

# The Royal College of Ophthalmologists



## Preferred Practice Guidance

### Diabetic Retinopathy Screening (DRS) and the Ophthalmology Clinic set up in England

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Scientific Department  
17 Cornwall Terrace  
London NW1 4QW

Telephone: 020 7935 0702  
Facsimile: 020 7487 4674  
[www.rcophth.ac.uk](http://www.rcophth.ac.uk)

## Background

Diabetic Retinopathy (DR) is the most common cause of visual loss in the working age population of the UK. In response to the 1989 St Vincent Declaration<sup>1</sup> to reduce blindness by 1/3<sup>rd</sup> by 2010 the English National Screening Programme for Diabetic Retinopathy (ENSPDR<sup>2</sup>) was set up, forming part of the National Service Framework for Diabetes with the aim to reduce visual impairment due to diabetic eye disease. Systematic comprehensive screening for DR is embedded in the national programme for health and has been backed by the DH<sup>3</sup>.

Currently, the Primary Care Trusts (PCTs) are responsible for implementing ENSPDR in England, and have each established a model of delivery to suit local circumstances. PCTs are grouped under the Strategic Health Authorities and are answerable to the Department of Health. PCTs are responsible for establishing and maintaining a central diabetic register of the known diabetic population aged 12 years and over, that is used to populate the call/recall system of local DRS software. The Diabetic Register numbers are compared with the local GPs' QOF (Quality Outcome Framework) returns to judge overall capture. Since 2007, the PCTs are required to send screening appointments to 100% of their eligible diabetic population and have 20 quality assurance (QA) targets applied to all aspects of the screening, grading, referral, treatment and exclusion process. 5 of these QA targets are delivered directly by the ophthalmology team.<sup>4</sup>

Annual photographic screening for each patient is established using NHS Purchasing and Supply Agency (PASA) approved equipment (camera and software) in the majority of programmes. All Diabetic Retinopathy Screening (DRS) programmes assess retinopathy using 2 standard digital fundus photographs of each eye that are graded and referred according to the national guidelines (Table - 1). Each programme in ENSPDR employs accredited graders to analyse and grade each image set to conform to the ENSPDR classification system (Table - 1). Primary grading involves disease no disease grading or full disease grading and all images graded as having retinopathy are subjected to secondary grading for internal quality assurance (QA). Additionally 10% of images graded with 'no disease' are subjected to second grading for QA. Any discrepancy in grading between first and second grader is subjected to arbitration grading, which is usually undertaken by an ophthalmologist with experience in diabetic retinopathy screening.<sup>5</sup>

Table 1 ENSPDR classification of diabetic retinopathy<sup>6</sup>

Grade	Defining features	Outcome
R0	No diabetic retinopathy	Annual recall in screening programme
R1	Background diabetic retinopathy	Annual recall in screening programme
R2	Pre-proliferative diabetic retinopathy	Refer to ophthalmology (to be seen within 13 weeks)
R3	Proliferative retinopathy / Advanced proliferative features	Refer to ophthalmology (to be seen within 2 weeks)
M1	a) exudate within 1 disc diameter (DD) of the centre of the fovea  b) circinate or group of exudates within the macula  c) any microaneurysm or haemorrhage within 1 DD of the centre of the fovea only if associated with a best VA of +0.3 logMAR (6/12) or worse	Refer to ophthalmology (to be seen within 13 weeks)
M0	No lesion within 1DD (disc diameter) or VA better than 0.3LogMAR with no exudates within 1dd (i.e. does not meet any of the categories of M1)	Annual recall in screening programme
P	Photocoagulation scars present	
U	Ungradeable	

All patients identified by DRS as having sight threatening retinopathy (R2, R3 and M1) are referred to ophthalmology clinics, usually held within the hospital eye service (HES) for further clinical care. Each DRS programme is required to submit a comprehensive annual report to the ENSPDR. The report requires data feedback from HES for timeliness of appointments, clinical outcomes, including data for CVI registration due to DR<sup>7</sup> and other reports relating to the 20 National QA standards.

### **Clinical Leadership**

Implementing DRS is a major undertaking for ophthalmology departments and requires an appropriate set up for administration, clinical care and clinical governance and robust infrastructure involving hardware, software and trained, skilled manpower appropriate for each task. Depending on the local model of DRS, ophthalmology departments may

be involved in implementing the whole of the local DRS programme or in only providing clinical care to patients with referable retinopathy and other pathology found on retinal image sets. This paper confines discussion to the ophthalmology clinic aspect of DRS.

The DRS requires clinical leadership and ENSPDR recommends that a medical retina specialist takes on this role.<sup>8</sup> The Royal College of Ophthalmologists (RCOphth) endorses this recommendation and encourages local clinical leadership by a consultant ophthalmologist specialising in medical retina (Retinologist). Clinical leadership for the whole screening programme should be considered a much wider role than lead consultant role for the diabetic population looked after at the secondary care level. The former may include the latter. This paper would elaborate on the lead consultant role for the secondary care level. Previous College documents elaborate on DRS<sup>5</sup> and clinical care for DR<sup>6</sup>. This paper focuses on the specific patient pathways and clinical features of the ophthalmological care of patients referred by the local DRS. This is expected to be common to all programmes irrespective of the provider for screening and grading up to the point of referral.

### **Data Collection**

ENSPDR has gradually matured in to a robust screening programme with well defined QA requirements. It emphasizes the need for regular, prospective data collection, monitoring and comparison of data with set standards and confirmed by Do Once And Share (DOAS) <sup>7</sup>.

Ophthalmology departments are under pressure to meet these requirements in addition to existing contractual commitments that the hospitals have with the commissioning PCT. As ENSPDR arrangements vary widely, it is difficult to issue guidance for commissioning that would fit each area. However, in general it would be advisable that ophthalmology departments engage directly with the commissioners about local DRS arrangements and issues for the ophthalmic department. As ENSPDR requires data collection, monitoring and submission of data outside the normal administration duties of ophthalmology departments, in order to fulfill QA requirements, appropriate resources need to be identified and funded at the outset (Box -1).

As recommended by the ENSPDR workbook, a consultant with medical retina expertise should be the designated lead consultant for diabetic eye care to lead, co-ordinate and oversee DRS programme related developments in the ophthalmology clinic. (The DRS programme would have a clinical lead and the same individual may undertake both these roles).The lead consultant for DRS should be supported by appropriate management and administration staff in establishing patient care pathways, monitoring QA and data collection and feedback. It is

expected that the lead consultant for DRS will be engaged in ascertaining that staff engaged in clinical care of DR patients meet the standards required by the ENSPDR<sup>9</sup>. (S)he would be required to ensure the dataset is completed for the annual return for the local DRS. The job plan of the lead consultant for DRS should reflect this.

In terms of investigation facilities, the HES needs to have access to the DRS photographs and image manipulation as well as grading software compatible with the local programme<sup>10</sup>. In addition there should be access to fundus photography, fluorescein angiography and OCT scanning equipment, preferably with high definition. Attention should be drawn to the need for technical staff to help provide these services.

It is also recommended that a clinical patient record software is available, ideally linked to the DRS images so as to have a streamlined approach to grading as well as serving as the clinical EPR. The lead consultant at the HES should ensure/ facilitate appropriate training of the clinical staff in the use of such software, with appropriate time allowance. The lead consultant should be supported by appropriate clinical staff and administration staff to establish patient care pathways, and clinical governance policies. It is also advised that policy documents regarding care of diabetic patients in the HES be established and reviewed regularly<sup>11</sup>.

#### Box -1. Resource requirements for DRS

- Additional pressure on ophthalmology
- Extra resources needed to meet ENSPDR requirements
- Establish dedicated clinical leadership for DRS
- Establish dedicated administration structure
- Establish dedicated diabetic retinopathy clinics
- Ensure appropriate software and hardware available (Clinical and administrative)

#### Hospital Interface with DRS

ENSPDR recommends<sup>8</sup> that DR referrals are made using screening software. In most ophthalmic units, this still remains to be a paper based referral system, though it is recognized that electronic referrals would be advantageous. Considering the emphasis put on tracking referrals and timeline for clinical episode, a dedicated DRS administration set up is required at the HES. Such set up would be best served by a team who can engage with the local DRS administration team on a regular basis to capture all the electronic referrals and manage clinic bookings for the DRS patients. Such a team would be pivotal in monitoring capacity, reducing non-attendance and collection of data for audit.

A clear referral pathway needs to be established and agreed with all screeners and local DRS for all cases and specifically for high risk referrals R3 so that they can be prioritised (e.g. fax/ phone call with a dedicated line)

Currently some hospitals cover more than one PCT and hence more than one DRS programme. In such instances, it may be difficult to have single DRS software. Similarly some DRS programmes may refer patients to different hospitals and each hospital patient administration system (PAS) may have a different electronic interface. In such circumstances, it is important that communication is maintained by a combination of paper, post, email and telephone calls, with clearly identified and agreed methods that is available to all involved in the DRS. In addition, the GPs need to have data from both HES and DRS in order to co-ordinate the overall care of the diabetic patient, it would be advisable that compatible electronic software is sought to facilitate seamless transfer of information between the primary and secondary care. As the software used in the HES, DRS and the primary care are not integrated at present, integration of demographic data on HES system remains an issue. It would be useful to engage in further developments of such systems to enhance patient care.

It can be recommended that an administration lead is identified within the HES to liaise with the DRS programme and ensure that patients do not fall between HES and DRS and for smooth cohesive administration of diabetic eye care systems in the hospital. Depending on the number of referrals expected in the eye department, additional personnel would be needed to support the administration lead. The work required of the administration staff would include the tasks listed in box 2:

Box -2. Administration tasks.

- Tracking referrals from DRS (might be more than one referring programme)
- Tracking discharges to DRS
- Making appointments in Diabetic eye clinic
- Investigate DNA, check PAS details, contact to ensure 2nd appt is kept
- Notify DRS and GP of any persistent DNA
- Treatment session appointments: Laser / injections
- Rescheduling
- Discharge log
- CVI log
- Vitrectomy ref log
- Waiting times monitoring against ENSPDR targets

It is important to establish local policies and protocols for each unit, especially for the non attendance (DNA) and notification of persistent non-attendees to the programme administration and GP.

### **Clinical staff and roles**

ENSPDR recommends that the diabetic patients are seen in dedicated diabetic eye clinics and that the clinical staff engaged in the care of these patients are appropriately trained (Box 3). Such clinics should have suitably qualified and experienced personnel meeting the ENSPDR requirements. The clinicians undertaking such care are required to undertake grading as per the ENSPDR and may be required to take online assessments for QA purposes. The nominated lead ophthalmologist for the DRS would ensure that the right staff with the right skills deliver clinical care of diabetic patients at the right times. Trainee ophthalmologists engaged in such clinics should be supervised for the work they undertake; appropriate to the level of their experience and the stage of their training. This is to ensure QA and help with logistics of data collection requirements. It is also recommended, as emphasised by the ENSPDR that the lead consultant for the DRS oversees approval of staff engaged in the clinical care.<sup>12</sup>

All staff in the diabetic eye clinic should have access to details of the screening photographs and results available in the clinic room when the patient is being assessed.<sup>13</sup> Discussion of grades and clinic findings should occur with the senior ophthalmologist in the clinic as appropriate. It is important that all staff engaged in the diabetic eye clinic are aware of the referral criteria from ENDRSP and should follow local discharge policy appropriately to minimise risk of such discharged patients being referred back to the HES because of pre-existing poor vision or unchanging retinopathy, for example.

It would be preferable to hold clinics for new referrals from DRS, staffed by a more experienced ophthalmologist (retinologist). Such clinics for slit lamp assessment of DR patients should comply with the waiting time targets but should also allow for dedicated slots for urgent cases in addition to the routine cases. The clinician will be required to assess the patient and grade as per the ENSPDR grading to provide feedback data to the DRS on regular basis.

Currently, most eye departments have paper based medical records. The clinicians would be required to document in their HES records as well as in the DRS software regarding the final grading and clinical outcome. It is recommended that efforts are made to establish more efficient ways of recording clinical findings and feedback of data in the ENSPDR format while minimising duplication. There is potential for using an EPR system that

can link up with DRS software in extracting relevant data including images for the ophthalmologist and after the clinical episode is completed by him/her, relevant data is sent back to DRS software to meet the ENSPDR requirements.

#### Box -3. Staff for DRS eye clinic

##### Clinical Staff:

- Lead consultant for DR clinics
- Consultant ophthalmologist with medical retina interests
- Ophthalmologists with medical retina interests
- Trainee ophthalmologists under supervision
- Allied health professionals under supervision

##### Support staff:

- DR clinic nurse
- Ophthalmic photographer
- Ophthalmic technician
- Clinic co-coordinator/failsafe

### **Patient pathway**

To achieve the aim of ENDRSP of reducing blindness, setting a patient care pathway for DR is paramount. The local needs and organisational factors should be considered in planning the DRS patient journey. It can be suggested that to comply with the ENSPDR standards and to impart timely treatment for the patients, a one stop service for assessment and treatment seem ideal. However, unlike the AMD service, the demand for clinical work for DRS is at least 4-5 times for sight threatening retinopathy alone and hence at present a fully fledged one stop service seems difficult to establish. A carefully planned two stop service – segregating assessments from treatment sessions seem more practical but would need adequate resources - clinical, technical and supportive - to ensure timely treatments.

### **New patients**

It is also useful to streamline new patients' pathway from follow ups to improve efficiency and to be able to comply with ENSPDR (Box 4). New patients referred from the DRS programme will require systematic slit lamp assessments and comparison with grading done in the primary care setting. It is preferable that a more experienced ophthalmologist is engaged in new patient clinics. The full assessment and grading as per ENSPDR needs to be completed at this visit. If a patient needs treatment for DR, it is expected that the treatment episode will take place as soon as possible and within the maximum time duration stipulated by the ENSPDR. Decision regarding final grading outcome in the outpatient clinic needs to be recorded and communicated to the local DRS programme after each new patient clinic visit. It is also expected that the local DRS will be informed of the appropriateness of the referral for QA purpose.

In a dedicated DR clinic, enough time should be available for history taking including relevant systemic history, assessment of photographs, examination and ancillary test results (if required) and completion of minimum dataset required for the DRS. Recognising that good control is essential to prevention of progression of retinopathy enough time should be available to appraise the patient on retinopathy, preventive measures and potential treatment needs for complications of diabetes, in order to improve patient care outcomes in the long term, (see appendix 1). It is expected that in a dedicated new patient clinic up to 8-10 patients can be booked for DR assessment and management. It is essential that there is ready access to retinal photographs to document retinopathy as necessary and that an optical coherence tomography (OCT) scan as well as fundus fluorescein angiography (FFA) should also be available. The OCT scan is increasingly being used to identify macular oedema and its use is likely to be even more needed in diabetic eye clinics.

If a patient is discharged from the clinic it is imperative that the local DRS is notified so that the discharged patient is re-entered on the local screening programme. If the patient needs follow up this needs to be arranged back in dedicated DR clinics. The patients needing laser treatments should be given a treatment appointment if this is not carried out as one stop. The booking and tracking system for laser clinics should meet the fail safe requirements of the DRS. The patients who do not attend appointment (DNAs) should be identified at the clinic and a local policy for managing DNAs should be in place. It is national policy that a new patient referred from DRS with identified sight threatening retinopathy is given a second chance to attend and not be discharged after the first non-attendance but are offered another appointment in the diabetic clinic as soon as possible<sup>14</sup>.

#### Box 4. New Patient Care Pathway

- Establish new patients pathway
- Experienced ophthalmologist/ retinologist
- Access to grading software and images
- Complete ENSPDR grading
- Feedback to local programme on the outcome
- Discharged patients policy- (back on DRS)
- Set up and adhere to DNAs policy
- Encourage use of EPR system

#### **Follow up clinics**

Follow up of diabetic retinopathy patients should be in dedicated clinics. The clinics should be staffed with appropriate clinicians who are experienced in the assessment and treatment of DR. The clinicians should

record DR grading as per the ENSPDR especially if the patients are booked for laser treatment so as to meet the DRS data collection requirement. The lead ophthalmologist for DRS should review follow up times for the diabetic patients to ensure that systems are in place to review follow up patients with DR at the right times<sup>15</sup>. If trainees are engaged in the clinical follow up of DRS patients, appropriate supervision should be available. Clinics should allow time for discussion with senior ophthalmologists as well as for appropriate clinical tests and their interpretation.

The clinic should allow access to DRS photographs and software with grading. Each patient's clinical record should include ENSPDR grading and this should be communicated to the local programme on annual basis at least. If a patient is to be discharged back to the DRS programme this should be clearly communicated to the local programme so that there is no drop out from the screening programme.<sup>16</sup> If a patient is treated with laser, this is required to be notified to the DRS programme on an annual basis and hence it is recommended that grading is done at the time of listing for treatment.

Clinics should allow time for discussion with senior ophthalmologists as well as for appropriate clinical tests and their interpretation. It is recommended that in a specific DRS follow up clinic up to 12-13 patients can be booked depending on the clinicians engaged in the clinic. If the service is set up with a combination of new and follow up clinics appropriate adjustments should be made. It is recommended that consideration is given to accommodate urgent cases and cases for urgent treatment needs; and hence overbooking of clinics should be avoided.

### **Laser clinics**

Laser photocoagulation is the standard of care for diabetic maculopathy and proliferative retinopathy. It is shown that timely, appropriate laser treatment can reduce the risk of vision loss in these patients by 50%.<sup>17</sup>

To ensure the treatments are delivered in timely manner, a dedicated booking system should be established for laser clinics (two stop service model). A laser clinic co-coordinator will need to monitor the clinic bookings, DNAs and recall, as well as ensuring data set is completed for annual return.

The laser clinic should only be staffed by appropriate ophthalmologists who have the required knowledge, experience and skills of undertaking the retinal laser treatments. If a trainee ophthalmologist is involved in such sessions, such sessions should be supervised by a suitable senior ophthalmologist. The trainees should have completed a local laser safety course and should have undertaken an educational course for laser use.

The laser clinic should have access to digital retinal photographs, fluorescein angiograms and OCT scans (if previously taken) of the patient at the time of laser. It is recommended that comprehensive data about laser treatment are recorded along with ENSPDR grading at the time of laser treatment. Such data can be logged on to clinical EPR software which would allow prospective audit of data for the department and facilitate the trainees' logbook.

DNAs in the laser clinics should be follow up promptly and local policy on their management should be well documented and should be adhered to.

### **New treatment options**

Evidence of new treatment options for both diabetic maculopathy and proliferative diabetic retinopathy is gathering pace. Intravitreal therapies, using steroid preparations as well as anti-VEGF agents is increasingly finding its way in clinical practice. Currently no licensed products are available for diabetic retinopathy per se, however, clinical use of intravitreal triamcinolone, dexamethasone, bevacizumab, pegaptanib and ranibizumab have been shown to be promising. It is therefore important that the HES considers implications of such treatment options in the care of DR patients and services are planned so as to accommodate such therapeutic advances.

### **Interaction with diabetic physicians**

As the screening programmes mature, the referrals to the HES of sight threatening retinopathy are likely to improve. The ophthalmology departments will be under pressure in managing these referrals for clinical assessments as well as treatment, while collecting and supplying outcome data, aiming to reduce burden of visual loss in these patients. Clear referral pathways should be developed in conjunction with the diabetologists for patients with advanced retinopathy. In some services, it may be possible to establish joint clinics with diabetologists or diabetes specialist nurses. Multi disciplinary team meetings between ophthalmologists, diabetologists, diabetes specialist nurses and GPs may be considered to enhance patient care.

### **Conclusions:**

The ENSPDR requirements of the HES have increased pressure on ophthalmology departments. This poses a challenge as well as an opportunity for the ophthalmologists to reorganize clinical care for diabetic patients. It is vital that appropriate resources are made available for ophthalmology departments to set up diabetic clinics meeting the clinical standards required by the ENSPDR. This document has outlined a preferred set up for diabetic retinopathy clinics. It is important that all

members of the health team have regular feedback on the progress of DRS to optimise patient pathways and reduce unnecessary referrals

**Lead author:**

Mr Faruque Ghanchi, Consultant Ophthalmologist, Bradford Royal Infirmary, Bradford

The lead author has previously acted as a consultant advisor for Pfizer and Allergan, and has received educational travel grants from Alcon, Allergan, Bausch & Lomb, Novartis and Pfizer in the past.

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Miss Caroline Styles, Consultant Ophthalmologist, Queen Margaret Hospital NHS Trust, Dunfermline

Ms Gilli Vafidis, Consultant Ophthalmologist, Central Middlesex Hospital, London

A review of this guidance will take place in 2012.

# Diabetic Retinopathy Clinic Pathway

Faruque Ghanchi

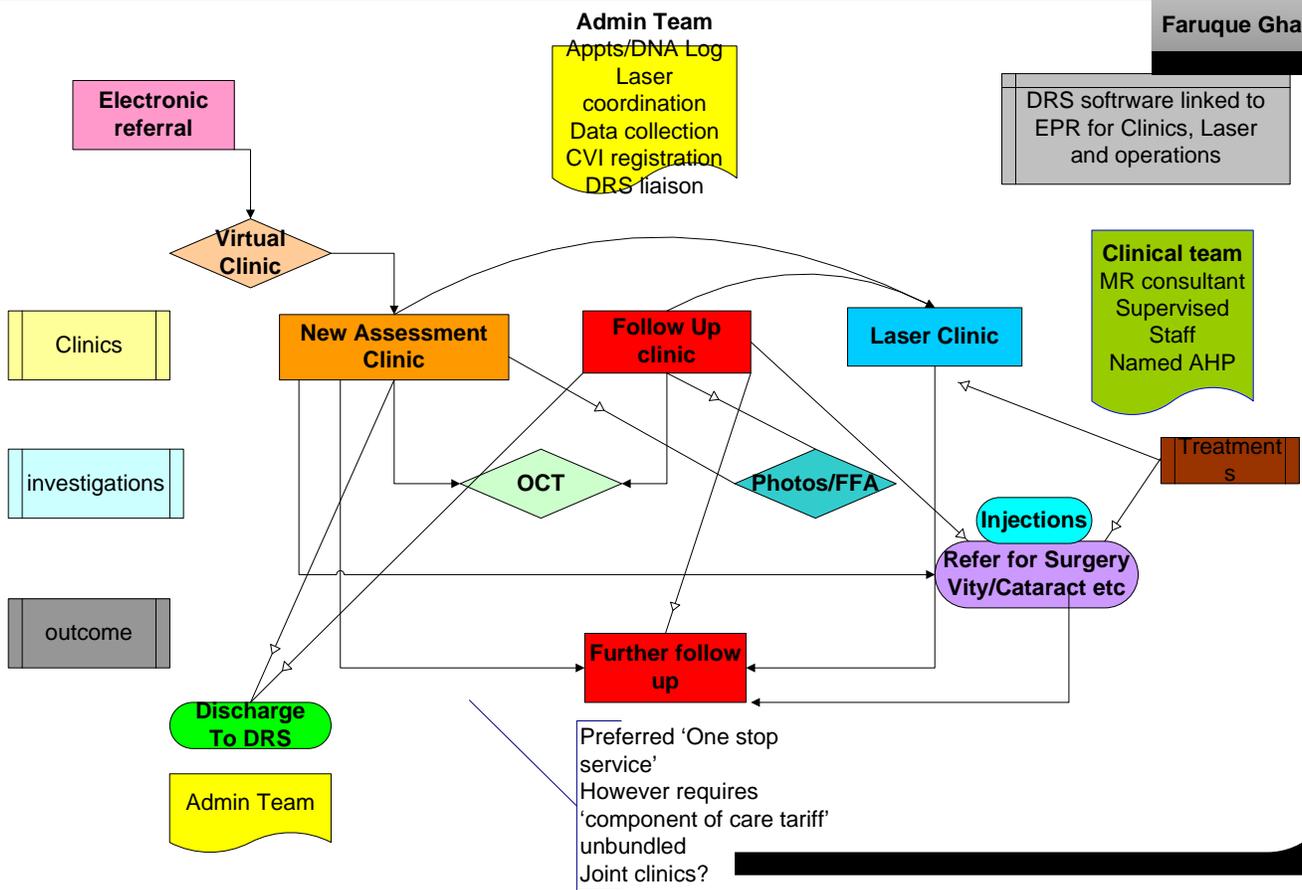


Figure 1. Flow chart – Diabetic eye clinic service model.

## Appendix-1:

### Systemic risk factor management targets for patients with diabetes<sup>a</sup>

Aggressive treatment of hyperglycaemia and hypertension is crucial in the primary prevention and progression of diabetic retinopathy.

Application of these targets needs to be individualised to the patient, based on an assessment of relevant benefits and risks.

#### HbA1c

Patient and physician should jointly agree an individualised target:

- <6.5% is the aspiration
- <7.0 or <8.0 may be acceptable
- a % reduction over a specified time is an alternative approach

Team working as recommended in DAFNE (Dose Adjustment for Normal Eating) should be in place.

#### Blood Pressure (BP)

- Patients with diabetic retinopathy should have a target BP of 130/80
- In the presence of co-existing nephropathy this should be lower.

#### Lipids

Target lipid values

- TC < 5.0 mmol/l
- LDL-c < 3.0 mmol/l
- TG < 2.3

Commence statins in:

- patients with diabetes aged 40 or over
- patients with diabetic retinopathy aged 19 or over

<sup>a</sup>Diabetes Management and the Eye, Liverpool, UK, Report of Conference Final Version – May 2008

## Appendix 2:

The ENSPDR guidance applies to England however Northern Ireland and Wales have adopted the English QA standards. Scotland use different standards but the set up for ophthalmic service for diabetic retinopathy clinics can be similar (personal communication - Caroline Styles). Details of Scottish clinical standards for DR can be found at <http://www.nhshealthquality.org/nhsqis/files/Diabetic%20Retinopathy%20%20Standard.pdf> .

## References:

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<sup>1</sup><http://www.idf.org/webdata/docs/SVD%20and%20Istanbul%20Commitment.pdf>

<sup>2</sup><http://retinalscreening.nhs.uk/pages/default.asp>

<sup>3</sup>[http://www.dh.gov.uk/dr\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/documents/digitalasset/dh\\_087122.pdf](http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_087122.pdf), p 42.

<sup>4</sup><http://retinalscreening.nhs.uk/userFiles/File/Service%20Objectives%20and%20Quality%20Assurance%20Standards%20-%20Release%206%205%202009-06-16.pdf>

<sup>5</sup>Essential Elements in Developing a Diabetic Retinopathy Screening Programme, Workbook 4.3 Release 4.3, UK NATIONAL SCREENING COMMITTEE 16 June 2009

<sup>6</sup>Essential Elements in Developing a Diabetic Retinopathy Screening Programme, Workbook 4.3 Release 4.3, UK NATIONAL SCREENING COMMITTEE 16 June 2009

<sup>7</sup>Essential Elements in Developing a Diabetic Retinopathy Screening Programme, Workbook 4.3 Release 4.3, UK NATIONAL SCREENING COMMITTEE 16 June 2009

<sup>8</sup>Essential Elements in Developing a Diabetic Retinopathy Screening Programme, Workbook 4.3 Release 4.3, UK NATIONAL SCREENING COMMITTEE 16 June 2009

<sup>9</sup>Guidance on failsafe in the diabetic retinopathy screening programme. Linda Garcivan and Fionna O'Leary, ENSPDR, October 2008.

<sup>10</sup>Guidance on failsafe in the diabetic retinopathy screening programme. Linda Garcivan and Fionna O'Leary, ENSPDR, October 2008.

<sup>11</sup>Guidance on failsafe in the diabetic retinopathy screening programme. Linda Garcivan and Fionna O'Leary, ENSPDR, October 2008.

<sup>12</sup>Guidance on failsafe in the diabetic retinopathy screening programme. Linda Garcivan and Fionna O'Leary, ENSPDR, October 2008.

<sup>13</sup>Guidance on failsafe in the diabetic retinopathy screening programme. Linda Garcivan and Fionna O'Leary, ENSPDR, October 2008.

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<sup>14</sup>Guidance on failsafe in the diabetic retinopathy screening programme. Linda Garcivan and Fionna O'Leary, ENSPDR, October 2008.

<sup>15</sup>Guidance on failsafe in the diabetic retinopathy screening programme. Linda Garcivan and Fionna O'Leary, ENSPDR, October 2008.

<sup>16</sup>Guidance on failsafe in the diabetic retinopathy screening programme. Linda Garcivan and Fionna O'Leary, ENSPDR, October 2008.

<sup>17</sup>ETDRS findings, Summary at <http://www.nei.nih.gov/neitrials/viewStudyWeb.aspx?id=53>