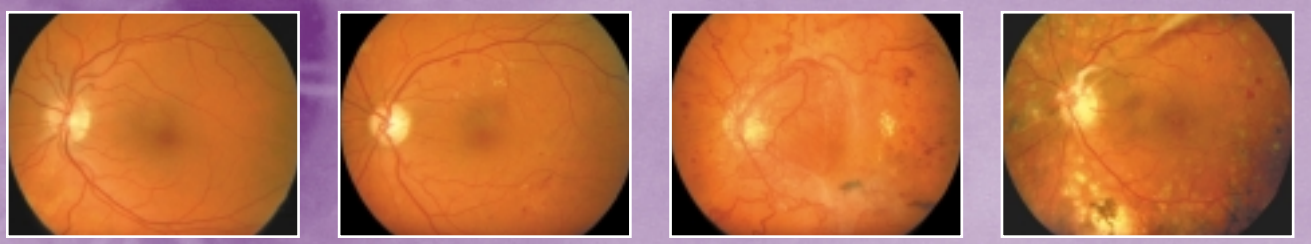
NHS SCOTLAND

DIABETIC RETINOPATHY SCREENING SERVICES IN SCOTLAND: RECOMMENDATIONS FOR IMPLEMENTATION



A REPORT BY THE DIABETIC RETINOPATHY SCREENING IMPLEMENTATION GROUP

JUNE 2003

SCOTTISH EXECUTIVE

NOTES

NHS Quality Improvement Scotland was established on 1st January 2003, joining together five bodies – Clinical Standards Board for Scotland (CSBS), Health Technology Board for Scotland (HTBS), Clinical Resource and Audit Group (CRAG), Nursing & Midwifery Practice Development Unit (NMPDU), and Scottish Health Advisory Service (SHAS). During an interim period NHS Quality Improvement Scotland work will be taken forward in three strands:

- Setting of standards/quality indicators, and monitoring and inspecting performance, incorporating the work of SHAS and CSBS.
- Health technology assessment, incorporating the work of HTBS.
- Nursing, midwifery and allied health professions practice development, and the support of clinical effectiveness, incorporating the work of NMPDU and CRAG.

For the period up to the end of 2002, this report refers to the old names. From January 2003, the report refers to NHS Quality Improvement Scotland.

A note about registers and clinical management systems
The terms register and clinical management system are often used interchangeably. This report adopts the following terminology: A clinical management system is the software which supports the clinical management of patients. A diabetes register is a list of people with diabetes and is a product of the clinical management system.

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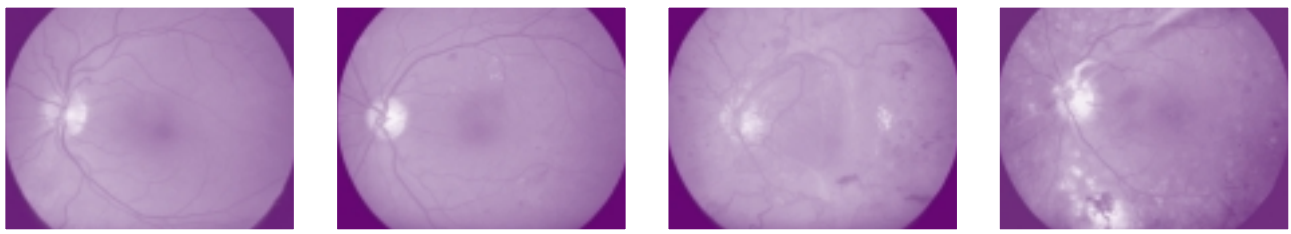

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Figures, Tables and Boxes

Supplementary Documents

- **Standards Document** (NHS Quality Improvement Scotland Diabetic Retinopathy Screening Standards Working Group)
  Publication of draft Standards: May 2003
- **DRS Manual for NHS Boards** (First edition)
  (National Services Division)
  Expected publication date: September 2003
- **Training Handbook for Retinal Screeners**
  Expected publication date: June 2003
- **National patient information leaflet (in English)**
  Expected publication date: June 2003

Diabetic Retinopathy Screening: **Foreword**

Diabetic retinopathy is a common complication of diabetes affecting the blood vessels of the retina. It is the leading cause of blindness amongst people of working age in Scotland. However, if detected early enough laser therapy can prevent the progression of the disease and save sight for many years in most patients.

Many people with diabetes are already receiving regular screening for retinopathy but there are significant variations across the country in terms of coverage and quality. The challenge is to ensure that all people with diabetes have access to an effective, high quality screening service.

The importance of eye screening as part of high quality diabetes care was recognised by *Our National Health: A plan for action, a plan for change* which indicated that: "The [Scottish Diabetes] Framework will include plans to establish a national screening for diabetic retinopathy." This report represents the latest step in turning this commitment into an effective service for patients.

The Scottish approach to screening for diabetic retinopathy has been developed in a very co-ordinated and pragmatic way. First, the clinical evidence of the effectiveness of diabetic retinopathy screening was reviewed by colleagues at the Scottish Inter-collegiate Guidelines Network (SIGN) and published in SIGN 55. The next step was the publication of a Heatlh Technology Assessment on the *Organisation of services for diabetic retinopathy screening* by the Health Technology Board for Scotland (now part of NHS Quality Improvement Scotland). Thirdly, the Scottish Diabetes Framework highlighted eye care as one of the "first stage priorities" of diabetes and undertook to implement the recommendations of the Health Technology Assessment. Next, NHS Quality Improvement Scotland published clinical standards for diabetic retinopathy screening. And now this report sets out how improved retinopathy screening will be delivered in Scotland.

There remains much to do before a comprehensive retinopathy screening service, based on digital imaging, is in place and the objective of ensuring that this service is available to all people with diabetes by March 2006 will be challenging. Nevertheless, with clarity about information and goals now established, and significant funding being made available by the Scottish Executive to support the central costs of the service, the target for implementation is achievable.

Preventing visual impairment and blindness in diabetes is an important goal which will require the co-opeartion and support of a wide range of stakeholders including NHS Boards, health care professionals, National Services Division, NHS Quality Improvement Scotland and, crucially, people with diabetes themselves. I commend the enthusiasm and hard work of professionals and colleagues that has brought this work forward. I look forward to working with all these groups to secure the recommendations of this report.

Malcolm Chisholm MSP
Minister for Health and Community Care

Diabetic Retinopathy Screening

Diabetic Retinopathy Screening:
Executive Summary

Introduction

Key statement 1. The Health Technology Assessment report by HTBS sets out the model of eye screening for diabetic retinopathy to be implemented in Scotland. This report by the Diabetic Retinopathy Screening Implementation Group (DRSIG) endorses the recommendations of HTBS whilst extending and developing some of the report's themes, particularly the practical issues of implementation.

Key statement 2. NHS Boards are responsible for ensuring that all appropriate people with diabetes in their area are offered diabetic retinopathy screening (DRS). The responsibilities of the National Services Division (NSD), NHS Quality Improvement Scotland and the Scottish Executive to support and monitor DRS are outlined in this report.

Key statement 3. All patients with diabetes aged 12 and over in Scotland will be offered diabetic retinopathy screening using digital photography within an organised NHS Board programme that meets the recommendations of the HTBS report and this report produced by the DRSIG. A comprehensive programme will be fully operational throughout Scotland by March 2006.

Key statement 4. In order to implement appropriate quality assurance, NHS boards which have established schemes based on slit lamp examination will need to implement a digital camera scheme by March 2006.

Overview of the Screening Process

Key statement 5. To ensure consistency, local provision of DRS must follow the nationally agreed rule set. The rule set will be published in the DRS Manual. No individual Board will be permitted to define its own rules.

Patients and the Public

Key statement 6. NHS Boards must clearly articulate what the screening programme is designed to achieve and the public must be made aware of its limitations.

Key statement 7. Diabetic retinopathy screening will not remove the need for regular general eye examination by optometrists to monitor changes in refraction and to detect other eye disease.

Key statement 8. Patient perceptions and the promotion of confidence together with patient information, involvement and empowerment, equity of access and emotional and practical support will be key to the successful implementation of DRS. To ensure these important issues are incorporated in the programme, service uptake and patient satisfaction will be measured. A patient information leaflet to be used nationally will be provided in the DRS Manual for NHS Boards.

Key statement 9. NHS Boards should ensure that information about low vision and rehabilitation services is readily available.

Key statement 10. Patients should be represented on the executive group of the DRS collaborative network; (see key statement 39). In addition, a sub group should be set up to monitor the views of patients and ensure that the DRS programme meets their needs.

Key statement 11. The diabetic retinopathy screening programme is a form of direct patient care. Informed but implied consent to screening is therefore applicable.

Local Developments

Key statement 12. All NHS Boards in Scotland are taking steps to develop diabetic retinopathy screening programmes but none is so far advanced that the proposals in this report will inhibit local development and implementation.

Staffing

Key statement 13. Conventional professional boundaries should not be allowed to constrain staffing structures for the screening programme. For example, retinal screeners and graders may be nurses, optometrists, orthoptists, medical photographers or others who may not have experience in healthcare but who receive appropriate training, accreditation and monitoring.

Key statement 14. There is an urgent requirement to include retinal photographers in the patient group direction on the use of eye drops for mydriasis.

Training

Key statement 15. Training and accreditation in diabetic retinopathy screening must be carried out to the appropriate quality standard. NHS Education should be responsible for the accreditation of training. NSD should be responsible for commissioning an appropriate, locally delivered training scheme.

Key statement 16. A training handbook for screeners and graders will be published by June 2003.

Grading

Key statement 17. The Scottish Diabetic Retinopathy Grading Scheme 2003 should be assessed for effectiveness and efficiency and reconsidered as appropriate in the light of new developments in the UK and abroad.

Key statement 18. The Scottish Diabetic Retinopathy Grading Scheme 2003 can be used manually and NHS boards are encouraged to adopt it as soon as possible. However, until a national grading software programme has been procured, use of the Scottish Diabetic Retinopathy Grading Scheme 2003 should be at the discretion of each individual Board.

Cameras and Image Transmission

Key statement 19. Digital technology for cameras and image transmission has provided the opportunity for a national screening programme to be introduced at a reasonable cost. It provides permanent and accessible clinical photographs for quality monitoring and review.

Key statement 20. Digital technology will continue to advance but the specification required to support diabetic retinopathy screening may now be defined. To this end, the DRSIG will continue to contribute to UK wide discussions to agree the appropriate specification in conjunction with camera manufacturers.

Key statement 21. Because technical developments have occurred so rapidly there is limited evidence to help formulate the minimum camera specification or to assess the utility of different options for image compression. Research is required to determine the optimum pixel resolution required for adequate screening. These issues should be kept under review by the DRS collaborative network (see key statement 39).

Software to Support Diabetic Retinopathy Screening

Key statement 22. A fully comprehensive software solution is required for the effective and efficient provision of diabetic retinopathy screening. Such a system must integrate or interface the functions of image acquisition, call/recall, grading and quality assurance. On behalf of NHS Boards and Trusts, NSD should commission work to define the full specification of the system and bring it into operation.

Key statement 23. Until the software to support DRS is developed, piloted and implemented, NHS Boards should offer DRS to patients using standard clinic appointment systems.

Key statement 24. Diabetic retinopathy screening is an integral part of diabetes care and must be fully linked to the local clinical management system. The demographic data to populate the DRS system will be supplied by the local clinical management system. The results of the screening process (including a compressed image) must be fed back into the local clinical management system. DRS software will be compatible with SCI-DC.

Key statement 25. To avoid the risk of missing some patients, it is essential to adhere to the guiding principles of a standardised approach with integral failsafe arrangements and effective monitoring and evaluation. NSD will specify the standards and principles.

Key statement 26. Fully comprehensive software to support diabetic retinopathy screening should be procured centrally rather than by each NHS Board independently. The commissioning process will determine how this will be provided in practice – what will be purchased centrally and what will be the responsibility of NHS Boards.

Key statement 27. In order to ensure consistent standards of service delivery and quality assurance, all NHS boards must either use the nationally developed software, or satisfy NSD that an alternative system can deliver fully comparable results.

Key statement 28. The full specification of the software and proposals to deliver it will be produced by NSD by July 2003.

Key statement 29. A fully comprehensive software solution to support diabetic retinopathy screening will be made available by September 2004 and fully implemented by no later than September 2005.

Quality Assurance and Standard Setting

Key statement 30. The NHS Quality Improvement Scotland Working Group on Diabetic Retinopathy Screening should produce standards for DRS. These standards will cover the following topics: responsibilities, service specification, communication, patient information, call/recall and failsafe, the screening process, quality assurance, referral and treatment. Draft standards should be published by May 2003.

Key statement 31. Quality assurance requires that for each grader randomly sampled images are checked by a level 3 grader. Initial estimates suggest that a minimum of 200 images per grader per annum will be required. This will be finalised in the NHS Quality Improvement Scotland Standard.

Key statement 32. NSD should be responsible for commissioning a national proficiency testing scheme.

Impact on Ophthalmology Services

Key statement 33. The net effect on ophthalmology services of the introduction of a national diabetic retinopathy screening programme is likely to be modest. The impact should, however, be monitored by NHS Boards.

Key statement 34. Protected staff time for quality assurance and level 3 grading must be provided.

Key statement 35. Referrals to ophthalmology from screening should be seen according to clinical priority as determined by the screening photograph. Waiting times should be audited by NHS Boards.

Key statement 36. Technical failures (i.e. ungradeable images) must be contained within the screening programme in order to prevent ophthalmology services from being overwhelmed.

Key statement 37. The screening programme should provide capacity for ophthalmologists to return to screening those patients who, after treatment or otherwise, no longer have referable retinopathy and who may therefore re-enter the screening cycle without continuing to attend an ophthalmologist.

Key statement 38. All ophthalmology services must have access to digital photography. In addition, ophthalmologists will require access to the Diabetes Clinical Management System (SCI-DC) and NHS Network.

National Support and Monitoring

Key statement 39. A DRS collaborative network should be established to support and facilitate the implementation of DRS across Scotland. This network should be directed by an executive group comprising individuals from NHS Boards, various relevant professions involved in the retinal screening programme and patient representatives.

Key statement 40. By June 2003 a lead clinician should be appointed to act as chairman of the executive group. A part time commitment of one half day session per week is suggested for a period of three years.

Key statement 41. A full-time DRS network co-ordinator should be appointed by NSD as soon as possible to initiate and support the network and facilitate exchange of information between screening centres.

Key statement 42. A DRS Manual for NHS Boards should be published and maintained by NSD, on behalf of the DRS collaborative network. The DRS Manual should contain detailed guidance on establishing and managing a DRS programme and include a collation of all relevant standards and policies, standard letters and contact details. A first edition of the DRS Manual should be published by September 2003.

Key statement 43. The main method for assessment of the performance of NHSScotland in the operation of DRS will be the reviews undertaken by NHS Quality Improvement Scotland which will evaluate the published Diabetic Retinopathy Screening Standards. Review visits will commence when DRS services are in operation. In the interim, information about progress towards improving DRS will be published as part of the NHS Quality Improvement Scotland review of the diabetes services, in the annual Scottish Diabetes Survey and in the Diabetes Annual Reports published by NHS Boards.

Key statement 44. ISD should be involved in defining the national dataset to be used by the DRS programme. A subset of the dataset should be identified as key performance indicators to be included as a routine SMR return.

Key statement 45. People with diabetes are strongly encouraged to attend for screening, but attendance cannot be compulsory. Although NHS Boards are required to offer screening to all appropriate patients, they cannot be held responsible for those who choose not to attend. Research is required to explore why some people do not take up the offer of screening.

Patient Information

Key statement 46. Patients require appropriate and consistent information about the Scottish screening programme for diabetic retinopathy. A single patient information leaflet has been developed and will be published in the DRS Manual and on the website. The manual will also contain example letters to patients and healthcare professionals to ensure consistency of messages to patients throughout the invitation, screening and treatment process.

Key statement 47. Patient information should be accessible to people with impaired vision and should conform with RNIB guidance (2001).

Key statement 48. Patient information leaflets should be available in relevant minority languages. Urdu, Punjabi, Hindi, Chinese and Gaelic texts will be particularly relevant for Scotland. These leaflets should be created centrally and made available for general use via the diabetes website.

Research

Key statement 49. The research topics identified in the HTBS report as well as further research questions which become apparent should be developed so that appropriate modification of the screening programme might be introduced in the light of experience.

Key statement 50. The newly established Diabetes Research Group should explore ways of ensuring that the research requirements of the DRS programme are implemented.

Funding Requirements

Key statement 51. NHS Boards should provide funding to implement a comprehensive DRS programme in their area. Collaboration between areas to achieve optimal use of resources will result in important cost savings. NHS Boards should therefore explore appropriate opportunities to combine, for example, call/recall units for diabetic retinopathy with other NHS Board screening units, or with diabetic screening offices in other boards. NHS Boards should also explore the potential to realise savings from joint provision of screening across board boundaries.

Key statement 52. The Scottish Executive, National Services Division and NHS Quality Improvement Scotland should provide the resources necessary to implement the central components of diabetic retinopathy screening, to include central co-ordination, specification and documentation of standards, central elements of QA (including proficiency testing), a DRS Manual, a training handbook, software procurement and patient information material.

Key statement 53. Procurement of cameras on a UK basis may secure significant economies of scale and is the preferred option, provided that the UK user requirements are similar to the Scottish user requirements and that UK procurement does not unduly increase project or financial risk, or delay the implementation timetable. Although the benefits of UK procurement may not be achievable in the short term, development of close contacts with UK colleagues will make joint working easier in the future.

Diabetic Retinopathy Screening: **Introduction**

1. There is a national epidemic of diabetes. It is believed to affect about 3% of the population, and 5% of the population aged over 50 years. The number of people with this condition is forecast to double by the year 2015, largely due to an increase in the prevalence of Type 2 diabetes. Diabetes is associated with significant morbidity and early mortality. It increases the risk of blindness, renal failure and amputation. Much of this could be prevented by provision of effective integrated care.

2. Diabetic retinopathy is the biggest single cause of blindness and visual impairment amongst working age people in Scotland.[1] Up to 10% of people with diabetes have retinopathy requiring ophthalmological follow-up or treatment.[2,3,4] In its early stages, diabetic retinopathy is symptom-free and progression of disease can be prevented by laser treatment or by improved metabolic[2,5,6,7] and blood pressure control,[7] so detection by regular screening is beneficial.

3. The importance of eye screening as part of high quality diabetes care was recognised by *Our National Health: A plan for action, plan for change*[8] which indicated that: "The Framework will include plans to establish a national screening strategy for diabetic retinopathy." The Scottish Diabetes Framework[9] highlighted eye care as one of the 'first stage priorities' of diabetes and undertook to implement the recommendations of the Health Technology Board for Scotland (HTBS).

4. The Health Technology Board for Scotland has determined the most effective and efficient approach to achieving, implementing and sustaining a quality assured, national screening programme for diabetic retinopathy that takes account of patient preferences.[10] In his statement that launched the report in April 2002, Malcolm Chisholm, the Minister for Health and Community Care expressed his support for the introduction of a screening programme, establishing a group chaired by Dr Jeffrey Jay – the Diabetic Retinopathy Screening Implementation Group (DRSIG) – to define key national and local requirements to establish the programme. Membership of the Group is set out in Annex B.

5. NHS Boards are expected to implement a diabetic retinopathy screening programme in line with the recommendations of the Health Technology Board for Scotland. This report sets out the expected timetable for action and the work in hand to support implementation. Although some elements of diabetic retinopathy screening will take some time to develop, this should not constrain NHS Boards from making progress to improve the availability of screening to people with diabetes.

Key statement 1: The Health Technology Assessment report by HTBS sets out the model of eye screening for diabetic retinopathy to be implemented in Scotland. This report by the Diabetic Retinopathy Screening Implementation Group (DRSIG) endorses the recommendations of HTBS whilst extending and developing some of the report's themes, particularly the practical issues of implementation.

Key statement 2: NHS Boards are responsible for ensuring that all appropriate people with diabetes in their area are offered diabetic retinopathy screening (DRS). The responsibilities of the National Services Division (NSD), NHS Quality Improvement Scotland and the Scottish Executive to support and monitor DRS are outlined in this report.

6. The position with regard to the application of HTBS advice has been clarified by the Minister for Health in a Parliamentary Answer of 12th March 2002: *"NHSScotland should take account of advice and evidence from the Health Technology Board for Scotland (HTBS) and ensure that recommended drugs or treatments are made available to meet clinical need. The Executive will monitor NHS Boards' adherence to HTBS advice and will follow up any non-adherence".* However, the Scottish Executive acknowledges that a comprehensive diabetic retinopathy screening programme will be introduced gradually. All NHS Boards are expected to have fully implemented diabetic retinopathy screening by March 2006, although it is anticipated that most boards will be able to implement a full service considerably earlier.

Key statement 3: All patients with diabetes aged 12 and over in Scotland will be offered diabetic retinopathy screening using digital photography within an organised NHS Board programme that meets the recommendations of the HTBS report and this report produced by the DRSIG. A comprehensive programme will be fully operational throughout Scotland by March 2006.

7. A significant proportion of people with diabetes are currently being screened for retinopathy. There must be no diminution of service during the transition from current screening arrangements to a more systematic, comprehensive programme based on digital photography. In developing diabetic retinopathy screening services, NHS Boards should initially target patients who have not been screened at all or who have not been screened for a long time.

8. The DRSIG strongly endorses the approach to the screening process recommended by the HTBS. The key features of this approach (such as the use of digital photography, the three-stage process in relation to the use of mydriasis and the three-level grading procedure) are outlined in Annex F. Full details can be found in the HTBS report.

Key statement 4: In order to implement appropriate quality assurance, NHS Boards which have established schemes based on slit lamp examination will need to implement a digital camera scheme by March 2006.

9. The DRSIG acknowledges that further modifications to diabetic retinopathy screening in Scotland will be required as the programme is developed. The HTBS report recommends a number of areas for further research (e.g. clinical effectiveness, organisational issues, patient issues and economic evaluation). Additional research needs will also be identified in the light of experience. Research is considered in more detail below (see paragraph 98).

10. Implementation of diabetic retinopathy screening in Scotland will require a number of supporting documents. The purpose and content of these documents is outlined below. These documents will be available within the next nine months.

- Standards Document (to be produced by NHS Quality Improvement Scotland), (see paragraph 65).
- DRS Manual for NHS Boards (to be produced by NSD), (see paragraph 87).
- Training Handbook for Retinal Screeners, (see paragraph 41).
- National patient information leaflet, (see paragraph 95).

Diabetic Retinopathy Screening:
Overview of the Screening Process

11. The HTBS report set out the objectives of the Scottish screening programme as:

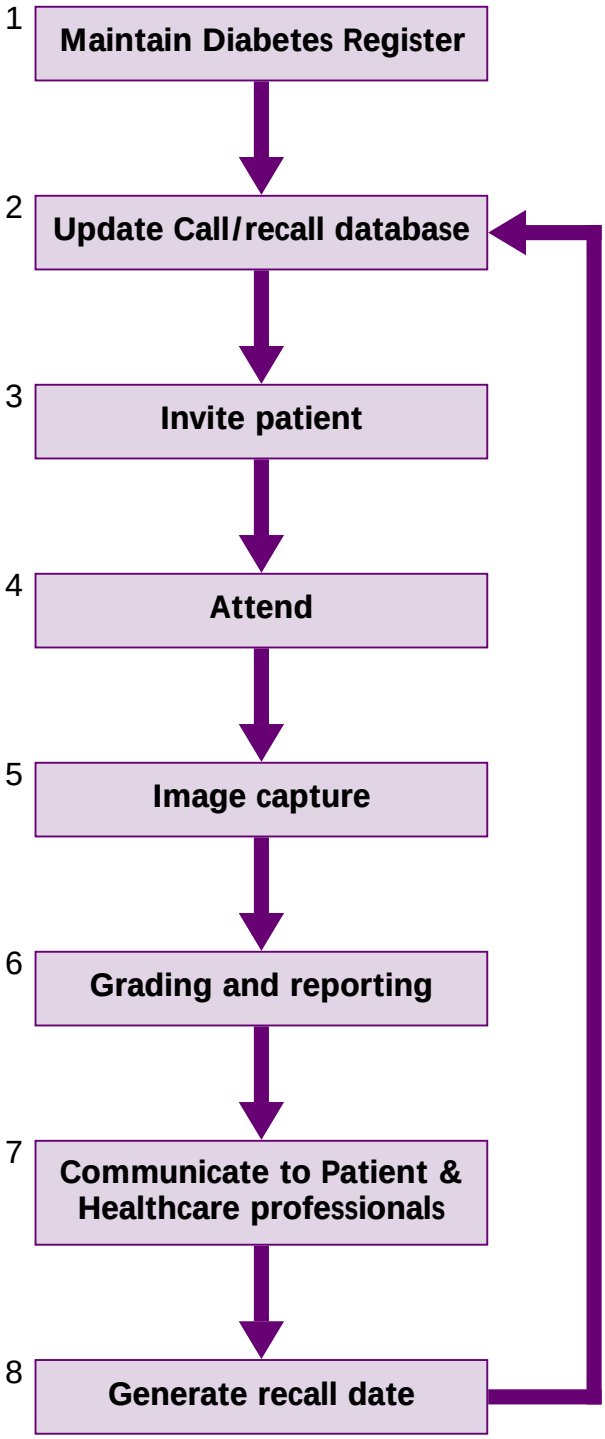
- ***Primary objective.*** The detection of referable (potentially sight-threatening) retinopathy so that it can be treated.
- ***Secondary objective.*** The detection of lesser degrees of diabetic retinopathy. This can have implications for the medical management of people with diabetes in terms of blood pressure and glycaemic control, important risk factors for STDR (sight threatening diabetic retinopathy).

12. The basic process of retinopathy screening can be simply described and Figure 1 below outlines the main stages. The difficulty arises in operating the system to a high standard consistently over a long period of time, whilst at the same time maintaining fail-safe procedures to ensure that all appropriate patients are offered regular screening and are referred for appropriate treatment when they need it.

13. One of the most important elements of operating DRS is the rule set which determines how patients flow through the system. Such rules, for example, define exclusion criteria and set out how patients who did not attend (DNA) or could not attend (CNA) should be handled. It is essential to ensure that patients do not inadvertently drop out of the routine annual invitation to screening e.g. by moving NHS Board of residence, moving GP practice, or changing name or address; by error, accident, mis-keying details or unauthorised clinical decision. Drawing upon the experience of existing DRS schemes and upon the lessons learned in the operation of other national screening programmes, the national rule set for DRS is currently being developed and will be published in the DRS Manual.

Key statement 5: To ensure consistency, local provision of DRS must follow the nationally agreed rule set. The rule set will be published in the DRS Manual. No individual Board will be permitted to define its own rules.

Figure 1: Overview of the diabetic retinopathy screening process



14. It is essential to develop software to enable the screening process to operate efficiently and consistently. Further details of how and when the software to support DRS will be developed are outlined below (see paragraph 52).

Diabetic Retinopathy Screening:
Patients and the Public

Patient Expectations

15. The public may have an unrealistic view, encouraged by legal judgements, that screening is expected to guarantee prevention of disease, or in this case, its complications. Any diabetic retinopathy screening programme must therefore ensure the public have a realistic expectation of what the programme is designed to achieve.

16. Given that the service to be introduced is designed to reduce the risk of retinopathy, the DRSIG considered whether to recommend that the programme be called a 'risk reduction programme' rather than a 'screening programme'. However, it was concluded that because 'screening' was such a familiar term it should continue to be used but that it should be emphasised that diabetic retinopathy screening did not and could not offer any guarantee that a patient would never suffer loss of vision.

17. All literature must state clearly what the diabetic screening programme cannot provide. NHS Boards must inform patients that the identification of co-existing eye disease is not a function of the diabetic retinopathy screening programme.

18. There is convincing evidence that the identification of diabetic retinopathy at the appropriate stage will reduce the risk of serious loss of vision in most cases if modern treatment is applied. However, the threat of serious loss of vision remains even with effective screening for the following reasons:

- Not all cases of retinopathy will be detectable even with digital photography.
- Accelerated forms of diabetic retinopathy can develop between screening intervals.
- Even with effective treatment performed to the highest standards, some patients will not respond.

Key statement 6: NHS Boards must clearly articulate what the screening programme is designed to achieve and the public must be made aware of its limitations.

Key statement 7: Diabetic retinopathy screening will not remove the need for regular general eye examination by optometrists to monitor changes in refraction and to detect other eye disease.

Measuring Success

19. Although technical efficiency and clinical effectiveness are important, the DRS programme must also meet the needs of patients. The screening process should be characterised by partnership, dialogue, negotiation and choice. Patient satisfaction with the DRS service must be monitored alongside the clinical aspects of the programme.

Key statement 8: Patient perceptions and the promotion of confidence, together with patient information, involvement and empowerment, equity of access and emotional and practical support will be crucial to the successful implementation of DRS. To ensure these important issues are incorporated in the programme, service uptake and patient satisfaction will be monitored. A patient information leaflet to be used nationally will be provided in the DRS Manual for NHS Boards.

Emotional and Practical Support

20. Patients need time and support to make sense of the medical information they receive, especially where such information may imply significant change in their lives. There should be a named contact person with whom to discuss screening outcomes or treatment options. Patients will want to choose when, where, and from whom to receive emotional support; in addition to nursing, nurse counselling, medical and social work staff, eye clinic liaison officers (where appointed) can fulfil this task. Voluntary organisations working in the fields of diabetes and visual impairment also offer emotional help and support, and may host user-led self-help groups. Where it comes to the attention of screening staff that a patient is experiencing practical difficulty arising from the effects of diabetes in general, or of diabetic retinopathy in particular, referral to a social work agency should be discussed. Patients who develop problems with their sight and require low vision aids or rehabilitation assessment should be referred promptly to the appropriate services.

Key statement 9: NHS Boards should ensure that information about low vision and rehabilitation services is readily available.

Patient Representation

21. Patients, carers and their representatives should be involved in the development of diabetes services and in the implementation and monitoring of the DRS programme. NHS Boards should consider how best to achieve this in the context of local circumstances. At a national level, patients should be represented on the DRS collaborative network (see paragraph 85).

Key statement 10: Patients should be represented on the executive group of the DRS collaborative network (see key statement 39). In addition, a sub group should be set up to monitor the views of patients and ensure that the DRS programme meets their needs.

Consent to Screening

22. The report of the Confidentiality and Security Advisory Group for Scotland (CSAGS) – Protecting Patient Confidentiality, Final Report[11] – states that implied consent for multiple uses of healthcare data, as in the case of disease registers, is acceptable. It is expected that the developing regional diabetes registers will provide the diabetic retinopathy screening programmes with the patient data (diagnosis and demographics) to allow those patients to be called for screening. Once the patient has been invited to attend for screening the use of the patient identifiable data then comes under the category of direct patent care. Patients must be informed about the uses to which their data may be put but consent can be assumed.

Key statement 11: The diabetic retinopathy screening programme is a form of direct patient care. Informed but implied consent to screening is therefore applicable.

23. NHS Boards must have clear mechanisms for identifying and acting on refusals by following the principles set out in the CSAGS report. NHS Boards must also ensure patients are made aware of the implications for themselves should they decline the offer of being screened.

24. The progress being made by NHS Boards to provide retinopathy screening to all people with diabetes in their area was surveyed during the second half of 2002. A summary of the findings can be found at Annex H. A number of areas have already made significant progress. The DRS programme in Grampian follows the specifications of the HTBS report very closely and has provided valuable experience on which to base the recommendations in this report. The developing programme in Glasgow also offers helpful insights into how best to establish a new DRS service.

Key statement 12: All NHS Boards in Scotland are taking steps to develop diabetic retinopathy screening programmes but none is so far advanced that the proposals in this report will inhibit local development and implementation.

Diabetic Retinopathy Screening: **Staffing**

Key statement 13: Conventional professional boundaries should not be allowed to constrain staffing structures for the screening programme. For example, retinal screeners and graders may be nurses, optometrists, orthoptists, medical photographers or others who may not have experience in healthcare but who receive appropriate training, accreditation and monitoring.

Camera Operator/Retinal Screener

25. The camera operator will be responsible for taking retinal photographs and ensuring they are of adequate quality. Camera operators will also be responsible for downloading digital images to a central database, which would ideally be linked to the regional diabetes register. If the camera is housed in a mobile unit, then the camera operator will also drive the van. Camera operators may also be trained as graders but as a minimum requirement they must be able to recognise an unsatisfactory image so that appropriate action (by following the 3 stage protocol) may be taken to allow mydriatic photography to be performed at the same visit.

Instillation of Eye Drops

26. The three-stage screening process for diabetic retinopathy recommended for use in Scotland will require the instillation of eye drops for mydriasis (pupil dilation) in a minority of cases when required to obtain a satisfactory image. At present, doctors and optometrists are allowed to instil eye drops and for the purpose of mydriasis under a Patient Group Direction (PGD) nurses may also apply drops. Other groups of personnel who may act as screeners may be able to fulfil the requirements of a PGD if changes are made to the regulations. NHS Quality Improvement Scotland and the National Screening Committee are seeking changes to the UK regulations.

Key statement 14: There is an urgent requirement to include retinal photographers in the patient group direction on the use of eye drops for mydriasis.

27. In the meantime, local arrangements may be made to avoid undue restriction to screening work. For example, as retinal screening will take place in a variety of locations such as hospital clinics or GP practices there may be other staff available to install eye drops. A medical photographer in a hospital clinic may therefore have access to a nurse who could administer the eye drops if necessary.

Graders

28. A three-level system for grading digital retinal images is recommended. This multi-level approach should reduce the number of unnecessary referrals to ophthalmology. Level 1 graders will grade images for image quality and the presence or absence of diabetic retinopathy. Images with any retinopathy (whatever level) will be passed on to the level 2 grader. Any individual undertaking this should have undergone a recognised and accredited training programme. In due course it is hoped this role will be performed by automated grading systems. Level 2 grading will involve an examination of all remaining pictures. It is anticipated that this will be between 20% and 30% of the total. These Graders will be required to undergo a more intensive training programme which has been recognised and accredited. The purpose of level 2 grading is to identify sight threatening retinopathy and other retinal problems that may be amenable to treatment. Such images will be passed on to the level 3 grader for a final assessment to be made. The role of level 3 graders (who usually but not necessarily will be ophthalmologists) is to confirm or refute the need for referral to ophthalmology. Patients stay within the screening programme until referral by a level 3 grader to ophthalmology. Level 1 and level 2 grading could in some circumstances be performed by camera operators who have received sufficient training. This would give a greater variety to the post and make it more interesting and sustainable for the long term.

Administrator

29. An administrator is required in each area providing a DRS service to organise the call and recall system and to run it. They would also be responsible for audit data and quality assurance checks on both the Camera Operators and the Graders. Such administrators may not necessarily need to perform the quality assurance themselves but would need to organise it. They would, however, be involved in performing the audits. The Administrator would have responsibility for ensuring that the results of the graded images are returned to the GPs, Diabetes Clinics and Ophthalmologists where relevant and ensure that the results and preferably the images themselves are linked into the Regional Diabetes Register. The administrators would also arrange training for new Camera Operators and Graders. They may require secretarial support. Specialist IT support would be needed to maintain links between the Regional Diabetes Register and the screening programme (e.g. obtaining the demographic data from the Regional Register which will feed the call/recall system; transferring the digital images and reports back into the Regional Register).

Quality Assurance

30. A suitably qualified and trained individual will be needed to undertake quality assurance on the quality of the photographs and the grading results. Each grader will need to have a proportion of their photographs audited annually. The quality assurer may be the administrator or ophthalmologist or other suitably trained individual. External quality assurance will be performed by the DRS Network Co-ordinator. More detail about quality assurance issues is included below (see paragraph 65).

Strategic Management Issues

31. Although the Administrator will be in charge of day to day running of the Retinal Screening Programme there needs to be a lead clinician in overall charge of strategic issues with regard to retinal screening and its interface with Primary Care, Diabetes Registers and Hospital Diabetes Clinics. This individual would also be expected to take responsibility for making decisions about new technological developments and for the policy for patients who do not attend. This may be a Public Health Physician or some other relevant individual. The lead clinician would be expected to participate in the DRS collaborative network described below (see paragraph 85).

32. To create efficiency, smaller NHS Boards should work together to provide the screening service for their population. Grading could also be centralised or retained locally. Centralising and sharing services has considerable cost benefits (see paragraph 103) but may also have significant organisational benefits. Cross-boundary schemes will require careful implementation.

Optometrist Involvement in the National Screening Programme

33. Optometrists have an important role to play in the national screening programme. They could contribute to the screening programme in a number of ways which can be adapted and developed to suit local needs:

(a) Within the community, as an interim measure, to maintain an existing scheme using slit lamp biomicroscopy, while digital cameras are being introduced.

(b) Within the community as part of a new scheme in which digital cameras will be sited in optometry practices.

(c) Within the community providing a service using digital cameras sited in GP practices or community hospitals.

(d) Within hospitals as either hospital optometrists or sessional community optometrists using digital cameras.

(e) As primary or secondary graders.

(f) By providing slit lamp biomicroscopy examination where digital photography has failed to provide a satisfactory image. This could be performed in the local community practices or in central locations.

34. Existing schemes utilising optometrists and slit lamps will need to be modified by evolution and agreement locally to meet the requirements outlined in this report, in particular the need to align existing arrangements for training, accreditation and quality assurance with the NHS Quality Improvement Scotland proposals. In addition, the move to digital photography will need to be made to meet the deadline for the implementation of a fully digital screening service by March 2006. IT, call/recall, registers and grading will also have to be introduced to meet the requirements of the national scheme. It may be desirable for those optometrists involved in the programme to be linked to NHSnet. It will be vital not to lose the support of those participating in existing schemes during the transitional phase.

35. New community schemes involving optometrists will ideally use digital photography at the outset. However, NHS Boards could consider using slit lamp biomicroscopy if that enabled a scheme to be introduced quickly where otherwise (perhaps because of funding constraints) a rapid introduction of a digital programme would not be feasible. A precise timetable for moving to digital cameras must be specified. Training, assessment, and accreditation will need to be in line with national guidelines recognising that because of their professional qualifications the additional training requirements for optometrists will differ from other providers.

36. Indicative fees for optometrists are dealt with in the section on funding requirements (see paragraph 107). Costing for optometrists will depend on the optometrist's role (see paragraph 33).

37. It is likely that some digital cameras will be sited centrally within hospitals. Hospital optometrists, where available, may be able to act as primary or secondary screeners or graders. Their particular skills could also be utilised for training other staff and to reduce the additional burdens on ophthalmology. Community optometrists with a special interest in diabetes may also be prepared to act in this capacity on a sessional basis. Experienced optometrists might also undertake level 3 grading with agreement of ophthalmologists and after appropriate training.

38. In the unusual circumstance of a domiciliary examination being required the normal arrangements for domiciliary optometric examinations should apply.

Diabetic Retinopathy Screening: **Training**

39. All those involved in providing DRS services should be receiving a quality assured programme of continuing professional development in line with specified minimum continuing training requirements as well as being subject to regular appraisals, assessments and reaccredidation. Continuing education will be required to prepare for changes in the service which will occur as the DRS programme evolves.

40. Retinal screeners and graders will require specific training, accreditation and regular performance assessment. Topics to be covered include:

- Clinical knowledge and skills
- Imaging and IT skills
- Operational issues
- Grading.

41. A Training Steering Group has been established in Scotland and this group has produced a training manual and developed a training curriculum that is in the pilot stage. To date, two courses have been run, the first in Grampian, and the second in Tayside. NHS Education has been asked to accredit the training curriculum and training materials. In order to ensure that appropriate training is available and accessible for the whole of Scotland, NSD should liaise with users to assess training requirements and commission appropriate training centrally on behalf of NHSScotland. Training should be delivered as locally as possible to enable the photographers to be trained on equipment relevant to them. In addition, local training will allow the local ophthalmologist (who is also likely to be the level 3 grader) to deliver the training on grading and so develop confidence in the graders' ability.

Key statement 15: Training and accreditation in diabetic retinopathy screening must be carried out to the appropriate quality standard. NHS Education should be responsible for the accreditation of training. NSD should be responsible for commissioning an appropriate, locally delivered training scheme.

Key statement 16: A training handbook for screeners and graders will be published by June 2003.

42. Ideally, staff should be trained to standards that are uniform throughout the UK. To this end the training handbook and curriculum developed in Scotland by the Training Steering Group are being considered for adoption throughout the United Kingdom.

43. The grading scheme recommended by HTBS has been reviewed and amended in the light of concerns about its complexity and in order to bring it into line with the emerging UK scheme. The revised scheme – the Scottish Diabetic Retinopathy Grading Scheme 2003 – is included in Annex E.

Key statement 17: The Scottish Diabetic Retinopathy Grading Scheme 2003 should be assessed for effectiveness and efficiency and reconsidered as appropriate in the light of new developments in the UK and abroad.

44. The Scottish Diabetic Retinopathy Grading Scheme 2003 can be used manually and NHS Boards are encouraged to adopt it as soon as possible. However, to be used most efficiently, a grading scheme based on observable features depends upon software. Grading software must be integrated with call/recall software. Ideally grading and call/recall would be combined in the same software package but as a more realistic option two systems could be integrated. The decision is largely a technical one and will be made as soon as possible. In any event, grading software should be procured centrally. The full advantages of the Scottish Diabetic Retinopathy Grading Scheme 2003 will not be achieved without appropriate software.

Key statement 18: The Scottish Diabetic Retinopathy Grading Scheme 2003 can be used manually and NHS Boards are encouraged to adopt it as soon as possible. However, until a national grading software programme has been procured, use of the Scottish Diabetic Retinopathy Grading Scheme 2003 should be at the discretion of each individual Board.

Diabetic Retinopathy Screening:
Cameras and Image Transmission

45. A national screening programme for diabetic retinopathy implies a standardised screening technology. However, the operational difficulties of implementation must be recognised and consequently a pragmatic approach will be necessary as the programme develops. It is therefore important to provide practical guidance for NHS Boards to develop their own service, making best use of existing technology with recommendations for improvement.

Key statement 19: Digital technology for cameras and image transmission has provided the opportunity for a national screening programme to be introduced at a reasonable cost. It provides permanent and accessible clinical photographs for quality monitoring and review.

46. The technology is developing rapidly and there is now a bewildering choice of cameras and interfaces. The following topics need careful consideration:

- Camera interface
- Camera resolution
- Storage of images
- Image transmission and bandwidth requirements
- Image compression ('lossy' vs 'lossless')
- Screen resolution and display technology

47. In view of the rapidly changing technology, guidance about which cameras to use needs to evolve as change and circumstance dictate. A Four Nations Working Group set up by the National Screening Committee has been working in consultation with the manufacturing and software industry to produce a recommended specification for cameras. A specification was published in February 2003 and can be found on he NSC website A National Screening Programme for Sight-Threatening Diabetic Retinopathy <www.nscretinopathy.org.uk>. The intention is to regularly update these recommendations.

Key statement 20: Digital technology will continue to advance but the specification required to support diabetic retinopathy screening may now be defined. To this end, the DRSIG will continue to contribute to UK wide discussions to agree the appropriate specification in conjunction with camera manufacturers.

Camera Choice

48. A useful minimum camera resolution is necessary to underpin effective screening and it should be noted that many sites have been effectively using cameras with resolutions of around 800 x 600 pixels for several years.

The HTBS report cites the UK National Screening Committee (NSC) recommendation of 20 pixels/degree – a resolution of 1365 x 1000 minimum resolution. Existing cameras should continue to be used but with a plan to meet the new minimum resolution standard (1365 x 1000) as time and circumstance permit. Available cameras with a resolution of 1360 x 1024 pixels meet this requirement. All new camera procurement must match this minimum standard. In ascertaining compliance with the minimum standard allowance must be made for the size of black image masks and the reduction in effective resolution inherent in single chip cameras.

Image Size

49. Increased image size is likely to become available as technology advances. It is, however, important to note that effective grading is not simply a function of image size or resolution. Extremely large images are impractical because the image may need to be reduced to avoid excessive scrolling. Where any form of image reduction has been employed, the reduction/compression mechanism must be evaluated and accredited to ensure screening sensitivity is not affected by the reduction. Evidence gained through a formal controlled trial would provide sufficient evidence for accreditation. Experience of such trials in Tayside is available. Any method employed must not be capable of being altered by the user and if a compressed image standard has passed scrutiny, no deviation from this standard can be permitted. Lossless compression should be employed where possible.

Key statement 21: Because technical developments have occurred so rapidly there is limited evidence to help formulate the minimum camera specification or to assess the utility of different options for image compression. Research is required to determine the optimum pixel resolution required for adequate screening. These issues should be kept under review by the DRS collaborative network; (see key statement 39).

Display Technology

50. Recommendations on display technology all conclude that images should be viewed 1:1 or pixel for pixel during grading. In addition, excessive scrolling should be avoided by the use of monitors of a resolution appropriate to the resolution of the image utilised. 60% of the image must be viewable on the screen, vertically and horizontally, at any one time. As stated earlier, this may imply the reduction of very high-resolution images prior to screening. Screen size is dictated by the resolution of images to be graded and the resolution of the display necessary to avoid excessive scrolling. CRT (Cathode Ray Tube) monitors are preferable to TFT (Thin Film Transistor) flat screen displays because of the larger contrast range available on CRT monitors. Calibration and the quality assurance of monitors used for retinal grading is possible using photopic luminance calibration. This is under investigation and may permit the future recommendation of TFT flat screen monitors.

Siting of Cameras

51. In addition to technical considerations, there will be a need for individual areas to determine the appropriate configuration of cameras to suit local geography and methods of working. The screening software must be sufficiently flexible to cope with the different ways in which image capture may be managed. This may include a mix of static cameras in hospitals, mobile units and community based cameras. An important operational consideration will be integrating the annual review process at diabetes clinics and the DRS programme. Where hospitals have static cameras it might be more convenient for patients to have their eyes screened as part of the annual review, rather than being called for a second appointment for retinopathy screening. The screening process must be able to ensure not only that all appropriate patients are invited for screening, but also that patients are not recalled unnecessarily. The importance of effective software to manage these potentially complex patient flows cannot be underestimated.

Diabetic Retinopathy Screening: **Software to Support Diabetic Retinopathy Screening**

52. The diabetic retinopathy programme must be supported by appropriate information management and technology. To ensure consistency of standards across the country NHS Boards will need to adopt the same or compatible software. A single integrated system to cover all the required functions of screening has many attractions but practical considerations (including cost constraints) may dictate a solution based upon separate inter-linking modules. The exact specification of the software which should be adopted will not be clear until a full specification has been developed and its procurement undertaken. This section of the report sets out the principles which this exercise must follow and recommendations about how the process should be managed.

53. Although it is not possible at this stage to specify the detail of the software solution, it is possible to describe the component functions and explain how they must interact. Figure 2 below presents an overview of the system. The key elements are:

- Interface with the Local Diabetes Register
- Patient management and recall
- Image capture
- Grading and reporting images
- Audit and statistical analysis
- Quality assurance

Key statement 22: A fully comprehensive software solution is required for the effective and efficient provision of diabetic retinopathy screening. Such a system must integrate or interface the functions of image acquisition, call-recall, grading and quality assurance. On behalf of NHS Boards and Trusts, NSD should commission work to define the full specification of the system and bring it into operation.

Key statement 23: Until the software to support DRS is developed, piloted and implemented, NHS Boards should offer DRS to patients using standard clinic appointment systems.

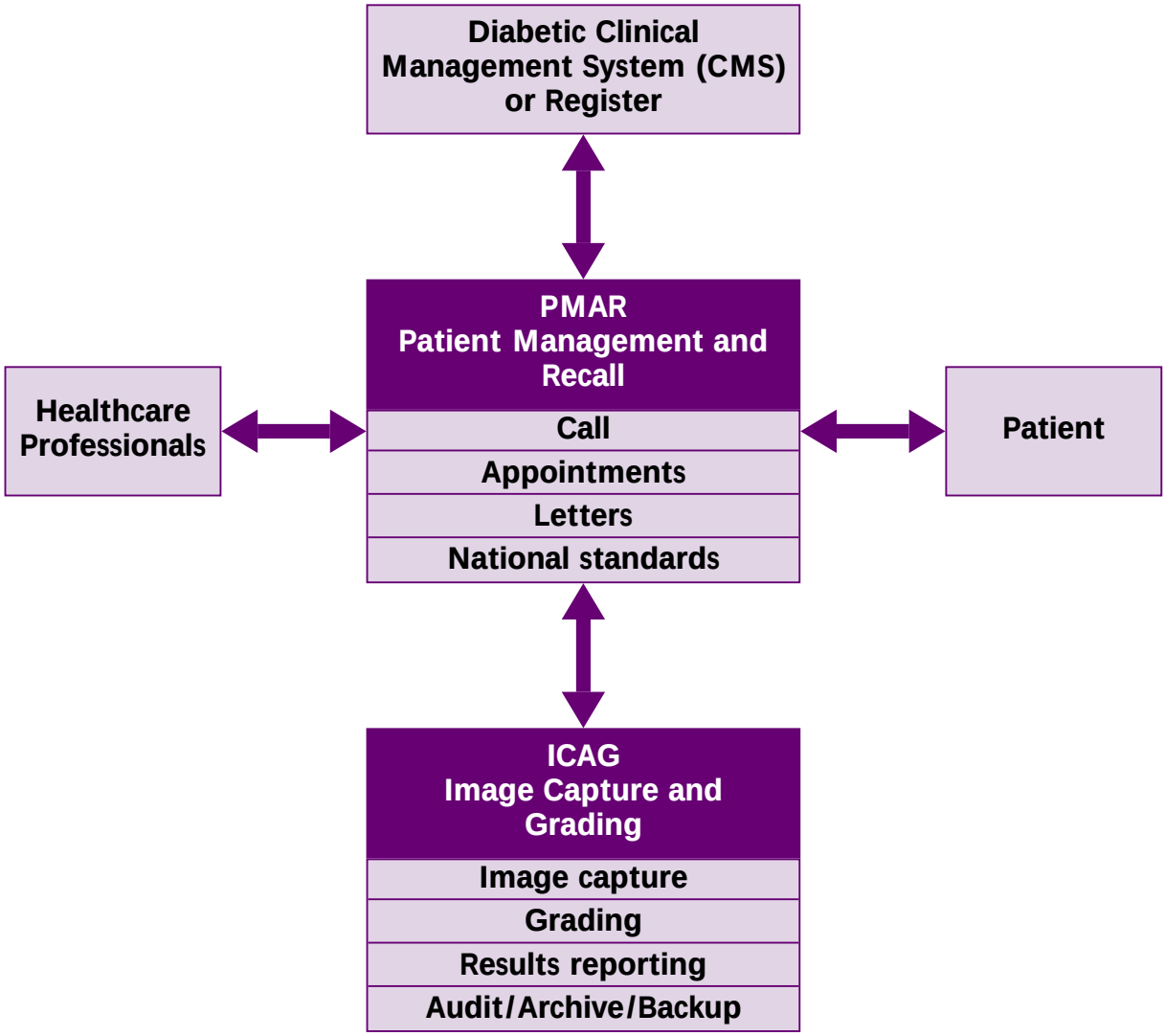
54. Interface with the Local Diabetes Register. It is the responsibility of the NHS Board to create and maintain a Diabetes Register. In time, all NHS Boards will have a clinical management system (CMS) which will include data for all patients with diabetes in their area. In most cases, this system will be SCI-DC, (see Annex G). Demographic information from the register will be used to prime the call/recall database. The results of screening, including images, will be fed back into the register. Pragmatic solutions will need to be employed until these local registers are fully operational. Software will need to be able to accommodate areas which choose not to use SCI-DC. The use of the CHI number is essential in all aspects of interface and interchange between all components of the systems involved in providing this service.

Diabetic Retinopathy Screening

Key statement 24: Diabetic retinopathy screening is an integral part of diabetes care and must be fully linked to the local clinical management system. The demographic data to populate the DRS system will be supplied by the local clinical management system. The results of the screening process (including a compressed image) must be fed back into the local clinical management system. DRS software will be compatible with SCI-DC.

55. Patient management and recall. The system will generate all call/recall standard letters and will be responsible for the management of patients who do not attend (DNA) or cannot attend (CNA). A list of the required letters is set out below (see Box 2, page 48). The system needs to keep track of all the letters generated and alert the screening co-ordinator when actions are overdue. The system will control the booking and arrangement of all screening sessions. It will also provide data for monitoring national standards for clinic uptake and revisit targets. It will be able to pass on data containing action recommendations as well as interface with ophthalmology department records so that feedback on treatment and referral outcomes can be monitored. The system needs to be "time aware" on these movements and provide reports to support the monitoring national standards. It must generate all letters to patients, GPs, Optometrists, Ophthalmologists and Diabetologists.

Figure 2: System overview showing how the components of retinopathy screening interact



Key statement 25: To avoid the risk of missing some patients, it is essential to adhere to the guiding principles of a standardised approach with integral failsafe arrangements and effective monitoring and evaluation. NSD will specify the standards and principles.

56. Image capture. The software will be expected to capture images in acceptable (accredited) file format, resolution and quality, edit or add patient information on the front end and label images on capture. It should allow images captured by community optometrists and distributed by CD to be imported. Further information about cameras and image transmission is included above (see paragraph 45). It is possible that a supplier wishing to provide software may also wish to supply cameras and associated software. This may have advantages for the NHS in terms of avoiding disputes about responsibilities if problems arise. Any procurement exercise will clearly specify the standards to be delivered but will be open to proposals which secure optimum value.

57. Grading and reporting images. The software will need to support manipulation and enhancement of images using methods that do not alter the original image (such as zoom facility, contrast/brightness, red free – the ability to take red out of the image); allow flexible input of grading criteria complying with national standards; keep a record of who graded the image; produce a grading report to send to the GP and keep for screening service records; produce a patient report; and allow images from previous screening episodes to be viewed on the same screen as images currently being graded. There must be the capability to record changes at secondary or tertiary grading in either classification or in the action to be taken. Changes should remain distinct at each subsequent stage and not overwrite previous stages. The software must be capable of operating for individual patients or for whole clinics. A flag system must be incorporated so that sequential grading can identify and log urgent cases. This will allow higher level graders to extract appropriate cases for early attention. Further information about grading issues is included above (see paragraph 43).

58. Archiving and backup. Archiving and backup software must be able to produce archives on either removable media or over networks. Archived material must include images and clinical data and must be in industry standard formats which can be read by generic software; not solely by the software which created them.

59. Audit and statistical analysis. It will be necessary to be able to interrogate the system so that all information remains accessible. Audit data will be determined according to the national standards and the system must be capable of producing queries on each parameter stored such that audit of individual screeners, graders, centres, cameras or other relevant components is possible. Automated printed reports are useful for regular enquiries but the system also needs the ability to export data for ad hoc reporting. The system must be capable of exporting summarised clinical data, grading results, outcomes and service levels with selection of batches of images for QA. Audit must respect patient confidentiality.

60. Quality assurance. Since a proportion of all images will be re-evaluated for quality assurance purposes, the dataset must allow recording of two screening results for each image with a field to record which interpretation is adjudicated correct in the case of discrepancies. Random selection of a set of images for QA should be achievable within the IT system. To enable quality assurance and the management of images captured in the community, an ability to export images to, and import from CD is necessary. Further information about quality assurance is included below (see paragraph 65).

61. IT support. The exact standards for communication with other software systems to be specified in the national screening programme have still to be defined. Exportation from a system must be sufficiently simple for local IT staff to operate. It is essential that any approved systems comply with recognised standards for integrity and security of data. This implies effective backup, product maintenance contracts and product update procedures.

Developing and Procuring Software

62. The complexity and risk associated with developing and procuring this key piece of software and the importance of consistent application of standards and quality assurance demands a single Scottish solution to support the DRS programme.

Key statement 26: Fully comprehensive software to support diabetic retinopathy screening should be procured centrally rather than by each NHS Board independently. The commissioning process will determine how this will be provided in practice – what will be purchased centrally and what will be the responsibility of NHS Boards.

Key statement 27: In order to ensure consistent standards of service delivery and quality assurance, all NHS Boards must either use the nationally developed software, or satisfy NSD that an alternative system can deliver fully comparable results.

63. NSD will develop the system specification and seek information from suppliers. It is likely that a number of options will be offered both in terms of the software itself and how this might be supplied (e.g. via a Prime Contractor arrangement or a Managed Service approach). Issues such as system maintenance will also be considered.

Key statement 28: The full specification of the software and proposals to deliver it will be produced by NSD by July 2003.

64. Taking the process from the development of the software specification, through a procurement exercise to the implementation phase will take some time. During this period NHS Boards will need to prepare the local infrastructure (e.g. ensuring the quality and

completeness of their patient register, purchase cameras and train staff) whilst at the same time continuing to screen patients. The DRS collaborative network (see paragraph 85) is expected to have an important role in facilitating the sharing of ideas about how to establish an efficient local DRS service. Smaller Boards and the island Boards in particular are urged to explore opportunities to work jointly with other areas to achieve best value.

Key statement 29: A fully comprehensive software solution to support diabetic retinopathy screening will be made available by September 2004 and fully implemented by no later than September 2005.

Diabetic Retinopathy Screening:
Quality Assurance and Standard Setting

65. Quality Assurance is defined as: 'improving performance and preventing problems through planned and systematic activities including documentation, training and review'. All NHS Boards are currently reviewing their screening systems following publication of the HTBS report. However, as the recent survey showed, very few local services incorporate any quality assurance measures to check screening quality. Uniform national standards are required to ensure that all patients receive adequate retinopathy screening. National standards for the DRS programme will be defined by NHS Quality Improvement Scotland. Additional operational details will be defined nationally and included in the DRS Manual.

66. NHS Quality Improvement Scotland has the remit to develop and run a quality assurance process for clinical services provided by NHSScotland. For screening programmes, NHS Quality Improvement Scotland has an additional responsibility to ensure adequate quality assurance is in place for each programme. NHS Quality Improvement Scotland will produce a set of clinical standards specifically for diabetic retinopathy screening (DRS).

67. Existing NHS Quality Improvement Scotland standards for cervical and breast screening programmes and general diabetes services, in conjunction with information from the HTBS Technology Assessment report, will be used to produce the draft DRS standards. The standards development process will also be guided by the recommendations contained in this report.

Key statement 30: The NHS Quality Improvement Scotland Working Group on Diabetic Retinopathy Screening should produce standards for DRS. These standards will cover the following topics: responsibilities, service specification, communication, patient information, call/recall and failsafe, the screening process, quality assurance, referral and treatment. Draft standards should be published by May 2003.

68. The NHS Quality Improvement Scotland draft standards will be reviewed following formal consultation and piloting, and in the light of evidence emerging from the DRS programme. There may be merit in allowing this process to be extended to allow the standards to be fully tested in practice before being finalised. Reviews will be undertaken once DRS services are in operation. A decision regarding the timing of review visits will need to take account of the extent to which DRS programmes have been established.

69. The standards published by NHS Quality Improvement Scotland will include elements common to all national screening programmes (e.g. register, call/recall issues) and those that relate solely to diabetic retinopathy (e.g. quality assurance of graders and equipment). These standards will underpin the quality assurance arrangements for the DRS programme. However, the detail of how these standards should be applied in practice will need to evolve as the programme develops and as lessons are learned. Guidance on quality assurance will be made available in the DRS Manual which will be revised in the light of experience.

70. Although the focus must be on implementing national standards, the introduction of a consistent quality assurance regime must be tempered by pragmatism during the development of the DRS programme and in light of the uncertainty surrounding a number of issues including the minimum proportion of digital photographs which should be quality assured by a level 3 grader.

71. No screening programme can be foolproof and it is inevitable that some images with signs of retinopathy, or more seriously, sight-threatening retinopathy will be missed. Quality assurance is required in order to minimise the number of errors. It is estimated that approximately a tenth of all images viewed within the DRS programme will be for the purposes of quality assurance (i.e. level 3 grader or equivalent, checking a proportion of images graded by level 1 graders and level 2 graders, not previously referred to the level 3 grader). The performance of level 3 graders will be monitored through regular audit undertaken by the DRS Network Co-ordinator which will allow any outliers to be swiftly identified. The standards for quality assurance will be determined by NHS Quality Improvement Scotland and may be revised in the light of experience.

Key statement 31: Quality assurance requires that for each grader randomly sampled images are checked by a level 3 grader. Initial estimates suggest that a minimum of 200 images per grader per annum will be required. This will be finalised in the NHS Quality Improvement Scotland Standard.

72. If it becomes a reality, automated grading would allow a larger number of images per grader to be regraded. Indeed, it may in time prove possible to automate all level 1 grading. This will be kept under review as the technology develops.

73. One of the most important standards for assuring the quality of the DRS programme will be to ensure that all graders and screeners are properly trained and accredited. All graders must work to the same standards. Grading standards will be maintained by regular proficiency testing.

Key statement 32: NSD should be responsible for the national organisation of proficiency testing.

74. NHS Boards will be accountable for monitoring and performance management of the screening service and for overseeing the day-to-day "quality control" QA. Other monitoring arrangements are outlined below (see paragraph 90).

Diabetic Retinopathy Screening:
Impact on Ophthalmology Services

75. Any national screening programme will be expected to have some impact on ophthalmology services. The National Screening Committee's report suggested this impact might be very considerable as they estimated that, for a population of 600,000 (prevalence of diabetes 2.5%) 8% would be referred in the first year with referrals falling to about 3% only by year 4. However, based on the structure of the screening programme recommended for Scotland and the insights gained in Grampian and Tayside (two health boards with considerable experience of operating a screening service) it is believed that the impact on ophthalmology will be manageable. Ophthalmologists have a central role in the quality assurance of the DRS programme and as level 3 graders. NHS Boards must provide adequate protected clinical time for these functions. In Grampian one weekly session of protected ophthalmology time for quality assurance and level 3 grading has been provided. A number of ophthalmologists will also be involved in the provision of training.

Key statement 33: The net effect on ophthalmology services of the introduction of a national diabetic retinopathy screening programme is likely to be modest. The impact should, however, be monitored by NHS Boards.

Key statement 34: Protected staff time for quality assurance and level 3 grading must be provided.

Referable Retinopathy

76. The Grampian screening programme started in February 2002. For the first 3,000 patients screened, the referral rate for patients new to ophthalmology has been 4.2%. Similar figures have also been found in Tayside where using a similar grading system to the National Screening Committee (NSC). New referrals to ophthalmology have consistently been in the range of 3-4% over an eight-year period, screening 3,500-4,500 patients per annum. In Lanarkshire, new referrals to ophthalmology currently run at 2.5%.

77. In Grampian, the commonest referable grade has been diabetic maculopathy (see table 1 below).

Table 1: Referable Grades (including patients already attending ophthalmology)

Referable Grades	Referable	%
Maculopathy	✔	7.6
Severe retinopathy	✔	0.2
Early proliferative	✔	0.2
High-Risk proliferative	✔	0.2
No retinophathy	✘	67.0
Mild retinopathy	✘	16.0
Moderate retinopathy	✘	0.6
Technical failures	✘	7.8

Source: Grampian Retinal Screening Programme.

78. The Scottish Diabetic Retinopathy Grading Scheme 2003 enables referrals to ophthalmology to be seen according to clinical priority. However, this will be of little value if waiting times for referrals to ophthalmology are excessive. This should be monitored.

Key statement 35: Referrals to ophthalmology from screening should be seen according to clinical priority as determined by the screening photograph. Waiting times should be audited by NHS Boards.

Technical Failures

79. Single field non-mydriatic photography has yielded a technical failure rate of 8-9% in an established screening programme over 12 years (Tayside). A recent research project showed that subsequent mydriasis reduces the failure rate to around 4%. Research in Grampian has shown that one-field photography has a lower technical failure rate than two field (3.5% vs. 4.5%). The main reason for technical failure (despite the use of mydriasis) appears to be cataract.

80. Patients for whom it is not possible to obtain an image from a digital camera even with mydriasis require slit-lamp biomicroscopy. It is expected that these patients will be examined within the screening system in a separate session by one of the level 2 graders, or by a community optometrist. Ophthalmology departments would not be able to contain the workload within existing resources if technical failures were to be referred to them.

Key statement 36: Technical failures (i.e. ungradeable images) must be contained within the screening programme in order to prevent ophthalmology services from being overwhelmed.

Returning Patients to the Screening Programme

81. The facility for ophthalmologists to discharge patients safely back to the screening programme after treatment will be crucial to allow ophthalmology departments to absorb the impact of the screening programme. Stable patients who at present have to attend hospital ophthalmology clinics for regular review will in future attend the screening programme.

Key statement 37: The screening programme should provide capacity for ophthalmologists to return to screening those patients who, after treatment or otherwise, no longer have referable retinopathy and who may therefore re-enter the screening cycle without continuing to attend an ophthalmologist.

82. The DRSIG recommends the following guidelines to help identify patients currently attending hospital ophthalmology clinics who are suitable for transfer to the screening programme:

- Patients with moderate background retinopathy can be discharged to the screening programme provided there are facilities for 6-monthly follow-up within the programme.
- Patients with observable maculopathy can be discharged to the screening programme provided there are facilities for 6-monthly follow-up within the programme.
- Patients with maculopathy or macular oedema can be discharged following successful laser treatment if they no longer meet the criteria for referral.
- Patients with complete regression of proliferative retinopathy can be discharged following successful laser treatment if they no longer meet the HTBS criteria for referral.
- Patients with proliferative retinopathy who have had laser treatment but who have residual new vessels can be discharged to the screening programme provided there is photographic evidence that there has been no progression of the new vessels over a period of 6 months.
- The presence or absence of laser burns should have no effect on the decision to refer, monitor or discharge patients.
- All patients that are discharged must have baseline digital retinal photographs sent to the screening programme.

- Finally, the DRS programme director must have the right to refuse discharged patients if it is felt that their retinal photographs suggest continued observation by the hospital ophthalmologist is appropriate.

Linking Ophthalmology to the Screening Programme

83. In order to support the screening programme effectively, ophthalmology departments should be provided with the necessary equipment and IT.

Key statement 38: All ophthalmology services must have access to digital photography. In addition, ophthalmologists will require access to the Diabetes Clinical Management System (SCI-DC) and NHS Network.

Diabetic Retinopathy Screening:
National Support and Managing

84. Providing retinopathy screening to people with diabetes is the responsibility of NHS Boards. However, in order to assist boards to meet their obligations and to ensure that consistent standards are applied and monitored across the country, central co-ordination and support is required to:

- provide guidance and to help disseminate and share knowledge
- support quality assurance
- provide leadership
- ensure that appropriate training is available.

85. The DRSIG consider that the most appropriate mechanism to fulfil these tasks is a collaborative network guided by NSD.

Key statement 39: A DRS collaborative network should be established to support and facilitate the implementation of DRS across Scotland. This network should be directed by an executive group comprising individuals from NHS Boards, the various relevant professions involved in the retinal screening programme and patient representatives.

Key statement 40: A full time DRS network co-ordinator should be appointed by NSD to initiate and support the network and facilitate exchange of information between screening centres.

Key statement 41: By June 2003 a lead clinician should be appointed to act as chairman of the executive group of the DRS collaborative network. A part-time commitment of one half-day session per week is suggested for a period of three years.

86. The collaborative network might develop into a more formal Managed Clinical Network. This will depend upon the needs of the service and consideration of the relationship with the diabetes MCNs in each NHS Board area.

DRS Manual

87. One of the main responsibilities of the DRS network co-ordinator would be to prepare and maintain a DRS Manual for use by NHS Boards which will contain detailed guidance about establishing and running a DRS service; standardised patient information, letters and other materials, including:

- Most recent statement of policy for Scotland (from SEHD circular)
- Detailed Specification of the service to be delivered
- NHS Quality Improvement Scotland national standards

- Detailed guidelines for effective call/recall arrangements (including exclusion criteria)
- Specification of the national minimum data set required to be submitted for the annual Scottish Diabetes Survey
- List of lead contacts in each NHS Board area
- Summary of HTBS recommendations
- Professional guidelines on (a) cameras; (b) mydriasis; (c) reasons for exclusion from screening; (d) criteria for referral to ophthalmology including recommendations for urgency of referral for different circumstances; (e) others taken from DRSIG report
- Patient and professional information leaflets (templates and good practice examples)
- Other guidelines and protocols that represent good practice and are approved by the Executive Group of the DRS collaborative network.

88. The manual is largely a collation of information and guidance from other sources, especially the HTBS report. The objective is to publish a first edition by September 2003. Thereafter, the manual would require to be kept up to date by regular revision.

Key statement 42: A DRS Manual for NHS Boards should be published and maintained by NSD, on behalf of the DRS collaborative network. The DRS Manual should contain detailed guidance on establishing and managing a DRS programme and include a collation of all relevant standards and policies, standard letters and contact details. A first edition of the DRS Manual should be published by September 2003.

89. A first objective for NHS Boards in implementing retinopathy screening was highlighted in the Scottish Diabetes Framework. The Framework recognised eye care as one of the first stage priority issues, and set a target that all people with diabetes should have their eye status (retinopathy) recorded on the local diabetes register by September 2003. The 2002 Scottish Diabetes Survey[12] showed that by September 2002 of those patient registered, almost three-quarters had been screened, but that over a quarter of patients either had never been screened, or had no recorded result (see Annex C).

Monitoring the DRS Programme

90. The DRS programme will be monitored in five complementary ways which together will ensure that national standards are effectively applied:-

- Quality control – reviewing and checking of all the aspects of performance to determine that they meet the agreed standards.
- External quality assurance – regular audit by the National DRS Co-ordinator to ensure that routine quality control systems are working effectively.
- National Review – periodic NHS Quality Improvement Scotland review of standards.
- SMR Returns – mandatory collection of key performance indicators compiled nationally by ISD.
- Other reporting mechanisms – Performance Assessment Framework, annual Scottish Diabetes Survey, Diabetes Annual Report produced by NHS Boards, local clinical governance arrangements).

Key statement 43: The main method for assessment of the performance of NHSScotland in the operation of DRS will be the reviews undertaken by NHS Quality Improvement Scotland which will evaluate apply the published Diabetic Retinopathy Screening Standards. Review visits will commence once DRS services are in operation. In the interim, information about progress towards improving DRS will be published as part of the NHS Quality Improvement Scotland review of the diabetes services, in the annual Scottish Diabetes Survey and in the Diabetes Annual Reports published by NHS Boards.

Key statement 44: ISD should be involved in defining the national dataset to be used by the DRS programme. A subset of the dataset should be identified as key performance indicators to be included as a routine SMR return.

Review of Diabetes Services

91. Diabetes services will be subject to a NHS Quality Improvement Scotland review during 2003. The diabetes standards to be reviewed were published in final form in October 2002.[13] The existing standards which relate to eye care are set out in Box 1 opposite. The standards specific to DRS referred to above (paragraph 65) are in addition to these more general service standards.

Box 1: Diabetes Clinical Standards defined by NHS Quality Improvement Scotland (formerly the Clinical Standards Board for Scotland)

Clinical Standards: Diabetes

Clinical Review

Standard Statement. All people with diabetes are offered annual or more frequent examination, where clinically indicated, to monitor the management and progression of their condition. There is intervention as required, and support for the modification of lifestyle factors.

Criteria

There is a protocol to ensure that all people with diabetes are offered review of the following indicators on an annual basis, or more frequently where clinically indicated, from diagnosis.

4. Eye examination for diabetic retinopathy according to HTBS recommendations. (Essential)

17. Referring practitioners (including optometrists, with patient consent) are given feedback regarding the outcome of their referrals. (Desirable)

Clinical Management: Eyes

Standard Statement. All people with diabetes who have identified signs of developing diabetes-related, sight-threatening retinopathy, according to HTBS grading recommendations are referred to an ophthalmologist for assessment and, if necessary, treatment.

Criteria

1. There is a referral process to a consultant ophthalmologist-led service for people with diabetes with identified signs of developing diabetes-related, sight-threatening retinopathy according to HTBS grading recommendations.

2. All people whose eye examination has revealed retinopathy have their glycaemic control and blood pressure reviewed and treated as clinically indicated.

3. All people with active proliferative diabetic retinopathy are offered laser treatment.

Clinical Standards Board for Scotland (2002). Clinical Standards: Diabetes. Second Edition

Measure of Success: Number of People Being Screened

92. One of the key measures of the success of the DRS programme will be the proportion of people with diabetes screened each year. This aspect of the performance of NHS Boards will be monitored but it is realised that screening rates depend on the decisions of individual patients whether or not they wish to attend.

Key statement 45: People with diabetes are strongly encouraged to attend for screening, but attendance cannot be compulsory. Although NHS Boards are required to offer screening to all appropriate patients, they cannot be held responsible for those who choose not to attend. Research is required to explore why some people do not take up the offer of screening.

93. Chapter 7 of the HTBS HTA report outlines issues related to patients' needs and preferences which should be considered in establishment of the national diabetic retinopathy screening service. The report identified the requirement for clear information about the need for screening, the limitations of screening, what would happen during screening and subsequent treatment as well as the need for timely reporting of results. To achieve this, effective information must be provided to people with diabetes and to healthcare professionals. There must also be good communication between professionals and people with diabetes, with provision of support where required.

94. NHS Glasgow is establishing a diabetic retinopathy screening programme in line with the HTBS recommendations. They have drafted a suite of letters for patients and professionals for all stages of the process (initial and follow-up invitations, referral and reporting results). All letters have been produced according to RNIB standards and are suitable for people with visual impairment. These letters should be piloted and modified in the light of patient comments). When finalised, the suite of letters will be included in the DRS Manual for use across Scotland. Box 2 below sets out the range of letters required.

95. In addition, a patient information leaflet is required to inform people with diabetes about the diabetic retinopathy screening programme in Scotland (including the screening process, its limitations and possible outcomes) and so enable them to make an informed decision about attending screening. It should have space available for the addition of information about local arrangements (e.g. location and contacts). Several examples of leaflets from regional programmes were provided in the HTA report and two good general texts are available from RNIB Scotland <www.rnib.org.uk> and Diabetes UK <www.diabetes.org.uk>. A national leaflet has been created and will be inserted in the DRS Manual and published on the diabetes website <www.diabetesinscotland.org> for use throughout Scotland.

Box 2: Diabetic Retinopathy Screening Programme Standard Letters

A diabetic retinopathy screening programme requires a range of different standard letters. A full suite of letters will be available in the DRS Manual. The intention is that all letters will be produced automatically by the software systems associated with image collection and grading.

1. Letter to patient giving time and date of appointment and details of what happens at examination
2. Letter to patient saying that they did not attend and requesting them to make a further appointment
3. Letter to patient saying that they cancelled and giving another appointment date
4. Letter to patient indicating no retinopathy exists and that they will be recalled in 1 year
5. Letter to patient indicating mild background retinopathy exists and that they will be recalled in 1 year
6. Letter to patient indicating observable maculopathy exists and that they will be recalled in 6 months
7. Letter to patient indicating that they have been referred to an ophthalmologist for further examination
8. Letter to patient requesting that they attend a slit lamp examiner for further examination (ungradeable photograph, bad photograph)
9. Letter to GP with results of retinal screening examination and action taken
10. Letter of referral to ophthalmologist with results of retinal screening examination (maculopathy, severe background retinopathy, proliferative retinopathy)
11. Letter to patient reminding them that they should have their eyes checked by slit lamp examination because of a technical failure
12. Letter to GP with results of retinal screening examination (slit lamp)
13. Letter to patient reminding them of request to attend for retinal screening
14. Letter to GP after 3 DNAs or CNAs by patient
15. Letter to patient, for second and subsequent year inviting them to attend for retinal screening
16. Letter to eye department receptionist with enquiry regarding patient already attending for eye examination

96. Boards will need to fund production of these leaflets. Information should follow RNIB guidance[14] to ensure accessibility to people with impaired vision. Translations should also be available. This will be dependent on the local diabetic population but given the prevalence of diabetes in ethnic minorities, translations particularly in Urdu, Punjabi, Hindi, Chinese and Gaelic should be provided. Leaflets in other languages should be made available on request. To reduce duplication these translations would be best organised nationally and made available on the diabetes website.

Key statement 46: Patients require appropriate and consistent information about the Scottish screening programme for diabetic retinopathy. A single patient information leaflet has been developed and will be published in the DRS manual and on the website. The manual will also contain example letters to patients and healthcare professionals to ensure consistency of messages to patients throughout the invitation, screening and treatment process.

Key statement 47: Patient information should be accessible to people with impaired vision and should conform with RNIB guidance (2001).

Key statement 48: Patient information leaflets should be available in relevant minority languages. Urdu, Punjabi, Hindi, Chinese and Gaelic texts will be particularly relevant for Scotland. These leaflets should be created centrally and made available for general use via the diabetes website.

97. The importance of special initiatives to communicate with teenagers is understood and should be considered after the general patient information leaflet is available.

98. The HTBS report identified a number of areas requiring additional research, audit and development. These will test assumptions and allow improvement in the national programme in the light of experience.

Clinical effectiveness

- Evaluate the role of mydriasis and multiple/single fields in screening by retinal photography;
- estimate failure rates in the proposed system;
- test quality assurance measures for slit lamp evaluation to ensure that they reach a high and uniform quality standard;
- evaluate the use of automated grading by computer;
- assess the role of scanning laser ophthalmoscopy in diabetic retinopathy screening.

Organisational issues

- Investigate the possibility of less frequent screening in some patient groups;
- develop a national training and accreditation scheme for all those undertaking retinal grading;
- develop a national treatment protocol for the administration of the mydriatic agent tropicamide;
- establish a robust quality assurance scheme;
- examine the use of compressed JPEG images, lossless compression and laptop screens for grading;
- use current expertise to equip mobile retinal screening units for the national programme, ensuring easy access for patients.

Patient issues

- determine barriers to attendance for screening;
- evaluate factors that encourage screening attendance (and those most and least likely to be influenced by the intervention):
  - educational material (leaflets, videos, media for a variety of sub-groups);
  - written reminders (benefits of multiple reminders and style of invitation);
  - advertising campaigns (press, television and radio);
  - use of educators;
  - peer education (particularly for teenagers);
  - dissemination points.

Economic evaluation

- Monitor attendance rates geographically and for different modalities;
- estimate initial levels of diabetic retinopathy;
- estimate net effect on both referrals and treatments for diabetic retinopathy;
- estimate net effect on both referrals and treatment for macular oedema;
- estimate net effect on proportion of the diabetic population who are registered blind;
- estimated budget vs. actual costs.

Key statement 49: The research topics identified in the HTBS report as well as further research questions which become apparent should be developed so that appropriate modification of the screening programme might be introduced in the light of experience.

99. Whilst some of these questions will be answered in the course of operating a systematic screening programme, others will require specific research funding. The Scottish Diabetes Group and the Chief Scientist Office jointly have recently established a Diabetes Research Group to provide a focus for diabetes research in Scotland and to assist those with research ideas to obtain grants. The DRSIG recommends that the Diabetes Research Group support research into retinopathy screening.

Key statement 50: The newly established Diabetes Research Group should explore ways of ensuring that the research requirements of the DRS programme are implemented.

100. The DRSIG was pleased to note that the Grampian Diabetes Retinal Screening Programme, Grampian Primary Care Trust, in conjunction with the Department of Bio-Medical Physics, Aberdeen University, have been awarded a full grant by the Chief Scientist Office to investigate the "role of automated grading of diabetic retinopathy in a primary care screening programme". It is hoped that this study of the images of approximately 6,700 patients will confirm earlier pilot work thus enabling the introduction of automated level-one grading into the Scottish Diabetic Retinopathy Screening Programme.

101. It is hoped that with the support of the Scottish Diabetes Group, the implementation of the DRS programme and the creation of the DRS collaborative network will also see an increase in the number of collaborative research projects being developed both within Scotland and with other parts of the UK.

Diabetic Retinopathy Screening:
Funding Requirements

102. The HTBS report included detailed calculations to assess the cost of implementing a DRS programme in Scotland. These calculations have been updated in the light of additional information (including a request for information to clarify the full costs of call/recall and grading software), new developments and the recommendations of this report. The analyses have also been extended to provide the costs of implementing alternative screening scenarios (for example if screening were all hospital based or all mobile van based) for each NHS Board. Both the figures from the original HTBS report and the updated costings are available from the HTBS (Health Technology Assessment) section of the NHS Quality Improvement Scotland website <www.nhshealthquality.org>. However, the costs remain substantially the same and the conclusion is unchanged – that moving from an opportunistic screening approach to a national systematic DRS programme is cost effective.

103. Implementation in Scotland of a fully operational, national DRS programme (on the basis of a diabetic population of 150,000) will require approximately £2.5 million capital over three years and around £3 million per annum in revenue to operate once fully established. For most NHS Boards this represents between £150,000 and £350,000 per year. This is not all 'new money' because most Boards are already screening a significant number of people with diabetes. Cost efficiency will be increased if NHS Boards provide services jointly.

Key statement 51: NHS Boards should provide funding to implement a comprehensive DRS programme in their area. Collaboration between areas to achieve optimal use of resources will result in important cost savings. NHS Boards should therefore explore appropriate opportunities to combine, for example, call/recall units for diabetic retinopathy with other NHS board screening units, or with diabetic screening offices in other boards. NHS Boards should also explore the potential to realise savings from joint provision of the service across board boundaries.

104. The SEHD has made it clear that every NHS Board must ensure that they provide DRS for all patients who require it and has accepted that full implementation may take until March 2006. In reporting progress on implementation, NHS Boards will be expected to clarify the funding arrangements to deliver the DRS programme in the long term.

Components of the DRS Programme

105. NHS Boards are responsible for providing DRS services. However, a number of functions need to be provided centrally and will be organised more economically on a national basis. Such central support will also make it more likely that uniform standards and protocols will be adopted across the country. Box 3 outlines where organisational responsibility rests for funding different components of the diabetic retinopathy screening programme.

Key statement 52: The Scottish Executive, National Services Division and NHS Quality Improvement Scotland should provide the resources necessary to implement the central components of diabetic retinopathy screening, to include central co-ordination, specification and documentation of standards, central elements of QA (including proficiency testing), a DRS manual, a training handbook, software procurement and patient information material.

Box 3: Responsibility for funding components of the diabetic retinopathy screening programme

Component	Responsibility to fund
Central co-ordination. Costs of running the DRS Collaborative network, including the DRS Network Co-ordinator and the Clinical Lead.	SEHD/SDG
Standards documentation.	NHSQIS
DRS Manual. Publication and maintenance.	NSD
Training Handbook.	SEHD/SDG
Training.	NHS Boards (a)
Diabetes registers.	NHS Boards + SCI-DC
Software – specification, co-ordination of procurement, purchase.	NSD/SEHD
Software – implementation.	NHS Boards
Proficiency testing.	NSD/SEHD
Procurement of digital cameras – central co-ordination.	SEHD/SDG (b)
Purchase of digital cameras.	NHS Boards
Local administration costs (including regional call/recall offices).	NHS Boards
Mobile units (purchase or lease).	NHS Boards
Staff costs - Nurses - MTOs - Optometrists - Camera Operators - Graders - Consultant Diabetologists - Ophthalmologists	NHS Boards

(a) NSD will have a role in commissioning training.

(b) The main options for procuring digital cameras are for NHS Boards to manage their own procurement, to organise a Scotland-wide procurement exercise, or to seek to put in place a UK procurement. If central co-ordination is required, this cost will be picked up centrally.

106. Discussions have been held to explore the potential to develop the specification and procurement of cameras on a UK rather than Scottish basis. The success of these discussions will depend upon how closely the user requirements of Scotland match the rest of the UK. Given that UK specification and procurement approach could increase the effectiveness of negotiations with suppliers, the DRSIG welcomes these moves. However, it is strongly recommended that Scotland should not be delay its implementation timetable for DRS unless it is certain that a UK approach will be successful and beneficial. Moreover, the increased complexity of managing a UK project may also increase the project risk and make delivery of Scottish requirements more difficult to achieve. The potential savings must be balanced against these potential risks.

Key statement 53: Procurement of cameras on a UK basis may secure significant economies of scale and is the preferred option, provided that the UK user requirements are similar to the Scottish user requirements and that UK procurement does not unduly increase project or financial risk, or delay the implementation timetable. Although the benefits of UK procurement may not be achievable in the short term, development of close contacts with UK colleagues will make joint working easier in the future.

Indicative Fees for Optometry Services

107. Discussions with the bodies representing Optometry in Scotland have led to consensus on an appropriate fee structure to enable the skills of optometrists to be utilised in a primary care setting. There is no central mechanism for determining such fees and each NHS Board has the authority to negotiate with optometrist within their area. However, the DRSIG was encouraged by all sides to provide an indicative fee structure. Box 4 sets out indicative levels of fees for various optometry services.

Box 4: Indicative fees for optometry services to support the DRS programme

1	Diabetic Retinopathy Screening using single field non-mydriatic retinal photography and primary grading of the image.	£15.00
2	Mydriasis and second set of digital images in cases of technical failure with 1 above and primary grading of the image.	£10.00
3	Mydriatic imaging and primary grading of the image (i.e. cases where previous screening has identified that non-mydriatic screening is ineffective).	£20.00
4	Secondary grading of images provided by 1 & 2 above and or visualised in 5 below including immediate provision of outcomes and triage discussion with patients.	£10.00
5	Slit lamp biomicroscopy with mydriasis including primary grading in cases of technical failure in 1 & 2 above or following referral from other screeners.	£25.00

Diabetic Retinopathy Screening: **Conclusions**

108. Diabetic retinopathy screening is an essential part of good diabetes care and a key component of the Scottish Executive's Scottish Diabetes Framework. Launching the HTBS report on the organisation of diabetic retinopathy services in April 2002 Malcolm Chisholm, Minister for Health and Community Care made it clear that effective eye screening should be offered to all people with diabetes in Scotland who require it. This report makes recommendations for delivering that commitment as well as summarising the work which has been undertaken since last April. Progress has been made on a number of fronts including the development and piloting of training courses for screeners and graders, the definition of standards for DRS by NHS Quality Improvement Scotland and the specification of the software to support the screening programme. Locally too, significant progress is being made to populate diabetes registers and to put in place the resources required to deliver a DRS service. Providing a comprehensive, consistent and robust diabetic retinopathy programme presents a complex problem which cannot be addressed overnight. Having considered the functional and organisational requirements, and the capacity of current services, the DRSIG have put forward a series of pragmatic recommendations to ensure that retinopathy screening is made widely available within a reasonable timescale. The challenge now is to put these recommendations into practice.

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**Between May 2002 and January 2003 Susan Pellegrom was seconded to NSD on a part-time basis to support the DRSIG.*

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Number of People with Diabetes and Number Receiving Diabetic Retinopathy Screening

Based upon the figures in Tayside, which is recognised as having the most accurate diabetes register, it is estimated that about 3% of the Scottish population has diabetes (see Table 1). However, numbers are increasing rapidly and the figure of 153,438 is almost certainly a conservative estimate. It has been calculated that about 13,000 newly diagnosed cases of diabetes are identified every year.

All NHS Boards have diabetes registers, but these currently show significant variation in coverage and completeness. The 2002 Scottish Diabetes Survey reported 103,835 registered diabetic patients. Of these registered patients, 60% are reported to have been screened within the last 15 months and a further 14% to have been screened more than 15 months ago; (see Table 2).

Table 1: Expected number of people with diabetes in Scotland

	Population (a)	% of Scottish pop	Expected Diabetic pop Age std rate/100 (b)	Expected Diabetic pop Age std (Number)
Scotland	5,114,600	100.0%	3.00	153,438
1 Argyll & Clyde	423,500	8.3%	3.06	12,940
2 Ayrshire & Arran	373,400	7.3%	3.16	11,802
3 Borders	106,900	2.1%	3.44	3,678
4 Dumfries & Galloway	145,800	2.9%	3.47	5,057
5 Fife	350,400	6.9%	3.06	10,724
6 Forth Valley	278,000	5.5%	2.99	8,318
7 Grampian	523,400	10.2%	2.92	15,309
8 Greater Glasgow	904,400	17.7%	2.87	25,984
9 Highland	208,600	4.1%	3.16	6,590
10 Lanarkshire	562,000	11.0%	2.85	16,027
11 Lothian	783,600	15.3%	2.84	22,268
12 Orkney	19,480	0.4%	3.24	631
13 Shetland	22,440	0.4%	2.83	634
14 Tayside	385,500	7.5%	3.25	12,546
15 Western Isles	27,180	0.5%	3.42	930

(a) Estimated population figures at 30 June 2000

(b) expected figure has been calculated by applying national age-specific rates to NHS Board population. Differences in expected rate between NHS Boards reflects differences in age structure only. The rate does not take account of sex, ethnicity or deprivation which will also have an influence on the prevalence.

Table 2: Number of people with diabetes who have been screened for retinopathy

	Registered patients with diabetes (2002 SDS)	Screened in last 15 mths (Number)	Screened in last 15 mths (%)	Screened >15 mths (number)	Screened >15 mths (%)
Scotland	103,755	62,564	60%	14,555	14%
1 Argyll & Clyde	9,522	4,618	48%	1,411	15%
2 Ayrshire & Arran	8,998	6,436	72%	0	0%
3 Borders	2,929	2,332	80%	301	10%
4 Dumfries & Galloway	5,156	1,911	37%	969	19%
5 Fife	9,881	5,601	57%	1,108	11%
6 Forth Valley	6,845	2,659	39%	4,052	59%
7 Grampian	5,726	3,150	55%	924	16%
8 Greater Glasgow	4,191	2,953	70%	497	12%
9 Highland	2,156	2,012	93%	144	7%
10 Lanarkshire	16,358	10,018	61%	532	3%
11 Lothian	18,912	11,731	62%	2,799	15%
12 Orkney	377	0	0%	0	0%
13 Shetland	608	0	0%	0	0%
14 Tayside	11,277	8,562	76%	1,818	16%
15 Western Isles	819	581	71%	0	0%

Source: Scottish Diabetes Survey 2002

Variations between NHS Boards primarily reflect different stages of development of local registers rather than real differences in prevalence rates. For example, the Greater Glasgow register at present includes date from only three LHCCs, and the Highland data includes only patients seen in secondary care.

Diabetic Retinopathy Screening: **Annex D**

Diabetic Retinopathy Screening Implementation Timetable

April 2002	Publication by the Health Technology Board for Scotland of health technology assessment on *Organisation of Services for Diabetic Retinopathy Screening.*
April 2002	Publication by the Scottish Executive of the *Scottish Diabetes Framework.*
November 2002	Publication of HDL(2002)81 – *Developing services for people with diabetes.*
Feb-Sept 2003	NHS Quality Improvement Scotland Diabetes Services review visits.
May 2003	Publication of draft clinical standards for Diabetic Retinopathy Screening by NHS Quality Improvement Scotland.
June 2003	Publication by the Scottish Diabetes Group of *Diabetic Retinopathy Screening Services in Scotland: Recommendations for Implementation.*
June 2003	Publication of HDL – *Implementation of Diabetic Retinopathy Screening.*
June 2003	Publication of Diabetic Retinopathy Screening Training Handbook for Screeners and Graders.
June 2003	Appointment of a DRS network co-ordinator.
June 2003	Appointment of a lead clinician for the DRS collaborative network.
July 2003	Full specification of software solution published by NSD.
September 2003	Publication of first edition of *DRS Manual.*
September 2003	All people with diabetes will have their eye status (retinopathy) recorded on the local diabetes clinical management system. (Milestone, Scottish Diabetes Framework).
September 2004	Fully comprehensive software to support diabetic retinopathy screening will be made available.
September 2005	Comprehensive software to support diabetic retinopathy screening implemented.
March 2006	A comprehensive DRS programme will be operational throughout Scotland.

Scottish Diabetic Retinopathy Grading Scheme 2003

Retinopathy	Description	Outcome
R0	No diabetic retinopathy anywhere	**Rescreen 12 months**
R1 (mild)	Background diabetic retinopathy BDR – mild • At least one dot haemorrhage or microaneurysm with or without hard exudates	**Rescreen 12 months**
R2 (moderate)	BDR – moderate • Four or more blot haemorrhages (i.e. ≥ AH standard photograph 2a) in one hemi-field only (Inferior and superior hemi-fields delineated by a line passing through the centre of the fovea and optic disc)	**Rescreen 6 months** (or refer to ophthalmology if this is not feasible)
R3 (severe)	BDR – severe Any of the following features: • Four or more blot haemorrhages (i.e. ≥ AH standard photograph 2a) in both inferior and superior hemi-fields • Venous beading (≥AH standard photograph 6a) • IRMA (≥ AH standard photograph 8a)	**Refer ophthalmology**
R4 (proliferative)	Proliferative diabetic retinopathy PDR Any of the following features • New vessels • Vitreous haemorrhage	**Refer ophthalmology**
R5 (enucleated)	Enucleated eye	**Rescreen 12 months** (other eye)
R6 (inadequate)	Not adequately visualised Retina not sufficiently visible for assessment	**Technical failure** Arrange alternative screening examination

Diabetic Retinopathy Screening

Maculopathy	Description	Outcome
M1 (Observable)	Lesions within a radius of >1 but ≤ 2 disc diameters of the centre of the fovea • Any hard exudates	**Rescreen 6 months** (or refer to ophthalmology if this is not feasible)
M2 (Referable)	Lesions within a radius of ≤ 1 disc diameter of the centre of the fovea • Any blot haemorrhages • Any hard exudates	**Refer ophthalmology**

Coincidental findings	Description
Photo-coagulation	Laser photocoagulation scars present
Other	Other non-diabetic lesion present • Pigmented lesion (naevus) • Age-related macular degeneration • Drusen maculopathy • Myelinated nerve fibres • Asteroid hyalosis • Retinal vein thrombosis

Grading note

This grading scheme is not intended to be done by levels. It is meant to be done by features. The grader reports the presence or absence of each of the following features for each hemisphere and then derives the level for the individual eye:

- Dot haemorrhages or microaneurysm
- 4 or more blot haemorrhages (i.e. ≥ standard photography 2a)
- Venous Beading (≥ AH standard photograph 6a)
- IRMA (≥ AH standard photograph 8a)
- New vessels
- Vitreous haemorrhage

AH = Airlie House. Airlie House standard photographs available at: http://eyephoto.ophth.wisc.edu/ResearchAreas/Diabetes/DiabStds.htm

Health Technology Assessment Advice 1: Organisation of services for diabetic retinopathy screening

Screening attendance		DRSIG Recommendation
People diagnosed with either type 1 or type 2 diabetes mellitus and aged over 12 years, or post puberty, should be included in the national screening programme unless they are unlikely to benefit from screening.	*HTA Report 1, Sections 6.5 Advice 2.2*	Exclusion criteria to be included in DRS Manual and will be built into patient management and recall software. [Paragraph 87].
No upper age limit is suggested, but the following people are unlikely to benefit from screening: • those who are already undergoing regular reviews by an ophthalmologist • those who are medically unfit to receive laser treatment (as determined by their GP), or • those who are irreversibly blind.	Advice 2.3	Exclusion criteria to be included in DRS Manual and will be built into patient management and recall software. [Paragraph 87].
Appointment cards should be available in large print and information should be prepared in accessible formats (large print, disk, audio).	*HTA Report 1, Section 7 Advice 2.4*	Examples and templates of patient information will be included in the DRS Manual. [Paragraphs 87 & 93].
Up to two written reminders are recommended to encourage attendance. Additional reminders have been shown to be ineffective. Instead, health professionals should discuss any barriers to screening attendance with people with diabetes.	*HTA Report 1, Section 7 Advice 2.5*	Examples and templates of patient information will be included in the DRS Manual. [Paragraphs 87 & 93].
Special attention should be given to targeting those who have never attended screening or who have not attended recently.	*HTA Report 1, Section 7 Advice 2.6*	Examples and templates of patient information will be included in the DRS Manual. [Paragraphs 87 & 93].
To encourage uptake of screening, a choice of venues and appointment times should be made available, surroundings should be pleasant and welcoming, and those attending should be treated as individuals.	*HTA Report 1, Section 7 Advice 2.7*	Patient satisfaction with the DRS service should be monitored. [Paragraph 19]. Collaboration and communication between areas to be facilitated in order to share good practice. [Paragraph 84].

Diabetic Retinopathy Screening

Screening process		DRSIG Recommendation
The national screening programme must be fully quality assured with systematic call/recall, failsafe (see paragraphs 2.12 and 2.14) and follow-up	*HTA Report 1, Section 6.14 Advice 2.8*	Quality standards will be defined by NHS Quality Improvement Scotland. [Paragraph 65]. Development of software to support DRS to be funded by Scottish Executive. [Paragraph 105].
To be effective, the national screening programme must be integrated with routine diabetic care. Clinicians responsible for the ongoing care of people with diabetes must be informed of results, not only for sight-threatening retinopathy requiring referral to an ophthalmologist, but also for any retinopathy.	*HTA Report 1, Section 6 Advice 2.9*	Software for DRS will be fully integrated with diabetes clinical management systems (SCI-DC). [Paragraph 54].
Digital photography, with or without mydriasis (dilation of the pupils with eye drops), is of sufficient sensitivity and specificity to be used in a population based, systematic diabetic retinopathy screening programme. Furthermore, it produces a permanent record of the retinal image that is useful for quality assurance purposes.	*HTA Report 1, Section 5 Advice 2.10*	Scotland should be moving towards a fully camera based system. The DRSIG report establishes a timetable for the delivery of the key stages. [Paragraph 6].
Some people with diabetes are deterred from attending screening visits by the need for eye drops. Furthermore, as digital photography without mydriasis has been shown to be cost effective for screening purposes, it is recommended as the first stage in the screening programme, unless the individual is known to need mydriasis.	*HTA Report 1, Section 7.3.3.6 Advice 2.11*	DRSIG endorses the three-stage process recommended by HTBS. [Paragraph 5].
HTBS recommends that people with diabetes should be screened annually using the following three-stage process. (1) Macular single field digital retinal photography, without mydriasis, for each eye. (2) If there is a technical failure, macular single field digital retinal photography, with mydriasis for each eye. (3) If there is a technical failure with mydriatic digital photography, biomicroscopy with a slit lamp. Visual acuity, with refractive correction if required, should be recorded for each eye immediately prior to the screening examination.	*HTA Report 1, Section 9.2 Advice 2.12*	DRSIG endorses the three-stage process recommended by HTBS. [Paragraph 5].

If mydriasis is used, tropicamide is the recommended agent. It must be administered by a professional complying with the Patient Group Directions and the possible adverse effects of the mydriatic agent should be clearly explained to patients. Mydriatic agents can cause blurred vision and sensitivity to light for up to six hours, or longer in isolated cases. Other rare side effects may include glaucoma and allergic reactions.	*HTA Report 1, Section 3.5.3 Advice 2.13*	The question of Patient Group Directions needs to be resolved. [Paragraph 26].
Retinal images should be graded according to the Scottish Diabetic Retinopathy Grading System. A three-level grading process is recommended, with images referred up to the next level if the grader identifies any potential sign of retinopathy.	*HTA Report 1, Section 6.10 Advice 2.14*	DRSIG endorses a modification of the grading system recommended by HTBS. [Paragraph 43].
All graders must be specially trained, accredited and competent, with the more experienced professionals involved in the second (optometrist/ senior grader) and third (ophthalmologist) levels of grading.	*HTA Report 1, Section 6.13.5.1 Advice 2.15*	A training manual for graders will be published and appropriate training courses will be established. [Paragraph 41/42].
Accredited optometrists are well suited to be part of the national screening programme, for the first and second level grading and screening with digital retinal cameras, or for slit lamp screening of those not amenable to digital cameras. Their value for money will depend on the fee charged and the cost of local alternatives.	*HTA Report 1, Section 6.13.3 Advice 2.16*	DRSIG report includes recommendations regarding. optometrist fees. [Paragraph 107].
Results of screening should be communicated to people with diabetes and GPs in a timeous manner. The timeframe for this should be agreed at the outset of the national programme as part of the quality standards.	*HTA Report 1, Section 7 Advice 2.17*	This will be included in the standards to be published by NHSQIS. [Paragraph 65].
Direct ophthalmoscopes should only be used opportunistically for persistent non-attenders who would not otherwise receive a retinal examination.	*HTA Report 1, Section 5 Advice 2.18*	DRSIG endorses this view.
Further research should be undertaken as the screening programme is rolled out to enable optimal service provision.	*HTA Report 1, Section 9.3.7 Advice 2.19*	The DRSIG supports the need for research. [Paragraph 98/99].

Technical requirements		DRSIG Recommendation
In the short-term, simple standardised call/recall systems should be established locally or regionally, which can be integrated into the national system being developed under the Scottish Care Information – Diabetes Collaboration (SCI-DC). This will require the inclusion of optometrists on the NHSnet to facilitate the appropriate flow of data between health professionals.	*HTA Report 1, Section 6.8 Advice 2.20*	Work to define and develop a national call/recall system is ongoing [Paragraph 52].
The screening programme should use digital retinal cameras for all individuals amenable to photography. Higher resolution digital cameras (of at least 1365 x 1000 pixels) are recommended. Image transfer should use a direct digital route to avoid degradation of quality. The image should be graded on a computer or terminal with a cathode ray tube (CRT) monitor of at least 19 or 21". Images should be graded at capture resolution until further evidence on the acceptability of compressed JPEG images becomes available.	*HTA Report 1, Section 6.11 Advice 2.21*	Guidance about cameras and image transmission is included in this report. [Paragraph 45-49].

National and local structure		DRSIG Recommendation
The National Services Division (NSD) will work with the Clinical Standards Board for Scotland (CSBS) and NHS Boards to ensure a consistent, coordinated approach to the national screening programme through the creation of national specifications and the sharing of good practice and audit results.	*HTA Report 1, Section 6.15 Advice 2.22*	NHS Quality Improvement Scotland are leading on work to produce national standards. [Paragraph 65]. The DRS collaborative network will provide a mechanism to share good practice and audit results. [Paragraph 84].
CSBS will develop and publish national standards for the programme with NHS Boards, based on the work of the National Standards Screening Committee and will review the performance of NHS Boards against these standards.	*HTA Report 1, Section 6.15 Advice 2.23*	NHS Quality Improvement Scotland will publish draft national standards in May 2003. [Paragraph 65]. Reviews will be undertaken once DRS services are in operation [Paragraph 68].
NHS Boards should identify a 'named individual' who is empowered to take local responsibility for the diabetic retinopathy screening programme and work in close collaboration with NSD to plan the local rollout and implementationof the programme.	*Advice 2.24*	NHS Boards should appoint a lead clinician [Paragraph 31]. NSD will appoint a DRS network co-ordinator to foster collaboration and communication and support local implementation. [Paragraph 85].
A subgroup of the Local Diabetes Service Advisory Group should monitor and report on the local diabetic retinopathy screening programme.	*HTA Report 1, Section 3.2.3 Advice 2.25*	No specific recommendation made. However, a subgroup of the LDSAG would ensure that retinopathy screening remains firmly integrated with other aspects of diabetes care.
NHS Boards should plan, establish and commission screening services to meet the needs of local populations according to the national specification, with local variation agreed where appropriate. Options based in health facilities, mobile units and optometric practices are compared in the report and this information should be considered in the local context. For efficiency, collaboration between neighbouring NHS Boards is recommended.	*HTA Report 1, Section 6.4 and Section 8 Advice 2.26*	DRSIG looks to each NHS Board to undertake a needs assessment and define the best means of delivering DRS to their population. The network DRS collaborative will promote and encourage collaboration. [Paragraph 84]. The potential to share facilities should be explored. [Paragraph 103].
NHS Boards should promote screening uptake and provide information in keeping with national standards and in conjunction with the Health Education Board for Scotland (HEBS).	*HTA Report 1, Section 7 Advice 2.27*	A patient information leaflet to inform people about the screening process and to promote uptake has been developed. [Paragraph 95].

Information needs		DRSIG Recommendation
NHS Boards should monitor local performance of the programme using CSBS standards and agree any action required, particularly in response to the regular CSBS peer reviews of performance against national standards.	*HTA Report 1, Section 6.14 Advice 2.28*	Local systems for QA (in line with standards set by NHSQIS) must be put in place by NHS boards and monitored by local clinical governance arrangements. [Paragraph 65]. A framework for inter-board sharing and support will be facilitated by the 'DRS network Co-ordinator'. [Paragraph 84].
NHS Boards should record the local performance of the screening programme within their overall Diabetes Annual Report which, according to the Scottish Diabetes Framework, all NHS Boards will be expected to produce.	*Advice 2.29*	DRSIG endorses this recommendation. [Paragraph 90].
People with diabetes and all health professionals involved in the delivery of diabetic care should be informed about the screening programme, including the screening process, its limitations and possible outcomes. A variety of methods should be used to determine the most effective and efficient approaches for specific audiences.	*HTA Report 1, Section 7.3.1.3 Advice 2.30*	Examples and templates of patient information will be included in DRS Manual. [Paragraph 87].
Before attending screening, people with diabetes should be informed of the possible need for mydriasis and its effects. They should be informed that if mydriasis is used: • their eyes will be more sensitive to light • driving is not recommended for at least two hours after mydriasis • the effects may last longer in some individuals. This information should be available in accessible formats (large print, disk, audio).	*HTA Report 1, Section 3.5.3 Advice 2.31*	Examples and templates of patient information will be included in DRS Manual. [Paragraph 87].

SCI-DC – Scottish Care Information Diabetes Collaboration

The SCI-DC (Scottish Care Information – Diabetes Collaboration) Project aims to deliver effective information technology solutions to diabetes services in NHSScotland. The Scottish Diabetes Framework identified that well-managed, integrated diabetes care must be underpinned by effective information technology systems, and the SCI-DC Project was initiated to drive forward the IM&T milestones identified. The project aims to support the Scottish Diabetes Framework and the building of regional Managed Clinical Networks by the provision of supporting IT software and services. The project is funded for three years from April 2002.

SCI-DC is directed by a clinically-led Steering Group with strong representation from both primary and secondary care. The SCI-DC Steering Group is chaired by paediatrician Dr Kenneth Robertson. This group reports to the Scottish Diabetes Group – the national steering group responsible for the implementation of the Scottish Diabetes Framework and for ensuring the co-ordination of national diabetes developments. It also reports to the IM&T Programme Board, the national planning and co-ordinating body for IM&T developments in NHSScotland, via the SCI Programme Board.

Project Management is provided by the Information Systems Support Group of the Information and Statistics Division of the Common Services Agency. The Project Team operates from the Clinical Technology Centre at Ninewells Hospital in NHS Tayside.

The SCI-DC project will be delivered in two phases. The first phase builds on the success of the Lanarkshire Diabetes System (LDS) and the Diabetes Audit and Research in Tayside Scotland (DARTS) systems and aims to maximise the benefits associated with these systems by making them freely available across NHSScotland. Some development work has been required to produce generic, robust and supportable production versions of these systems for national roll-out, and the resulting products are known as SCI-DC Clinical and SCI-DC Network, respectively. Central funding is available to assist with the procurement of hardware in support of the roll-out programme.

The SCI-DC products are complimentary, each with a different focus. SCI-DC Clinical is designed to provide hospital clinic-based support, delivering such features as the automatic generation of GP letters. An interface has been developed to take the clinical data captured by SCI-DC Clinical for automatic update of the patient record held on SCI-DC Network.

SCI-DC Network allows for the identification of all people with recorded diagnoses of diabetes in the area, and provides full support for the Scottish Diabetes Survey. Its regionally customisable web pages allow access to standardised treatment guidelines for decision support, and

provide access to patient leaflets and local information such as clinic times and eye van schedules. SCI-DC Network allows for automated practice audit in support of clinical governance, and contains such features as graphical representation of laboratory results over time, allowing for longitudinal risk to be gauged and providing a focus for discussion with patients.

The first phase of the project has three main objectives. The first is to introduce widespread use of IT systems to diabetes services across Scotland in a short time frame. The second is to deliver the benefits and maximise the potential of systems which have been tried and tested in a clinical environment over a significant time period. The third is to pave the way for the introduction of enhanced clinical functionality to be offered by phase 2 of the project.

The second phase of the project develops and extends clinical functionality to provide more closely integrated and fully-functional IT solutions for the use of those involved in diabetes care. This phase builds on the functionality provided by SCI-DC Clinical and SCI-DC Network and extends it to ensure that it remains relevant, effective, forward-looking and sufficiently flexible to support different ways of working. The need for ease of access to integrated solutions, extended support for multi-specialty clinical care, and the facilitation of call/recall for diabetic retinopathy screening are all recognised as critical components of this second phase. The principal concept underpinning the SCI-DC initiative is the creation of a single shared electronic record for use by all involved in the care of patients with diabetes mellitus.

The roll-out phase of the project started in the summer of 2002. Implementation programmes are currently underway in four Health Board areas (October 2002), and implementation planning is in progress with those areas wishing to start implementation of the SCI-DC products in the coming year.

SCI-DC Steering Group also took responsibility for reviewing and updating the diabetes dataset. This has now been published as the Scottish Diabetes Core Dataset. SCI-DC products will continue to evolve and will be fully compliant with the national dataset. Although the use of the software produce by SCI-DC is not mandatory for health services in Scotland, it is expected that all data collection systems will, over time, be compatible with the core dataset.

More information about SCI-DC can be found on the website at www.DiabetesInScotland.org. Contact with the project should be made through Julie Falconer, SCI-DC Project Manager,
email julie.falconer@isd.csa.scot.nhs.uk or telephone 0131-551 8431.

Annex H: Barriers to Implementation

Barriers to Implementation	Argyll and Clyde	Ayrshire and Arran	Borders	Dumfries and Galloway
Links to CHI	CHI contact block downloaded from Sema every 6 months	No direct links to CHI. Diabetes register updated with CHI from practice returns	Access database populated manually by CHI	No data returned
Validity of local registers	Access database updated by Diabetes Facilitator – validated by registered GP	LDS system updated on yearly basis with info from practices. Random check done yearly	No validation at present	No data returned
Variability of QA	Annual post-grad meetings for optometrists and other key players	Regular feedback to practices of RS data. QA systems under review	No QA at present	No formal QA at present
Systematic approach to screening	Current screening covers >1/3 of patients via accreditated optometrists or hospital clinic	Current screening by accreditated optometrists + GPs. 73% patients on register have been screened	Dilated fundoscopy/ VA at GPs, hospital clinics and optometrists	Approx 80% diabetic population screened by optometrists. Majority by direct ophthalmoscopy
Call/recall standardised	No comprehensive system in place – either done by GP, hospital clinic or optometrist	No specific system in place – plans to develop local system while waiting for SCI-DC	Hospital clinics check date of last screening in GP letter. Primary care – unsure	Currently main by *ad hoc* arrangements between GPs and optometrists
Access to digital technology	No digital camera in use at present. Bid submitted	Three digital cameras, two hospital sites, one optometry practice	No access at present. One optometrist has digital camera	One digital camera in Eye Clinic. Possible use of camera in one optometrist practice
Accreditation	Annual post-grad meetings funded out of QA budget. Optometrists willing to be involved in audit/ clinical effectiveness	Retraining of optometrists/GPs on a yearly basis by Cons Ophthalmologist	Optometrists undertake training test by Consultant Ophthalmologist	No formal training/ accreditation programme in place
Funding	Funding for current system reached ceiling. Bids for digital cameras, software plus personnel submitted to Board	Optometrists paid £25/ examination. Sub-group just set up undertaking options appraisal	Optometrists receive standard HB fees x 2 (check amount?) Bid submitted for diabetes facilitator	Pre-implementation stage, draft plan and estimated costings submitted
General comments	Keen to implement standardised programme – require pump priming to do so, however, part of HB prioritisation process	Clinical concerns re non-mydriasis lack of digital cameras in optometry practices – substantial capital investment training	RS sub group set up recently to look implementing HTBS recommendations. Diabetes dev. seen as secondary care issue	Plans to introduce mobile digital screening. Community optometrists retest screening failures
Training	No formal training at present	Done by Consultant Ophthalmologist	Done by Consultant Ophthalmologist	No formal training at present
IT – screening software, etc.	IT support poor – particularly in Acute Trust. Obtain optometry data via CD-ROM?	No specific software. Limited IT support – funding withdrawn for development of LDS system	No support from IT for local register. Desire to implement SCI-DC	No IM&T system at present. Awaiting national roll out of SCI-DC

Diabetic Retinopathy Screening

Barriers to Implementation	Fife	Forth Valley	Grampian	Greater Glasgow
Links to CHI	Area register on Access database. No links to CHI	CHI data entered manually	Plans to obtain one of CHI download to populate register/retinal screening system	Not at present
Validity of local registers	Validation in primary care all practices signed up to maintaining register	Register updated manually – facilitator visits practices. 20-month cycle	No formal validation at present	Will be done through SCI – Clinical
Variability of QA	No formal QA	1st QA sampling practices of RS data QA systems under review	10% of all 1st level images, 10% all 2nd level images not passed on for 3rd level grading	In planning as part of new programme
Systematic approach to screening	40 optometrists provide community-based screening – approx 10,000 patients with diabetes	SDS – 78% screened. Hospital-based optometry programme	Current system exceeds HTBS recommendations	Implementation stage – four fixed cameras at four hospitals, non-mydriatic protocol
Call/recall standardised	Done by optometrists	Currently run from hospital diabetes system – will lose this when move to SCI Clinical Develop one locally?	Call/recall for retinal screening via Access database. Currently RS software does not support this	None at present – bid submitted for more funding to support this
Access to digital technology	None at present – proposal for optometrists to purchase	Two digital cameras – Stirling, Falkirk, Do not meet recommended standard. Bids submitted to update/extend current service	Three digital cameras Two mobile and one fixed 1 CR5/2 CR6 plus D30s	Four digital cameras procured
Accreditation	Accreditation programme in planning for optometrists	No	Accreditation of screeners through QA process	New staff will be trained and accreditated
Funding	Recurring funding – £12.50/optometrist/ screen. NHS grant to purchase digital cameras	Current funding – £40/50K, recurring. About to review current programme in light of HTBS recommendations	Revenue funding in place	Capital, recurring funding allocated
General comments	3 optometrists shown strong interest in being involved in new screening service	Hardware issues Ophthalmology issues Software issues Financial issues	Wide geographical area – issues of patient travel and equity of access	Key issue – must have register in place. Foresee huge health gain with implementation of RS programme
Training	Training done by ophthalmologists/ optometrists	Dept of Ophthalmology	Training course developed locally – providing standard for national course	Training to be provided by national RS training group
IT – screening software, etc.	Plans to link optometrists to NHS Net and then to SCI network	Greatest concern – implementation of SCI-DC means loss of call/recall	Plan to use JPEG compressed images for grading	IM&T system that meets requirements being implemented as part of a new programme

Barriers to Implementation	Highland	Lanarkshire	Lothian	Orkney
Links to CHI	CHI data are linkage to Labs/SCI Store and register	Preferred option – automatic linkage between register and CHI. Issues of consent outstanding	CHI – on register record record	No
Validity of local registers	Diabetes facilitator visits practices, inputs data directly. No formal validation	Updating done in real time in clinics. No validation	Data collected manually on laptop. Six practices have online access to Lanarkshire system	Register in planning, to be linked to SCI network
Variability of QA	No current QA of optometrists. 10% hospital images checked by Cons Ophthalmologist	Almost all images rechecked by Cons in clinics	No formal QA at present. Some audit of referral to ophthalmology	No QA
Systematic approach to screening	One digital camera in hospital clinic. GPs refer to local optometrists – slit lamp examination	90% patients screened in hospital clinics. Now also run GP only clinic	Clinics – approx 50% diabetic population. Sixty optometrists – slit lamp examination	Early stages of planning. Three options – buy in other service, fixed camera/hospital, local optometrist
Call/recall standardised	Currently GP is responsible. Some optometrists operate call/recall	Call/recall operated as part of normal clinic procedures	Hospital clinics/GPs – standard systems. Optometrists do in islolation	No call/recall system at present
Access to digital technology	One CR5/Sony One CR6/D30 on order	Three digital cameras (Topcon) in place at hospital sites. No plans to update	One camera meets HTBS standard Four cameras/hospital clinics 2/3 in optometry practices	One camera that meets HTBS spec. in optometrist/Kirkwall
Accreditation	Training course and accreditation by Cons Ophthalmologist and Diabetologist	No formal accreditation procedures in place	Optometrists accredited by Cons. Ophthalmologist on hold pending national training course	None at present
Funding	Bid being submitted to Board for capital and revenue funding	Submitted bid to HB for funding since HTBS report – to increase clinic sessions and provide programme manager	Draft report being prepared to upgrade system and bid for further funding	No specific funding identified at present
General comments	Claryifying and agreeing role of optometrists. Overcoming tensions between primary and secondary care	Key issue – QA of service because so many people involved not planning to involve optometrists	Keen to see national standards for call/recall fail-safe, training and patient information	Key issues – funding and establishment of diabetes register
Training	Current 'in house' training provided	Currently 'on the job' training provided by Diabetologists and Ophthalmologists	No formal training at present. Would use national training course for graders	No formal training/ accreditation at present
IT – screening software, etc.	Bid for retinal screening system about to go to tender	Priority to link cameras to LDS system. Poor after sales advice and support from camera company	SCI-DC Clinical and Network to be implemented by end of year. IT support has been a problem	Options appraisal – bandwith problems if provide distributed service, online transfer, e.g. to Grampian difficult. Could use CD-ROM.

Diabetic Retinopathy Screening

Barriers to Implementation	Shetland	Tayside	Western Isles
Links to CHI	No link to Board CHI at present	Yes – electronic link with nightly updates	No links – entered manually
Validity of local registers	GP returns put on computer database	Manual validation of data and web-based for primary/secondary care	Register validated and updated daily by one person
Variability of QA	Informal feedback from ophthalmologist on optometrist referral	10% all images double graded and monthly reports produced	Current QA undertaken by Ninewells
Systematic approach to screening	Options paper drafted – plan to link to Grampian service?	Pre-implementation stage – combine static and mobile eye screening to meet national recommendations	HB contract with Tayside mobile unit to screen at all GP practices in Western Isles
Call/recall standardised	Done by practices or ophthalmology clinic	Call/recall arranged at practice level – awaiting national dev. of SCI-DC	None at present. Possibly develop system with Strathclyde University
Access to digital technology	Ophthalmologists use mobile cameras. One optometrist has digital camera does not meet HTBS requirements	One static/one mobile plan to buy third one, appoint additional screener/grader	Using Tayside mobile. Clinicians do not see requirement to upgrade to HTBS recommendations
Accreditation	Visiting ophthalmologists	No accreditation currently	N/A
Funding	Opportunistic screening at present, mentioned in Health Plan, no figures available	Recently obtained recurring funding to implement programme meets national standards	Ongoing funding for mobile screening in place
General comments	Issues with logistics – small numbers, long distances, optometrists not viable because of QA	Limited by funding until recently – now ready to move forward	Wish to continue non-mydriatic protocol. Screening in van limits disabled access. Difficult to screen patients not picked up by van in remote/rural areas
Training	N/A	Will participate in HTBS training programme. Currently in-house supervision/dev. of staff	N/A
IT – screening software, etc.	Agreed data record (including RS data) between GPs, Cons, diabetologists. To be integrated with local ECCI system	Elements of national system implemented through SCI DC audit tool. New software incorporates all screening reporting for HTBS	Paper-based recording identification, invitation, recall, attendance and results

Diabetic Retinopathy Screening: **Annex I**

Glossary

BDR	Background Diabetic Retinopathy
CD	Compact Disc
CHI	Community Health Index (unique patient number)
CMS	Clinical Management System
CNA	Could Not Attend
CRT	Cathode Ray Tube
CSAGS	Confidentiality and Security Advisory Group for Scotland
CSBS	Clinical Standards Board for Scotland (now part of NHS Quality Improvement Scotland)
DNA	Did Not Attend
DRS	Diabetic Retinopathy Screening
DRSIG	Diabetic Retinopathy Screening Implementation Group
GP	General Practitioner
HDL	Health Department Letter
HEBS	Health Education Board for Scotland
HTA	Health Technology Assessment
HTBS	Health Technology Board for Scotland (now part of NHS Quality Improvement Scotland)
ICAG	Image Capture and Grading
IM&T	Information Management and Technology
ISD	Information and Statistics Division
IT	Information Technology
JPEG	Joint Photographic Experts Group (still image compression format)
LDSAG	Local Diabetes Service Advisory Group
LHCC	Local Health Care Co-operative
MCN	Managed Clinical Network
NHS	National Health Service
NSC	National Screening Committee
NSD	National Services Division
PDR	Proliferative Diabetic Retinopathy
PGD	Patient Group Direction
PMAR	Patient Management and Recall
QA	Quality Assurance

RNIB	Royal National Institute for the Blind
SCI-DC	Scottish Care Information Diabetes Collaboration (See Annex G)
SDG	Scottish Diabetes Group
SDS	Scottish Diabetes Survey
SEHD	Scottish Executive Health Department
SIGN	Scottish Intercollegiate Guidelines Network
SMR	Scottish Morbidity Record
STDR	Sight threatening diabetic retinopathy
TFT	Thin Film Transistor
WHO	World Health Organisation

Organisations and Contacts

Scottish Diabetes Group and Sub-Groups
Website address: http://www.DiabetesInScotland.org

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