.3 Optometric Screening Services



1.6 The screening appointment

Care should be taken to ensure that the identity of the person being screened is securely established by:

- a) asking to see the letter of appointment and double checking the NHS number against the patient record; and
- b) asking the individual to state his or her full name, address, and date of birth and checking that the details match the patient record.

The screening appointment should include two digital colour photographs of each eye by a trained and accredited screener after mydriasis.

1.6.1 Communication of results

Results should be communicated to **all** patients in writing as soon as possible, as well as to those clinicians, providing their diabetic care (GP and diabetologist if applicable). The concept of 'no news is good news' is not acceptable in a national screening programme.

Standard result letters are available from <http://www.nscetinopathy.org.uk/result-letters.html> and should be used with minimal local amendment only.

1.6.1.1 What can the screener tell the patient?

The time that the photograph is taken may be a good opportunity for patient education on the importance of screening, and the significance of the result. However throughput of patients at the screening venue is also important, so this will have to be brief. Careful grading takes time and requires suitable equipment and lighting and these are usually not available in a screening environment. In addition images need to go through a process of internal quality assurance involving more than one grader. The definitive result should only be given to the patient at the end of this process.

Many patients will be anxious about the result, and expect to be told straight away. This situation does not arise in other screening programmes, where no image is immediately visible. It is largely a matter of managing expectations.

Whilst it is desirable for patients to be shown the images if they wish to view them, and for general information to be given about the retina and diabetic retinopathy, great care must be taken not to mislead the patient about the outcome of the grading process. They should be told that a careful scrutiny of the images using appropriate equipment will be undertaken and checked, and that the final result will be given in writing. Patients who need **urgent referral** will however need to be advised of this as soon as it is known to ensure that they can make themselves available at short notice for treatment.

The decision as to whether or not screeners and graders will give verbal interim feedback is the responsibility of the clinical lead for each programme.

The National Screening Programme considers that a system which may be regarded as safe will involve written feedback only after full quality assurance.

Before any programme considers giving verbal interim feedback they should be entirely confident that the screeners and graders selected are qualified to give feedback and all quality assurance measures are in place. They would need to comply with the following points:

- a) The final result should always be given in writing to the GP and patient after quality assurance and the patient should be aware of the timescale;
- b) Only those accredited for full disease grading should give feedback;
- c) If a verbal response is given this should be recorded verbatim on the patient record;
- d) Screeners giving feedback can be discretionary within or between programmes;
- e) There will be an extra competence developed in communicating results, which screeners who give feedback would be expected to have attained;
- f) Grading to provide verbal interim feedback should be on suitable equipment to display the image.

Further guidance as to what information should be given to patients and also three Patient Information leaflets on *Eye Screening for People with Diabetes*, *Diabetic Retinopathy*, and *Preparation for Laser Treatment* are available from <http://www.nscletinopathy.org.uk/leaflets.html>.

1.6.2 Administration of eyedrops (FIXED, MOBILE, OPTOMETRIC)

What is mydriasis?

Mydriasis is the dilatation of the pupil to facilitate retinal photography. To improve the quality of captured images, a mydriatic agent such as *guttae tropicamide 0.5% or 1.0%* is usually applied prior to retinal photography. In some cases *guttae phenylephrine 2.5%* may also be required.

1.6.2.1 Safe systems of work

It is important, whatever the model of delivery, that safe systems of work are in place governing the administration of eye drops. Clear, written processes and protocols in relation to this, which should include detailed information about contra-indications and adverse reactions, should be maintained within the screening programme in a place easily accessed by the screeners. These should form the basis of training of staff who should also undertake the relevant modules in the National Certificate.

Access to medical advice in an emergency is also a consideration. Care should be taken to ensure that people presenting for screening are aware, prior to the appointment, of risks with regard to eye drops, actions they should take in the event of problems, and the fact that it will not be safe to drive for at least four hours after the appointment. The programme manager should ensure that the information that is sent to patients with the letter of invitation adequately covers these facts, and screeners should ensure that those attending to be screened have understood that information.

The Medicines and Healthcare products Regulatory Agency (MHRA) advises as follows:

a) Is Tropicamide 0.5% and 1.0% a prescription only medicine (POM)?

Yes. However the medicines legislation regulates the requirement for a prescription in different ways depending on whether the eyedrops are being sold, supplied, administered parenterally (by injection) or externally.

b) Is Phenylephrine 2.5% a POM as well?

No. Phenylephrine 2.5% is a Pharmacy (P) medicine. P medicines may be obtained by anyone for administration in the course of a business provided they are to be used within their licensed indications.

c) Does that mean that screeners can only administer eye drops if there is a prescription or other order such as a Patient Group Direction (PGD) or Patient Specific Direction (PSD)?

Not necessarily. The MHRA says that medicines legislation places no legal restriction on who can administer/instil eye drops such as tropicamide 0.5% and 1.0% and phenylephrine 2.5%, for the purposes of dilating the pupil for screening. This advice, however, is limited to **administration** only and not to the sale or supply of tropicamide. It is the wholesale acquisition, sale and supply of these eye drops that is restricted by the legislation and this might affect which organisations and individuals can legally acquire eye drops.

d) So who can legally acquire eyedrops?

The wholesale supply of medicine is regulated by medicines legislation. Generally, the wholesale supply of POMs is restricted to specified classes of person such as NHS Trusts, doctors and pharmacists. Some registered health professionals may also obtain certain POMs on a wholesale basis. This includes the wholesale supply of tropicamide to optometrists (but does not extend to dispensing opticians).

e) So how does that affect screening programmes in practice?

The following paragraphs are intended to provide information about the legalities of common scenarios involving the use of eye drops in retinal screening programmes. They are not definitive and while the MHRA is happy to offer further clarification where necessary, organisations should also be prepared to obtain their own legal advice.

i) NHS Organisations

Retinal screeners employed by NHS bodies such as hospitals and Primary Care Trusts can access eye drops obtained by those bodies for administration in the course of their business. No prescription, PGD, PSD or other order is required.

It is possible that agency staff operating within a Trust and under close supervision, and covered by the trust's insurance may be in a similar position but the MHRA suggest that individual trusts that intend to rely on this take advice from the trust's lawyer before doing so.

NHS bodies entering into an arrangement with an independent provider (or anyone else who is not part of their organisation) to provide screening services should be aware that unless they have a wholesale dealer's licence, they cannot legally supply stocks of POM and P medicines to that provider.

ii) Optometrists' Practices

An optometrist may lawfully obtain stocks of tropicamide as well as P medicines for administration in the course of his/her business. Within the practice, the optometrist could allow employees to access these medicines for administration only, for example, in retinal screening procedures. There may be a question as to whether this is appropriate in terms of the optometrist's professional practice but this will be a matter for the professional body, the College of Optometrists, the current advice being: "If the optometrist themselves is not instilling the drop to the patient, the optometrist should be on the premises whilst this is being done so that they can intervene if necessary". Further advice can be reviewed on the College of Optometrists website at http://www.college-optometrists.org/coo/download.cfm?uuid=E040B4CB-E554-80C1-9D8414ABF25FAD9B&type=ethics_guidelines.

iii) Independent Companies providing screening and grading services

Trusts using independent sector providers, such as companies providing screening and grading services, who employ **registered health professionals (such as nurses)** to administer eyedrops could enter into an arrangement to do this under a Patient Group Direction (PGD). The PGD would need to be authorised by the Trust concerned. In these circumstances, the company can obtain wholesale supplies of the medicines to be administered under the PGD. It should be noted that not all retinal screeners are registered healthcare professionals and the National Certificate alone will not result in that status.

There are no other specific provisions in medicines legislation for independent companies providing screening and grading services who are not registered with the Healthcare Commission to obtain wholesale supplies of POMs. However, an optometrist who is employed by an independent company is entitled to order and receive wholesale supplies of tropicamide. Legal advice obtained by the MHRA indicates that these supplies can be distributed to screeners employed within the same company. Again, whether this is appropriate or not in terms of the optometrist's professional practice is a matter for the General Optical Council (GOC). It may be prudent for optometrists to seek specific advice from the GOC when the company is supporting more than one programme, particularly those geographically dispersed where close supervision is problematical, the current advice being: "If the optometrist themselves is not instilling the drop to the patient, the optometrist should be on the premises whilst this is being done so that they can intervene if necessary".

This advice has been scrutinised and agreed by the MHRA, the body that is responsible for medicines legislation. An extended version of this advice containing the relevant legal references regarding the administration of eyedrops is available from <http://www.nscretinopathy.org.uk/eyedrops.html>.

1.6.2.2 Known risks of mydriasis (FIXED, MOBILE, OPTOMETRIC)

The risk of acute glaucoma is incredibly rare. This subject was reviewed by Ranjit Pandit in Diabetic Medicine (Pandit RJ, Taylor R. Mydriasis and glaucoma: 'Exploding the myth. A systematic review'. Diabet Med. 2000 Oct; 17(10):693-9). The article concluded that, in a systematic review of published research 1933-1999, the risk of inducing acute glaucoma following mydriasis with tropicamide alone is close to zero, no case being identified. The risk with long-acting or combined agents is between 1 in 3,380 and 1 in 20,000.

The presence of chronic glaucoma constitutes no additional risk. The article concluded that mydriasis with tropicamide alone is safe even in people with chronic glaucoma.

Mydriasis with tropicamide should be advised in all patients when thorough retinal examination is indicated except in the following circumstances:

- Cataract surgery with iris lenses (usually pre 1978);
- Known allergy to Tropicamide or any of its ingredients;
- Eye surgery less than two weeks before.

If acute glaucoma were to be precipitated in a screening programme the patient information should indicate exactly what a patient should do (contact numbers etc). This is safer than it happening one evening in an at risk patient as the pupil dilates to adapt to normal night time conditions and the person not knowing what to do.

1.6.3 Image standards (FIXED, MOBILE, OPTOMETRIC)

A definition of acceptable image quality is provided in Appendix 3.

An online image test set system is being developed for all those involved in image grading, as part of the external quality assurance scheme: see section 2.3.

1.6.3.1 Poor quality images

In some parts of the country there will be a higher incidence of poor quality images because the prevalence of untreated cataract will be higher. There are variations across England in the uptake of cataract services by the local population. In the Gloucestershire diabetic eye study, patients from whom ungradable images were captured had a 10.5% incidence of sight threatening diabetic retinopathy.

Hence it is important that arrangements are made within a screening programme for these patients to be examined either by an ophthalmologist or by a trained and accredited person supervised by an ophthalmologist (as in the Scottish programme).

If the latter option is used, only relatively few of these individuals will be trained and accredited in order to provide appropriate quality assurance of this examination.

In 2000, the NSC working party recommended screening with two 45-degree fields of each eye from evidence given in two published studies, in addition to other published work (details in Appendix 4).

For what to do with the technical failures / poor quality images, see section 1.7.13.

1.6.4 Optometric based schemes (OPTOMETRIC)

It has been agreed at National level in England that an optometrist should grade a minimum of 500 imagesets of people' with diabetes in order to participate as grader in a screening programme but there is no minimum number requirement to be eligible to photograph the patients and send the imagesets to a grading centre as part of the national programme.

1.6.5 Issues relating to poor quality images (OPTOMETRIC)

- a) In the Gloucestershire Study, 3.7% of patients had unassessable images (including those with cataract), of whom 10.3% had referable retinopathy. If one had an optometric scheme for 15,000 patients and an attendance rate of 90% leaving 13,500 patients having digital photography by 40 optometrists - 338 per optometrist and this would leave 9 patients per optometrist with unassessable images. It would be very difficult to quality assure 40 optometrists examining 9 patients each with unassessable photos. These patients would be poor dilators or have media opacities and are a group who are particularly difficult to examine and yet will have a 10.3% incidence of significant retinopathy. Schemes may be designed so that optometrists examine this group but they should be arranged so that only relatively few of these individuals will be trained, accredited and regular samples of individual outcomes quality assured by their local ophthalmologist in order to provide appropriate quality assurance of this examination (as in the Scottish scheme).
- b) In areas with a higher incidence of untreated cataract, there might be a first round effect of having higher numbers and more patients referred in for cataract extraction by these examinations but then this should even out to similar numbers.

1.6.6 Standard relating directly to the screening appointment

One national standard relates directly to the screening appointment and technical failures / poor quality images:

Standard 5. Objective - to ensure photographs are of adequate quality. (FIXED, MOBILE, OPTOMETRIC)

Measure:

Percentage ungradable patients in at least one eye, including cataracts:

Minimum standard < 10%; achievable standard < 5%

Percentage ungradable patients in at least one eye, once cataracts have been excluded: Minimum standard < 5%; achievable standard < 3%

Comment:

The exclusion of cataract in these figures will have to be determined by clinical examination once a patient with an unassessable image is referred on for a clinical assessment within the quality assured screening programme.

1.7 Image grading (FIXED, MOBILE, OPTOMETRIC)

Any grading should include the [English Retinopathy Minimum Grading Classifications](#) as shown in Appendix 1. Screening programmes wishing to collect more data than this or to refer at an earlier stage in any of the groups are at liberty to do so provided this minimum [classification](#) is collected for comparison between screening programmes.

The National Screening Programme has been developed to detect Sight-threatening Diabetic Retinopathy and not to detect other eye conditions. However, other eye conditions may be detected during routine grading:

1. to refer in other sight threatening conditions; and
2. to have an audit trail back to see if confounders for DR (drusen / AMD, MNF, asteroid hyalosis) were detected.

These conditions should be managed in accordance with protocols drawn up locally. Advice on categories of eye conditions where referral would normally be appropriate may be found on the National Screening Programme website at <http://www.nscretinopathy.org.uk>.

It is generally considered that grading more than half of the working day might be too tiring for an individual and jobs should be considered to take this into consideration. In addition a [10 minute](#) break should be taken after every hour of grading. Grading is usually best performed in rooms that have low lighting.

Reports should be produced in a timely manner for all screened individuals, perhaps with a fast tracking mechanism for those flagged up at the screening appointment as needing more urgent grading.

[External Test Sets](#) are being developed for all those involved in image grading so that a standard set of images will be graded at intervals and results compared against the nationally approved grading. The monitor used for grading should be at least 17" diagonally and for full disease grading a CRT screen is preferred, although LCD technology is rapidly improving (See Section 3.4.3). These screens need to be cleaned regularly to ensure that marks do not obscure pathology.

1.7.1 Is it possible to use automated analysis at the present time?

Software packages seem to be getting reasonable results for the detection of microaneurysms and some other features of background DR. However, it would be very embarrassing for any screening programme to miss a tumour or other clinically significant data and the current recommendation is that a trained and accredited grader will need to look at all images until the software has developed further and it is capable of identifying securely a good range of clinically significant data.

1.7.2 Image quality

Appendix 3 contains a definition of image quality. Please note that if any referable retinopathy is seen in a poor quality image the patient should be referred promptly to be seen in clinic soon as R3 may be present but not visible on the image.

1.7.3 Management of ungradable images

It is important that arrangements are made within a screening programme for patients with ungradable images to be examined either by an ophthalmologist or by a trained and accredited person supervised by an ophthalmologist (as in the Scottish scheme). If the latter option is used, only relatively few of these individuals will be trained and accredited in order to provide appropriate quality assurance of this examination. It may still not be possible to assess a very small number of patients due to a range of disabilities (for instance it may not be possible for a patient to hold still in one position either for assessment or for treatment).

It should be noted that some patients with ungradable images may be unsuitable for treatment due to a condition that is not going to be improved with treatment in either eye. The advice given in the exclusions paper at <http://www.nscoretinopathy.org.uk/exclusions.html> should be followed. Clearly great care must be taken before such a decision is made.

1.7.4 Grading outcome matrix

Pathway 2: full disease grading **FOR SCHEMES WHERE THERE IS NO SPECIFIC ORDER OF SENIORITY BETWEEN GRADING LEVELS**

First full disease grade	Second full disease grade	Next step	Letter to patient and GP (GP letter should be coded)
R0	R0	annual rescreening	'no retinopathy'
R0	R1	local decision over whether to arbitrate	if no arbitration: 'background retinopathy'
R0	R2 / M1	arbitration level grading	according to arbitration level grade
R0	R3	direct referral to eye clinic	'proliferative diabetic retinopathy'
R1	R0	local decision over whether to arbitrate	if no arbitration: 'background retinopathy'
R1	R1	annual rescreening + improved diabetic control	'background retinopathy'
R1	R2 / M1	arbitration level grading	according to arbitration level grade
R1	R3	direct referral to eye clinic	'proliferative diabetic retinopathy'
R2 / M1	R0	arbitration level grading	according to arbitration level grade
R2 / M1	R1	arbitration level grading	according to arbitration level grade
R2 / M1	R2	referral to eye clinic	'preproliferative diabetic retinopathy'
R2 / M1	R3	referral to eye clinic	'proliferative diabetic retinopathy'

R3	not required	referral to eye clinic	'proliferative diabetic retinopathy'
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In cases where arbitration level grading is indicated, the results of this arbitration level grade will override previous grades and outcomes are as for an agreement over grading level (shaded in the table above).

In cases where a referral is indicated, a 'referral level grade' may take place before the referral is made. The results of this referral level grade will override previous grades and outcomes are as for an agreement over grading level (shaded in the table above).

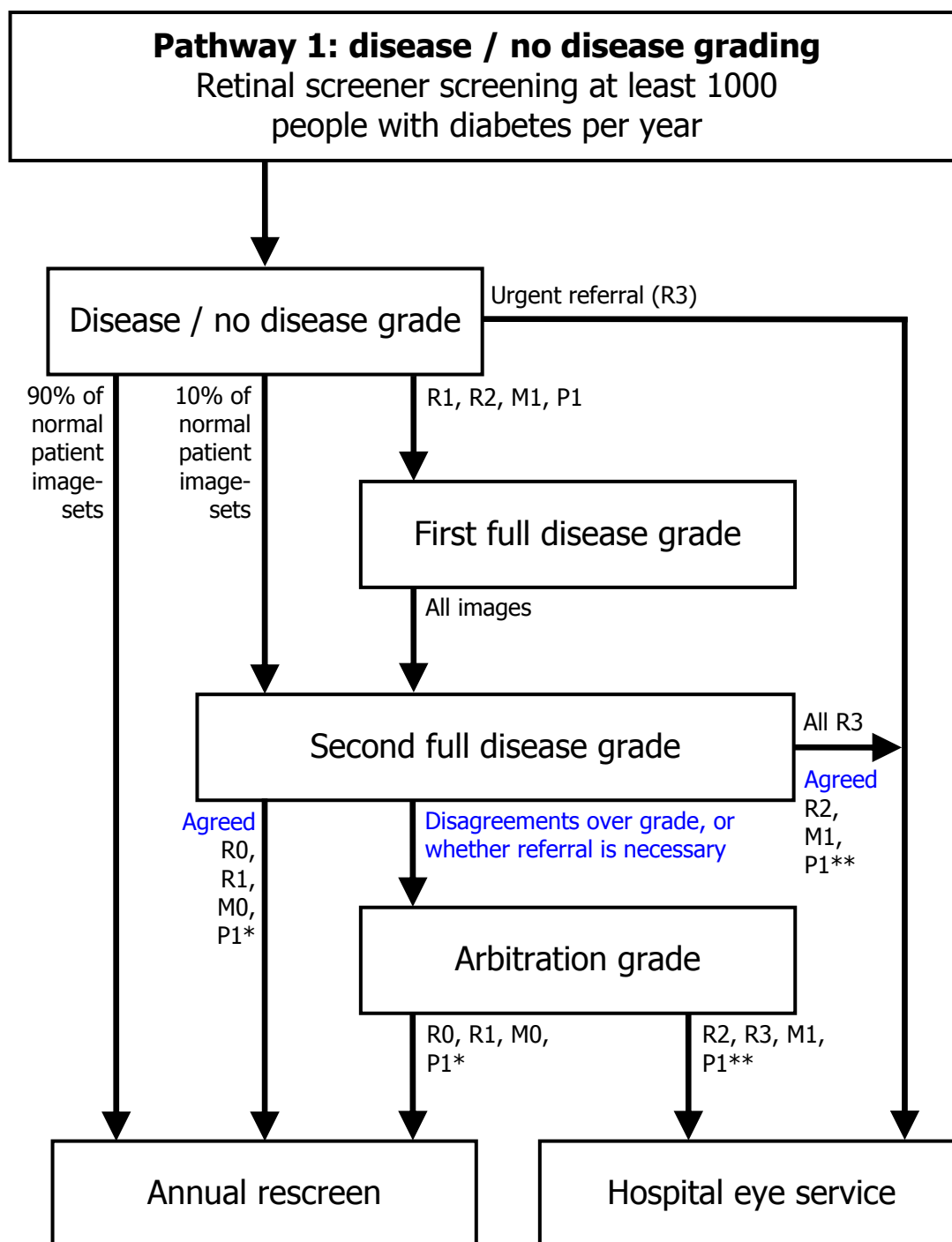
1.7.5 Optional referral level grade

At the point that referral is considered, schemes work well if an ophthalmologist has the chance to look at the images to decide whether he or she feels that referral is required before the referral is actually made. This reduces unnecessary referrals to eye clinics. Alternatively programmes may wish to implement a dedicated ophthalmology clinic for slit-lamp biomicroscopy of screen positive patients. This can be combined with examination of patients with ungradable images. Quality assurance of this level with a percentage being examined by a colleague is recommended.

1.7.6 Grading and Quality Assurance of grading (FIXED, MOBILE)

The recommendation is that *all graders grade a minimum of 1000 imagesets each year. The type of grade should be appropriate to their level of accreditation. There are two possible routes for a grading pathway:*

1.7.7 Pathway 1: disease / no disease grading



* stable treated diabetic retinopathy
** unstable treated diabetic retinopathy

This involves 3 stages of grading prior to any referral to an arbitration level grader

Stage 1 can take place at the screening appointment or in the grading centre. The grader sifts patient image sets into disease and no disease without grading the level

of disease. Urgent referrals (R3) should be passed for immediate assessment by an ophthalmologist

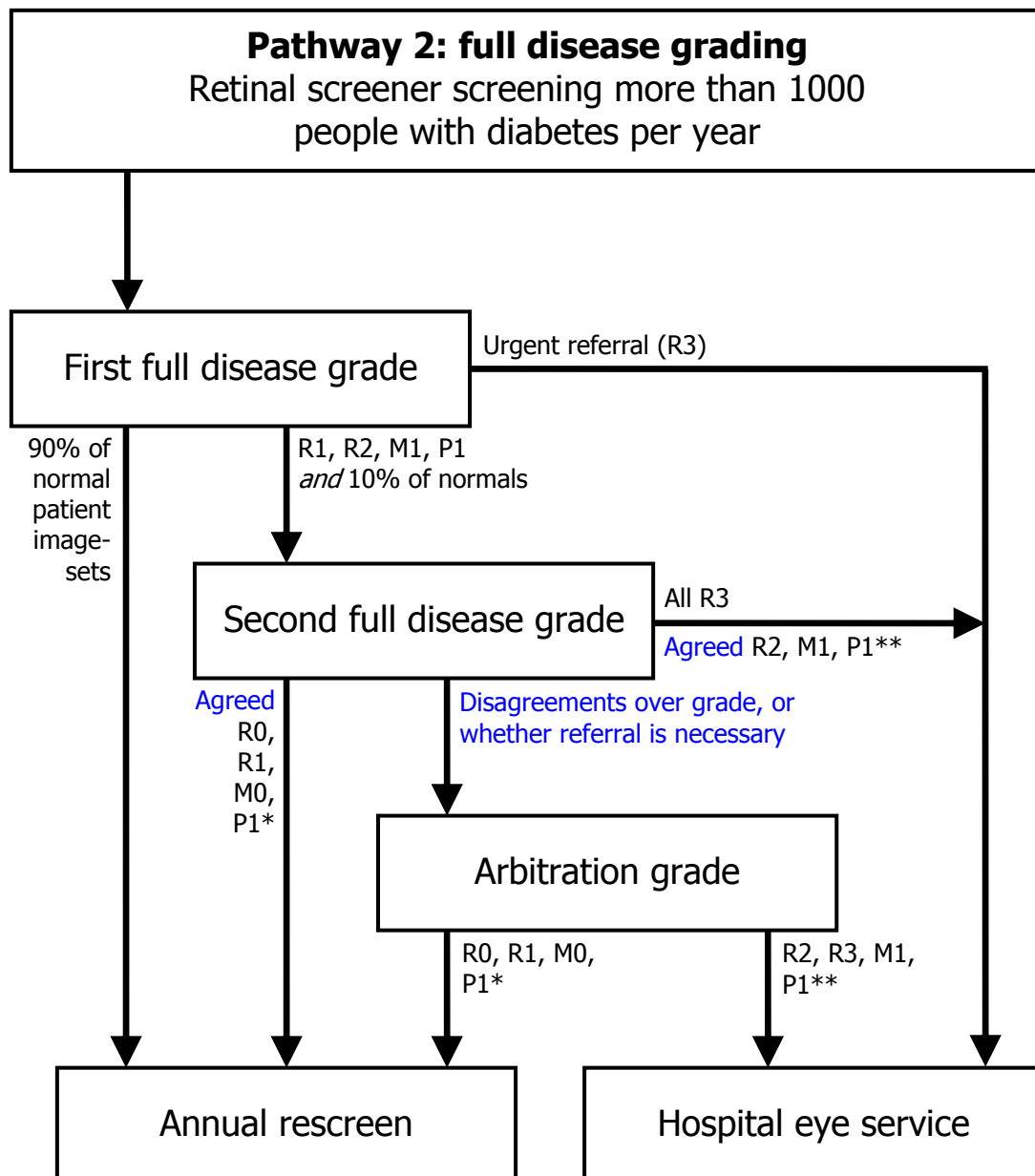
Stage 2: *A random 10% of the patients' normal image sets from each grader at disease / no disease grade, together with all the abnormal image sets should be passed for a first full disease grade by a different grader accredited to carry out that level of grading. That second grader should not see the result of the first grader prior to grading.*

Stage 3: All referable image sets should also be passed to a different grader who should carry out a second full disease grade on them without seeing the result of the earlier grade prior to the exercise.

Arbitration grade: If there is a difference of opinion between the two full disease graders about **referral** then those image sets should be referred onwards for an arbitration grade by a suitably qualified and experienced professional who will decide whether or not the patient should be referred to the ophthalmology service or back into the screening programme.

The clinical lead of the programme, taking into account the respective skills and experience of the graders and the screening interval existing in the programme, must make the decision regarding whether differences of grade should also be referred for an arbitration grade. Factors that should be taken into account are the experience and aptitude of the staff and the screening interval.

1.7.8 Pathway 2: full disease grading



* stable treated diabetic retinopathy
** unstable treated diabetic retinopathy

This involves 2 stages of grading prior to any referral to an arbitration grade.

Stage 1: A grader accredited to do so carries out a full disease grade on all image sets. Urgent referrals (R3) should be passed to the grading centre for immediate assessment by an ophthalmologist.

Stage 2: A different grader will assess a random 10% of the no disease image sets and carry out a second full grade on all the disease image sets from the stage 1 grade. That second grader should not see the result of the first grader prior to grading.

Arbitration: If there is a difference of opinion about referral between the two graders then those image sets should be referred onwards for an arbitration grade by a suitably accredited and experienced professional who will decide whether or not the patient should be referred to the ophthalmology service or back into the screening programme.

The clinical lead of the programme, taking into account the respective skills and experience of the graders and the screening interval existing in the programme, must make the decision regarding whether differences of grade should also be referred for an arbitration grade. Factors that should be taken into account are the experience and aptitude of the staff and the screening interval.

1.7.9 Standards relating directly to diabetic retinopathy grading

The following 4 of the 19 national standards relate directly to the grading centre for mobile and fixed location services:

Standard 6: Objective - to ensure grading is accurate

Standard 7: Objective - to ensure optimum workload for graders, to maintain expertise and avoid errors due to tiredness.

Standard 8: Objective - to ensure timely referral of abnormal screening results (e-mailed or posted).

Standard 9: Objective - to ensure both GP and patient are informed of all test results.

Standard 6. Objective - to ensure grading is accurate.

Comment: This standard is being considered and other measures are also being considered for grading accuracy and further information will be given in the next edition of the workbook:

Minimum standard:

Programmes must provide evidence of internal QA activity in annual reports and for peer-review QA visits.

Standard 7. Objective - to ensure optimum workload for graders, to maintain expertise and avoid errors due to tiredness.

Minimum standard:

Each optometrists/ophthalmologist should grade a minimum of 500 patients' imagesets per annum.

Each grader should read a minimum of 1000 patients' imagesets per annum.

Achievable standard:

Each grader should read a minimum of 1500

Standard 8. Objective - to ensure timely referral of abnormal screening results (e-mailed or posted).

Measure:

Time between screen and grading when flagged by screener as fast-track referral.

Minimum standard:

95% referred within 1 calendar week.

| 100% referred within 2 calendar weeks

Achievable standard:

98% referred within 1 week.

Standard 9. Objective - to ensure both GP and patient are informed of all test results.

Measure:

Time before posting notification letters to GP and patient.

Minimum standard:

70% in less than 3 weeks.

| 100% in less than 6 weeks

Achievable standard:

95% in less than 3weeks.

1.7.10 The grading & QA centre in optometric schemes (OPTOMETRIC)

Note that Sections 1.7 to 1.7.5 apply to all screening programmes, including those with any optometric element.

Trained and accredited optometrists would participate in the grading for the national programme in the following ways:

- a) Any grading should include the national minimum dataset as shown in Appendix 1. Screening programmes wishing to collect more data than this or refer at an earlier stage in any of the groups are at liberty to do so as long as this minimum dataset is collected for comparison between screening programmes.
- b) The recommendation is that an optometrist performing grading should grade a minimum of 500 patients' imagesets per annum. It is desirable that an optometrist should see an enriched sample of grading including as high a proportion as possible of second disease level grading, so ensuring that he or she sees a greater number of disease imagesets than he or she would see if grading only first full disease imagesets..
- c) All the imagesets revealing any diabetic retinopathy (usually approximately 30%) and a random 10% of those images with no retinopathy should receive a second full disease grade. The selection of images to be passed on to the second grader should be carried out at the administration centre to which all imagesets should be forwarded.
- d) All those images where there is a difference in opinion about retinopathy referral should be seen by an arbitration level grader. The clinical lead must decide, taking into account the experience of the graders and the screening interval of the programme whether differences in grade should be sent to arbitration level grading.
- e) It is generally considered that grading more than half of the working day might be too tiring for an individual and jobs should be considered to take this into consideration. In addition a 10 minute break should be taken after every hour of grading.
- f) Reports should be produced in a timely manner for all screened individuals, with a fast tracking mechanism for those flagged up at the screening appointment as needing more urgent grading.

1.7.11 Standards relating directly to grading in optometric schemes

The following 3 of the 19 national standards relate directly to the grading centre in optometric schemes:

Standard 7 for Optometrists - Objective: To ensure optimum workload for graders and to maintain expertise.

Measure:

Imagesets graded per annum.

Minimum standard: Each optometrist should grade a minimum of 500 imagesets each year.

Achievable standard: Each grader should grade a minimum of 1500 patient imagesets per annum.

Standard 8 – Objective: to ensure timely referral of abnormal screening results (e-mailed or posted).

Measure:

Time between screen and grading when flagged by optometrist as fast-track referral.

Minimum standard: 95% referred within 1 calendar week.

100% referred within 2 calendar weeks

Achievable standard: 98% referred within 1 week.

Standard 9. Objective - to ensure both GP and patient are informed of all test results.

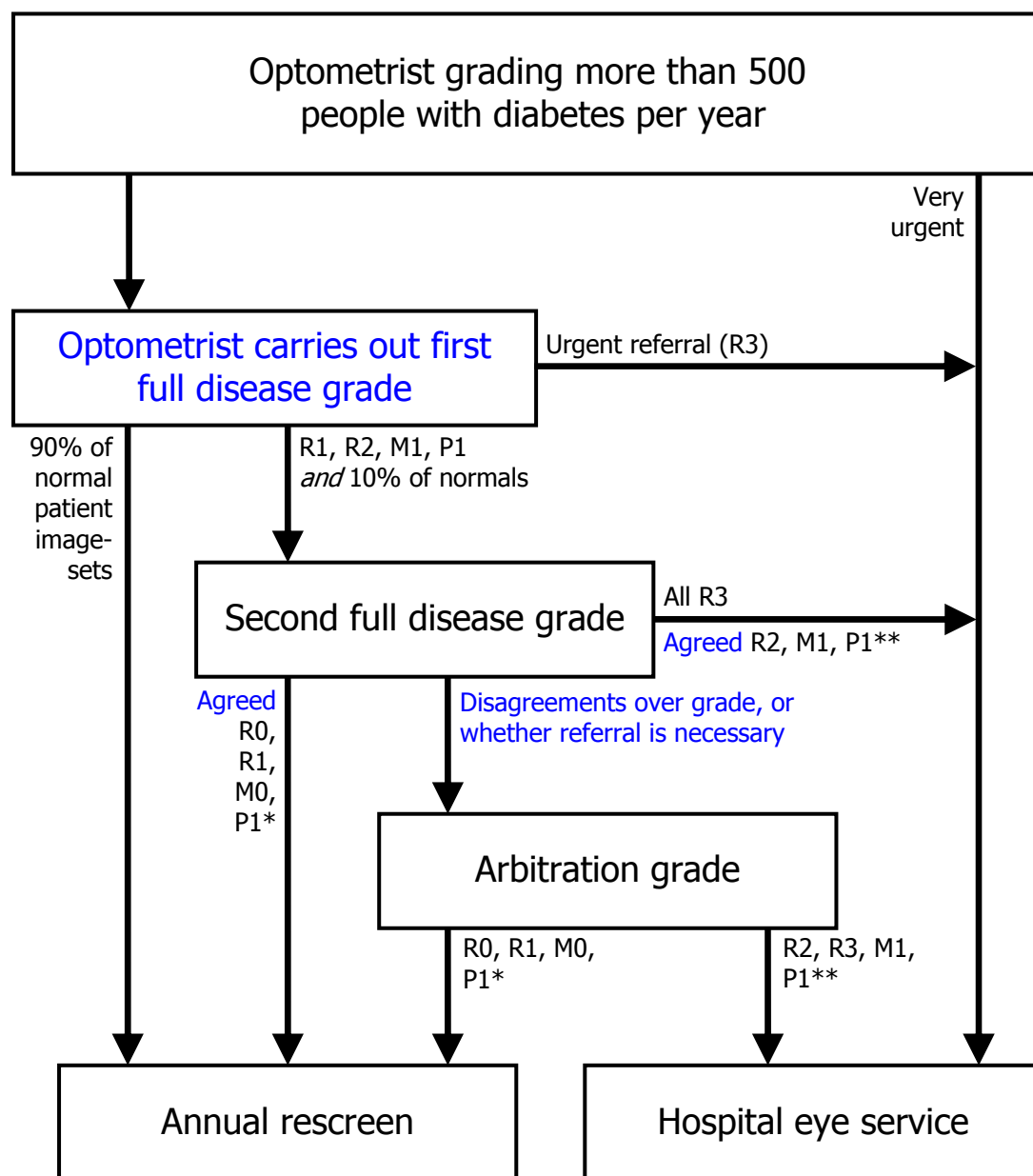
Measure: Time before posting notification letters to GP and patient.

Minimum standard: 70% in less than 3 weeks.

100% in less than 6 weeks.

Achievable standard: 95% in less than 3 weeks.

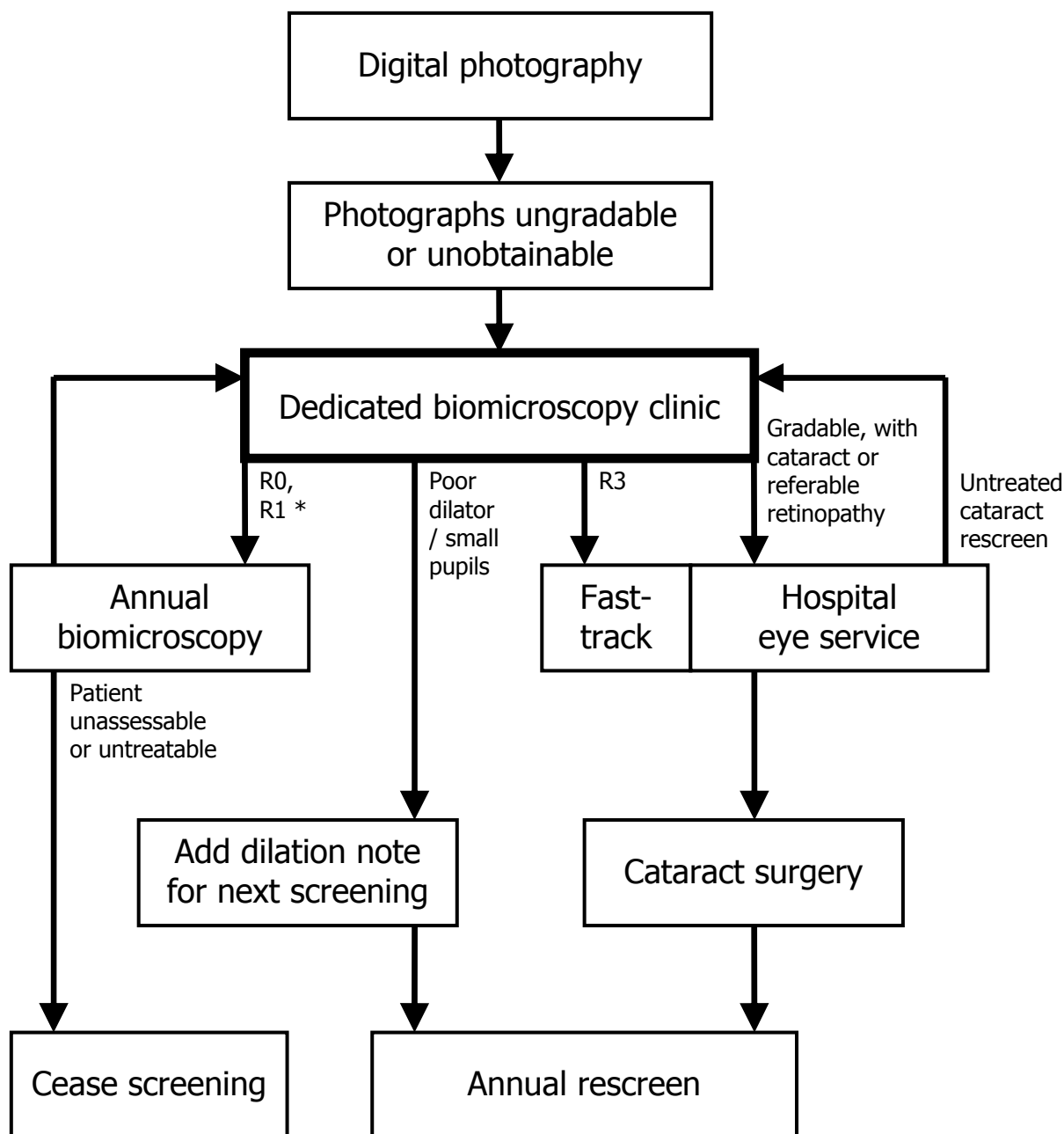
1.7.12 Grading pathway for optometric schemes



* stable treated diabetic retinopathy
 ** unstable treated diabetic retinopathy

1.7.13 Ungradable pathway diagram

(see Appendix 3 for definition of image quality)



* annual biomicroscopy should only usually be considered for patients refusing or unsuitable for cataract treatment.

1.8 Ophthalmology clinic appointment and treatment

Issues relating to the Ophthalmology clinic appointment and treatment are:

- a) False negatives from the screening programme should be identified and the reasons examined (i.e. an individual who was screened within the previous 12 months and not referred from the screening programme but subsequently presents with sight threatening diabetic retinopathy to an ophthalmology clinic).
- b) False positives from the screening programme should be identified and results should be fed back to the screening service.
- c) Impact on ophthalmology services – there is known to be a first pass effect on ophthalmology services when a screening programme commences in an area, which has not previously had a screening programme. Referral rates on this first round have varied between 6-10% and laser treatments have been approximately 2% **or more** of the screened population. Most studies have shown that the requirement for laser treatments then returns to the level that existed prior to the screening programme. The most recent workload study from Gloucestershire also found this return of laser treatments to previous levels after the first round, but the overall workload relating to people with diabetes remained higher than prior to commencement of the service. This study was complicated by the rise in number of people with diabetes in the county (1,400 per annum for a population of 550,000). This rise seems to be occurring throughout England.
- d) **The clinical lead should ensure that processes are in place to ensure that**
 - i) **only medical retinal specialists in ophthalmology carry out assessments for diabetic retinopathy;**
 - ii) **the screening programme receives (including through electronic systems if available) written report of the retinal status of those seen and reviewed for diabetic retinopathy in the eye clinic. That report should be in a form that accords with the information required in the English Retinopathy Minimum Grading Classification at Appendix 1;**
 - iii) **the screening programme is notified in writing (or through electronic systems) either of the next date for assessment in the eye clinic or of the decision to refer the patient back into the screening programme;**
 - iv) **it is possible to collect data for the relevant aspects of the national standards, in particular relating to timescales for eye clinic appointments, laser treatments and outcomes of treatment;**
 - v) **the screening programme and graders are given structured feedback with regard to inappropriate referrals.**

1.8.1 Standards relating directly to the ophthalmology clinic appointment

The following 5 of the 19 national standards relate directly to the Eye Clinic appointment and treatment:-

Standard 9. Objective - to ensure timely consultation for all screen-positive patients

Standard 10. Objective - to ensure timely treatment of those listed by ophthalmologist

Standard 11. Objective - to minimise overall delay between screening event and first laser

Standard 13. Objective - to follow up screen-positive patients.

Standard 14: Objective – to minimize the anxiety associated with screening.

Standard 10. Objective - to ensure timely consultation for all screen-positive patients.

Minimum standard:

Time between notification of positive test and consultation:

1. Proliferative DR/Advanced DED, R3 - 70% in less than 2 weeks..
2. Preproliferative DR, R2 - 70% in less than 13 weeks.
3. Maculopathy, M1 - 70% in less than 13 weeks
4. All retinopathy grades – less than 18 weeks

Achievable standard:

Time between notification of positive test and consultation:

1. Proliferative DR/Advanced DED, R3 - 95% in less than 2 weeks.
2. Maculopathy, M1 - 95% in less than 13 weeks.
3. Preproliferative DR, R2 - 95% in less than 13weeks.

Standard 11. Objective - to ensure timely treatment of those listed by ophthalmologist.

Minimum standard:

Time between listing and first laser:

1. Proliferative DR - 90% in less than 2 weeks.
2. Maculopathy - 70% in less than 10 weeks.

Achievable standard:

Time between listing and first laser:

1. Proliferative DR - 95% in less than 2 weeks.
2. Maculopathy - 95% in less than 10 weeks.

Standard 12. Objective - to minimise overall delay between screening event and first laser.

Minimum standard:

Time between screening and first laser does not exceed:

1. For patients referred as R3 - 70% within 4 weeks.
| 100% in less than 6 weeks
2. For patients referred as M1 - 70% within 15 weeks.

| 100% in less than 26 weeks.

Achievable standard:

Time between screening and first laser does not exceed:

1. For patients referred as R3 - 95% within 4 weeks.
2. For patients referred as M1 - 95% within 15 weeks.

Standard 13. Objective - to follow up screen-positive patients.

Minimum standard:

DNA rate for ophthalmology clinic:

- 1) For PDR (R3) within 1 month, less than 10%.
- 2) For PPDR (R2) within 6 months, less than 10%;
- 3) maculopathy within 6 months, less than 10%.

Achievable standard:

DNA rate for ophthalmology clinic:

- a) For PDR within 1 month less than 5%.
- b) For PPDR (R2) within 6 months, less than 5%
- c) For maculopathy within 6 months less than 5%.

Standard 14. Objective - to minimise the anxiety associated with screening.

Measure:

Monitor inappropriate referrals following screening

1. False positive rate of DR test (photograph)
2. Neither photograph or clinical examination warranted referral.

Minimum standard (including both groups):

25% of patients referred.

Achievable standard (including both groups):

20% of patients referred.

1.9 Clinical care pathway

This pathway links the NSC and NICE guidelines for the early treatment of diabetic retinopathy from identification of the presence of diabetes through to referral into a screening programme, grading and referral for treatment or back into the screening programme.

On diagnosis of type 1 or type 2 diabetes, examine eyes:

- Record best corrected visual acuity, with spectacles or pinhole as appropriate
- Dilate pupils with tropicamide
- Examine for diabetic retinopathy using 2-field digital photography

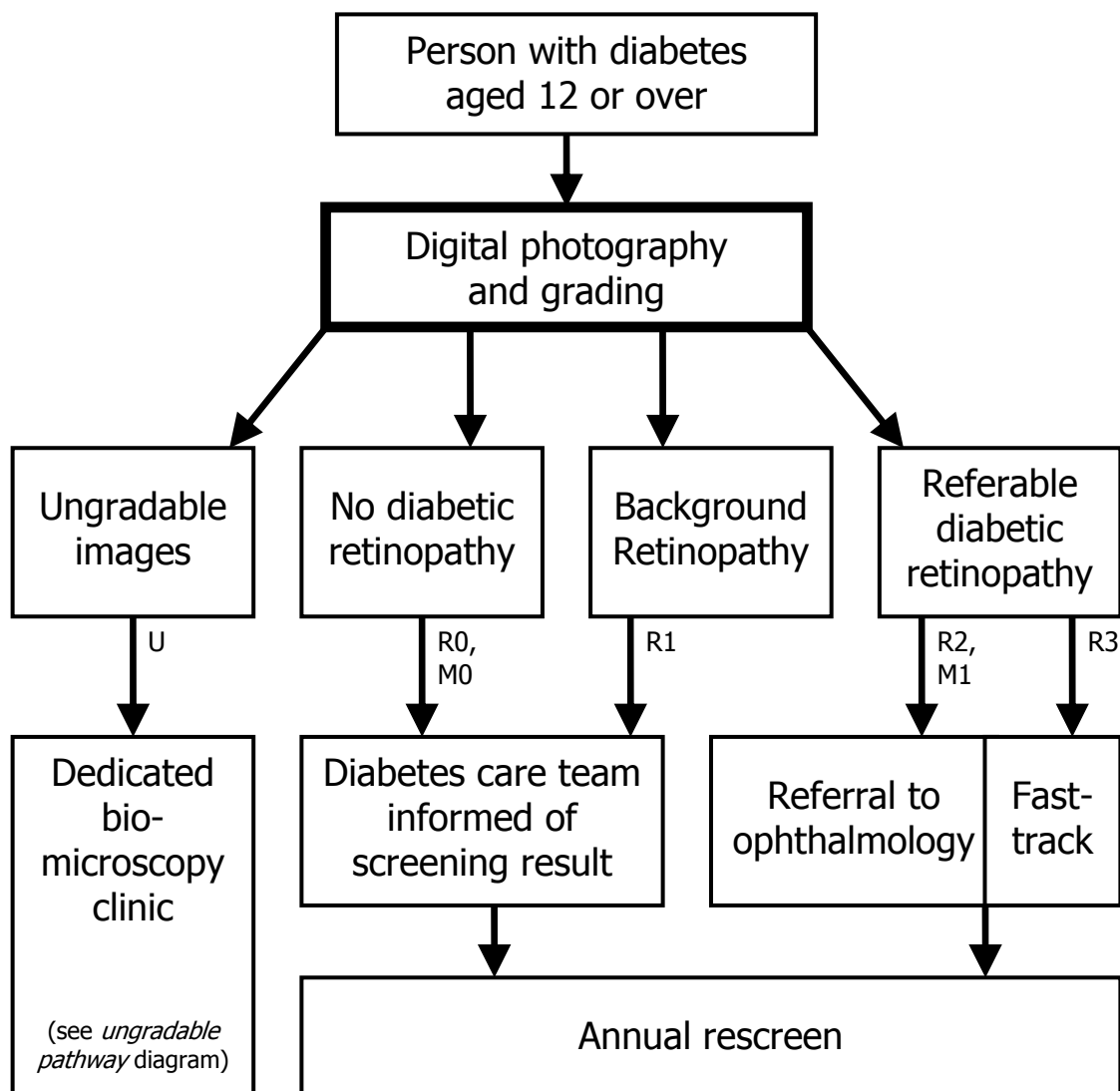
Retinopathy ↓ R1, R2, R3, M1

No retinopathy ↓ R0, M0

- Maintain good blood glucose control
- Maintain good blood pressure control
- Control any abnormal blood lipids
- Manage retinopathy according to severity:

Routine diabetes care
Arrange annual screening

Background retinopathy R1 <ul style="list-style-type: none"> • microaneurysm(s) • retinal haemorrhage(s) 	Routine diabetes care Arrange annual screening
Pre-proliferative retinopathy R2 <ul style="list-style-type: none"> • venous beading, venous loop or reduplication • intraretinal microvascular abnormality (IRMA) • multiple deep, round or blot haemorrhages • (CWS - careful search for above features) 	<i>Achievable standard:</i> 95% seen by ophthalmologist in <13 weeks <i>Minimum standard:</i> 70% seen by ophthalmologist in <13 weeks 100% seen by ophthalmologist in <18 weeks
Maculopathy M1 <ul style="list-style-type: none"> • exudate within 1 disc diameter (DD) of the centre of the fovea • circinate or group of exudates within the macula • retinal thickening within 1DD of the centre of the fovea (if stereo available) • any microaneurysm or haemorrhage within 1 DD of the centre of the fovea only if associated with a best VA of $\leq 6/12$ (if no stereo) 	<i>Achievable standard:</i> 95% seen by ophthalmologist in <13 weeks <i>Minimum standard:</i> 70% seen by ophthalmologist in <13 weeks 100% seen by ophthalmologist in <100%
Proliferative retinopathy / rubeosis iridis R3 <ul style="list-style-type: none"> • new vessels on disc (NVD) • new vessels elsewhere (NVE) • pre-retinal or vitreous haemorrhage • pre-retinal fibrosis \pm tractional retinal detachment 	<i>Achievable standard:</i> 95 % seen by ophthalmologist <1 week <i>Minimum standard:</i> 70% seen by ophthalmologist in <1 week 100% seen by ophthalmologist in <2 weeks
Very urgent <ul style="list-style-type: none"> • sudden loss of vision • retinal detachment 	Emergency referral to ophthalmologist (same day)

1.10 Patient care pathway

Section 2: Quality Assurance

Summary of quality assurance considerations:

- There are two categories of quality assurance: a), internal quality assurance that forms part of the every day processes in a screening programme and b) external quality assurance where there is a completely objective assessment of programmes and there is a comparative analysis of the outcomes. Both are essential aspects of any screening programme
- There are seven key components to a screening programme, administration, screening test, grading, referrals, treatment and follow-up, information system to manage all above and quality assurance.
- The purpose of QA is to reduce the probability of error, ensure that errors are dealt with competently and sensitively, help professionals and organisations improve year on year, set and re-set standards (national responsibility)
- Specific standards have been set for the programme, at two levels- a minimum acceptable level and that achievable by top quartile of services- see Appendix 2
- All screening programmes should close the loop with an audit of screening failures, to review the screening history, and previous images/results where appropriate.
- It is necessary to monitor both disease negatives, to ensure that disease is not being missed, and disease positives, to minimise inappropriate referrals (and associated patient anxiety).
- All disease positive cases should be reviewed prior to issue of a referral appointment - this will also ensure prompt referral to an ophthalmology clinic of serious disease without swamping clinics and causing unnecessary alarm to patients.
- The screening and grading pathway needs to be followed closely to ensure that clinically significant data is accurately assessed and referred promptly where appropriate.
- Ungradable imagesets should result in a referral to a dedicated slit-lamp biomicroscopy clinic under the supervision of an ophthalmologist. It is important that only a limited number of highly trained and quality assured individuals carry out this assessment to ensure that each sees sufficient numbers and those assessors can be quality assured.
- Programmes should measure their performance against the national quality standards, the current ones being found at Appendix 2, and explained in detail at the relevant place in this Workbook.
- **All programmes should complete an annual report on their year end performance and submit it to reports@nscretinopathy.org.uk by 31 October each year. The template for the annual report and the definitions can be found at <http://www.nscretinopathy.org.uk/qa.html>. The primary purpose of the report is to enable effective self-review and to provide a structured method against which to assess programmes strengths and weaknesses against the standards. Programmes should complete each section. Where information is not available this needs to be the subject of internal review and a plan of action put in place to enable the data to be collected in the next year.**

- Organisation of External Quality Assurance is currently under discussion but it [may be necessary for SHAs to set up](#) Regional Quality Centres, [which would have to be funded by PCTs](#).
- External Quality Assurance has 3 main functions: the monitoring of ongoing programme performance against the quality standards at Appendix 2, the organisation of peer-review visits and the administration of an external proficiency testing system for all graders
- A population base of approximately 500,000 people or not less than 12,000 patients with diabetes is the smallest size recommended for a programme. In common with other screening programmes it is expected that smaller PCTs will need to join together to provide a full screening programme.
- Such scale of programmes should also ensure that graders will see sufficient images each year to gain and maintain expertise in disease identification, that they do not work in isolation and there are sufficient staff in place to provide some flexibility for sickness etc.

Quality assurance falls into two distinct categories. Internal QA is a key part of the day-to-day running of screening programmes measured against national standards, whereas external QA provides a completely objective assessment of all programmes against national standards and a comparative analysis of outcomes. Most of the information in this section has been supplied by Linda Garvican.

2.1 Principles

A screening programme consists of several key components:

- 1 Administration: identification of eligible patients, invitations and results
- 2 Screening test
- 3 Grading
- 4 Referrals
- 5 Treatment and follow-up
- 6 Information system to manage all above
- 7 Quality assurance

The emphasis should be on a complete and integrated programme.

The UK National Screening Committee has indicated that quality assurance is an essential component of any national screening programme. Those performing screening are in a reverse ethical position from usual healthcare – an approach is made to an apparently healthy person, with the implication of benefit. However no screening test is 100% sensitive or 100% specific. The requirement for screening for diabetic retinopathy is that it should be at least 80% sensitive and 95% specific, but this recognises that there will be several false positives and some false negatives where disease is missed.

The aim of quality assurance (QA) is to:

- Reduce the probability of error
- Ensure that errors are dealt with competently and sensitively
- Help professionals and organisations improve year on year

- Set and re-set standards (national responsibility)

QA should be a continuous process of improvement, which involves all stages of screening pathway and all professional groups. Specific standards have been set for the programme, at two levels- a minimum acceptable level and that achievable by top quartile of services, the current standards table being at Appendix 2. This will allow comparison with other programmes, in the region and nationally.

2.2 Internal Quality Assurance

In order to demonstrate that these standards are being achieved both internal and external monitoring are required. In many laboratory-based screening programmes, results are numbers generated by automatic machines, so internal QA is also machine- based. Where tests are based on visual perception, as in screening for breast or cervical cancer and diabetic retinopathy, QA focuses on the performance of each individual – usually by internal checking and external test sets of images/slides

All screening programmes should close the loop with an audit of screening failures, to review the screening history, and previous images/results where appropriate. In this case possible screening failures may include:

- those patients who present with symptomatic diabetic retinopathy in the interval between screens
- those patients who present with symptomatic diabetic retinopathy but were not invited or did not attend for screening
- patients in whom there has been a marked and unexpected deterioration in retinopathy since the previous screen. In this case previous images should be reviewed to ensure that misgrading had not occurred.

Simply monitoring of referral rates is not sufficient. In the case of diabetic retinopathy the rate of referrals in existing photographic programmes is between 3% and 10%.

It is dependent on the incidence of eye disease in the diabetic population, which in turn is dependent on the quality of diabetic control- blood pressure as well as glycaemic control- within the community over the last 20 years. Some screening services have observed a decline in referral rates after the first few years of the programme as more severe disease was identified and treated, but in other areas referral rates have persisted at higher levels. This is not a reflection on the quality of the screening programme.

It is necessary to monitor both disease negatives, to ensure that disease is not being missed, and disease positives, to minimise inappropriate referrals (and associated patient anxiety). The National Advisory group recommends that 10% of disease negative cases should be re-graded independently as part of the internal QA system. It is particularly important to have some quality assurance of disease negatives, as they will be returned to routine recall intervals.

All screen positive cases should be reviewed prior to issue of a referral appointment- this will also ensure prompt referral of serious disease without swamping clinics and causing unnecessary alarm to patients. Programmes will usually have fast-track referral systems for sight-threatening diabetic retinopathy.

This 10% approach was originally used in the cervical screening programme. The NHSCSP has now moved to a process of rapid review, where each negative slide is scanned by a second screener or checker prior to reporting. Screening takes about 8 minutes per slide and rapid review only about one minute. Rapid review of all negatives may be preferable to full review of only 10%, but unfortunately it is unlikely to be achievable within the new diabetic retinopathy screening programme, until computer aided detection systems become available.

Similarly radiologists in the breast screening programme prefer to 'double read' all screening mammograms, but this is proving impossible given the national shortage of radiologists willing to be involved.

In fact graders are less likely to make errors where retinopathy is clearly sight - threatening. As in other screening programme difficulties and disputes are more likely to arise over borderline disease, which may or may not be in need of referral and treatment.

How internal quality assurance fits into the screening process: The full set of QA standards can be seen at Appendix 2 and explained in detail at the appropriate part of Section 1, but the table below summarizes some of the central features:

Screening	Quality assurance
Photographs are taken and graded by an accredited grader, either in the presence of the patient or at a grading centre.	<p>A sample of 10% of disease negatives (R0 and M0) are re-graded independently by a second accredited grader.</p> <p>All those images with some abnormality are checked by a second accredited grader.</p> <p>All disputes related to referral [i.e. R1/R2 or M1] are subject to arbitration by a higher-level opinion (usually an ophthalmologist, diabetologist or other healthcare professional specialising in this field – see glossary on page 67). It is also good practice to arbitrate between R0 and R1. If this is not possible such disagreements should be monitored closely, and audited to determine whether there are patterns of under- or over-calling.</p>
The patient may be shown the images and given general information about the eye, but great care must be	The patient must be told that this is subject to quality assurance checks, and the final result will be given in writing once the

<p>taken to ensure that the patient is not unwittingly misled as to the result. <i>Guidance as to what information should be given to patients is available at section 1.6.1</i></p>	<p>image has been assessed in detail, in optimal conditions and using specialised equipment, and the result has been quality assured.</p>
<p>Patients with ungradable images are invited to attend a dedicated slit-lamp biomicroscopy clinic under the direction of the ophthalmologist. This may be held in the community and staffed by a limited number of optometrists.</p>	<p>The ophthalmologist specialising in this field is responsible for the quality assurance of this clinic.</p>
<p>All patients with referable levels of retinopathy (R2/3, M1, unstable P1) should be referred to the hospital eye service.</p>	<p>The ophthalmologist may also wish to review all R2/3, M1 and unstable P1 prior to assessment of the patient by the hospital eye clinic.</p> <p>Inappropriate referrals should be monitored by the Hospital Eye Service.</p>
<p>Patients present with symptomatic retinopathy, or with an unexpected screen-detected deterioration since last screen.</p>	<p>Screening history should be audited and the previous images reviewed.</p>

2.2.1 Inter-grader agreement reports

Because systematic screening for diabetic retinopathy is a new initiative, the workforce employed by screening programmes is relatively inexperienced. Further, a variety of grading and quality assurance models are used. While this will allow the National Screening Programme to determine which models and methods of working are safest and most efficient, screening programmes have no baseline against which to compare their performance, and the effectiveness of any particular grader can only be assessed by direct supervision.

National grading protocols advise that most imagesets (all those with any disease and 10% of those with no disease) should be examined by at least two sets of eyes, neither having knowledge of the grade suggested by the other. Where programmes are of sufficient size (over 12,000 people with diabetes), it is therefore possible to gain some understanding of grader performance by comparing the final grading outcome across graders who have examined the same images. A high level of agreement will indicate that graders are working consistently, whereas large numbers of discrepancies could indicate a problem with the performance or training of a particular grader.

In time, providing programmes are using software that records comparable data based on the Diabetic Retinopathy Screening Dataset (supplemented by the Quality Assurance Standards and Service Objectives and the related definitions and

explanatory notes), it will be possible to compare local inter-grader performance with national trends.

It is important to recognise that inter-grader agreement is a measure of consistency of grading but not necessarily of objective high standard. In order to ensure a consistently high standard of grading, it is necessary to supplement this method with standardised accreditation (for at least some of the workforce in every programme) and external quality assurance using gold-standard test imagesets and expert assessment.

2.3 External Quality Assurance

Mechanisms for Quality Assurance support at Regional level are being discussed [with the Department of Health](#). It is not yet clear whether External QA and Programme Monitoring will be organised at national or SHA level. Other screening programmes have centrally funded quality assurance, which should be independent of performance monitoring of NHS Trusts. [However it may be that Strategic Health Authorities might have to provide for the necessary type of Quality Assurance requirements at this level, and cover about ten to twelve screening services, with a service funded by PCTs. When there is further information from the Department of Health with regard to how this will be managed and funded SHAs will be notified.](#)

Either way Quality Assurance needs to be led by a QA Director, who could be from a public health or ophthalmology background but working independently of local services. The QA Director would have committed sessions/Programmed Activities for the task, together with both QA management and administrative support. Other members of the QA team would be representatives of the different professional groups involved in running the diabetic retinopathy screening services [within that region or nationally], i.e. ophthalmologist, diabetologist, optometrist, retinal screener, grader, programme administrator/office manager, public health specialist and GP, who would be funded on a sessional basis.

The organisation of QA will be determined at a national level in conjunction with the Department of Health and UK National Screening Committee. In the meantime individual SHAs should not attempt to establish separate QA organisations or systems. It is extremely important that Quality Assurance and Programme Monitoring are consistent across England to the same framework and standards, as in other national screening programmes.

The national Quality Assurance System would have three main functions related to external quality assurance of the service:

- Ongoing programme monitoring by collection and analysis of performance data, as in the national minimum data set, from each screening service, to ensure that the [19](#) key quality standards were being achieved. This will be achieved by the collection and analysis of the data in the Annual Reports at national level
- Organisation of a series of visits, to each screening service. These QA visits would ensure that the local programmes had sufficient resources and were providing a comprehensive service. They would enable services to develop best

practice and learn from each other. It is hoped that these can be multidisciplinary and peer-review visits, and include appropriate experts to address any recognised issues in individual programmes.

- Administration of an external proficiency testing system, for all graders, using test sets of images with previously agreed gradings. This will complement the internal QA checking systems and ensure that systematic grading errors were not going undetected in whole services, where a single individual is generally the final arbiter.
- All those involved in grading images, including retinal screener/graders, optometrists, diabetologists and ophthalmologists, would be expected to participate in grading these test sets at regular intervals.
- This external test set is being developed as an on-line assessment to be taken regularly. It would be administered in a similar way to the new Certificate examination. All screening programmes will be invited to contribute material to make up the image sets. Feedback will be immediate.

2.4 Practical size for a diabetic retinopathy screening programme

The papers on the website (<http://www.nscaretinopathy.org.uk>) include a costing exercise for a typical programme. Cost estimates have been based on a theoretical health economy/diabetes network with a population of 500,000, of whom 3% have been diagnosed with diabetes, and hence 15,000 patients requiring screening. Why was this figure chosen, and what is a sensible size for planning a screening programme for diabetic retinopathy?

The practical size is dictated by the incidence of the disease in the eligible screening population. The national team believes that a programme should cover a total population of 350,000 to 1 million, including a minimum of 12,000 people with diabetes. The minimum figure should be sufficient to ensure that robust statistical data is produced to guide those running programmes as to its effectiveness measured against each standard. It would also be large enough to support the practical and quality considerations detailed below.

This is therefore likely to mean a network of PCTs, depending on their size and demographic factors such as age and ethnic mix. Patient flows into Hospital Eye Services should also be taken into account. A single large inner city PCT with a high proportion of residents from black and minority ethnic groups, with a high incidence of diabetes, may achieve these numbers. In some parts of the country the recorded incidence may be as low as 2.9%, although below this level **may be** to be due to under-ascertainment of cases.

There are two strands, which affect this decision

- Practical considerations of running a service
- Ability of a service to meet national standards and maintain internal quality assurance

2.4.1 Comparison with other screening programmes

The other national screening programmes are all organized for populations greater than a single PCT, and some operate on population sizes of 3-4 million. When ***Shifting the Balance of Power*** was implemented it was recognised that it was inappropriate for PCTs to manage these services individually. Lead PCTs in each area commissioned and provided public health input on behalf of several neighbours.

With current reconfiguration into larger PCTs this arrangement may be replaced by single PCT commissioning or possibly the function being taken over by the new Regional Specialist Commissioning groups, co-terminous with the 10 new SHAs from April 2007.

Newborn blood spot screening programmes generally cover regions with about 50,000 births per annum, so that the laboratory will see a few cases of the very rare phenylketonuria and hyperthyroidism per annum. This becomes even more relevant as even rarer conditions such as MCADD (possibly on 1 per 20,000 births) are added to the Guthrie test.

Breast screening programmes are generally organized on the basis of whole cities or counties, and serving up to 140,000 eligible women. Ideally boundaries are co-terminous with cancer networks, but this does not apply everywhere since the screening programmes were established prior to the publication of the Calman-Hine report and subsequent NHS Cancer Plan. Even though breast cancer is a very common disorder only about 53 invasive cancers are detected per 1,000 women aged 50-64 who are screened.

Cervical screening has been historically provided by cytology laboratories in most acute hospitals but this is changing with the impact of liquid based cytology and pathology modernisation. Laboratories are expected to read over 15,000 and preferably 25,000 smears per annum, which again generally means serving more than one PCT. The primary care agency handling the call-and-recall aspects of this programme is usually much larger, such as a whole county, and relates to several laboratories.

2.4.2 Practical and quality considerations for running a service

A general principle of all screening programme is that all staff involved are committed to providing the service. They should all have participation as a major part of their job description and working week. The service should not depend on odd sessions by those who normally have other roles.

A screening programme for diabetic retinopathy will encompass four key elements:

- call-and-recall and programme administration
- digital photography
- grading of digital photographs
- assessment and treatment of screen-detected retinopathy in hospital eye clinics.

It needs to be provided by a multidisciplinary team of administrators, photographers, graders and ophthalmologists, and will work most efficiently if there is internal back-up of skills and the ability to cover leave and maintain the programme for 50 weeks per annum.

For a programme to be practically successful and cost effective, each of these elements therefore needs a critical mass of staff.

The office needs to be manned 5 days a week all year round, which implies a team of 2-3 part time clerical staff to support the programme manager. This team (2WTE) could handle the administration of appointments and letters for 12-20,000 patients, and a smaller workload would not be cost effective.

Photographers and graders need to work closely together. In some programmes the photographers perform initial risk assessment whilst the patient is present. In others they rotate between days out taking photographs in the community and days at base grading images. The quality standards stipulate that an expert grader should be grading at least 1000 patients per annum but they can do up to 5000. This ensures that they see the whole spectrum of disease sufficiently frequently to maintain expertise. It is sensible and cost effective to have a team of about 3 expert graders - a grader should not work in isolation because of quality assurance requirements. The team will provide a critical mass to cover leave, and to be able carry out internal quality assurance and discuss more difficult cases.

In the case of optometric schemes an optometrist [involved in the grading pathway](#) should grade a minimum of 500 patients' imagesets.

All abnormal results and 10% of patients with no retinopathy need to be reviewed by a second grader for internal QA.

Dedicated diabetic retinopathy or medical retina clinics need to be run regularly, but are not going to be worthwhile or sufficiently frequent to see screening referrals within quality timescales unless there is a sufficient flow of patients. If 5 to 8% of those screened need to be referred, this implies a screening population of about 15,000, to channel into regular weekly clinics. It would also be very complicated for a Hospital Eye Service to be trying to provide separate services for different screening programmes in its catchment area.

Thus a service covering a population of less than 12,000 people with diabetes is not recommended.

Section 3: IT considerations

Systematic screening requires the capture and management of digital images, so it is not possible to provide administration for a systematic screening programme using files of paper notes. Instead, screening programmes must procure specialised software to organise the capture and management of digital images as well as patient administration and reporting. This section describes the IT hardware, software and infrastructure required to support systematic digital screening.

3.1 General guidance on IT procurement

For the reasons outlined above, all systematic screening programmes will require the following components of an IT system:

- a) Appropriate digital cameras (section 3.2)
- b) Appropriate management software (section 3.3)
- c) Appropriate IT infrastructure and support (section 3.4)

To assist screening programmes in procuring appropriate digital cameras and management software, national procurement processes have been carried out through the NHS Purchasing and Supply Agency (PaSA), allowing the purchase at a fixed price of cameras and software that meet a minimum specification, without a local NHS tender process. The advantages of a national tender process include:

- a) No requirement for a lengthy, complex procurement process at local level;
- b) Access to better prices than could be achieved by local programmes;
- c) Detailed, standardised contracts with nationally agreed performance levels and for both the supply and support of cameras and software;
- d) Pre-agreed alignment with relevant national standards; and
- e) Agreed processes for the development and incorporation of changes to standards at a national level.

The procurement of IT infrastructure for systematic screening will require detailed consideration of:

- i) the proposed screening model and any technical challenges that this might introduce (for example, synchronisation of data from laptops or data exchange with optometric practices);
- ii) local IT arrangements, particularly where existing IT infrastructure forms part of the screening programme's method of operation; and
- iii) national IT strategy, and particularly the proposed introduction of systems through NHS Connecting for Health and the Local Service Providers.

Local IM&T committees will need to be aware of software purchases so that they can be assessed and aligned with local and national IT strategy.

£27m central capital allocation was made available to screening programmes for the development of essential infrastructure, and particularly for the purchase of cameras

and software. Where cameras and software have not yet been purchased by a screening programme, some capital may remain to support this process.

3.1.1 Specific considerations relating to IT provision

The following factors are likely to increase the complexity, and therefore the cost, of software provision and support:

- Increasing the number of sites at which software is installed
- Increasing the number of users to be trained and using the system
- Migrating existing patient records or screening information into a new system
- Administration from multiple locations or by multiple protocols / processes
- Customisation of an out-of-the-box product to follow local protocols or procedures

Programmes are recommended to consider the following when scoping IT provision:

- Screening management software should ideally be available in the hospital eye clinic. This will facilitate feedback from ophthalmologists on all patients with diabetes (necessary for annual returns from programmes) and will also allow access to digital retinal images from the hospital eye clinic (along with diagnosis tools to facilitate the identification of subtle pathology, such as red-free and monochrome filters).
- Where possible, digital retinal images should be captured upon discharge from the screening clinic as a reference against which diabetic change can be measured. Without discharge images, assessment of Stable Treated Proliferative Diabetic Retinopathy is meaningless.
- Automated systems to manage screening registers and to feed back screening results to GPs should be implemented and maintained. The process of managing a collated list of patients to screen is labour-intensive and error-prone.

3.2 Digital cameras

The recommended cameras for use in the National Screening Programme in England are non-mydratic digital fundus cameras to be used following mydriasis.

In general, two types of digital fundus cameras are available: those with an integrated sensor and those with a removable digital camera back (which is usually a consumer digital camera of the type that can be purchased on the high street). The following considerations may affect the choice of sensor type:

Considerations relating to cameras with an integrated sensor

- Integrated sensor is usually designed for retinal imaging (appropriate resolution / image characteristics)
- Generally more compact / portable
- Generally – though not always – less susceptible to ingress of dust
- Sensor repair / replacement can be expensive

Considerations relating to cameras with a removable digital camera back

- Digital camera back can be repaired or replaced independently of the fundus camera body
- Digital camera back can usually be upgraded if a better unit becomes available on the consumer market
- Cleaning of sensor tends to be easier
- Market is driven by consumer forces so sensor may not be ideal for digital retinal imaging (for example, only available at very high image resolutions resulting in large image sizes)
- Can be more delicate; usually requires additional cables / power supply
- Can be more susceptible to ingress of dust

3.2.1 PaSA framework agreement for digital fundus cameras

The cameras available under the PaSA framework agreement have been evaluated against detailed criteria for suitability in a diabetic retinopathy screening programme. All screening programmes, including those employing optometric screeners, are advised to use cameras, which meet this specification.

A re-procurement was carried out in September 2006 to evaluate cameras according to the most recent requirements of the National Screening Committee. The list of cameras available under the PaSA framework agreement is available to NHSnet users at <http://nww.pasa.nhs.uk/diabeticretinopathy>. Where programmes have already purchased digital fundus cameras for screening, it is suggested that these continue to be used for the remainder of their working lives unless they significantly fail to meet the minimum standards outlined at <http://www.nscretinopathy.org.uk>. Please contact the support team (detailed in section 3.4, below) with any specific queries.

3.2.2 Compression and downsampling

The digital images produced from the image sensor tend to be very large, which can hinder efficient storage and transfer. To reduce the image size, *downsampling*, *compression*, or a combination of these techniques can be applied in the camera. Downsampling converts an image to a lower resolution, for example reducing an image from a 12 Megapixel sensor to 6 Megapixels. The effect of downsampling is that images will appear more 'blocky' or *pixellated* if they are magnified for close examination. Lossy compression (such as JPEG) reduces the detail visible in an image but vastly reduces the file size. High levels of compression may introduce *image artefacts* which can mask clinically significant pathology and interfere with the grading process.

However, appropriate levels of downsampling and compression can reduce the image size to less than 10% of its original size with little or no practical effect on the detection of clinically significant pathology. Further research is required into appropriate levels of downsampling and compression. However, on currently available digital cameras, it is recommended that the highest quality JPEG compression setting is used (for example, 12:1 rather than 20:1 compression).

Other camera settings (such as ISO and white balance settings) will affect image quality. It is recommended that the advice of camera suppliers is sought on the best settings for a particular camera and that these are checked periodically.

Examples of the effect of differing compression ratios are given in the table below:

Camera	Sensor / digital back	Output resolution setting in megapixels	Output resolution		Uncompressed file size	Fine / high quality compression	Medium compression
			H	V			
Canon CR6/DGi	Canon EOS 10D	6.29	3072	2048	18.9MB	1.57MB	944KB
	Canon EOS 10D	2.79 *	2048	1360	8.4MB	696KB	418KB
	Canon EOS 20D	8.19	3504	2336	24.6MB	2.0MB	~1.0MB
	Canon EOS 30D	8.19	3504	2336	24.6MB	2.0MB	~1.0MB
	Canon EOS 30D	4.31 *	2544	1696	12.9MB	1.2MB	~600KB
Kowa Non-Myd alpha D	integral	1.95	1600	1216	5.8MB	486KB	292KB
Kowa Non-Myd 7	Nikon D100	6.00	3008	2000	18.0MB	n/a	2.4MB
Topcon NW6s	Nikon D1H	2.62	2000	1312	7.9MB	656KB	394KB
	Nikon D1x	5.90	3008	1960	17.7MB	1.47MB	884KB
	Nikon D1x	2.62 *	2000	1312	7.9MB	656KB	394KB
	Nikon D2x	12.21	4288	2848	36.6MB	3.11MB	1.8MB
Zeiss VisuCam NM Pro	integral	4.30	2196	1956	12.9MB	n/a	540KB

* denotes an output resolution obtained by downsampling

Note that a camera which produces '.JPG' image files has already applied some level of downsampling / compression. Subsequent compressions are likely to result in the loss of clinically significant information, and are not recommended without thorough testing to ensure that no clinically significant detail is lost. In most cases, the '.JPG' image produced by the camera should be stored without further conversion by the software.

Storage and image transfer are becoming increasingly economical and there are few cases where the image produced by a correctly configured fundus camera is too large to be manageable. Compression technologies vary greatly, but for practical purposes 2.5MB is recommended as the upper file size limit, whilst images under 400KB are unlikely to contain the level of detail required to detect subtle pathology.

It is important to remember that most screening encounters will result in 4-6 images, so a single screening episode with 2.0MB images could create over 12MB of data. In a programme screening 15,000 people with diabetes per annum, this could amount to over 180GB, a storage requirement unmatched by most hospital departments. Note that available network bandwidth can be a significant factor in transferring and backing up this level of storage.

3.2.3 Image availability and retention

Grading should always be carried out on the images produced by the digital camera. It is recommended that images captured at the previous screening episode always be available to image graders for comparison.

All original images must be kept for a minimum of 8 years, and all images must be retained until patients reach the age of 26.

3.2.4 Hand-held fundus cameras

Hand-held fundus cameras are available that meet most of the national recommendations except for field of view. It has been suggested that they might be used for patients in Nursing homes. However, the opinion of the Project Advisory Group is that it would be more cost-effective to transport these patients for screening in a hospital provided they are fit enough to receive treatment if test positive. There is considerable research evidence to support the use of non-mydratic 45 degree cameras in diabetic retinopathy screening but very little available evidence relating to hand-held 30 degree cameras. Hence, until further evidence becomes available they do not fall within the recommendations.

3.3 Management software

All screening programmes will require specialised management software to index and manage the large number of digital images that will be generated by the programme as well as to ensure secure patient administration and to produce reports and performance management data.

3.3.1 PaSA framework agreement for management software

A national procurement of appropriate management software was carried out through NHS PaSA in 2003. The following companies were successful under this tender process:

Clinisys Solutions Ltd (formerly Sysmed Ltd, formerly Apareo Ltd)
Digital Healthcare Ltd
Orion Imaging Ltd (now wholly owned by Clinisys Solutions Ltd)
Siemens plc (not currently active in the English market)

Details of the tender process and the successful applicants are available to NHSnet users at <http://nww.pasa.nhs.uk/diabeticretinopathy>.

The contracts of all software suppliers under the PaSA framework agreement require that the following be incorporated within their software:

- The Diabetic Retinopathy Screening Dataset, detailed at <http://www.nscretinopathy.org.uk/supplier-implementation.html>;
- The Diabetic Retinopathy Message Specifications, described and explained in the document [Message specifications in plain English](#); and

- The NSC annual report template, available from <http://www.nscretinopathy.org.uk/qa.html>

Programmes may procure management software from any supplier. However, they should ensure each of the specifications listed above are incorporated within the software and that processes are in place to manage inevitable future changes as the national screening programme matures and evolves.

Programmes considering the purchase of software outside the PaSA framework must comply with the laws and rules applying to public sector procurements, or risk a penalty. Local procurement departments will provide guidance on how this should be approached and any factors that may affect the process (e.g. the aggregate cost of more than one package from a given supplier).

3.3.2 NHS Connecting for Health

The diabetic retinopathy programme has been working with NHS Connecting for Health (formerly the NHS National Programme for IT, NPfIT) to align approved software with national systematic IT standards and processes. It is hoped and expected that this work will be merged into the NHS Connecting for Health as it is rolled out over coming years. The software from each of the NSC-approved suppliers has been engineered in a modular fashion, so that as NHS Connecting for Health projects such as the Personal Demographics Service (PDS) and Choose and Book become available nationally, it will be easier to integrate them into established screening services.

We still await firm and detailed information as to which aspects of the diabetic retinopathy programme's 40-page Output Based Specification are to be delivered as part of the core solution that Local Service Providers (LSPs) are contracted to deliver to Trusts. The OBS lists approximately 150 requirements for an effective screening service, each of which has been met by the suppliers with PaSA framework agreements. Negotiations are ongoing with LSPs regarding the standards that they will be required to meet under their contracts and when these solutions will be delivered. When this has been confirmed we will be in a better position to advise on the extent to which LSP solutions will assist SHAs in offering effective retinopathy screening programmes and meeting NSF and other performance targets. Trusts waiting for LSP software should consider that it is uncertain whether, and to what extent, additional costs will have to be expended to provide solutions that meet diabetic retinopathy programme specifications.

3.4 Image and data considerations

3.4.1 Archiving and backup of images / data

Archiving involves moving previous images to backup or nearline storage so that they are no longer instantly available but can be retrieved if necessary. This may reduce ongoing storage requirements. Patient and screening data are usually very small in comparison to images and should not be archived unless a patient dies or moves away from the programme.

Backup involves regularly copying images and associated data to a secure location in case of fault or damage to the server or data. Given the quantity of data involved, this should be discussed with local IT departments and considered as part of ongoing programme costs. Programmes should also consider disaster recovery: tested processes to restore the operation of the programme following serious problems such as fire or damage by a computer virus.

3.4.2 Image / data transfer

Methods of image and data transfer will depend on the screening model and available IT infrastructure. Ideally, high-speed networks will allow instant transfer of images and data from the point of capture to a single, central sever. However, mobile screening programmes may rely on occasional synchronisation between screening laptops and a central server. In this case, it is recommended that synchronisation take place at least weekly, to ensure that grading can be completed promptly and that the programme centre has an up-to-date record of patients screened. Additional processes may be required to manage patients requiring urgent attention.

Where appropriate networks are available, messaging specifications have been produced to allow the secure transfer of images and patient data. The major consideration when transferring patient data (particularly from the location of photography to the central management service, or from the central management service to a remote grading location) is available bandwidth. If all screening is carried out at a single site such as a diabetes centre, local networks should provide a means for immediate transfer of all images and associated data. Where remote sites are involved, such as GP surgeries or optometry practices, it may be necessary to rely on other networks such as NHSnet, N3 or (where appropriate local permission has been obtained) commercial broadband. Because the size of patient data is generally negligible in comparison to the size of digital images, it may be possible to operate a 'hybrid' data transfer approach where patient data are transferred immediately, with images being transferred when network capacity is available (for example, overnight).

Image transfer by removable media, such as USB data key or DVD-R, is strongly discouraged due to the complexities of managing transfer processes. Transfer by removable media should be regarded as an interim measure whilst more secure transfer processes are developed.

The central database server should be hosted on a network connected to NHSnet or N3, to allow future integration with the central Personal Demographics Service (PDS), and to facilitate the transfer of screening history between programmes when a patient moves.

3.4.3 Monitors / display panels for grading

The two main considerations relating to the monitor ('computer screen') used for grading are physical size and resolution. A physical size of at least 17 inches diagonally is recommended, and preferably 19 inches.

The NSC camera specification contains advice on monitor resolution and viewing. The increasing availability of high quality flat panel displays at lower prices means that there has been a huge shift in sales of monitors away from CRTs. It is probable that commercial pressures will mean CRT monitors begin to disappear from production.

Flat panel displays (also known as LCD or TFT panels) are available in resolutions of up to 1600x1200 at fairly reasonable prices and good ones give excellent quality viewing. Resolutions higher than this are available but increase the cost considerably. The current camera specification says that high-resolution images may be re-sized for viewing so long as the effective resolution equals or exceeds the minimum imaging resolution of 20 pixels per degree. It also says that at least [65%] of the image should be visible at once.

With the specified field of view of 45° x 40° the minimum resolution equates to 900x800 pixels. So on a screen of resolution 1600x1200, so long as no more than 33% of the screen vertically and 43% horizontally is taken up by software menus, buttons and toolbars, then even if the image is sized such that the whole field of view is visible, it will still effectively equal or exceed the minimum resolution when displayed. This is likely to be the case with most grading software. If the image is enlarged so that 65% is visible vertically (which is the limiting direction), then the effective resolution is just over 30 pixels per degree.

The conclusion to be drawn from this is that viewing an image on a screen with a resolution of 1600x1200 means that the viewing criteria can always be met, regardless of the original image size. Displays with a resolution of 1024x768 or less are likely to be too small for grading.

The configuration and location of a CRT or flat panel display is as important as the choice of display. Care should be taken in selecting brightness, contrast and colour balance / colour temperature settings to maximise the visibility of diabetic pathology and minimise eye strain. Unlike CRTs, it is essential that flat panel displays are used at their 'native resolution': changing the resolution away from this value in Windows will introduce blur which could affect accuracy of grading. Displays should be clean, positioned away from bright or uneven light, and correctly positioned for comfortable use.

Experience has shown that although both CRTs and flat panel displays can be suitable for grading, staff adapt to the particular characteristics of a display with repeated use. It is therefore undesirable for graders to switch regularly between one type of monitor and another. Laptop panels are generally less bright and have less contrast than powered flat panel displays and are rarely suitable for image grading.

3.5 Technical support

A national support team, based in Cheltenham, is available to answer technical and general queries. The first point of contact for all centres should be the national helpline:

telephone: 08454-224468 / fax: 08454-224420

e-mail: support@nscretinopathy.org.uk

Fionna O'Leary, Programme Manager with legal background

Christian Martin, National Technical Development Manager

Donna Prentis, National Programme Support Officer

Simon Knee, Regional Technical Support Officer (London and South East)

Steve Powderly, Regional Support Officer (North of England)

3.6 Frequently Asked Questions relating to IT considerations

The contracts on the PASA web-site seem very long. Why is that necessary?

There are **two** separate contracts. The first deals with the **SUPPLY** of the software, its installation, testing, staff training and final acceptance. The second is the **SUPPORT** contract that deals with how the software is going to be maintained and supported once the software is installed. Each contract is divided into two main parts:-the overarching **terms and conditions** that set the framework within which the second part of the contract (all the **schedules**) operates. PASA is there to help you to work through them and complete them not least because there are several Trust/site specific matters that must be addressed in them so that they can be tailored to individual requirements. (See the PaSA web-site using NHSnet <http://nww.pasa.nhs.uk/diabeticretinopathy>) The contents of the schedules vary from contractor to contractor and each one has schedule terms unique to them. The supply contract will end when you have signified acceptance and payment has been effected. The support contract will last for up to 3 years with a possible 2 year extension. You may want, particularly in the early days to limit the period to 1 year in order to ensure that the contractor is delivering effectively. That aspect of the contract is important as Trusts will want to have the confidence that when there are problems there is a good enough infrastructure to deal with them smoothly. The reason why the contracts are long is because considerable attention has been given to determining levels of service, so adverse consequences can follow should they fail to be met.

Is the fact that some suppliers are more expensive than others mean that the more expensive/cheaper have been assessed by the NSC as being better/worse than the others?

No. The price simply reflects the contractor's final offer, the pricing of one contractor being kept confidential from the others during the bidding process.

Where are the prices and how can they be compared?

Schedule G of the SUPPLY contract deals with pricing issues, and also Schedule E of the support contract. The former contains a costings scenario so that Trusts have the opportunity of comparing prices from one company to another based on similar criteria (in this instance a Primary Care Trust managing 15,000 patients using a mix of clinics, mobile units and optometrist schemes). It also, where possible deals with hourly, daily and/or weekly rates for services that are not included in the core contract price. PaSA has agreed to provide a separate costing/pricings folder on their web-site (see above) so that all the contractor's costings scenarios can be compared

But what if what we want is not the same as the costings scenario?

There may be many variations on the price depending on the elements of supply and service that the Trust seeks. It is essential that each Trust identifies each element of software and service that they need carefully and makes sure that they really understand what it is they are getting for their money. Contractors have different approaches to pricing bands, some allowing a greater number of patients for a particular licence fee, some have unlimited use licence fees, or charge different rates for out of hours help-desk cover.

When you are assessing potential costs make it clear whether you are purchasing for a single primary care trust, several or an SHA, know how many users at any one time, whether you wish to install in several sites or just one, if you have mobile units and how many, optometrist schemes and if so how many optometrist centres/users. If you are purchasing for larger units or intending to expand the size of your existing operation find out whether there are unlimited use licences and whether, on the particular facts of your service, if it is cheaper to buy in this way. Are you likely to be using the software at weekends or out of hours. If so, support during those times will add to the contract price, as the contractor help desks are only open between 8a.m to 5 or 6 p.m. Mon – Friday excluding public and bank holidays. Establish clearly whether they charge for fixes outside that cover time and run checks (both with the contractor and with the Trusts that use them) as to how often outside hours cover has been required and given. Check their specific contract terms. What if the fault is not with their software? How is this handled?

Trusts also need to be clear about the infrastructure that it has to provide so that the software can be run, as far as possible, to optimal standards. This means checking, amongst other things, on existing Trust hardware provision, the quality of network connections, laptop capacity, back-up facility, RAID or other such similar reconstruction software, training timetable and technical support. Some suppliers are willing to provide hardware but that is not included in the costing scenario grid.

How do we know which contractor is best for us?

Having established what services you think you want and compared costs, look at each product to see which ones deliver the solutions you are seeking.

Ask the contractor to provide you with a list of all the Trusts etc where their products are already installed and in use (or, if installed abroad, where, the type of scheme and functionality) and contact details. This will enable you to establish whether they have a tried and tested system or not. Ask whether & for how long they have held contracts of this type and size and whether and to what extent they have been renewed. This will give you some idea of the view of existing users' willingness to stay with the supplier. Find out what other contracts they deal with.

Check with Trusts, which have existing contracts, on their experiences with regard to installation and training as well as maintenance and support. If at all possible go and see a system in use in a clinical environment.

Contractors have taken different approaches with regard to pricing. Some charge the substance of their price in the very early stages of entering into the contract, frontloading the price on the installation of the software and the basic training and attributing relatively little to support and maintenance. Others spread out their charges more evenly over the 3 year period so that a lower proportion of charges attaches to the installation of the software and basic training and a higher amount may be charged in relation to software support. All have been required to provide specified deliverables (e.g. provision and installation of software, training, testing etc) before being entitled to invoice the Trusts.

In that respect it is also true to say that different contractors may have set different levels of liquidated damages (amounts that they are due to pay against poor performance). The higher the percentage of liquidated damages the greater the financial incentive is for performance - providing the Trust goes to the trouble of keeping records and enforces it.

Whilst there can be an incentive for Trusts to spend capital sums up front and early it is only common sense to also take into account that once the substance of the money is handed over to the contractor there is not the same **financial** incentive to keep on delivering high levels of service over a three year period compared with those who spread their charges for support more evenly year by year.

If the contractor does have high up front charges you may want to run especially careful checks on their performance with regard to continuing service levels e.g. faults, help desks and fixing, as you will not have the same ability to withhold as much money/ impose financial penalties as you would with the contractors who spread their charges more evenly, and attribute more to maintenance and support. It is therefore particularly important with those who front-load their charges on software installation to be satisfied as to their long term performance by checking their performance with existing users. For instance: How often are problems experienced? Do they deal with fault reporting swiftly and effectively?

Look carefully at the schedules to see whether the terms of one suits you better than the others.

What if a contractor is not delivering what we expected or is providing poor support?

Firstly, make sure that it really is a contractor problem. Trusts will have to ensure that they have procured hardware sufficient to meet the supplier's recommendations (unless the supplier is also providing the hardware, in which case there will be additional charges over those described in Schedule G). They will also have to ensure that they have good back up systems and disaster recovery. Read Schedule D of the Supply & of the Support Contract to establish what are the Trusts responsibilities. It may be necessary to tailor these to the realities of your Trust using the Change Control Procedures (see schedule H in the Supply Contract & Schedule F in the Support Contract.) PaSA will be willing to assist you in drawing this up. It is possible that the problems arise from poor connection for web-based products, or from the installation of other incompatible software.

If you are satisfied that the responsibility for the problem is not the Trust's various performance targets for the **contractors** have been set (**see Section A1.2 to section A5 of the Supply and all of Schedule A in the Support contract**) including timescales for installation, levels of help desk cover, response times and fix times with regard to logged faults, system response times regarding such matters as (for example) time for accessing data input, on-line enquiries, obtaining reports and calling up 4 digital images at a certain compression level.

It will be important that Trusts monitor those performance targets carefully and that it keeps careful records of any measurable failure to meet them together with details of

the efforts made to address them and the responses.

FEEDBACK

Finally, help us to help you. Complete the feedback form on the <http://www.nscaretinopathy.org.uk> web-site so that we can learn from your experiences when it comes to selecting suppliers next time.

3.7 Procuring off-list Software

Screening services considering the purchase of software not approved by the diabetic retinopathy programme must comply with the laws and rules applying to public sector procurements, or risk a penalty. Local procurement departments will provide guidance on how this should be approached and any factors that may affect the process (e.g. the aggregate cost of more than one package from a given supplier).

In addition trusts procuring from off-list suppliers should ensure that the specification the software must meet at least equals the standards set by the diabetic retinopathy programme and includes the implementation of the diabetic retinopathy screening programme's messaging specifications available on the HL7 web-site at <http://www.hl7.org.uk>.

Section 4: Glossary of Terms / Appendixes

4.1 Glossary of Terms

Screening terminology can be confusing, particularly as the same term can mean different things to different screening services. This workbook has been standardised to use the following terms for various screening activities. For consistency, those producing guidelines or reports are encouraged to use these terms rather than potentially ambiguous phrases such as 'secondary grading'.

<p>Screeener (See S.1.5.1)</p>	<p>This term can be used in two ways depending on the context:</p> <p>In general it is used to describe anyone involved in the process of identification of sight threatening diabetic retinopathy in a screening programme for diabetic retinopathy (including grading). This group may include medical photographers, healthcare assistants, GPs, diabetologists, ophthalmologists and optometrists.</p> <p>However it is sometimes necessary to distinguish between the activities that take place at the patient appointment and the process of disease identification. In those circumstances the term 'screeener' refers to the person who measures visual acuity and administers dilatation drops and/ or operates a fundus camera to capture images of the patient's retina.</p> <p>This should not be confused with screening in its wider sense as a public health service.</p>
<p>Grader / Grading</p>	<p>The grader examines the retinal images for evidence of diabetic change in the eye and assesses those images for disease against the minimum dataset at Appendix 1.</p>
<p>Disease / no disease grade</p>	<p>This is an initial assessment of patient imagesets to determine whether or not there is disease present without trying to grade the presence of disease fully against the minimum dataset at Appendix 1. This can result in urgent referrals to clinics. This is an optional assessment, but if followed will result in all imagesets revealing disease being forwarded for a first full disease grade by a different and fully accredited grader together with a random 10% on no disease imagesets..</p>
<p>First full disease grade</p>	<p>This is the first full assessment of the level of retinopathy, maculopathy and possible other complications in the eye by a grader accredited to do this. The minimum set of information to be captured in</p>

a first full grade is listed in Appendix 1. In the event that there has been a simple **disease/no disease grade** event already a random 10% of the no disease imagesets identified at that stage will be further reviewed by the **first full disease** grader.

Second full disease grade	This is a reassessment of the level of retinopathy, maculopathy and possible other complications in the eye by a grader accredited to do so. This must be carried out in all cases where a first full disease grade indicates evidence of diabetic change in the eye. In the event that there has been no simple disease/no disease grade the second full disease grader will also assess a random 10% of images where no diabetic change is evident (as a quality assurance measure).
Arbitration grade	An arbitration grade is carried out in the event that there is disagreement between the first full disease grader and the second full disease grader on the level of disease or whether or not there should be a referral. Usually this will be done by an ophthalmologist or an experienced screener, accredited to the highest level, who has been approved for this level of work by the lead clinician. Most grading centres find it helpful if arbitration grading is carried out on all referable retinopathy diagnosis in advance of a referral to an ophthalmology department for treatment in order to reduce the number of avoidable referrals to eye-clinics.
Patient imageset	A patient imageset is the set of images which are captured for a single patient during screening . Usually, a patient imageset consists of four images – one macular and one nasal for each eye.

Appendix 1: NSC Retinopathy Grading Standard**Retinopathy (R)**

Level 0	None	
Level 1	Background	microaneurysm(s) retinal haemorrhage(s) ± any exudate not within the definition of maculopathy
Level 2	Pre-proliferative	venous beading venous loop or reduplication intraretinal microvascular abnormality (IRMA) multiple deep, round or blot haemorrhages (CWS - careful search for above features)
Level 3	Proliferative	new vessels on disc (NVD) new vessels elsewhere (NVE) pre-retinal or vitreous haemorrhage pre-retinal fibrosis ± tractional retinal detachment

Maculopathy (M)

exudate within 1 disc diameter (DD) of the centre of the fovea
circinate or group of exudates within the macula
retinal thickening within 1DD of the centre of the fovea (if stereo available)
any microaneurysm or haemorrhage within 1DD of the centre of the fovea only if associated with a best VA of $\leq 6/12$ (if no stereo)

Photocoagulation (P)

[evidence of focal/grid laser](#) to macula
[evidence of peripheral scatter laser](#)

Unclassifiable (U)

[Unobtainable / ungradable](#)

Appendix 2: Service objectives and quality assurance standards**Release 5, January 2007**Amendments from the standards published in version 3.2 of the workbook are indicated in ***bold italic*** type.Terms defined or further explained in the guidance notes which accompany these standards are indicated with a broken underline.

	Objective	Criteria	Minimum standard [all programmes]	Achievable standard [top quartile]
1	To reduce new blindness due to diabetic retinopathy.	<p>1. Annual new <u>certifications of severe visual impairment / visual impairment, <i>predominantly due to diabetic retinopathy</i></u>, compared to 1990/1 rates of 9.5 & 9.3 respectively per million per annum (national data).</p> <p>2. Local identification of <u>incident visual acuity <i>predominantly</i></u> due to diabetic retinopathy:</p> <p>6/60 or worse in the better seeing eye. <i>[LogMAR equivalent +1.0]</i></p> <p>6/18 or worse in the better seeing eye. <i>[LogMAR equivalent +0.5]</i></p> <p><u>Local services will need to <i>prospectively</i> audit both certifications of visual impairment and incidence of specified visual acuity in order to establish a baseline.</u></p>	<p>10% reduction within 5 years <i>of start of screening programme.</i></p> <p>10% reduction within 5 years <i>of start of screening programme.</i></p> <p>10% reduction within 5 years <i>of start of screening programme.</i></p>	<p>40% reduction within 5 years <i>of start of screening programme.</i></p> <p>40% reduction within 5 years <i>of start of screening programme.</i></p> <p>40% reduction within 5 years <i>of start of screening programme.</i></p>

	Objective	Criteria	Minimum standard [all programmes]	Achievable standard [top quartile]
2	To invite all eligible persons with known diabetes to attend for the DR screening test.	<p>Completeness of database:</p> <p>a) Proportion of GPs <u>participating</u></p> <p>b) % of <u>known people with diabetes on register</u></p> <p>c) Percentage of <u>eligible</u> people with diabetes <u>invited</u>.</p> <p>d) Single collated list of all people with diabetes</p> <p>e) Systematic call/recall from a single centre of all people eligible for screening on the collated list</p> <p>f) All newly diagnosed patients must be offered screening within three months of the programme being notified of their diagnosis</p>	<p>90%</p> <p>90%</p> <p>100%</p> <p>100%</p>	<p>98%</p> <p>98%</p>
3	To ensure database is accurate.	Accuracy of addresses on database of persons age 12 or more, as determined by <u>Post Office returns</u> .	95%	98%
4	To maximise the number of invited persons accepting the test.	Percentage of <u>eligible</u> persons <u>accepting</u> the test: <ol style="list-style-type: none"> 1. Initial screen 2. <u>Repeat screen</u> 	<p>70%</p> <p>80%</p>	<p>90%</p> <p>95%</p>
5	To ensure photographs are of adequate quality.	Percentage ungradable patients in at least one eye.	<u>Raw ungradable, U <10%</u>	<u>Raw ungradable, U <5%</u>
6	To ensure grading is accurate.	<p>Inter- and intra-grader agreement</p> <ol style="list-style-type: none"> 1. For <u>referable images</u> 2. For non-<u>referable images</u> 3. <u>Ungradable</u> images <p>Advice on internal quality assurance processes will be developed nationally.</p>	<i>Programmes must provide evidence of internal QA activity in annual reports and for peer-review QA visits.</i>	

	Objective	Criteria	Minimum standard [all programmes]	Achievable standard [top quartile]
7	To ensure optimum workload for graders, to maintain expertise.	<p>1. Optometrists / ophthalmologists</p> <p>2. All other screener/graders</p>	<p>Each optometrist or ophthalmologist should grade a minimum of 500 patient imagesets per annum</p> <p>Each grader should grade a minimum of 1000 patient imagesets per annum</p>	Each grader should grade a minimum of 1500 patient imagesets per annum
8	To ensure timely referral of patients with R3 (fast-track) screening results (e-mailed or faxed).	<p>Time between <u>screening encounter</u> and issue of referral request:</p> <p>Flagged by screener/grader as R3 fast-track referral, where secondary grading and appropriate referral actioned within 1 week.</p>	<p>95% referred within 1 calendar week</p> <p>100% referred within 2 calendar weeks</p>	98% referred within 1 week
9	To ensure GP and patient are informed of all test results	Time between <u>screening encounter</u> and <u>issuing of result letters</u> to GP and patient.	<p>70% <3 weeks</p> <p>100% <6 weeks</p>	95% <3 weeks
10	To ensure timely consultation for all screen-positive patients.	<p>Time between <u>notification of positive test</u> and <u>consultation:</u></p> <p>1. Proliferative DR/Advanced DED, R3</p> <p>2. PPDR, R2</p> <p>3. Maculopathy, M1</p> <p>4. All retinopathy grades</p>	<p>70% <2 weeks</p> <p>70% <13 weeks</p> <p>70% <13weeks</p> <p>100% < 18 weeks</p>	<p>95% <2 weeks</p> <p>95% <13 weeks</p> <p>95% <13 weeks</p>

	Objective	Criteria	Minimum standard [all programmes]	Achievable standard [top quartile]
11	To ensure timely treatment of those listed by ophthalmologist.	Time between <u>listing</u> and <u>first laser treatment</u> , following screening: 1. Proliferative DR, R3 2. Maculopathy, M1	90% <2 weeks 70% <10 weeks	95% <2 week 95% <10 week
12	To minimise overall delay between screening event and first laser treatment.	Time between <u>screening encounter</u> and <u>first laser treatment</u> , if listed at <u>first visit</u> to hospital eye service following screening, does not exceed: 1. For patients <u>referred as</u> R3 2. For patients <u>referred as</u> M1	70% <4 weeks 100% <6 weeks 70% <15 weeks 100% <26 weeks	95% <4 weeks 95% <15 weeks
13	To follow up <u>screen-positive</u> patients (failsafe).	Combined cancellation and DNA rate for ophthalmology clinic 1. For PDR [R3] within 1 month 2. For PPDR [R2] within 6 months 3. For maculopathy within 6 months	<10% <10% <10%	<5% <5% <5%
14	To minimise the anxiety associated with screening due to inappropriate referral.	Monitor <u>inappropriate</u> referrals following screening 1. <u>False positive rate of DR test</u> (photograph) 2. Neither photograph or clinical examination <u>warranted</u> referral	25% of patients referred	20% of patients referred

	Objective	Criteria	Minimum standard [all programmes]	Achievable standard [top quartile]
15	<i>To ensure timely re-screening.</i>	<i>Time to re-screening compared to annual screening interval.</i>	<i>70% of eligible patients on database re-screened within 12 months of previous screening encounter</i> <i>or</i> <i>95% of eligible patients on database re-screened within 15 months of previous screening encounter</i>	
16	<i>To ensure the public and health care professionals are informed of performance of the screening programme at regular intervals</i>	<i>Production of annual report.</i>	<i>Production of annual report, for preceding financial year, according to national standard, by 31st October.</i>	

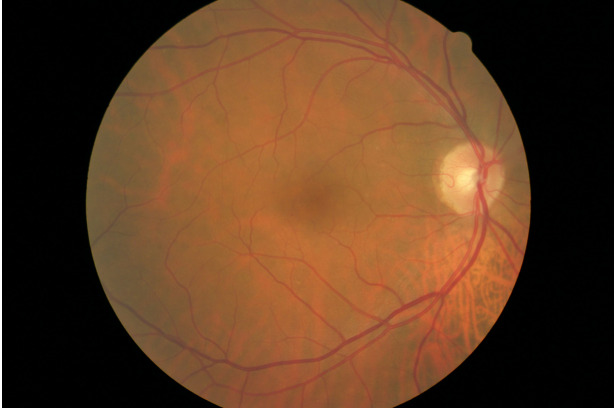

	Objective	Criteria	Minimum standard [all programmes]	Achievable standard [top quartile]
17	<i>To ensure the service participates in quality assurance</i>	<i>External quality assurance.</i>	<i>1. Evidence of participation of all graders in external image test set scheme</i> <i>2. Participation in peer-review visit programme</i> <i>3. Annual submission of <u>national minimum dataset</u> by 31st October.</i>	
18	<i>To optimise programme efficiency and ensure ability to assure quality of service</i>	<i><u>Minimum programme size.</u></i>	<i>Population including 12,000 people diagnosed with diabetes on current patient list</i>	<i>Population including 15,000 people diagnosed with diabetes on current patient list</i>
19	<i>To ensure that screening and grading of retinal images are provided by a trained and competent workforce</i>	<i>Accreditation of screening and grading staff in accordance with national standards</i>	<i>All staff should be accredited for their role within two years of appointment, or by April 2008 for existing staff in established programmes</i>	

Appendix 3: Definition of acceptable image quality

- Photographers should capture 2 x nominal 45° fields per eye (1 x fovea centred, 1 x disc centred).
- A combined assessment of field position and image quality should be made for each eye.
- Images must be graded for diabetic eye disease only if the grader is confident the quality is sufficient.
- All grading is to be performed by trained and accredited staff.

A combined assessment of field position and image quality is made in the software as follows:

GOOD

Macular image centre of fovea $\leq 1DD$ from centre of image & vessels clearly visible within 1DD of centre of fovea & vessels visible across $>90\%$ of image	AND	Disc image centre of disc $\leq 1DD$ from centre of image & fine vessels clearly visible on surface of disc & vessels visible across $>90\%$ of image
		

ADEQUATE

Macular image centre of fovea $>2DD$ from edge of image & vessels visible within 1DD of centre of fovea	AND	Disc image complete optic disc $>2DD$ from edge of image & fine vessels visible on surface of disc

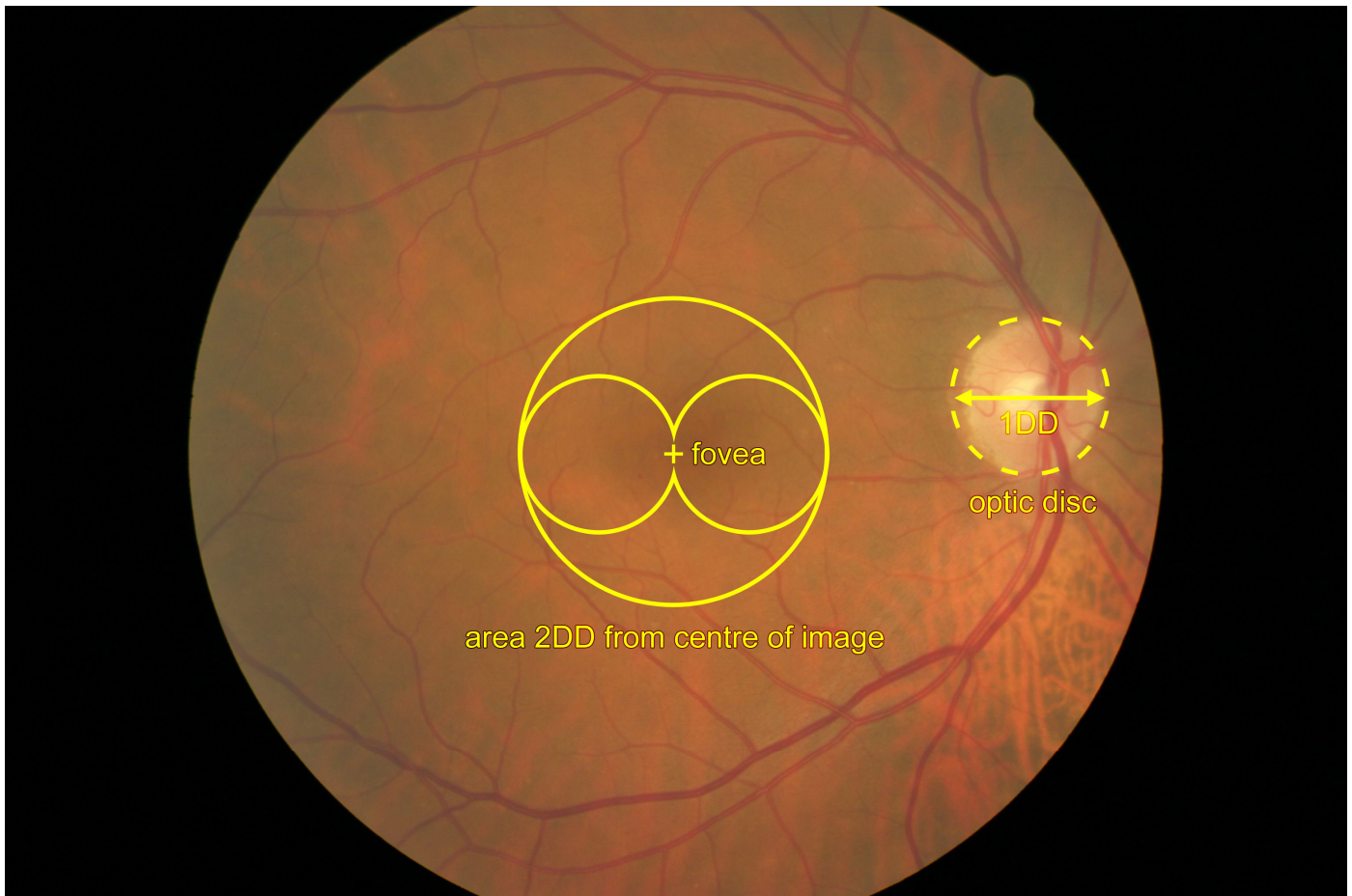
In some unusual cases (particularly in patients with a large disc), an image may fall within both **good and adequate** categories above. In such cases, the image should be classified as **good**.

INADEQUATE (ungradable)

Failure to meet definition of **adequate** above UNLESS referable diabetic retinopathy (R2, R3, M1, unstable treated proliferative diabetic retinopathy) visible anywhere in the eye.

Definitions of disc, fovea, 1DD

The image shown below is a perfectly aligned macular view of the right eye. The fovea lies at the centre of the image and is marked '+'.



Appendix 4: References, academic papers, etc

Ref: 6.4 Poor quality images

- 1) Moss, S, Meuer, S, Klein, R, Hubbard, L, Brothers, R & Klein, B. Are Seven Standard Fields Necessary for Classification of Diabetic Retinopathy? *Invest Ophthalmol Vis Sci* 1989;30:823-828.
- 2) Aldington, S, Kohner, E, Meuer, S, Klein, R & Sjolie, A. Methodology for retinal photography and assessment of diabetic retinopathy: the EURODIAB IDDM Complications Study. *Diabetologia* 1995;38:437-444.

Further work has supported this recommendation:

- 1) Scanlon PH, Malhotra R, Thomas G, Foy C, Kirkpatrick JN, Lewis-Barned N, et al. The effectiveness of screening for diabetic retinopathy by digital imaging photography and technician ophthalmoscopy. *Diabet Med* 2003;20(6):467-74.
- 2) Scanlon PH, Malhotra R, Greenwood RH, Aldington SJ, Foy C, Flatman M, et al. Comparison Of Two Reference Standards In Validating Two-Field Mydriatic Digital Photography As A Method Of Screening For Diabetic Retinopathy. *Br J Ophthalmol*. 2003; in press