Health Technology Board for Scotland

NHS SCOTLAND

Health Technology Assessment Report 1

Organisation of services for diabetic retinopathy screening

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1 EXECUTIVE SUMMARY

Background to Diabetic Retinopathy Screening and this Assessment

1. The Health Technology Board for Scotland (HTBS) estimates that there are approximately 150,000 people with diabetes in Scotland.

2. Approximately 5–10% of all people with diabetes have sight-threatening retinopathy (NHS CRD, 1999). Diabetic retinopathy is the biggest single cause of blindness and visual impairment in Scotland among people of working age. The rising prevalence of diabetes means that it will remain a major health and economic problem in Scotland.

3. The personal and social costs of blindness in terms of higher liability to dependence, potential loss of earning capacity, and increased likelihood of greater social support needs, are significant for individuals, for the caring services and for society.

4. In its early stages, diabetic retinopathy is symptom free and progression of disease can be prevented by laser treatment; so early detection by regular screening is beneficial.

5. A comprehensive survey by HTBS has shown that there is wide variation in the provision of diabetic retinopathy screening across Scotland. No National Health Service (NHS) Board has all the components in place to undertake quality assured population screening for diabetic retinopathy. Initiatives are underway to establish the screening service, but these are generally at early stages of development.

6. *Our National Health: a plan for action, a plan for change* (Scottish Executive Health Department, 2000a) recognised that NHSScotland should create a national screening strategy for diabetic retinopathy. **The *Scottish Diabetes Framework* (Scottish Diabetes Framework Working Group, 2001) recognises eye care as one of its most urgent priorities and declares the target that all people with diabetes will have their eye status (retinopathy) recorded on the local diabetes register by September 2003.**

7. **This HTBS Health Technology Assessment aims to determine 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 requirements.**

The Aims of The National Screening Programme

1. The primary objective of the programme is the detection of referable (sight-threatening) retinopathy.

2. A secondary objective is the detection of lesser degrees of diabetic retinopathy. This can have implications for the medical management of people with diabetes. It should be noted however that sensitivity for the detection of the earliest features of retinopathy (i.e. any retinopathy) may be low.

Health Technology Assessment Evidence

1. This Health Technology Assessment used systematic literature searching to identify evidence published in scientific literature. It also used evidence submitted by professional groups, patient groups, manufacturers, other interested parties and experts and undertook primary research with patients to elicit their views and preferences.

2. For clinical effectiveness, guidelines produced by the National Institute for Clinical Excellence (NICE), the Scottish Intercollegiate Guidelines Network (SIGN) and the UK National Screening Committee (UK NSC) were used as the starting point for assessment. Additional relevant studies were identified and added to the overall analysis.

3. The patient issues component used published scientific literature, educational materials from patient groups, patient surveys, discussions at the HTBS patient workshops and focus group work undertaken by HTBS in Scotland.

4. For the economic evaluation, information was obtained from existing UK diabetic retinopathy screening programmes and a comprehensive systematic literature review was carried out. A large number of scientific, technical and medical databases and the websites of key economic research groups in the UK, and abroad, were searched. From this, 1,388 citations were identified initially as being of possible use. Full text versions of 114 were obtained. Twenty-seven of these were used to inform modelling and three provided significant information for the model.

Clinical Effectiveness

1. Studies that screened people with diabetes and used a Gold Standard of seven-field stereoscopic photography or biomicroscopy by ophthalmologist were evaluated in detail for the clinical effectiveness analyses.

2. Failure rates were summarised according to individual study specifications.

3. Sensitivity and specificity estimates were combined for relevant combinations of screening technology/operator using receiver operating curves. Sensitivities were directly compared by standardising to a uniform value of specificity.

4. Meta-analysis was performed by modality/operator on all studies that fulfilled prestated selection criteria.

5. There are two main approaches to screening for diabetic retinopathy: ophthalmoscopy and biomicroscopy (slit lamps) or retinal photography with subsequent grading. All sensitivities and specificities were calculated for the detection of referable (sight-threatening) retinopathy.

6. Direct ophthalmoscopy does not achieve sufficient sensitivity to act as a screening test for sight-threatening disease and therefore should not be the basis of the Scottish national programme. However, it may be used for opportunistic screening in those who persistently default from the systematic national programme.

7. Indirect ophthalmoscopy (biomicroscopy) using a slit lamp has been shown to be sensitive and specific enough to be viable as a model for a national screening programme when used by appropriately trained individuals. It carries the disadvantage that there is no permanent record of the image for quality assurance or for monitoring progressive changes. However, biomicroscopy will be essential for screening failures from other modalities.

8. Retinal photography, with one or two fields (photographs), has been shown to achieve high sensitivity and specificity for sight-threatening disease. Advantages of digital photography are ease of image acquisition and storage, and quality assurance. The image may be transmitted electronically, facilitating external quality assurance. Consequently, digital retinal photography is the screening modality of choice.

9. Some eye pupils are small and need to be dilated with eye drops (mydriasis) before screening is performed. Furthermore, if more than one image per eye is required mydriasis is essential because of constriction of the pupil caused by the first photographic flash.

10. This HTBS Health Technology Assessment has found no clear evidence that mydriasis or the routine use of more than one image significantly alters the sensitivity or specificity of screening for the detection of referable (sight-threatening) retinopathy.

11. Studies using older (not digital) retinal cameras indicate that the proportion of unusable images is probably slightly lower when mydriasis is used and new studies suggest that this also applies to digital retinal cameras.

12. HTBS considered the evidence on imaging failure rates with and without mydriasis. In the most recent study of digital cameras, the failure rate was 20%. This is judged to be acceptable in the context of the three-stage failsafe procedure being recommended.

13. Studies canvassing patient opinion have suggested that mydriasis may reduce attendance for retinopathy screening because of its temporary effects on vision.

14. If mydriasis is used, tropicamide is the recommended agent. It must be administered by a professional complying with the Patient Group Directions (section 3.5.3) or on a named patient basis. The possible effects of the mydriatic agent should be clearly communicated to patients.

15. The ultra wide field scanning laser ophthalmoscope. It is a form of scanning laser ophthalmoscope with a field of view of 200 degrees internal angle which does not require mydriasis. Due to the paucity of evidence available on the use of this technology in diabetic retinopathy screening it is not recommended for use in the national screening programme until its technical failure rate and accuracy can be reliably determined.

Organisational Issues

1. The main organisational features of the proposed national screening programme in Scotland are:
    - strong quality assurance mechanisms;
    - systematic call/recall of all eligible patients (see point 6);
    - trained professionals;
    - recorded outcomes and robust quality assurance;
    - integration with the overall process of care for those with diabetes; and
    - evaluation and research as an integral part of the programme.

2. The national screening programme must be organised within current health service structures in Scotland, under the auspices of the National Services Division (NSD), who will ensure a consistent coordinated approach to the implementation of the national programme according to national quality standards.

3. Diabetic retinopathy screening is just one component of diabetes care and to be effective, the national screening programme must be integrated with routine diabetes care as outlined in the Scottish Diabetes Framework. Tight glycaemic control and careful blood pressure control both reduce the development and progression of diabetic retinopathy in type 1 and type 2 diabetes. Clinicians responsible for ongoing diabetic care must be fully informed of results, not only of sight-threatening retinopathy requiring referral to the ophthalmologist but also of any retinopathy.

4. The Clinical Standards Board for Scotland (CSBS) will work with the NSD to develop quality standards for this national screening programme, using generic screening standards being developed for other national screening programmes in Scotland, with additional items specific to diabetic retinopathy.

5. NHS Boards will have responsibility for implementation of the programme in their area to meet the needs of local people and for the monitoring of screening performance.

6. All patients diagnosed with either type 1 or type 2 diabetes mellitus and aged over 12 years, or post-puberty should have annual examinations of the retina.

7. No upper age limit is suggested, but those who are already undergoing regular reviews by an ophthalmologist, those who are medically unfit to receive laser treatment (as determined by their general practitioner) or who are completely blind, will not benefit from screening. However, for those under the care of an ophthalmologist, it is essential that the specialist retinal examinations are fully integrated into the medical record and call/recall systems for screening.

8. In the medium term, a fully integrated call/recall system will be developed as part of the national Information Management and Technology (IM&T) system Scottish Care Information – Diabetes Collaboration (SCI-DC). In the short-term, local systems should be designed to complement this emerging system

9. Screening using higher resolution digital cameras (1,365 x 1,000 pixels) is recommended, with images graded at capture resolution (i.e. not compressed). Image transfer should use a direct digital route to avoid degradation of quality. The image should be graded on a computer with a 19 or 21 inch cathode ray tube (CRT) monitor.

10. Any suitably trained, accredited and competent professional (diabetologist, ophthalmologist, optometrist or retinal screener) can grade the digital images, supported by second opinions, if necessary, from ophthalmologists and/or diabetologists. The same staff may be used for both grading and screening given suitable training for both roles.

11. A training, accreditation and continuing education programme is being developed for health professionals, to accompany this national screening programme. It aims to achieve uniform by high standards, whatever the background of the health professional. It was piloted in two Board areas in Scotland in spring 2002 and should be used as a framework for all training in Scotland.

12. A standard grading nomenclature for diabetic retinopathy is essential for consistent grading and so the newly defined Scottish Diabetic Retinopathy Grading System should be used.

13. Those patients who have sight-threatening retinopathy should be referred to a specialist eye clinic at the most convenient ophthalmology department and treated according to the Royal College of Ophthalmologists guidelines.

14. The clinical IM&T functions of the retinopathy screening programme should be consistent with the national Information Technology (IT) system for diabetes care that is being established in Scotland. Furthermore, the screening result and image should be incorporated into the computerised medical record.

15. 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. Optometrists should be linked with the national IM&T systems (e.g. NHSnet) and must adhere to the national quality assurance processes.

Patient Issues

1. The individuals involved in this screening programme are unlike those involved in most other screening programmes because they are already undergoing routine medical care for their condition. Also, unlike other screening programmes, patients are of both sexes, come from a wide age range and there is a higher prevalence in some ethnic minorities.

2. In common with all aspects of diabetes, patients must be empowered to help manage their disease; this requires support from, and collaboration between, clinical and patient organisations.

3. Diabetic retinopathy screening will be just one component of the annual screening programme for people with diabetes. Consequently, the goal should be to synchronise

this screening visit with other healthcare visits. However, this will need to be balanced against local capacity and the recognition that some patients would like a choice of venue and appointment time.

4. Patient preferences for diabetic retinopathy screening include a desire for clear, timely information about all aspects of screening, choice of screening venue and appointment time and a desire to be treated as an individual, rather than just 'another eye'.

5. Patient research has revealed that mydriasis is an undesirable feature of screening and some individuals would not return for screening if mydriasis was used.

6. Patients should be informed of the possible need for mydriasis and its effects before attending the screening visit. It should be clearly explained that there will be an increased sensitivity to light and that driving is not recommended for at least two hours after mydriasis, but that effects may last longer in some individuals.

7. A variety of methods should be used to inform patients about the screening process and to encourage screening attendance. It will be particularly important to encourage those who have never previously attended screening to do so and to prepare specific approaches to address all groups of patients (e.g. the young, those from ethnic minorities, etc.).

8. Research is required to determine the most efficient methods to increase screening uptake. For example, it has been shown that the issuing of more than two written reminders is not effective, but that contact with a health professional may help to overcome fears associated with screening.

9. Appointment cards and patient information should be available in accessible formats (large print, disk, audio).

10. General practitioners and patients should be informed of results in a timely fashion. The timeframe should be agreed at the outset of the national programme as one of the quality standards.

Economic Evaluation

1. The economic evaluation uses cost minimisation analysis to calculate the cost per screen for seven possible screening options. Five options of these assume a mydriatic national screening programme whilst the other two options are based on a non-mydriatic programme. The options also vary by location (hospital, GP's surgery or within a modified van) and by staff numbers (single or double staffing for the mydriasis options).

2. An economic evaluation has been used to model differences in the outcomes of two possible screening programmes on the existing population with diabetes. The model compares the effectiveness, measured in mean increase in sight days, of moving to either a non-mydriatic or a mydriatic national screening programme.

3. The utility gains, in terms of mean sight years, are expressed as quality adjusted life years (QALY), using values reported in the NSC report. Combining the QALY data with the costing information yields a cost per QALY of moving from an opportunistic

programme to a national screening programme based on either mydriasis or non-mydriasis. The analysis also shows the cost per QALY of moving from a systematic non-mydriatic based programme to a systematic mydriatic-based national screening programme.

4. Costings are based on information obtained from several large area diabetic retinopathy screening programmes within the UK. This allows comparison between the seven possible screening options. The costings assume a working year of 200 days during which units are operational, with an unfilled slot percentage of 5%. Staff costs take a midpoint from the relevant NHSScotland salary scale. Capital costs are from manufacturer quotes and have been annualised at a 6.0% real discount rate. There is no clear evidence on how patient travel and attendance costs vary between screening options. It has thus been assumed that average patient costs are the same for each option.

5. The final stage in the economic evaluation is to provide financial forecasts of the costs to NHSScotland of adopting the recommended three-stage protocol for a national screening programme for people with diabetes.

6. The following table presents the costs per screen for the seven screening options:

Cost per Graded Screen (including fixed costs)	Mobile GP-based one staff	Mobile GP-based two staff	Mobile Van-based one staff	Hospital-based two staff	Hospital-based one staff
Mydriatic	£32.28	£33.11	£30.06	£27.94	£26.56
Non-Mydriatic	..	..	£21.09	..	£21.04

To cost optometrist screening, £1.49 grading and £10.45 fixed costs should be added to the local optometrist's fees.

7. The components that have most influence on these costs are the patient turnaround times, and, for mobile units, the daily drive time required. Patient turnaround times for the base cases are 20 minutes for mydriatic photography with one staff member, 15 minutes for mydriatic photography with two staff members and 10 minutes for non-mydriatic photography. The base case daily drive time is two hours. These assumptions have been varied in the report to allow NHS Boards to calculate the likely costs within their areas, and to compare these with community optometrist charges.

8. The cost minimisation analysis indicates that single staffed, hospital facilities and single staffed, van-based, mobile units are least cost and that a non-mydriatic screening programme is cheaper than a mydriatic screening programme, if the faster turnaround times can be achieved.

9. For a programme based on non-mydriatic screening, the average costs of hospital-based screening are similar to the costs of operating a van-based facility. Local circumstances should determine which service is used. For rural areas, the costs of a mobile service should be compared to the level of optometrist fees. Major factors will be acceptable daily drive times and patient travel time.

10. The modelling shows that moving to systematic screening from an opportunistic programme is cost-effective for all people with diabetes.

11. Adopting a three-stage process for the national screening programme is estimated to cost NHSScotland approximately £3.7 million in the first year and £1.9 million per annum thereafter. The screening programme will result in more people with diabetes requiring some form of treatment to improve their sight. The additional annual treatment costs could be around £65,000.

The HTBS Proposed Model for Diabetic Retinopathy Screening

1. A quality assured national diabetic retinopathy screening programme is proposed that is sufficiently flexible to accommodate the needs of patients living in all communities (urban, rural and island) in Scotland.

2. Following evaluation and analysis of data and evidence available up to January 2002 on clinical effectiveness, organisational issues, patient issues and economics, HTBS proposes that the national systematic screening programme for diabetic retinopathy in Scotland uses 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.

   HTBS believes this sequential and pragmatic model optimises clinical effectiveness, cost-effectiveness and patient preferences. Evidence suggests that in approximately 80% of people, images suitable for grading and detection of referable (sight-threatening) retinopathy will be obtained through undilated pupils, so mydriasis will not be needed in the majority of patients. However, no patient will be denied mydriasis when it is necessary and patients known to require mydriasis should start at the second stage. This sequential, potentially three-stage, process is felt to be both efficient and failsafe.

3. The screening/grading will be performed by appropriately trained, accredited and competent professionals.

4. A national survey (Appendix 2) indicates that a large number of local schemes exist in Scotland but none meets the required specifications of a national scheme. It is important that the introduction of the national screening programme for diabetic retinopathy does not disadvantage these existing schemes but allows for their enhancement to meet the approved quality assured specifications.

5. Screening must be accessible to all patients, whether they receive community-based and/or hospital-based diabetic care. HTBS has made no restrictive recommendations

on the organisation of the programme in any area, or precluded any professional groups from participating in the screening programme. The local implementation must allow easy access for patients and may include services in diabetes centres, primary healthcare facilities, mobile vans or community optometrists.

6. Several important research questions have been identified in this Health Technology Assessment. One of the key questions relates to the performance of the sequential three-stage screening model. This will be addressed in the first year of the roll out of the programme, taking account of data arising from this programme and that available elsewhere, particularly in the rest of the UK. This will allow modifications to be made to improve the efficiency of the Scottish screening programme.

7. HTBS recommends that the national programme for diabetic retinopathy screening is achieved by building upon established local systems: evolution rather than revolution, with best practice and learnings shared across Scotland. This will be achieved with the help of the Scottish Diabetic Group who will be taking forward implementation of this programme in 2002.

2 INTRODUCTION

The Health Technology Board for Scotland (HTBS) uses the internationally recognised definition of Health Technology Assessment as a multidisciplinary field of policy analysis that considers the medical, social, ethical and economic implications of the development, diffusion and use of health technology (INAHTA, 2001).

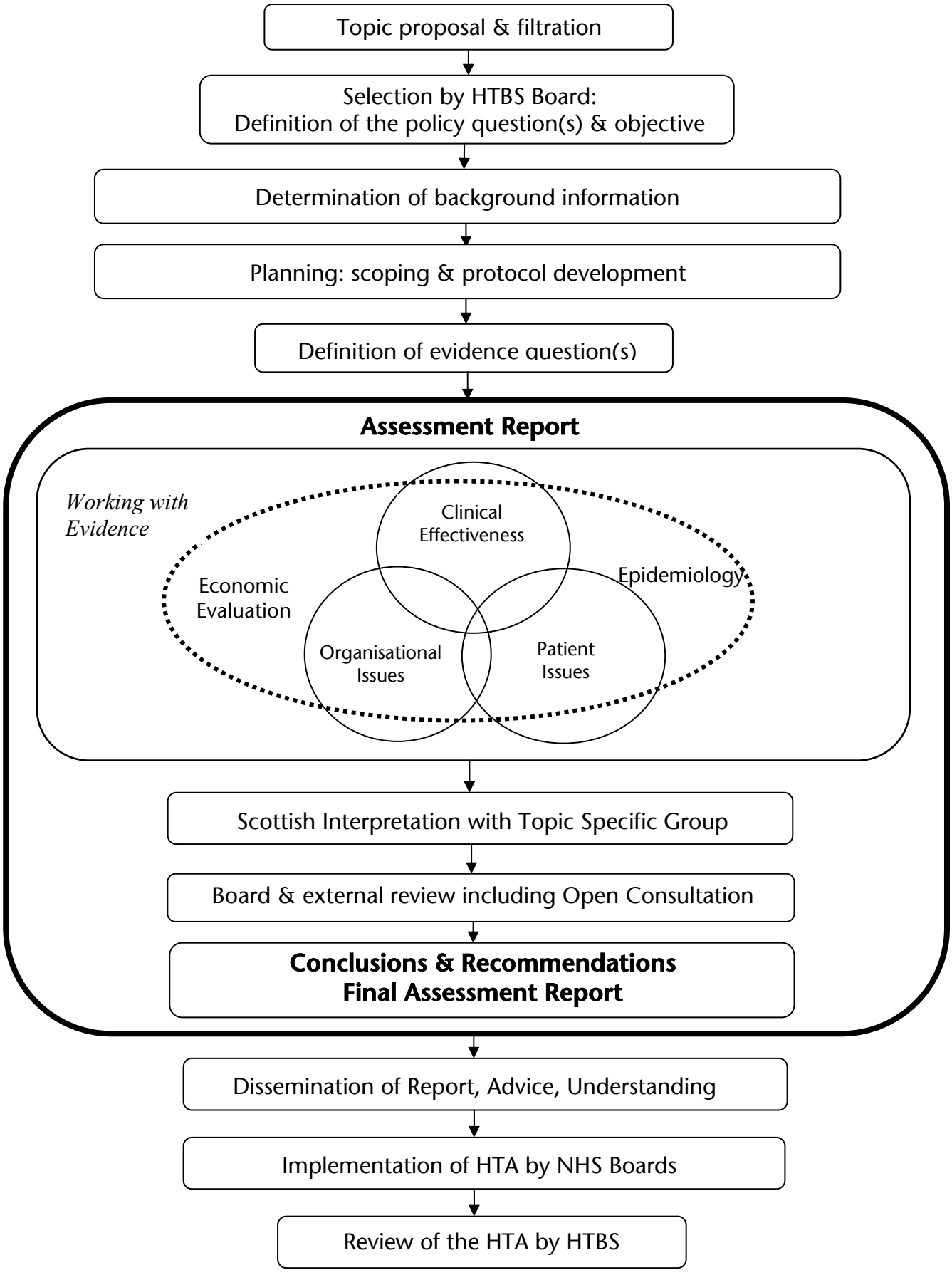
This form of Health Technology Assessment takes account of the four components identified in Figure 2-1: clinical effectiveness, organisational issues, patient issues and economic evaluation. National and international evidence is critically appraised, taking account of Scottish circumstances, so that clear and practicable recommendations can be made to NHSScotland. The aim is to influence decision-making based on critically appraised evidence and shared best practice.

This Health Technology Assessment follows the process published by HTBS in January 2001 (HTBS, 2001) involving submission of evidence from a wide variety of sources, robust analyses undertaken by expert staff, use of a multidisciplinary expert Topic Specific Group (TSG) to collect and critique evidence and analyses, quality assurance by the HTBS Governance Board and wide-ranging open consultation.

The key objective of this Health Technology Assessment is to determine the most effective and efficient approach to achieving, implementing and sustaining a quality assured, comprehensive national screening programme for diabetic retinopathy that takes account of patient requirements.

This detailed, scientific assessment report has been updated throughout the assessment process to take into account the views of expert reviewers and consultation comments. It is accompanied by *Health Technology Assessment Advice 1: Organisation of services for diabetic retinopathy screening* (HTBS, 2002a) that summarises the Health Technology Assessment findings and an *Understanding HTBS Advice: Diabetic retinopathy screening in Scotland* (HTBS, 2002b) document, which is suitable for, among others, the general public, patients and carers.

Figure 2-1 Health Technology Assessment (HTA) process



3 BACKGROUND

3.1 Introduction

3.1.1 Rationale for this Health Technology Assessment

In 1989, a meeting of international diabetes experts and patient group representatives resulted in the *St Vincent Declaration* (WHO, 1989). It specified research and organisational goals to improve diabetes care and set five-year targets for reduction of complications arising from diabetes. In 1995, a multidisciplinary group in the UK issued a key target to reduce new blindness due to diabetes by at least one-third (St Vincent Joint Task Force for Diabetes, 1995). This goal was set for the year 2000, but has not yet been achieved in Scotland.

When deciding upon its first topics for Health Technology Assessment, HTBS noted the Government's commitment in *Our National Health: a plan for action, a plan for change* (Scottish Executive Health Department, 2000a), to establish a national screening strategy for diabetic retinopathy.

> In 2001, we will launch a Scottish Diabetes Framework to draw together existing guidance and best practice in order to raise the standard of diabetes care. The Framework will include plans to establish a national screening strategy for diabetic retinopathy. Although there are SIGN guidelines already in place and much work being done in diabetes, we need to consolidate and build on this in order further to raise the standard of care.

The *Scottish Diabetes Framework* (Scottish Diabetes Framework Working Group, 2001) was launched in November 2001 and will shape the delivery of diabetic care in Scotland over the next five to ten years. **The *Scottish Diabetes Framework* (Scottish Diabetes Framework Working Group, 2001) recognises eye screening as one of its most urgent priorities and declares the target that all people with diabetes will have their eye status (retinopathy) recorded on the local diabetes register by September 2003.**

Important work has been undertaken over the past few years in the field of diabetic retinopathy screening. The SIGN guideline (SIGN, 2001) evaluates the clinical effectiveness of methods for prevention of visual impairment in people with diabetes (section 5.3.1). The National Institute for Clinical Excellence had been developing a clinical guideline on diabetes and this was published at the time this report went to press (NICE, 2002). However, a draft form of the full guideline supporting the NICE guidance was available for use in December 2000 (Hutchinson *et al*., 2000a). This was used as a base for clinical effectiveness work and is little changed in the final version (Hutchinson *et al.,* 2001). Also, the UK NSC (UK NSC, 2000) has considered many aspects of the establishment of a screening service for diabetic retinopathy. These documents give insights into the key requisites for a screening programme, but they do not fully address issues related to the organisation of such a programme in Scotland, including patient issues, or an economic evaluation of various diabetic retinopathy screening service options. This HTBS Health Technology Assessment will consider these issues in the light of new analyses using published data and other evidence available up to February 2002.

The aim of this Health Technology Assessment is to advise on a comprehensive screening strategy for diabetic retinopathy that is based upon best available evidence, is feasible and sustainable. The goal is to introduce a quality-assured, effective and efficient, systematic national screening programme that is integrated with clinical services for diabetes in primary,

secondary and community care; it should take account of patient requirements in order to provide a service in which patients have confidence, hope, empowerment, clarity and knowledge.

3.2 Description of Health Problems in Scotland

3.2.1 Epidemiology of diabetes

Diabetes is a common, lifelong disease that results in an impaired ability to control the amount of sugar in the blood.

Type 2 (non insulin-dependent) diabetes is the most common form of diabetes. Type 2 diabetes usually appears in people aged over 40 and has a high prevalence in people of South Asian and Afro-Caribbean origin. The remainder of the diabetic population have type 1 (insulin-dependent) diabetes, which usually occurs before the age of 40, often in childhood.

The first Scottish Diabetes Survey (Scottish Diabetes Survey Monitoring Group, 2001) was published by the Scottish Executive in November 2001. Sixteen percent were recorded as having type 1 diabetes. In addition to prevalence levels which are similar to those found in the HTBS survey (section 3.6), this survey gives age and sex distributions by NHS Board - for the whole of Scotland. Fifty-three percent of those registered were male. Twenty-two percent were under 45 years, 33% were between 45 and 64, 24% between 65 and 74 and 21% were 75 or over.

The Audit Commission (2000) estimated that diabetes currently affects approximately 3% of the population in the UK and that this figure may double by 2010 as a result of obesity and an ageing population.

The Diabetes UK Campaign 2001 *Too many, too late,* stated that there are approximately 120,000 people who have been diagnosed with diabetes in Scotland and there could be as many as 90,000, as yet undiagnosed. These prevalence data were extrapolated from the Diabetes Audit and Research in Tayside Scotland (DARTS) project (Evans *et al.*, 2000) and those undiagnosed were extrapolated from Forrest *et al.* (1986b), Harris *et al.* (1987) and Simmons *et al.* (1991).

The baseline survey carried out by HTBS (section 3.6) suggests that the recorded prevalence of diabetes is approximately 2.5%. However, as the establishment of diabetes registers is now mandatory across Scotland, recorded prevalence is likely to increase with improved case ascertainment as has occurred elsewhere (Grimshaw *et al.*, 1999). Examples of this are seen in Lanarkshire, where the recorded prevalence of diabetes has risen from 2.0% to 2.8% in four years and in Tayside where prevalence has increased from 2.2% to 2.5% from 1991 to 2001.

Taking account of some under recording, if the true prevalence is 3% in the Scottish population, of 5,120,000, this implies that an estimated 153,600 people in Scotland have diabetes, i.e. **approximately 150,000 people in Scotland have diabetes**.

3.2.2 Multi-specialty nature of diabetes care

Diabetes can lead to premature death and long-term complications. However, with regular assessment and good management the serious complications associated with diabetes can be minimised.

All people with diabetes require access to comprehensive care, to maximise quality of life by detecting and treating the disease and its complications at an early stage, to minimise premature morbidity and mortality. This requires close collaboration between many healthcare professionals to ensure:

- continuing education;
- annual checks of eyes and vision, kidney function, feet and general well-being;
- assessment of risk factors for macrovascular and microvascular diseases such as glycated haemoglobin (HbA1c), blood pressure, cholesterol, anaemia and smoking habits;
- assistance with self-monitoring and injection techniques;
- eating and lifestyle advice; and
- regular reviews of progress and treatment.

The *Scottish Diabetes Framework* (Scottish Diabetes Framework working Group, 2001) and associated standards developed by the CSBS (2001) cover all aspects of diabetes care. Screening for diabetic retinopathy is just one vital component of diabetes care that must be integrated with this overall care package.

3.2.3 Organisation of diabetes care in Scotland

In view of the multi-specialty nature of diabetes care, Diabetes UK advocates the model of local diabetes services advisory groups (LDSAGs) that provide a forum for monitoring, reviewing and appraising local services. (www.diabetes.org.uk/ldsags/more.htm) The *Scottish Diabetes Framework* (Scottish Diabetes Framework Working Group, 2001) has endorsed the creation of LDSAGs at Board level, as a key step in the development of formal managed clinical networks (MCNs) for diabetes care in each NHS Board.

The *Scottish Diabetes Framework* also recommends that:

- MCNs for diabetes care should be established at Board level;
- Boards will be responsible for the clarity of network arrangements – this will be coordinated through the successful model of LDSAGs;
- each Board will publish a publicly available annual diabetes report as well as submitting information to the Scottish Diabetes Survey (Scottish Diabetes Survey Monitoring Group, 2001);
- the local report will contain a clear statement of specific service and clinical improvements, and objectives for service improvement;
- MCN coordination groups/LDSAGs will be truly multi-disciplinary/multi-professional with representation from patients playing a central role;
- MCN coordination groups/LDSAGs will develop a clear policy of patient involvement and dissemination of information to patients;
- the MCN coordination group/LDSAG will oversee a local quality assurance programme consistent with the standards established by the CSBS; and

- the MCN coordination group/LDSAG will establish a clear educational, training and continuing professional development programmes as an integral parts of the network.

Effective care involves partnerships between patients and all healthcare professionals who contribute to diabetes care in a locality. This philosophy and culture applies at least as much to systematic screening for diabetic retinopathy as it does to all other aspects of effective care provision.

3.3 Diabetic Eye Disease

Retinopathy and maculopathy both commonly threaten the sight of people with diabetes.

Background (Non-Proliferative) Diabetic Retinopathy (BDR)
Diabetic retinopathy is a complication of diabetes that affects the small blood vessels of the retina. Diabetes can cause these small blood vessels to block off resulting in the retina being starved of food and oxygen. If enough small blood vessels block then the eye tries to grow new blood vessels (proliferative diabetic retinopathy).

Proliferative Diabetic Retinopathy (PDR)
The new vessels created by proliferative diabetic retinopathy are useless because they grow into the middle of the eye. They can cause blindness by bleeding and/or by pulling the retina off the back of the eye.

Sight-threatening Diabetic Retinopathy (STDR) and Referable Retinopathy
The term sight-threatening diabetic retinopathy and referable retinopathy are often used interchangeably, leading to confusion. Sight-threatening diabetic retinopathy refers to the presence of new vessels and/or clinically significant macular oedema. Referable retinopathy refers to retinopathy that should be examined more frequently, often in a more detailed way, as it is anticipated that there is a high chance that sight-threatening retinopathy will occur soon. (Ideally ophthalmologists would only wish to see patients with sight-threatening retinopathy, because it is these patients who require assessment for laser treatment.)

Maculopathy
If small blood vessels block off in the centre of the retina then sight can be affected before new blood vessels are formed. This can be a result of the damaged vessels leaking fluid and blood (focal maculopathy) or simply because so many small vessels are damaged that that part of the retina ‘dies’ (ischaemic maculopathy). Early detection and stringent control of risk factors is the most important aspect of treatment.

Retinopathy can be detected by two-dimensional retinal images alone but the thickening of the macula associated with maculopathy cannot be directly detected and must be inferred from other abnormalities. This makes the impact of screening on maculopathy less clear. Consequently, this HTA focuses on a screening programme for diabetic retinopathy.

Screening and Laser Treatment
In its early stages, retinopathy causes no symptoms, so if it is to be detected and treated before it becomes sight-threatening, regular retinal examination is necessary. Timely laser photocoagulation is effective at treating the new vessels in the retina to prevent the extensive neovascularisation, haemorrhage, traction and detachment of the retina that leads to visual impairment.

Exudative or focal maculopathy responds well to laser treatment, but laser treatment is not effective for the treatment of ischaemic maculopathy. Diffuse maculopathy may not always respond very well to laser treatment. In such patients, laser may be best reserved for when vision first starts to decline, as recently suggested by the Early Treatment of Diabetic Retinopathy Study (ETDRS) group (1991). Decline in vision may be reported by the patient or detected on testing visual acuity (VA), as recommended by the UK National Screening Committee (UK NSC) and should result in referral for further investigation.

Visual problems caused by diabetic retinopathy are one of the most common specific complications of diabetes (NHS CRD, 1999). The percentage of patients newly diagnosed with type 2 diabetes who have some retinopathy is not clear but thought to range between approximately 20% and 40% and approximately 5–10% of all people with diabetes have sight-threatening retinopathy (NHS CRD, 1999). Blindness is one of the most feared complications of diabetes with an incidence of 50–65 per 100,000 diabetic population per year in Europe (SIGN, 2001). Furthermore, diabetes is the most common cause of blindness in people of working age in industrialised countries (Williams, 1994).

The UK NSC report (UK NSC, 2000) presents the following results from peer-reviewed articles. Untreated, between 6–9% of people with proliferative retinopathy or severe non-proliferative disease would become blind each year. However, laser treatment for proliferative retinopathy with high-risk characteristics achieved a relative risk reduction in severe visual loss of 51.5%. This protection has been shown to endure for over ten years in two-thirds of laser-treated patients and epidemiological data indicate that each successful treatment will give at least five years of preserved sight. With appropriate medical and ophthalmological care, blindness may be prevented in at least one eye in over 90% of patients with proliferative retinopathy.

3.3.1 Blindness due to diabetic retinopathy in Scotland

Cormack *et al.* (2001) have studied social work department blindness registration records in Fife from the period 1990–9 to identify those patients whose main diagnosis was diabetes. Out of 2,529 people with diabetes, the mean number of blind registrations per year due to diabetes was 4.3 (95% CI 3.3 to 5.3).

At the end of December 1999, the prevalence of blindness due to diabetes was 210 per 100,000 diabetic population and the incidence of blindness due to diabetes was 64 per 100,000 diabetic population per year (95% CI 49 to 79 per 100,000 diabetic population per year) (Cormack *et al*., 2001). However, these are probably underestimates of the level of disease because the only record of legally recorded blindness in the UK comes from social work records. Also, patients may have mixed aetiology and diabetes may not be specifically identified. Furthermore, existing routine health service record systems do not reliably identify patients with diabetic eye disease or events associated with healthcare of diabetic eye disease. Consequently, special surveys or clinical audits are needed at present to identify the real burden of diabetic retinopathy and to link cases identified to previous screening histories. *The Report of the Certification and Registration Working Group* (Scottish Executive, 2001a) summarises the start of an initiative that will improve the extent of blindness registrations. HTBS has written to this group to stress that the clear recording of underlying disease, particularly that of diabetes, should be carried out in the new scheme.

The Royal National Institute for the Blind (RNIB) Scotland (Consultation comment, 2002) has determined that in Scotland in 1996, approximately 35,000 people were registered blind or partially sighted. By determining prevalence by age-group and applying this to the Scottish population they estimate that this figure should be nearer 87,000, i.e. the true figure for those who are blind or visually impaired may be more than double that registered. However, it is unclear whether those who are blind (as opposed to visually impaired) or those with diabetic retinopathy would be more likely to register. Even so, this seems to confirm that the data from Fife registration records (Cormack *et al* 2001) will lead to an underestimate of those who are blind as a result of diabetes.

3.3.2 General eye examinations

In the last fiscal year (2000/2001), Scottish health service statistics showed that optometrists performed 35,347 general eye examinations on people with diabetes (Common Services Agency Information & Statistics Division, 2001). This is only 20% of the estimated diabetic population.

Diabetic retinopathy screening will not obviate the need for a regular general eye examination to monitor changes in refraction and to detect other eye diseases. However, if patients are undergoing annual eye screening, it may be possible to increase the time between general eye examinations to more than one year. The College of Optometrists guidelines (2001b) on this should be followed.

3.4 Perspectives

3.4.1 The purpose of the Scottish national screening programme for diabetic retinopathy

The second report of the UK NSC (UK NSC, 2001) defines screening as:

> A public health service in which members of a defined population, who do not necessarily perceive they are at risk of, or are already affected by, a disease or its complications, are asked a question or offered a test, to identify those individuals who are more likely to be helped than harmed by further tests or treatment in order to reduce the risk of a disease or its complications.

Clearly, diabetic retinopathy screening accords well within this definition.

For the national diabetic retinopathy screening programme in Scotland the goal is to reduce the rate of avoidable visual loss from diabetic retinopathy using an effective and efficient, quality assured process that takes account of patients' needs and preferences.

The objectives of the Scottish screening programme may be stated quite simply 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.

It should be noted that sensitivity for the detection of the earliest features of retinopathy (i.e. *any* retinopathy) might be low in the screening programme and so regular checks are essential.

3.4.2 Introduction of systematic screening

Experience from the Scottish Breast Screening Programme (Forrest, 1986a; Anon, *Lancet* editorial, 17 August 1985; Scottish Office, 1999), the Scottish Cervical Cytology Screening programme (Scottish Cervical Screening Programme, 2000) and programmes in other countries such as New Zealand and Iceland have shown clearly that the establishment and maintenance of population-based systematic screening programmes is complex. The introduction of the 'technology' of systematic screening for diabetic retinopathy in Scotland will require detailed attention to organisational and training issues as well as to the choice of the screening tests or procedures. There must be explicit responsibilities at NHS Board level to determine optimal approaches for the local population, but local approaches must link in to a national unified system for diabetes, which has comprehensive audit and quality assurance mechanisms in place.

3.5 Description of the Technology

3.5.1 Retinal imaging devices

Screening for diabetic retinopathy and maculopathy is accomplished by imaging the retina of the eye through the pupil. Various instruments exist for this purpose. Ophthalmoscopes are instruments containing an arrangement of lenses and a source of illumination that allows direct visual inspection of the interior of the eye. The hand-held direct ophthalmoscope forms part of the armamentarium of most GPs but studies have reported low screening accuracy for this instrument (section 5.3.5.4) and hence the indirect ophthalmoscope or biomicroscope illuminated by a slit lamp, is preferred by many optometrists and ophthalmologists. The biomicroscope (slit lamp) has an added advantage in that it gives a stereoscopic view which allows an appreciation of depth. These devices are part of the standard tool kit for optometrists and are thus widely used across Scotland.

Retinal cameras are newer technologies that allow photographs of the retina to be taken. They consist of an optical system that is designed to focus on the retina. On top of the optical system an image capture device such as a 35 mm film or a digital camera is mounted. The current established Gold Standard photographic method for diagnosis of retinopathy uses seven overlapping stereoscopic fields with an angle of view of 30 degrees. However, this method would be too time consuming for a mass screening programme. The cameras for screening generally have an angle of view between 45 and 50 degrees. This allows the whole of the posterior pole of the eye to be captured in a single image but it may still be necessary to view the more peripheral retinal areas and hence two or more overlapping images can be taken. The early retinal cameras used conventional photographic film but modern cameras produce digital images that can be stored on a computer for subsequent review (section 6.10). Most published studies reported in section 5 have used conventional film cameras.

All these imaging methods are non-invasive and require no contrast enhancement agents. However, it is usually easier to image the retina when the pupil is dilated and so mydriatic eye drops are often used in conjunction with these instruments. Many retinal cameras use the light of a wavelength, to which the eye does not respond for focusing and this allows an image to

be taken without mydriasis. Such cameras are referred to as non-mydriatic. However, the pupil does constrict in response to the camera flash, and so only one image can be taken in a short time span, and peripheral field shots on the nasal side of the optic disc are intrinsically difficult without mydriasis.

The most recent development in imaging is the ultra wide angle scanning laser ophthalmoscope, which is a new development in scanning laser ophthalmoscope technology that has been awarded its CE mark in Europe. It produces digital images similar to a retinal camera but with a wider angle of view (200 degrees) allowing the entire retina to be viewed on a single image. The image size has a resolution of up to 2,000 x 2,000 pixels, with 20 μ per pixel on axis and 40 μ per pixel off axis. It uses a collimated laser beam to scan the fundus and so can penetrate cataracts and does not require mydriasis. The digital information is received as a full colour composite image using red and green laser wavelengths that can be instantly viewed, enlarged and separated, if necessary. Images can be written to CDs and/or electronically transferred. The average image time for both eyes is stated by the manufacturer to be five minutes.

3.5.2 Image interpretation

The protocol that specifies how to classify the pathological features observed during retinal imaging and the subsequent grading of the patients is an important part of the screening system (section 6.9). It should be sensitive and specific to the conditions to be detected, clearly specified and capable of producing reproducible results from different observers.

3.5.2.1 Technical failure

With any digital device a technical failure may occur, that is failure to obtain an image of adequate quality for reliable grading. A structured definition of image quality is presented below.

Image Quality Grade	**Description**
1 (best)	Nerve fibre layer visible
2	Nerve fibre layer not visible
3	Small vessels blurred
4	Major arcade vessels just blurred
5 (worst)	Significant blurring of major arcade vessels in >one-third of image

In the vast majority of cases, the image will be degraded because of cataract or small pupils. The image quality grade that should be considered to be indicative of a technical failure is subjective and depends on whether any retinopathy is to be detected or just STDR.

3.5.3 Eye drops

Eye drops are administered for pupil dilation (mydriasis). Mydriacyl® (tropicamide BP) is a short-acting cholinergic agent licensed for mydriasis and the British National Formulary (BMA and RPSGB, 2001) notes its use in retinal photography. Minims phenylephrine hydrochloride is licensed for topical use in the eye as a mydriatic agent and may be indicated to dilate the pupil in diagnostic or therapeutic procedures. Some services in Scotland use these

drops in combination for mydriasis prior to retinal examination (but there is no clear indication for this).

During consultation it was identified that topical ocular anaesthetic (such as proxymetacaine hydrochloride) is used by some ophthalmologists in Scotland to ease the stinging that can be associated with instillation of tropicamide.

As mobile units permit the administration of drops outside a general healthcare setting, all those administering the drops should be trained about the possible side-effects, contra indications and potential for interactions with tropicamide. Furthermore, as eye drops take 20 minutes to achieve full effect, waiting facilities will be required for patients after the eye drops have been administered.

Eye drops may be legally administered on a *named patient basis* by any (appropriately trained) individual, using a prescription written in advance for each patient attending screening. However, as eye drops are only required for patients in whom a non-mydriatic digital retinal photograph is ungradeable (section 9.2.2), only a minority of patients are expected to require eye drops. Consequently, it will not be possible to determine these patients in advance of screening (when the prescriptions are written). An alternative approach to using named patient prescriptions for everyone, is to administer eye drops to a group of patients not individually identified in advance, using a Patient Group Direction. The Patient Group Direction is a legal written instruction drawn up by doctors, pharmacists or other health professionals for the administration of named medicines in an identified clinical situation. It must be authorised by a senior member of the NHS Trust (e.g. a clinical governance lead) and prescription is restricted to a limited set of professionals.

The Medicines Control Agency (MCA) is currently consulting on changes to the legislation regarding *Patient Group Directions* with a plan to implement changes in 2002 (http://www.mca.gov.uk/). Annex B of the MCA consultation document indicates the information that must be given in a *Patient Group Direction*. The new proposals from the Medicines Control Agency also seek to extend the current directions, which restrict prescription to ambulance paramedics, pharmacists, health visitors, midwives, nurses, optometrists and chiropodists to include radiographers, orthoptists and physiotherapists. Under the current and newly proposed legislation only an optometrist or Grade D nurse would be allowed to administer eye drops under a *Patient Group Direction* in the national screening programme (not retinal screeners).

Discussion is underway between HTBS and the Medicines Control Agency to determine whether this can be extended to cover retinal screeners and this should be clarified at the implementation stage of this screening programme.

3.6 Current Service Provision of Diabetic Retinopathy Screening in NHSScotland

The Scottish Executive undertook a survey (Scottish Executive Health Department, 2001) in 2000 (Appendix 3) to identify the extent of services for diabetic retinopathy screening across Scotland. The responses demonstrated large variability in service provision for diabetic retinopathy screening across Scotland; but also various examples of good practice which could be shared in areas throughout Scotland where systems are currently under development.

Some areas do not yet have registers fully in place, are unsure of the number of people with diabetes in their area and have no systematic screening in place, but one area (the Western

Isles) screens 93% of all known diabetic patients over the age of 12 annually (using the Tayside mobile screening unit).

The survey indicates that a variety of methods exist for delivery of screening, including mobile vans, static cameras located in healthcare facilities and local optometrists. As there was no consistency in screening methodology across the country, HTBS undertook a more detailed baseline survey in June 2001 about diabetic retinopathy screening service provision with each NHS Board. The HTBS questionnaire is presented in Appendix 4. All 15 NHS Boards in Scotland responded to this detailed questionnaire and so this survey provides invaluable information about current service provision from the whole of Scotland. The full listing of responses is presented in Appendix 2, with a detailed overview in Appendix 5. In summary:

- No NHS Board has all the components required for a comprehensive population-based systematic screening programme for diabetic retinopathy in place at the present time. Most areas, however, report initiatives to establish such services, the majority being at the early stages of development.

- Diabetes registers are stated as 'established' in seven Board areas, 'being developed' or 'being populated' in six further areas and 'being planned' in the remaining two Board areas. However, updating of the established registers varies from daily to annually with a similar variation in the frequency and depth of quality assurance checking. Linkage of the diabetes register to NHS Board Community Health Indexes (CHIs) (Womersley, 1996) also varies considerably.

- While use of standardised data collection sheets is stated to be in place in ten NHS Board areas, systematic collection and compilation of the results in order to enable organised call/recall is only in place in four areas.

- Accreditation of 'screeners' (section 6.12.5.1) is organised locally, usually by ophthalmologists. These have focused upon community optometrists with some hospital clinicians and 'a few GPs' in some areas. Formal refresher training after accreditation is also in place in at least five Board areas. No scheme appears to have a national context.

- Formal quality assurance of registers, the screening test and overall screening process is highly variable with most areas being at the very early stages of development. The baseline survey identified only four NHS Board areas where audit of cases of diabetic retinopathy took place and only two areas where audit of the previous screening history of new cases took place.

- Most Boards have established steering groups using the LDSAG model (section 3.2.3).

- Four NHS Board areas state that there is organised screening using digital camera technology. The other areas use a mixed model of accredited optometrists (and some GPs) with some digital camera use mainly within hospital clinic settings. Two NHS Boards are at the earliest stage of setting up programmes.

- Most areas reported use of Board or Trust 'development monies', audit budgets or other funds to employ facilitators or to purchase equipment. While three areas

reported substantial recent investment, others stated that existing or historical funding was either now insufficient or uncertain for future full systematic screening to be sustained or achieved.

- Three hundred optometrists are involved in the current opportunistic and local systematic screening programmes in Scotland. Another unpublished survey performed by the Common Services Agency (CSA) of NHSScotland indicated that during 1999/2000, optometrists in seven NHS Boards performed 8,494 diabetic screening tests (S. Patel, Personal communication, 2001).

4 SOURCES OF EVIDENCE

The Health Technology Assessments undertaken by HTBS use international evidence from a variety of sources: published literature, grey literature (e.g. academic and government reports, website publications, conference abstracts), information submitted from a variety of interested parties and primary research to determine health service needs and patient views.

To determine the status of the provision of screening across Scotland, HTBS designed and undertook a detailed survey of all NHS Boards in Scotland (Appendix 4).

The following interested parties were invited to submit evidence for this assessment. All but one group submitted evidence or commented on the Consultation Report.

Manufacturers
All members of the Association of British Healthcare Industries: one submission received from Optos plc.

(Further evidence was taken from websites of the following manufacturers – Zeiss, Haag-Streit, Canon, Topcon.)

Professional/Specialist groups
College of Optometrists
Scottish General Practitioners' Committee
Royal College of Ophthalmologists
Association of British Clinical Diabetologists
Royal College of Nursing (Scottish HQ)
Breast and Cervical Screening Coordinators' Group
Royal College of Physicians (Edinburgh)
Royal College of Physicians and Surgeons of Glasgow
Royal College of General Practitioners (Scotland)
Scottish Association of Health Councils
Social Work Services Group

Patient groups
Diabetes UK
RNIB

For clinical effectiveness, the section on prevention of visual impairment of the SIGN guideline (2001) on *Management of Diabetes*, the draft NICE Guideline (Hutchinson *et al.*, 2000a) and the report of the UK NSC (2000), were used as the main bases for evidence. These reports were augmented with additional published references identified by the HTBS expert TSG and key publications issued in 2001 and early 2002 (section 5). Two datasets from studies using digital cameras, which were finalised in 2001, were also submitted and analysed in detail (Olson *et al*., 2001 and Scanlon *et al*., 2002).

For organisational and patient issues, focus was placed on the submitted evidence, selected literature references and grey literature from a variety of sources. For patient issues, focus group work was also commissioned to determine patient views.

For the economic evaluation, information was obtained from existing UK diabetic retinopathy screening programmes and a comprehensive systematic literature review was performed.

In addition, the TSG (Appendix 1) who assisted HTBS staff with this assessment submitted a variety of forms of evidence including patient leaflets, NHS Board Joint Investment Fund plans, position papers, job descriptions, etc. Also, special advisers from across the UK submitted valuable information about existing local screening programmes (sections 8 & 9).

A six-week public consultation was also held on the consultation draft of this Health Technology Assessment Report. This began with a public meeting and workshops to discuss issues related to patients, mydriasis, audit and organisation of the proposed screening model.

The report was also issued to interested parties across the UK and was available from the HTBS website for comment. Thirty-three written comments were received on the report during the consultation period, from a variety of individuals and organisations, including patients, optometrists, Health Councils, Colleges, voluntary organisations and academic units. HTBS is grateful for the detailed manner in which many people read the report and for the constructive critiques offered. The comments generally welcomed the breadth of the assessment and indicated areas that would need extra thought particularly with regards to implementation. These comments can be read in full on the HTBS website (www.htbs.co.uk).

Nine comments were received after the end of consultation. To ensure fairness to all consultees, these comments have not been officially included as part of the consultation.

5 CLINICAL EFFECTIVENESS

Summary

- Studies have produced inconsistent technical failure rates for screening methods but all methods will result in some failures. Two modern studies of digital photography with mydriasis have found failure rates of between 4% and 12%. Older studies of conventional photography without mydriasis found failure rates within a range from 5% to 14%. Direct comparisons suggest that mydriasis may occasionally result in a successful image when non-mydriatic imaging fails.

- Statistically robust meta-analyses of the joint sensitivity and specificity of a variety of eye screening devices/operators from studies using appropriate blinding and Gold Standards yielded the following results:

    - Direct ophthalmoscopy has low sensitivity and is not recommended for a systematic screening programme. However, it will remain useful for persistent defaulters who would otherwise receive no retinal examination.

    - There are no recent studies of slit lamps used by optometrists, which have Gold Standard evaluations performed blinded to other results. Evidence available from older studies indicates low sensitivity (62%) for 95% specificity. This would be expected to be higher with a trained and accredited optometrist.

    - For digital photography and trained graders, at 95% specificity the sensitivity is 88% (95% CI 60% to 98%) with mydriasis and 86% (95% CI 31% to 100%) without mydriasis. Thus comparable screening accuracy is achieved with digital cameras, with or without mydriasis. There is considerable uncertainty associated with each estimate, largely due to the small number of disease positive individuals included in the two studies in this meta-analysis.

- For mydriatic photography, there is evidence to indicate that the accuracy of images with one or two fields is similar.

- Insufficient evidence is available to judge the suitability of the ultra wide angle scanning laser ophthalmoscope for diabetic retinopathy screening. Studies in the United Kingdom are underway in people with diabetes. These plan to provide information about failure rates and accuracy in diabetic retinopathy screening and will need to be critically appraised when they become available.

- The only side-effects associated with screening relate to the instillation of eye drops for pupil dilation. Local side-effects (such as blurred vision and sensitivity to light) may occur for up to six hours, or longer in isolated cases. In rare cases, side-effects such as glaucoma or an allergic reaction may occur.

5.1 Search Strategy

A large body of evidence is available on the clinical effectiveness of screening for diabetic retinopathy. This includes a number of recent, high-quality, reviews by UK research groups (SIGN, 2001; UK NSC, 2000; Hutchinson *et al.*, 2000a). In order to avoid duplication, the HTBS clinical effectiveness analyses use these reviews as a basis for further detailed analysis, augmenting them with additional references identified by the HTBS Topic Specific Group and key publications issued in 2001.

Details of the sources searched by SIGN, the NSC and NICE are presented in Appendix 6.

5.2 Methods for the Evaluation of Clinical Effectiveness

The effectiveness of screening for diabetic retinopathy may be reduced by two separate types of failure. Firstly, the chosen method may fail to produce a clear image for evaluation, this is known as technical failure (section 3.5.2.1). Secondly, after successful imaging, the screening result may differ from the true state of the patient (called a false positive or false negative result). The impact of these two modes of failure on screening effectiveness can be considered separately.

5.2.1 Outcome measurements

The purpose of retinopathy screening is to detect diabetic eye disease for which a clinical intervention is required. Referable (diabetic) retinopathy (section 3.3) requires referral to an ophthalmologist (section 6.9). Detection of less severe disease (any retinopathy) is also important for more general disease management and can influence decisions to try to improve glycaemic or blood pressure control. Referable retinopathy has the greatest implications and is the focus of the economic evaluation (section 8). Hence, it is also the focus of this clinical effectiveness section.

In designing a screening programme the technical failure rate of the screening method is an important outcome. The failure rate is the proportion of patients in whom the screening method fails to return a useful assessment of the extent of diabetic eye disease. This may occur because of other eye conditions which obscure the retina or because infirmity or other circumstances interfere with the screening process.

After technical failures have been excluded, the measures used in clinical effectiveness studies of screening technologies are usually expressed as sensitivity and specificity. Sensitivity and specificity may be calculated by considering the decision matrix, which arises from a diagnostic test that yields a dichotomous (positive/negative) result. Four combinations of test result and disease state are possible (European Agency for the Evaluation of Medicinal Products, 2001).

		True disease state	
		Present	Absent
Test result	Positive	True Positive (TP)	False Positive (FP)
	Negative	False Negative (FN)	True Negative (TN)

Sensitivity is the probability that a test result is positive given the subject has the disease. In a suitable experiment, the sensitivity can be estimated by: TP/(TP+FN). Specificity is the probability that a test result is negative given a subject does not have the disease. In a suitable experiment, the specificity can be estimated by: TN/(TN+FP).

The term 'accuracy' is used to refer to the probability that a screening test will reveal the true disease state for a randomly selected patient. It will vary with the prevalence of the condition to be detected and is thus not often estimated in clinical studies. Furthermore, it does not distinguish false negative and false positive test results. However, it can be a useful concept in discussion of alternative screening methods for the same population.

5.2.2 Methods for estimating sensitivity and specificity

Interpretations of test screening methods performed on groups of diabetic patients were compared with methods expected to give accurate results (Gold Standard).

The screening method can be considered as a combination of the mechanical imaging process, which will be performed according to a clinical protocol, and a set of rules which specify how the images are to be interpreted and what combination of observations should lead to referral to an ophthalmologist. Variation in this set of rules will result in changes in the sensitivity of the method. However, a reduction in sensitivity will usually be offset by an increase in specificity and vice versa. Different studies may use different sets of rules and, since primary interest is in the inherent ability of the screening devices, it is usual to combine the sensitivity and specificity using a mathematical model of the dependence between the two. This allows a single index of screening performance to be analysed, which, under certain assumptions, is independent of the set of rules for interpretation of the image.

The approach to modelling used in this report is set out in Appendix 7. It allows the performance of a screening test to be described in terms of a curve relating sensitivity to specificity – for historical reasons called a receiver-operator characteristic (ROC) – and hence calculation of the likely sensitivity at various specificities (achieved by alterations in the rules of interpretation).

The performance of each screening method is characterised by a measure of its ability to discriminate people with retinopathy from those without. These measures are combined across studies using a random effects meta-analysis model (Der Simonian and Laird, 1986).

5.2.3 Benefits and disbenefits

For the purpose of the effectiveness assessment, the primary outcome of screening is considered to be the accurate detection of referable disease. This is a clinical variable and the true benefit – detection and successful treatment of disease – will be considered within the cost-effectiveness analysis. In addition to clinical consequences, it is generally the case that patients are spared unnecessary anxiety when screening accuracy is high. Incorrect referrals impact both on the patient and on the ophthalmology service to which the referral is made. Failure to produce a sufficiently clear image for grading also incurs a disbenefit as such patients will have to be subjected to additional tests. Generally speaking, the imaging process does not carry important risks but the use of mydriasis can cause adverse effects, discomfort and inconvenience (see section 5.3.6.1).

5.3 Clinical Effectiveness Results

5.3.1 Quantity and quality of research available

A number of reviews were consulted to inform the clinical effectiveness work of HTBS.

Chapter 6 of the SIGN guideline on the *Management of Diabetes* (SIGN, 2001) deals with the prevention of visual impairment and section 6.2 deals specifically with diabetic retinopathy screening. The main SIGN recommendations are listed below. The HTBS analysis has endorsed the recommendations of SIGN and comments are included only where some development is necessary for application within a national screening programme.

- Systematic annual screening for diabetic retinal disease should be provided for all people with diabetes.
- Patients with type 2 diabetes should be screened from diagnosis.
- Patients with type 1 diabetes should be screened from age 12 years. If onset of type 1 diabetes is post-puberty, screening should start three years after diagnosis.

For simplicity of organisation and patient education, HTBS recommends that in the case of onset of type 1 diabetes post-puberty, screening should nevertheless commence from diagnosis in the national screening programme.

- Retinal photography or slit lamp biomicroscopy used by trained individuals should be used in a programme of systematic screening for diabetic retinopathy.

The type of retinal photography appropriate for screening is not discussed in detail and SIGN note that the HTBS Health Technology Assessment would determine the most efficient, effective and comprehensive national screening programme.

- Dilated direct ophthalmoscopy should only be used for opportunistic screening.
- Screening modalities should aim to detect sight-threatening retinal disease with a sensitivity $\geq$80% and specificity $\geq$95%.

It should be noted that the recommendations on sensitivity and specificity are based on level four evidence (expert opinion only). The analyses presented in this report look more closely at what can be achieved with current technology and give a more sophisticated view and address

the technical failure rate. The technical failure rate aspired to in the *St Vincent Declaration* (WHO, 1989) was less than 5%.

- Patients with ungradeable retinal photographs should receive slit lamp and indirect ophthalmoscopy examination where possible.
- Where possible and practical, screening should be performed at a site convenient to patients.
- Retinal photographs should be graded using digital images or 35 mm film by an appropriately trained grader.

This report will argue against conventional slide photography for technical reasons unrelated to clinical efficacy.

- At least 1% of all screening events (photography or slit lamp) should be reviewed.

The design of a reliable quality assurance system depends on several factors and this recommendation appears somewhat simplistic. However, HTBS strongly agrees that adequate quality assurance is an essential element of a screening process (section 6.13).

Two other key reviews were the UK NSC's recommendations on *Preservation of Sight in Diabetes* (UK NSC, 2000); a risk reduction programme, and the draft report on *Clinical Guidelines for Type 2 Diabetes* sponsored by NICE and collaboratively written by members of the Royal College of General Practitioners, the Royal College of Physicians, and the Royal College of Nursing with Diabetes UK. For brevity, this document will be referred to as 'the NICE Guideline' (Hutchinson *et al*., 2000a).

These were based on systematic literature searches and the NICE Guideline (Hutchinson *et al*., 2000a) gives a description of some of the difficulties inherent in the interpretation of the studies identified. Studies differ in the nature of the Gold Standard test procedure, whether a Gold Standard was included, the severity of retinopathy to be detected, the handling of cases in whom no interpretable test result could be obtained, and the type of patients enrolled. The general problem appeared to be that few studies were identified which had been specifically and appropriately designed to give information relevant to a large-scale screening programme. Despite these difficulties, it is possible to combine the results of selected studies with caveats as detailed in sections 5.3.4 & 5.3.5 of this report and in Appendix 7. These analyses have selected appropriate studies from the NICE Guideline (Hutchinson *et al.,* 2000a) and added new studies and other older studies identified by members of the HTBS Topic Specific Group.

5.3.2 Description of studies excluded by HTBS

Some studies included in the NICE Guideline (Hutchinsons *et al.,* 2000a) have been excluded by HTBS for calculations of screening accuracy. Most of these evaluated agreement between screening methods rather than concordance of a screening method with a Gold Standard. Studies that evaluated methods not appropriate for a national screening programme were also excluded.

5.3.2.1 Exclusion of the Penman study

A single study was judged to employ appropriate methodology but has nonetheless been excluded from the calculations. This was a study by Penman *et al*. (1998) of mydriatic photography in a group of Egyptian diabetic patients. (To avoid confusion it should be noted that, although the title of this paper refers to 'nonmydriatic retinal photography', the text explains that this was through a dilated pupil.) The reasons for this exclusion are firstly that the technical failure rate was high and appeared to result from a high proportion of other eye abnormalities suggesting a clinical setting differing in an important way from that in Scotland. Secondly, it became apparent that the most important comparison required for evaluation of screening techniques is that between mydriatic and non-mydriatic photography. This has been done using two studies (Klein *et al*., 1985; Pugh *et al*., 1993), which examined both techniques in the same patients. Thus, biases due to patient characteristics and study procedures can be discounted.

5.3.3 Description of studies included

All studies with relevant data were included for assessment of technical failure rates.

For analysis of accuracy, the included studies were:

Those in the NICE Guideline (Hutchinson *et al.,* 2000), which fulfilled the following criteria:

- The use of a credible Gold Standard: either seven-field stereoscopic photography or slit lamp investigation (biomicroscopy or indirect ophthalmoscopy) by a qualified ophthalmologist;
- a sample of diabetic patients;
- within patient comparisons;
- all patients accounted for in study report;
- different methods of investigation reported – not interobserver variation for a single method; and
- adequate masking where appropriate.

(Some of these studies used older technologies and screening methods. This will be highlighted in discussions.)

Additional studies identified by HTBS were:

- Burnett *et al.*, 1998;
- Leese *et al.*, 1997; and
- Olson *et al.*, (Evidence submission, 2001).

Attachment 1 of Appendix 7 presents the number of patients in the clinical effectiveness studies and associated cases of detected retinopathy.

5.3.4 Failure rates of screening methods

The frequency with which photography proves impossible is generally not well reported. This is possibly because the studies are conducted from the point of view of diagnosis – i.e. when an adequate photograph is available, is it informative? – rather than from the point of view of

a screener who must decide how to get a view of the eye that allows a referral decision to be made.

The SIGN Guideline (2001) states:

> Between 3% and 14% of retinal photographs are ungradeable although this rate may be improved by digital imaging (Taylor, 1996; Harding *et al.*, 1995). Slit lamp biomicroscopes with dilated indirect ophthalmoscopy used by properly trained individuals can achieve sensitivities similar to retinal photography, with a lower technical failure rate (Hutchinson *et al*., 2000b).

Failure rates were not reviewed in the NICE Guideline (2000), but a number of the studies within this review provide some evidence, which is presented in the sections relating to each screening method below.

Three concomitant questions arise:

1. Does mydriasis significantly reduce the proportion of failures for photography?
2. Does digital photography have lower technical failure rates than photography using colour slides?
3. If photography fails, do other methods of screening perform better?

This last question is difficult because while photography produces a permanent image, which can be reviewed in order to reach a consensus on gradeability, ophthalmoscopy and slit lamp does not. The decision as to whether an ophthalmoscopic inspection has provided adequate data is purely that of the operator. Thus, it must be recognised that the failure rates from retinal photography and ophthalmoscopy are judged by different criteria. Data that may illustrate this issue are given in Lairson *et al.* (1992). Here, although an ophthalmologist using both direct and indirect ophthalmoscopy reported no failures to visualise, 49 false negatives were recorded in 347 examinations. This was higher than from photographic methods – 29 without mydriasis, 14 with mydriasis – and may suggest that difficult visualisation tended to result in a negative finding. The reference method in this study was seven-field 30 degree stereoscopic photography.

Both seven-field photography and indirect ophthalmoscopy by an ophthalmologist are used as reference standards in screening studies and this level of disagreement found by Lairson *et al.* (1992) raises concerns over the validity of calculations of sensitivity and specificity based upon them.

5.3.4.1 Failure of non-mydriatic photography

One of the largest studies of single-field non-mydriatic photography was Buxton *et al.* (1991). Of 6,304 Polaroid images 5% were found to be unusable. Another 19% were graded as having ‘some detail’ and were interpreted by the graders. In Williams *et al.* (1986) no detail was visible in 5.8% (7/120) eyes photographed with a 45 degree non-mydriatic camera.

5.3.4.2 Failure of mydriatic photography

Five-field non-stereoscopic photography through dilated pupils was used as a reference standard by Forrest *et al.* (1987). From 508 eyes, 26 images (5.1%) were ‘unobtainable for clinical reasons’. Of the remaining 482, 12 (2.5%) were unassessable due to cataracts/ptosis and a further 32 (6.6%) were rated unassessable for other reasons. However, of these last, 11 in a subset of 16 that were rephotographed proved assessable. Hence, perhaps, only ten ([5/16] x 32) were truly unassessable. This suggests that 9.4% might have required non-

photographic imaging in a screening programme. Gibbons *et al.* (1994) found a 4.2% (6/143) failure rate for two-field[1] photography. A further 6% of photographs had rather poor quality but were interpretable by an ophthalmologist. A further study, Gibbons *et al.* (1998), used two-field 45 degree slides as a reference standard and only 1.7% of 1,245 were ungradeable. However, 22% were omitted from the study as being less-than-good. Harding *et al.* (1995) compared three-field 45 degree photography with slit lamp biomicroscopy. Of 326 patients, six (1.8%) were ungradeable by either method. A further 46 of 640 photographic images (7.2%) were considered ungradeable. Thus 9% of images overall would have required review by an alternative method. Of the 46 ungradeable photographs, 12 were due to problems with posture or tremor, the other 34 due to eye defects. Penman *et al.* (1998) judged 22% (92/427) right eye, single-field photographs to be ungradeable in a group of Egyptian people with diabetes. This may be somewhat high because ten patients were judged to be unsuitable for photography on the basis of ophthalmoscopy and no attempt was made to photograph them. Media opacities were present in 35% of eyes.

The mean technical failure rate in the studies of mydriatic photography was 7%. Mean technical failure rate in studies without mydriasis was 5.5%. However, this low figure for non-mydriatic photography is strongly dependent on the large study by Buxton *et al.* (1991).

The discussion above is of failure rates using conventional photography. A retrospective review of images from a moderate resolution (800 x 600) camera (Taylor and Riley, 2001) found a technical failure rate of 30/257 (11.7%) and a steep increase with age beyond 70. Olson *et al.* (Evidence submission, 2001) provided a direct comparison of technical failure rates in higher resolution (1,024 x 1,024) digital and conventional photography. Two fields per eye were imaged and the definition of failure was that any of the four images per patient be ungradeable. Twenty-six of the 586 (4.4%) patients had technical failures by digital imaging whilst 70/586 (11.9%) failed with conventional slide photography. If the definition of technical failure was restricted to the macular image, these rates became 3.5% and 8.1% respectively.

5.3.4.3 Direct comparison of mydriatic and non-mydriatic photography

Klein *et al.* (1985) investigated single-field 45 degree photography with and without mydriasis. The reported failure rates were 6.8% (5/74) with and 12.7% (8/63) without mydriasis. Three fields from a 30 degree stereoscopic camera used as a reference failed in 3% (3/99) of cases but undilated direct ophthalmoscopy failed in 17% (16/94). Lairson *et al.* (1992) performed both two-field (nasal and stereoscopic macular) 45 degree photography with mydriasis and single-field 45 degree without mydriasis. Recorded failure rates were 3.7% (13/351) with mydriasis and 14% (49/351) without mydriasis. The comparison in this case is confounded with the numbers of fields, which, in addition, meant that the comparison could not be masked. An additional methodological doubt in this study is raised by the decision to assess the test for each patient in the same order. It was hoped that a time interval between assessments would render the assessments independent, but if this failed the assessment would be biased in favour of the test assessed later – mydriatic two-field. Thus, it is unclear whether the lower failure rate is due to mydriasis, the presence of extra information, or preconceptions of the reader about preferred methodology.

Research is ongoing in this area and two studies by Leese (Research protocol, 2001) and Scanlon *et al*. (Evidence submission, 2002) will shortly provide more information.

[1] Possibly single-field stereoscopic – reporting unclear.

5.3.4.4 Are failures of photography associated with disease?

Conflicting evidence has been found on the question of whether diseased eyes are more likely to result in technical failures of imaging. In the study by Harding *et al.,* (1995) many of the eyes judged ungradeable by photography were considered abnormal on ophthalmological review by slit lamp. Five of the eight failures on non-mydriatic photography in Klein (1985) were judged to have microaneurysms or more severe non-proliferative diabetic retinopathy (NPDR). On the other hand, Pugh *et al.* (1993) found that 10/50 (20%) of patients were ungradeable by undilated photography, and the 3/13 (23%) ungradeable by dilated photography had moderate retinopathy, or worse. This compares with 74/351 (21%) in the entire study, suggesting no association between gradeability and retinopathy. These inconsistent findings do not provide adequate support for a recommendation to refer technical failures directly to ophthalmological departments.

5.3.4.5 Failure of laser scanning ophthalmoscope

For the ultra wide angle scanning laser ophthalmoscope, a study by Baumal and Puliafito (2000) reported that 19/86 (22%) of images were not assessable. These data relate to a general eye examination in healthy patients and use an older version of the scanning laser ophthalmoscope and so are of limited value. During consultation, presentations of two small US studies were submitted using a newer device for diabetic retinopathy screening. The larger of these was in 66 people (44 with diabetes) (Zhu *et al.,* 2001). This reported a failure rate in people with diabetes of 7%. Clearly there is a paucity of data here upon which to be making any judgments and evidence from larger trials is awaited (5.3.5.10).

5.3.4.6 Failure of conventional ophthalmoscopy

The failure rate of ophthalmoscopy due to cataracts or a poor view is reported in Forrest *et al.* (1987) as 4.3%. It is not clear what form of ophthalmoscope was used. In Penman's study (1998), 23/427 (5.3%) could not be visualised by indirect ophthalmoscopy.

5.3.4.7 Conclusion with respect to failure rates of retinal imaging

One study (Klein *et al.*, 1985) suggested a reduction in technical failure rate with the use of mydriasis but the result was not statistically significant. A larger study (Lairson *et al.*, 1992) showed a similar effect but it was not clear that this was due to mydriasis. Studies with current technology are needed. The failure rate of photography with mydriasis averaged over the studies considered here is 7% while that without mydriasis is 5.5%. Differing definitions of failure complicate interpretation of these figures. It is fair to say that no strong evidence has been found to suggest that mydriasis reduces failure rates but that those studies containing a direct comparison favour the hypothesis.

A different, but important, issue with respect to mydriasis was raised by Klein *et al.* (1985) who asked for patient preferences and estimated that dilation was unacceptable to 6% of patients with a further 5% stating that it was acceptable only if necessary.

The study by Olson *et al.* (Evidence submission, 2001) has indicated that lower technical failure rates are achievable with digital photography than with conventional slide photography. As most of the current evidence relates to conventional photography and the screening programme is likely to use digital cameras, this is an important finding. If digital photography reduces the technical failure rates for non-mydriatic photography in a similar

way this is likely to be a viable screening option, but reliable estimates of technical failure rates for non-mydriatic digital photography should be determined early in the screening programme.

When the failure rate for ophthalmoscopic investigations has been reported it was not greatly different from photography and this may indicate that changing between the two imaging methods will not unduly increase the number of ophthalmological referrals due to the inability of the screener to come to a decision. However, as discussed above, definition of technical failure for these techniques is not the same and hence such comparisons must be viewed with caution.

Limited data are available on the failure rate associated with the ultra wide angle scanning laser ophthalmoscope.

5.3.5 Accuracy of retinal imaging methods

The following section reviews the sensitivity and specificity of retinal screening by various methods using only those screening episodes that were technically successful.

5.3.5.1 The Gold Standard method

The single most important feature of any study testing diagnostic accuracy is the inclusion of a Gold Standard reference method. This is an alternative way of performing the diagnosis, which is known to be very accurate. It is debatable whether a Gold Standard exists in the detection of diabetic retinopathy but various methods are thought to have better properties than others. The two methods, which might possibly be considered as Gold Standard, are seven-field stereoscopic photography and indirect ophthalmoscopy or biomicroscopy with a slit lamp carried out by a skilled ophthalmologist through dilated pupils. However, these methods have been compared in four of the studies discussed by NICE (Kinyoun *et al.*, 1992; Pugh *et al.*, 1993; Moss *et al.*, 1985; Schachat *et al.*, 1993) and do not show perfect agreement. Hence, it is clear that one or both allow fairly frequent errors in detecting retinopathy. It is not possible to decide objectively which is in error but Kinyoun *et al.* (1992) did subject disagreements to an expert review, which tended to favour the seven-field photography with two errors, over the indirect ophthalmoscopy with 12 errors. Moss *et al.* (1985) also examined the disagreement closely and concluded that many involved detection of microaneurysms from photographs that were not detected by ophthalmoscopy. No matter which method was correct, this might suggest that disagreements tend to happen in milder disease states.

The direct comparisons of indirect ophthalmoscopy (used by an ophthalmologist) with seven-field photography also raises questions about the standards of 80% sensitivity and 95% specificity seen as desirable by the St Vincent Joint Task Force for Diabetes (1995). Since these standards were not invariably met in comparisons of these two 'Gold Standard' methods, they may represent an unrealistic target for other methods.

5.3.5.2 Methods of screening

Deciding which methods of screening will be appropriate for a national screening programme is not simply a matter of selecting a particular imaging method and a policy for the use of mydriasis. There is also the question of who should operate the device and, for photographic methods, interpret the results. This question is addressed in a number of studies but may, of

course, occasionally be confounded by the use of different devices by different professionals. Hence, it may be impossible to differentiate between effects due to operators and screening devices.

Other features also varied between studies. Some studies were restricted to patients who had not had a diagnosis of retinopathy before or who were not in the current care of an ophthalmologist. The nature of the conditions detected also varied: any retinopathy, PDR and STDR being common choices. In addition, the camera technology has changed and improved over the years in which these studies were performed. An important change is that the current digital cameras allow immediate viewing of the image so that imaging failures can be immediately logged and re-attempted if appropriate.

The number of images of each eye obtained with a retinal camera is also a choice that may affect the accuracy of screening. The cameras employed as a Gold Standard in many studies use seven stereoscopic images in an overlapping pattern, each with an incident angle of 30 degrees at the camera. The cameras that have been assessed for screening use an incident angle of about 45 degrees (i.e. larger coverage) but only a single image or two images have usually been tested. A non-mydriatic camera can only take a single image in a short time span since the flash causes the pupil to contract. It can, of course, take multiple images with mydriasis in the same way as a mydriatic camera.

There is limited evidence concerning the number of fields that should be viewed with a retinal camera. Interestingly, on average the studies using a single-field gave marginally better results than those with two or more fields. However, this may be due to differing failure rates and it is clear that this question is still very much a matter that requires further well-designed clinical trials. The SIGN Guideline (2001) does not give a judgement on this issue but the NSC guideline (UK NSC, 2000) recommends the EURODIAB protocol of 2 x 45 (or 50) degree fields (section 6.9).

5.3.5.3 Issues in analysis of screening studies

Any set of retinal images may be interpreted with more or less stringent criteria for retinopathy. As these criteria are relaxed, the number of patients considered to have retinopathy will increase – thus increasing the sensitivity but simultaneously decreasing the specificity. This dependence of sensitivity and specificity means that neither index can ever make sense if presented alone. It also means that sensitivity and specificity estimates should not be combined across studies without allowing for the dependence. This issue alone requires that a statistical model be used for rational synthesis of a number of diagnostic or screening studies. In comparing differing imaging methods, an adjustment should ideally be made for the effect of different operators – e.g. GPs or optometrists. However, particular imaging methods tend to be associated with particular operators and hence such analyses can lead to unrealistic conclusions about the performance associated with certain operators with instruments they do not generally use. For this reason it is better to report results only for imaging methods with specific types of operator.

A further issue, which varied between studies, was the treatment of image failures. Most studies excluded such failures from analysis, but a few (Pugh *et al.*, 1993; Lairson *et al.*, 1992) treated them as positive diagnoses. For the purpose of planning a screening programme, it may be best to separate the issues of technical failure and clinical diagnosis. Combining them would imply that the only strategies for dealing with image failure would be either

referral to an ophthalmologist or assuming them clear of retinopathy. Thus, where sufficient data have been presented, the sensitivities and specificities used exclude failures.

5.3.5.4 Statistical model combining all studies with Gold Standard comparators

The main features of this analysis are:

1. It does not consider studies that did not include a comparator that could be a Gold Standard – e.g. inter-observer agreement studies for photographs.
2. Converts sensitivity and specificity to a single variate using ROC curves to model the effects of varying the index of suspicion.
3. Analyses of estimates of accuracy for 'any retinopathy' and more severe 'referable' retinopathy separately. Papers that studied 'referable', 'proliferative' or 'sight threatening' retinopathy were included in the more severe category.

It should be noted that this statistical technique does not allow for the possibility that a supposed Gold Standard is less than perfect. Such potential imperfections could be allowed for if credible bounds could be placed upon the accuracy of the standard but such bounds are not available.

A further analytical complication with the studies used by NICE is that several groups were often compared with a single Gold Standard within a study with respect to detection of a number of different conditions. Thus, correlations may also exist between apparently separate comparisons. This issue would be best addressed within a meta-analysis of individual patient data that are not available to these authors, and so is ignored in the current analysis.

The studies contributing to the meta-analyses of sensitivity and specificity by operator are listed in the Table 5-1.

Table 5-1 Studies contributing to the meta-analyses of sensitivity and specificity by operator

Analysis	Studies
GP/Direct ophthalmoscope	Buxton *et al.*, 1991
Optometrists/Direct ophthalmoscope	Buxton *et al.*, 1991
Others/Direct ophthalmoscope	Buxton *et al.*, 1991
Graders/Mydriatic photography	Klein *et al.*, 1985 Pugh *et al.*, 1993 (Penman *et al.*, 1998*)
Graders/Non-mydriatic photography	Klein *et al.*, 1985 Pugh *et al.*, 1993
Optometrists/Biomicroscope	Kleinstein *et al.*, 1987 Leese *et al.*, 1997 Olson *et al.*, 2001
Ophthalmologists/Biomicroscope	Pugh *et al.*, 1993 Moss *et al.*, 1985

* The study by Penman *et al.* (1998) is not included in the primary analysis but the robustness of the results to this exclusion is reported in Appendix 7.

Appendix 7 presents full details of the model and a listing of the dataset used in the meta-analysis, with details of the number of patients included and those disease positive included in Attachment 1 of that appendix.

Many consultation comments have been received about the paucity of evidence on non-mydriatic photography. It is therefore important to note that using the statistically robust study exclusion criteria there are only two studies suitable for evaluation of either of mydriatic or non-mydriatic retinal photography. Each study involved mydriasis and non-mydriasis and so they both provide a good basis for comparison of results with and without mydriasis. There were 407 patients in the two studies who received mydriatic photography and 368 who received non-mydriatic photography.

Table 5-2 presents the estimated sensitivities for selected specificities for detection of more severe diabetic retinopathy (STDR, referable or PDR) by various operators using various viewing methods. For comparison with the aspirations of the *St Vincent Declaration (WHO, 1989)* (80%) the sensitivities at 95% specificity are shown in bold. The figures for detection of any retinopathy are given in Appendix 7.

Table 5-2 Estimated sensitivities (95% CI) vs. specificities for STDR, referable retinopathy or PDR (Various screening modalities)

GP using direct ophthalmoscope through dilated pupils				
Specificity	85%	90%	**95%**	97%
Sensitivity	64% (56%,73%)	55% (46%,64%)	**40% (32%,50%)**	32% (24%,41%)
Optometrist using direct ophthalmoscope through dilated pupils				
Specificity	85%	90%	**95%**	97%
Sensitivity	68% (62%,73%)	59% (53%,64%)	**44% (38%,50%)**	35% (30%,41%)
Other professional using direct ophthalmoscope through dilated pupils				
Specificity	85%	90%	**95%**	97%
Sensitivity	88% (74%,95%)	82% (65%,92%)	**71% (51%,85%)**	62% (42%,79%)
Mydriatic photography graded by trained graders				
Specificity	85%	90%	**95%**	97%
Sensitivity	96% (81%,100%)	94% (73%,99%)	**88% (60%,98%)**	83% (51%,97%)
Non-mydriatic photography graded by trained graders				
Specificity	85%	90%	**95%**	97%
Sensitivity	96% (54%,100%)	93% (44%,100%)	**86% (31%,100%)**	80% (23%,99%)
Optometrists with slit lamp				
Specificity	85%	90%	**95%**	97%
Sensitivity	82% (63%,93%)	75% (54%,90%)	**62% (39%,82%)**	53% (30%,75%)
Ophthalmologist with slit lamp/indirect ophthalmoscope				
Specificity	85%	90%	**95%**	97%
Sensitivity	97% (90%,99%)	95% (85%,99%)	**91% (76%,97%)**	86% (68%,95%)

5.3.5.5 Accuracy of Gold Standard

The bottom row of the table differs from the others in that ophthalmologists with slit lamps are not an available screening option. Indeed, this modality has been regarded as a Gold Standard in evaluating other methods. To calculate sensitivities for this row seven-field photography has, arbitrarily, been taken as the preferred Gold Standard. However, it should

be borne in mind that it is not possible to determine whether discrepancies between these two methods arise from errors in one or the other. The reason for presenting this comparison is firstly to emphasise that the methods do occasionally disagree and therefore neither can be assumed error-free and secondly to suggest that these sensitivities provide a realistic upper bound on what might be expected of any screening method. While these figures achieve the St Vincent criteria (WHO, 1989) of 80% sensitivity at 95% specificity the 95% confidence interval on the sensitivity extends from 76% to 97%. Hence, these studies do not provide conclusive evidence that the St Vincent criteria (WHO, 1989) are achievable for detection of STDR. The sensitivity estimate for detection of any retinopathy is 79% (95% CI 60 to 91) at a specificity of 95% and so the St Vincent criteria (WHO, 1989) were not achieved in this case (see Appendix 7).

5.3.5.6 Accuracy of photography

The point estimates of sensitivity for mydriatic and non-mydriatic photography interpreted by trained graders are almost identical. However, due to the small number of cases in the studies, the confidence intervals for both methods are wide and hence these results should be interpreted with caution. Some supplementary evidence lends weight to the conclusion that these point estimates are more trustworthy than the confidence intervals suggest. Firstly, the discrimination of any retinopathy with non-mydriatic photography had 86% (95% CI 68,96) sensitivity. In contrast to STDR, this confidence interval for any retinopathy screened with non-mydriatic photography is sufficiently narrow to exclude low levels of sensitivity. This lends support to the belief that non-mydriatic photographs achieve a high level of definition. Any failure of non-mydriatic photography to reveal fine detail would be expected to affect adversely this comparison since the distinction between normal pathology and mild retinopathy may be based on only one dot haemorrhage or microaneurysm. Secondly, studies of non-mydriatic photography in which professions other than trained graders screened for referable retinopathy suggest a sensitivity of 72% (95% CI 52,86). It seems likely that the accuracy of this group would be inferior to that achievable with specifically trained graders.

One clear conclusion from these results is that no overall difference was found between the effectiveness of mydriatic and non-mydriatic photography when the results were restricted to those images judged to be readable by each method.

If the Penman *et al.* study (1998) is added to this comparison, it suggests that mydriatic photography is appreciably less accurate than non-mydriatic. This conclusion seems unlikely to be valid but, if true, it might be viewed as strengthening the recommendations of this report and hence the exclusion of the study can in no way undermine the conclusions. The results of analyses with and without the data from Penman *et al.* (1998) are reported in Appendix 7.

5.3.5.7 Accuracy of photography with one or two fields

Table 5-2 does not differentiate mydriatic photographic screening using a single image of the macula alone from screening using two or more fields per eye. One study (Klein *et al.*, 1985) has looked at single image and another (Pugh *et al.*, 1993) has looked at two images. The estimates of sensitivity are shown below.

Table 5-3 Estimated sensitivities (95% CI) vs. specificities for STDR, referable retinopathy or PDR (Mydriatic: one vs. two field)

Mydriatic photography graded by trained graders – one-field				
Specificity	85%	90%	**95%**	97%
Sensitivity	99% (76%,99%)	98% (69%,99%)	**96% (55%,99%)**	93% (46%,99%)
Mydriatic photography graded by trained graders – two-field				
Specificity	85%	90%	**95%**	97%
Sensitivity	94% (66%,99%)	90% (56%,99%)	**82% (41%,98%)**	76% (33%,97%)

This unexpected superiority of the single-field, which disagrees with expert opinion, may be a chance effect since the confidence intervals for sensitivity at 95% specificity for two-field photography extends from 41% to 98% while that for one image is from 55% to 99%. However, this analysis does suggest that more evidence is required concerning the necessity for a two-field protocol.

Evidence is provided by Olson *et al.* (Evidence submission, 2001) who has made a direct comparison of one image with two images, both with mydriasis, albeit using a research registrar rather than a trained grader. This study of 586 patients estimated sensitivity and specificity for referable eye disease using digital photography with mydriasis of 94% (95% CI 85 to 99) and 87% (95% CI 85 to 90) for a two-field protocol compared with 93% (95% CI 83 to 98) and 87% (95% CI 84 to 90) for a one-field protocol. In other words, almost identical accuracy was obtained.

5.3.5.8 Accuracy of slit lamps used by optometrists

It should be noted that there is little evidence within the studies considered by NICE regarding optometrists using slit lamps – a small study by Kleinstein *et al.* (1987) in which a sensitivity of 74% and specificity of 84% were estimated for STDR – and none for 'other professionals'. However, ophthalmologists achieve good results with them. Most of the evidence concerning optometrists using slit lamps comes from Leese *et al.* (1997), Olson *et al.* (Evidence submission, 2001), Burnett *et al.* (1998) and Prasad *et al.* (2001), which were not part of the NICE evidence base.

Burnett *et al.* (1998) reported a programme of retinal screening by optometrists in North London. A sample of 28 patients referred to ophthalmology, and 88 not referred, were assessed by a consultant or registrar ophthalmologist with a slit lamp. All the negative screens and 22/28 positive screens were confirmed. This suggests a sensitivity of 100% (95% CI 84 to 100) and a specificity of 94% (95% CI 87 to 98). These figures are better than those found in the other studies. However, the confirmation by ophthalmologist in this study was not masked. Thus, the assessments were not independent. A similarly designed but larger study by Prasad *et al.*, (2001) used 27 locally accredited optometrists to test 4,904 patients. This study estimated a sensitivity of 76% and a specificity of 95%. The question being answered in each of these studies might be worded 'was the initial referral decision acceptable to the ophthalmologist?'. This may be rather different from the question that underpins the meta-analysis: 'was the initial referral decision identical to that which the ophthalmologist would have made in the absence of any knowledge of the optometrist's recommendation?'. Consequently, direct comparison of the sensitivity and specificity obtained with other studies is not valid and so this study was not included in the meta-analysis. However, these studies do demonstrate that there were not many strongly held differences in clinical opinion over the

non-referrals and that sensitivity levels higher than the 62% achieved with 95% specificity in the meta-analysis may be achieved with appropriately trained optometrists.

5.3.5.9 Accuracy of ultra wide angle scanning laser ophthalmoscope

Little evidence is currently available for the ultra wide angle scanning laser ophthalmoscope in diabetic retinopathy screening. One US study (Zhu *et al*., 2001) of 66 people (44 with diabetes) used slit lamp biomicroscopy as the Gold Standard and three retinal graders. It is stated that the sensitivity to the presence of any diabetic retinopathy was 89% in the first screener, with specificity 100% and this was consistent across the other graders. However, this information was only presented in PowerPoint slides in a manufacturer's submission and cannot be verified.

5.3.5.10 Future research

Research is underway (Leese, 2001) to compare the digital retinal images obtained using undilated pupils (single-field) and dilated pupils with tropicamide 1% (multiple fields), with the Gold Standard of slit lamp biomicroscopy by a trained ophthalmologist. In this study, 400 patients will receive all methods of evaluation using a modern camera. Sensitivity, specificity, failure rates and costs will be evaluated for all methods. This research is due to be finalised in 2002 and should be considered at the outset of the national screening programme.

Two NHS R&D Health Technology Assessments addressing specific aspects of diabetic retinopathy screening are due for publication early in 2002. One of these, by Scanlon *et al.* (Evidence submission, 2002), studies the introduction of an organised diabetic retinopathy screening programme in Gloucestershire and planned to include 3,650 people with diabetes. Each patient was to receive two-field digital photography with mydriasis and one-field digital photography without mydriasis compared with the Gold Standard examination of slit lamp examination by an ophthalmologist. Hence, this study will provide important information at the rollout of this HTBS Assessment.

Two studies using the ultra wide angle scanning laser ophthalmoscope are planned in people with diabetes in the UK. These will provide information on technical failure rates, screening accuracy, economic aspects and patient acceptability. One of these new studies will compare the performance of ultra wide angle scanning laser ophthalmoscope with and without mydriasis, with digital photography and slit lamp biomicroscopy (both with mydriasis). For each modality, two images will be taken. A sample size evaluation will be performed after 75 patients and up to another 75 patients will be entered. Images will be blinded, randomised and assessed in blocks of 150 images, to avoid reviewer fatigue. Images will be graded according to the Welsh Community Diabetic Retinopathy Scale.

5.3.5.11 Conclusions concerning screening accuracy

The sensitivity achieved by a GP or optometrist with a direct ophthalmoscope was very low (approximately 40% for 95% specificity) and so this method should not be used for systematic screening. However, the direct ophthalmoscope will remain useful for opportunistic screening in persistent defaulters who would otherwise receive no retinal examination.

The meta-analysis indicated lower accuracy for the use of slit lamps by optometrists than photographic screening. However, other studies not included in the meta-analysis, using

specifically trained optometrists, demonstrated higher accuracy. As slit lamps will always be required for those not amenable to digital photography, it is clear that training, accreditation and quality assurance will be essential (6.12.5.1).

Retinal cameras achieved the highest levels of accuracy of any practical screening method in these studies and have the major advantage of providing permanent images for quality control and clinical review. Digital retinal cameras showed similar accuracy to conventional photography and have the additional advantages of easily transmissible and storable images, lower intensity flash, and the potential to move to automated grading systems (6.9.1). This should be the preferred screening equipment within a national screening system.

Retinal cameras provided high levels of accuracy but a percentage of technical failures was encountered in all studies. Most of the data on technical failure rates relate to conventional photography and data are insufficient to estimate the level of technical failure likely in a screening programme with digital retinal cameras. However, a recent study (Olson *et al*., Evidence submission, 2001) estimated a rate of about 4.4% for a two-field protocol with mydriasis and 3.5% for one-field with mydriasis. These rates were significantly lower than those achieved with conventional photography in the same patients.

Retinal photography with mydriasis, which allows the collection of multiple images, is the standard technique for diabetic retinopathy screening in many countries. However, there appears to be little difference between the accuracy and failure rates of modern cameras when used with or without mydriasis. Therefore, it is recommended that all cameras should be non-mydriatic, as these cameras can be used with or without mydriasis (but mydriatic cameras can only be used with mydriasis). The issue of mydriasis will be addressed further in the patient issues section and economic evaluation.

5.3.6 Disbenefits

5.3.6.1 Adverse effects

The main source of adverse effects associated with diabetic retinopathy screening arises from the instillation of eye drops used for mydriasis. Tropicamide BP and phenylephrine hydrochloride are used in local diabetic retinopathy screening schemes in Scotland (section 3.5.3). Although a number of side-effects are listed with these agents, major adverse effects (such as glaucoma and allergic reactions) are extremely rare. However, as mobile units permit the administration of drops outwith a general healthcare setting, all those administering the drops should be trained about the reported side-effects, contra indications and potential for interactions with tropicamide.

Tropicamide is contraindicated for use in closed angle glaucoma. However, Pandit and Taylor (2000) found that the risk in these patients was negligible and recommended use in all patients irrespective of perceived glaucoma risk. In practice, very few systemic problems are experienced with these drops and so a pragmatic treatment protocol should be agreed nationally.

Phenylephrine hydrochloride is contraindicated in ‘long-standing insulin dependent diabetes mellitus’ so its use cannot be recommended as standard in the national screening programme.

The most common adverse reactions to these agents occur locally, these being blurred vision and sensitivity to light. The British National Formulary (British Medical Association and the

Royal Pharmaceutical Society of Great Britain, 2001) states that patients should be warned not to drive for up to one to two hours after mydriasis. However, Jude *et al.* (1998) found that patients with diabetes who met the visual legal requirements to drive (Binocular visual acuity ≤6/9) prior to dilation may not fulfil the requirements post-dilation. Post-dilation, sunglasses did not improve the binocular visual acuity and so did not enhance the ability to drive post-dilation. They note that the time course of the phenomenon requires further study but recommend that patients should be warned not to drive after mydriasis for at least two hours. However, as identified in the patient issues section (section 7.3.3.1), some people experience the local side-effects of eye drops for much longer than two hours. This can cause concern and this possibility should be communicated to patients. Consequently, patients should receive notification prior to attending the screening visit of the potential need for mydriasis, the effects that they may anticipate with the eye drops and what to do if they are concerned with the duration of these effects.

5.3.6.2 Conclusions about disbenefits

The main source of disbenefits associated with diabetic retinopathy screening arises from adverse effects following the instillation of eye drops for mydriasis. Local side-effects affect the ability to drive and may last for several hours. Other side-effects such as glaucoma and allergic reactions are rare. In the screening programme, use of Patient Group Directions to administer the eye drops to those who need them will be required.

6 ORGANISATIONAL ISSUES

Summary

- The Scottish national screening programme for diabetic retinopathy should be fully quality-assured according to standards specified by the Clinical Standards Board for Scotland and integrated with other clinical management systems for the care of people with diabetes.

- The National Services Division will help plan the roll out and implementation of the national programme with NHS Boards.

- NHS Boards should identify a 'named individual' who is authorised to take local responsibility for the diabetic retinopathy screening programme. NHS Boards should determine the optimal mode of screening delivery to suit their population and national contracts be used for procurement of equipment. They should work closely with GPs to undertake the call/recall of patients suitable for diabetic retinopathy screening and to communicate the screening result to the patient.

- One of the key obstacles to moving to the systematic national programme is the creation of a clinical IM&T system that is integrated with the national IT system for diabetes care being established in Scotland (SCI-DC). 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 SCI-DC.

- Patients diagnosed with either type 1 or type 2 diabetes mellitus and aged over 12 years or post-puberty should have annual examinations of the retina, unless they are medically unfit for laser treatment.

- Screening should use the three-stage model outlined in section 9.2, which is based on the use of non-mydriatic digital cameras initially without mydriasis, but using mydriasis and then slit lamps, if technical failures occur.

- Higher resolution digital retinal cameras (1,365 x 1,000 pixels) are recommended. Image transfer using a direct digital route is preferred to avoid degradation of quality. Until further evidence about image compression is available, images should be graded at capture resolution. The image should be graded using a modification of the CRAG grading system, called the Scottish Diabetic Retinopathy Grading System on a terminal or personal computer with a CRT monitor of at least 19 or 21 inches.

- Grading of retinal images should be performed according to a three-level process, with photographs referred to the next level if the grader identifies any potential sign of retinopathy. All graders must be specially trained, accredited and competent with the more experienced professionals involved in the second and third levels.

- Slit lamp examinations will be needed for patients not amenable to digital photography. These examinations should be undertaken according to quality assured procedures by accredited individuals.

6.1 Organisation of Systems

There is considerable literature on soft systems methodology and key success factors needed within 'complex human activity systems' such as those for systematic population-based screening (Checkland, 1999). An important component for the management of complex systems is the creation of 'information systems' and ensuring that the 'people' components of the entire 'system' are enhanced by the 'Information Technology' (IT) components and not the reverse.

Experience has demonstrated that a national screening programme requires central coordination. In Scotland this will be achieved with the help of the National Services Division (NSD) within the Common Services Agency of NHSScotland.

The organisational structure of national screening programmes in Scotland is presented in Appendix 8 and in section 6.14 the responsibilities of the organisations are discussed.

To ensure that the national screening programme for diabetic retinopathy is introduced rapidly, and achieves the required standards, the technology, IT infrastructure and professional input must all be coordinated. This section presents experiences/lessons from a variety of screening experiences across the UK, so that best practice may be shared and a national solution found to the problems, which are currently being tackled by individual Boards.

6.2 Learning from other Screening Programmes

Guidance on the Scottish Breast and Cervical Screening Programmes was updated in NHS Circular MEL (1999) 82 (Scottish Executive Health Department, 1999a). Guidance is provided on commissioning each programme as 'a comprehensive entity' with details provided about specific services, quality assurance processes, standards and individual roles, responsibilities and accountabilities.

These existing Scottish screening programmes provide good models for establishment of quality assurance mechanisms and national standards. However, it must be remembered that a diabetic retinopathy screening programme is also quite different. Its aim is to screen people from a wide age range (from teenagers through to the elderly) of both sexes, who are already involved in clinical care to manage their disease. Consequently, diabetic retinopathy screening must be fully integrated into comprehensive diabetes care and this will be facilitated by the work undertaken on the *Scottish Diabetes Framework* (Scottish Diabetes Framework Working Group, 2001).

6.3 Screening Issues

Two essential features of a systematic retinal screening programme will be integration into the overall care for individuals with diabetes and adequate quality assurance.

Systematic diabetic retinopathy screening is a fundamental component of overall care of individuals with diabetes. While the process of eye examination may not always be carried out at the same time or in the same place as other diabetes checks, it is essential that relevant clinicians, as well as the person with diabetes, have ready access to the findings of retinal examinations. The organisation of the screening visit and subsequent results must be managed

as part of the totality of care. A variety of healthcare providers may be involved in providing patient care and all (or most) of these will wish to access and contribute to a shared care record. This is different from most screening programmes that offer a test to apparently healthy individuals. However, the ethical issues surrounding, for example, informed consent, quality assurance or minimising risks of harm from screening remain relevant.

The organisation of a systematic screening programme has three main strands: the 'patient journey' and the associated health service functions of 'service provision', and 'programme management'. These are shown in schematic outline in Table 6-1.

Table 6-1 Key aspects of a screening programme

Patient	Service Provision	Programme Management
Identify person	Maintain population register* and screening 'diary'	Coordination of individual components and overall programme
Invite person	Invitation and recall Education and information	Planning and work scheduling
Screen person	Apply screening test	Quality assurance of test process
Advise on result and future action	Interpret test and determine future action	Evaluation of screening test and quality assurance of screening process
Provide diagnostic assessment and treatment as necessary	Referral protocols Investigation, treatment and follow-up	Training Staff recruitment and retention Workload implications for each activity
Provide follow-up as necessary	Follow-up and fail safe education and information	Information for quality assurance and programme monitoring
Information provision and support to individuals	Education and emotional support Programme monitoring and reporting	Clinical governance and formal performance review

*As a result of issues related to data protection, the term 'register' is sometimes replaced by 'clinical information system'. This report will use the term 'register' throughout.

6.4 Modes of Delivering Screening

There are three main ways in which diabetic retinopathy screening can be offered to patients:

1. In a fixed medical facility (e.g. hospital outpatient unit).
2. From a mobile unit:
   - ***i.*** with the camera and associated equipment taken into a medical facility (e.g. GP's surgery); and
   - ***ii.*** taken to a local site, with patients entering the van to have the examination.
3. By a community optometrist.

The mobile facilities are custom-made and the specifications of the equipment in the van and the van itself will depend on whether option ***i*** or ***ii*** is chosen.

For option ***i***, a smaller van can be used, but robust equipment must be used to transport the camera and associated equipment into the medical facilities. The Grampian screening programme uses such a van. It has a hydraulic lift, special arrangements to secure the equipment in the van and a custom-made trolley to carry the equipment safely. The availability of accommodation for this option must be established and indeed the Scottish General Practitioners' Committee (SGPC) (Consultation comment, 2002) would recommend that this option only be used as a last resort, where the screening facility can be accommodated without straining other clinical services.

For option ***ii***, the van must be big enough to allow patients to have the screening test in the van and also to allow patients to wait for screening. The Tayside screening programme uses a van the size of a Ford Transit and a parking facility is required close to an electricity supply, so that the van can be plugged in. The Tayside van has been modified to provide air conditioning running from the diesel: to cope with hot summer conditions and the cold winter conditions experienced in Scotland. This van does not include disabled access and it is currently only used to take a non-mydriatic image, so little space for waiting is needed.

Analyses that will help individual Boards to determine optimal screening modalities to suit the needs of their local populations are presented in the economic evaluation (section 8).

It is recommended that a national contract be organised for procurement and fit-out of diabetic retinopathy screening vans: taking account of current experience in local UK diabetic retinopathy screening programmes and remembering the need to enable disabled people to be screened.

6.5 Population to be Invited for Screening

The SIGN Guideline (2001) recommends that all people with diabetes should be offered systematic screening for diabetic eye disease. It states that people with type 2 diabetes should be screened from diagnosis (Grade A evidence). For people with type 1 diagnosis, it is recommended that screening start at age 12 or at onset of puberty, whichever is first, or if onset of type 1 diabetes is post-puberty, screening after three years duration is recommended (Grade D evidence). For simplicity of organisation and patient education, HTBS recommends that in the case of onset of type 1 diabetes post-puberty, screening should nevertheless commence from diagnosis in the national screening programme. Furthermore, only those who are capable of benefiting from receiving laser treatment should be screened (i.e. excluding those who are blind or medically unfit for treatment).

The screening programme does not need to include those under regular review by ophthalmologists in the hospital setting, but it is essential that information from specialist retinal examination is fully integrated into the medical record and call/recall systems for retinopathy screening. In a computer-based system, exclusion of a small proportion of patients should not pose many administrative problems, provided that all individuals known to have diabetes can be identified and that their records can be linked to the retinal screening results and clinical management recommendations of previous retinal examinations. A key issue concerns the process for invitation and, in particular, clearly definition of 'who' has 'responsibility' for this task. This is covered later in the section on quality assurance (section 6.13) and GP involvement (section 6.12.2).

6.6 Screening Interval

The Scottish Intercollegiate Guidelines Network (2001) assessed a number of studies performed to evaluate the optimal frequency of diabetic retinopathy screening, including options to evaluate patients at low risk bi-annually. As general diabetic screening for other complications takes place annually and this is the screening interval recommended by the NSC (UK NSC, 2000), annual screening is recommended in the Scottish programme. However, further research is required to establish those who are at low risk of developing sight-threatening retinopathy to consider increasing the screening interval for these patients.

6.7 Clinical IM&T

6.7.1 IM&T developments related to diabetes in NHSScotland

The Scottish Care Information (SCI) initiative is at the centre of the new Scottish Executive IM&T policy (Scottish Executive Health Department, 2001b). It includes a series of projects to create national, integrated IM&T systems, which can be used to support clinicians in the care of diabetes, cancer, mental health, coronary heart disease and pharmacy systems. A clinical steering group is directing each initiative, and SCI-DC will support the care of diabetic patients across primary, secondary and community care.

The SCI-DC plans two parallel streams of activity; firstly, the consolidation roll out and support of existing systems, and secondly, the development of a new national system incorporating the best of existing systems and converging with other new strategic, national developments.

The SCI-DC will build on the existing systems in the Lanarkshire Diabetes System (LDS) and DARTS project. This work will be linked with other NHSScotland IT systems, such as the General Practice Administration System Scotland (GPASS) and the work on national patient registers and electronic patient records undertaken by the Information and Statistics Division (ISD).

Therefore, it is essential that any clinical IM&T recommendations for diabetic retinopathy screening are consistent with the SCI-DC. For the call/recall issues, IT links from patient records systems in general practice are needed to aid the development of registers, populating screening lists and recording of results. The screening result and image also need to be incorporated into the computerised medical record. Furthermore, to permit participation of optometrists in the scheme, it will be essential to consider how they can be linked into the NHS confidential web-based system for transferring clinical records (NHSnet).

6.7.2 Clinical IM&T required for diabetic retinopathy screening

Any IM&T system for retinopathy screening should fulfil the following functions:

- identification, invitation and recall of eligible people with diabetes for screening;
- recording attendance for screening and results;
- incorporation of results into the patient's electronic medical record; and
- monitoring the screening process.

In the short-term, simple standardised call/recall systems should be established at local or regional level, which can be integrated into the national system being developed under SCI-DC.

6.7.3 Identification, invitation and recall

Call/recall systems must be able to identify all individuals eligible for screening and ensure seamless transition as patients move through NHSScotland.

The eligible population (section 6.5) can best be identified from the area diabetes register. This is a comprehensive register of all people with diabetes who are resident in a defined NHS Board region; this will include their names, addresses and dates of births, as well as the names and addresses of their GP.

At NHS Board level, the HTBS survey has shown that there is considerable work to be done to ensure comprehensive ascertainment of residents with diabetes. Several Boards are only able to estimate numbers. Established registers have taken several years to compile and quality assurance checks and procedures are, in most cases, at the early stages of development. Support for GP participation in the screening programme including submission of names of eligible individuals is therefore essential (section 6.12.2).

With computerisation, a simple invitation system will be implemented with the GP's participation and consent, both for initial screening and for subsequent routine repeat visits. A centralised approach to implementing this call/recall function will take time to develop. In the short-term, the only way to deliver screening using consistent datasets across Scotland is to develop a simple application designed for that purpose. An MS Access or similar database would suit and would provide a focus for regional screening in the immediate future. If regions are committed to this approach, an upgrade to a more tightly integrated, centralised solution, as part of SCI-DC will be simplified. In addition, the use of a standard database would lead to standardisation of call/recall mechanisms.

The HTBS survey shows that even where systematic diabetic screening programmes are in place in Scotland, call/recall capability is at the earliest stages of development. Experience from other population programmes based upon the CHI (Womersley, 1996) such as those for childhood immunisation, child health surveillance, and breast and cervical screening, has shown the benefits of a national central index for locating and following up individuals who move. Universal use of the CHI number in NHS information systems for patient identification should facilitate the design of IT systems to minimise the risk that an individual may be overlooked.

The CRAG dataset for diabetes (Scottish Executive Health Department, Clinical Resource and Audit Group, 2000a) (Appendix 9) includes data fields defined for retinal screening. Although this does not currently include standards for a call/recall system, the intention is to ensure each region commits to using consistent methods of call/recall that can be supported by one simple screening management database.

6.7.4 Attendance for screening and results

A simple record will be developed giving identification particulars, date of attendance, current retinal status, previous need for mydriasis and essential clinical information. This record will accompany the digital images and will facilitate the clinical decision-making process in terms of routine recall, repeat screen or referral for assessment.

Some individuals may, for clinical or other reasons, be too unwell to participate in systematic screening or to receive laser treatments. The call/recall process will also need to accommodate such circumstances. It is proposed that lists of patients who will be invited for screening will be sent to their GPs for approval before invitations to attend are issued (see 6.12.2).

6.7.5 Incorporation of results into the electronic medical records

The date of attendance and result will be added to the computerised diabetic record and sent to the GP. If a referral for assessment is made, the record will be flagged to expect a final diagnosis and this will provide a check that an appropriate referral has taken place.

6.7.6 Monitoring the screening process

Linkage to the local clinical diabetes information system is essential so that the diagnosis of diabetic retinopathy can be added to the diabetes record. Together with the records from the call/recall system the following aspects of the process can be monitored: acceptance rates, self referrals, cases of retinopathy detected by screening, proportion of people with diabetes referred for assessment, proportion receiving laser therapy, and incidence of visual impairment.

6.7.7 IM&T implementation plan

The following implementation plan is proposed:

Stage 1: Short-term implementation with call/recall at local level

- Definition of a retinal screening dataset;
- ascertainment of the data linkage requirements to populate regional screening databases;
- development of a simple, standardised, retinal screening administration database;
- procurement of additional retinal cameras and the development of screening software;
- initial testing of the administration database in one region; and
- gradual wider implementation and database seeding across Scotland.

Stage 2: Medium term implementation using SCI-DC:

- Collaboration and integration with national IM&T strategy;
- design and implementation of SCI outpatients, LDS and DARTS interfaces;
- incorporation of the retinal screening and administration dataset into SCI-DC;
- gradual migration to SCI-DC from the MS Access-based administration database;
- development of web screening mechanisms incorporating best of breed capability such as automated retinal grading and incorporating extensive educational material*; and
- incorporation of automated primary care links as part of SCI-DC.

*Web browsing is currently only possible with compressed images and so further research into the acceptability of compressed images is of vital importance (section 6.10).

6.8 Data Protection

Until recently, the use of patient identifying information in NHSScotland was governed by the *Data Protection Act* (Great Britain, 1984) and common law on privacy and confidentiality. The law has now changed as a result of the *Data Protection Act* (Great Britain, 1998) and the *Human Rights Act* (Great Britian, 2000) – for example data protection rules now extend to manual as well as computerised information and there are new personal rights to privacy for every citizen. The effect of this is to require users of data to be more transparent, accountable and responsive to the needs of individuals. The *Data Protection Act* (1998) has important implications for the handling of patient data and collation of data from a variety of sources via a patient identifier with identificable characteristics.

The Scottish Executive and the Confidentiality and Security Advisory Group for Scotland (CSAGS) have consulted since spring 2001 on proposals to ensure good practice in the involvement of patients in decisions about their personal health information. The Consultation Paper (The Confidentiality and Security Advisory Group, 2001) is currently available. This consultation has highlighted the need for both change in professional culture, and computer systems which remove identifying details of patients where there is no need to know. The consultation does not propose changes in the use of personal health information for direct patient care or for uses such as the essential management of the health service. It recommends the use of informed but implied consent in direct care scenarios and when using patient identifiable information to keep services running. It is proposed that the screening programme for diabetic retinopathy screening falls within the remit of direct patient care, but clear recommendations will be made for this screening programme as well as other national screening programmes when the final CSAGS report is published in spring 2002.

This guidance must also be considered in the context of the General Medical Council's (GMC's) document *Good Medical Practice* (General Medical Council, 2001) and other relevant professional guidance on data protection.

6.9 Grading

At the outset a three-level system is recommended for grading digital retinal images is recommended, similar to that used in Bro Taf (section 6.11.1). This multi-level approach should reduce the number of unnecessary referrals to ophthalmologists.

Initial graders would identify images with any potential sign of retinopathy and send them to second level graders (e.g. senior graders or optometrists). These graders would then review the images and pass on those with suspected referable retinopathy for final grading by an ophthalmologist. The ophthalmologist would also perform the quality assurance of a percentage of the images. To provide a clear career structure for the 'initial graders', they should be trained to achieve accredited 'senior' level status so that grading levels one and two can be combined.

A standard grading nomenclature for diabetic retinopathy screening is essential for consistent grading, for internal and external quality assurance purposes, for ease of exchange of data between clinical information systems, and for agreement on referral thresholds. The grading system needs to be of sufficient complexity to enable triage of patients into appropriate clinical outcomes, e.g. referral to ophthalmology, routine re-screen, re-screen at reduced interval, but as this is a screening programme it should not be unnecessarily complex. The important break points are the presence of *any* diabetic retinopathy and the presence of *referable* or *potentially sight-threatening* diabetic retinopathy. The latter category may include the presence of lesions within the vicinity of the macula.

In the report of the CRAG Working Group on IT to Support Shared Care in Diabetes (Scottish Executive Health Department, Clinical Resource and Audit Group, 2000) its diabetes dataset recommends a ten-point mutually exclusive grading nomenclature with the presence or absence of maculopathy assessed separately. In the CRAG dataset the term background diabetic retinopathy (BDR) is used in place of non-proliferative diabetic retinopathy (NPDR). The dataset does not include definitions of each level, but refers to The Royal College of Ophthalmologists 1997 guidelines for diabetic retinopathy for the precise definition of the grades. These are based on the EURODIAB feature-based grading system, which in turn was validated using two overlapping 45 degree photographic fields against the Gold Standard of a modified Airlie House classification applied to seven-field 30 degree photography, as used in the definitive Early Treatment of Diabetic Retinopathy Study (ETDRS) (1985).

The National Screening Committee through its Photographic Grading and Disease Management Working Party (UK NSC, 2000) has produced an alternative category-based grading system to the EURODIAB system. There are differences in terms of the number of grades defined and the requirement for any lesion counting – severity being assessed in comparison with standard photographs. As in the CRAG nomenclature, maculopathy is assessed separately, but there are important differences in that the main area of interest is less (circle of radius 0.5 DD vs. 1.0 DD), except where circinate exudates are present, in which case the area of interest is substantially larger. Haemorrhages alone in the macula are disregarded in the absence of a reduction in visual acuity. The NSC grading system is pragmatic, based on consensus expert opinion, but does not have a rigorous outcome-related evidence base, and has not been widely adopted in screening programmes elsewhere in England and Wales.
Table 6-2 compares the two systems, and is set out so that in each row there is rough equivalence. The NSC system reduces the retinopathy grades to four based on the requirement to identify both any retinopathy and sight-threatening retinopathy.

Table 6-2 Comparison of CRAG and NSC grading systems.

CRAG		NSC	
1	*No diabetic retinopathy anywhere*	R0	*No diabetic retinopathy*
2	*Background diabetic retinopathy (BDR) – mild* At least one dot haemorrhage or microaneurysm with or without hard exudates	R1	*Background diabetic retinopathy* At least one dot haemorrhage or microaneurysm or blot haemorrhage of extent less severe than NSC standard photo one, with or without exudates
3	*BDR – moderate* Any one of the following: Four or more blot haemorrhages per quadrant in one to three quadrants Venous beading in one quadrant only Cotton wool spots in one or more quadrants	R2	*Preproliferative diabetic retinopathy* Any of the following: Multiple blot haemorrhages of density in any area more severe than NSC standard photo one Venous beading Venous loop or reduplication IRMA Cotton wool spots are not diagnostic of R2, but should promote a careful search for other lesions
4	*BDR – severe* Any one of the following: Four or more blot haemorrhages per quadrant in four quadrants Venous beading in two or more quadrants IRMA in one quadrant		
5	*BDR – very severe* The presence of any two categories for BDR – severe		

6	*Proliferative diabetic retinopathy (PDR)* New vessels outwith a radius of one disc diameter of the centre of the optic disc	R3	*Proliferative diabetic retinopathy* Any of the following: New vessels on optic disc (NVD) New vessels elsewhere (NVE) Pre-retinal or vitreous haemorrhage Pre-retinal fibrosis ± tractional retinal detachment
7	*PDR – High risk* New vessels within a radius of one disc diameter of the centre of the optic disc		
8	*Advanced diabetic eye disease* Any of the following: Vitreous haemorrhage Rubeosis Iridis Retinal detachment		
9	*Enucleated eye*		
10	*Not adequately visualised* Retina not visible sufficient for assessment	U	*Ungradeable* Images ungradeable due to any of Poor quality Photographs not obtainable
Macula	*Diabetic maculopathy present* Hard exudates and/or microaneurysms or haemorrhages within a radius of one disc diameter of the centre of the fovea	M	*Maculopathy* Exudate within a radius of half a disc diameter of the centre of the fovea. Circinate or groups of exudates within a circle centred on the fovea with a radius equal to the distance between the centre of the fovea and the temporal margin of the disc. Any microaneurysm or haemorrhage within a radius of half a disc diameter of the centre of the fovea only if associated with a visual acuity (VA) of ≤ 6/12
		P	*Photocoagulation* Presence of photocoagulation scars
		OL	*Other lesions* Central/branch retinal occlusion Age-related macular degeneration/drusen Glaucomatous disc cupping Cholesterol emboli Asteroid hyalosis Pigmented lesion Myelinated nerve fibres

In the NSC system, R0 and R1 do not require referral whilst R2 and R3 require referral and urgent referral respectively. In the CRAG system, R2 is divided into three categories of BDR (moderate, severe and very severe), which might allow the option for a reduced screening interval for the BDR moderate group as opposed to referral. The NSC system includes advanced diabetic eye disease with proliferative retinopathy on the basis that both would necessitate urgent referral. The definition of diabetic maculopathy is quite different in the two systems, with a three-step process and an effectively twice-as-large area of potential interest in the NSC system.

The CRAG grading system is an objective, reproducible methodology for two fields that has an evidence base that relates grade to risk. A similar system, but one that was modified for one field has been shown to be effective in the detection of referable retinopathy (Olson *et al*, Evidence submission, 2001). This has been modified further by the HTBS Topic Specific Group to produce the Scottish Diabetic Retinopathy Grading System (SDRGS). This is presented in (Table 6-3) and should be used in Scotland for all retinal grading, including one- or two-field photography and slit lamp examination.

The modifications comprise:

- disregard of cotton wool spots in isolation, as these lesions have no greater prognostic significance than hard exudates (ETDRS, 1991);
- addition of a separate record for laser photocoagulation burns and other significant non diabetes-related coincidental lesions;
- an alteration to the grading rules for single-field photography to guarantee no possibility of undergrading background diabetic retinopathy (BDR) at any break point; and
- inclusion of grading of lesions at the macula that are most likely to respond to treatment.

Outcome of screening is determined by the highest grade in either eye.

Table 6-3 Scottish Diabetic Retinopathy Grading System

Grade	Two-field or slit lamp	Single macular field photography
1	*No diabetic retinopathy anywhere*	*No diabetic retinopathy anywhere*
2	*Background diabetic retinopathy (BDR) – mild* • At least one dot haemorrhage or microaneurysm with or without hard exudates	*BDR – mild* • At least one dot haemorrhage or microaneurysm with or without hard exudates
3	*BDR – moderate* Any one of the following: • Four or more blot haemorrhages per quadrant in one to three quadrants • Venous beading in one quadrant only (Quadrants defined by two perpendicular lines intersecting at the centre of the optic disc, with one line also passing through the centre of the fovea)	*BDR – moderate* • Four or more blot haemorrhages in one hemi-field only (Inferior and superior hemi-fields delineated by a line passing through the centre of the fovea and optic disc)
4	*BDR – severe* Any one of the following: • Four or more blot haemorrhages per quadrant in four quadrants • Venous beading in two or more quadrants • IRMA present (one or more quadrants)	*BDR – severe* Any one of the following: • Four or more blot haemorrhages in both inferior and superior hemi-fields • Venous beading present • IRMA present
5	*BDR – very severe* • The presence of any two categories for BDR severe	*BDR – very severe* • The presence of any two categories for BDR severe
6	*Proliferative diabetic retinopathy (PDR) – early* • New vessels outwith a radius of one disc diameter of the centre of the optic disc	*PDR – early* • New vessels outwith a radius of one disc diameter of the centre of the optic disc
7	*PDR – high risk* • New vessels within a radius of one disc diameter of the centre of the optic disc	*PDR – high risk* • New vessels within a radius of one disc diameter of the centre of the optic disc
8	*Advanced diabetic eye disease* Any of the following: • Vitreous haemorrhage • Rubeosis Iridis • Retinal detachment	*Advanced diabetic eye disease* Any of the following: • Vitreous haemorrhage • Rubeosis Iridis • Retinal detachment
9	*Enucleated eye*	*Enucleated eye*
10	*Not adequately visualised* • Retina not visible sufficient for assessment	*Not adequately visualised* • Retina not visible sufficient for assessment

Macula M1	*Diabetic maculopathy early* • Microaneurysms, haemorrhages or exudates within a radius of ≥ 1 but ≤ 2 disc diameters of the centre of the fovea	*Diabetic maculopathy early* • Microaneurysms, haemorrhages or hard exudates within a radius of ≥ 1 but ≤ 2 disc diameters of the centre of the fovea
Macula M2	*Diabetic maculopathy observable* • Circinate or groups of hard exudates within a radius of > 1 but ≤ 2 disc diameters of the centre of the fovea	*Diabetic maculopathy observable* • Circinate or groups of hard exudates within a radius of > 1 but ≤ 2 disc diameters of the centre of the fovea
Macula M3	*Diabetic maculopathy referable* • Microaneurysms or dot haemorrhages within a radius of 1 disc diameter of the centre of the fovea • Blot haemorrhages within a radius of 1 disc diameter of the centre of the fovea • Any hard exudates within a radius of 1 disc diameters of the centre of the fovea	*Diabetic maculopathy referable* • Microaneurysms or dot haemorrhages within a radius of 1 disc diameter of the centre of the fovea • Blot haemorrhages within a radius of 1 disc diameter of the centre of the fovea • Any hard exudates within a radius of 1 disc diameters of the centre of the fovea
Photo-coagulation	*Laser photocoagulation scars present*	*Laser photocoagulation scars present*
Other	*Other non-diabetic lesion present* • Pigmented lesion • Age-related macular degeneration/ drusen • Myelinated nerve fibres • Asteroid hyalosis • Retinal vein thrombosis	*Other non-diabetic lesion present* • Pigmented lesion • Age-related macular degeneration/ drusen • Myelinated nerve fibres • Asteroid hyalosis • Retinal vein thrombosis

Referable retinopathy comprises any of: BDR of grade moderate or worse; PDR; or diabetic maculopathy observable (M2) or worse. However, patients graded BDR moderate or diabetic maculopathy observable (M2), in the absence of other features of referable retinopathy need not necessarily be referred to an ophthalmologist as laser therapy would not be indicated immediately. However, this policy should only be followed if arrangements can be made to re-screen these groups at six monthly intervals. In the absence of a facility to offer re-screening at a six month interval all patients whose worst eye is graded as BDR moderate or diabetic maculopathy observable should be referred to an ophthalmologist.

It may still be questioned why a more simplified grading scheme cannot be used, which combines grades 4–8 as one item to indicate referral. The grading system will be an important tool in the training of graders, allowing quick identification of errors, reference material for

audit, prioritisation of patients for examination by ophthalmologists and easier adaption given experience in the programme, allowing refinement of referrals. However, it would not seem necessary to record formally the individual features identified in levels two and three for mild to moderate background diabetic retinopathy.

As shown in Table 6-4, it will be possible to make comparisons between the Scottish Diabetic Retinopathy Grading System (SDRGS) and the NSC grading system, if this is required.

The Scottish Diabetic Retinopathy Grading System should be used by all those involved in grading in the national screening programme. Furthermore, as this is a new scheme, careful training will be required about the use of the grading system in the context of the national screening programme (section 6.12.5.1). It will also be essential to evaluate the grading scheme and modify it, as necessary, with experience from the national programme.

Table 6-4 Comparison between Scottish Diabetic Retinopathy Grading System and NSC grading system

SDRGS		NSC	
1	No diabetic retinopathy anywhere	R0	No diabetic retinopathy
2	Background diabetic retinopathy (BDR) - mild	R1	Background diabetic retinopathy
3	BDR – moderate	R2	Preproliferative diabetic retinopathy
4	BDR – severe		
5	BDR – very severe		
6	Proliferative diabetic retinopathy (PDR) - early	R3	Proliferative diabetic retinopathy
7	PDR – high risk		
8	Advanced diabetic eye disease		
9	Enucleated eye		
10	Not adequately visualised	U	Ungradeable
Macula M1	Diabetic maculopathy early	M	Maculopathy
Macula M2	Diabetic maculopathy observable		
Macula M3	Diabetic maculopathy referable		
Photoco-agulation	Photocoagulation scars present	P	Photocoagulation
Other	Other non-diabetic lesion	OL	Other lesions

6.9.1 Automated grading

Automated detection of diabetic retinopathy has progressed rapidly in the last decade, and commercial programmes are now becoming available (Hipwell *et al.*, 2000; Ege *et al.*, 2000; Lee *et al.*, 2001). Research work is also being undertaken in this field by the TIDES project (Gray *et al.*, 1998) at the Tennent Institute in Glasgow.

Automated techniques have the advantage of repeatability and the algorithms can be set for any particular sensitivity or specificity. Individual human graders tend to have their own internal reference points, which are difficult to standardise, even with training, leading to intra- and inter-observer variability.

Grading of photographs or digital images is a repetitive task and where two-thirds are expected to be normal this leads to fatigue and boredom (Hipwell *et al.*, 2000). Computers do not face these problems but they are heavily reliant on images being of a sufficient quality to enable analysis. Images will therefore have to be graded for image quality before being processed. This is, however, a far simpler and quicker task than actually grading the image.

In a screening context, assuming a prevalence of retinopathy of 30%, it is has been estimated that automated grading, acting as a first level grader, could correctly classify 51% of a diabetic population as having no retinopathy.

However, to date, automated grading has not been used in a large screening programme. The largest study recruited 586 patients (Olson *et al.*, Evidence submission, 2001) but this is small in comparison to the total number of people with diabetes to be screened in Scotland. These have not been fully validated for use in a national programme, but they could provide significant advantages in terms of efficiency. Therefore, they should be systematically studied early in the screening programme.

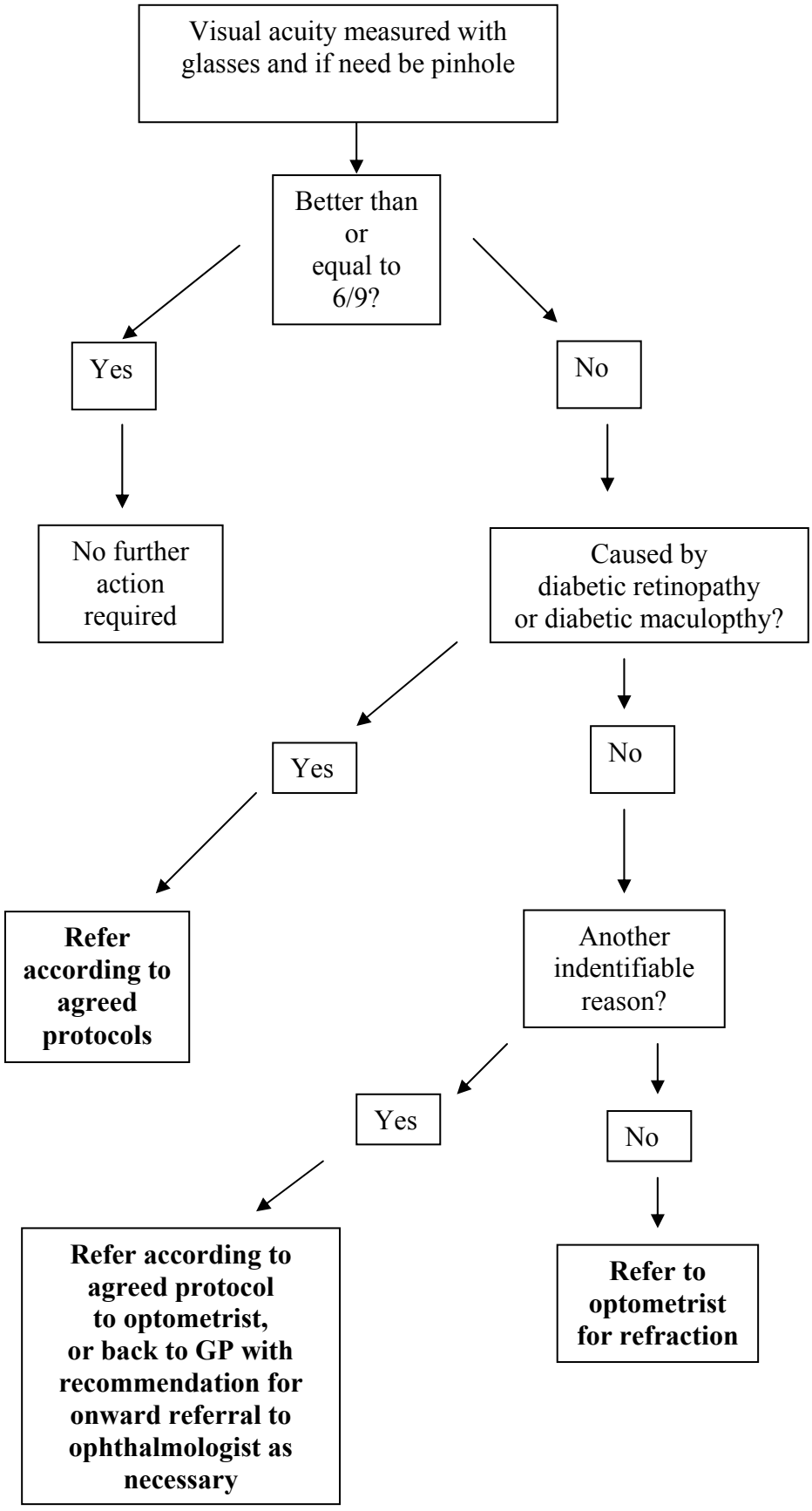
6.9.2 Visual acuity testing

There is no evidence that measurement of visual acuity adds to the diagnostic yield in the detection of diabetic retinopathy when combined with an otherwise adequate method of visualisation of the retina. However, as visual acuity is the objective measure of the fundamental outcome of the screening programme (preservation of vision through detection and treatment of diabetic retinopathy) it should be measured and recorded at the time of retinal screening. These data will provide valuable information on the numbers of patients who fulfil criteria for blindness (visual acuity in the best eye being worse than 3/60) for the purposes of the Scottish Diabetes Survey.

Visual acuity testing should be performed for each eye individually, in a standardised way using the patient's normal refractory correction, prior to mydriasis (if used). A Logmar chart is preferable for use, with results for each eye separately reported in Snellen format. Where the recorded visual acuity is 6/12 or worse the assessment should be repeated using pinhole refractory correction, and the best recorded visual acuity reported.

The process for visual acuity testing is presented in Figure 6-1.

Figure 6-1 Measurement of visual acuity



6.10 Retinal cameras and software necessary for manipulation of digital images

From an IT perspective, of prime concern in the procurement of new cameras and software is ensuring that images and the results of any screening can easily be extracted. Initiatives such as TOSCA (Zahlman, 2001) are attempting to provide value added services, such as automated initial grading, that Scotland may wish to implement in the longer term. To make the most of these opportunities, flexibility is vital. The most flexible camera solutions provide a TWAIN interface to the cameras. This allows the design of screening software to meet specific needs without relying on the development timescales of a camera manufacturer or forcing procurement of cameras from any one manufacturer. In addition, the cost of screening software from camera manufacturers is often high. If many new cameras are required, there may be a good economic argument for developing screening software for NHSScotland.

A simple MS Access retinal screening database that incorporates digital image capture and image manipulation is already available for use in NHSScotland (in Tayside). Here the Topcon TWAIN driver is used to physically capture the image. The MSAccess database coordinates the capture of this image via the driver provided. It displays and stores the image, and provides image manipulation facilities. Images are then compressed and uploaded to the website.

The image captured by the camera is initially stored as a fine grid of coloured dots (pixels). In digital systems, where the image is captured directly by a computer terminal two methodologies are currently used. The most common method relies on an analogue output from a video camera (most commonly operating at a 625 line TV standard), which is digitised in the capture PC by a frame grabber capture card installed in the PC. When the TV standard is in use, as is the case in the widely used Sony 3 chip DXC 950P camera, a digital image of medium resolution (785 x 576 pixels) is obtained. More modern higher resolution cameras using charged couple devices (CCD) or complementary metal oxide semiconductors (CMOS) can offer a true digital output via SCSI or USB connections, or a high resolution analogue output following digital to analogue conversion, requiring subsequent re-digitisation within the capture PC. The National Screening Committee (UK NSC, 2000) states that the current generation of medium resolution TV video cameras using analogue to digital conversion are inadequate for the purpose of diabetic retinal screening. They recommend the use of a true digital camera with a resolution of at least 1,365 x 1,000 pixels, such as the JVC KY-F7OU (CCD sensor) or the Canon D30 (CMOS sensor). This statement is based on the theoretical pixelation required to resolve a lesion with the diameter of a small microaneurysm. There is, however, little evidence on the performance of the various resolutions in the detection of lesions in actual practice or on the effect on the sensitivity for detection of referable retinopathy.

Scottish Healthcare Supplies (SHS), within the Common Services Agency of NHSScotland supply a procurement service to NHSScotland. They can provide comparative evaluations of equipment required by the health service and for the national breast screening programme they provide professional advice to NSD for the purchase and maintenance of all mobile breast units. They have been responsible for the procurement of non-mydriatic digital retinal cameras for the Glasgow region to use in this national scheme and the draft procurement document for Glasgow is presented in Appendix 10. To ensure best value for money, SHS should be involved in the equipping of this national screening programme, wherever possible.

6.10.1 Image compression

The use of a higher resolution camera does have some disbenefits. Image file size is between 4 Mb and 9 Mb compared to 1.3 Mb for medium resolution devices. This has significant implications for storage and transmission over networks of limited bandwidth. Some high resolution cameras have been found to suffer from significant internal noise that degrades the image. This can be dealt with by noise reduction filters within the camera, although these intrinsically reduce resolution by smoothing the captured image. For storage, the grid of pixels can be recoded into a more efficient form. However, some forms of image compression can reduce the quality of the picture and its use is an area of current debate.

A small study of 49 diabetic fundi (Newson *et al.*, 2001) photographed using 35 mm transparencies were digitised to tagged information file format (TIFF) using a scanner with a resolution of 3,000 dots per inch. The images were then converted to JPEG files at 0%, 70%, 80% and 90% compression, randomised and graded on a laptop computer with a super extended graphics array (SVGA), thin film transistor flat (TFTF) screen (1,024 x 768 pixels, 0.28 mm dot pitch). The images were presented in random order to two masked graders. The Gold Standard comparator was the original 35 mm image projected to a diameter of 1.4 μm (x 4,300). At 90%, 80%, 70% and 0% compression, the sensitivities (specificities) were 0.38 (1.0), 0.5 (1.0), 0.65 (0.83) and 0.72 (0.84) respectively. These results demonstrate a reduction in sensitivity with increased image compression. However, it is interesting to note that even with no compression, the sensitivity is less than 80%. The authors indicate that this was as a result of using the TFTF screen.

It is unclear how the scanning of 35 mm transparencies in this study relates to current digital systems where the image is captured directly by the PC, so the value of these results is questionable. Also, results for smaller levels of compression would be of interest. However, the conclusions regarding the low sensitivity and use of the TFTF screen are of relevance.

Monitor resolution is an important consideration because a three million pixel image cannot be viewed pixel for pixel on most systems. A 19 or 21 inch monitor running at a screen resolution of 1,600 x 1,200 will only display two-thirds of such an image. To make an image fit the screen, pixels will be merged and some information lost. This effect may be particularly marked in TFTF screens. Consequently a CRT monitor is recommended for grading purposes, but a laptop screen would be acceptable for immediate assessment of technical quality. For all screens, the best definition will be obtained if the image is viewed full-size and scrolled for grading as required.

Another small study of 68 diabetic fundi (Basu *et al*., 2001) compared photographs by the Sony DXC-950P (1.3 Mb) with the JVC KY–F70U (4 Mb), and investigated the effect of four levels of JPEG compression (20–50 KB). Microaneurysms and drusens were more easily detected against Sony's better contrasting background, but the JVC detected more lesions in the peripheral, less illuminated, portions of the Sony image. However, adjusting brightness and contrast allowed compensation for the differences between cameras. With regards to compression, there was no loss of lesion detection between the bitmap and JPEG formats for all four compression levels. In 11/68 of the fundi, tiny microaneurysms were detected by ophthalmoscopy, which had been missed by both cameras.

This study is more relevant to the options being considered in this screening programme. It suggests that image compression is not a major problem with either the older or newer cameras. However, the quality of the study is questionable. An appropriate Gold Standard has

been used, but it is unclear how many graders were used and whether there was any masking or randomisation of images.

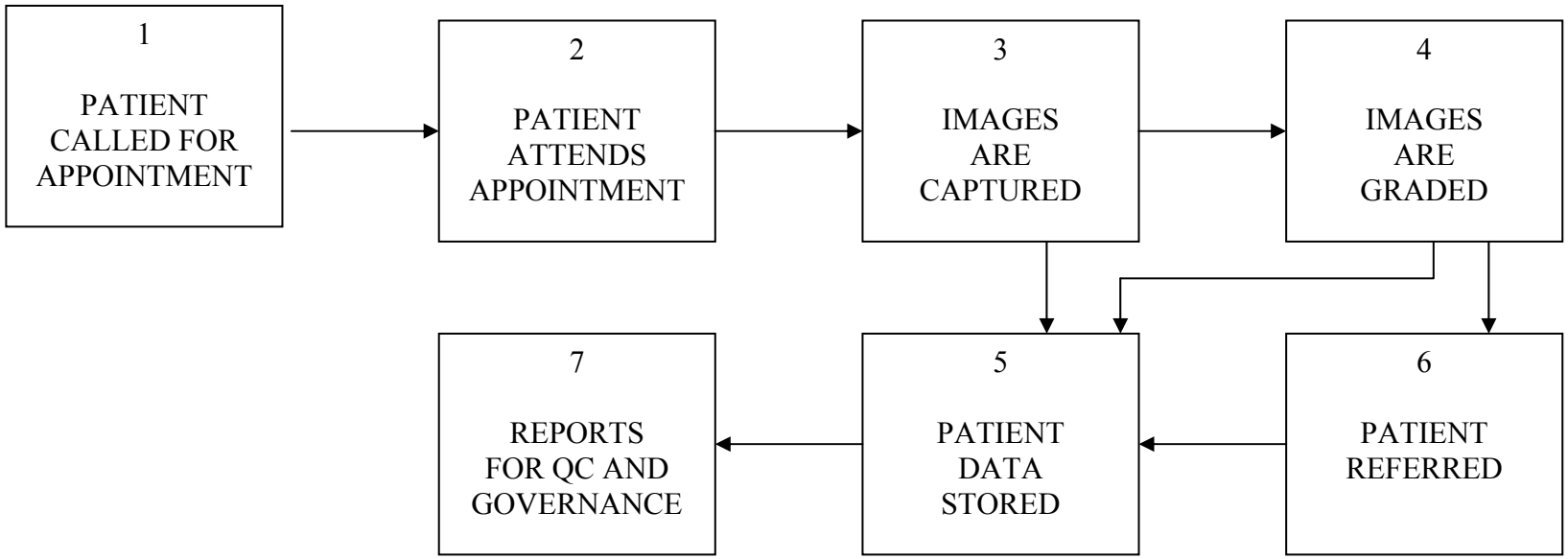
Some new algorithms may claim to achieve compression with no loss of information (lossless compression), but these will require further investigation.

Image compression is an important issue, given the size of uncompressed image files and the impact transfer of large files will have around the system, but significantly reduced sensitivity cannot be allowed so until some relevant results are presented studying the impact of compressed images, it would seem wise to use uncompressed images.

6.10.2 Image flow around the system

To illustrate the information flow for the digital images and integration with the clinical system, the process used in the Grampian screening programme is presented in Figure 6-2.

Figure 6-2 Image information flow (Grampian Diabetes Retinal Screening Service)



1	Letter sent to patient calling them for an appointment with the Retinal Screening Service
2	Patient attends retinal screening appointment at fixed or mobile site
3	Retinal images captured using digital camera
4	Images are graded by first-, second- and third-level graders
5	At all stages patient data is stored on a computerised system
6	If necessary patient is referred onto ophthalmology service
7	Reports produced for quality control and clinical governance to monitor the service

6.11 Examples of Large Diabetic Retinopathy Screening Service Programmes in the UK

6.11.1 The Bro Taf diabetic retinopathy screening service

The Bro Taf Health Authority in Wales has established a systematic diabetic retinopathy screening scheme with digital cameras, which has been a helpful model for the national diabetic retinopathy screening programme in Scotland.

In 2000, Bro Taf had a population of approximately 742,373 people and an estimated prevalence of diabetes of approximately 2.34% (17,372 patients). The service uses three mobile screening units using digital cameras with mydriasis. The organisational infrastructure of the service is presented in the diagram in Appendix 11. The service is based at one hospital, with one central service manager. Each van is staffed by a photographer and healthcare assistant. The vans travel to hospitals or community locations and the screening takes place at that site. The unit spends two to four days at each site.

Patients are referred by their GP, practice nurse or hospital consultant via a screening request form. Retinopathy screening coordinators located at four hospitals schedule screening sessions and contact patients directly about their appointments. (Registers are not in place, but these data regarding diabetic patients who require screening are held on a dedicated computer system to aid call/recall.) Sessions are scheduled three months in advance and patients are sent appointments approximately four weeks in advance. Timings may vary between localities.

Laptop computers are used for image acquisition and on return to base images are uploaded through the network onto the service database.

All images are graded by trained non-medical retinal primary graders using specially developed software with image manipulation facilities. Those graded as having sight-threatening retinopathy or with difficult or questionable images are reassessed by the screening service clinicians. A percentage of all images graded as normal are also checked. At fortnightly intervals, difficult cases and the appropriateness of referrals are reviewed with consultant ophthalmologists. Internal and external quality control systems are in place.

The retinopathy screening coordinators distribute the screening results to diabetologists within five working days for sight-threatening cases and to GPs or diabetologists in 20–25 working days for the remainder of patients.

6.11.2 Optometry schemes

The Staffordshire diabetic screening service started in 1995 and covers approximately 90% of the known diabetic population in the area. It involves 143 accredited optometrists (out of a total of 146) and all GP practices. A slit lamp with Volk lens is used with mydriasis. The importance of a team approach to patient care including ophthalmologists, optometrists, GPs, diabetologists, diabetes nurse specialists, dieticians and chiropodists was stressed. A local training scheme that was agreed against a national framework was implemented, with accredited practitioners and agreed referral protocols. The total number of examinations made annually is 13,098 or 18,400 single visits in an 18-month period. The service costs £12.50 per

patient and is estimated to have saved 2,912 hospital appointments over 18 months. A clinical audit scheme was established from the outset. However, the Director of Public Health suspended the clinical audit of hospital referrals after the scheme had been running for two years because no false positives were identified.

In Argyll and Clyde an optometrist-based retinopathy screening scheme was established in 1994 using mydriasis and direct ophthalmoscopy. In spring 2000 this was altered to utilise slit lamps, with direct referral to an ophthalmologist if necessary. The focus of the scheme is on the need for joint working with other members of the primary care team, recognising that the GP has the overall responsibility for the care of the patient. Since 1996, a protocol has been agreed with the area NHS Board. The scheme involves initial and ongoing training to receive accreditation. For audit purposes, 10% of all negatives are recalled and examined by ophthalmologists.

6.12 Staffing and Professional Involvement

The *Scottish Diabetes Framework* (Scottish Diabetes Framework Working Group, 2001) commends the adoption of LDSAGs (section 3.2.3) at NHS Board level and the development of Managed Clinical Networks for diabetes (MEL (1999)10) (Scottish Executive Health Department, 1999b). It will also be important to identify 'lead clinicians', 'key contacts' and programme coordinators. These are likely to be individuals who also have other responsibilities and they should not be confused with programme managers who are likely to have well-defined key functions and responsibilities specific to screening or other aspect of the service. In addition, controls on patient identifiable data (section 6.8) will require explicit arrangements for Caldicott Guardian and the Clinical Negligence and other risk indemnity scheme (CNORIS) requirements. All of these individuals should have 'named person' authority with clear remits, authorisation, support and accountability arrangements explicitly in place.

6.12.1 Organisation of staffing

The HTBS survey shows that the staffing needs of each NHS Board may be markedly different. Facilitation of local service design, specialist skills transfer and bridging through local transition processes (section 9.3.6) will be best done with a national specialised overview. Consequently, the National Services Division will have a key role to play in implementation and roll out of the systematic screening programme.

The report on the *Quality Improvement Review of Cervical Screening Call/Recall Arrangements in Scotland* by the Scottish Cervical Screening Programme review (2000) highlighted that the key components of that programme were highly dependent on a small number of individuals, who are often in low salary grades. Major review exercises of screening programmes have detrimental effects upon public perceptions but they also are harrowing for individuals working within or with these programmes. This can lead to long-term effects upon recruitment and retention of individuals with key skills and expertise. The setting up of a screening programme for diabetic retinopathy will therefore require careful planning and substantial managerial effort. Recruitment and retention of staff and the identification of support and training needs are key issues for all the professional groups who contribute to the screening programme.

Examples of the staffing structure for the Bro Taf Service are presented in Appendix 11, with accompanying job descriptions for the screening service manager and the retinopathy

screening coordinator presented in Appendix 12. Another sample job description for a retinal screener, as proposed by the British Diabetic Association (1997b) is presented in Appendix 13.

6.12.2 GP involvement

Unlike other screening programmes, individuals for diabetic retinopathy screening will not be all those of a certain sex and over a certain age, and those unfit to receive laser treatment will need to be identified. Cooperation of GPs within the national quality assurance programme will be essential to populate a diabetes register and screening database.

The Scottish General Practitioners Committee (SGPC) (Consultation comment, 2002) welcomes the proposals to produce a high-quality screening programme for diabetic retinopathy that delivers a high level of service to all Scottish patients using a multidisciplinary approach. However, the SGPC highlights the resource issues associated with GP involvement in the programme and the need to move as much of the administrative functioning of the service to the coordinating function within the national screening service.

Various models for GP involvement in breast and cervical screening programmes are available within Scotland. A similar model is planned for diabetic retinopathy screening, which would depend on close links between the GP and an administrative screening office, to ensure that as much administrative work as possible was performed by the screening office, particularly the issues relating to call/recall. Models could be built on the following basis:

- Initial visit to the practice by screening coordinator at the screening office, explaining the services and the options for GP practice participation.
- Individual practices prepare a personalised pro-forma letter (based on a national template), advising a patient that they will shortly be called for screening and encouraging them to attend.
- A list is sent to the practice giving the names of the patients whom the screening service thinks need to be called for screening. The practice 'cleans' this list, indicating patients who should not be called (e.g. due to death, terminal illness, bed bound, loss of sight etc.). This provides the ‘agreed’ list for invitations and corrections to address etc.
- The screening office merges the cleaned list with the pre-prepared letter pro-forma and produces the individualised letters of encouragement for the practice's population. These letters could be sent to the practices, signed by the GP, and posted by the practice or generated centrally and dispatched by the screening office.
- Shortly afterwards the screening service sends out screening appointments to patients, using the information from the cleaned list. After screening, timely notification of screening results to the GP and then to the patient is essential to avoid unnecessary anxiety (section 7.3.3).

6.12.3 Optometrist involvement

There are 905 optometrists in Scotland and 22 ophthalmic medical practitioners. Appendix 14 presents their distribution by NHS Board. As shown in the HTBS baseline survey (Appendix 2), 235 optometrists are involved in retinal screening in Scotland and 168 of these are working in NHS Boards with formal accreditation requirements.

Optometrists could perform retinal photography or slit lamp examinations, or both, and given their experience could undertake first and second level grading (either locally or in a central setting on a sessional basis). It may also be possible to train specialist optometrists (e.g. those currently working full-time in hospital settings) to undertake level three grading and associated responsibilities (e.g. quality assurance and training duties). Currently fees for optometrist participation in diabetic retinopathy screening vary across Scotland. For the national programme, it would be preferable to establish national fees for optometrists' services to the national programme.

The following features can also be stated about optometrist practices:

- conveniently located in most local communities, even in rural areas;
- open at times to suit patients and offer individual appointment times where convenient to patients;
- optometrists can advise patients of the outcome of screening at once and can recognise and rectify screening failures at once if using digital cameras;
- most people with diabetes have to attend an optometrist for refraction, so using an optometrist avoids duplication of visits by patients; and
- optometrist fees include all overheads and non attenders are not reimbursed.

Optometrists participating in the national screening programme should complete appropriate training to learn all aspects of the national programme, be accredited and named on lists for identification by those in NHS Boards organising the local service.

Optometrists will be subject to the ongoing audit and quality assurance standards set for all other screeners/graders in the national programme, including the specification on the minimum number of patients that should be screened.

6.12.4 Ophthalmologist involvement

The UK NSC (2000) has estimated that in the first year 8% of those screened will be referred to ophthalmology. However, these figures represent the worse case scenario, where there has been no previous monitoring. The NSC notes that in reality it is estimated that about 60% of people with diabetes will have been examined in some way in the last year and 80% in the last two years.

Referral and treatment by an ophthalmologist should follow the standards specified in the eye care section of the *Clinical Standards: Diabetes* (CSBS, 2001).

In the Scottish programme, extra ophthalmological input is likely to be required for training and accreditation purposes, for both the digital cameras and slit lamps. The Scottish Executive has set up a working group to consider the impact of the screening programme on ophthalmologist's workload and in Scotland the impact is not anticipated to be as large as that arising from the NSC programme.

The Scottish Diabetic Retinopathy Grading Scheme recommended in this HTBS Health Technology Assessment (6.9) should reduce the workload safely by maintaining certain categories of patients within the screening programme who according to NSC criteria would otherwise be referred. It is also anticipated that optometrists could be used rather than ophthalmologists to undertake slit lamp examinations for those not amenable to digital photography and current experience in Scotland indicates that specialist optometrists or retinal screeners may be able to undertake quality assurance.

6.12.5 Training

Training will be essential to explain the various aspects of the national screening programme to the professionals involved.

All contact between a health professional and a patient can provide an opportunity for opportunistic health education. This is particularly true in the case of diabetes, where lifestyle factors are important in disease management. Consequently, all professionals who meet people with diabetes should receive training on good communication skills and should be aware of the diabetic retinopathy screening programme so that they can encourage attendance.

The most substantial training requirements for the national diabetic retinopathy screening programme are for:

- retinal screeners – trained to photograph and grade digital retinal images;
- retinal graders – trained to grade digital retinal images; and
- photographers – trained to photograph (and determine whether a digital image is ungradeable).

6.12.5.1 Training for retinal screeners/graders

Specialist training of retinal screeners/graders is a fundamental element in the establishment of an efficient and effective screening programme for diabetic retinopathy. This will require training, accreditation, continuing appraisal, creation of external links, standard operating procedures and quality assurance.

HTBS recommends that for formal accreditation of a retinal screener/grader an approved training programme should be followed, resulting in a satisfactory final assessment by a single national accreditation body (by assessment of theory and practice). The training programme should be modular to accommodate the needs of the different groups (and backgrounds) of those who might participate (e.g. nurses, photographers, optometrists, medical technical officers and medical practitioners) and the needs in different localities. It may be provided by a number of different providers under the auspices of a single national accreditation body but training should be undertaken according to national standards and quality assurance (section 6.13).

Outcomes of training should include clinical and technical skills, patient management and confidentiality, communication skills, quality assurance and audit, and IT skills. For retinal screeners and photographers, it will be essential that training is sufficient for the individual to determine when a photograph is a technical failure, so that the patient may be given eye drops or if that fails, given a slit lamp examination. For the retinal graders, detailed training in the use of the SDRGS proposed in section 6.9 will be necessary.

A training programme is under development in Scotland (A.Ellingford, Personal communication, 2001; J. Olson, Personal communication, 2001). The steering group for this training programme is multidisciplinary including a diabetologist, senior retinal screening coordinators, ophthalmologists, public health consultant, diabetic retinopathy screening project manager, optometrist and patient. They aim to set standards for training, design the training (including delivery, content and examination) of the course for level one graders and accredit individuals/organisations to deliver the course. A pilot of this training programme

was run in Grampian in January 2002 and a second modified training programme is to be undertaken in Glasgow in spring 2002.

The current proposal for this training programme is that it will include an initial two- or three-week course, followed by workshops and lectures. Courses should be small, with approximately six to eight delegates per course. It was planned that following the initial teaching course, in the first three months the trainee could work 40% of the time with an experienced grader with the remaining 60% of the time spent in actual grading. For the following three months, it would be appropriate to have only 20% of work fully supervised. Continued learning and support would be achieved through distance learning packages facilitated through a website and also a training manual is currently being drafted.

In Grampian, retinal screening nurses undertook the pilot training course for seven days (over a two-week period). After two days of grading, all could perform level one grading competently (and were working towards competency for level two grading). The retinal screening nurses then undertook approximately four weeks practice screening patients prior to the commencement of grading alone. Following this, they acted as level one graders, with 10% of their work audited on a weekly basis by a level three grader and all patients with referable retinopathy or maculopathy audited by level two graders.

A number of national bodies have a keen interest in the training of retinal screeners. Organisations such as the Royal College of Ophthalmologists, the British Association of Retinal Screeners, the College of Optometrists, the British Ophthalmic Photographers' Association, the Royal College of Nursing, the Association of Optometrists, the Scottish Committee of Optometrists, Glasgow Caledonian University and Diabetes UK should be kept informed of advancements in Scotland and collaboration with these bodies is encouraged.

Those undertaking slit lamp examinations should also be fully trained and accredited. The College of Optometrists provides a training and accreditation programme for community optometrists undertaking diabetic eye care using slit lamps. The programme is being redrafted, but the most recent outline is presented in Appendix 15. Although this training progamme is currently established for slit lamps, it could easily be modified according to the training framework being established for the national screening programme. This would need to include the components that are unique to the Scottish system, such as the use of digital cameras, the three-stage screening process, the grading scheme, IT requirements, call/recall and quality assurance requirements, etc.

6.13 Quality Assurance

The HTBS Baseline Survey has clearly identified the absence of systematic and comprehensive quality assurance processes throughout Scotland in 2000. A whole systems approach within an organised learning culture (Checkland, 1999) is needed to move from the rather haphazard position at present towards a model that is both consistent and relevant to the present reality of NHSScotland (Scottish Executive Health Department, 2001b).

The quality assurance process must be capable of enabling activities at an individual level (patient or practitioner) as well as at population levels (practice, hospital, local healthcare cooperatives (LHCC), Board or national).

Quality assurance standards and processes for different components of the programme should be set nationally as in other screening programmes (MEL (1999) 82) (Scottish Executive

Health Department, 1999a) by the Clinical Standards Board for Scotland (CSBS) in liaison with the National Services Division.

Entry to the national screening programme requires informed consent and failure to obtain this could be considered as negligent. It is essential to be able to demonstrate that each eligible individual has been given the opportunity to make an informed decision. Key to all of this is clear presentation and dissemination of agreed policies, procedures and responsibilities. The roles and responsibilities, for example, of a GP to their patient, need to be considered alongside their complementary roles and responsibilities within a national systematic population-based screening programme. The policy for areas of potential ambiguity or confusion should be clearly stated within the national guidance and operational procedures designed to 'fail safe', protect and respect each eligible individual being considered for invitation for screening.

Patient issues are central to any screening programme (section 7) and to maximise uptake it is essential to instil public confidence in the programme. One important method for achieving this is to have patient/public involvement in the development and monitoring of the programme. This is a central value of the work of the Clinical Standards Board for Scotland and experience shows that patients are keen to participate in such activities.

The NSC report (UK NSC, 2000) proposes quality standards for a diabetic retinopathy screening programme covering 15 objectives, from reducing blindness registrations to ensuring timely responses. In Scotland, a number of areas with systematic local schemes have audits in place.

Areas for which standards should be established include:

- quality assurance of population register and call/recall systems;
- quality assurance of screening register (including data items and standard data sheet);
- quality assurance of optical devices and image capture equipment (cameras, reporting software and monitors should be properly maintained and tested to demonstrate their ability to resolve an image of a test object);
- training and accreditation of graders/screeners for digital photography and slit lamps;
- quality assurance of 'negatives' (Scottish Office, 1995);
- quality assurance of register of 'positives';
- quality assurance of screening history of 'positives';
- programme coordination, governance and scrutiny; and
- quality assurance of treatment.

These standards will be divided into those elements that are 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). The former will be defined according to standards being created for all national screening programmes in Scotland by the Clinical Standards Board for Scotland. The latter will be specific to this programme and designed at the outset of the programme. Helpful insights into the standards that might be used are available from other experienced sources.

Audit data are key to monitor standards and improve performance. At the HTBS Open Day, two workshops were held to discuss audit issues. The participants in the workshops included a wide variety of professionals and patients. All participants agreed that for the screening programme to be successful there must be public confidence in, and public accountability for, the screening programme. There must also be clear identification of the roles and

responsibilities of all those involved in the programme, including the Scottish Executive, NHS Boards, GPs, optometrists and people with diabetes.

The workshop thought that minimum standards should be set for the following issues:

- sensitivity;
- specificity;
- patient acceptability;
- population coverage;
- referrals to ophthalmologist;
- referrals to laser treatment;
- number with visual impairment;
- number blind; and
- timely reporting of screening result to GP (section 7.3.3.4).

Incorporating any continuous re-evaluation of sensitivity and specificity into the programme is likely to prove unfeasible because of the necessity of obtaining Gold Standard re-examinations of patients who are screened negative. As an alternative it is envisaged that further evaluation of these measures will be produced by an ongoing programme of research aimed at service improvement (see section 9.3.7). It is important, however, to assess the main sources of potential human error in the retinal imaging process. This will involve checks on grading errors, misclassification of images as technical failures, and the proportion of images rated as technical failures. The checks must be sufficiently accurate to detect problems at the level of an individual grader or photographer.

This section suggests many outcomes that would be of interest to evaluate in the screening programme. However, it is important not to overburden data collection, but to allow sufficient evidence to be gathered to check the quality and efficiency of the scheme. The CSBS will evaluate these suggestions for their work in setting national audit standards.

6.14 Screening Management Responsibilities in NHSScotland

As described in the quality assurance section (6.13), clear specification of management responsibilities is essential, so the following section outlines the organisational responsibilities based on the current structures in NHSScotland.

Scottish Executive Health Department

- Takes advice from the NSC regarding screening programmes in the UK;
- takes advice from HTBS on the most clinical and cost-effective strategy for organising the screening programme taking account of patient preferences in NHSScotland;
- makes policy decisions regarding implementation, timing, coverage, structure, funding and oversight of screening programmes;
- directs NHS Boards to implement policy, CSBS to develop and publish quality standards and may instruct the NSD to provide national coordination;
- monitors the performance of NHS Boards, CSBS and NSD in implementing policy and holds these bodies to account in achieving the policy objectives of the screening programme; and
- evaluates the impact of the policy on the health of the people of Scotland (i.e. in the longer term has introducing a screening programme had the planned impact on reducing blindness due to diabetes?).

National Services Division (NSD)

- Works with NHS Boards and the CSBS to ensure a consistent coordinated approach to the implementation of national policy on screening programmes;
- facilitates the development of a national specification for the diabetic retinopathy programme incorporating national quality standards as the basis for NHS Board Service Agreements;
- facilitates national meetings for NHS Boards to share good practice and results, and consider audit and quality assurance results; and
- works with the ISD in the CSA to aggregate data and make information available to NHS Boards, the Scottish Executive and others.

Clinical Standards Board for Scotland (CSBS)

- Publishes national standards for screening programmes;
- reviews performance against national standards and reports to NHS Boards on results achieved, with recommendations for action; and
- publishes reports on performance of the programme against standards every three to five years.

NHS Boards

- 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 implementation of the programme.
- Promote screening uptake and publicise benefits;
- assess the needs of the population for screening services;
- plan, establish and commission local screening services to meet the needs of their resident populations according to the national specification, with local flexibility where appropriate;
- monitor performance of the programme and agree action required in collaboration with local screening units, GPs and diabetes services;
- initiate action as required in response to three-yearly CSBS peer reviews of performance against national standards;
- coordinate the various agencies involved in the delivery of screening within the NHS Board area (e.g. hospitals, primary care centres, specialist centres); and
- produce an annual report on the performance of the screening programme.

Screening Offices

Screening offices may serve one NHS Board area or, more efficiency, one regional office could cover several NHS Board areas.

The screening office will be expected to undertake the following duties:

- the screening office coordinator will be accountable to the Governance Board of the local NHS Board(s) (through the Director(s) of Public Health) and ultimately the Chief Executive in all management matters;
- establish call/recall mechanisms for locality-based accredited screening options, working with GPs to ensure appropriate call/recall;
- ensure regular multidisciplinary meetings to review cases and any problems with the organisation of the programme; and
- ensure monitoring by minuted meetings every few months involving a lead from each of the various disciplines involved locally, along with the screening office coordinator.

6.15 Conclusions Concerning Organisational Issues

The Scottish national screening programme for diabetic retinopathy should be integrated with other clinical management systems for people with diabetes as outlined in the *Scottish Diabetes Framework* (Scottish Diabetes Framework Working Group, 2001). The screening programme should be fully quality assured according to standards specified by the CSBS and coordinated by the NSD to ensure a consistent approach.

All people with diabetes aged over 12 or post-puberty are eligible for screening annually unless they are medically unfit to receive laser treatment. Those unfit to receive treatment will need to be identified with the help of GPs, whose involvement in the call/recall system will be vital.

The main technology used in the programme will be non-mydriatic digital cameras, with slit lamps used to screen those not amenable to digital photography. In addition, all patients should receive a visual acuity test. A variety of modalities are available to provide these options and experience can be gained by evaluating programmes from across the UK (as presented in section 8). NHS Boards should establish the needs of patients in their area and plan, establish and commission local screening provision, working with other Boards to increase efficiency wherever possible.

Evidence related to image capture and manipulation is discussed extensively in this report and minimum requirements for technical specifications are presented. In addition to the optical equipment to be used, issues such as call/recall, etc. must be considered. This is best achieved by a simple standardised database, which can be developed to integrate with the emerging national IT system for diabetes, SCI-DC.

All images should be graded using the Scottish Diabetic Retinopathy Grading Scheme. Retinal grading can be undertaken by a variety of healthcare professionals, but all must be appropriately trained, accredited and competent. The outline of a national training programme is presented and it is recommended that this be used across Scotland.

Many health professionals are involved the care of people with diabetes. All should be educated about the importance of the diabetic retinopathy screening programme so that they can support and encourage patients to attend (see section 7).

7 PATIENT ISSUES

Summary

- In common with all aspects of diabetes, patients must be empowered to help manage their disease; this requires support and collaboration from clinical and patient organisations.
- Patients must be informed of the need for diabetic retinopathy screening and the process involved.
- The goal should be to coordinate diabetic retinopathy screening with other diabetes screening visits, wherever possible.
- Patient preferences include a desire for clear, timely information about all aspects of screening, choice of screening venue and appointment time and a desire to be treated as an individual, rather than 'another eye'.
- One study and various consultation comments indicate that some patients do not like mydriasis and that the information provided about the effects of mydriasis is often inadequate. Consequently patients should be informed of the possible need for mydriasis and its effects before attending the screening visit. It should be clearly explained that there will be an increased sensitivity to light and that driving is not recommended for at least two hours after mydriasis, but that effects may last longer in some individuals.
- Use of a variety of educational approaches (written, video, posters, television, World Wide Web, personal contact) is worthwhile and must be targeted to suit specific audiences.
- Appointment cards should be available in large print and information should be prepared in accessible formats (large print, disk, audio).
- Studies show that use of more than two written reminders has little impact on attendance rates and in such cases direct contact with a diabetes facilitator is useful to discuss any barriers to screening.
- Special attention should be given to target those patients who have not attended screening for a long period.
- If possible, patients should be given a copy of their retinal photographs.
- Results of screening should be communicated to patients 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.

7.1 Background

The consideration of patient issues is key to any Health Technology Assessment and fits with Scottish aims to create a patient-centred NHS.

For any screening programme, success depends upon continued consistently high levels of uptake, thus patient satisfaction with the scheme, their preferences and willingness to return for screening are of vital importance. Key issues to be considered include delivery of the service, patient information and education.

Other screening programmes involve a clearly defined group of individuals who often have no other health concerns are often targeted at one sex and a very specific age range. For diabetic retinopathy, the screening population is much broader, covering patients from their teens through to old age, of either sex and with the possibility of other related health problems. People with diabetes are expected to follow dietary advice and may be on medication to help control the diabetes or its associated complications. They will also be expected to attend for a variety of annual screening visits and so coordination with healthcare initiatives is particularly important.

The screening of elderly patients raises questions about accessibility of the service, which are particular relevant for this service given that approximately 45% of people with diabetes in Scotland are aged 65 or more (Scottish Executive, 2001).

7.2 Methods for Evaluation of Patient Issues

The qualitative questions relating to patient issues have not been reviewed systematically, but have been investigated using a variety of grey literature and published sources including:

- a Health Technology Assessment about diabetes education (Corabian and Harstall, 2001);
- various published papers about recruitment strategies for diabetic retinopathy screening from other countries;
- educational materials from Diabetes UK;
- HTBS Open day workshops on patient issues;
- focus group work;
- surveys of patient attitudes to NHSScotland breast screening programme (SHPIC, 1997); and
- the patient group summary from the NSC report (UK NSC, 2000).

A Cochrane review of interventions for improving coverage of screening schemes for diabetic retinopathy (Grimshaw *et al.*, 2001) is underway and may provide important information for consideration in this national screening programme in the future.

7.3 Results

7.3.1 Informing and empowering people with diabetes

The *Expert Patient Report* (Department of Health, 2001) recognises that people who live with chronic medical conditions are often in the best position to know what they need to manage their own condition. However, support is needed and the collaboration of patient and clinical organisations is crucial to develop effective self-management initiatives. Furthermore, a

person with diabetes must be considered as a member of the multidisciplinary team helping to determine appropriate disease management. Likewise the patient has a clear responsibility to cooperate in healthcare and for diabetic retinopathy the key responsibility of the patient is to attend screening regularly.

Informing patients about diabetes, its complications and control is essential. Information should be provided in a manner that is relevant and appropriate to the needs of patients (e.g. considering age, language and culture). However, education is not sufficient to create change. Methods should be used which consider psychological and motivational aspects of behavioural change. Patient empowerment is essential and people with diabetes need to be supported and encouraged to take an active role in their own healthcare. *The Health Promoting Health Service Framework* (HEBS, 2001) is available in NHSScotland to support staff in this work.

A recent Health Technology Assessment on *Patient diabetes education in the management of adult type 2 diabetes* (Corabian and Harstall, 2001) found that in the last decade there has been a move for formal patient diabetes education to focus on patient-centred perspectives, self-efficacy, self-management and empowerment issues. However, quantitative research on the value of formal patient diabetes education is limited and studies are generally of poor quality, with no evidence on long-term outcomes in terms of diabetic control. Further investigations are needed to determine what methods are most effective and which categories of patients would benefit most from these educational interventions.

The complications of diabetes must be explained sensitively to patients' taking account of the patient's situation. Patients should not be overloaded with information at the time of initial diagnosis and the fear felt by patients should be recognised. Ongoing support and encouragement is essential (UK NSC, 2000).

With teenagers, it must be recognised that a non-critical approach, which permits open discussion of issues such as drug and alcohol interactions is particularly important. There may also be a role for peer education in this group.

Many barriers including language, cultural beliefs and attitudes, and length of residency in a country can hinder the provision of healthcare. Recruitment for breast and cervical screening programmes in Australia has shown consistently lower participation rates for groups from culturally diverse backgrounds (Lee *et al.*, 2000). Also, it must be recognised that it may be difficult to encourage the homeless, those living in institutions, people with mental health problems or learning difficulties to attend screening and methods to maximise involvement of these patients should be considered.

Diabetes UK (formerly the British Diabetic Association) produces a wide variety of educational material about diabetes. General educational material includes information about the diabetic retinopathy and the importance of annual screening. They also produce a specific booklet entitled *Diabetes and your eyes* (British Diabetic Association, 1997a). Young people have special needs and Diabetes UK produce general diabetes educational leaflets targeted at children, with a separate one for teenagers. Carers of children with diabetes are in particular need of support and knowledge. The Royal National Institute for the Blind/Scotland also provides advice with *See It Right* guidelines (RNIB, 2001) and *An effective communication* pack for healthcare professionals providing information to patients.

The potential of web-based technology has been discussed in section 6.7 and this includes important possibilities for patient education and interaction. All information should be presented in formats that are internationally recognised as suitable for the visually impaired (Bobby compliant). For mobile screening units, the ability to provide accurate information about the location and timing of mobile screening sessions over the World Wide Web will be particularly valuable.

All information about the diabetic retinopathy screening programme should be prepared or made available in accessible formats (large print, disk, audio, etc.). It would seem appropriate to have appointment cards available in large print or at least have a flag for this requirement on the call recall system.

In Scotland, liaison should take place with the Health Education Board for Scotland and NHS Board Health Promotion Departments to facilitate educational activities and encourage attendance at screening visits. Also, NHS24 should be fully aware of the diabetic retinopathy screening programme, along with other diabetes care and services, so that they can clearly inform patients about the services offered.

7.3.1.1 The role of health professionals

A variety of professionals will be involved in provision of care to people with diabetes. A sensitive approach is required by all professionals to increase patient awareness and understanding, encourage patient self-management and ongoing commitment to screening and other healthcare initiatives.

Unlike other screening programmes that screen otherwise healthy patients, people with diabetes are more likely to discuss health management issues with their local pharmacist. Hence pharmacists have an important role to play in patient education. This has been recognised by the Royal Pharmaceutical Society of Great Britain (RPSGB) in their report: *Practice guidance for community pharmacists on the care of people with diabetes* (RPSGB, 2001). The RPSGB report notes that education does not necessarily lead to improvement. A pharmacist may provide additional motivational support, which, along with education, may lead to behavioural change and improvement.

The RPSGB report notes that diabetes education is often poor in the elderly person with type 2 diabetes particularly those who live in residential and nursing homes (where between 7 and 10% have diabetes) and so pharmacist involvement in such communities may be particularly beneficial. The report provides specific guidance on education about complications, however the current information about screening for diabetic retinopathy is unclear and could be updated in line with this Health Technology Assessment. It is important to assist pharmacists in their interactions with diabetic patients and special leaflets may be appropriate for pharmacist distribution. Also, local pharmacists should be informed when a mobile unit is in their area, to help encourage attendance by diabetic patients.

The National Pharmaceutical Association (NPA) is drafting a report which highlights that community pharmacists see people with diabetes up to five times more than any other healthcare provider (National Pharmaceutical Association, 2001). The NPA report promotes the role of the community pharmacist in providing appropriate individual health promotion messages and education for people with diabetes. HTBS will work with the NPA to ensure that their educational material takes account of this Health Technology Assessment.

A multiprofessional group including doctors, pharmacists, nurses, dieticians and podiatrists has been brought together by the National Board for Nursing, Midwifery and Health Visiting for Scotland to identify core competencies for a broad range of healthcare professionals working in diabetes in each of their professions.

The College of Optometrists places great emphasis on the role of optometrists in patient education and care in relation to diabetic retinopathy screening (as discussed in section 6.12.3) and likewise retinal screeners/photographers will have an important educational role to play.

For those professionals actually undertaking diabetic retinopathy screening, it is important for them to communicate with the individual being screened, exactly who they are and what their role is, why the screening is being undertaken and what will happen subsequent to the screening visit.

7.3.1.2 Patient information about diabetic retinopathy screening

The national programme for diabetic retinopathy screening should provide information in advance to people about the need for screening, the process of screening, the outcome and the limitations of screening. The UK NSC (2000) stress that screening should be provided to help individuals make better informed choices about their health, but that individuals must have a realistic expectation of what a screening programme can deliver. It notes that while screening has the potential to improve quality of life through early diagnosis, it is not a fool-proof process. Screening can reduce the risk of developing the complication, but it cannot guarantee protection.

A range of communication tools will be required to provide information about the national screening programme. These will need to be tailored to a variety of target audiences and people with diabetes should be involved in developing such resources. The tools should be pre-tested in representative samples of patient groups and integrated with established and trusted communication channels.

One common form of communication is a patient information leaflet. Such leaflets should be drafted for the national scheme, with local modification as required and used in conjunction with other promotional materials. Circulation of the leaflets could include public libraries, health promotion units, family planning clinics, and pharmacies. They may be made available for passive collection or used by health professionals as a tool to aid discussions with patients. For the more general areas, a general leaflet about diabetes would probably be sufficient, with specific diabetic retinopathy screening leaflets available on request.

A selection of patient information leaflets to inform about diabetic retinopathy screening services is presented in Appendix 16. These are specific to local schemes and would need to be adopted for the Scottish national scheme, with sufficient space to permit inclusion of local information about the screening scheme.

For the national screening programme, key issues to present in a leaflet are:

- the importance of screening – the benefits and limitations;
- the reasons that these screening tests are different from standard eye examinations;
- the method of screening being offered;
- the possible need for eye drops and effects that may be experienced;

- if retinopathy is detected, the treatments possible and expected outcomes;
- channels for further help and support;
- data protection rights and confidentiality controls to ensure individual privacy while maximising public benefit;
- the time when the result may be expected; and
- a contact person to discuss any concerns about screening or the result or ensuing treatment.

In the case of diabetic retinopathy, provision of material for the partially sighted, in large, clear print in line with RNIB guidance (2001), is particularly important. Furthermore, as the prevalence of diabetes is between three and four times higher in communities of Asian and Afro-Caribbean origin than in those of white origin (Scottish Diabetes Framework Working Group, 2001) patient information leaflets should be available in relevant languages. Diabetes UK issues documents for the Chinese and for South Asian people in Urdu, Gujarati, Bengali, Hindi and Punjabi. Gaelic, Urdu and Punjabi texts will be particularly relevant for Scotland. In such groups of patients, specific campaign work targeted to each audience may be needed.

7.3.2 Methods to improve screening attendance

For many people (those who normally attend screening), a personalised invitation and up to two written reminders will be sufficient to secure screening attendance. However, for certain groups, such as teenagers, ethnic minorities, the elderly and those from areas of deprivation, a range of specifically designed strategies may be necessary.

Basch *et al.*, (1999) recognised that certain groups may be less likely to attend screening visits and that focusing on high-risk subgroups is a good strategy for improving overall attendance rates. Consequently they performed a randomised study evaluating the effect of education on African Americans between 1993 and 1995. The outcome was attendance for a digital retinal examination (with mydriasis) within six months of randomisation. The study included 280 people with diabetes, from five medical clinics in New York, who had not received a retinal examination within the previous 14 months and were not blind or did not have advanced eye disease in both eyes. Each clinic provided patient educational services and printed diabetes patient education materials, and three of the clinics had certified diabetes educators. Randomisation was stratified by clinic and sex. The control group received the routine medical education provided by their clinic. The intervention group received, in addition, a three component educational programme: a low literacy, nine-page colour booklet, a motivational video and semi-structured telephone education and counselling. The booklet and video were posted at randomisation. The telephone component was initiated approximately one week after randomisation. The health educator worked to identify reasons for, and/or, barriers to having a dilated retinal examination. Focused problem solving then guided the subject to make an informed choice about receiving the screening examination. Follow-up calls were made and individually tailored mailings of tip sheets provided practical strategies for overcoming specific barriers. The median number of calls made was four and the median time spent per patient was 53 minutes. When a patient attended for screening a congratulatory letter was sent and they were encouraged to go for an examination annually. After six months the control group were sent the intervention booklet along with a cover letter urging them to attend a digital retinal examination if they had not attended one in the previous 12 months.

In this study, 273 of the 280 (98%) patients were followed to the six month outcome. The mean age was 55 years and approximately 70% were unemployed. The intervention was completed by 130 of the 137 patients in the intervention group (95%). The most common

reason for not scheduling or keeping a screening appointment was an acute health problem. Other reasons included family problems, lack of time and inclement weather.

Within the six month period, 55% of patients in the intervention group had attended digital retinal examination compared to 27% in the control group. A stepwise logistic model was fitted evaluating several possible predictors including sex and clinic. The odds ratio for examination status associated with receiving the intervention was 4.3, with 95% CI (2.4, 7.8). This highly significant result indicates that a patient-targeted educational intervention can substantially increase rates of diabetic retinopathy screening in African Americans. The authors note that this intervention may have significance for a wider population and the relative costs and effectiveness associated with each component of the intervention should be studied in a wider clinical setting.

Advertising campaigns can be used to improve education and encourage screening visit attendance. In 1998, Greater Glasgow Health Board (1998) ran an advertising campaign over an eight-week period to promote their breast screening service. During this period, 506 women completed questionnaires about the service and advertising campaign. Forty-three per cent of the women were aware of the advertising campaign and 86% felt that breast screening should be advertised more. They found the campaign images and messages reassuring, supportive and credible, and felt that advertising could be used to raise awareness of the service, make women more conscious of the benefits of screening and change public perceptions of the screening process. In 2000, it was recommended that the Scottish breast screening service should adopt standard branding on all stationery and publications and that invitation letters should be made clearer and shorter to make them more user friendly. Learning from their experience will be important when the national diabetic retinopathy screening programme is established.

Legorreta *et al.* (1997) studied the effect of a 'reminder' intervention for a diabetic retinopathy screening programme in California, USA, in 1995, comparing attendance to that in the previous two years. The study identified 19,397 people with diabetes aged 18 years or older who were sent educational materials and a report of their current diabetic retinopathy status. In 1995, 26% of patients received a diabetic retinopathy examination, this was significantly higher than the previous two years (approximately 20% in each of the previous two years). This result is somewhat difficult to interpret given the low overall rate of those attending for screening and the non-randomised design.

Prela *et al.* (2000) performed a study in Montana, USA, on 6,546 Medicare beneficiaries with diabetes. A reminder letter was sent to a random selection of two-thirds of these patients to attend diabetic retinopathy screening at the beginning of 1996. The median age of patients was greater than 75 years old. Three months after the letters were issued there was a significant increase in the percentage of patients attending screening in the group that received the reminder letter (19.4% vs. 17.2%), but at six months this benefit was lost, with 32.9% of those receiving the letter attending screening compared to 32.4% of those who hadn't received a letter. This randomised study did not demonstrate the benefit of a reminder letter in this predominantly elderly population, in which the overall screening rate was again very low.

This short-lived effect of mailed patient reminders has also been demonstrated in other studies (eg. Brooks *et al.*, 1996; Halbert *et al.*, 1999). Halbert *et al.* (1999) performed a randomised study of 23,740 people with diabetes from 1996–7 in California, USA. They selected a population of people with diabetes who had no record of a digital retinal examination. Patients were randomised to a single intervention or multiple intervention group. All patients

then received the first communication, which included educational materials and a report of their previous diabetic retinal examination. The multiple intervention group then received additional reminders at three, six and nine months. The median age of patients was in the range 56–64 years. The results showed that after the first communication a similar percentage of patients attended for screening. After the second reminder was sent to those in the multiple intervention group a higher percentage attended screening in this group, but the effect was small. For the third and fourth reminders, no differences between the single and multiple interventions could be demonstrated. At the end of the study 35.4% of patients in the single intervention group had attended screening, compared to 37% in the multiple intervention group. This difference was statistically significant, but it is a very small difference clinically, and the cost-effectiveness of issuing multiple reminders beyond the second reminder is questioned. Consequently, the authors state that it may be more appropriate to direct resources into other avenues of improving screening rates, such as telephone follow-up and increased involvement of physicians.

Livingston *et al*. (1998), report the outcome of focus groups involving health professionals and people with diabetes (21/50) in Australia. Five groups of ten members per group were established. They emphasised the advantage of local networks to promote the benefits of early detection and local screening programmes, the need for GPs to distribute educational material to patients and the importance of reminders. As a result of these focus groups, Lee *et al.*, (2000) performed a pilot study to identify strategies to encourage people with diabetes to attend a community-based non-mydriatic diabetic retinopathy screening programme in Australia. Screening occurred at a local venue, with a local number to call for day or evening appointments and transportation was provided. Two urban and two rural sites were studied. In the rural areas, the camera was portable permitting wide geographic coverage with seven towns visited in each area over four- and five-week periods. In the urban areas the screening took place over two- and three-week periods. In order to complement existing screening services, the 45% of the population with diabetes who did not have their eyes examined regularly were targeted to attend screening.

In this study, promotion for each site started three months prior to screening. In all sites, the GP was sent a letter of introduction and brochures, and asked to register people with diabetes into the programme. This was followed up with a personal visit from a member of the programme staff. Articles were published in local and national newspapers before and during screening. The recruitment strategies were modified with experience at each site. The targeted recruitment strategies were use of community networks (including patient groups, Lions clubs, Rotary, church groups, ethnic resource centres, senior citizens groups), GPs, pharmacists, diabetes educators, leaflets (in a variety of languages), posters, media, use of bilingual support workers and block appointments at screening centres with interpreters.

A total of 1,197 people with diabetes were examined at the screening sites. This represented 15% of people with diabetes (compared with the 45% targeted). In the rural communities, 91% were English speaking, compared to only 52% in urban communities. In rural communities 21% had never been checked for retinopathy compared to 30% in urban communities. This screening programme was able to screen an additional proportion of the diabetic population, increasing attendance at screening from 55% to 70%.

During the course of screening, participants mentioned that they had seen the programme promoted often three or four times before they scheduled an appointment. This supports the marketing strategy called the ‘Three Hit Theory’ seeing an advertisement three times marks the starting point of the advertisement’s effectiveness. A heavy influx of calls to book

screening appointments was noted directly after the mail-out at each site. Thus the importance of this form of invitation and the need for good registries is noted.

Although the study of Lee *et al.* (2000) is not randomised, it presents an interesting variety of methods for encouraging screening attendance. Evaluation of the clinical and cost-effectiveness of these in the Scottish national screening programme would be worthwhile.

Jepson *et al.* (2000) undertook a systematic review evaluating the determinants of screening uptake and interventions for increasing uptake. They identified many of the issues outlined in the studies described in this section and concluded that attempts to increase the uptake of screening should be pursued alongside initiatives to increase informed uptake. Furthermore, individuals who previously participated in screening were more likely to be subsequently screened, so efforts could be focused on identifying and encouraging attendance among those who have never previously participated in screening.

7.3.3 Patient views on screening services

7.3.3.1 HTBS Open Day workshop on patient issues

The HTBS Open Day used to launch the consultation report was attended by many people with diabetes, who provided invaluable input to a variety of discussions on the day. Their input to the workshops on 'patient issues' is summarised here.

Patients highlighted the need for clear, relevant information about the aims and process of the screening programme, the different types of retinopathy, treatment possibilities and benefits (i.e. halting progression of retinopathy to avoid visual impairment). It was debated how detailed and explicit the information should be, but no clear consensus was achieved. There was much discussion about the timing of the information. Those who had visual impairment as a result of diabetic retinopathy were keen that this complication and the benefits of screening should be communicated as soon as possible to a person newly diagnosed with diabetes. However, others noted that at diagnosis, a person may be overwhelmed, but that after a time (e.g. 12 months) that person may have gained more confidence and understanding that they can manage the diabetes and would then be able better to digest the information. There is also a need for continuing reinforcement.

Concerns were raised about the timing of the screening appointments. If people are having to take time off work for general diabetes screening and for retinal screening, it may affect attendance rates, so early evening or weekend retinal screening should be offered.

There was general discontent about the use of eye drops and lack of information provided. Some patients were not informed of the effects of the eye drops and others had their vision affected for much more than the two hours indicated. In one case, the eye drops affected the ability of a patient to see clearly for the rest of the day, and as a result, the patient was very reluctant to receive them again. It was accepted that the duration of action of the eye drops is unpredictable and individual patients have different reactions, but this should be clearly communicated to reduce subsequent anxiety.

There was some discussion about the receipt of immediate results following screening and whether the photographer should be able to give any feedback, or whether patients should wait until the report has been sent to their GP. No consensus was reached, but it was agreed that providing all patients with a copy of the retinal photograph would be helpful. It was also

recognised that GPs should receive timeous information about the screening outcome and a target of one to two weeks was considered to be ideal.

7.3.3.2 Scottish focus groups on diabetic retinopathy screening

Partners in Change is a capacity-building initiative commissioned by the Scottish Executive to strengthen working between people who use health services and people who work in the health service. During 2001/2002, as part of the *Scottish Diabetes Framework* (Scottish Diabetes Framework Working Group, 2001), Partners in Change conducted focus groups for people with diabetes to find out what it is like to live with diabetes.

In the autumn of 2001, HTBS asked Partners in Change to extend the remit of this work to include specific focus groups to discuss diabetic retinopathy with a variety of groups of people with diabetes. The groups involved were:

- people from ethnic minorities (with translators);
- older people;
- younger people;
- people with learning disabilities; and
- staff.

Four to eight people were invited to attend each focus group. The report from these meetings is currently being drafted and will be available on the HTBS website (www.htbs.co.uk). Preliminary findings indicate the following preferences and views.

Patients want:

- integrated services, where they are considered as people with a life and commitments external to diabetes and not simply as 'an eye in one clinic and a foot in another clinics';
- a choice of venues to attend screening;
- the ability to choose appointment times (particularly if working);
- support, and to know if they can bring a friend;
- information about public transport;
- welcoming attitudes and comfortable surroundings;
- to be given information and not to have to ask for it; and
- results to be given as soon as possible after the screening test with a clear explanation of the meaning of the result.

Staff views highlighted that:

- comfortable venues outside hospitals may be conducive to attendance;
- patients should be asked why they do not attend screening regularly;
- make the most of every opportunity to give information and encourage people to have their checks but understand that individuals may be overloaded with information, so it is important to talk to people when they are receptive;
- recognise that some patients feel unable to take on the responsibility involved with diabetes and that the manner in which health professionals communicate can make patients feel blamed, which can in turn affect screening attendance;
- a reminder letter or phone call may increase attendance; and
- need for general awareness raising in the population about diabetes, indicating the seriousness and need for regular checks.

7.3.3.3 RNIB Scotland consultation response

RNIB Scotland gave a detailed consultation response, which is available on the HTBS website. Key points not addressed elsewhere in the report are presented here.

The RNIB questioned 200 patients in-depth (85% aged 65 or more) about their experiences during and following their visit to an eye clinic. The resulting report, *Patients Talking 2* (McBride, 2001), identified that emotional support was the key missing component for the patients' eye screening/clinic journey.

Key findings were the lack of counselling and support for people facing serious and permanent sight loss. There was a lack of information and explanation about procedures throughout the whole patient journey in the eye clinic and following an appointment less than 40% received information about low vision services. Seventy percent of people wanted to talk to someone about their fears at the outset, but only 19% were given this opportunity. Sixty percent would have liked to have been able to call someone after the clinic to discuss concerns, but only 10% were given the opportunity to do so.

7.3.3.4 NSC patient expert group

Three people with diabetes were involved in the NSC expert panel on diabetic retinopathy screening. They visited six different diabetic retinopathy screening programmes (UK NSC, 2000). Their recommendations are shown in the following bullets:

- Screening should take place in an environment that is easily accessible and friendly to the patient.

  (In the programme that used mydriatic digital photography in a van, the limited clearance (six feet) and lack of wheelchair access was noted. One of the major concerns of the three people with diabetes was that patients were not always informed directly of results, or that GPs were not routinely informed of results within a reasonable timeframe. The ethos that 'no news is good news' is not acceptable.)

- Patient information should be in large print. It should discuss treatment, the facts that PDR is symptomless and ensure clear instructions are given for appointments and locations. The use of other media (local radio, audio and video tapes) should be considered.

  (The importance of explaining the availability of effective treatment, which could be given as an outpatient, should be explained.)

- Patient education is vital in order to ensure responsible self-care. Patients should be given information and allowed to make their own choices. Continuing professional support and encouragement are essential.

The NSC patient expert panel also reported on a visit to test the ultra wide angle scanning laser ophthalmoscope. They found the system to be patient-friendly and not having to have mydriasis was appreciated.

The patient preferences for the ultra wide angle scanning laser ophthalmoscope are confirmed in other reports submitted by the manufacturer. Unfortunately, limited scientific evidence is

currently available about the accuracy of the ultra wide angle laser scanning ophthalmoscope for diabetic retinopathy screening (section 5.3.5.9). However, new studies are underway comparing it with standard screening techniques in a diabetic clinic, which will elicit patient preferences and provide information regarding turnaround time, accuracy and failure rates.

7.3.3.5 Breast screening survey

The Scottish breast screening programme has undertaken a survey of patient preferences in relation to the provision of a mobile screening unit in south east Scotland (Fraser, 2000). Invitations were sent out to 469 women who had not responded to an earlier invitation to attend a hospital screening visit. They were invited to attend a mobile unit and 109 women returned questionnaires about the service.

The main reasons for not attending the hospital unit screening visit were:

Centre too difficult to get to	49%
Nervous/anxious about having a breast X-ray	27%

The main reasons for attending the mobile screening visit were:

Mobile screening in local area easier to get to	74%
Doctor's letter stressed importance	43%
Friends/family encouragement	25%

Very likely to attend next screening appointment:

At mobile unit	84%
At hospital unit	25%

7.3.3.6 Mydriasis

Patients find the lower flash intensity of the digital camera more comfortable than Polaroid cameras (Taylor *et al.*, 1999). However, the study of patient preferences (Klein *et al.,* 1985) shows that some patients are distressed by the instillation of eye drops and would not return for screening. As the benefit of mydriasis (and thus the need for eye drops) is questionable, the proposal to have a non-mydriatic retinal examination, then a mydriatic retinal examination if a technical failure occurred, is likely to improve screening attendance. As a technical failure cannot be predicted, the implications of using eye drops should be clearly communicated in advance to all patients (section 5.3.6.1).

Several consultation comments also noted the difficulties that mydriasis causes patients, confirming that little information is currently provided in advance to explain the effects of mydriasis. Also, the variability in the duration of the effects of the eye drops was confirmed.

7.4 Conclusions

Patient empowerment is needed for everyone with diabetes. An understanding of the different needs of the wide range of people who have diabetes (young, old, culturally diverse, etc.) is essential and a variety of educational materials should be made available. For diabetic retinopathy screening, the fear of going blind must be recognised and handled sensitively. The benefits of attending regular screening visits and the procedures involved need to be explained. The technologies and techniques used in the screening programme should be described and those technologies that are still under study for diabetic retinopathy screening (e.g. the ultra wide angle scanning laser ophthalmoscope) should be identified. The possible

need for eye drops and transient effects on vision should be communicated prior to the screening visit, indicating that driving is not recommended for at least two hours after mydriasis, but that the effects last longer in some individuals. After screening, to reduce the anxiety associated with waiting for a screening result, people with diabetes want the results to be reported to their GP, and to them, in a timeous manner.

Patient education is essential and innovative motivational initiatives should be considered to encourage attendance at screening because it is recognised that standard educational approaches do not always increase motivation or promote cognitive reappraisal. All health professionals who have contact with people with diabetes should receive basic instruction in the benefits of the screening programme to increase their own awareness and equip them to encourage their patients to attend screening. When mobile units are utilised it will be important for such health professionals to be informed so that they may provide particular support to patients at this time.

Methods to maximise screening uptake should be investigated. This relies on the provision of information about the need for, and benefits of, the screening programme, along with the provision of a screening service that does not adversely inconvenience the patient (e.g. with choices regarding venues and appointment times).

The research into the effectiveness of patient reminders suggests that more than two reminders is not effective and a wide range of methods may be needed to encourage non-attendees, including written reminders, advertising campaigns, use of educators and local community groups. This is consistent with learning theory which suggests that interactive communication processes can achieve the cognitive and behavioural learning required for change (awareness of a problem and an understanding of how it can be handled). Consultation with facilitators (counsellors) may be particularly valuable to allow discussion and clarification of sensitive issues that may be creating barriers to screening attendance.

The largest benefit of screening will probably be experienced by those who have never previously attended diabetic eye screening or have not attended for a long time. Special methods for communication with these patients should be considered.

Patient information is often used to encourage people to attend screening by emphasising the positive aspects of the programme. However, patient information that is primarily persuasive through reassurance has limitations. Raffle (2001) suggests that information aimed at increasing uptake in this way may ignore the principle of patient autonomy, risk legitimate anger from patients when unrealistic expectations are not met, place patients at risk if they ignore symptoms due to their lack of understanding, and prevent informed public debate about services. While the national screening programme aims to maximise uptake, patient information for the programme needs to be balanced and to address these serious issues by explaining the limitations and possible adverse effects of screening, as well as the benefits. The potential disadvantages of this approach are the need for more staff time to explain both the limitations and benefits of screening to patients and the risk of reduced uptake of screening, which has implications for cost-effectiveness (Raffle, 2001). Rather than using patient information to promote uptake, the key lever for maximising uptake should be a screening programme that reflects patients' known needs and preferences.

8 ECONOMIC EVALUATION

Summary

- The cost minimisation analysis indicates that a national diabetic retinopathy screening programme within NHSScotland should be implemented using single staffed hospital facilities or single staffed van-based, mobile units.
- For a non-mydriatic screening programme, the average cost of hospital screening is similar to the costs of a mobile facility. Local circumstances should determine which service is used. For rural areas, the costs of a mobile service should be compared to the level of the fees for community optometrists. Boards should work together to optimise service procurements across Scotland.
- The base case costs of the options for a systematic screening programme are presented in Table 8-1. The two-stage models assume a digital camera is used and people not amenable to digital photography receive a slit lamp examination.

Table 8-1 Cost per graded screen (including fixed costs)

	Mobile GP-based 1 Staff	Mobile GP-based 2 Staff	Mobile Van-based 1 Staff	Hospital-based 2 Staff	Hospital- based 1 Staff
Mydriatic (two-stage)	£32.28	£33.11	£30.06	£27.94	£26.56
Non-Mydriatic (two-stage)	..	..	£21.09	..	£21.04

To cost optometrist screening £1.49 grading and £10.45 fixed costs should be added to local optometrists fees.

- Non-mydriatic photography is cheaper than mydriatic photography, if faster patient turnaround times are achieved. Single staffing of units is cheaper than double staffing. The shorter patient turnaround times from double staffing do not offset the higher staff costs.
- Mobile provision, where screening occurs inside a van, is cheaper than mobile provision where screening takes place within GP premises, when the cost of space in general practices is taken into account. The daily drive time significantly affects the cost per screen. In some rural areas it may be cost-effective to screen using local optometrists rather than mobile units.
- A move from opportunistic screening to a national systematic screening programme for diabetic retinopathy is cost-effective.
- For the national diabetic retinopathy screening programme, based on the three-stage proposal outlined in section 9, there is an increase in cost per graded screen of between £0.80 and £1.50 compared to a simple two-stage non-mydriatic option (failures going directly on to slit lamp). The financial forecast for this preferred three-stage model is approximately £3.7 million in the first year and £1.9 million thereafter. There may also be additional annual downstream costs of around £65,000 arising from more treatments. In reality, the initial costs will be spread over more than one year.

8.1 Objectives

Economic evaluation can be applied to a range of questions relevant to screening for diabetic retinopathy. These include identifying the cost per graded screen, the costs and benefits of moving from the present opportunistic screening programme, the cost and benefits of a non-mydriatic based screening programme compared to a mydriatic based programme to a systematic national screening programme and the cost per QALY under each modality. The cost per graded screen is useful for comparing different screening options that are comparable in effectiveness. The cost-effectiveness analysis combines cost and effectiveness information to enable comparisons of modalities that have different clinical outcomes.

A number of screening modalities can be envisaged, with there being choice as to the location of screening, the professional(s) involved, the optical device used and the use of mydriasis. Clinical effectiveness analyses and organisational issues result in the recommendation that digital retinal cameras be the principal optical device. How this recommendation interacts with other issues is explicitly evaluated in a multi-stage economic analysis to help NHS Boards determine what service delivery structure is optimal for their region.

The objectives of the economic evaluation are to:

- calculate the cost per graded screen for a variety of different service delivery modalities, primarily using digital retinal cameras, highlighting inefficient modalities that are likely to be of greater cost to NHSScotland, but with no obvious increase in patient benefits;
- simulate the patient benefits of a move from opportunistic screening to systematic screening under a variety of scenarios and screening modalities;
- simulate the cost-effectiveness of a move from opportunistic screening to systematic screening under a variety of scenarios and screening modalities, by applying costs to patient screens and patient treatments; and
- provide financial forecasts of systematic screening, together with an indicative budget for the implementation of the systematic screening programme as recommended within this report.

8.2 Methods

The economic evaluation used a systematic literature search to identify existing literature relevant to diabetic retinopathy screening. This search, combined with discussions with experts enabled an initial cost minimisation analysis to be undertaken. Seven screening options were identified for the modes of delivery outlined in section 6.4, for which good information on costs (including grading costs) and patient throughput information was available (section 8.4.1.2). The cost per screen under each option was calculated and sensitivity analysis undertaken.

Davies *et al.*, (1996) set out a model of a patient journey through various stages of diabetic retinopathy. The model was developed using Scottish costs and patient data to inform on the cost-effectiveness of moving to a Scottish national screening programme for people with diabetes.

8.3 Search Strategy

For the economic evaluation of diabetic retinopathy screening, a scoping search was undertaken to gauge the quantity and quality of the existing literature, with particular attention being paid to finding studies by other HTA organisations, systematic reviews and research in

progress. Following this, a wide range of databases (see Appendix 6) and websites were selected to carry out a full literature review. Three databases (NHS EED, HEED and Econlit) were chosen specifically for their coverage of economics information, and the websites searched included those of the world's major health economics research units. Efforts were made to capture unpublished data by searching databases such as SIGLE and Dissertation Abstracts and by scanning appropriate websites. No date limits were imposed. All databases were searched from their starting date until the latest material available, during July 2001. The only restriction put on the search was that, due to time and cost considerations, foreign language documents were not appraised directly. In all cases however, where the search strategy did retrieve foreign language documents, an English language abstract was available and this was scanned for important information.

The topic was split into three concepts namely: diabetic eye disease; screening; cost-effectiveness. A search for all the probable synonyms for each concept was carried out, and then the results from each concept were added together. Searches were performed using the available subject headings (e.g. MeSH, EMTREE etc.) and free text terms.

The full list of sources searched and a copy of the Medline search strategy are given in Appendix 6. The Medline strategy was adapted to search the other databases. A complete listing of all the search strategies can be obtained by contacting HTBS. Also contained within Appendix 6 is a flowchart showing the number of studies identified then included in each stage of the review process.

This systematic literature review was also supplemented by a number of papers supplied by the Topic Specific Group of Experts, and by evidence submitted by interested parties.

8.3.1 Data extraction

The literature search identified 27 papers that could inform the economic analysis and modelling. These ranged from papers yielding specific data items such as patient turnaround times, to those developing models for the assessment of the patient impact of screening and the cost-effectiveness of screening. Throughout this economic section, specific data items drawn from the identified studies have been referenced through footnotes, but all these papers have not been summarised as their application is limited.

To model the cost-effectiveness of screening, two main methodologies were identified within the literature;

- identifying the cost per true positive from sensitivity and specificity data, coupled with prevalence rates for sight-threatening eye disease; and
- modelling patients' progression through retinopathy and their likelihood of blindness, and how screening may impact upon this.

Typically, cost-effectiveness analysis based upon the cost per true positive detected showed more expensive screening methods as identifying more true positives. Dominance in terms of a cheaper method identifying more true positives was unusual. Consequently, it is not clear whether this method can be applied to decisions about which screening method is most cost-effective. This report has instead adopted a modelling approach to identify end patient benefits and the costs associated with these, while recognising that this involves considerably more assumptions and uncertainty than the cost per true positive approach.

Three of the 27 studies identified provided key elements to the economic analysis, and have been summarised in Appendix 17. James *et al.* (2000) provided the costing basis for opportunistic screening undertaken by GPs, a significant element of opportunistic screening and hence key to assessing the cost-effectiveness of a move from opportunistic to systematic screening. Both Davies *et al.* (1996) and Vijan *et al.* (2000) provided the basic model structures that were used to identify what additional data would be required, though subsequent modelling adopted the model structure of the School of Management at the University of Southampton (http://www.management.soton.ac.uk/retinopathy1,2001).

8.4 Costs per Graded Screen of Systematic Screening

8.4.1 Methodology

This section outlines the main methodological principles used to cost the elements of a possible national screening programme from the perspective of the NHS provider and patient. Appendices 18, 19 and 20 have fuller information on each element.

Average costing (being the total annual costs divided by the number of screens examined each year) rather than marginal costing (being the cost of producing one extra screen) has been used throughout. This is because it is judged that the use of average costs is more likely to give an accurate estimate of costs in the long run.

Where possible, market prices have been used to measure costs. However, there is no observable price for using some items, for example the use of accommodation in hospitals and GP surgeries, as required for some modalities. Yet often such accommodation is a scarce resource and using it for screening will have an opportunity cost in terms of activities displaced. The average cost of provision has been taken as a proxy for the long-term opportunity cost through this may differ from opportunity costs in the short-term.

Staff costs take a midpoint of the relevant NHSScotland salary scale, coupled with appropriate allowances for superannuation and employer national insurance contributions. No allowance has been made for training other than that related to the training of screeners and graders as outlined in section 6.12.5.1. (Ellingford; Personal communications and Leese, Personal communications), *The Unit Costs of Health and Social Care 2000* (Netton and Curtis, 2000) does provide some figures for other professionals' qualification costs. However, these tend to include post-qualification training such as working as a house officer that has an output of economic value, which limits the applicability of the stated qualification costs.

Capital costs have been annualised using the anticipated lifespan of the capital equipment[2] and the financial discount rate of 6.0% (real). The impact of resale values for capital equipment is not explored. Work by HTBS has shown that, given the preponderance of staffing costs, even moderate resale values for optical equipment and transport have little impact upon costs per screen.

[2] Screening equipment costs from Topcon, and Grampian and Tayside screening programmes. Van purchase and maintenance costs from A.M. Phillip and Renault, Glasgow. Van conversion costs from Tayside, Grampian and Teeside screening programmes.

8.4.1.1 Fixed costs

Fixed costs are defined to be those that do not vary with the level of output. Given the decision that the principal optical device to be used for systematic screening is a digital camera, then a national screening programme will involve a number of "constants" regardless of activity levels and final service delivery modalities. From section 6, it can be determined that the fixed costs are:

- national coordination;
- local health board coordination;
- Screening offices and call recall operation;
- development and maintenance of call recall software; and
- development and maintenance of image capture software.

The staff requirements for both national and health Board level coordination are taken from expert opinion within the TSG (Colquhoun, Personal communications, 2001; Reay, Personal communications, 2001).

The costings assume there will be ten regional screening offices established to coordinate the administrative workload of call recall, with amalgamation of offices across smaller Board areas. The cost of these screening offices could depend upon the level of activity but the effect of different call recall protocols upon the overall cost of regional screening offices is minor, assuming most people with diabetes are screened annually. Consequently, regional screening offices are costed as fixed cost elements.

Screening offices (section 6.14) are taken to be responsible for sending and processing prior notification lists to general practices, the issuance of invitations, the issuance of single reminders and the notification of results to people with diabetes and their GPs.

No allowance has been made for payments to GPs for the processing of prior notification lists. Within the Breast Cancer Screening Programme some Boards have agreed local payments to GPs for this service but there is no nationally agreed scheme. For diabetes, 91% of practices currently receive payment under the Chronic Disease Management Programme for the care of their patients with diabetes that is intended to cover the additional care aspects (ISD, Personal communication, 2001). Provided that call recall software integrates with GPASS and other systems in use, it is hoped that the additional work requirement per patient with diabetes will be limited.

The cost of the development and maintenance of call recall software is indicative and based upon costing provided by those operating similar software for the breast cancer, cervical cancer and colorectal cancer screening programmes (CMT, Personal communication, 2001). If such software was developed within NHS Scotland, then the contract would be tendered and costs may differ from those stated.

The development and maintenance costs of image capture software have been provided through the expert opinion of the programmer within the DARTS system (Boyle, Personal communication, 2001) who has been involved in similar work within Tayside. These costs are primarily related to programmer staff costs. Again, it is an indicative figure and will vary, in particular, according to the number of camera and image capture systems, with which it must be compatible.

8.4.1.2 Variable and total costs per screen

The principal variable cost elements are the cost per screen and the cost per grading of each screen. These costs will vary between modalities due to differences in the location of screening, the professional(s) involved, the optical device used and the use of mydriasis. As already noted, the principal optical device is the digital retinal camera, but a proportion of those with diabetes are not amenable to this and will require slit lamp examination. Consequently, the cost per screen by slit lamp examination is also required.

Information from the present screening systems operating within NHSScotland and the NHS in England and Wales has enabled a variety of screening modalities to be costed, varying by location, staffing, optical device and mydriasis. For the camera-based options, cameras can be fixed within hospitals or taken out into the community in vans. Mobile units may operate their cameras within the van, or take the camera into GP premises.

A single photographer, responsible for both performing the photography and the administration of eye drops (according to *Patient Group Directions* – section 5.3.6.1) can staff units using mydriatic photography. Alternatively, a nurse may be employed to administer the eye drops, freeing the photographer to concentrate upon photography. Units using non-mydriatic photography only require one photographer.

The photographic screening modalities which have been costed are:

1. mydriatic, mobile, GP-based, double staffed;
2. mydriatic, mobile, GP-based, single staffed;
3. mydriatic, van-based, single staffed;
4. mydriatic, hospital-based, double staffed;
5. mydriatic, hospital-based, single staffed;
6. non-mydriatic, hospital-based, single staffed; and
7. non-mydriatic, van-based, single staffed.

All mydriatic options take two fields, whereas non-mydriatic modalities only take one-field. All modalities assume that those not amenable to digital photography receive a slit lamp examination.

Overheads for use of NHSScotland hospital and GP premises have been included in the economic appraisal, although there may not be any cash payments from the screening service provider to the hospital administrator or to individual GPs. The costs are an estimate of the long-term costs of providing such space. Each Health Board should consult local GPs on these costs: if there are no long-term costs because such space is not a scarce resource then the Board may be able to exclude accommodation costs from the individual costings.

For hospital-based options, the overhead allowance per attendee is taken from the relevant PAMS section of *Scottish Health Service Costs 2000* (Common Services Agency Information and Statistics Division, 2000). Overheads for GP premises have been taken from *Unit Costs of Health and Social Care 2000* (Netton and Curtis, 2000), an hourly figure being derived by dividing by GP working hours as a proxy for surgery opening hours. It is recognised that the cost of general practice premises will show considerable regional variation. Pressure upon general practice accommodation is particularly acute in urban areas, and the cost of provision may only approximate the opportunity cost of the other programmes competing for surgery space. Similarly, the screening activity may require using accommodation in GPs' surgeries for only a few days per year and average costing may poorly reflect the opportunity cost of

this. The utilisation of space in hospitals will be much more intensive and screening is likely to have a constant demand for space in the hospital setting.

Note that there is no explicit costing of screening by optometrists by either digital retinal photography or by slit lamp examination. The fees for such services will be locally or nationally negotiated and are outwith the scope of this HTA. An indicative fee of £20 per screen is used; however, NHS Boards should substitute this with the actual negotiated fee, making due allowance for grading and fixed costs.

Grading is taken to follow a three level procedure (section 6.9), with an initial first level passing questionable cases up to second level graders. These in turn assess which cases should be passed on to ophthalmologists for review. Optometrist photographic screening is taken to be subject to only level two and level three grading, optometrists deciding whether their images are of sufficient concern to be passed to level two grading.

To arrive at the average variable cost per graded screen for the digital camera screening modalities, it is not sufficient to sum the average cost per camera screen with its associated average grading cost. This fails to take into account the slit lamp examinations required for those not amenable to digital photography. The proportion of slit lamp examinations required also differs between mydriatic and non-mydriatic photography. Consequently, the overall average cost per screen is the cost per graded camera screen multiplied by the proportion amenable to photography plus the cost per slit lamp examination multiplied by the proportion requiring slit lamp examination. As the cost per slit lamp examination varies depending upon location, for hospital-based photography the cost of a hospital-based slit lamp examination (£11.61 per screen) is used. For mobile photography, an estimated cost of an optometrist-based slit lamp examination (£20 per screen) is used.

Summing the average fixed costs per screen with the average variable cost yields the overall total cost per screen, for each screening modality.

8.4.2 Assumptions

The prevalence of diabetes has been assumed to be 3% throughout, to reflect the likelihood of increased prevalence and diagnosis in the medium to long-term. An 80% attendance rate has been assumed in the base case.

The working year is assumed to be 200 days, to allow for holidays, absenteeism, routine training and, maintenance of equipment, etc.

A key element of the costings is patient turnaround times, these showing both geographic variation due to differing local practices and variation due to the screening method employed. The patient turnaround times employed are taken from expert experience of local screening programmes[3], giving a greater weight to those from within NHSScotland. This suggests turnaround times of ten minutes for non-mydriatic photography, 15 minutes for mydriatic photography operated by a photographer with nursing support and 20 minutes for mydriatic photography operated by a single photographer[4]. However, as noted, variation within these figures applies across the UK. One English unit indicated that they could undertake three

[3] Screening programmes in Tayside, Argyle and Clyde, Grampian, Teeside, Exeter and Wales, coupled with TSG input

[4] Average of 21 minutes turnaround time: Grampian screening programme.

mydriatic examinations in 20 minutes (i.e. turnaround time of seven minutes). As the screening visit must include a visual acuity test (section 6.9.2) and emphasis is placed on patient support and communication, it is felt that this is not likely to be achievable in the Scottish programme. The effect of the variation in turnaround times is explored for the base case cost per screen for each modality and for the cost-effectiveness of moving from opportunistic screening to systematic screening, within the relevant sensitivity analyses sections.

Another key element in the costing of mobile options is the average total daily drive time, as this reduces the time available for screening. The base case analysis has assumed an average total daily drive time of two hours. This is sufficient to yield the number of screen slots available per day. However, it is unlikely that all slots will be filled. Experience from the Scottish Breast Cancer Screening Programme suggests that once the programme is established, invitations can be matched to previous local attendance rates and an unfilled slot percentage of 5% can be achieved. While this will be overly optimistic in the short-term, costings have taken the unfilled slot percentage to be 5% in order to reflect the likely long-term costs of a national screening programme.

All current mydriatic photography programmes take two fields per eye and so only 12 patients can be graded per hour, contrasting with 20 patients per hour as single field non-mydriatic photography.

It is assumed that 5% of all images are reviewed for quality assurance by a consultant ophthalmologist (SIGN, 2001).

In the base case, it has been assumed that those not amenable to photography will be automatically sent an invitation to slit lamp examination by the call recall software. Again, this is intended to reflect experience in the programme in the long-term, with only a few new diagnoses and a small number of people with diabetes crossing over to being unsuitable for photography each year. In the short-term, more people with diabetes may be referred to slit lamp examination from a photographic session, although GPs may be able to reduce this through the prior notification lists.

Note that while patient travel and attendance costs are not insignificant and will affect attendance rates, there is no clear evidence as to the extent of these and how they may differ between screening modalities. Phillips *et al.* (1997) report patient travel costs but these show considerable variation between locations. There is some evidence that patient out-of-pocket travel expenses are higher in urban areas[5] within the Welsh screening programme, but it is not immediately clear how this can be applied to the Scottish context. In the absence of clearer evidence it has been assumed that average patient travel costs will be similar between the different screening modalities, enabling them to be disregarded in the costing per screen. Implementation and service structure design will also be required to take account of patient travel costs in order to maintain attendance rates. This may tend to equalise patient travel times and costs between the modalities as they are established.

It is recognised that full implementation of a national screening programme may occur over a number of years, being rolled out as registers become established and populated. As a consequence, the results of the following section have been presented as annualised figures, rather than as capital and recurrent costs.

[5] Urban £2.55, Rural £1.77; Phillips *et al*, 1997.

8.4.3 Results

Details of all calculations can be found in Appendices 19 and 20. Totals of table columns and stated totals may differ due to rounding.

8.4.3.1 Fixed costs

Table 8-2 Fixed costs

	Annualised Cost
National coordination	£67,936
Health Board coordination	£370,734
Regional screening offices	£628,957
Call Recall software	£187,026
Image capture software	£30,000
Total	**£1,284,653**

8.4.3.2 Variable and total costs per screen

Table 8-3 Variable and total costs per screen: base case

Variable and Total Costs per Screen: Base Case	Screen[6]	Grading	*Variable Sub* Total	Fixed Costs	Total
Mydriatic, mobile, GP-based, two staff	£19.58	£3.08	£22.65	£10.45	£33.11
Mydriatic, mobile, GP-based, one staff	£18.75	£3.08	£21.83	£10.45	£32.28
Mydriatic, van-based, one staff	£16.52	£3.08	£19.60	£10.45	£30.06
Mydriatic, hospital-based, two staff	£14.41	£3.08	£17.49	£10.45	£27.94
Mydriatic, hospital-based, one staff	£13.04	£3.08	£16.11	£10.45	£26.56
Non-mydriatic, hospital-based, one staff	£8.68	£1.95	£10.63	£10.45	£21.09
Non-mydriatic, van-based, one staff	£8.64	£1.95	£10.59	£10.45	£21.04

The base case costing in Table 8-3 clearly shows the increase in cost associated with mydriasis. This is due to the longer patient turnaround times involved in the administration of eye drops and the taking of two fields per eye. For example, the non-mydriatic hospital-based modality can achieve 7,698 screens per annum, in comparison to 5,130 for hospital-based mydriatic screening with two staff, falling to 3,848 for hospital-based mydriatic screening with one staff.

Turning to staffing, whilst nursing support for the administration of eye drops and checking of visual acuity reduces patient turnaround times, the increased throughput is not sufficient to offset the increase in staff costs. This effect is more marked within the hospital setting where the difference in the cost per screen is around £1.40, which would rapidly multiply in the context of a national screening programme performing over 150,000 screens annually. However, in the mobile context where it is assumed that two hours of the day is lost to driving, the lower patient turnaround times resulting from double staffing helps spread capital

[6] including the cost of slit lamps for patients not amenable to digital photography.

and accommodation costs over a proportionately greater increase in the number of screens than is the case in the hospital setting. As a consequence, the increase in the cost per screen from double staffing for mobile options within general practice premises is around £0.80 per screen.

Despite the allocated overhead per screen for accommodation within general practice premises being less than half that for accommodation within hospital premises, mobile screening operating within general practice premises remains more costly than static screening within hospitals. The lower overheads are not sufficient to offset the greater capital costs and the effect of drive times upon the overall cost per screen. For urban areas it appears to be most economic to provide screening through a static hospital-based unit if mydriatic photography is the modality chosen, provided that there is the population to guarantee sufficient throughput and that hospital-based screening proves acceptable to the diabetic population.

Mobile screening provides the option of greater community outreach, and may be the only practical option for rural areas without community optometrists. Using a self-contained adapted van is more cost-effective than using general practice premises (assuming there are opportunity costs to using such premises). This is because the overheads associated with using the general practice accommodation more than outweigh any capital and operational savings from operating a smaller van. This also assumes that an adapted van is acceptable to the diabetic population. While there is no experience of mydriatic screening within a van in NHSScotland, Tayside's experience of van-based non-mydriatic screening, coupled with Teesside's experience of van-based mydriatic screening suggests that this should be feasible.

8.4.4 Sensitivity analysis

8.4.4.1 Patient turnaround times

Univariate sensitivity analysis has been performed to explore the effect that different patient turnaround times have upon the total cost per screen of the different screening modalities. These take the base case of ten minutes for non-mydriatic photography, 15 minutes for mydriatic and two staff members, 20 minutes for mydriatic and one staff member and alter these times in two minute per patient intervals. The results of this are presented in Table 8-4, and are also presented in figures in Appendix 21.

Table 8-4 Cost per screen and patient turnaround times

	8 min	10 min	12 min	14 min	16 min	18 min	20 min	22 min	24 min
Mydriatic, GP-based, two staff	£24.56	£27.00	£29.44	£31.88	£34.32	£36.76	£39.20	£41.64	£44.08
Mydriatic, GP-based, one staff	£21.79	£23.54	£25.29	£27.03	£28.78	£30.53	£32.28	£34.02	£35.77
Mydriatic, van-based, one staff	£20.90	£22.43	£23.95	£25.48	£27.00	£28.53	£30.05	£31.58	£33.10
Mydriatic, hospital-based, two staff	£23.40	£24.70	£26.00	£27.29	£28.59	£29.88	£31.18	£32.48	£33.77
Mydriatic, hospital-based, one staff	£21.55	£22.39	£23.22	£24.06	£24.89	£25.73	£26.56	£27.40	£28.23
Non-mydriatic, hospital-based, one staff	£20.30	£21.08	£21.87	£22.65	£23.43	£24.22	£25.00	£25.79	£26.57
Non-mydriatic, van-based, one staff	£19.65	£21.04	£22.43	£23.82	£25.20	£26.59	£27.98	£29.37	£30.76

The results show that most mydriatic options are more sensitive, as measured by the absolute cost per screen, to changes in patient turnaround times than non-mydriatic options. Moreover, even assuming there is no time difference in screening patients using mydriasis, the mydriatic option is about 6% more expensive than the directly comparable non-mydriatic option.

The results also show the required changes in patient turnaround times required to equate costs per screen between the mydriatic options. For the GP-based mobile options, changes 'of around four minutes' to the turnaround times for double and single staffing are required to equalise costs per screen.

General Practice accommodation provides the option of double staffing; something, that is not available within the costed van-based mydriatic modality. However, given the difference in base case costs per screen, either the turnaround time of double staffing within general practice accommodation has to fall by around 20% or the turnaround time of the van-based mobile option has to rise by around 20% to equate their cost per screen.

Costings of mydriatic options have assumed a patient turnaround of 20 minutes, based upon the Grampian screening programme. However, evidence from Teesside suggests that as screening becomes better established patient turnaround times may improve. By retaining a ten minute turnaround time for non-mydriatic photography, but employing a turnaround time of 15 minutes for single staffed mydriatic photography and 12 minutes for double staffed mydriatic photography this can be explored. The results are shown in Table 8-5.

8.4.4.1.1 Variable and total cost per screen

Table 8-5 Variable and total cost per screen

	Screen[7]	Grading	Sub Total	Fixed Costs	Total
Mydriatic, mobile, GP-based, two staff	£15.91	£3.08	£18.99	£10.45	£29.44
Mydriatic, mobile, GP-based, one staff	£14.38	£3.08	£17.46	£10.45	£27.91
Mydriatic, van-based, one staff	£12.71	£3.08	£15.79	£10.45	£26.08
Mydriatic, hospital-based, two staff	£12.47	£3.08	£15.55	£10.45	£26.00
Mydriatic, hospital-based, one staff	£10.95	£3.08	£14.03	£10.45	£24.48
Non-mydriatic, static, hospital-based, one staff	£8.68	£1.95	£10.63	£10.45	£21.09
Non-mydriatic, van-based, one staff	£8.64	£1.95	£10.59	£10.45	£21.04

Even with the improvement in patient turnaround times, mydriatic photography remains considerably more expensive than non-mydriatic photography. Every £1.00 increase in costs per screen translates into an annual increase in screening programme costs of around £150,000. Given the increased capital costs associated with mydriatic photography, to equate the cost per screen between mydriatic and non-mydriatic photography requires that patient turnaround times for mydriatic photography be less than those for non-mydriatic photography.

8.4.4.2 Daily drive times within mobile options

Univariate sensitivity analysis has been performed to explore the effect that different daily drive times have upon the total cost per screen of the different mobile screening modalities. The results of this are presented in Table 8-6, and in greater detail in Appendix 22.

Table 8-6 Cost per screen and mobile drive times

	1.0 hr	1.5 hrs	2.0 hrs	2.5 hrs	3.0 hrs	3.5 hrs	4.0 hrs
Mydriatic, mobile, GP-based, two staff	£29.66	£31.14	£32.95	£35.20	£38.10	£41.97	£47.39
Mydriatic, mobile, GP-based, one staff	£29.00	£30.40	£32.12	£34.26	£37.02	£40.69	£45.84
Mydriatic, van-based, one staff	£26.90	£28.25	£29.89	£31.92	£34.51	£37.92	£42.60
Non-mydriatic,van-based, one staff	£19.49	£20.11	£20.88	£21.82	£22.52	£24.59	£26.74

The cost per screen is non-linear to total daily drive times[8]. Any reduction in drive times enables more patients to be seen each day, this effect being most marked for mydriatic mobile options with their longer patient turnaround times. Reducing drive time from two hours to one reduces costs per screen by about 7% for non-mydriatic and 10% for mydriatic modalities.

The results are more sensitive to increases in daily drive times. For mydriatic mobile screening modalities the cost per screen rapidly increases once daily drive times exceed two

[7] To include the cost of slit lamps for patients requiring this treatment.

[8] It should be noted that this non-linearity will also apply to a mobile unit for which the total daily drive times vary significantly between screening days. As a consequence, the average cost per screen will be greater than that for a mobile unit which has a similar daily drive time each day, even though the average daily drive time over the screening year may be similar. This effect increases in the variability of daily drive times.

and a half to three hours. Relatively little time remains for screening, the high patient turnaround times causing capital costs to be spread over a rapidly diminishing patient throughput. There is also a large deadweight staffing cost incurred by the longer drive times.

While double staffing within GP premises enables more patients to be seen within the remaining screening time so spreading capital costs over a greater number of patients than single staffing within GP premises, this is not sufficient to outweigh the near doubling of staff costs incurred during drive times. Drive times greater than those assumed in the base case increases the difference in the cost per screen between double staffing and single staffing within GP-based modalities due to these deadweight costs.

Note that the tables on daily drive time can be used to compare the drive time that would be required to equate the cost per screen from mobile provision within NHSScotland with local optometrist fees, as an aid to planning the use of mobile units and the areas best covered by community optometrists. If used in this manner, an overhead for grading and fixed costs of £11.94 per screen should be added to local optometrist fees.

8.4.4.3 All patients initially require photography

Experience within the national screening programme will make it possible to identify most patients who will not be amenable to photography but require slit lamp examination. However, in the first year such selection will be limited to GP diagnoses communicated through the prior notification lists. Base case costings have assumed that all patients requiring slit lamp examination are automatically appropriately referred. The effect of all patients requiring an initial photographic examination, with those not amenable to photography being referred for a further slit lamp examination is outlined in Table 8-7.

Table 8-7 Cost per screen: all patients require initial photography

	Base Case	All Require Photography
Mydriatic, mobile, GP-based, two staff	£33.11	£34.09
Mydriatic, mobile, GP-based, two staff	£32.28	£33.22
Mydriatic, van-based, one staff	£30.06	£30.86
Mydriatic, hospital-based, two staff	£27.94	£28.66
Mydriatic, hospital-based, one staff	£26.56	£27.64
Non-mydriatic, hospital-based, one staff	£21.09	£21.78
Non-mydriatic, van-based, one staff	£21.04	£21.73

The effect is most marked for the mobile, mydriatic modalities because these patients would be presented to optometrists for a slit lamp examination costing £20 per screen. The hospital-based slit lamp examinations are forecast to cost under £12 per screen.

The actual total cost per screen for each screening modality will lie somewhere between the base case and that where all require photography. As the screening programme becomes established, costs per screen will move towards the base case figures. There will remain a number of patients not amenable to photography who will still present for it, such as those newly diagnosed with diabetes or those previously amenable to photography developing conditions which makes the use of slit lamps necessary.

8.4.4.4 Allocated overheads within variable costs[9]

The cost per screen of both GP-based and hospital-based screening modalities are linear in the allocated overheads. The allocated overhead within hospital-based options is £4.00 per screen and any increase (decrease) in this will increase (decrease) the cost per screen by a parallel absolute amount.

For the GP-based modalities, the allocated overheads are effectively £2.00 for single staffed options and £1.50 for double staffed options, given patient turnaround times. An increase (decrease) in general practice overhead costs will increase (decrease) the cost per screen by a parallel amount. Thus, in areas where general practice accommodation costs are higher than assumed in the base case analysis there is likely to be little difference between the costs per screen from double staffing compared to that for single staffing. Moreover an increase in general practice accommodation costs will further widen the cost differential between mobile GP-based modalities and van-based modalities.

If general practice overheads are not a real cost because of the low usage of such premises, then the general practice option will still be slightly more expensive than the van option. This arises because the greater 'downtime' in setting up and clearing down equipment in the general practice option outweighs the additional cost of adapting a van. This effect is relatively small.

Allocated overheads within hospital-based mydriatic modalities would need to double to equate the cost per screen with mobile mydriatic modalities. For non-mydriatic modalities the cost per screen is approximately equal between the hospital-based and mobile modalities, and

[9] Note that this refers to allocated overheads within the variable costs of providing screens. It does not refer to the allocated fixed costs of the programme of £10.29.

any change in allocated hospital overheads has a corresponding effect upon the difference in the cost per screen.

8.4.5 Conclusions

Under the assumptions outlined above, the cost minimisation analysis indicates that a national diabetic retinopathy screening programme within NHSScotland should be implemented by establishing screening units within single staffed hospital facilities and within single staffed van-based mobile units. This assumes that van-based screening is acceptable to patients and yields similar attendance rates as GP-based screening. It also assumes that use of a single staff member is acceptable for adequate patient care.

All things being equal, in particular patient attendance rates, the costings suggest a protocol for service structure design within NHSScotland. Given that the variable costs for hospital-based mydriatic services are estimated to be around £16.10 per screen, some £3.50 less than the mobile option, then a hospital setting should be the default for service provision in urban areas. For urban areas, Health Boards should evaluate whether there is a sufficient local diabetic population, within reasonable patient travel times, to warrant the establishment of a hospital-basedunit, in comparison to the alternative of using mobile facilities and local optometrists to undertake slit lamp examinations.

For screening based around non-mydriatic photography there is no obvious default modality for service provision within urban areas. The average variable costs of hospital-based screening is very similar to that of operating a van-based programme. Both services are estimated to cost about £10.60 per screen. Local circumstances should determine whether urban provision is hospital-based or mobile-based, with the hospital catchment area having a significant bearing upon this. Mobile provision may also extend the catchment area beyond that reached by hospital-based provision.

For provision in more rural areas, potential mobile bases should be identified. The number of such bases will be influenced by the acceptable daily drive times from each base and the level of the optometrist fees. Again, if the diabetic population within the acceptable daily drive time is sufficient to ensure reasonable throughput this argues for mobile unit establishment. This does not preclude provision by community optometrist where these services are the most cost-effective.

8.5 Patient Impact Modelling

The cost minimisation approach adopted above is most useful when the outcomes of the two programmes are ‘equivalent’. The clinical effectiveness analyses demonstrate that the estimated sensitivity at 95% specificity is similar for mydriatic (88%) and non-mydriatic photography (86%) with trained graders. However, the associated 95% confidence interval is narrower for mydriatic (60%, 98%) compared with non-mydriatic (31%, 100%). There is a fairly high level of uncertainty in these results and so economic modelling has been undertaken of the two programmes to explore the relative cost-effectiveness of moving from an opportunistic programme to a systematic programme with and without mydriasis, and for moving from a systematic programme without mydriasis to a systematic programme with mydriasis.

8.5.1 Methodology

The technique used in economic modelling is to build a Markov model that models a patient's journey, using transitional probabilities between health states. Using published models for diabetic retinopathy screening as a basis, the Markov model derives the impact of moving from opportunistic screening to systematic screening upon age cohorts of people newly diagnosed with insulin dependent diabetes (IDDM) and non-insulin dependent diabetes (NIDDM).

The impact of the move from opportunistic screening to systematic screening is simulated for the current distribution of diabetes incidence rates, as reported by the School of Management of the University of Southampton (http://www.management.soton.ac.uk/retinopathy/), to give the long-term patient impact of the move from opportunistic to systematic screening.

Monte Carlo simulations, implemented through the computer package: Crystal Ball (Decisioneering Inc), are used to reflect the uncertainty around the sensitivities and specificities. The sensitivities and specificities distributions are as outlined in the clinical effectiveness section. The model is run 2,000 times for each case. Each iteration uses a value drawn from the distributions for sensitivities and specificities and then determines the patient impact that these imply.

8.5.2 Model inputs

The main source of the Southampton data
(http://www.management.soton.ac.uk/retinopathy/2001)
are Klein *et al*. (1985), being a study set in Wisconsin, USA. The Klein data, to include the transitional probabilities, had been adjusted to align the model outcomes to the population base used by Southampton. The significance of these changes to achieve an alignment is not clear.

As HTBS does not have access to the source data in the meta-analysis, there are no separate analyses on the sensitivities and specificities of the two modalities for insulin and non-insulin dependent patients. In the absence of better data, the model has used the same sensitivities and specificities for each group. HTBS recognise that the accuracy of each modality may vary between the two sub-groups of people with diabetes and will re-run the model when accurate Scottish information is available.

Other data problems arise because of the absence of accurate information about people with diabetes in Scotland. For example, in the short-term there may be an additional latency effect, with a greater patient impact due to a higher background prevalence of PDR. Prevalence of diabetes and retinopathy are presented in the Scottish Diabetes Survey (Scottish Diabetes Survey Monitoring Group, 2001). These estimates show considerable variation between NHS Board areas. The prevalence of PDR is not reported. Similarly, the prevalence rates for PDR reported by the University of Southampton School of Management (http://www.management.soton.ac.uk/retinopathy/2001) appear high, higher indeed than the more commonly reported 5.5% (Bachman and Nelson, 1996; UK NSC, 2000). Yet even this 5.5% background prevalence of PDR appears likely to be an overestimate since, under plausible assumptions, it would imply an annual incidence of blindness in the diabetic population of at least 0.20% to 0.25%.

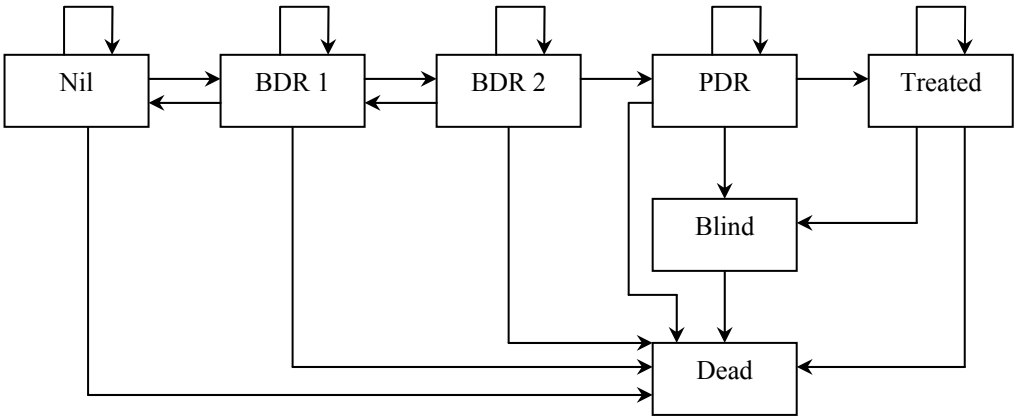
We conclude that the historic reported prevalence data for PDR appear likely to be too high, reflecting a past era when diagnosis of diabetes relied upon more severe symptomatic presentation by patients and the lower availability of an opportunistic screening programme.

However, the introduction of a greater focus on diabetes diagnosis may lead to the identification of more people with diabetes. Such people are unlikely to have been screened for eye problems. As these people are introduced into the national systematic screening programme there may be a short-term effect increase in the level of PDR observed by the programme.

The possible impact of this effect has been modelled through simulations. These use the higher prevalence data as reported by the University of Southampton School of Management (http://www.management.soton.ac.uk/retinopathy/2001). The analysis is presented in Appendix 25. The results show that the model is very sensitive to the level of PDR. A higher level of PDR increases substantially the sight days gained as a result of moving to a national screening programme, with people with IDDM gaining greatest benefit.

The model structure for people with diabetes follows that of the Davies et al. model (1996) of the progression of diabetic retinopathy. While the paper by Davies et al. (1996) only considers those with IDDM, the University of Southampton School of Management ((http://www.management.soton.ac.uk/retinopathy/2001) has since extended the model to incorporate those with NIDDM.

Figure 8-1 Model Structure



In figure 8-1, arrows show the possible transitions between the different health states, each having an associated annual probability. For those with PDR, the annual probability of treatment is the sensitivity of the relevant screening test conditional upon screening attendance. Both true and false positives are referred to ophthalmology. True positives are subsequently treated, this treatment conferring a lifetime reduction in the annual transition probability from PDR to blindness: the RRR of treatment. In the base case model, RRR is taken to be 70%, with sensitivity analyses performed for values of 50% or 90%.

The model groups those with IDDM and NIDDM into separate age cohorts, by both incidence and prevalence. The model calculates the average number of years of sight and the average number of years spent blind for people with diabetes within each cohort. As the model is simulated using Crystal Ball, the patient impact for each cohort is derived by simulating the

patient impact for those at the median age of each cohort. These patient impacts are then applied to all those within the relevant cohort.

To assess the impact of a move from opportunistic screening to systematic screening requires that opportunistic screening be characterised. But the degree to which people with diabetes within individual NHS Boards are examined for retinopathy varies widely, many NHS Boards having already started to implement systematic screening. Opportunistic screening is taken to be the screening which would occur in the absence of any such initiatives, this being assumed to be reflected in the inter-college audit of English health authorities as reported by Grimshaw *et al*. (1999) in the UK NSC report (2000) . This identifies optometrists, hospitals and GPs as providing opportunistic screening, in the absence of a systematic health authority programme.

Systematic screening is primarily by digital camera; both non-mydriatic photography and mydriatic photography being examined. The failure rates for these and associated percentage of slit lamp examinations are those set out in section 8.4.1.2 on screen costs.

Note that the model makes no allowance for macular oedema leading to a loss of central visual acuity among those with diabetes. The effect of a move from opportunistic screening using direct and indirect ophthalmoscopy, to systematic screening primarily using digital photography, upon the detection of macular oedema is unclear. There is little direct evidence of the differences in the sensitivities and specificities of digital photography for the detection of macular oedema, and macular oedema has not been considered within the modelling.

8.5.3 Results

The assumptions used are set out in Appendix 24. Table 8-8 presents the anticipated increase in the mean sight days per incident person with diabetes associated with a move;

- from opportunistic screening to systematic non-mydriatic photography;
- from opportunistic screening to systematic mydriatic photography; and,
- from systematic non-mydriatic photography to systematic mydriatic photography.

8.5.3.1 Patient impact: increase in average number of days of sight

Table 8-8 Patient impact: increase in average number of days of sight

	Opportunistic to: systematic non-mydriasis	Opportunistic to: systematic mydriasis	Systematic non-mydriasis to systematic mydriasis
	RRR 70%	RRR 70%	RRR 70%
All Patients	23	26	3
NIDDM All	16	18	2
IDDM All	130	148	18

The anticipated benefits of a move from opportunistic screening to systematic screening are greatest amongst people with IDDM. Thus the introduction of a national screening programme based on non-mydriasis can be anticipated to increase sight days on average for IDDM patients by some 130 days and for NIDDM by some 16 days. While the increase in the number of sight days is limited on average, it is noticeably higher among those with IDDM who have a greater probability of more rapid progression through the disease, and the benefit associated with a move to systematic screening is correspondingly higher. The increases are

small, being averaged over a large number of patients. But, most will not go blind. Among those detected and treated, the increase in days sighted will be much larger.

Given the data uncertainties, particularly as a result of the distribution for non-mydriatic photography, it is not clear that a strong conclusion can be drawn in respect of the effectiveness of moving from systematic non-mydriatic photography to systematic mydriatic photography. The relatively long tail implies a small probability that non-mydriatic photography has a much lower patient impact than mydriatic photography. When applied to the overall anticipated patient impacts, this reduces the average increase in sight days from non-mydriatic photography to below that of mydriatic photography.

8.5.4 Sensitivity analysis

Sensitivity analysis has been conducted on several key variables to include:

- *Treatment effectiveness*

There is considerable uncertainty about the reduction in the risk of blindness as a result of treatment. Relative risk reductions of 50% and 90% have been presented as feasible values, but there is a greater likelihood that the RRR is below 70 %, rather than above it. The 50% sensitivity is also the more conservative in terms of estimating the benefits from moving to a national screening programme.

- *Opportunistic screening characteristics*

There is considerable variation throughout Scotland between current screening modalities. The base case assumption is taken from the survey of English health authorities (Grimshaw *et al*.1999) within the NSC report (YKNSC, 2000). This may underestimate the degree of hospital- and optometrist-based care. Retaining the assumption of 60% attendance for opportunistic screening, the proportion of those seen by GPs can be reduced to 20% with the remaining 80% split equally between hospital- and optometrist-based screening[10].

- *IDDM opportunistic attendance rates*

There is also some uncertainty around the percentages of those with IDDM who attend opportunistic screening. Anecdotal evidence suggests that it is likely to be higher than that for those with NIDDM. A common 80% attendance rate between opportunistic and systematic screening can be assumed for all people with IDDM, retaining the assumption of 20% being seen by GPs, with the remainder equally split between hospital and optometrists.

- *Mydriasis and attendance rates*

As noted in the patient impact section, mydriasis is likely to reduce the percentage of patients willing to attend systematic screening. It may reduce the numbers willing to attend systematic screening by 5% (Klein *et al*., 1985). Those deterred from screening by mydriasis seem to be similarly unlikely to have previously attended opportunistic screening that requires mydriasis. Consequently, this 5% is assumed to fall back to opportunistic screening by GPs.

[10] In practice, the split between hospital slit lamp and optometrist slit lamp is irrelevant to patient impact given the assumption of them having the same distributions for their sensitivities and specificities, but it has a bearing upon cost-effectiveness due to their different costs.

8.5.4.1 Results

Table 8-9 shows the effect of each variable on the average number of sight days for incident cases of diabetes, contrasting it with an RRR of 70%.

Table 8-9 Patient impact sensitivity analysis: increases in sight days

	Opportunistic to: systematic non-mydriatic	Opportunistic to: systematic mydriatic	Systematic non-mydriatic to systematic mydriatic
Base case			
All	23	26	3
NIDDM	16	18	2
IDDM	130	148	18
RRR 50%			
All	14	16	2
NIDDM	10	12	1
IDDM	80	91	11
RRR 90%			
All	33	38	5
NIDDM	23	26	3
IDDM	198	225	27
Opportunistic screening			
All	18	21	3
NIDDM	13	15	2
IDDM	104	122	18
Opportunistic attendance rates			
IDDM	30	47	18
Mydriasis affect on attendance			
All	23	24	1
NIDDM	16	17	1
IDDM	130	138	8

8.5.5 Conclusions

As would be anticipated, lowering and increasing the treatment effectiveness considerably alters the benefits from introducing a systematic national screening programme.

Given the greater sensitivity of slit lamp examinations, an opportunistic screening programme that relies less upon GP examinations is more effective. This in turn reduces the effectiveness of a move from opportunistic screening to systematic screening. Possibly of more interest is that if those with IDDM are more likely to be seen and screened by slit lamp within hospital, the above sensitivity may be a better reflection of the impact of a move to systematic screening among those with IDDM.

The effect of a 5% deterrence factor arising from the use of mydriasis is to reduce the expected benefit in terms of additional sight days gained per patient from moving to a systematic screening programme. Under this sensitivity, the anticipated patient benefits from moving to a mydriatic programme from a non-mydriatic programme are reduced.

8.6 Cost-effectiveness of Screening

8.6.1 Methodology

To assess the cost-effectiveness of the move from opportunistic to systematic screening, events in the patient journey as identified in the model for assessing patient impact need to have the relevant costs attached. These include:

- the cost per screen;
- the cost per true referral and treatment;
- the cost per false referral;
- the cost of incident cases of blindness; and
- the cost of ongoing cases of blindness.

These are then discounted to give the cost in present value terms of an opportunistic screening programme, a systematic screening programme based around non-mydriatic photography and a systematic screening programme based around mydriatic photography. These costs are then subtracted from one another to give the net cost of a move from one screening programme to another.

Just as the cost of programmes requires a common unit of account, so the patient impact of different screening programmes have to be translated into a common unit of account. Quality adjusted life year multipliers are applied to the number of years spent in each health state. This yields the anticipated stream of QALYs within each cohort. These are then discounted to give the anticipated total QALYs under each screening programme. As with costs, these can then be subtracted from one another to give the net patient impact of a move from one screening programme to another.

The model has been implemented by running 2,000 iterations through Crystal Ball. Each iteration yields the set of costs and patient benefits that would result from the values of sensitivities and specificities that have been drawn from the relevant distributions for that iteration. This in turn yields a cost per QALY for the move from one screening programme to another, one cost per QALY value for each iteration. These values for each iteration are then ranked from least to most cost-effective, and the distribution of the cost per QALY graphed to give a Cost-effectiveness Acceptability Curve (CEAC).

Each CEAC shows the probability that the cost per QALY associated with a move from one screening programme to another is below a given value. These can also be interpreted as showing the probability that the cost-effectiveness of a move from one screening programme to another is below a given policy value, this policy value reflecting how much of the NHSScotland budget society should devote to saving one QALY.

For systematic screening the least cost NHSScotland modalities of providing mobile and static screening have been used. For both mydriatic photography and non-mydriatic photography this implies using the cost per screen for van-based mobile screening and single staffed-hospital based screening.

The cost of optometrist- and hospital-based screening within an opportunistic screening programme are taken from those of Appendix 20. Additional elements which require costing are:

- the cost per screen by GPs;
- the patients' out-of-pocket expenses for attending screening;
- the cost of true referral and treatment;
- the cost of false referrals;
- the cost of incident cases of blindness; and
- the cost of ongoing cases of blindness.

The cost per screen by GPs is derived from the timings reported in James *et al*. (2000), who report a requirement of five minutes of GP time coupled with five minutes of practice nurse time per screen. General practitioner and nurse times were costed from the *Unit Costs of Health and Social Care 2000* (Netton and Curtis, 2000) including overheads but excluding general training costs to maintain comparability with other staff costings, and due to the difficulties already alluded to of attributing the stated training costs.

Patient out-of-pocket expenses have taken an average figure from Phillips *et al*. (1997).

The costing of referrals to ophthalmology follows the same principles as previous costings, the details being given in Appendix 23. Laser treatment costs are taken from that reported by the Centre for Health Planning and Management within the NSC report (UK NSC, 2000), based upon data from the Royal Liverpool University Hospital.

The cost of incident and ongoing cases of blindness are taken from Gray *et al*. (2002). These only relate to the additional inpatient costs from incident and ongoing costs of blindness. It has not been possible to quantify any additional outpatient and social services costs. These costs are likely to understate the cost of blindness and thus the potential benefits of the national screening programme.

8.6.2 Assumptions

Modelling for cost-effectiveness imposes the same set of assumptions as used for the modelling of patient impact, including the split between mobile and static provision for both systematic mydriatic and systematic non-mydriatic screening being taken as 60:40. The balance between static and mobile provision will vary between Health Boards, many also involving community optometrists in service provision. The 60:40 split between mobile- and hospital-based provision is intended to be illustrative rather than an accurate reflection of the split which will occur within each Health Board.

Table 8-10 gives the Quality Adjusted Life Year values taken from those reported in the NSC report (UK NSC, 2000).

Table 8-10 Retinopathy quality of life values

One year spent with diabetes and	equals	years in perfect health (QALY)
No retinopathy		0.89
BDR		0.89
PDR		0.72
Blindness		0.45[11]

[11] Based upon 75% well adjusted and 25% poorly adjusted.

As required by HTBS procedures, the base case considers costs discounted at 6.0% and benefits discounted at 1.5%, with sensitivity analyses setting the benefit discount rate to 0% or 6%.

The concerns identified with the data inputs referred to in section 8.5.2 remain. Consequently conclusions are drawn at the population level only and not within individual age cohorts. As the national screening programme gets underway, it will be important to update the economic evaluation using inputs arising from the national programme.

8.6.3 Results

Table 8-11 presents the anticipated cost per QALY per incident person with diabetes associated with a move from;

- opportunistic screening to systematic non-mydriatic photography;
- opportunistic screening to systematic mydriatic photography; and,
- systematic non-mydriatic photography to mydriatic photography.

Table 8-11 Base case expected cost per QALY

	Opportunistic to Systematic Non-mydriatic	Opportunistic to Systematic Mydriatic	Systematic Non-mydriatic to Systematic Mydriatic
	RRR 70%	RRR 70%	RRR 70%
All Patients	£7,703	£10,270	£28,881
NIDDM All ages	£12,280	£16,370	£45,941
IDDM All ages	£1,216	£1,618	£4,545

Table 8-10 expected values, but given the uncertainty around sensitivities and specificities there is an associated uncertainty around the anticipated cost-effectiveness values. The CEACs for all those with diabetes, all those with NIDDM and all those with IDDM are presented in the following figures, with the CEACs for the separate age cohorts being presented in Appendix 24.

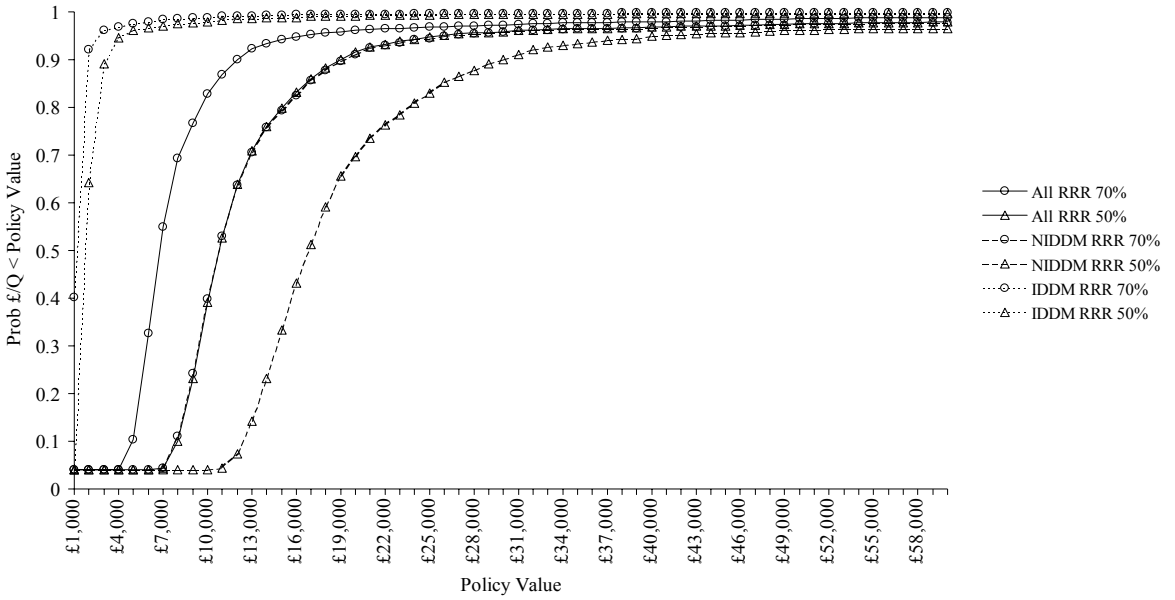
The results shown in Table 8-10 and graphs overleaf clearly show that a move from opportunistic screening to systematic screening is well within cost-effectiveness bounds for both those with NIDDM and those with IDDM in the base case.

As the CEACs show a high probability value (y-axis) for relatively small monetary (policy) values (x-axis) for all options in which age groups are combined, this demonstrates the cost-effectiveness of moving from an opportunistic screening programme to a systematic mydriatic or non-mydriatic programme. The cost-effectiveness of moving from a systematic non-mydriatic programme to a systematic mydriatic programme is not proven, with high monetary values required to achieve increased benefit in terms of QUALYs.

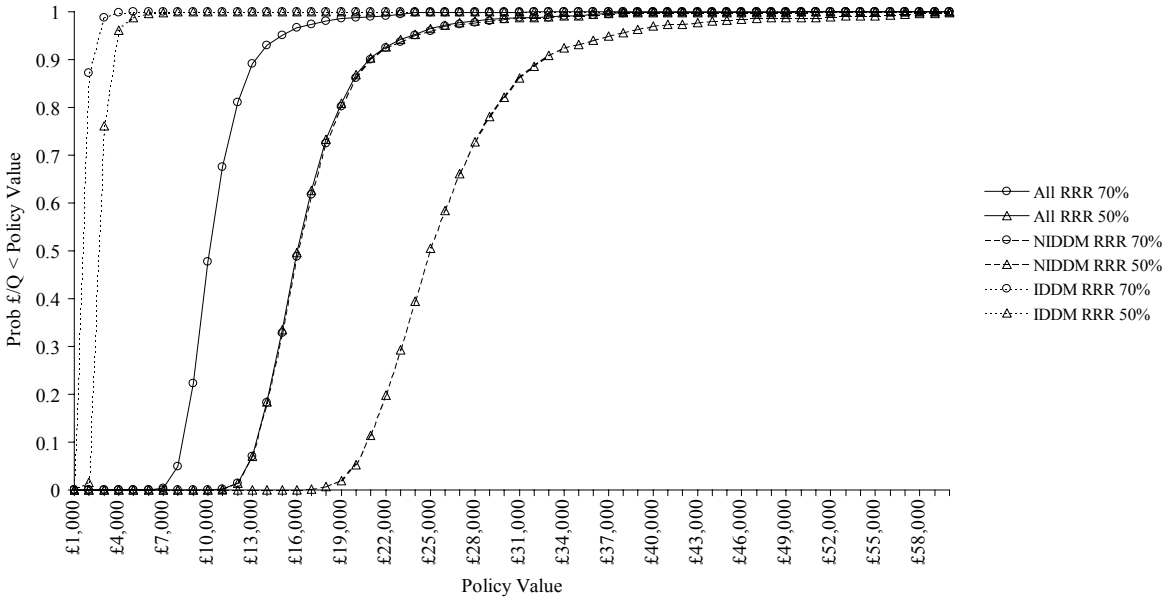
The data are less conclusive concerning whether systematic screening should be based around non-mydriatic or mydriatic photography. It suggests that a move from non-mydriatic to mydriatic photography is likely to be cost effective among those with IDDM, but this is not as clear among those with NIDDM. In the modelling this result arises because non-mydriatic photography has both a slightly lower central estimate for its sensitivity, and a distribution with a long tail into low sensitivity values.

As this report goes to press it is clear that one important element has not been allowed for in the economic model. This is a differential failure rate by age (see section 9.2.2). The model assumes two technical failure rates, one for the mydriatic option and one for the non-mydriatic option. However, as shown in section 9.2.2., new data reveal that the technical failure rate varies significantly with age. Therefore it will be important to include this in future economic models.

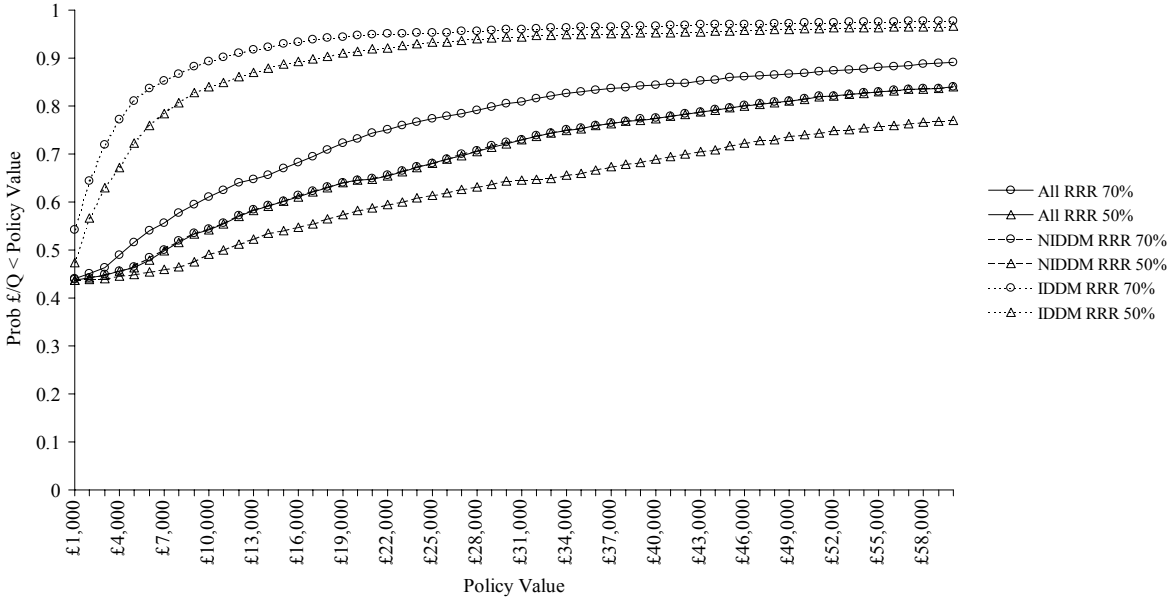
Opportunistic to Systematic Non Mydriatic: Benefit DR 1.5%
Incidence



Opportunistic to Systematic Mydriatic: Benefit DR 1.5%
Incidence



Systematic Non Mydriatic to Systematic Mydriatic: Benefit DR 1.5%
Incidence



8.6.4 Sensitivity analysis

With the current model, uncertainty surrounds many aspects of the move from opportunistic screening to systematic screening. It is important to investigate these to determine which are important for consideration in future models.

The performance of a screening test can be described in terms of a curve relating sensitivity to specificity, for historical reasons called a ROC. Estimation of the distributions of sensitivities and specificities assumed a 60:40 split in allocating the variability around the ROC curves. The resulting distributions are the only uncertainty that has been formally modelled within the base case analysis.

But uncertainty remains around the allocation of the variability associated with the ROC curves, as well as around the other parameters of the model. While the ROC curves' variabilities require an explicit assumption for sensitivities and specificities to be modelled, additional distributions could be placed upon the other parameters of the model. However, this is felt likely to mask rather than illuminate such uncertainty for readers of this report, and give a spurious certainty to the base case CEACs. As a consequence, more traditional univariate sensitivity analysis is employed to draw out the effects of these uncertainties. The variables explored are:

- the allocation of the ROC curves' variability between sensitivity and specificity;
- mydriasis and patient attendance rates;
- cost per screen;
- cost of blindness;
- call recall establishment without investment in digital photography;
- the pattern of opportunistic screening for those with IDDM;
- the quality of life associated with blindness; and
- the discount rate used for benefits.

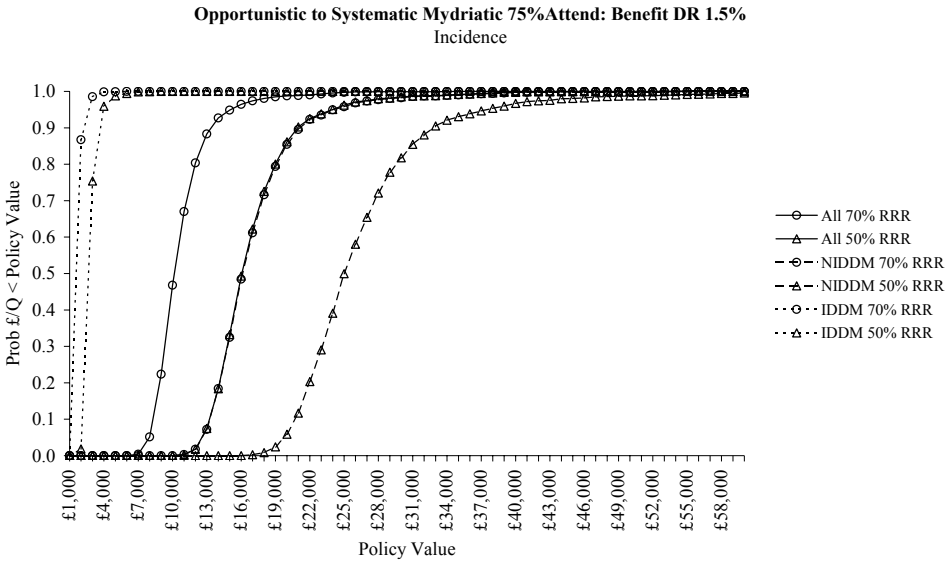
The impact upon cost-effectiveness ratios from changing the above are as would be expected, being reported in greater detail in Appendix 25. The effects of the key variables are summarised in Table 8-11.

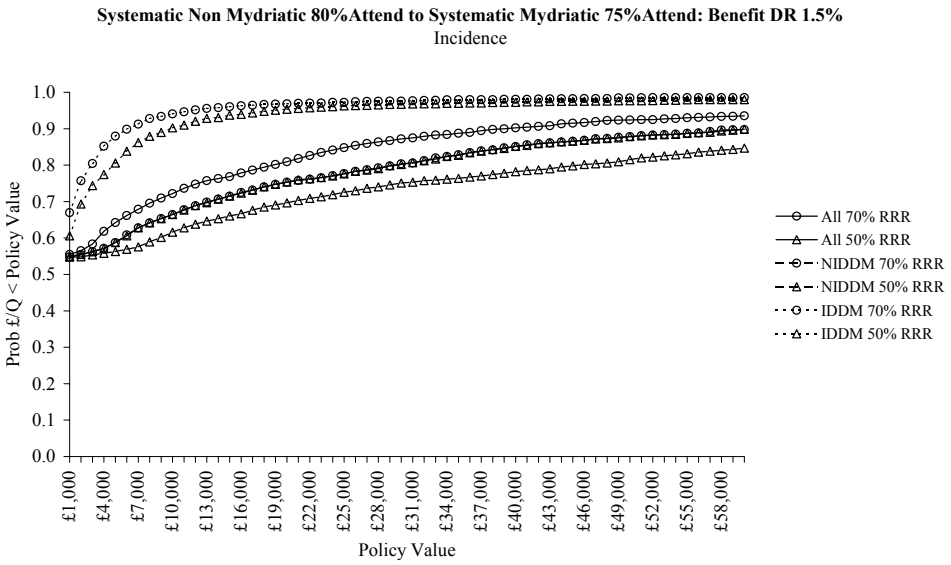
Table 8-12 Sensitivity analysis of expected cost/QALY

			Opportunistic to: systematic non-mydriatic	Opportunistic to: systematic mydriatic	Systematic non-mydriatic to systematic mydriatic
			RRR 70%	RRR 70%	RRR 70%
Base Case Values		All	£7,703	£10,270	£28,881
		NIDDM	£12,280	£16,370	£45,941
		IDDM	£1,216	£1,618	£4,545
ROC Variability		All	£7,715	£10,269	£25,422
Base Case	Adjusted	NIDDM	£12,294	£16,374	£40,651
60:40	80:20	IDDM	£1,218	£1,617	£3,974
Mydriatic Attend		All	£7,703	£10,286	£50,239
Base Case	Adjusted	NIDDM	£12,280	£16,393	£79,403
80%	75%	IDDM	£1,216	£1,621	£7,972
Blindness QoL		All	£10,283	£13,710	£38,572
Base Case	Adjusted	NIDDM	£18,421	£24,555	£68,912
0.45	0.54	IDDM	£1,404	£1,869	£5,249
Benefit Disc. Rate		All	£4,955	£6,607	£18,601
Base Case	Adjusted	NIDDM	£8,463	£11,282	£31,696
1.5%	0.0%	IDDM	£715	£951	£2,674
Benefit Disc. Rate		All	£23,608	£31,459	£88,158
Base Case	Adjusted	NIDDM	£32,216	£42,925	£120,106
1.5%	6.0%	IDDM	£4,894	£6,510	£18,233

This table indicates that the relative quality of life associated with blindness and the choice of discount rates have a fairly major impact on the cost-effectiveness. However, in all cases, the expected cost per QALY values are still relatively low when compared with other interventions.

If the attendance at mydriatic screening is reduced by 5%, there is little effect on the cost-effectiveness of a move from an opportunistic to a systematic programme, but the move from a systematic non-mydriatic programme to a systematic mydriatic programme is clearly much less cost-effective. The CEAC graphs for this situation are presented in the following figures.





8.6.5 Conclusions

In aggregate, there seems little doubt that a move from opportunistic to systematic screening for diabetic retinopathy appears justified on cost-effectiveness grounds.

The sensitivity analyses show that the cost-effectiveness ratios improve from adopting higher costs of blindness and a lower benefit discount rate. However, increased costs per screen, a lower difference in the quality of life associated with blindness and PDR and a higher discount rate for benefits reduce the cost-effectiveness.

The sensitivity analysis of a move from systematic non-mydriatic screening to systematic mydriatic screening shows that this is sensitive to the cost of blindness, patient attendance rates for mydriatic screening, costs per screen and discount rates. Higher discount rates, higher costs per screen, poorer attendance rates and reducing the relative quality of life for people with blindness relative to those with PDR all weaken the case for any move to systematic mydriatic screening. On balance, it seems likely that a non-mydriatic based screening programme will be more cost-effective than mydriatic screening.

Two important sets of inputs to the model will need to be determined as clinical experience in the national screening programme emerges. They are the sensitivity and specificity by IDDM/NIDDM and the failure rates by age.

The analysis has not addressed the issue of the optimal interval between screens. All those with diabetes are assumed to be offered an annual screen. There is the potential to reduce the frequency of screening among those with little likelihood of developing PDR between screens. This is likely to apply to most recently diagnosed cases, and to those with NIDDM whose previous screen results indicate little or no background retinopathy. This would further improve cost-effectiveness ratios. It is also not an option open to opportunistic screening.

A final caveat to the analysis should be noted, in that modelling has not considered the detection of macular oedema. Macular oedema leads to the loss of central VA and is the main reason for laser photocoagulation for those with diabetes (Kohner *et al*., 2001). This would tend to reduce the quality of life differential between PDR and blindness, as already explored within the sensitivity analysis. But it remains unclear what the effect of a move from opportunistic screening to systematic screening based around digital photography will be upon the detection of macular oedema. This should also be assessed through ongoing audit of the national screening programme.

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8.7 Financial Impact of Recommended National Diabetic Retinopathy Screening Programme

After drawing together all the components of the HTA, a 3-stage model for diabetic retinopathy screening will be recommended (section 9.2).

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; and
3. If there is a technical failure with mydriatic digital retinal photography, biomicroscopy with slit lamp.

This section provides financial costs for implementing and operating such a three-stage national programme.

8.7.1 Financial costs of a national three-stage screening programme

8.7.1.1 Methodology

The financial forecasts for the recommended screening programme use the same assumptions as outlined in section 8.4 but require additional assumptions concerning the accuracy with which patient needs can be predicted. Some people with diabetes will be amenable to non-mydriatic photography while others will require mydriasis for photographic screening. Other people will not be amenable to photographic screening and will require slit lamp examination. With perfect foresight, patients could be matched to the appropriate screening methods and slots booked accordingly.

The accuracy of predicting patient requirements will differ between the short-term and the long-term. In the short-term only proxy indicators such as age and length of diagnosis can be used, as identified by GPs through prior notification lists. In the longer term, previous

screening results will enable a much closer matching of patient requirements with the screening examination offered to them.

8.7.1.2 Assumptions

In the short-term it has been assumed that all patients present for non-mydriatic screening. Out of 1,000 patients presenting for non-mydriatic photography, 100 of these will prove not to be amenable to it and require mydriatic photography. A further 50 of these will prove not to be amenable to photography and require slit lamp examination elsewhere. The base case has assumed the full patient turnaround times as reported in Appendix 18 for each examination.

In the longer term the costings assume that among 1,000 patients, 960 are booked for photography with the remaining 40 being correctly booked for slit lamp examination. Of the 960, 910 are booked a non-mydriatic slot with the remaining 50 being booked into a mydriatic slot. Ten booked into a non-mydriatic slot require subsequent mydriatic photography, while 10 booked into a mydriatic slot require subsequent slit lamp examination.

In theory, the economic costs of establishing a systematic screening programme will be partially offset by savings from the abandonment of opportunistic screening but many of these economic savings may not result in financial savings. Possible reductions in the fees paid to optometrists for slit lamp examinations under opportunistic screening have been factored in as potential savings. The requirement for slit lamp examinations within hospital will be offset by the reduction in slit lamp examinations under opportunistic screening and the savings of over £0.55 million have been included. Savings from the reductions in GP opportunistic screening have not been included.

8.7.1.3 Results

The annualised costs per screen in the base case are outlined in Table 8-13.

Table 8-13 Three stage variable and total costs per screen

	Screen[12]	Grading	Total Variable Costs	Fixed Costs	Total
three stage, van-based, one staff, short-term	£10.23	£1.95	£12.18	£10.45	£22.63
three stage, van-based, one staff, long-term	£9.42	£1.95	£11.37	£10.45	£21.82
three stage, hospital based, one staff, short term	£9.47	£1.95	£11.42	£10.45	£21.87
three stage, hospital based, one staff, long term	£9.04	£1.95	£10.99	£10.45	£21.44

Further assumptions have to be made to translate that into budgetary figures. The costings assume the patient flows for the short-term; a 60:40 split between mobile provision and hospital-based provision and that provision is optimised at the Scotland-wide level, rather than at each Health Board level. These assumptions give rise to a requirement for 17 mobile units and eight hospital units. This in turn gives rise to the following budget.

[12] To include the cost of slit lamps for patients requiring this treatment.

Fixed Costs	**Year 1**	**Recurrent**
National coordination	£73,640	£65,840
HB coordination	£394,977	£361,827
Screening offices	£762,755	£594,755
Call recall software	£390,940	£163,570
Image capture software	£30,000	£30,000
Total fixed costs	*£1,652,312*	*£1,215,992*

Screening Costs	**Year 1**	**Recurrent**
Mobile units	£1,596,317	£453,628
Optometrist slit lamp	£68,640	£68,640
Hospital units	£735,504	£477,064
Grading	£237,067	£213,827
Total screening costs	*£2,637,528*	*£1,213,159*
Total Gross Direct Costs	**£4,289,840**	**£2,429,151**
Optometrist savings	£552,960	£552,960
Total Net Direct Costs	**£3,736,880**	**£1,876,191**

The national screening programme, using a three-stage protocol is thus forecast to cost some £3.7 million in the first year and around £1.9 million thereafter.

It remains unclear how the implementation programme will be rolled out, and the financial impact is presented on the basis of a cross over from opportunistic screening to systematic screening in one year. Modelling the roll out of the programme is beyond the scope of this HTA.

8.7.1.4 Sensitivity analysis

The assumption of the full patient turnaround times for each examination as stated in Appendix 18 may overstate total patient contact times for those receiving non-mydriatic photography but requiring subsequent mydriatic photography. These patient turnaround times each involve an element for the measuring of visual acuity, so providing for only one visual acuity test of five minutes among these patients would reduce the cost per screen as shown in Table 8-14.

Table 8-14 Variable and total costs: one visual acuity test

	Screen	Grading	Variable Costs	Fixed Costs	Total Costs
three stage, van-based, one staff, short-term	£9.86	£1.95	£11.81	£10.45	£22.26
three stage, van-based, one staff, long-term	£9.15	£1.95	£11.11	£10.45	£21.56
three stage, hospital-based, one staff, short-term	£9.28	£1.95	£11.22	£10.45	£21.67
three stage, hospital-based, one staff, long- term	£8.91	£1.95	£10.85	£10.45	£21.30

Allowing for some time saving from only one visual acuity test being performed for each patient reduces the average cost per screen slightly. The effect is slightly greater within the

mobile options, as would be anticipated given that camera costs and other capital equipment costs associated with screening have to be shared among a lower patient throughput. However, the effects are minor as the time savings apply to only a small percentage of patients.

As before, for the mobile options the daily drive time affects the overall average cost per screen, as shown in Table 8-15.

Table 8-15 Variable and total costs: drive time sensitivity

	1.0 hr	1.5 hrs	2.0 hrs	2.5 hrs	3.0 hrs	3.5 hrs	4.0 hrs
three stage, van-based, one staff, short-term	£20.88	£21.67	£22.63	£23.82	£25.34	£27.33	£30.07
three stage, van-based, one staff, long term	£20.22	£20.94	£21.82	£22.90	£24.27	£26.09	£28.58

Again, the average cost per screen is more sensitive to the daily drive time in the short-term than the long-term due to the slightly lower patient throughput in the short-term.

There remains some uncertainty around how many patients will not be amenable to non-mydriatic photography. Recent estimates from Gloucestershire (Scanlon *et al*., 2001) suggest this may be as high as 20%. Retaining the assumption that 5% require slit lamp examination this results in the costs per screen set out in Table 8-16.

Table 8-16 Variable and total costs: 20% sensitivity case

	Screen	Grading	Total Variable Costs	Fixed Costs	Total Costs
three stage, van-based, one staff, short term	£11.72	£1.95	£13.67	£10.45	£24.12
three stage, van-based, one staff, long term	£10.16	£1.95	£12.11	£10.45	£22.56
three stage, hospital based, one staff, short term	£10.26	£1.95	£12.20	£10.45	£22.65
three stage, hospital based, one staff, long term	£9.43	£1.95	£11.38	£10.45	£21.83

Some presenting for photography are booked for non-mydriatic photography but subsequently require mydriatic photography. If this percentage is large, a lower cost per screen could result from screening all patients with mydriatic photography. Given a patient turnaround time of ten minutes for non-mydriatic photography and 20 minutes for mydriatic photography, half of those presenting for photographic screening would need to be incorrectly booked for non-mydriatic screening to equalise the average cost per screen. If only one visual acuity check of five minutes is allowed for within those incorrectly booked for non-mydriatic photography, this proportion rises to two-thirds.

8.7.1.5 Conclusions

The three-stage screening protocol increases costs slightly, as compared with a programme based around non-mydriatic photography. This is most marked for mobile screening in the short-term, with an increase in the cost per screen of around £1.50. However, as the screening

programme becomes established and patients are better matched to their requirements, the cost increase is just over £0.70 per screen. Within the hospital-based options, the cost increases are less marked, costs per screen rising by around £0.80 and £0.40 in the short term and the long-term respectively. These cost increases are associated with an increased proportion of patients having a continuous photographic record, and with the quality assurance and clinical benefits already alluded to in this report.

The costing of the three-stage screening protocol has assumed that screening continues to operate smoothly. There will be instances where an unusual number of patients present for non-mydriatic photography but require mydriatic photography. This may disrupt the smooth operation of units and lead to cost increases, particularly in the short-term.

Similarly, if a high proportion of people who were booked into non-mydriatic screening slots subsequently require mydriatic screening, then costs will increase. The sensitivity analysis shows that between a half and two-thirds of the patients to be screened need to be screened using mydriasis before the costs of a three stage protocol are equivalent to one based on mydriatic photography. It is unlikely that the proportions would approach this level. Moreover, it should be borne in mind that the base case assumes a 5% unfilled slot percentage which allows for some slack in the system. That the three-stage screening protocol will result in a lower cost per screen than a programme based around mydriatic photography seems to be a robust prediction.

8.7.2 Downstream costs

Establishing a national screening programme will also impact on downstream costs by reducing the number of referrals for false positives, and increasing the number of referrals for true positives and laser treatment episodes. The unit costs of these have already been determined for the assessment of the cost-effectiveness of screening. Appendix 27 sets out a model that has been created to determine the changes in referral rates that may arise following implementation of a national screening programme. The model uses prevalence and incidence data to determine the prevalence of sight-threatening retinopathy that would be present in a population screened under an assumed pattern of steady state opportunistic screening. Systematic screening is then imposed upon this prevalence and incidence data to determine the impact upon referrals for false positives, referrals for true positives and laser treatment episodes.

In terms of the downstream costs of referral and treatment, an annual incidence of STDR of 1.3% suggests a prevalence of 2.7% under opportunistic screening. The impact for the base case is outlined in Table 8-17.

Table 8-17 Screening on downstream costs

Year	Reduction in false positives	Increase in number of treatments	Additional Costs
1	-3,036	1,139	£1,271,249
2	-2,995	424	£394,136
3	-2,983	228	£153,599
4	-2,980	174	£87,634
5	-2,979	159	£69,544
6	-2,979	155	£64,584

Increased downstream costs are anticipated in the early years of the programme as the backlog of cases are worked through. Programme roll out is likely to spread these costs more evenly over the initial years, to an average cost of perhaps £370,000. In the longer term, once the backlog of cases has been worked through, an annual increase in downstream referral and treatment costs of around £65,000 may be anticipated.

8.7.2.1 Sensitivity analysis

Uncertainty around the budgetary impact of screening on the downstream treatment costs is explored in greater detail in Appendix 27. The analysis suggests that with an incidence of sight-threatening retinopathy of only 1.0%, the anticipated increase in downstream costs would average around £250,000 in the initial years, before settling down to an annual increase of perhaps £20,000. For a higher incidence of 1.6% the anticipated increase in downstream costs would average around £490,000 over the first few years, before settling down to an annual increase of around £100,000.

8.7.3 Conclusions

The costing analysis suggests that provision of screening within NHSScotland should be through single staffed hospital-based units and single staffed van-based mobile units. The balance between provision within NHSScotland and provision by community optometrists will depend upon the dispersal of local populations with diabetes and upon local optometrist fee rates.

The budget estimate to establish a national screening programme, using a three-stage protocol is thus forecast to cost approximately £4.29 million in the first year and around £2.43 million per annum thereafter. Savings of over £0.55 million per annum in optometrist fees should be achievable giving a net cost of £3.74 million in the first year and £1.88 million thereafter. Money currently allocated to existing local hospital and mobile screening work is not qualified. These costings assume that all equipment and services are in place in the first year. In practice, the programme will be rolled out over a longer time frame but as implementation plans have not yet been agreed (section 9.3.8) it is difficult to make any firmer financial predictions at this stage.

Additional downstream costs will be incurred with the cost incurred from the higher number of patients being treated exceeding the savings from a lower number of false positives. These costs are estimated to be around £65,000 per annum in the long term.

9 DISCUSSION

9.1 Basis and Limitations of Findings from the Four HTBS Health Technology Assessment Components

This Health Technology Assessment has taken data and evidence from a wide range of sources (including many consultation and expert review comments) and has critically appraised it to ensure that analyses of clinical and cost-effectiveness are as robust as possible and that best practice related to organisational and patient issues can be shared across Scotland. Giving these factors appropriate weight has resulted in recommendations that differ markedly from other appraisals of diabetic retinopathy screening (NICE, 2002).

All analyses and appraisals were driven by the objective of the national screening programme, that is to detect STDR within a quality assured systematic screening programme that takes account of patients' needs.

This Health Technology Assessment was undertaken with no preconceptions about the most effective screening technology, operator, or mode of delivery and all possible combinations of these circumstances were compared wherever evidence was available. By contrast and almost inevitably, experts in the field whose opinions we have gathered in various ways, have tended to come to the question with certain preconceptions and assumptions. The most striking has been the assumption that mydriasis is necessary in all cases.

9.1.1 Clinical effectiveness (section 5)

There were no comparative studies of failure rates for digital photography, with and without mydriasis. However, the available studies indicate failure rates of between 4% and 12% with mydriasis and 5% and 14% without mydriasis. These results are difficult to compare given the quite different studies and retinal cameras used, so evidence with newer cameras in comparative studies will be important for early evaluation (see section 9.2.2).

This Health Technology Assessment has used the only robust method there is to analyse sensitivity and specificity, that is by evaluating their joint distribution. Separate analysis of the two parameters will not account for study specific issues such as disease prevalence and operator differences, which can be overcome with the joint analysis. The joint sensitivity and specificity has then been analysed using a meta- analysis that excludes studies without an appropriate blinded Gold Standard and excluding studies evaluating inter-rater agreement. Again, this is the only statistically robust approach that can be considered for the specific questions addressed in a screening programme.

The meta-analysis shows that direct ophthalmoscopy has low sensitivity at 95% specificity and so it should not be used in the systematic screening programme.

The only data relating to optometrists using slit lamps that could be included in the meta-analysis do not relate to fully trained screeners and so the relatively low sensitivity achieved (62%) may be increased if up-to-date blinded studies were performed.

There are insufficient data to judge the accuracy of the ultra wide angle scanning laser ophthalmoscope.

Of most interest are the results for digital photography with trained graders. These show that for 95% specificity, with mydriasis the sensitivity is 88% (95% CI 60 to 98) and without mydriasis the sensitivity is 86% (95% CI 31 to 100). These results derive from studies which each included screening with or without mydriasis and so comparison of the results is robust. The results show adequate sensitivity with either method, but somewhat greater uncertainty (wider confidence interval) with the non-mydriatic results. This is due to a slightly smaller number of disease positive individuals: 18 disease positive out of a total of 358 patients in the non-mydriatic studies and 21 disease positive out of 407 patients in the mydriatic studies. In fact, for both studies, the number of disease positive individuals is small. This contributes to the uncertainty in the results and indicates that more evidence is required, preferably on the higher resolution digital cameras that would be used in the national screening programme.

In the two mydriatic studies, one took one-field, whilst the other took two fields. When these are compared the sensitivity with two fields is slightly lower. This result is counterintuitive and as it comes from comparison across studies, it should be treated with caution. New data were submitted for assessment (Olson, Evidence submission, 2001) and compare one-field with two fields in a mydriatic study. This study shows almost identical sensitivity and associated confidence intervals for one or two fields.

Combining all the evidence on clinical effectiveness indicates that one-field non- mydriatic or mydriatic digital photography graded by trained graders would be suitable for the national screening programme.

9.1.2 Organisational issues (section 6)

As this Health Technology Assessment is about the organisation of a diabetic retinopathy screening programme, emphasis has been placed on all the organisational issues that need to be established to introduce and sustain a quality assured national screening programme. The context taken is that of NHSScotland, with its existing structures, and to ensure appropriate quality assurance responsibilities of all parties are made explicit (section 6.14).

The recommendation is that people with diabetes aged over 12 years or post-puberty should have annual examinations of the retina, unless they are medically unfit for laser treatment. The diabetic retinopathy screening programme should be integrated with other components of clinical care for diabetes, including evolving IM&T systems.

A quality assured system must provide a verifiable record of the effectiveness of the screening programme. In order to achieve this it must retain permanent records of primary screening events, in this case of retinal images. Consequently, digital photography should be the mainstay of the screening programme, with slit lamp examination for those in whom the digital photograph yields a technical failure.

Detailed information about screening equipment (cameras, software, hardware, etc.) is evaluated in section 6.10 and clear recommendations for national purchasing are made.

A standard grading nomenclature for diabetic retinopathy is essential for consistent grading, for internal and external quality assurance purposes, for ease of exchange of data between clinical information systems, and for agreement on referral thresholds. For this programme, the Scottish Diabetic Retinopathy Grading Scheme has been devised (for use with one or two fields), by adapting the CRAG grading system. Three-level grading should be undertaken, and a proportion of all images (both positive and negative) should be quality assured.

To create public confidence and have appropriate quality assurance of the programme it is essential that all graders are appropriately trained, accredited and competent. In Scotland, a modular training programme, with continuing education and accreditation is being developed for retinal screeners from a variety of professional backgrounds. This should provide the framework for all such retinal grading training programmes.

All aspects of quality assurance should be led by the Clinical Standards Board for Scotland, according to standards being established for all national screening programmes.

9.1.3 Patient issues (section 7)

The screening programme should be designed to take account of patients' needs and preferences concerning issues such as the screening location, environment and time of appointment to encourage screening attendance. There is also a need to inform, support and enable people with diabetes to understand the need for screening, the process to be undertaken and the limitations associated with screening. This will need to be done sensitively taking account of the requirements of different groups, particularly for those who do not regularly attend screening.

Administration of mydriatic agents is often associated with some discomfort and almost always induces a short-term visual impairment. The latter is frequently inconvenient for patients as they cannot drive or read for a few hours. The local side-effects experienced with eye drops were raised as an issue by many patients during the HTBS consultation and some individuals would be more inclined to attend screening if they did not need to have mydriasis.

9.1.4 Economic evaluation (section 8)

The economic evaluation compares seven different ways that screening might be offered using digital cameras, based on systems currently in operation in the UK. These analyses indicate that minimum cost is achieved per graded screen for non- mydriatic options in a hospital or van-based setting using one member of staff (approximately £21 compared with £28–£33 for mydriatic options).

Key drivers to these costs are patient turnaround times and drive times in mobile units. As the turnaround times have been a source of debate with English reviewers, extensive sensitivity analyses have been undertaken to show the effect of varying the turnaround time, but whatever assumptions are used, the non-mydriatic option is always cheaper (section 8.4.4.1). Summaries of cost by drive time are also presented to allow Boards to determine the most efficient screening option for their population.

A cost-effectiveness analysis is described in sections 8.5 and 8.6 that take account of the uncertainty associated with the estimates of sensitivity and specificity. The analyses evaluate a move from an opportunistic screening programme to either a systematic programme with mydriatic photography or a systematic programme with non-mydriatic photography. Then the cost-effectiveness of moving from a systematic non-mydriatic programme to a systematic mydriatic programme is evaluated.

Economic modelling is not an exact science and for these evaluations many assumptions have been made. The report has tried to explain clearly these assumptions and associated

limitations, presenting a variety of sensitivity analyses to determine the robustness of key assumptions.

The opportunistic programme is expected to screen 60% of targeted individuals each year (not necessarily with modalities of acceptable sensitivity) and for analytical purposes the systematic programme is only expected to increase this to 80%. Despite this, the analysis shows that a move to systematic screening with non-mydriatic or mydriatic photography is clearly cost-effective. However, the cost-effectiveness of moving from a systematic non-mydriatic programme to a systematic mydriatic programme is not clearly established.

Various sensitivity analyses have been performed (section 8.6.4). Of most interest for the organisation of the screening programme is a reduction in the screening uptake with mydriasis from 80% to 75%. This shows that although the move from an opportunistic programme to a systematic mydriatic screening programme would remain cost- effective, the cost-effectiveness of a move from non-mydriatic to mydriatic screening becomes increasingly uncertain. Overall, the sensitivity analyses provide reassurance about the cost-effectiveness results and indicate that either non-mydriatic or mydriatic systematic screening would be cost-effective when compared to opportunistic screening.

Overall the economic evaluation may be taken as indicating that the establishment of a national screening programme is a wise investment of resources.

9.2 The HTBS Recommendation for a National Screening Strategy for NHSScotland

Consideration of all the findings from the four components of this Health Technology Assessment indicate that non-mydriatic photography would be suitable for diabetic retinopathy screening and would be welcomed by patients. To ensure a failsafe system, patients who experience a technical failure without mydriasis should be offered mydriasis and have the photo retaken. If this fails examination by slit lamp will be necessary.

The three-stage screening process recommended by HTBS is thus:

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 retinal photography, biomicroscopy with slit lamp.**

(For all patients, visual acuity, with refractive correction if required, should be recorded for each eye immediately prior to the screening examination.)

A diagrammatic representation of this screening model is presented in Appendix 28.

9.2.1 Cost of the three-stage screening process

The cost/graded screen of the main modalities are estimated for this three-stage process in section 8.7.1, along with the financial forecast for the three-stage process. This shows that the estimated increase in cost for the three-stage process compared to the non-mydriatic options (which was actually two-stage allowing referral of failures to slit lamp examination) is estimated to be between approximately 80 p and £1.50 in the short-term, with the differential falling in the longer term.

9.2.2 Clinical effectiveness of the three-stage screening process

These recommendations do not reflect the process used in any current screening system, and given the expert critique of non-mydriasis, the evaluation of the first two stages of the process is of particular interest.

Dr Peter Scanlon, has given the HTBS statistician (J. Slattery) access to the dataset arising from his large study of a screening service in Gloucestershire during the final stages of the assessment (Scanlon, *et al,* Evidence Submission, 2002*).* This has enabled analyses of these first two stages to be undertaken. HTBS is extremely grateful to Dr Scanlon and his colleagues who, having worked so hard to collect these data, have allowed us free access to them and gave generously of their time to explain them.

9.2.2.1 Introduction to the 'Scanlon study'

The Gloucestershire screening service has recently completed a large-scale evaluation of screening effectiveness for the NHS Executive South and West Research and Development Directorate. (Scanlon *et al*., Evidence Submission 2002). In this project 3,611 diabetic patients were screened using both non-mydriatic single-field digital retinal photography and mydriatic two-field digital retinal photography. In addition 1,549 of these patients were assessed by an ophthalmologist using a biomicroscope. A biomiscroscpe examination by an experienced ophthalmologist provided the Gold Standard results.

From these data it is possible to evaluate the first two stages of the HTBS screening procedure – with the caveat that the mydriatic results were based on two images rather than one. However, given the results already discussed in the clinical-effectiveness section, it is expected that there will be little difference between screening evaluations from one or two fields.

It cannot be evaluated from these data what effect the third stage of biomicroscopy by an optometrist or a non-specialist doctor would have on referral rates or accuracy of referral.

9.2.2.2 Non-mydriatic photography

Analysis is restricted to the 1,542 patients with both non-mydriatic and a gold standard examination. Of these 321 (20.8%) were judged to have an ungradable image (technical failure) in one or both eyes. These failures were assessed using subjective but clearly defined criteria concerning the amount of detail of the vascular structure of the retina that was visible. For the remaining 1,221 patients the evaluations, based on the most diseased eye, are shown in Table 9-1.

Table 9-1 Screening results from gradable non-mydriatic photographs

		Non-mydriatic photography	
		Not STDR	STDR
Gold Standard	Not STDR	1045	48
	STDR	25	103

STDR: Sight threatening diabetic retinopathy

9.2.2.3 Mydriatic photography in first stage failures

Of the 321 patients with a technical failure for non-mydriatic photography, 73 (4.7% of 1,542) could not be graded with mydriasis. The remaining 248 were evaluated with mydriasis as shown in the Table 9-2.

Table 9-2 Screening results from mydriatic photography in technical failures of non-mydriatic photography

		Mydriatic photography	
		Not STDR	STDR
Gold Standard	Not STDR	171	33
	STDR	10	34

9.2.2.4 Combined results

Combining these two stages the results for a two-stage screening process are presented in Table 9-3.

Table 9-3 Screening results from the first two stages

		Two stages combined	
		Not STDR	STDR
Gold Standard	Not STDR	1,216	81
	STDR	35	137

This gives an odds ratio of 58.8 for a positive screen result when disease is present compared to when it is absent.

The sensitivity of this two-stage procedure restricted to successful screens is thus estimated as 137/172 (79.7% with 95% CI from 73.7 to 85.7) and the specificity as 1,216/1,297 (93.8% with 95% CI from 92.5 to 95.1).

It should be noted that this study included patients already in the care of an ophthalmologist for diabetic retinopathy. Hence the screen positive rate of (137+81)/1,542 (14.8%) should not be interpreted as a rate of new referrals.

The Gold Standard classification of the 73 patients who had an imgradeable image with mydriasis identified 7 (10%) with STDR and 66 (90%) without.

Thus if screening failures are considered as referable the sensitivity estimate becomes (137+7)/(35+137+7) (80.4%) and the specificity 1,216/(1,216+81+66) (89.2%).

The previous calculation has assumed that all patients with a technical failure of non-mydriatic photography would have both eyes dilated and re-evaluated and the dilated results would be used. This might be inefficient if only one eye failed to image with non-mydriatic photography. It is also possible to evaluate the results assuming that only eyes with non-

mydriatic technical failures are re-imaged. The classifications resulting from the end of the second stage are presented in Table 9-4.

Table 9-4 Screening results from first two stages with selective mydriasis by eye rather than by patient

		Two-stage with mydriasis by eye	
		Not STDR	STDR
Gold Standard	Not STDR	1,222	72
	STDR	38	132

This gives an odds ratio of 59.0 which is almost identical to that with both eyes re-evaluated. This suggests that re-evaluation of eyes rather than patients might be adequate. This is important since 57% of patients with non-mydriatic technical failures had them in only one eye.

9.2.2.5 Predictability of technical failures

In order to minimise inconvenience to patients it would be useful to give prior information that mydriasis was necessary or highly likely. One predictor of this likelihood is age and this was recorded within the Gloucestershire study. Figure 9-1 presents the total number of patients screened by age group in years, and the number who were technical failures without mydriasis are shown in black.

Figure 9-1 Patients screened and technical failures by age group

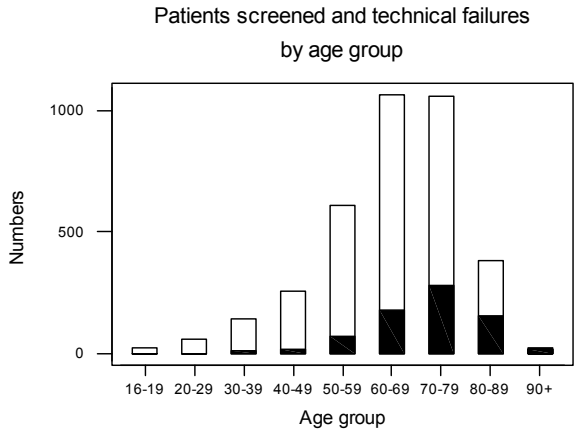

Table 9-5 Predictability of failures by age group

Age group	Technical failures
16–19	1/19 (5.3%)
20–29	0/59 (0.0%)
30–39	8/143 (5.6%)
40–49	16/254 (6.3%)
50–59	67/607 (11.0%)
60–69	175/1,061 (16.5%)
70–79	277/1,059 (26.2%)
80–89	152/379 (40.1%)
90+	15/22 (68.2%)
Total	**711/3,603 (19.7%)**

It is clear that age is quite a strong predictor of the need for mydriasis. However, in an annual screening programme it is likely that the strongest predictor will be the need for mydriasis on the previous screening occasion. Under the assumption that a patient who needs mydriasis in one year will need it from that date forward it is possible to estimate the proportion of patients who will require it for the first time in a year.

If it is assumed that the distributions as shown above represent a steady state system, any patient needing mydriasis for the first time must replace one who has died or left during the year. In order to calculate the numbers entering the distributions each year the age specific mortality rates for diabetes are required. Roper *et al.* (2001) have found in a UK population group that diabetes diagnosed before the age of 40 reduced life expectancy in both men and women by eight years. Hu *et al.* (2001) estimated an age adjusted relative odds for all cause mortality of around 3.39 for women with diabetes. For this calculation only rough estimates of hazard ratios are needed and it seems reasonable from the above to assume that these are independent of sex and age and to take Hu's value of 3.39.

Adding up across age groups of the distribution would lead to an estimate that about 106 of the 711 patients who needed mydriasis would die during the year. Thus the number requiring mydriasis for the first time the next year will also be 106. This is 3.7% of the 2,892 (i.e. 3,603-711) who would be invited for non-mydriatic screening. Thus it might be expected that mydriasis has to be used unexpectedly in one in 27 patients.

This calculation will not apply to the first year of screening when there will be little information about who will require mydriasis. According to the Gloucestershire data the proportion will be more like one in five for this year although others have suggested rather lower estimates.

Another concern is that the requirement for mydriasis may be less predictable than anticipated – with some patients needing mydriasis on some occasions but not on others. If this is so, the predictably non-mydriatic group may take rather longer than one year to become identified and the group invited for mydriatic screening would be rather larger than predicted from a single year of screening. Thus this issue should be subject to further evaluation during the screening programme.

9.2.2.6 Conclusions

The data from this large population-based study suggest that the first two stages of the three-stage screening programme recommended by HTBS will be feasible and effective.

The third stage remains untested but these data suggest that less than 5% of patients will require examination with a biomicroscope as part of the screening process.

9.3 Challenges for Implementation of the National Screening Programme

The HTBS baseline survey (section 3.6) has shown a variety of screening methods in current use for diabetic retinopathy across Scotland, some NHS Boards having systematic schemes in place, others at a much earlier stage. Even the best systematic schemes cannot be described as having a fully integrated, comprehensive, coordinated and quality assured diabetic retinopathy screening programme in place that meets the specifications of the national screening programme proposed in this Health Technology Assessment.

Each local NHS Board system will have specific challenges to address in order to introduce the nationally recommended programme. HTBS recommends that this is done by planned incremental building upon existing services: namely 'evolution' rather than 'revolution'. The key components cover:

- organisational issues;
- people issues;
- IT system issues;
- equipment issues; and
- provision of relevant resources.

9.3.1 Organisational issues

The *Scottish Diabetes Framework* (Scottish Diabetes Framework Working Group, 2001) proposes that each NHS Board will have a diabetes steering group (an LDSAG, section 3.2.3), that will oversee a managed clinical network for diabetes for the local population. A subgroup of the LDSAG should deal with the local diabetic retinopathy screening programme, where appropriate in collaboration with neighbouring programmes and with regional and national services. A formal process of local accountability and reporting is essential. A 'whole systems' approach should be adopted.

9.3.2 People issues

There are three main areas of 'people' activity.

9.3.2.1 Coordination and management of service change

This requires explicit resource for a designated 'national coordinator' with designated programme managers, information and administrative support and national quality standards established by the CSBS.

9.3.2.2 Use of existing local skills and expertise for call/recall, screening, reporting, acting upon screening test result and quality assurance

In some areas, screening will build upon existing programmes using 'accredited' optometrists, or fixed or mobile digital camera systems using screeners from a variety of backgrounds. In

all instances, accreditation, following nationally determined standards, participation in quality assurance and continuing professional development will be mandatory for all involved. Information and communication technology may enable regional or national centres to be established for grading of images within the national programme.

Hospital services providing diagnosis, assessment, treatment and follow-up must also be included in the quality assurance and clinical audit processes of the local screening programme.

The processes for systematic call/recall, for failsafe and follow-up should also build upon existing local models. Models exist which are practice-based or clinic-based. These should evolve towards population-based models linked to the area diabetes register which in turn will be linked to the CHI. The actual processes for dispatching invitation letters, recording subsequent screening test results and quality assurance of the screening activity must be coordinated and resourced to meet national quality standards, for example for result turnaround times.

Some individuals may not be suitable for screening by digital photography. Health professionals providing screening assessment using slit lamp biomicroscopy to such individuals must also participate in accreditation, quality assurance and refresher training. Clinical findings from these slit lamp screening examinations must also be included in the screening programme database as well as in the individual clinical record, according to nationally agreed definitions.

9.3.2.3 Recruitment of new staff

As the national programme evolves and is rolled out across Scotland, new staff from a variety of disciplines may be required and national model contracts should be established for contractors, such as community optometrists or GPs.

9.3.3 IT systems issues

In advance of the release of the national diabetes IT system SCI-DC, local systems in hospital, primary care and area diabetic register settings should capture minimum data items as recommended nationally, and adhere to the national definitions of each data item. This will facilitate future pump priming and merging of the national diabetes system. One component of this is the management and storage of digital retinal images. Currently, it is exceptional for community optometrists to be included in the NHS IT network. Consideration needs to be given to how best to include them, where appropriate, within the IT components of the systematic screening process.

9.3.4 Equipment issues

All digital photographic and IT systems associated with the screening process and the screening programme should comply with nationally determined specifications and standards. A mechanism to quality assure and coordinate these specialised aspects may be needed at a national level. Local developments should take place, therefore, in consultation with appropriate experts.

9.3.5 Provision of relevant resources

The HTBS survey has highlighted the variety of systems currently being used for diabetic retinopathy screening. Furthermore, individual areas have reported difficulties in obtaining funding, reflecting the competing priorities within local NHS systems.

Funding needs can be categorised as:

- capital costs for equipment and/or IT (with recurring capital charges);
- recurring costs for consumables, hardware maintenance contracts, etc.; and
- employment of staff involving various professional groups.

If the HTBS recommendations for a national programme are to be implemented, local health systems will need assistance to resolve local issues.

9.3.6 Examples of evolutional requirements to move to the three-stage screening model by various NHS Boards

The transition in Scotland from local diabetic retinopathy screening programmes to the proposed national programme will require much discussion with NHS Boards and will be highly dependent upon existing local structures and resources, but it is hoped that lessons will be shared among Boards.

As an illustration of what might be needed to implement the HTBS programme, some Topic Specific Group members have considered what their NHS Boards will need to do to implement the recommendations in this report.

Accounts of the status and evolutional requirements in the Highland and Grampian areas are presented here. Grampian is particularly interesting because it has undergone major developments in the last 18 months and has adopted the technical specifications in this report. Similarly, Glasgow has initiated a system in accordance with the recommendations of this report. This and other examples are presented in Appendix 29.

Highland

Diabetic retinal screening currently occurs in Highland in one of three ways:

1. Single-field undilated digital retinal photography for patients attending a hospital diabetic clinic in Inverness.

2. Direct ophthalmoscopy by consultant physician for patients attending hospital diabetic clinics in Caithness and Lochaber.

3. A retinal screening programme run by the Primary Care Trust that can be accessed directly by GPs. This provides for either slit lamp biomicroscopy by one of 17 accredited optometrists spread throughout the region or referral to a weekly digital retinal photography session (undilated, single-field) on a fixed camera in the Diabetes Centre, Raigmore Hospital, Inverness.

There is currently no formal coordination between the primary and secondary care screening activities. There is no provision for centralised call/recall, which is devolved to individual GPs, some optometrists and the secondary care hospital diabetic clinic. However, a regional register that will include the outcome of diabetic retinal screening is under construction and should allow an audit of overall uptake.

In terms of quality assurance, optometrists received training and accreditation once only, up to five years ago, and at present there are no firm plans for refresher courses or revalidation. There is no quality assurance check to ascertain the false negative rate among patients screened by optometrists. Digital images are graded by a single clinical assistant using a 17 inch high resolution CRT monitor, and a proportion of this work is systematically checked by a consultant ophthalmologist, with a negative predictive value to date of 100%.

A digital camera producing medium resolution images of 785 x 576 pixels (which does not meet the recommended minimum standard) is used. Capture is by Haag Streit EyeCap software to a 17 inch monitor that is also used for grading. Photography is performed by a medical photographer.

The grading protocol (for both optometrists and photography) is "in house" with nomenclature closely approximating to the terms of the NSC system (background, pre-proliferative, proliferative etc,) but the basis of the grade levels are not overtly defined. There is no formal arrangement for management of patients undergoing retinal photography who have technically inadequate photographs.

A number of optometrists have expressed an interest in using retinal photography for retinal screening.

To meet the HTBS recommendations the following would need to be addressed in Highland:

- development of systematic centralised call/recall for the eligible population;
- integration of the current separate secondary care and primary care based programmes;
- provision of a central administration office facility;
- more effective reporting of retinal screening results into the patient record (both primary and secondary care);
- introduction of quality assurance for all modalities of screening;
- migration of a community programme based predominantly on slit lamp examination by optometrists to one based around retinal photography. This might continue to involve optometrists with digital cameras;
- modification of the photography protocol to allow for mydriasis as per the HTBS model;
- adoption of the Scottish Diabetic Retinopathy Grading System and associated training implications;
- provision of facilities for examination of technical failure patients undergoing photography;
- increase in the capacity and local availability of digital retinal photography – eligible population circa 7,000 – two dedicated cameras or equivalent likely to be required;
- upgrade existing photography equipment to meet minimum technical standard – larger monitor for grading and higher resolution capture camera;
- discontinuation of systematic screening using direct ophthalmoscopy; and
- an increase in the budget. The current annual budget of £36,000 for the community programme provides for only approximately 1,500 examinations.

Grampian

The Grampian Diabetic Retinal Screening Programme has been under development for the past 16 months with piloting work and since spring 2002 has been undertaking live screening.

The programme has been built around an existing digital retinal camera located in a diabetic clinic in Aberdeen and two mobile units operating in GP surgeries and community hospitals, transported in dedicated vans.

The optical cameras are fitted with cameras which do not meet the recommended 1,365 x 1,000 pixel resolution, but there are plans to upgrade these cameras to the higher resolution early in 2002. Image capture is initially by Haag Streit EyeCap with subsequent on line and off line (for mobile units) transfer of images to Orion DRSS software for grading and reporting.

The DRSS software is also used for call/recall and scheduling of appointment sessions, and supports the three level grading structure suggested by HTBS.

The DRSS software is linked automatically for demographic purposes to a retinal screening register that is maintained by direct data input by GPs through web browser screens, and through a direct link to the Grampian CHI with regular updates. Summary reports are also placed automatically within the register.

Photography and first level grading are performed by four full time staff nurses, currently undergoing training. Grading activities are centralised and separated from photography. The photographic protocol requires routine mydriasis with tropicamide 1%, and involves two fields per eye as per EURODIAB. (section 6.9)

Grading is being undertaken according to the recommended Scottish Diabetic Retinopathy Grading System.

Second level grading is performed by optometrists and a retinal screening nurse previously trained in image grading, employed by the Trust on a sessional basis. The optometrists are also employed to provide slit lamp examination sessions for patients with a technical failure following photography.

There is a full time retinal screening coordinator operating from a regional retinal screening office in Aberdeen, where grading also takes place.

This programme closely approximates to the current draft HTBS recommendations with the following exceptions:

- photography protocol and mydriasis policy exceeds the HTBS recommendation;
- detailed methodology for the quality assurance has not yet been worked out, although this is intended to be a key part of the programme; and
- retinal screening activity currently conducted within hospital diabetic clinics (with both photography and direct ophthalmoscopy) needs to be integrated into the overall service.

9.3.7 Topics for further evaluation

During this Health Technology Assessment, the following areas of research, audit and development have been identified. These will test assumptions made in this report 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 automatic grading by computer; and
- 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; and
- use current expertise to equip mobile retinal screening units in the national programme, ensuring facilities allow disabled access.

Patient issues

- Determine barriers to screening attendance;
- evaluate factors that encourage screening attendance (and those most/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); and
  - dissemination points.

Economic evaluation

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

9.3.8 Implementation within national initiatives

As this is a national screening programme, a number of national organisations such as the National Services Division, the Clinical Standards Board for Scotland and the Scottish Executive will have a key role to play in the establishment of the programme in Scotland.

Diabetic retinopathy screening is one element of the care of people with diabetes and as outlined in various sections of this report it is essential that the national screening programme

is integrated with other aspects of clinical care. The Scottish Diabetes Group has been established to take forward the *Scottish Diabetes Framework* (Scottish Diabetes Framework Working Group 2001) considering all aspects of clinical care. HTBS is delighted that this group plans to produce a report to take forward the implementation of this HTBS Health Technology Assessment on the organisation of services for diabetic retinopathy screening by summer 2002.

10 ACKNOWLEDGEMENTS

HTBS is grateful to all members of the TSG (Appendix 1) who have given generously of their precious time (mainly at weekends, evenings and late into the wee hours!) to contribute constructively to the appraisal of the evidence and the writing of this report. We hope this has also achieved an important goal of sharing knowledge and best practice across Scotland.

The special advisers (Appendix 1) are thanked for reading early drafts of the report at a time when the conclusions were not entirely clear and the formatting made the large tome extremely difficult to read.

We are grateful to the individuals in each NHS Board who painstakingly completed the HTBS baseline survey. This provided an invaluable picture of the current screening systems employed across Scotland and will provide a useful benchmark to evaluate progress in the future.

All those who submitted comments during the consultation period, either verbally at the Open Meeting or in writing and who have helped to improve the assessment and highlight areas that lacked clarity, are thanked for their input.

We are particularly grateful to a number of senior experts associated with diabetic retinopathy screening throughout the UK who reviewed the report in its final stages. These reviewers made detailed comments in a very short timeframe, which have significantly helped the final rework of the text to clarify messages and the presentation of evidence.

HTBS would also like to give a special thanks to Dr Scanlon and his collaborators in the Gloucestershire Eye Unit study of retinal screening, for access to their hard won data and guidance in its use.

All patients and carers who contributed to the consultation are thanked for their open sharing of needs and issues, with special thanks to members of Diabetes UK in Scotland who 'road tested' a draft of the *Understanding HTBS Advice* document.

Finally, all staff are thanked for their enthusiastic input to this first Health Technology Assessment from the Health Technology Board for Scotland.

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GLOSSARY AND ABBREVIATIONS

Accountability	The process of reporting on discharge of responsibilities and tasks incurred by the position within an organisation.
Accreditation	A process, based on a system of external peer review using written standards, designed to ensure the quality of an individual, activity, service or organisation.
Appraisal (critical)	Evaluation of evidence from scientific studies against objective criteria.
Audit	The process of setting or adopting standards and measuring performance against those standards with the aim of identifying both good and bad practice and implementing changes to achieve unmet standards.
Annualisation	A means of converting capital costs into an annual figure based upon the equipment lifespan, initial cost, end of lifespan vale and financial interest rate.
BDR	Background Diabetic Retinopathy.
Biomicroscopy	A method of examination of the structures of the eye.
Blinding **(*see also* masking)**	Concealment of intervention in a controlled trial to ensure the absence of subjective bias in evaluation of intervention effects. (In this case, an example of interventions would be digital camera images with and without mydriasis.)
Bobby compliant	Web pages have been run through Bobby software to identify changes that need to be made to improve accessibility for users with disabilities.
Caldicott Guardian	The person in each NHS Board responsible for ensuring that patient identifiable information is kept confidential.
Capital costs	The cost of investment in items that remain useful beyond the period when costs are incurred.
Care Plan	A written document which is developed with the user, and which details the roles and responsibilities of all individuals involved in the person's care and when their care arrangements are to be reviewed.
Carer	A person, paid or unpaid, who regularly helps another person, often a relative or friend with all forms of care as a result of illness or disability. This term incorporates spouses, partners, parents, guardians, paid carers, other relatives, and voluntary carers who are not health

	professionals.
CCD	Charged couple devices.
CEAC	Cost-Effectiveness Acceptability Curve.
CET	Continuing Education and Training.
CHI	The Community Health Index is a unique patient identifier that is allocated to every patient registered with a GP in Scotland. It is entered onto a database that underpins a wide range of patient care processes in Scotland. There are strict controls on access to patient identifiable details – *see* Caldicott Guardian.
Chronic	Present over a long period of time. Diabetes is an example of a chronic disease.
CI	Confidence Interval.
Circinate Exudate	Circular material that is released from body tissues. Exudates form unwanted residues in the retina due to leakage from retinal blood vessels. Exudates may damage vision.
Clinical Effectiveness	The evaluation of benefit: risk in a standard clinical setting using outcomes of importance to the patient.
Clinical Governance	A framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.(Department of Health, 1998)
Clinical Information System	Another term for a register.
Clinical Trial	Research study conducted with patients, usually to evaluate a new treatment or drug. Each trial is designed to answer scientific questions and to find better ways to treat individuals with a specific disease.
CMOS	Complementary metal oxide semiconductors.
CNORIS	The Clinical Negligence and Other Risk Indemnity Scheme has two principal aims: 1. Financial efficiency through cost-effective risk pooling and claims management.

2. Effective risk management by encouraging a rigorous approach to treatment of risk.

Co-morbidity	The presence of co-existing or additional diseases with reference to either an initial diagnosis or the index condition that is the subject of study. Co-morbidity may affect the ability of affected individuals to function and also their survival; it may be used as a prognostic indicator for length of hospital stay, cost factors, and outcome or survival.
Contraindication	Any factors related to the patient's condition, medical history or other current treatments, which generally or absolutely preclude the use of the treatment in question.
Cost-effectiveness	Cost-effectiveness is used in its broadest form to encompass all forms of economic analysis.
Cost-effectiveness analysis	A form of economic analysis which compares two interventions in terms of both their costs and their effect upon patients, to ascertain whether the additional cost of the more expensive intervention gives rise to sufficient additional patient benefits to warrant the additional cost.
Cost-effectiveness ratio	The additional cost of the more expensive intervention as compared with the less expensive intervention divided by the difference in effect or patient outcome between the interventions. This gives a cost per effect, such as the additional cost per true positive from a screening test, or a cost per patient outcomes, such as the cost per QALY.
Cost minimisation	A form of economic analysis comparing two interventions that is appropriate if both interventions have the same patient outcome.
CRAG	Clinical Resource and Audit Group.
CRT	Cathode Ray Tube.
CSA	Common Services Agency.
CSAGS	Confidentiality and Security Advisory Group for Scotland.
CSBS	Clinical Standards Board for Scotland.
DARTS	Diabetes Audit and Research in Tayside Scotland.
Diabetes Mellitus	A condition in which the amount of glucose (sugar) in the blood is too high because the body cannot use it properly.

Diabetic Retinopathy	A complication of diabetes that affects the health and function of the retina by blocking off its small blood vessels.
Dietician	A specialist in nutrition who helps people with special health needs plan the types and amounts of foods to eat.
Digital Retinal Camera	A digital camera that takes computerised pictures (without using film) of the retina (back of the eye).
Discounting	A means of converting the value of future events to their value in the present period. Future costs are converted using a financial discount rate similar to the interest rate, while patient benefits are converted using the reported time preference for health benefits. This reflects society's preference for immediate benefits compared to benefits occurring in the future.
DoH	Department of Health (England).
EMTREE	Controlled vocabulary thesaurus for Embase (a health-related bibliographic database).
ETDRS	Early Treatment Diabetic Eye Study.
Evidence-based	The process of systematically finding, appraising, and using contemporary research findings as the basis for clinical decisions.
Failsafe	Back-up procedures that ensure individuals are not lost to follow-up through chance or error and which ensure delivery of the screening programme.
Follow-up	The measures taken to ensure appropriate actions are taken for patients with abnormal retinal images.
Field	A single image taken of the retina. Multiple fields can be taken to provide greater retinal coverage. Fields are also classified by their degree; e.g. 45 degrees. A field with a higher degree takes an image of a larger part of the retina than a field of a lower degree.
Fovea	A small pit or depression in the retina.
Fluorescein Angiography	The injection of dye into a vein in the arm. The dye circulates through the tiny blood vessels at the back of the eye and photographs are taken. These enable the ophthalmologist to see clearly the pattern of blood flow through the blood vessels and identify where there are problems.
Funduscopy	Examination of the fundus (the retina) of the eye through the pupil using a hand-held instrument.

Glycaemia	The presence of glucose in the blood.
Glycated Haemoglobin (HbA1c)	A test which indicates how well controlled diabetes has been in the preceding three–four months.
GMC	General Medical Council.
Gold Standard	A diagnostic test that has been critically evaluated and documented to identify the true disease state or true value of measurement.
GPASS	General Practice Administration System Scotland.
Grey Literature	That which is produced on all levels of government, academics, business and industry in print and electronic formats, not controlled by commercial publishers.
GP	General Practitioner.
GP-based	General Practice-based.
GRO	General Register Office.
Haemorrhage	Bleeding.
HbA1c	*See* glycated haemoglobin.
HDL	Health Department Letters.
Health care Professional	A person qualified in a health discipline.
HEBS	Health Education Board for Scotland.
HEED	Health Economics Evaluation Database.
HIP	Health Improvement Plan.
HTA	Health Technology Assessment is a multi-disciplinary field of policy analysis, which studies the medical, social, ethical and economic implications of development, diffusion and use of health technology.
HTBS	Health Technology Board for Scotland.
IDDM	Insulin dependent diabetes mellitus.

IM&T	Information Management and Technology.
INAHTA	International Network of Agencies for Health Technology Assessment.
Incidence	How often a disease occurs; the number of new cases of a disease among a certain group of people during a specific period of time.
Insulin	A hormone secreted by the pancreas. Insulin regulates the blood glucose level, and is important for growth and tissue repair.
Indication (therapeutic)	The diseases or conditions which a medicine has been authorised (licensed) to treat.
IRMA	Intro-Retinal Microvascular Abnormality.
Ischaemia	Reduction of the blood supply to a part of the body.
ISD	Information and Statistics Division.
IT	Information Technology.
LAN	Local Area Network.
JPEG	Joint Photographic Experts Group who work to produce standards for continuous tone image coding.
Laser Photocoagulation	Use of a highly focused light beam to treat diseased body tissue. In the eye this is used to treat damaged small blood vessels to stop them leaking or to treat an undernourished retina to stop the release of 'chemicals' that make new blood vessels grow.
LDS	Lanarkshire Diabetes System.
Laser Treatment	*See* laser photocoagulation.
LHCC	In Scotland, Local Health care Cooperatives are voluntary groupings of GPs and other local health care professionals intended to strengthen and support the primary health care team in delivering local care.
Local Diabetes Service Advisory Group (LDSAG)	A group of local diabetes service users, carers and providers who advise NHS Boards in matters relating to services for individuals with diabetes.
Macula	The area of the retina that is the centre of sight.
Macular Oedema	Fluid in the part of the retina that is at the centre of sight. It may be a

	result of leaking small vessels causing fluid to accumulate around the cells of the retina or may be a result of sick and dying cells ballooning up because they are starved of oxygen and food.
Maculopathy	A deterioration of the macula.
Managed Clinical Networks (MCNs)	Linked groups of health professional and organisations from primary, secondary and tertiary care, working in a coordinated manner, unconstrained by existing professional and NHS Board boundaries, to ensure equitable provision of high quality clinically effective services throughout Scotland.
Markov modelling	Markov models are analytical structures that represent patient flows through key health states of a disease and are commonly used for economic evaluations. Within a Markov mode, numerical values are assigned to the costs and outcomes of each health state. Over time, patients progress through the different health states based on transitional probabilities. Alternative clinical strategies can be modelled by synthesising the available data on epidemiology, costs and outcomes for each health state and the models can then be compared to measure incremental cost effectiveness.
Masking **(see also blinding)**	Concealment of intervention in a controlled trial to ensure the absence of subjective bias in evaluation of intervention effects. (In this case, an example of interventions would be digital camera images with and without mydriasis.)
Medication	Drugs prescribed to treat a condition.
Medicines Management	Organisation of various medications involving the timing, frequency and period of treatment.
MEL	Management Executive Letters.
Meta-analysis	Statistical method to combine the outcomes of more than one randomised clinical trial.
Microaneurysms	When diabetes damages small blood vessels, adjacent unaffected small vessels try to grow towards the diseased ones. This growth is ineffective and rather than a new blood vessel forming only a balloon or microaneurysm on the wall of the vessels appears. These microaneurysms may leak leading to oedema and haemorrhage in the retina.
Microvascular	Something that concerns small blood vessels.

Morbidity	The frequency (incidence and/or prevalence) of a particular disease or group of diseases.
Mortality multiplier	The effect that a given health state within a disease has upon the probability of death compared to that within the population at large of the same age, sex and possibly other characteristics.
Mortality rate	The number of deaths in a given population during a specified period of time.
MeSH	Controlled vocabulary thesaurus for Medline (and other health-related bibliographic databases).
MTO	Medical Technical Officer
Multidisciplinary	A multidisciplinary team is a group of people from different disciplines (both health care and non-health care) who work together to provide care for patients with a particular condition. The composition of multidisciplinary teams will vary according to many factors. These include: the specific condition, the scale of the service being provided and geographical/socio-economic factors in the local area.
Multidisciplinary System of Working	A method of working in a multidisciplinary team with protocols in place for most, of not all, eventualities.
Mydriasis	Dilation of the pupil of the eye by the insertion of drops.
Neovascularisation	The formation of new blood vessels.
NHS Boards	The role of the NHS Boards is to ensure the efficient, effective and accountable governance of the local NHS system. There are 15 NHS Boards in Scotland.
NHS	National Health Service.
NHS24	NHS24 is a special Health Board of NHSScotland that aims to give people across Scotland equal access to health advice, information and help, when they need it and as far as possible in one phone call.
NHS EED	NHS Economic Evaluation Database.
NHSScotland	National Health Service in Scotland.
NICE	National Institute for Clinical Excellence.
NIDDM	Non-Insulin Dependent Diabetes Mellitus.

NPA	National Pharmaceutical Association.
NPDR	Non-Proliferative Diabetic Retinopathy.
NSC	National Screening Committee.
NSD	National Services Division.
NVD	New Vessels on Optic Disc.
NVE	New Vessels Elsewhere.
Odds	The odds of a random event, E, occurring is the probability that it will occur divided by the probability that it will not occur.
Odds Ratio	The association between a random event, E, and some condition, A, expressed as the odds that E occurs when A is true divided by the odds that E occurs when A is not true.
Oedema	A collection of fluid. It may be a result of leaking small vessels causing fluid to accumulate around the cells of the retina or may be a result of sick and dying cells ballooning up because they are starved of oxygen and food.
Ophthalmologist	A medical doctor specially trained to diagnose and treat disorders of the eye. An ophthalmologist is qualified to prescribe medication, prescribe and adjust spectacles and contact lenses and is usually qualified to perform laser treatment and surgery.
Ophthalmoscopy	Use of an optical instrument (the 'ophthalmoscope') for inspecting the retina and other parts of the eye.
Opportunity cost	The opportunity cost of selecting a particular health technology is the amount of alternative health technologies that could have been obtained had that selection not been made.
Optician (Dispensing)	Fits, supplies and adjusts spectacles and contact lenses. An optician cannot examine the eyes or prescribe spectacles or medication.
Optometrist (Ophthalmic Optician)	Although not a doctor of medicine, an optometrist is specially trained to diagnose eye abnormalities and prescribe, supply and adjust spectacles and contact lenses.
Outcome	The end result of care and treatment. In other words, the change in health, functional ability, symptoms or situation of a person, which can be used to measure the effectiveness of care and treatment. Also

	referred to as patient impact or patient benefit.
Partners in Change	A programme of national and local projects designed to promote the involvement of patients throughout NHSScotland.
Patient	A person who is receiving medical treatment (especially in a hospital). Also a person who is registered with a doctor, dentist, etc and is treated by him/her when necessary. Sometimes referred to as a user.
Patient Group Direction	A legal written instruction drawn up by doctors, pharmacists and other health professionals for the sale, supply and administration, or administration, of named medicines in an identified clinical situation. It applies to groups of patients who may not be individually identified before presenting for treatment.
Patient Journey	The pathway taken through the healthcare system by the patient and as viewed by the patient.
PC	Personal computer.
PDR	Proliferative Diabetic Retinopathy. *See* Proliferative Retinopathy.
Photocoagulation	*See* laser photocoagulation.
Placebo	Dummy treatment that is given to some of the volunteers participating in a clinical trial. Patients can feel better even when the treatment they are given is a 'sugar pill' or placebo.
Prevalence	The number of existing cases of a disease among a certain group of people, usually at a specified point in time.
Prognosis	An assessment of the expected future course and outcome of a person's disease.
Proliferative Retinopathy	Diabetes can cause small blood vessels to block off resulting in the retina being starved of food and oxygen. If enough small blood vessels block then the eye tries to grow new blood vessels (proliferative retinopathy) that are prone to bleeding and pulling off the retina. *See* PDR.
QALY	Quality adjusted life year. A means of adjusting the benefits accruing to patients that takes into account the quality of life of each year.
Quality Assurance	Improving performance and preventing problems through planned and systematic activities including documentation, training and review.
R and D	Research and Development.

Randomised	Randomly allocated to one of more than one different choices of treatment.
RCT	Randomised, controlled trial.
Recurrent costs	Costs that are borne each year.
Register	A collection of similar information from individuals to compile an overview observation.
Retina	A layer at the back of the eye that is sensitive to light (like a film in a camera). The retina receives an image of whatever the eye is looking at through the lens at the front of the eye. The retina sends nerve impulses via the optic nerve to the brain, where the visual image is perceived – it is the 'seeing' layer of the eye. It is supplied by small blood vessels that can be damaged by diabetes.
Retinal Photography	Use of a camera to take pictures of the surface of the retina.
Risk Factor	A clearly defined occurrence or characteristic that increases the possibility that a person will get a disease.
RNIB	Royal National Institute for the Blind.
ROC	A receiver operating characteristic curve is used to evaluate the accuracy of any method of predicting a dichotomous outcome; it graphically represents the trade-off between false positive and false negative rates for every possible cut off. The graph plots the false positive rate on the x-axis and the true positive rate (1 – the false negative rate) on the y-axis. The area under the curve is of primary interest as it measures the correlation between the category predicted by the test and the true category into which the case falls.
RPSGB	Royal Pharmaceutical Society of Great Britain.
RRR	Relative risk reduction.
SCI	Scottish Care Information.
SCI-DC	Scottish Care Information – Diabetes Collaboration.
Scottish Diabetes Survey	Scottish Executive survey of NHS Boards, performed annually to build a national register of people with diabetes and to monitor diabetes care, with the aim of facilitating better healthcare.
Scottish Executive	The Scottish Executive is the devolved government for Scotland. It is

	responsible for most of the issues of day-to-day concern to the people of Scotland, including health, education, justice, rural affairs and transport.
SCSI	Small Computer Systems Interface.
SDRGS	Scottish Diabetic Retinopathy Grading System.
SEHD	Scottish Executive Health Department.
Sensitivity	The ability of a method to detect an abnormality when it is present (expressed as a probability or percentage).
Sensitivity Analysis	An exploration of the impact upon results of changing parameter values within a model.
SGPC	Scottish General Practitioners' Committee.
SHS	Scottish Healthcare Supplies.
Side-effect	A side-effect is an unpleasant and unwanted effect of treatment.
SIGLE	System for Information on Grey Literature.
SIGN	Scottish Intercollegiate Guidelines Network.
Slit Lamp Biomicroscopy	A method of examining the structures of the eye using a special microscope.
Specificity	The probability that a test result is negative given a subject does not have the disease.
Standard Operating Procedures	A set of procedures that specify in detail the processes to be followed in defined circumstances.
STDR	Sight-threatening diabetic retinopathy.
Summary of Product Characteristics	A legal document prepared for each medicine when it is authorised describing its therapeutic indications, method of administration, undesirable effects, method of action and chemical composition.
SVGA	Super extended graphics array.
Technical Failure Rate	Proportion of patients in whom the screening method fails to return a useful assessment of the extent of diabetic eye disease.

TFTF	Thin film transistor flat screen.
TIFF	Tagged information file format.
TIP	Trust Improvement Plan.
Transition probability	The probability or likelihood that the health of a patient changes from one state to another state within a given period.
Tractional Retinal Detachment	When the surface of the back of the eye becomes separated from the underlying structures by new blood vessels.
Trust	There are two types of trust in Scotland: Acute Hospital Trusts and Primary Care Trusts. Acute Hospital Trusts are responsible for a defined set of acute hospital services. Primary Care Trusts have the responsibility for the provision of the full range of primary care, community and mental health services. Both types of trust operate within the geographical boundaries of an individual NHS Board.
TSG	Topic Specific Groups are short-life groups designed to help with the appraisal of issues arising in a Health Technology Assessment, particularly those related to delivery of care in NHSScotland.
TWAIN	The TWAIN initiative was launched to establish a standard software protocol and applications programming interface that regulates communication between software applications and imaging devices.
Type 1 (insulin-dependent) Diabetes	Type 1 diabetes develops if the body is unable to produce any insulin. This type of diabetes usually presents before the age of 40. It is treated by insulin injections and diet.
Type 2 (non-insulin-dependent) Diabetes	Type 2 diabetes develops when the body can still make some insulin, but not enough, or when insulin that is produced does not work properly (known as insulin resistance). This type of diabetes usually appears in people over the age of 40, though often appears before the age of 40 in South Asian and African-Caribbean population. It is treated by diet alone or by diet and tablets or, sometimes, by diet and insulin injections.
Univariate	One way.
USB	Universal Serial Bus
VA	Visual Acuity is a measure of how well a person sees distant and close

	objects.
Vitrectomy	An operation to remove the blood that sometimes collects at the back of the eyes when a person has eye disease.
Vitreous Body	A jelly-like substance filling the eyeball. Also sometimes called 'vitreous humour'.
Vitreous Haemorrhage	Bleeding into the fluid in the middle of the eye from new blood vessels arising from a disease process at the back of the eye.
Volk lens	Lens designed to provide an aberration-free view of the fundus through a slit lamp.

Appendix 1

EXPERT ADVISERS

Topic Specific Group Members

Dr A. Morris (Chair)	Reader in Medicine and Diabetes	Ninewells Hospital, Dundee
Dr C. Brook	Clinical Director, Primary Care	St John's Hospital, Livingston
Mr R. H. R. Broughton	President	College of Optometrists
Mr D. Cline	Secretary, Scottish Diabetes Framework Working Group	Scottish Executive Health Department
Ms C. Colquhoun	National Coordinator for Scottish Screening Programme	Common Services Agency, NHSScotland
Dr D. Cromie	Consultant in Public Health Medicine	Lanarkshire Health Board
Mrs D. Evans	Director	National Services Division
Dr S. Gallacher	Consultant Physician	Southern General Hospital, Glasgow
Dr R. Harvey	Diabetes Physician	Dr Gray's Hospital, Elgin
Mrs D. Henry	National Manager	Diabetes UK, Scotland
Dr G. Leese	Consultant Endocrinologist	Ninewells Hospital, Dundee
Dr F. MacLeod	General Practitioner	Sheddens Medical Practice, Glasgow
Dr M. Nairn	Programme Manager	Scottish Intercollegiate Guidelines Network
Dr J. Olson	Consultant in Medical Ophthalmology	Grampian University Hospital NHS Trust
Dr L. Reay (part-time seconded to HTBS)	Consultant in Public Health Medicine	Argyll and Clyde Health Board
Ms M. Ryan	Prescribing Adviser	Lomond and Argyll Primary Care NHS Trust
Ms M. Scott	Diabetes Nurse/Facilitator	Lothian Primary Care Trust
Dr M. Small	Consultant Physician	Gartnavel General Hospital, Glasgow
Mr I. Wallace	Optometrist	Oban, Argyllshire
Ms J. Warner	Director of Reviews	Clinical Standards Board for Scotland

Register of Interests
One of these experts noted an interest in a software company, no other conflicts of interest related to this project were noted.

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Professor J. Forrester	Consultant Ophthalmologist	Grampian
Mr M. D. Gray	Optometrist	Malcolm Gray Optometrists, Staffordshire
Professor J Jay	Consultant Ophthalmologist	The Tennent Eye Institute, Glasgow
Dr M. Kenicer	Consultant in Public Health Medicine	Tayside Health Board, Dundee
Professor J. Mason	Health Economist	Centre for Health Services Research, University of Newcastle
Mr F. Munro	Optometrist	Scottish Committee of Optometrists
Professor D. Owens	Consultant Diabetologist	The Diabetic Unit, Penarth
Dr S. Patel	Optometric Adviser	Practitioner Services for the NHS in Scotland
Dr K. Robertson	Consultant Paediatrician (Chair Diabetes Framework – IT sub-group)	Royal Hospital for Sick Children, Glasgow
Dr H. S. Kohli	Medical Director	Health Technology Board for Scotland, Glasgow
Ms A. Single	Director of Communications and Public Involvement	Health Technology Board for Scotland, Glasgow

Appendix 2

HTBS SURVEY OF RETINOPATHY SCREENING IN SCOTLAND – MAY/JUNE 2001

Board	Key contact	Area diabetes register	Link to CHI	Estimated prevalence	Basis of estimate	Resident population	Estimated diabetic population
ACHB	CPHM (screening)	In Development	Yes	1.98%	CHI+Register	426,046	8,436
AAHB	Diabetes Coordinator	Established	No (planned)	2.21%	RG +Register	374,545	8,277
BHB	Lead Diabetes Clinician	Established	Yes (in process)	2.70%	CHI+Register	106,389	2,873
DGHB	Lead Diabetes Clinician	In Development	Yes (in process)	2.90%	RG +Register	147,280	4,271
FHB	Diabetes Coordinator	In Development	No (planned)	3.00%	RG +Register	348,214	10,446
FVHB	CPHM (screening)	In Development	No (planned)	2.02%	RG +Register	275,806	5,571
GHB	CPHM (screening)	In Development	No (planned)	2.20%	RG+Estimate	532,110	11,706
GGHB	CPHM (screening)	Early stages	No (planned)	2.10%	RG+Estimate	897,053	18,838
HHB	CPHM (screening)	In development	No (planned)	2.00%	RG+Estimate	210,418	4,208
LanHB	CPHM (screening)	Established	No (planned)	2.55%	RG +Register	559,150	14,258
LoHB	CPHM (screening)	In development	Yes (in process)	2.32%	RG+Estimate	774,528	17,969
OHB	Diabetes Coordinator	Early stages	Yes (in process)	2.50%	RG +Register	19,794	495
SHB	DPH	Established	No (planned)	2.40%	RG +Register	22,855	549
THB	Lead Diabetes Clinician	Established	Yes	2.20%	CHI+Register	391,397	8,611
WIHB	Diabetes Coordinator	Established	Yes	2.20%	CHI+Register	28,476	626
			Estimated National Prevalence – 2.29%			5,114,061	117,135

Key CHI – Community Health Index
RG – Registrar General Office of Scotland
HIP – Health Improvement Plan
TIP – Trust Implementation Programme

Key

AAHB	Argyll and Clyde NHS Board	HHB	Highland NHS Board
ACHB	Ayrshire and Aarran NHS Board	LanHB	Lanarkshire NHS Board
BHB	Borders NHS Board	LoHB	Lothian NHS Board
DGHB	Dumfries and Galloway NHS Board	OHB	Orkney NHS Board
FHB	Fife NHS Board	SHB	Shetland NHS Board
FVHB	Forth Valley NHS Board	THB	Tayside NHS Board
GHB	Grampian NHS Board	WIHB	Western Isles NHS Board
GGHB	Greater Glasgow NHS Board		

Board	Implementation of organised screening	Diabetes register used for call/recall	Current mode of delivery of screening	Optometrist involvement	Accreditation of screeners	Use of digital camera technology
ACHB	For 30%	Not yet	Hospital Clinic & Community Fixed	29 Optometrists	Yes for Optometrists	No
AAHB	For All	Yes	Hospital Clinic & Community Fixed	40 Optometrists	Yes for Optometrists	Beginning
BHB	For All	Yes	Hospital Clinic & Community Fixed	12 Optometrists	Yes for Optometrists	Partial
DGHB	For All	Not yet	Hospital Clinic & Community Fixed	16 Optometrists	Planned	Partial
FHB	For 80%	Yes	Hospital Clinic & Community Fixed	*c.* 50 Optometrists	Planned	Partial
FVHB	For most	Yes	Hospital Clinic & Community Fixed	5 Optometrists	Yes for Optometrists	Partial
GHB	For clinic only	Not yet	Hospital Clinic & Community Fixed	1 Optometrist	Planned	Partial
GGHB	For clinic only	Not yet	Hospital Clinic & Community Fixed	Not quantified	Planned	No
HHB	For some	Yes	Hospital Clinic & Community Fixed	20 Optometrists	Yes for Optometrists	Partial
LanHB	Beginning for all	Yes	Hospital Clinic & Community Fixed	none	Planned	Yes
LoHB	For All	Not yet	Hospital Clinic & Community Fixed	60 Optometrists	Yes for Optometrists	Partial
OHB	None	Not yet	Hospital Clinic & Community Fixed	none	Planned	No
SHB	None	Not yet	Hospital Clinic & Community Fixed	2 Optometrists	Yes	Partial
THB	For 50%	Yes	Hospital Clinic & Mobile Van	Mobile van	Yes for Camera	Established
WIHB	All	Yes	Mobile Van	Mobile van	Yes for Camera	Established

Board	Quality assurance of registers	Standard report for screening result		Referral protocol	Quality assurance audit of 'screen negative'
ACHB	Six monthly audit & feedback to GPs	Yes multi-part sheet	Yes	One audit reported	Not at present
AAHB	Monthly updates & annual feedback to GPs	Yes standard sheet	Yes	Not at present	Yes
BHB	Weekly with Clinic/annual feedback to GPs	Yes multi-part sheet	Yes	Not at present	Not at present
DGHB	Comparison with GP practice registers	Not universal	Yes	Not at present	Not at present
FHB	Being developed by Register Coordinator	Yes multi-part sheet	Yes	Planned	Yes and published
FVHB	Facilitator visits to GP/Clinic at annual review	Not universal	Yes	Not at present	Not at present
GHB	Being developed by Register Coordinator	Yes multi-part sheet	Yes	Not at present	Yes
GGHB	Being developed by Register Coordinator	Not universal	Not yet in place	Not at present	Not at present
HHB	Being developed by Register Coordinator	Yes standard sheet	Yes	Yes	Not at present
LanHB	Weekly with Clinic/annual feedback to GPs	Yes standard sheet	Not yet in place	Not at present	Not at present
LoHB	Being developed by Register Coordinator	Yes standard sheet	Yes	Yes	Not at present
OHB	Being developed by Register Coordinator	Not universal	Not yet in place	Not at present	Not at present
SHB	Being developed by Register Coordinator	Not universal	Not yet in place	Not at present	Not at present
THB	Daily with systematic cross checking with GPs	Yes standard sheet	Yes	Yes	Not at present
WIHB	Being developed by Register Coordinator	Yes standard sheet	Yes	Not at present	Yes

Board	Audit of screening history of 'positives'	Established programme steering group	Funding for diabetic retinopathy screening
ACHB	Not at present	Yes	Through local HIP process
AAHB	Yes	Not at present	Through Trust TIP process
BHB	Not at present	Yes	Through local HIP process
DGHB	Not at present	Not at present	Through local HIP process
FHB	Yes and published	Yes	Through local HIP process
FVHB	Not at present	Yes	Application being prepared
GHB	Yes	Yes	Funding allocated by Trust
GGHB	Not at present	Yes	Funding allocated from HIP
HHB	Not at present	Yes	Through local HIP process
LanHB	Not at present	Yes	Funding allocated from HIP
LoHB	Not at present	Yes	Through local HIP process
OHB	Not at present	Not at present	Through local HIP process
SHB	Not at present	Yes	Through local HIP process
THB	Not at present	Yes	Through local HIP process
WIHB	Yes	Yes	Through local HIP process

Appendix 3

SCOTTISH EXECUTIVE HEALTH SURVEY

1. Is an annual programme of retinopathy screening in place for all diabetic patients in your area?

2. If so, who manages the programme?

3. Is quality assurance written into the system?

4. What screening modalities are being used?

5. Is the retinopathy screening programme integrated with a pattern of care for diabetic patients?

6. Who within your Health Board area is the most appropriate person to contact to respond to any additional questions about diabetic retinopathy?

Appendix 4

HEALTH TECHNOLOGY BOARD FOR SCOTLAND

HEALTH BOARD QUESTIONNAIRE
TO FACILITATE HTBS ASSESSMENT OF
SERVICES FOR DIABETIC RETINOPATHY SCREENING

Please use best estimates for answers, or if you have no information enter '?'

If you need any help completing the form please call Karen Facey on 0141 249 6643 or Lewis Reay on 0141 842 7207

1. Estimation of the Population Denominator

1.1 At what stage is your Area Diabetes Register?
Please mark the box that describes your situation.

Early stages ☐ In development ☐ Established ☐

1.2 Who holds the diabetes register? _____

1.3 Is the diabetes register linked to your Board's CHI?

Yes ☐ No ☐

1.4 What is the estimated prevalence of diabetes in your Health Board population?

1.5 Was this prevalence calculated from:

Register ☐ Population figures ☐

Other ☐ Please explain _____

1.6 Are there known gaps in the ascertainment of cases in your area?

Yes ☐ State source of gaps _____
(e.g. 30% of general practices, nursing homes)

No ☐

1.7 Is the register updated?

Daily ☐ Weekly ☐ Monthly ☐ 6-Monthly ☐

Other ☐ Please state _____

1.8 Please describe briefly, how the data on your register are validated?

2. Technologies used for screening

2.1 What forms of retinal screening are used in your Area?

(Tick all boxes that apply and answer all relevant follow-up questions)

Digital cameras	☐	Go to question 2.2
Slit lamps	☐	Go to question 2.4
Other ophthalmoscopy	☐	Go to question 2.6
None	☐	Go to question 4
Other	☐	Please State _____

2.2 By mode of delivery, give details of the digital cameras used in your area for retinal screening:

Camera base (Mode of Delivery)	Number of digital cameras	Types of camera (Model(s) and attachment(s), if appropriate)	associated Software
In hospital			
From van			
In fixed community setting			
From mobile community setting			
Other, please state			

2.3 If there is a main contact person re. digital cameras in your area, please state their contact details (including e-mail if available):

2.4 Give details of the slit lamps used in your area for retinal screening by mode of delivery:

Mode of delivery	Number of slit lamps	Types of lamp Indicate type of lens used. Also is examination of retina only or also anterior segment of eye.
Hospital		
Fixed community setting		
Mobile community setting		
Other, Please state		

2.5 If there is a main contact person for slit lamp advice in your area, please state their contact details (including e-mail if available):

2.6 State what other forms of ophthalmoscopy equipment are used in your area (e.g. stereoscopic, Polaroid prints, 35mm film)

3. Staffing

3.1 Who performs the screening test and how many professionals do you have in your area?

(Please complete all boxes that apply.)

Optometrist (Community-based) ☐ Approximate number _____

Optometrist (Hospital-based) ☐ Approximate number _____

GP ☐ Approximate number _____

Hospital health care professional (specify below if appropriate) ☐ Approximate number _____

Other ☐

Please state specialism and number _____

_____

4. Call/Recall

4.1 How do you propose to have systematic call/recall?

(Tick all boxes that apply.)

Centrally ☐

GP based ☐

Hospital clinic ☐

Optometrist-based ☐

4.2 If multiple forms of call/recall are to be used, please describe how information will be shared between sources.

_____

_____

_____

_____

_____

5. Process to record screening test acceptance, result and recommendation

5.1 Do you have a standard data collection form for screening eye tests?

Yes ☐ If yes, please attach the form to the questionnaire.

No ☐

5.2 How are results stored?

Manually ☐

Computerised ☐

5.3 Who is responsible for holding the screening data?

5.4 Who has access to the screening data?

5.5 What percentage of screening test results are linked to the area Diabetes Register?

5.6 Who provides the information for input to the area Diabetes Register?
(Tick all that apply)

Optometrist ☐

GP ☐

Hospital health care professional ☐

Other ☐ Please state _____

5.7 What percentage of retinopathy screening tests is performed at the same time as the overall annual diabetes review?

6. Screen Positive Process

6.1 Does your area have referral protocols in place?

Yes ☐ Please attach the protocol to the questionnaire.

No ☐

7. Quality Assurance

7.1 Are all those who perform retinal screening accredited?

Yes ☐

No ☐ Please expand _____

_____

_____

_____

_____

7.2 Is there sampling for false negatives?

Yes ☐ No ☐

7.3 For those screened positive, is there linkage of screening to outcome?

Yes ☐ No ☐

7.4 For those identified as positive outwith the screening programme, is there linkage of outcome to screening?

Yes ☐ No ☐

7.5 For patients who present with diabetic retinopathy, is there a clinical audit of the previous screening history?

Yes ☐ No ☐

7.6 Where is laser treatment carried out for your residents?

Please identify a suitable contact person, if appropriate.

8. Funding

8.1 Describe how the entire programme is funded.

8.2 Describe your local process for funding service developments to the programme.

Appendix 5

SUMMARY OF THE HTBS BASELINE SURVEY

Background

In order to compile a baseline position for diabetic retinopathy screening throughout Scotland, a questionnaire survey of all 15 Health Board areas was carried out in May/June 2001. The survey was aimed at identifying the existence of features of a comprehensive systematic and quality assured screening programme in each Health Board area. The survey was designed to complement information obtained in a survey carried out in October 2000 by Mr David Cline, Health Planning and Quality Division of SEHD and one carried out in September 1997 by the Diabetes Registers and IT Systems Steering Group of CRAG.

The questionnaire (Appendix 4) was designed by HTBS and piloted in four different Health Board areas. The questionnaire was aimed at 'key contacts' in each Health Board area who would be reasonably placed to obtain relevant local information from local sources. Most of the 'key contacts' had been identified in the earlier surveys and subsequently confirmed at a national meeting on Diabetes Registers held in Edinburgh in January 2001. The Director of Public Health of each of the 15 Scottish Health Boards was also contacted, providing details of the survey, the questionnaire and the names of the identified 'key contacts'.

Replies were received from all 15 Health Board areas. These are tabulated in Appendix 2.

Characteristics of responders

Seven responders were public health consultants with an identified remit for other screening programmes and/or diabetes, three responders were identified lead diabetes clinicians, four responders were diabetes coordinators and one responder was the Director of Public Health. All of the responders indicated that local contact had been made with relevant colleagues to obtain details for individual questions.

Identification of local residents with diabetes

Six Health Board areas indicated that diabetes registers were established, seven indicated that registers were being developed (a few nearly established) and the remaining two Health Board areas indicated that work on creating a local diabetes register was at an early stage. However, the presence of local quality assurance measures to ensure the validity of the local register varied widely. Nine Health Board areas referred to the work of a diabetes 'facilitator' or 'coordinator' to encourage completeness of ascertainment and to cross check for validity of data items. Two further Health Board areas indicated their intention to employ a 'coordinator' and two areas stated that systems 'were being developed'.

Ascertainment of residents with diabetes was derived (or being derived) principally from local GPs (seven areas) and hospital diabetes clinics (five areas) but there was a wide range in frequency of updating details and in sharing recorded details with relevant clinicians (GP and/or hospital). Validation of completeness of ascertainment was well developed in a few Boards, but only at the planning stage in most areas.

Estimation of prevalence of diabetes in local Health Board populations

Estimated prevalence of diabetes varied from 1.98% to 3.00% but the basis for such estimates also varied considerably. Seven Health Board areas used their local diabetes register to provide the numerator and used the estimate of their resident population provided by the Registrar

General for Scotland to provide the denominator. Seven Health Boards used their local register for the numerator and their CHI to provide the denominator. The remaining four Board areas used estimates based on a variety of statistical methods and assumptions.

Based upon these returns and the General Register Officer (GRO) estimates of the population of Scotland, the reported prevalence of diabetes in Scotland derived from this survey is 2.29%.

It is clear, however, that the overall robustness of these estimates is poor with inconsistency of validation of diabetes registrations and of use of the same denominator. (A national annual diabetes survey has recently been initiated Scottish Diabetes Framework Working Group, 2001) which will, in time, improve the quality of this prevalence estimation.)

Existence of organised screening for diabetic retinopathy

In several areas, organised screening is already established but there is variability in the population known to be covered and in the screening methods used. Identification of a formal steering committee with 'named person' authority for quality assurance and clinical governance issues was similarly variable. Description of the existence of explicit quality assurance processes for an organised, comprehensive and systematic population screening programme also showed great variability. There was no area which demonstrated the existence of a comprehensive, quality assured systematic programme, although a few areas have clearly made considerable progress. Several other areas are actively working on specific aspects but clear evidence of comprehensive and systematic approaches was scanty.

Systematic call/routine recall

Invitations for screening to residents known to have diabetes took place in a variety of ways. One area has completed a third annual screening covering 93% of all known people with diabetes aged over 12 years (by a visiting mobile van using digital camera technology). Four further Board areas reported annual screening for people with diabetes recorded on their register with a further four Board areas reporting a systematic call/routine recall process in place but not yet covering all individuals recorded in the diabetes register. Some schemes are based in hospital clinic settings and others are in community settings. There was no standard approach for ensuring completeness of cover for invitation, for failsafe and follow-up or for quality assurance of this aspect of systematic screening.

Technologies used for screening

Three areas have no access to digital camera technology for screening. Two Board areas collaborate to provide digital camera retinal screening using mobile vans. One of these areas estimates that 50% of digital screening test results are linked to the diabetes register while the other estimates that all results are linked to the diabetes register. Ten further areas have digital camera retinal screening to varying degrees, each in fixed locations. The provision of screening services for diabetic retinopathy using digital camera technology and explicit quality assurance varies considerably in these ten areas.

Ten Board areas currently involve optometrists in some screening process. Seven of these areas have formal accreditation of optometrists and pay a fee to accredited optometrists. Each of the accreditation schemes has been developed locally, usually by, or with, the close involvement of local ophthalmologists. Some of these schemes have regular refresher training in place and can demonstrate specific quality assurance audits.

Use of standardised data collection of screening test findings is in place, to some degree, in 12 Board areas. Ten of these areas report computer-based recording systems. Similarly, the

adoption of locally agreed referral protocols is reported in ten areas. All areas reported that direct ophthalmoscopy took place in different settings (general practice, community optometrist, hospital clinics) but findings were not systematically recorded or audited. Recorded information related principally to digital photography or used standardised (local) reports provided by accredited clinicians, mainly optometrists with some general practice and hospital staff.

Funding for diabetic retinopathy screening

Funding for staff, equipment, IT, quality assurance and payment of fees to independent contractors was variable in both mechanism and amount. Most Health Board areas reported use in the past of Health Board or Trust 'development monies' or audit budgets or endowment funds to employ facilitators or to purchase equipment. Mechanisms to obtain new monies were described as 'through the HIP/TIP process' in eight areas, by 'business case' for four areas and not specified in the remaining three areas. Three Health Board areas reported substantial recent investment while others stated that existing or historical funding was either now insufficient or uncertain for future full systematic screening to be sustained or achieved.

Quality assurance of screening process

In addition to details of accreditation of 'screeners', evidence of quality assurance of the screening outcome was sought. Audit of 'false negative' screening findings was reported by only four Health Boards and audit of 'screen positive' outcomes in four other Health Boards. Audit of the screening history of new cases of diabetic retinopathy was reported from two areas and 'planned' in three other areas. Linkage of the records of patients with diabetic retinopathy to screening history was reported in three areas. Only one area reported both aspects to be in place.

Types of equipment models in use

Several Board areas reported details of the model of digital camera, imaging system and associated IT system. In addition, details were provided on slit lamp models and lens attachments, numbers and locations. A few areas appeared unable to provide this level of detail.

Conclusions

It is clear from the results of the surveys that a great deal of work is already taking place to provide retinopathy screening in Scotland. However, it is equally apparent that this provision is patchy in many parts of the country and in most places is insufficiently systematic. Nevertheless, these survey results provide a valuable baseline from which to evaluate progress towards the development of a more comprehensive diabetic retinopathy screening system. We gratefully acknowledge the assistance of all those who supplied information for the surveys.

Appendix 6

LITERATURE SEARCHES

Clinical and Cost-Effectiveness Literature Search – SIGN

The following sources were searched:
Medline
HealthSTAR
CINAHL (Cumulative Index to Nursing and Allied Health)
Cochrane Library
Embase
PsychINFO
Internet

Time period covered: 1991 – February 2000

Clinical Effectiveness Literature Search – NICE

The following sources were searched:
CINAHL
Cochrane Trials Register
Embase
HealthSTAR
Medline
Psychlit
Science Citation Index
Social Science Citation Index
HEED (Health Economics Evaluation Database)
NHS EED (NHS Economics Evaluation Database)
ECRI HTAIS
Trial Registers
Index to Scientific and Technical Conference Proceedings
HMIC
SIGLE (System for Information on Grey Literature in Europe)

Time period covered: 1983–July 1999

Clinical Effectiveness Literature Search – NSC

The following sources were searched:
MEDLINE
Handsearching of recent issues of key journals
Checking reference lists of articles retrieved
Contacting experts in the field

Cost-Effectiveness Literature Search – HTBS

The following databases were searched:
Cochrane Library including:
- Cochrane Database of Systematic Reviews
- Database of Abstracts of Reviews of Effectiveness
- Cochrane Controlled Trials Register
- NHS EED
- Health Technology Assessment Database

NRR (National Research Register)
HEED
ACP Journal Club (1991–)
Medline (1966–)
Premedline
Embase (1980–)
BIOSIS Previews (1970–)
CINAHL (1982–)
Current Contents (all editions) (1993–)
HealthSTAR (1975–2000)
Web of Science (1981–)
Econlit (1969–)
Dissertation abstracts (1861–)
SIGLE (1980–)

Web sites consulted were:
ISTAHC (International Society of Technology Assessment in Health Care)
(http://www.istahc.org/en/database.html)
Health Economics Research Unit, Aberdeen
(http://www.abdn.ac.uk/heru)
Centre for Health Economics, York
(http://www.york.ac.uk/inst/che/)
Health Economics Research Centre, Oxford
(http://www.ihs.ox.ac.uk/herc/)
Health Economics Research Group, Brunel
(http://http1.brunel.ac.uk:8080/departments/herg/home.html)
Centre for Health Economics Research and Development (CHERE), McMaster
(http://www.chere.usyd.edu.au)
Institute of Health Economics (IHE), Alberta, Canada
(http://www.ihe.ab.ca)
Health Economics Group (HEG), Newcastle
(http://www.ncl.ac.uk/deph/hegroup.html
SCHARR (School of Health and Related Research), Sheffield
(http://www.shef.ac.uk/uni/academic/R-Z/scharr/)
Health Economics Group, East Anglia
(http://www.uea.ac.uk/menu/acad_depts/hsw/hpp/hegwelc.htm)
LSE (London School of Economics and Political Science)
(http://www.lse.ac.uk/)
Southampton University Economics Department
(http://www.soton.ac.uk/~econweb/)
International Health Economics Association (iHEA)
(http://www.healtheconomics.org/cgi-bin/WebObjects/ihea)
NetEc

(http://netec.mcc.ac.uk/NetEc.html)
IDEAS (Internet Documents in Economics Access Service)
(http://ideas.uqam.ca/)
Diabetes UK
(http://www.diabetes.org.uk/)

Search Strategy

Database: MEDLINE
Coverage: <1966 to July Week 2 2001>
Host: Ovid
Date Searched: 24/07/01

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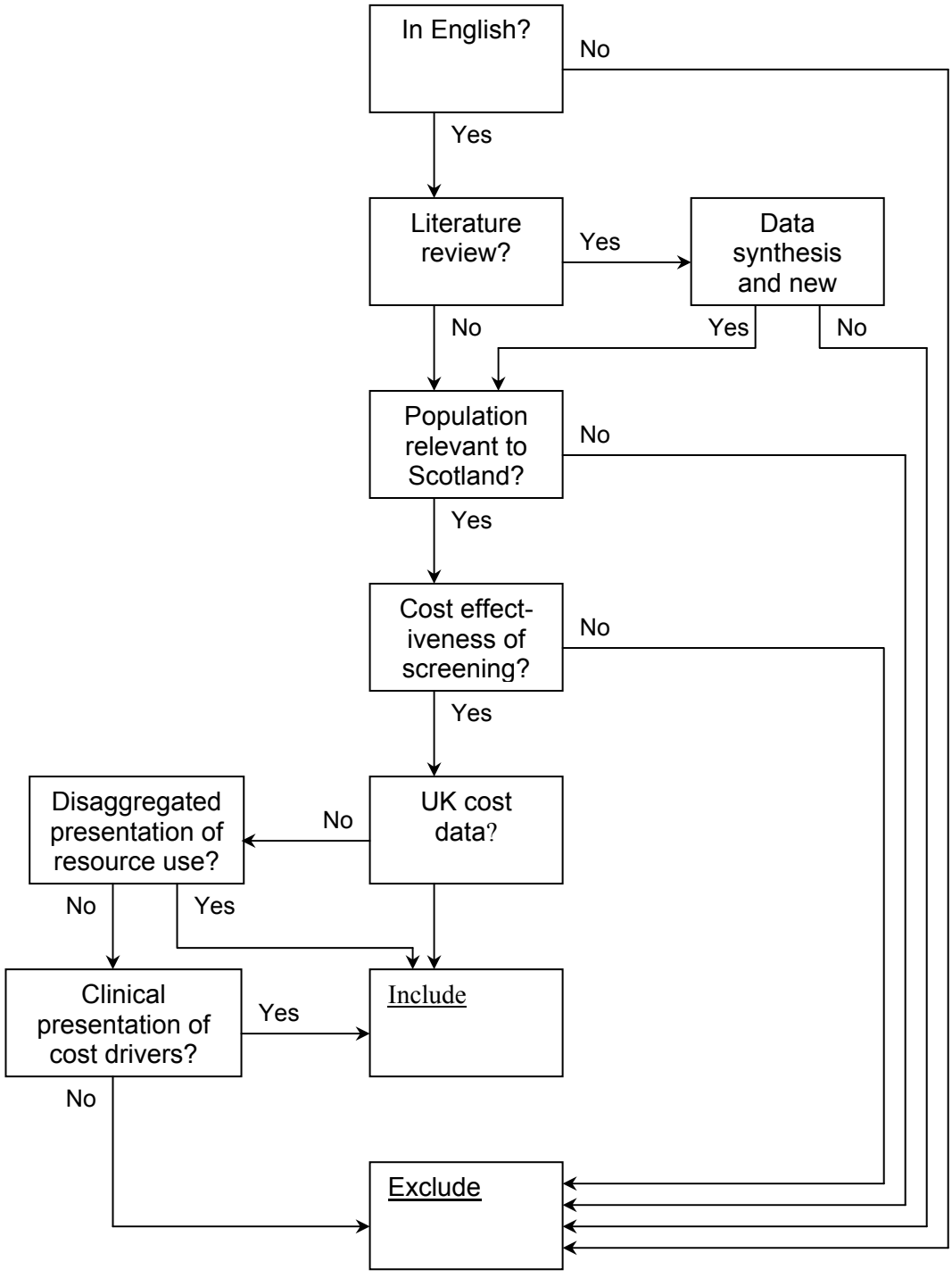
1 diabetic retinopathy/
2 exp diabetes mellitus/
3 glucose intolerance/
4 diabet$.tw.
5 iddm.tw.
6 niddm.tw.
7 eye/
8 exp retina/
9 exp retinal diseases/
10 vision/
11 visual acuity/
12 macular edema, cystoid/
13 eye$.tw.
14 retin$.tw.
15 vision.tw.
16 (vis$ adj3 impair$).tw.
17 (visual adj2 acuity).tw.
18 (macular adj2 (edema or oedema)).tw.
19 maculopathy.tw.
20 neovasculari?ation$.tw.
21 microaneurysm$.tw.
22 blind$.tw.
23 sight$.tw.
24 or/7-23
25 or/2-6
26 24 and 25
27 1 or 26
28 mass screening/
29 vision screening/
30 ophthalmoscopy/
31 ophthalmology/
32 optometry/
33 photography/
34 mydriasis/
35 exp mydriatics/
36 screen$.tw.
37 detect$.tw.
38 ophthalmo$.tw.
39 optometr$.tw.

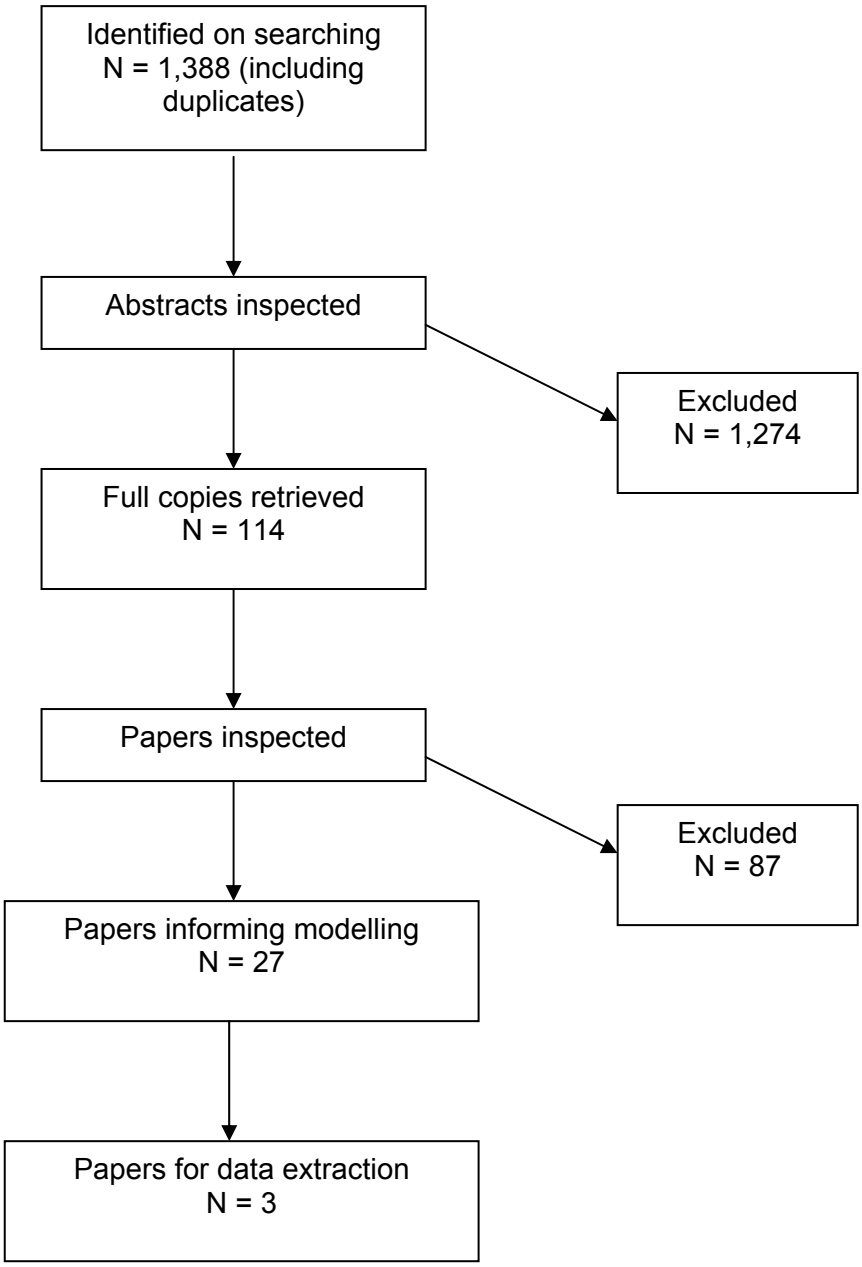
40 photograph$.tw.
41 slit?lamp?.tw.
42 fund?scop$.tw.
43 camera$.tw.
44 mydria$.tw.
45 dilat$.tw.
46 or/28-45
47 exp economics/
48 exp quality of life/
49 budgets/
50 economic$.tw.
51 "quality of life".ti,ab.
52 "quality adjusted life year?".tw.
53 qaly$.tw.
54 cost$.tw.
55 budget$.tw.
56 price$.tw.
57 pricing$.tw.
58 financ$.tw.
59 or/47-58
60 27 and 46 and 59

The search strategy was formulated with assistance from Francesca Chappell, Information Officer at SIGN and Moira Napper, Information Officer, HERU, University of Aberdeen.

Exclusion Criteria for Cost-effectiveness Review



Flow chart of identification and inclusion of studies: Cost-effectiveness



Appendix 7

CLINICAL EFFECTIVENESS ANALYSIS: MODEL AND DATA LISTING

Mathematical model

Diagnostic and screening studies are designed assuming that the population to be tested can be divided into two discrete groups, those with the condition of interest (cases) and those without (non-cases). In order to evaluate the performance of any new screening test we must be able to discriminate these groups accurately using some established procedure which is referred to as a Gold Standard test. The results obtained from the Gold Standard are compared with those from the new test.

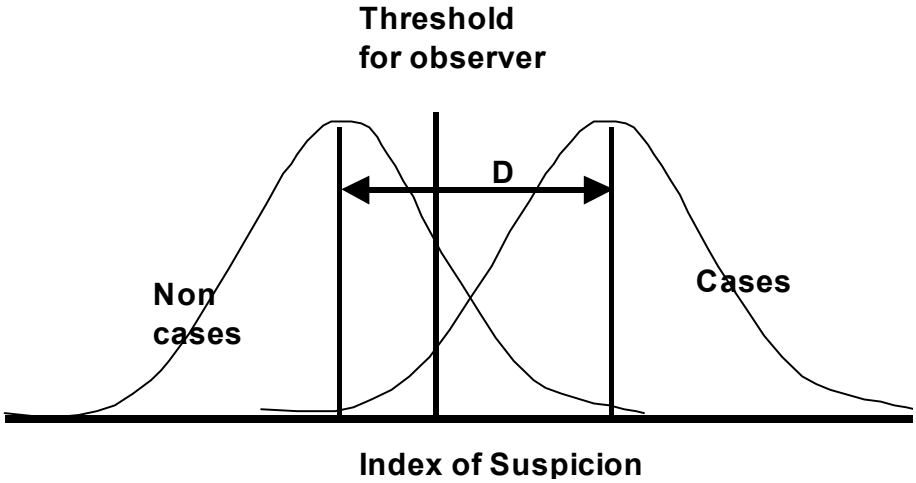
When the new screening method is to be used it will classify a certain proportion of cases as positive for the condition. This proportion is the sensitivity of the test. It will also classify a certain proportion of non-cases as positive; this is (1–specificity). If the test is to be useful it is clear that sensitivity must be greater than (1–specificity). This condition is necessary for the test to have any power to discriminate cases from non-cases. A result of this observation is that any analysis of a screening test which does not simultaneously consider both sensitivity and specificity cannot possibly prove the worth of the test.

When comparing two tests, they may be easily ranked if both the sensitivity and specificity of one is higher than the other. However, when the sensitivity of one is higher but the specificity is lower no ranking is possible unless we know more about the relationship between sensitivity and specificity. A mathematical model for this is presented below.

Consider the process of grading a patient for diabetic retinopathy on the basis of a retinal image. Various features of the image including numbers of haemorrhages and microaneurysms, cotton wool spots, intra-retinal microvascular anomalies, etc. will be observed and classified. Different observers will produce different results for this process depending on factors such as their familiarity with the process but experts may also differ depending on their personal belief concerning the degree of certainty which must be present before a positive diagnosis can be made. An expert with a lower threshold of certainty will classify more patients as positive and hence have a higher sensitivity, but also a lower specificity.

A model for this assumes that every image can be placed on a uni-dimensional scale which summarises the degree of suspicion that a given grader would feel that the image represented a disease state. Those who were truly cases should fall mainly at the high end of the scale and non-cases at the lower end. The two distributions are illustrated below:

Figure A7-1: Estimating joint sensitivity-specificity



Under this model two observers with different thresholds at which they diagnose retinopathy will have different sensitivities and specificities when grading the same set of images. The sensitivity is the area under the right hand distribution and to the right of the threshold, the specificity is the area under the left hand distribution and to the left of the threshold.

The property of the process which is invariant to choice of grader and which describes the inherent ability of the test to discriminate cases from non-cases is the separation of the two distributions relative to their standard deviation. The shape of the distribution will also have an effect and we are assuming Gaussian curves of equal standard deviation. The Index of Suspicion can be linearly rescaled without altering any features relevant to this discussion so the standard deviation may be taken as 1.

If Y_{sens} is the estimate of sensitivity and Y_{spec} is the estimate of specificity, we can then estimate the separation of the distributions as:

$$D = \Phi^{-1}(Y_{sens}) + \Phi^{-1}(Y_{spec})$$

Where $\Phi(z)$ is the integral under the standard Gaussian distribution from $-\infty$ to z.

The use of this transformation has several advantages. Firstly, it allows the effect of variation in observer thresholds for diagnosis to be removed from the analysis, secondly, it converts the bivariate analysis of sensitivity and specificity to a univariate analysis of D, and thirdly, it allows calculation of the sensitivity corresponding to any specificity for a given value of D.

If this last advantage is to be of clinical use an additional assumption must be made. This is that graders can be trained to alter their threshold for diagnosis to achieve any point on the curve relating sensitivity to specificity. It may be felt unwise, therefore, to extrapolate beyond the range of values of specificity observed within studies.

A problem with the transformation arises if either sensitivity or specificity is estimated to be 100%. Under these circumstances the value used has been set at the midpoint between 100% and the lower 95% confidence bound of the estimate. This value depends on the size of the study and puts greater weight on larger studies.

The weight, w, given to the result from any study when combining it with other studies is the reciprocal of Var(D). This we have estimated by:

$$1/w = Var(D) \approx Var(Y_{sens})/\{\phi(\Phi^{-1}(Y_{sens}))\}^2 + Var(Y_{spec})/\{\phi(\Phi^{-1}(Y_{spec}))\}^2$$

where $\phi(z)$ is the standard Gaussian distribution at z.

The standard test of heterogeneity and the usual random effects meta-analysis estimates can be calculated as recommended by Cochran (1983).

Selection of studies

The study design of the trials included within the NICE report (Hutchinson *et al*., 2000a) report was reviewed. For inclusion in this analysis the following basic criteria had to be satisfied.

1. The use of a credible Gold Standard: either seven-field stereoscopic photography or slit lamp investigation (biomicroscopy or indirect ophthalmoscopy) by a qualified ophthalmologist.
2. A sample of diabetic patients.
3. Within patient comparisons.
4. All patients accounted for in study report.
5. Different methods of investigation reported – not interobserver variation for a single method.
6. Adequate blinding where appropriate.

Using these rules resulted in the selection of eight studies from the initial 18 which gave information on accuracy of screening methods. Although methodologically sound, one of these seven studies (Penman *et al*., 1998) was in an African population who appeared to have a high burden of other eye disease and we have excluded this study from the main results but include discussion of the effect of this exclusion. One of the selected studies and an additional three studies gave information on agreement between the two comparators we had selected as appropriate Gold Standards. Details of the reasons for exclusion are given in Appendix 7a.

The HTBS TSG identified a further two studies (Leese *et al*., 1992; Olson *et al*., Evidence submission, 2001) which provide appropriate data and these were included in relevant analyses.

Analyses performed

The seven imaging techniques used in these trials were mydriatic direct ophthalmoscopy, (nine groups), non-mydriatic direct opthalmoscopy (one), biomicroscopy with a slit lamp (one), non-mydriatic photography (six), and mydriatic photography with one image (one), two images (two) and three images (one). The professions operating them were grouped as GPs, photographic graders, ophthalmologists, optometrist and others (this included hospital doctors).

From the data we would like to be able to both rank the professions operating the instruments and the instruments themselves for screening accuracy whilst adjusting each for variation in the other. However, it is worth noting that such a comparison may not be very robust. The reason for this is that direct comparisons between the four types of observer could only be done within the mydriatic direct ophthalmoscopy group. No photographic graders could use the ophthalmoscopes and all other imaging methods were used by exactly one type of observer. Given this, and the consideration that we would expect some interaction between type of observer and type of imaging instrument – since different professions will specialise – we decided to concentrate on a few combinations of instrument and observer only. These were:

- GPs with direct ophthalmoscopes through dilated pupils;
- optometrists with direct ophthalmoscopes through dilated pupils;

- other professionals with direct ophthalmoscopes through dilated pupils;
- trained graders using mydriatic camera images;
- trained graders using non-mydriatic cameras images;
- GP/optometrist/other non-specialist grading non-mydriatic camera image;
- optometrists using biomicroscopes with a slit lamp

Studies included in each comparison

The studies which contributed to the analysis of each of the combinations of instrument and observer are listed below.

Table A7.1

Analysis	STDR	Any retinopathy
GP/Direct ophthalmoscope	Buxton *et al.,* 1991	
Optometrists/Direct ophth	Buxton *et al.,*1991	
Others/Direct ophthalmoscope	Buxton *et al.,* 1991	
Graders/Mydriatic photography	Klein *et al.,* 1985 Pugh *et al.*, 1993 (Penman*) *et al.,* 1998	Klein *et al*., 1985 Pugh *et al.,* 1993 (Penman*) *et al.,*1998
Graders/Non-mydriatic photography	Klein *et al.,* 1985 Pugh *et al.,* 1993	Klein *et al.,* 1985 Pugh *et al.,* 1993
Non-specialist/Non-mydriatic photography	Buxton *et al.,* 1991 Williams *et al.,*1986	
Optometrists/Biomicroscope	Kleinstein *et al.,* 1987 Leese *et al.,* 1997 Olson *et al.,* 2001	Kleinstein *et al.,* 1987 Olson *et al.,* 2001

* The study by Penman *et al*. (1998) is not included in the primary analysis but the robustness of the results to this exclusion is reported.

Results

The following results were obtained for discrimination of STDR. The estimates are those from a random effects model (Der Simonian and Laird, 1986).

Table A7.2
Estimated separation of patients with Sight Threatening Diabetic Retinopathy (STDR) from those without STDR

	Mean D	No. of groups	X^2 homogeneity	95% CI for D
Mydriatic direct ophthalmoscopy/GP	1.41	1	-	1.18–1.64
Mydriatic direct ophthalmoscopy/optometrist	1.50	1	-	1.35–1.65
Mydriatic direct ophthalmoscopy/other	2.19	1	-	1.67–2.71
Mydriatic photography/grader	2.84[1]	2	0.65 (1 df)	1.91–3.77
Non-mydriatic photography/grader	2.74	2	2.66 (1 df)	1.14–4.34
Non-mydriatic photography/other	2.22	4	12.3 (3 df)	1.70–2.74
Slit-lamp/optometrist	1.95	3	5.4 (2 df)	1.37–2.53

These results can be interpreted in terms of the sensitivity which would be achieved at any value of specificity. The following values are estimated in the table below.

Table A7.3
Estimated sensitivity (95% CI) to STDR at fixed value of specificity

Specificity=	80%	85%	90%	**95%**	97%
Mydriatic direct ophthalmoscopy/GP	71% (63%–79%)	64% (56%–73%)	55% (46–64%)	**40**% **(32%–50%)**	32% (24%–41%)
Mydriatic direct ophthalmoscopy/optometrist	74% (69%–79%)	68% (62%–73%)	59% (53%–64%)	**44% (38%–50%)**	35% (30%–41%)
Mydriatic direct ophthalmoscopy/other	91% (80%–97%)	88% (74%–95%)	82% (65%–92%)	**71% (51%–85%)**	62% (42%–79%)
Mydriatic photography/grader	98% (86%–100%)	96% (81%–100%)	94% (73%–99%)	**88**% **(60%–98%)**	83% (51%–97%)
Non-mydriatic photography/grader	97% (62%–100%)	96% (54%–100%)	93% (44%–100%)	**86**% **(31%–100%)**	80% (23%–99%)
Non-mydriatic photography/other	92% (80%–97%)	89% (75%–96%)	83% (66%–93%)	**72**% **(52%–86%)**	63% (43%–80%)
Slit lamp/optometrist	87% (70%–95%)	82% (63%–93%)	75% (54%–90%)	**62**% **(39%–82%)**	53% (30%–75%)

The following results were obtained for discrimination of any retinopathy:

[1] If the Penman *et al*. (1998) study is included this becomes 2.48 with 95% CI from 1.71 to 3.24 corresponding to a sensitivity of 80% at 95% specificity.

Table A7.4
Estimated separation of patients with *any* diabetic retinopathy from those without diabetic retinopathy

	Mean D	No. of groups	X^2 homogeneity	S.E. of D
Mydriatic direct ophthalmoscopy/GP	-	0	-	
Mydriatic direct ophthalmoscopy/optometrist	-	0		
Mydriatic direct ophthalmoscopy/other	-	0	-	-
Mydriatic photography/grader[2]	3.09	2	2.78 (2 df)	0.97–5.20
Non-mydriatic photography/grader	2.74	2	0.26 (1 df)	2.11–3.36
Slit lamp/optometrist	1.62	2	0.03 (1 df)	1.42–1.82

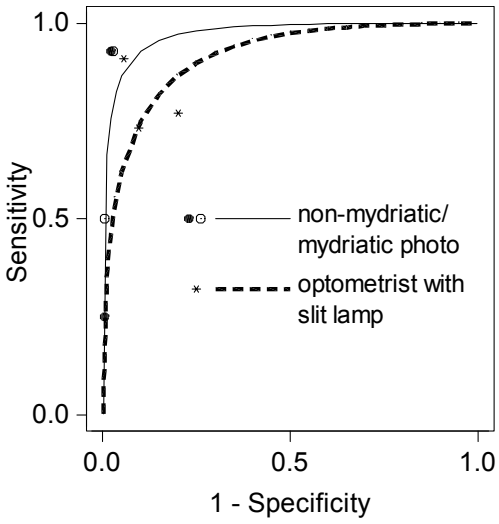
Table A7.5
Estimated sensitivity (95% CI) to *any* diabetic retinopathy at fixed value of specificity

Specificity=	80%	85%	90%	**95%**	97%
Mydriatic direct ophthalmoscopy/GP	-	-	-	-	-
Mydriatic direct ophthalmoscopy/optometrist	-	-	-	-	-
Mydriatic direct ophthalmoscopy/other	-	-	-	-	-
Mydriatic photography/grader	99% (55%–99%)	98% (47%–99%)	96% (37%–99%)	**93% (25%–99%)**	88% (18%–99%)
Non-mydriatic photography/grader	97% (90%–99%)	96% (86%–99%)	93% (79%–98%)	**86% (68%–96%)**	80% (59%–93%)
Slit lamp/optometrist	78% (72%–84%)	72% (65%–78%)	63% (55%–70%)	**49% (41%–57%)**	40% (32%–48%)

The estimated ROC curves for mydriatic and non-mydriatic photography in screening for STDR are identical. They are compared below with that for optometrists using slit lamps. The symbols represent the results of individual studies.

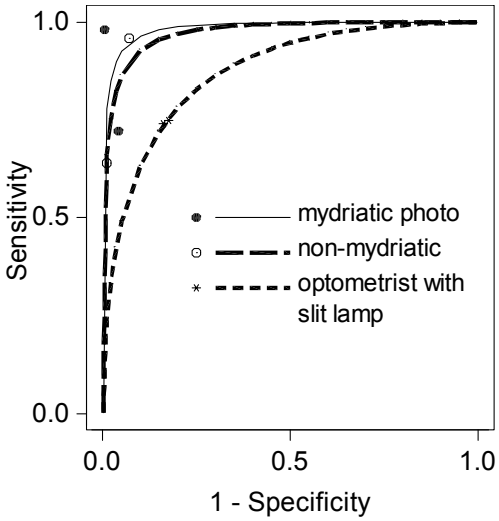
[2] With the Penman *et al*. (1998) study this becomes 2.25 with 95% CI from 1.72 to 2.78 corresponding to a sensitivity of 73% at 95% specificity.

Figure A7.2 Estimated ROCs for STDR



The estimated ROC curves for the same three screening techniques detecting any form of retinopathy are shown below.

Figure A.7.3 Estimated ROCs for any retinopathy



Comment on performance of Gold Standard methods

Although neither of the assumed Gold Standards are considered practicable screening methods, it is interesting to investigate the agreement between them when both were included in a study. To do this we have, arbitrarily, assumed that the seven-field photography returns the true value and calculated the sensitivity and specificity of slit lamp investigation by an ophthalmologist. However, it should be borne in mind that this reveals nothing about the relative accuracy of the methods. If the slit lamp were assumed accurate, less than perfect accuracy would be estimated for the photography.

Table A7.6
Separation achieved by ophthalmologists with slit lamp

	Mean D	No. of groups	X^2 homogeneity	95% CI for D
Referable retinopathy	2.96	2	1.70 (1 df)	2.34–3.57
Any retinopathy	2.46	4	26.6 (3 df)	1.91–3.01

Table A7.7
Sensitivity (95% CI) for ophthalmologist with slit lamp

Specificity=	80%	85%	90%	**95%**	97%
Referable retinopathy	98% (93%–100%)	97% (90%–99%)	95% (85%–99%)	**91**% **(76**%**–97**%**)**	86% (68%–95%)
Any retinopathy	95% (86%–98%)	92% (81%–98%)	88% (73%–96%)	**79**% **(60**%**–91**%**)**	72% (51%–87%)

If both these methods were truly Gold Standards the agreement between them would be perfect since both would be giving the correct answer. Since both methods are generally considered of a higher accuracy than the methods suggested for screening, it seems reasonable to view these results as providing standards for the best that we could expect of a screening method. In this respect it is interesting to note that the sensitivity for any retinopathy at a specificity of 95% is only 79%. This is just below the benchmark set by the *St Vincent Declaration*. (WHO, 1989*)*

Single-field and two-field photographic methods interpreted by graders

In the results given in tables A7.2–7.5 single-field and two-field mydriatic photography were combined. A single study was available of each method interpreted by trained graders. Comparison of the results of these studies is shown below.

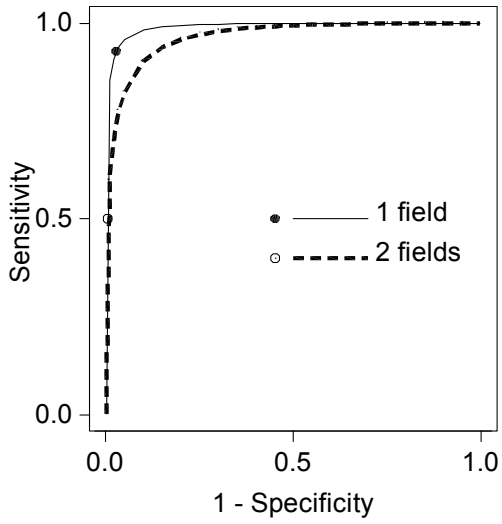
Table A7.8
Separation of STDR by one- or two-field photography

	Mean D	No. of groups	X^2 homogeneity	95% CI for D
One field (Klein *et al.,* 1985	3.39	1	-	1.77–5.00
Two fields[3] (Pugh *et al.,* 1993	2.58	1	-	1.44–3.70

Table A7.9
Sensitivity (95% CI) to STDR of one- or two-field photography

Specificity=	80%	85%	90%	**95%**	97%
One field (Klein *et al., 1985*	99% (82%–99%)	99% (76%–99%)	98% (69%–99%)	**96**% **(55%–99%)**	93% (46%–99%)
Two field (Pugh *et al.,* 1993)	96% (73%–99%)	94% (66%–99%)	90% (56%–99%)	**82**% **(41%–98%)**	76% (33%–97%)

The difference between the performance of one-field and two-field photography is not statistically significant. However, it is surprising that the point estimates favour the superiority of a single field protocol. The estimated ROC curves and the point estimates from the studies are shown below.



Another study (Olson *et al*., Evidence Submission, 2001) has compared mydriatic one-field and two-field protocols directly. This study employed a research fellow to interpret the images and hence it is not included here. Almost identical accuracy was found for one image and two images.

[3] With Penman study *et al., (*1998) included this becomes 2.24 with 95% CI from 1.57 to 2.90 corresponding to a sensitivity of 73% at 95% specificity.

Assessment of whether studies collected data from which accuracy could be derived

Selection criteria

1. The use of a credible Gold Standard: either seven-field stereoscopic photography or slit lamp investigation (biomicroscopy or indirect ophthalmoscopy) by a qualified ophthalmologist.
2. A sample of diabetic patients.
3. Within patient comparisons.
4. All patients accounted for in study report.
5. Different methods of investigation reported – not inter-observer variation for a single method.
6. Adequate blinding where appropriate.

Excluded studies

1. Forrest RD, Jackson CA and Yudkin JS. 1987. Screening for treatable diabetic retinopathy: a comparison of different methods. *Diabetes Res*, **5,** 39–42.

Only 72 people with diabetes were included in this study in 282 subjects. Fifty-nine of the 72 were established diabetics while 13 were detected via a screening programme. The Gold Standard was five-field photography. The Gold Standard is probably accurate – though different from those specified – however, the population included is clearly very different from the target population for screening.

2. Gibbons RL, Kinsella F, Young S *et al*. 1994. Screening for diabetic retinopathy in general practice using 35 mm colour transparency fundal photographs. *Practical Diabetes*, **11,**203–206.

This was an inter-observer agreement study for photographic images.

3. Gibbons RL, Owens DR, Allen JC et al. 1998. Practical application of the European Field Guide in screening for diabetic retinopathy by using ophthalmoscopy and 35 mm retinal slides. *Diabetologia*, **41,**.59–64.

This was an inter-observer agreement study. Comparison was made with interpretation of the same set of two retinal images by a grading centre. No Gold Standard was included.

4. O'Hare JP, Hopper A, Madhaven C *et al*. 1996. Adding retinal photography to screening for diabetic retinopathy - a prospective study in primary care. *BMJ*, **312**(7032),679–682.

This study evaluated the additional accuracy achieved by adding a single photographic image to direct ophthalmoscopy. This is not a screening option under consideration. The reference standard was a combination of direct ophthalmoscopy and review of the test photographs by an ophthalmologist, thus it has similarities to an inter-observer study.

5. Reenders K, deNobel E, van den Hoogen H *et al*. 1992. Screening for diabetic retinopathy by general practitioners. *Scand J Prim Health Care*, **10,**306–309.

No Gold Standard in study.

6. Ryder REJ, Close CF, Krentz AJ et al. 1998. A 'fail-safe' screening programme for diabetic retinopathy. *J R Coll Physicians Lond*, **32,**134–137.

No Gold Standard in study.

7. Lienert RT. 1989. Inter-observer comparisons of ophthalmoscopic assessment of diabetic retinopathy. *Aust N Z J Ophthalmol*, **17,** 363–368.

This study used direct ophthalmoscopy by an ophthalmologist as a comparator. This is not a generally accepted Gold Standard.

8. Van der Kar W, van der Velden HGM, van Weel C *et al*. 1990. Diagnosing diabetic retinopathy by general practitioners and by hospital physician. *Scand J Prim Health Care*, **8,**19–23.

This was an inter-observer agreement study for fundus photography. No Gold Standard was included.

Studies not addressing screening methods considered for Scottish scheme

Three of the studies examined only the agreement between the two methods assumed as Gold Standard – slit lamp investigation by an ophthalmologist and seven-field fundus photography. Whilst such information is useful for this assessment, in that it sheds light on the validity of the above assumption, it does not inform directly concerning the accuracy of screening methods.

9. Kinyoun JL, Martin DC, Fujimoto WY *et al*. 1992. Ophthalmoscopy versus fundus photographs for detecting and grading diabetic retinopathy. *Invest Opthalmol Vis Sci*, **33**(6),1888–1893.

10. Schachat AP, Hyman L, Leske MC *et al.* 1993. Comparison of diabetic-retinopathy detection by clinical examinations and photgraph gradings. *Arch Ophthalmol*, **111**(8),1064–1070.

11. Moss SE, Klein R, Kessler SD *et al*. 1985. Comparison between ophthalmoscopy and fundus photography in determining severity of diabetic retinopathy. *Ophthalmology*, **92**(1),62–67.

The direct and indirect ophthalmoscopy results in this study were evaluated by three observers who were free to confer. The estimated accuracy may be better than would be achieved by a single observer and it seems reasonable to assume it would be as good as the best qualified observer.

Comments on included studies

The following studies supplied information on screening methods under evaluation for the Scottish programme. They were judged to be acceptable on the basis of the six inclusion criteria but were of variable quality and some comments on methodological problems in interpretation are given.

12. Klein R, Klein BEK, Neider MW *et al*. 1985. Diabetic retinopathy as detected using ophthalmoscopy, a non-mydriatic camera and a standard fundus camera. *Ophthalmology*, **92,**485–491.

Only three 30 degree fields were used to provide a Gold Standard rather than seven. These covered roughly the same area as the 45 degree screening photographs. Thus the question answered by the study was not ‘Was the test result correct?’ but ‘Did the test result agree with the best data obtainable from the same retinal area?’. There is clear concern that this may

overestimate screening accuracy. However, other criteria were satisfied and it was decided, on balance, that this study should be included.

13. Penman AD, Saddine JB, Hegazy M *et al*. 1998. Screening for diabetic retinopathy: the utility of nonmydriatic retinal photography in Egyptian adults. *Diabet Med*, **15,**783–787.

The general analytical approach of this study was to estimate agreement between slit lamp investigation by an ophthalmologist and retinal photography. Since one of these is a presumed Gold Standard it seemed reasonable to reinterpret the results in terms of accuracy. However, it should be noted that the authors do not consider slit lamp investigation to constitute a Gold Standard. Although this study met the methodological acceptance criteria there is evidence that the population studied may have differed from Scottish patients in terms of the burden of other eye disease. Thus estimates in tables exclude this study and discussion is included in the text.

14. Kleinstein RN, Roseman JM, Herman WH et al. 1987. Detection of diabetic retinopathy by optometrists. *J Am Optom Assoc*, **58,**879–882.

This study had an unusual design. It included only 14 patients and 25 eyes but assessments were made by 19 optometrists and compared with seven-field fundus photography. The patients were systematically selected over a range of severity of retinopathy. No estimates of inter-optometrist variability were given. Although there are some concerns about how the results of this study translate into clinical practice it does conform to the selection criteria.

15. Williams R, Nussey S, Humphrey *et al*. 1986. Assessment of non-mydriatic fundus photography in detection of diabetic retinopathy. *BMJ*, **293,**1140–1142.

The same assessors were used for photographic and slit lamp investigation – hence there may be some doubt over the adequacy of blinding.

16a. Lairson DR, Pugh JA, Kapadia AS *et al.* 1992. Cost-effectiveness of alternative methods for diabetic retinopathy screening. *Diabetes Care*, **15**(10),1369–1377.

16b. Pugh JA, Jacobson JM, Van Heuven WAJ *et al*. 1993. Screening for diabetic retinopathy: the wide-angle retinal camera. *Diabetes Care*, **16**(6),889–895.

The above two papers address the same study. It was a generally high-quality study. The only doubt concerns the systematic ordering of grading for the two-test methods – first single-field non-mydriatic and then three-field mydriatic. Although some time was left between gradings, this means that independence cannot be tested. The rationale underlying the decision appears to have been that more information was bound to be supplied by the three-field photography than the single field. Thus the hypothesis the study was intended to investigate was presupposed to be true in designing the analysis. A better approach is to randomise the order of grading and adjust for any effects associated with the sequence of grading.

17a. Buxton MJ, Sculpher MJ, Ferguson BA *et al*. 1991. Screening for treatable diabetic retinopathy: a comparison of different methods. *Diabet Med*, **8,**371–377.

17b. Sculpher MJ, Buxton MJ, Ferguson BA *et al.* 1991. A relative cost-effectiveness analysis of different methods of screening for diabetic retinopathy. *Diabet Med*, **8**(7),644–650.

18. Harding SP, Broadbent DM, Neoh C *et al.* 1995. Sensitivity and specificity of photography and direct ophthalmoscopy in screening for sight-threatening eye disease: the Liverpool diabetic eye study. *BMJ*, **311,** 1131–1135.

19. Leese GP, Tesfaye S, Dengler-Harles M, Laws F, Clark DI, Gill GV, Macfarlane IA. Screening for diabetic eye disease by optometrists using slit lamps. JRCollPhysicians Lond, **31** (1):65-9.

20. Olson JA, Strachan FS, Hipwell JH, Goatman K, McHardy KC, Forrester JV, Sharp PF. The value of digital imaging compared with retinal photography and slit-lamp bio-microscopy by trained optometrists in screening for diabetic retinopathy: the Aberdeen diabetic eye study [Evidence Submission].

Although this study is as yet unpublished, the authors have provided HTBS with access to tabulated data and answers to detailed questions.

Studies included in clinical effectiveness evaluations.
Number of subjects with and without retinopathy.
Table A.7a-1 Referable retinopathy (STDR/PDR)

Study	Screening method	Disease +ve	Disease -ve
Buxton 1991	Mydriatic direct ophth /GP	122	2,228
Buxton 1991	Non-mydriatic photo/GP	111	1,968
Buxton 1991	Mydriatic direct ophth /Opt	21	374
Buxton 1991	Non-mydriatic photo/Opt	17	340
Buxton 1991	Mydriatic direct ophth/Other	30	386
Buxton 1991	Non-mydriatic photo/Other	30	374
Harding 1995	Mydriatic direct ophth	46	274
Harding 1995	Mydriatic photo	45	275
Klein 1985	Mydriatic photo	15	54
Klein 1985	Non-mydriatic photo	14	43
Klein 1985	Non-mydriatic direct ophth	57	20
Kleinstein[1] 1987	Mydriatic indirect ophth	57	399
Leese 1997	Mydriatic indirect ophth	11	92
Olson	Mydriatic indirect ophth	26	457
Olson	Mydriatic photo (two image)	54	492
Olson	Mydriatic photo (one image)	57	499
Penman[2] 1998	Mydriatic photo	5	320
Pugh 1993	Mydriatic photo	6	332
Pugh 1993	Non-mydriatic photo	4	297
Williams 1986	Non-mydriatic photo	46	67

Table A.7a-2 Any retinopathy

Study	Screening method	Disease +ve	Disease -ve
Klein 1985	Non-mydriatic direct ophth	57	20
Klein 1985	Non-mydriatic photo	37	11
Klein 1985	Mydriatic photo	55	14
Kleinstein[1] 1987	Mydriatic indirect ophth	304	152
Olson	Mydriatic indirect ophth	111	374
Olson	Mydriatic photo (two image)	150	400
Olson	Mydriatic photo (one image)	150	407
Penman[2] 1998	Mydriatic photo	73	252
Pugh 1993	Non-mydriatic photo	164	137
Pugh 1993	Mydriatic photo	183	155
Williams 1986	Non-mydriatic photo	71	42

[1]Kleinstein study based on repeat assessment of 25 eyes
[2]Penman study based on eyes not individuals

Appendix 7b Datasets

Table A.7b-1 Dataset for PDR/STDR

Retin-opathy	Ref	Reader	Test	Sens	Spec	Pos-itive	Neg-ative	D	Study
ST/RR	Slit	GP	MDOP	0.53	0.91	122	2228	1.41602	Buxton *et al.,* 1991
ST/RR	Slit	GP	NMRP1	0.54	0.97	111	1968	1.98123	Buxton *et al.,* 1991
PR	photo30	gra	MRP1	0.93	0.972	15	54	3.38683	Klein *et al.,* 1985
ST/RR	Slit	gra	MRP2	0.6	0.95	5	320	1.8982	Penman *et al.,* 1998
PR	photo30	gra	MRP2	0.5	0.995	6	332	2.57583	Pugh *et al.,* 1993
PR	photo30	gra	NMRP1	0.25	0.995	4	297	1.90134	Pugh *et al.,* 1993
PR	photo30	gra	NMRP1	0.93	0.98	14	43	3.52954	Klein *et al.,* 1985
ST/RR	Slit	Oph	MDOP	0.65	0.97	46	274	2.26611	Harding *et al.,* 1995
ST/RR	Slit	Oph	MRP3	0.89	0.86	45	275	2.30685	Harding *et al.,* 1995
ST/RR	Slit	Oph	NMRP1	0.93	0.96	46	67	3.22648	Williams *et al.,* 1986
ST/RR	Slit	Opt	MDOP	0.48	0.94	21	374	1.50462	Buxton *et al.,* 1991
ST/RR	photo30	Opt	MIOP	0.77	0.8	57	399	1.58047	Kleinstein *et* al,, 1987
PR	photo30	Opt	NDOP	0.53	0.9	57	20	1.35682	Klein *et al.,* 1985
ST/RR	Slit	Opt	NMRP1	0.47	0.95	17	340	1.56958	Buxton *et al.,* 1991
ST/RR	Slit	Oth	MDOP	0.67	0.96	30	386	2.1906	Buxton *et al.,* 1991
ST/RR	Slit	Oth	NMRP1	0.67	0.97	30	374	2.32071	Buxton *et al.,* 1991
ST/RR	Slit	Opt	MIOP	0.91	0.945	11	92	2.93895	Leese *et al.,* 1997
ST/RR	Slit	Opt	MIOP	0.731	0.904	26	457	1.92053	Olson *et al.,* 2001
ST/RR	Slit	Oth	MRP2	0.944	0.872	54	492	2.72516	Olson *et al.,* 2001
ST/RR	Slit	Oth	MRP1	0.93	0.87	57	499	2.60218	Olson *et al.,* 2001

Table A7b-2 Dataset for any retinopathy

Retin-opathy	Ref	Reader	Test	Sens	Spec	Pos-itive	Neg-ative	D	Study
AR	Slit	GP	MDOP	0.45	0.935	18	23	1.38844	Lienert *et al.,* 1989
AR	photo30	Opt	NDOP	0.84	0.75	57	20	1.66895	Klein *et al.,* 1985
AR	photo30	gra	NMRP1	0.64	0.99	164	137	2.68481	Pugh *et al.,* 1993
AR	photo30	gra	NMRP1	0.959	0.93	37	11	3.21499	Klein *et al.,* 1985
AR	Slit	Oph	NMRP1	0.96	0.98	71	42	3.80443	Williams *et al.,* 1986
AR	Slit	gra	MRP2	0.85	0.83	73	252	1.9906	Penman *et al.,* 1998
AR	photo30	gra	MRP1	0.98	0.995	55	14	4.62958	Klein *et al.,* 1985
AR	photo30	gra	MRP2	0.72	0.96	183	155	2.33353	Pugh *et al.,* 1993
AR	Slit	Opt	MIOP	0.748	0.824	111	374	1.59893	Olson *et al.,* 2001
AR	Slit	Oth	MRP2	0.833	0.792	150	400	1.77947	Olson *et al.,* 2001
AR	Slit	Oth	MRP1	0.8	0.875	150	407	1.99197	Olson *et al.,* 2001
AR	photo30	Opt	MIOP	0.74	0.84	304	152	1.63781	Kleinstein *et al.,* 1987

Appendix 7C - Calculations for combined studies

The following tables show the calculations performed to combine results across different studies. The methods used are those of DerSimonian and Laird (1986). It should be noted that these authors use the letter D to denote an intermediate result in their calculation. To avoid confusion with the outcome variable, this quantity is renamed Δ.

Key

N	Number of studies combined
D	Outcome variable
W	Weight for study
C1	W x D
C2	$(D - \sum WD/\sum W)^2$
C3	$W \times (D - \sum WD/\sum W)^2$
Q	ΣC3
C4	W x W
SW2	$(\Sigma W^2 - (\Sigma W)^2/N)/(N - 1)$
U	$(\Sigma W/N - SW2/\Sigma W) \times (N - 1)$
Δ	$(Q - N + 1)/U$
C5	$1/(\Delta + 1/W)$
C6	D x C5
D*	ΣC6/ΣC5 Random effects estimate
LCB	$D^* - 1.96 / \sqrt{(\Sigma C5)}$
UCB	$D^* + 1.96 / \sqrt{(\Sigma C5)}$

It should be noted that the random effects estimate is not used unless Q is greater than the degrees of freedom (N –1). When this is not the case the fixed effect – the weighted mean of C1 – is used and is written in bold to indicate this.

All calculations are identified as either AR (Any Retinopathy) or STDR (Sight Threatening Diabetic Retinopathy)

Others using non-mydriatic cameras STDR									
			N=	**4**					
	D	**W**	**C1**	**C2**	**C3**	**C4**		**C5**	**C6**
Buxton	1.98123	57.4732	113.8676	0.010114	0.581261	3303.169		4.521916	8.958956
Williams	3.22648	6.4225	20.72207	1.310301	8.415405	41.24851		2.782041	8.976198
Buxton	1.56958	9.4573	14.84399	0.262366	2.481271	89.44052		3.231183	5.0716
Buxton	2.32071	13.6967	31.78607	0.05708	0.781804	187.5996		3.61329	8.385399
Totals	9.098	87.0497	181.2198	Q=	12.25974	3621.457		14.14843	31.39215
	Mean=	21.76243	2.081796		SW2=	575.6816		D*=	2.218773
					U=	45.44752		LCB=	1.697696
					Δ=	0.203746		UCB=	2.73985

Optometrists using slit lamps for STDR									
			N=	**3**					
	D	**W**	**C1**	**C2**	**C3**	**C4**		**C5**	**C6**
Kleinstein	1.58047	25.76	40.71291	0.042158	1.085982	663.5776		5.161132	8.157015
Leese	2.93895	3.0489	8.960565	1.32977	4.054337	9.295791		2.070723	6.08575
Olson	1.92053	13.161	25.2761	0.018154	0.238924	173.2119		4.330539	8.316931
Totals	6.43995	41.9699	74.94957	Q=	5.379243	846.0853		11.56239	22.5597
	Mean=	13.98997	1.785793		SW2=	129.4639		D*D*=	1.951127
					U=	21.81056		LCB=	1.374716
					Δ=	0.154936		UCB=	2.527538

GP using mydriatic direct ophthalmoscope STDR									
			N=	**1**					
	D	**W**	**C1**	**C2**	**C3**	**C4**		**C5**	**C6**
Buxton	1.41602	69.9412	99.03814						
Totals	1.41602	69.9412	99.03814	Q=	0				
	Mean=	69.9412	**1.41602**		SW2=			D*=	
					U=			LCB=	
					Δ=			UCB=	

Other using mydriatic direct ophthalmoscope STDR									
			N=	**1**					
	D	**W**	**C1**	**C2**	**C3**	**C4**		**C5**	**C6**
Buxton	2.1906	14.3678	31.4741						
Totals	**2.1906**	14.3678	31.4741	Q=	0				
	Mean=	14.3678	**2.1906**		SW2=			D*=	
					U=			LCB=	
					Δ=			UCB=	

Graders using mydriatic photography STDR									
			N=	**3**					
	D	**W**	**C1**	**C2**	**C3**	**C4**		**C5**	**C6**
Klein	3.38679	1.4674	4.969776	0.850702	1.248321	2.153263		1.365847	4.625839
Penman	1.8982	2.9799	5.656446	0.320644	0.955488	8.879804		2.588994	4.914428
Pugh	2.57583	2.9984	7.723369	0.012404	0.037194	8.990403		2.602947	6.704749
Totals	7.86082	7.4457	18.34959	Q=	2.241002	20.02347		6.557788	16.24502
	Mean=	2.4819	2.464455		SW2=	0.771993		D*=	2.47721
					U=	4.756434		LCB=	1.711829
					Δ=	0.050669		UCB=	3.24259

Graders using mydriatic photography excluding Penman* et al. *(1998) study									
			N=	**2**					
	D	**W**	**C1**	**C2**	**C3**	**C4**		**C5**	**C6**
Klein	3.38679	1.4674	4.969776	0.296469	0.435039	2.153263		1.988818	6.735709
Pugh	2.57583	2.9984	7.723369	0.071006	0.212906	8.990403		6.458073	16.6349
Totals	5.96262	4.4658	12.69314	Q=	0.647944	11.14367		8.446892	23.37061
	Mean=	2.2329	**2.8423**		SW2=	1.171981		D*=	2.76677
					U=	1.970465		LCB=	2.092386
					Δ=	-0.17867		UCB=	3.441155

Graders using non-mydriatic photography STDR									
			N=	**2**					
	D	**W**	**C1**	**C2**	**C3**	**C4**		**C5**	**C6**
Pugh	1.90134	1.837	3.492762	0.790655	1.452434	3.374569		0.729136	1.386335
Klein	3.52954	2.2103	7.801342	0.546139	1.207131	4.885426		0.781526	2.758426
Totals	5.43088	4.0473	11.2941	Q=	2.659564	8.259995		1.510661	4.144761
	Mean=	2.02365	2.790528		SW2=	0.069676		D*=	2.743673
					U=	2.006434		LCB=	1.148997
					Δ=	0.827121		UCB=	4.338349

Graders using mydriatic photography with single image STDR									
			N=	**1**					
	D	**W**	**C1**	**C2**	**C3**	**C4**		**C5**	**C6**
Klein	3.38679	1.4674	4.969776	0.222935					
Totals	3.38679	1.4674	4.969776	Q=					
	Mean=	1.4674	**3.38679**		SW2=			D*=	
					U=			LCB=	
					Δ=			UCB=	

Graders using mydriatic photography with two images STDR									
			N=	**2**					
	D	**W**	**C1**	**C2**	**C3**	**C4**		**C5**	**C6**
Penman	1.8982	2.9799	5.656446	0.115507	0.3442	8.879804		4.336016	8.230625
Pugh	2.57583	2.9984	7.723369	0.114086	0.342076	8.990403		4.375296	11.27002
Totals	4.47403	5.9783	13.37981	Q=	0.686276	17.87021		8.711312	19.50064
	Mean=	2.98915	**2.238063**		SW2=	0.000171		D*=	2.238543
					U=	2.989121		LCB=	1.574472
					Δ=	-0.10496		UCB=	2.902613

Graders using mydriatic photography with two images STDR without Penman									
			N=	**1**					
	D	**W**	**C1**	**C2**	**C3**	**C4**		**C5**	**C6**
Pugh	2.57583	2.9984	7.723369						
Totals	2.57583	2.9984	7.723369	Q=					
	Mean=	2.9984	**2.57583**		SW2=			D*=	
					U=			LCB=	
					Δ=			UCB=	

Optometrists using mydriatic direct ophthalmoscopy STDR									
			N=	**2**					
	D	**W**	**C1**	**C2**	**C3**	**C4**		**C5**	**C6**
Buxton	1.50462	11.695	17.59653						
Totals	1.50462	11.695	17.59653	Q=					
	Mean=	11.695	**1.50462**		SW2=			D*=	
					U=			LCB=	
					Δ=			UCB=	

Graders using mydriatic photography AR									
			N=	**3**					
	D	W	C1	C2	C3	C4		C5	C6
Penman	1.9906	24.4636	48.69724	0.037883	0.926758	598.4677		6.708636	13.35421
Klein	4.62958	0.54	2.499973	5.974818	3.226402	0.2916		0.510195	2.361987
Pugh	2.33353	23.2076	54.15563	0.021991	0.510361	538.5927		6.610527	15.42586
			0	4.775256	0	0			
Totals	8.95371	48.2112	105.3528	Q=	4.663521	1137.352		13.82936	31.14206
	Mean=	16.0704	2.185236		SW2=	181.2894		D*=	2.25188
					U=	24.62017		LCB=	1.724827
					Δ=	0.108185		UCB=	2.778934

Graders using mydriatic photography without Penman* et al. *(1998) AR									
			N=	**2**					
	D	**W**	**C1**	**C2**	**C3**	**C4**		**C5**	**C6**
Klein	4.62958	0.54	2.499973	5.034817	2.718801	0.2916		0.282462	1.307679
Pugh	2.33353	23.2076	54.15563	0.002726	0.063262	538.5927		0.57752	1.34766
			0	5.691756	0	0			
Totals	6.96311	23.7476	56.6556	Q=	2.782063	538.8843		0.859982	2.655339
	Mean=	11.8738	2.38574		SW2=	256.91		D*=	3.087669
					U=	1.055442		LCB=	0.974124
					Δ=	1.688452		UCB=	5.201214

Graders using non-mydriatic photography AR									
			N=	**2**					
	D	**W**	**C1**	**C2**	**C3**	**C4**		**C5**	**C6**
Pugh	2.68481	8.946	24.01831	0.002993	0.026775	80.03092		-3.45632	-9.27955
Klein	3.215	1.0293	3.3092	0.226084	0.232708	1.059458		1.753073	5.63613
Totals	5.89981	9.9753	27.32751	Q=	0.259482	81.09037		-1.70324	-3.64342
	Mean=	4.98765	**2.739518**		SW2=	31.33707		D*=	2.139109
					U=	1.846184		LCB=	
			0.620573		Δ=	-0.40111		UCB=	

Agreement between supposed Gold Standards STDR									
			N=	2					
	D	W	C1	C2	C3	C4		C5	C6
Pugh	2.39946	3.367	8.078982	0.473266	1.593485	11.33669		2.453512	5.887105
Moss	3.13277	51.057	159.9498	0.002058	0.105084	2606.817		7.68258	24.06776
Totals	5.53223	54.424	168.0288	Q=	1.698569	2618.154		10.13609	29.95486
	Mean=	27.212	3.087403		SW2=	1137.168		D*=	2.955267
					U=	6.317394		LCB=	2.339636
					Δ=	0.110579		UCB=	3.570899

Agreement between supposed Gold Standards AR									
			N=	**4**					
	D	**W**	**C1**	**C2**	**C3**	**C4**		**C5**	**C6**
Schachat	3.06519	31.339	96.05999	0.272472	8.539013	982.1329		3.421557	10.48772
Kinyoun	2.60567	5.269	13.72928	0.003902	0.020562	27.76236		2.221507	5.788515
Pugh	1.60147	20.344	32.58031	0.886857	18.04223	413.8783		3.230913	5.174211
Moss	2.56022	145.181	371.6953	0.00029	0.042051	21077.52		3.741907	9.580105
Totals	9.83255	202.133	514.0649	Q=	26.64385	22501.3		12.61588	31.03055
	Mean=	50.53325	2.543201		SW2=	4095.62		D*=	2.459641
					U=	90.81374		LCB=	1.907822
					Δ=	0.260355		UCB=	3.011461

Optometrists using slit lamp AR									
			N=	**2**					
	D	**W**	**C1**	**C2**	**C3**	**C4**		**C5**	**C6**
Olson	1.59893	44.506	71.16198	0.000405	0.018006	1980.784		660.4056	1055.942
Kleinstein	1.6378	47.7297	78.1717	0.000352	0.01679	2278.124		-299031	-489753
Totals	3.23673	92.2357	149.3337	Q=	0.034797	4258.908		-298370	-488697
	Mean=	46.11785	**1.619044**		SW2=	5.196121		D*=	1.637886
					U=	46.06151		LCB=	
					Δ=	-0.02095		UCB=	

Appendix 8

ORGANISATION OF NHS BOARD COMMISSIONED SCREENING PROGRAMMES IN SCOTLAND

NATIONAL COORDINATION AND SUPPORT
- Undertaking functions best done once for all NHS Boards/Trusts involved

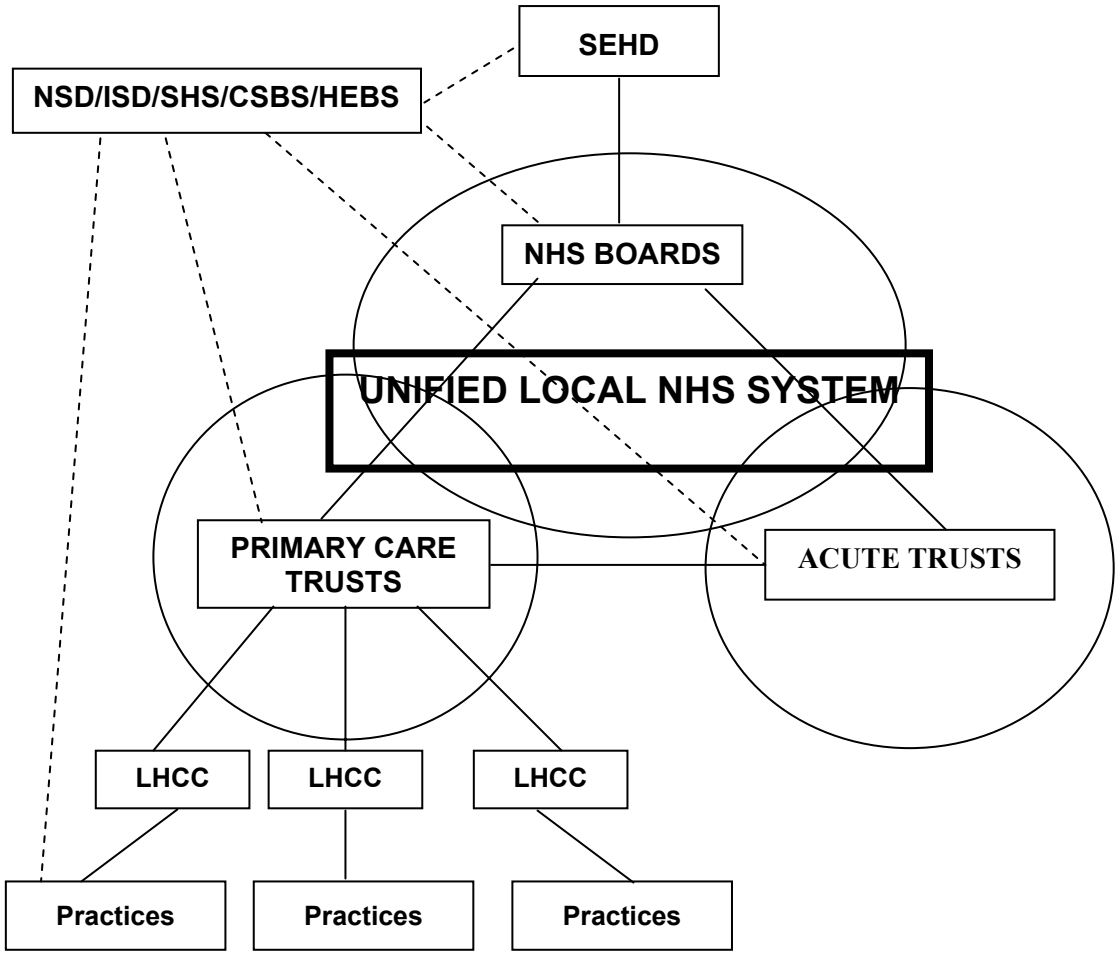
NSD
- Facilitating a consistent and coordinated approach across Scotland
- Bringing together key groups:
  - NHS Board co-ordinators
  - Heads of Screening Programmes in Trusts
  - Quality assurance leads in different disciplines
- Specifying standards for IT call/recall system

ISD
- Aggregating and feeding back information
- Compilation and interpretation of statistics on activity, cost, performance

HEBS
- Patient information leaflets

CSBS
- Comparative assessment of performance against quality standards/peer review

SHS
- Purchasing standardised equipment/technical quality assurance



SEHD ROLE
- Set policy
- Evaluate policy
- Research and development
- Holds NHS Boards to account for performance against standard and achievement of objectives of screening programmes

NHS BOARD STRATEGIC ROLE
- Sets strategy for local implementation
- Responsible for achieving objectives
- Assessing needs
- Performance management of clinical/cost effectiveness of screening programme
- Initiating action when necessary on CSBS reports of performance against standards
- Funding services to meet needs
- Ensures robust call/recall arrangements
- Clinical governance
- Promotes uptake
- Holds Trusts to account for service delivery and clinical quality

TRUSTS/PRIMARY CARE OPERATIONAL ROLE
- Responsible for clinical governance
- Assuring quality
- Staffing
- Operational planning and management
- Provision and upkeep of facilities
- Local coordination between hospitals and primary care
- Service Delivery
- Communication with GPs/service users

Notes: (1) Line of accountability follows solid
(2) Dotted lines show where links are needed to co-ordinate a national screening programme.

Appendix 9

CRAG CLINICAL CARE DATASET FOR DIABETES: EYE CARE DATA

Field description	Field name	Parameter	Note
Visual Acuity – left (corrected)	VA_L	4 characters	44
Visual Acuity – right (corrected)	VA_R	4 characters	44
Permanent blindness as defined	BLIND	0 / 1 / 2 / 3	45
Year of onset of permanent blindness	YRBLIND	Yyyy	
Retinal status – left	RETINA_L	1 / 2 / 3 / 4 / 5 / 6 / 7 / 8 / 9 / 10	46
Retinal status – right	RETINA_R	1 / 2 / 3 / 4 / 5 / 6 / 7 / 8 / 9 / 10	46
Diabetic maculopathy – left	MACULA_L	1 = present; 2 = absent	
Diabetic maculopathy – right	MACULA_R	1 = present; 2 = absent	
Cataract present - left	CATART_L	1 = Yes; 2 = No	
Cataract present - right	CATART_R	1 = Yes; 2 = No	
Previous cataract extraction – left eye	CAT_EXT_L	1 = Yes; 2 = No	
Previous cataract extraction – right eye	CAT_EXT_R	1 = Yes; 2 = No	
Previous vitrectomy – left eye	VIT_L	1 = Yes; 2 = No	
Previous vitrectomy – right eye	VIT_R	1 = Yes; 2 = No	
Year of commencement of first diabetes related laser therapy	YRLASER	Yyyy	
Commencement of course of laser therapy for diabetic retinopathy to left eye on this date	LASER_L	1 = Yes; 2 = No	47
Laser therapy to left eye on this date	LASER_LD	1 = Yes; 2 = No	48
Reason for laser therapy to left eye on this date	LASER_LRE	1 / 2 / 3 / 4	49
Commencement of course of laser therapy for diabetic retinopathy to left eye on this date	LASER_R	1 = Yes; 2 = No	47
Laser therapy to right eye on this date	LASER_RD	1 = Yes; 2 = No	48
Reason for laser therapy to right eye on this date	LASER_LRE	1 / 2 / 3 / 4	49
Method of eye examination	EYE_METH	1 / 2 / 3	50
Who interpreted the finds of the most recent full eye examination?	EYECHECK	1 / 2 / 3 / 4 / 5	51

Notes

44	Visual acuity should be recorded in the corrected state as either: 6/4, 6/5, 6/6, 6/9, 6/12, 6/18, 6/24, 6/36, 6/60, 3/60, CF (counting fingers), HM (hand movements), PL (perception of light).
45	1 = Diabetic cause; 2 = Non-diabetic cause; 3 = Blind – cause unknown; 0 = not blind. Permanent blindness is defined as permanent visual acuity corrected (i.e. wearing corrective lenses) of <3/60 (i.e. CF, HM or PL) in the better eye.
46	1 = No retinopathy; 2 = Background diabetic retinopathy (BDR) mild; 3 = BDR moderate; 4 = BDR–severe; 5 = BDR–very severe; 6 = Proliferative retinopathy (new vessels more that 1DD from disc); 7 = High risk proliferative retinopathy (new vessels at or within 1DD of disc); 8 = Advanced diabetic eye disease; 9 = Enucleated; 10 = Not adequately visualised. Incorporates and replaces SIGN item which allowed three options for Diabetic Retinopathy – Present/Absent/Not visualised. This grading is consistent with the Royal College of Ophthalmologists Report – Guidelines for Diabetic Retinopathy 1997, and is based on the Airlie House grading system used by the Early Treatment of Diabetic Retinopathy Study (ETDRS). Levels 2 and 3 are classed as low risk BDR, 4 and 5 as high risk requiring referral. See Royal College Report for precise definition of grades.
47	Adaptation of SIGN item – now specifies diabetic cause.
48	Record of each and every episode of laser treatment.
49	1 = diabetic maculopathy; 2 = proliferative diabetic retinopathy; 3 = high risk non proliferative diabetic retinopathy; 4 = non diabetic reason.
50	1 = retinal photography; 2 = direct ophthalmoscopy; 3 = slit lamp biomicroscopy
51	1 = diabetologist; 2 = ophthalmologist; 3 = optometrist; 4 = retinal screener; 5 = GP

Appendix 10

EXAMPLE OF PROCUREMENT SPECIFICATION FOR EQUIPMENT TO BE USED IN THE NATIONAL SCREENING PROGRAMME FOR DIABETIC RETINOPATHY

Glasgow Diabetes Project

Retinal Screening Systems

Specification of Need

Authors: David Frame, Allan Jenkins, Ian Laidlaw

Client: Greater Glasgow Primary Care NHS Trust

Version: 5.1

Status: Draft

1. Background

One aim of the Glasgow Diabetes Project is to introduce a screening programme to detect diabetic retinopathy in its early stages.

This disease is symptom free and progression can be prevented by laser treatment, so early diagnosis and treatment using regular screening is beneficial. There is a draft consultation assessment report suggesting the way forward is a national screening strategy however this specification details only Glasgow's requirements.

This document is a Specification of Needs for the supply of retinal screening cameras and associated hardware and software to the Glasgow Diabetes Project on behalf of the Greater Glasgow NHS Board.

2. Guidance

The tender reply **MUST** be structured to allow easy reference to the numbered points in this document. Responses are required to **ALL** points or an explanation for its absence.

Two statements are used in this document:

MUST The supplier **MUST** either conform to these specifications or give reasonable alternatives. These specifications will attract the highest weightings in the evaluation of replies.

SHOULD The supplier may be able to conform to these specifications. If unable to do so, the reason **MUST** be clearly stated. Lower weightings will be given to these points in the evaluation of replies.

3. Evaluation of replies

All Tenders will be evaluated by a team, including the Project Manager, Scottish Healthcare Supplies and staff from the client screening sites.

The evaluation process will consist of a review and scoring of financial summary, technical summary and any other relevant details.

4. Scope

The scope of the tender **MUST** include the provision of the following:

1. Four retinal screening camera stations, and any associated technical equipment
2. Four grading stations and any associated technical equipment
3. One central server with online and offline storage
4. The computing equipment required to control the cameras and to write the images produced to offline storage media, and any technical equipment necessary to connect the computers to the networks within the sites in which the cameras are situated

5. The software to control the cameras, the capture, storage, manipulation and management of the images produced by the cameras, and writing to and retrieving from offline storage media
6. The training required in the effective use of the cameras, associated technology and software
7. The ongoing support and maintenance of the cameras, associated technology and software for image manipulation, grading and reporting
8. Provision of consultancy / assistance with the installation and configuration of all hardware and software components.
9. Additional client licences required to enable consultants to access and manipulate the images at PCs remote from the Camera or Grading stations.

The scope of the tender **SHOULD** include the provision of the following:

1. The software required for call and recall of patient and for the scheduling of screening sessions.

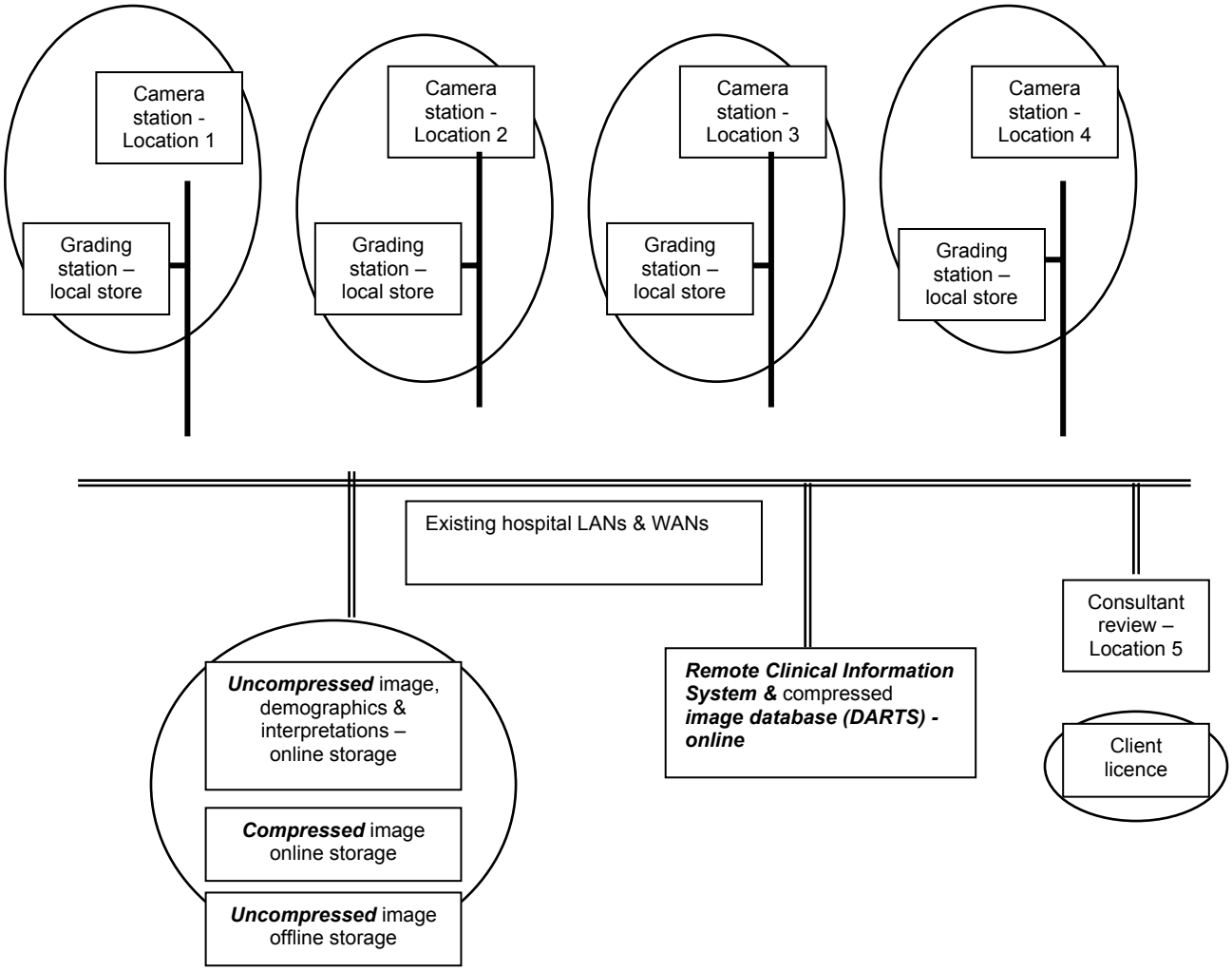
The following terms are used in this document:

"Camera Station" is used to describe the devices (e.g. optical retinal camera, digital camera, computer, monitor, and ancillary equipment) required to acquire the image and image identifying information.
"Grading Station" is used to describe the device(s) (separate PC and monitor) on which diagnostic grading and recording of the interpretation will be performed.

Network communications fall outwith the scope of the tender, but suppliers should nevertheless state clearly in their response the minimum network requirements and performance that their proposed solution assumes. Similarly, the equipment **MUST** be capable of connection to all common network topologies and protocols.

The Glasgow Diabetes Project is at liberty to accept all or part of the overall scope of the tender from the supplier.

The likely layout of the "system" is illustrated on the next page.



Note – Circled items indicate scope of this tender

The above configuration is designed to:

- provide flexibility on the implementation
  (e.g. (i) compressed data may be stored in the screening system, in the Clinical Information System or in both;
  (ii) relocate all Grading Stations to a single location), and
- maximise the benefits of existing facilities
  (e.g. local printers/administration facilities).

5. Scale, location & timescale

Four complete retinal screening digital cameras (camera stations) **MUST** be provided along with four grading workstations and central online and offline storage. These will be sited at the following locations in Glasgow and operate as one system:

- Gartnavel General Hospital (screening camera station and 1 grading workstation)

- Glasgow Royal Infirmary(screening camera station and 1 grading workstation)
- Victoria Infirmary(screening camera station and 1 grading workstation)
- Southern General Hospital (screening camera station and 1 grading workstation)
- Site for central online & offline storage device to be decided (Glasgow Diabetes Project on behalf of Greater Glasgow NHS Board) – a statement of how this service might be delivered **MUST** be included (to include necessary computer hardware and software).

Each patient will have one photograph taken of each eye.

Each camera system **MUST** be capable of coping with the throughput of patients requiring to be screened, as given in the statistics below.

The estimated number of patients is given below:

- Currently identified 20,000 rising to 30,000 over 5 years
- Increase after 5 years – 5% per annum.

The systems are required now, sited at the above locations. Suppliers **MUST** state the time frame for installation.

6. Statement of Need

6.1 Operational Needs

The image capture device **MUST** be a true charge coupled device camera.

The resolution of the camera **MUST** be at least 1365 x 1000 pixels, with full colour capture.

The system (both camera stations and grading stations) **MUST** be provided with a viewing monitor (type cathode ray tube), with a screen resolution of 1600 x 1200, and full colour capability.

The electronic interface for the collection of digital information **SHOULD** be TWAIN compliant, to allow the use of software not provided by the supplier for the capture of images, or to enable the development of specialist software to meet specific needs by NHSScotland.

The camera / computer system **MUST** support direct image transfer from the CCD device to the PC without intermediate conversion to analogue signal.

Image manipulation software provided **MUST** be able to manipulate images at full capture resolution.

The software provided **MUST** be able to capture and store the images at full resolution in a recognised standard format, such as TIFF, as well as storing the produced images at lower resolution in a recognised standard format, such as JPEG.

The software **MUST** be able to support the simultaneous display of several images of the same eye made at different times, for purposes of comparison.

The software **MUST** be able to support the display of several images at the same time of one eye made at the same time from different viewing positions for comparison.

The software **MUST** allow for input of interpretation of the images by the operator. This feature **MUST** be controlled by password access and be logged with relevant details permanently stored with the results.

The software **MUST** support a structured retinal grading system as defined by NHS Scotland (see HTBS Diabetic Retinal Screening Consultation Report 14th November 2001 & Appendix 1)

Each system **MUST** provide a security system which enables all personally identifiable information to be stored to a level of confidentiality acceptable to NHSScotland.

The software **SHOULD** be capable of printing:

- A single photograph
- Multiple photographs taken at the same time
- Multiple photographs taken at different times
- Textual reports with or without photographic images.

The software **SHOULD** be capable of providing facilities for scheduling retinal screening photography sessions, and for patient call and recall at defined intervals

Each system **MUST** be capable of being operated by either:

- technical staff, with no medical / optometric background, or
- nursing staff, with no technical background

6.2 General Software and Computer characteristics

The overall system and software has the following characteristics:

- **SHOULD** provide a user friendly windows style software platform.
- **MUST** provide for on line transfer of captured images and associated identifying patient demographics from the camera stations to the server with minimal user intervention.
- **MUST** provide for off line storage and retrieval of retinal images at capture resolution on removable media where necessary
- Each Grading Station **MUST** provide storage online for a minimum of 250 uncompressed photographs including identifying patient demographics and interpretations.
- Central online storage **MUST** be provided for a minimum of 5,000 uncompressed photographs including identifying patient demographics and interpretations.
- Central online storage **MUST** be provided capable of storing approximately 250,000 compressed photographs over 5 years.

- Central offline storage **MUST** be provided capable of storing approximately 250,000 uncompressed photographs over 5 years.
- Remote access to the central online database to review, validate and monitor results (including image manipulation) **MUST** be possible from a separate location. The supplier **MUST** state any licence cost and installation implications of remote use.
- The retinal screening software **MUST** be capable of automatically exporting summary retinal screening reports and representative compressed images on line to an external database which will form the regional diabetes register and Clinical Information System.
- The retinal screening software **MUST** be capable of automatically importing demographic information on the eligible population for retinal screening from an external database which will form the regional diabetes register and Clinical Information System.
- The retinal screening software **MUST** be capable of importing summary retinal screening reports and representative compressed and uncompressed images from external files.
- Configuration of screen and report formats **MUST** be possible.
- The performance of the grading stations and central server **SHOULD** permit images requested from the server to appear on screen within a maximum 2 second response time. Suppliers **MUST** clearly state the network bandwidth constraints required to achieve this.
- In the event of a system failure the system **MUST** be capable of rapid restoration to the point of failure with no loss of data. Suppliers **MUST** provide a detailed server specification to meet this requirement, which **SHOULD** include RAID disc storage and an uninterrupted power supply.
- **SHOULD** comply with DICOM3 (Digital Imaging Communications in Medicine).
- On line help **MUST** be available.
- **MUST** satisfy connectivity requirements for NHS Net 3rd Party connections. Further details available from ISSG Telecoms (0131 551 8475)
- The supplier **MUST** state the consequences of power failure/interrupt.
- All software and hardware **MUST** be year 2000 compliant.

6.3 Health & Safety

The supplier **MUST** confirm compliance with BSEN60601-1 and all relevant UK and EU electrical, mechanical safety legislation.

The supplier **MUST** confirm compliance with relevant regulation regarding shipping, labelling and information on hazardous substances. COSHH data **MUST** be available for all reagents.

6.4 Data Quality Assurance

The system **MUST** enable a secure audit trail to be created, maintained and reported. This **MUST** include a record of the detail of all changes (e.g. what the change is, who made it, when, previous versions).

The system **SHOULD** support internal QA reporting / alerts to highlight the differences between interpretations.

6.5 Installation

The supplier **MUST** specify the requirements for space, electrical supply, and any other environmental conditions which must be met.

The equipment **SHOULD** be available for delivery within 4-6 weeks.

The supplier **MUST** state what assistance is given during initial setting up at time of installation.

6.6 Training

Training for the camera operators **MUST** be provided in the use of the camera, the IT equipment and the associated software.

Training **MUST** be provided at a time which can be mutually agreed between the Glasgow Diabetes Project and the supplier.

The training **SHOULD** be provided on-site in Glasgow.

CD ROM Help facilities or other PC software **SHOULD** be available for in-house reference.

6.7 Support, Maintenance & Reliability

There **MUST** be simple and automated procedures for:-
- Start-up
- Shut down
- Back up

Time for these procedures **MUST** be stated. They **SHOULD** be less than 5 minutes each.

Daily maintenance time **SHOULD** be zero.

Weekly maintenance time **SHOULD NOT** exceed 15 minutes.

The supplier **MUST** indicate what features and functions have been incorporated in the system design to ensure reliability.

The system **SHOULD** operate over a range of room temperatures (15 - 25°C).

Suppliers **SHOULD** give details of typically experienced downtime.

Suppliers **SHOULD** state whether secure modem support for problem solving is available and, if provided, **MUST** state how security will be implemented and maintained.

Suppliers **MUST** state in which format basic trouble shooting guidelines are available e.g. CD ROM, software feature, or handbook.

Suppliers **MUST** provide ongoing problem solving support.

Suppliers **MUST** provide ongoing regular maintenance.

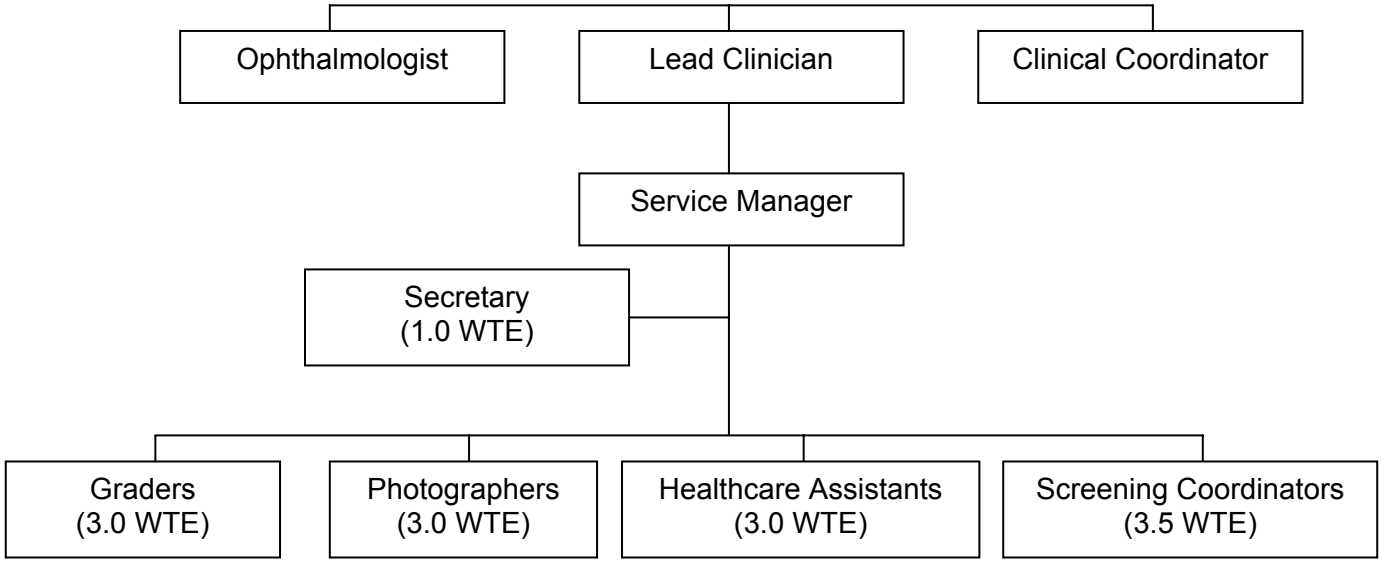
The maintenance agreement available with the camera and associated equipment **MUST** be stated including guaranteed response time, location of nearest engineer, number of available engineers in the UK and location of the service base.

6.8 Reference sites

The supplier **MUST** be able to supply the names and addresses of at least two reference sites who may be visited by members of the evaluation team, and who are prepared to write a letter detailing experience with the camera system and the supplier.

Appendix 11

ORGANISATIONAL STRUCTURE OF THE DIGITAL CAMERA DIABETIC RETINOPATHY SCREENING SERVICE IN BRO TAF



Appendix 12

BRO TAF JOB DESCRIPTIONS

Screening Service Manager

CARDIFF AND VALE NHS TRUST
JOB DESCRIPTION

JOB DETAILS

Job Title:	**Screening Service Manager** (Bro Taf Diabetic Retinopathy Screening Service)
Grade:	Whitley Senior Manager Payscale 24
Department/Directorate:	Diabetic Retinopathy Screening Service
Base:	Llandough Hospital
Service Group:	Medical and Regional Services

ORGANISATIONAL ARRANGEMENTS

Accountable to:	Lead Clinician – Bro Taf DRSS Directorate Manager – Medical Services
Responsible for:	Bro Taf DRSS multidisciplinary team and service provision
Liaises with:	Local and Regional Health Authority staff; local Health Groups (all Wales); primary care – GPs, District Nurses, Optometrists; secondary care – Ophthalmologists, Diabetologists, Nurses; local Diabetic Services Advisory Groups; community Health Council; diabetes UK; national Assembly for Wales; and external companies providing service equipment/software; General public.

JOB PURPOSE

To provide comprehensive managerial support to the Bro Taf DRSS multidisciplinary team in addition to managing, coordinating, planning and quality assuring all aspects of the service ensuring the provision of diabetic retinopathy screening across the Bro Taf district, and to assist in progressing a collaborative approach for retinopathy screening throughout Wales, and the UK.

DUTIES AND RESPONSIBILITIES

1. To manage multidisciplinary team at the Service base including recruitment and selection of staff, individual performance review, monitoring attendance/sickness, and assessing training requirements.

2. To manage Screening Coordinators based at neighbouring hospitals by providing advice and support on a day-to-day basis on a variety of issues including continual validation of patient lists, a smooth and effective operation of call and recall systems, timely distribution of retinopathy report, ophthalmology referrals and patient results.

3. To ensure ongoing compliance and development of quality assurance for all elements of the service ranging from administration, to photography, to three-tier grading.

4. To organise and deploy mobile screening units throughout the Bro Taf locality, ensuring equitable provision of service and ensuring the ongoing maintenance of screening equipment.

5. To maintain the departmental IT infrastructure ensuring ongoing service delivery within a department that uses state of the art technology for image acquisition, storage, analysis and retrieval.

6. To prepare and review quarterly activity reports to the Bro Taf DRSS Steering Committee, and to recommend and lead the implementation of any changes to improve service efficiency.

7. To analyse and report on various types of data, information and statistics relating to the DRSS and to monitor and control any non-Service requests for data by participating in the Bro Taf DRSS Data Ownership Group.

8. To manage the DRSS revenue budget, oversee the capital expenditure and liaise with Finance and Directorate Managers on budget planning and monitoring.

9. To draft and write Standard Operating Procedures for all Service activities.

10. To ensure compliance with statutory requirements and implement and adhere to Trust policies and procedures.

11. To communicate with primary and secondary care sectors, Health Authority staff and voluntary groups, to ensure the dissemination of up-dates on service activity and operational changes, and to provide appropriate lectures and seminars as requested.

12. To represent the Bro Taf DRSS on relevant external committees, and in dealings with other organisations.

13. To attend question and answer sessions for patients and relatives to promote awareness and to progress patient feedback to improve service delivery.

14. To liaise with interested parties concerning the development and organisation of similar services throughout the UK, and globally, to work towards achieving a collaborative approach for retinopathy screening throughout the UK.

HEALTH AND SAFETY REQUIREMENTS

All employees of the Trust have a statutory duty of care for their own personal safety and that of others who may be affected by their acts or omissions. Employees are required to cooperate with management to enable the Trust to meet its own legal duties and to report any hazardous situations or defective equipment.

FLEXIBILITY STATEMENT

The content of this Job Description represents an outline of the post and is therefore not a precise catalogue of duties and responsibilities. The Job Description is therefore intended to be flexible and is subject to review and amendment in the light of changing circumstances, following consultation with the post holder.

Date Prepared: June 2000

Prepared By: P Webb, Service Manager

Date Reviewed: June 2000

Reviewed By: T Legge, Assistant General Manager

Screening Coordinator

CARDIFF AND VALE NHS TRUST

JOB DESCRIPTION

JOB DETAILS

Job Title:	**RETINOPATHY SCREENING COORDINATOR (Vale of Glamorgan locality)**
Grade:	**Whitley A&C 3**
Department/Directorate:	**Diabetic Retinopathy Screening Service Medicine**
Base:	Llandough Hospital
Service Group:	Medical Services

ORGANISATIONAL ARRANGEMENTS

Accountable to:

1. Managerially and professionally accountable to Service Manager at Llandough Hospital

2. Liaises with multi-disciplinary team, primary and secondary care sectors, primary care audit group, patient groups and patients.

JOB PURPOSE

To be responsible for the accurate and timely call/recall of patients for retinal screening, and to be responsible for distributing screening reports to primary and secondary care sectors as part of a district-wide Diabetic Retinopathy Screening Service for the Bro Taf diabetic population.

DUTIES AND RESPONSIBILITIES

1. To allocate screening appointments in accordance with service protocols and notify patients of appointments within specified timescales.

2. To deal with telephone and mail enquiries in respect of screening appointments allocated, rescheduling and cancelling appointments as necessary.

3. To notify primary and secondary care sectors of patients' inability or refusal to attend for screening, in accordance with service protocols.

4. To generate automatic screening reports for the primary care sector from the departmental computer system, ensuring secondary care consultants receive copies as appropriate and ensuring follow-up intervals are in accordance with service protocols.

5. To generate automatic screening reports for ophthalmology referrals, ensuring primary and secondary care sectors are notified in a timely manner of referrals by fax and/or telephone, then post.

6. To record the outcome of ophthalmology referrals within pre-set parameters, taking action to chase up any outstanding outcome letters with ophthalmology secretaries, consulting the service manager when experiencing difficulty in obtaining information.

7. To issue the service manager with ophthalmology outcome details as required.

8. To develop and maintain ongoing relationships with the primary care sectors in respect of holding a valid list of patients suitable for screening, in accordance with screening protocols.

9. To identify and assess sites where retinopathy screening may be carried out, taking into account accommodation standards to ensure that locations are suitable for public transport access, disabled access, etc., and chosen to maximise the use of screening resources.

10. To issue the service manager with dates and venues for future screening clinics, as requested, in order to allow the overall screening schedule for the service to be scheduled and each area given equitable access based on population demand.

11. To assist in covering telephone enquiries for screening coordinator colleagues during sickness and annual leave.

12. To participate in meetings for local patients groups as deemed suitable by the screening service, e.g. updating members on locality issues.

13. To participate in the departmental quality assurance process by providing data and information on locality issues, as requested by the service manager.

14. To record any IT problems in connection with departmental software, in accordance with service protocols.

15. To comply with all departmental Standard Operating Procedures.

16. To respect and adhere to the Trust's Patient Confidentiality Policy with all patient data accessed.

17. To participate in on-going training and accreditation programmes.

HEALTH AND SAFETY REQUIREMENTS

All employees of the Trust have a statutory duty of care for their own personal safety and that of others who may be affected by their acts or omissions. Employees are required to cooperate with management to enable the Trust to meet its own legal duties and to report any hazardous situations or defective equipment.

FLEXIBILITY STATEMENT

The content of this Job Description represents an outline of the post only and is therefore not a precise catalogue of duties and responsibilities. The Job Description is therefore intended to be flexible and is subject to review and amendment in the light of changing circumstances, following consultation with the postholder.

Date Prepared:	May 2001
Prepared by:	P S Webb, Screening Services Manager
Date Reviewed:	May 2001
Reviewed by:	A Evans, Assistant HR Manager

Appendix 13

SAMPLE JOB DESCRIPTION – RETINAL SCREENER

(British Diabetic Association, 1997)

Job Summary

The retinal screener will carry out retinal photography and eye examination using an ophthalmoscope. Retinal photography will be undertaken using both the fixed camera in the Diabetes Centre and the Mobile Eye Screening Unit. The screener will drive the mobile eye screening unit between sites as necessary.

Background

Diabetes is the commonest cause of blindness in the working population of Western nations. Effective treatment for diabetic eye disease is now available, but its impact upon blindness in the population depends entirely upon the effectiveness of screening for early treatable eye disease. Because the progression of eye disease cannot be predicted accurately, screening must be carried out at least annually for each person with diabetes.

The Mobile Retinal Camera concept was developed in the mid-1980s. Twelve units are now functioning nationally. The results of the studies to date have demonstrated the effectiveness of the camera. Screening for eye disease using two methods (Polaroid photography and direct examination of the eye using an ophthalmoscope) is required to achieve sensitivity approaching 100% in detecting eye disease requiring treatment.

Duties of the Post

1. To screen patients using retinal photography, ophthalmoscopy and visual acuity testing.

2. Basic interpretation of retinal photographs.

3. To liaise with clinic staff in all locations to ensure a smooth flow of patients to the screening unit. This involves liaison with the clinics to ensure that the advanced booking patients is satisfactory.

4. To drive the screening unit between clinics as required.

5. To collect operational data including clinical and retinal information and to ascertain the outcome of referral to ophthalmologists.

6. To undertake occasional teaching related to retinal screening within the diabetes centre.

7. To take part in the ongoing R&D activities of the Diabetes Centre.

Training

Training will be provided for the four major tasks: testing visual acuity, taking high-quality retinal photographs, performing ophthalmoscopy, and basic interpretation of retinal appearances.

Attributes required

It is essential that the retinal screener is able to establish rapid friendly and professional relationships with people as patient cooperation is essential for adequate eye examination. Previous experience of dealing with people and a degree of maturity is essential. A moderate degree of manual dexterity and coordination is required. Previous experience of photography is not essential. The individual must be able to organise their own work and to work unsupervised. A degree of flexibility in day to day working hours is required in order to provide screening at distant sites. A clean driving licence is essential.

Professional liaison

The retinal screener will work under the direction of the senior retinal screener, and ultimately the Consultant in Charge of retinal screening. Interaction with diabetes specialist nurses, clinical nurses, practice nurses, reception staff and both junior and senior medical staff is an important part of this job.

Accountability

Clinical accountability to the Consultant in Charge of retinal screening, via the senior retinal screener. Administrative accountability to the manager of the Diabetes Centre.

Salary

Medical Technical Officer 3 scale or higher depending upon training and qualifications.

DRAFT ADVERTISEMENT

Diabetes eye screener/driver is required for the Diabetes Eye Screening Service in the ____ health district. The post will be based in____, but will involve work in clinics throughout the district. The work is interesting, varied and demanding. Training in retinal photography and eye examination will be provided and previous experience in this field is not essential. A clean driving licence is vital. Further details may be obtained from (___Trust).

Appendix 14

DISTRIBUTION OF OPTOMETRISTS IN SCOTLAND

Contracting Authority (CA)	OMP	Ophthalmic Practitioner	Total Registered per CA	Estimated Active Contractors
Ayrshire & Arran	0	105	105	53
Borders	7	41	48	24
Dumfries & Galloway	0	80	80	40
Fife	6	158	164	83
Forth Valley	3	103	106	54
Grampian	0	97	97	49
Greater Glasgow	10	307	317	160
Highland	4	37	41	21
Lanarkshire	6	223	229	116
Lomond & Argyll	0	123	123	62
Lothian	10	193	203	103
Shetland	0	4	4	2
Orkney	0	2	2	1
Renfrew & Inverclyde	0	137	137	69
Tayside	6	87	93	47
Western Isles	0	4	4	2
West Lothian	2	78	80	40
Scotland Total	**22**	**905**	**1,833**	**927**

OMP=Ophthalmic Medical Practitioner

Appendix 15

OPTOMETRISTS TRAINING AND ACCREDITATION WITH INDIRECT OPHTHALMOSCOPY

Draft, The College of Optometrists, October 2001

The training of screeners is an important element in the establishment of an efficient and effective optometry screening programme for diabetic eye disease. Training is necessary in order to teach the epidemiology, natural history and signs of diabetic eye disease, and to indicate clearly those patients who should and should not be referred.

The form of the training programme will vary between localities and depend upon the experience of those practitioners taking part in the scheme. In order for a training element of a local community diabetic eyecare scheme to be accredited by the College of Optometrists training should, however, include the following components:

1. **An introduction to local diabetes care services:**

   - The role of optometry within the overall clinical service structure.
   - The local optometry screening framework.
   - Communication routes and all relevant paperwork.

2. **General medical aspects of diabetes:**

   - The pathology of diabetes and its classification.
   - Epidemiology, predisposing and risk factors.
   - Treatment and monitoring.
   - Patient education and its importance.
   - Non-ophthalmic complications of diabetes.
   - Other medical problems that may coexist.

3. **The ophthalmic aspects of diabetes:**

   - Changes in refractive error (hypermetropic and myopic shifts).
   - Iris and rubeosis.
   - Cataract
   - The epidemiology and classification of diabetic retinopathy, including risk factors
   - The pathology of diabetic retinopathy
   - The recognition and grading of fundus changes
   - The relative risks to vision from various forms of retinopathy.
   - The treatment of retinopathy and its results.
   - The use and complications of mydriatics.

4. Assessment:

At the completion of the training the skills of the participant should be assessed. The assessment should contain the following elements:

- A test of knowledge using multiple choice questions or other suitable format.
- Visual recognition of ocular diabetic complications; especially sight threatening, or potentially sight threatening, changes which require onward referral, including;
  - An assessment of photographic or digital images.
  - An examination of patients.
- A test of proficiency in binocular indirect ophthalmoscopy techniques.

NB. An assessment binocular indirect ophthalmoscopy may be incorporated in the examination of diabetic patients.

Examination techniques

It is expected that all participating practitioners will be proficient in specified investigative techniques as laid down locally, eg. indirect ophthalmoscopy, Goldmann applanation tonometry and slit-lamp biomicroscopy. Where practitioners are not proficient in specified techniques it should be determined locally whether suitable training should be provided.

5. Maintenance of Skill Levels:

Continuing Professional Development

Training and development for optometrists and other professional people is not a one-off activity but a continuous and ongoing process. It is expected that all optometrists will comply with the requirements of the College CET Scheme.

Local community diabetic eyecare schemes should therefore incorporate the following elements:

- Re-training and re-assessment for continued accreditation and participation in the scheme.
- A re-training and re-assessment period of no more than 2 years.

Minimum Patient Numbers

Schemes should recognise that participating practitioners must examine a sufficient number of patients on a regular basis in order to maintain skills and expertise achieved during a training programme. Local community diabetic eyecare schemes should therefore include a locally agreed minimum requirement for patient contacts under the scheme.

Appendix 17

DATA EXTRACTION: KEY STUDIES FOR ECONOMIC MODELLING

<table>
<tr><td>Study Paper</td><td colspan="3">Davies et al., 1996</td></tr>
<tr><td>Study Perspectives</td><td>Clinical Data Sources</td><td>Screening Technology</td><td>Results</td></tr>
<tr><td>Develop techniques to evaluate screening modes for insulin dependent diabetic retinopathy</td><td>Insulin dependent patients aged under 35</td><td rowspan="3">Screening options include ophthalmologists, GPs or optometrists</td><td rowspan="8">Where screening sensitivities are high the frequency of screening makes little difference to years of sight saved but does make a difference if screening sensitivities are close to 50%</td></tr>
<tr><td>Study Population</td><td>Economic Data Sources</td></tr>
<tr><td>Liverpool and Denmard</td><td>Not applicable</td></tr>
<tr><td>Outcome Measures</td><td>Method of Analysis</td><td>Discounting</td></tr>
<tr><td>Average years of sight saved</td><td>Simulation of data and comparison to prevalence information</td><td>Not used</td></tr>
<tr><td colspan="3">Assumptions: The model assumes a patient progresses through several states from no retinopathy to proliferate retinopathy and treatment using observed data from clinical trials. Various screening options, each with its own sensitivity and specificity and a risk of severe visual loss reduced following treatment were modelled to measure the effects of screening options.</td></tr>
<tr><td colspan="3"></td></tr>
<tr><td colspan="3">Comments: The model can be developed to explore the benefits of screening non-insulin dependent diabetics.</td></tr>
<tr><td colspan="3"></td></tr>
</table>

<table>
<tr><td>Study Paper</td><td colspan="3">James et al., 2000</td></tr>
<tr><td>Study Perspectives</td><td>Clinical Data Sources</td><td>Screening Technology</td><td>Results</td></tr>
<tr><td>Cost-effectiveness of systematic screening</td><td>2 studies within the Liverpool diabetic eye study</td><td rowspan="2">Mobile screening unit using 3-field photography with mydriasis vs. opportunistic service using ophthalmoscopy</td><td rowspan="7">Cost-effectiveness of systematic programme was £209/true case detected, an incremental reduction of £32/true case compared to opportunistic screening.</td></tr>
<tr><td>Study Population</td><td>Economic Data Sources</td></tr>
<tr><td>5,000 diabetic patients in Liverpool</td><td>Liverpool Trust data and GP costs from Netten & Dennett</td><td></td></tr>
<tr><td>Outcome Measures</td><td>Method of Analysis</td><td>Discounting</td></tr>
<tr><td>Cost of true case detected</td><td>Modelling of 2 methods</td><td>Not applicable</td></tr>
<tr><td colspan="3">Assumptions: Baseline prevalence of 14.1% of sight-threatening eye disease .</td></tr>
<tr><td colspan="3"></td></tr>
<tr><td colspan="3">Comments: accurate data on sensitivity, specificity and compliance is needed to complete analysis .</td></tr>
<tr><td colspan="3"></td></tr>
</table>

Study Paper	Vijan *et al*., 2000		
Study Perspectives	**Clinical Data Sources**	**Screening Technology**	**Results**
Benefit of annual vs. less frequent eye screening intervals for non-insulin dependent diabetics	Epidemiological studies	Ophthalmologists	Annual retinal screening for low risk patients may not be warranted on basis of cost-effectiveness.
Study Population	**Economic Data Sources**		
Hypothetical patients based on the US population of diabetic patients over 40.	Medicare reimbursement costs		
Outcome Measures	**Method of Analysis**	**Discounting**	
Gains in sight days and QALYs from annually screening and costs of screening	Monte Carlo simulation and repeated samples from a multivariate distribution of ranges	Not applied	
Assumptions: Incidence of progressing through to proliferative retinopathy assumed to be related to level of glycemic control **.**			
Comments: Costs are not directly relevant to Scottish costs and screenings methods are more varied.			

Appendix 18

COSTING ASSUMPTIONS

Base Case Costing Assumptions	
Population	5,120,000
Diabetes prevalence	3.0%
Screening attendance	80%
Unfilled screening slots	5%
Diabetics not amenable to digital photography	
Mydriatic digital photography	5%
Non-mydriatic digital photography	8%
Grading % passed to next level	
Level 1 to level 2	33%
Level 2 to level 3	33%
Quality assurance review %	5%
Ophthalmology referral angiograms % – true +ves	20%
Optometrist fee	£20
Equipment maintenance %	5%
Financial discount rate	6%

Timings	**Drive Time**	**Preparation/ Setting up/ Dismantling**	**Per Patient**
Mydriatic, mobile, GP, one staff, digital camera	2 hrs	30 min	20 min
Mydriatic, mobile, GP, two staff, digital camera	2 hrs	30 min	15 min
Mydriatic, mobile, van, one staff, digital camera	2 hrs	20 min	20 min
Mydriatic, static, hospital, one staff, digital camera	..	15 min	20 min
Mydriatic, static, hospital, two staff, digital camera	..	15 min	15 min
Non-mydriatic, mobile, van, one staff, digital camera	2 hrs	20 min	10 min
Non-mydriatic, static, hospital, one staff, digital camera	..	15 min	10 min
Mydriatic, static, hospital, two staff, slit lamp	..	15 min	10 min
Mydriatic grading	..	..	5 min
Non-mydriatic grading	..	..	3 min
Ophthalmology referral – true +ves	..	..	25 min
Ophthalmology referral – false +ves	..	..	15 min

Appendix 19

FIXED COSTS

National Coordination (Established within CSA)						
Item	**Number**	**Lifespan**	**Unit cost**	**Year 1**	**Recurrent**	**Annualised**
Capital Equipment						
PC	2	3	2,000	4,000		1,498
Printers	1	5	800	800		190
Furniture	2	10	1,500	3,000		408
Consumables						
Travel	1		1,500	1,500	1,500	1,500
Sundries	2		250	500	500	500
Telephone	2		200	400	400	400
Staffing						
Grade 4/5 C/O WTE	1.0		22,750	22,750	22,750	22,750
Grade 7/8 C/O WTE	1.0		40,300	40,300	40,300	40,300
Equipment Maintenance			390	390	390	390
Total				**73,640**	**65,840**	**67,936**

Health Board Coordination (12.5 Large HB Equivalent)						
Item	**Number**	**Lifespan**	**Unit cost**	**Year 1**	**Recurrent**	**Annualised**
Capital Equipment						
PC	8.5	3	2,000	17,000		6,367
Printers	4.3	5	800	3,400		808
Furniture	8.5	10	1,500	12,750		1,732
Consumables						
Travel	6		1,500	9,000	9,000	9,000
Sundries	6		250	1,500	1,500	1,500
Telephone	6		200	1,200	1,200	1,200
Staffing						
Project Facilitator	6.0		23,114	138,684	138,684	138,684
Consultant	2.5		65,766	164,415	164,415	164,415
Clerical	2.5		18,200	45,500	45,500	45,500
Equipment Maintenance			1528	1528	1528	1528
Total				**394,977**	**361,827**	**370,733**

Call/Recall Software Development and Maintenance			
Item	**Year 1**	**Recurrent**	**Annualised**
System Development	291,000		17,460
Server Development	28,000		1,680
Software and Development	35,000		2,100
Environment	1,400	700	784
Consumables		135,000	135,000
Contingency	35,540	14,870	17,002
Total	**390,940**	**163,570**	**187,026**
Indicative figures from CMT, end user PC and printer costs within budget for local screening offices			

Image Capture Software Development and Maintenance	Year 1	Recurrent	Annualised
Total	**30,000**	**30,000**	**30,000**
Indicative figures from Tayside Screening Programme			

Call/Recall (Hospital-based)						
Item	**Number**	**Lifespan**	**Unit cost**	**Year 1**	**Recurrent**	**Annualised**
Capital Equipment						
PC	2	3	2,000	4,000		1,498
Printers	2	5	800	1,600		380
Fax	1	5	200	200		48
Letter folder	1	10	4,000	4,000		543
Franking machine	1	10	4,000	4,000		543
Furniture	2	10	1,500	3,000		408
Consumables						
Paper	60,000		0.004	240	240	240
Envelopes	25,000		0.009	225	225	225
Toner	60,000		0.007	420	420	420
Patient Education Leaflet	12,000		0.050	600	600	600
Postage	25,000		0.200	5,000	5,000	5,000
Telephone	2		200	400	400	400
ISDN	1		800	800	800	800
Staffing						
Grade 4/5 C/O WTE	1.0		22,750	22,750	22,750	22,750
Grade 2/3 C/O WTE	1.0		18,200	18,200	18,200	18,200
Equipment Maintenance			550	840	840	840
Hospital Buildings	225		11	2,475	2,475	2,475
Unit Sub-Total				**68,750**	**51,950**	**55,370**
Unit No.	10			687,500	519,500	553,700
Additional Allowances	3		25,085	75,255	75,255	75,255
Total				**762,755**	**594,755**	**628,955**

The costs of call/recall software development and maintenance are taken from an indicative costing by SchlumbergerSema, which has developed and run similar software in other screening programmes for NHSScotland. These are not firm figures, and any contract would be required to go to tender. Their basis is as below.

Call/recall software development and maintenance is based upon 15 NHS Boards handling approximately 150,000 people with ten administrative screening offices connected to NHSNet. The system would be run from a central server, with access to CHI/UPI databases for each NHS Board area and a similar call/recall to cytology system and will allow new patient registrations and patient movement in/out functions. The system will be rolled out to an initial pilot site, followed by full roll-out after a three month trial period.

The system will have a batch interface and an online interface to the CHI applications. The system will have approximately 12 menu screens and 30 data entry and control screens, but will have no payments calculations. It will provide 20 standard reports with a Business Objects capability, permitting creation of adhoc customised output reports.

Production, development, testing and training environments are all required. A system user manual and training guide is required. Customer training will be carried out on-site and it is assumed that no more than four staff will need to be trained at each operational centre. Technical services and desktop support will be done by staff already covered by the NHSScotland/Sema cost model. Helpdesk services will be provided by the Sema NHSScotland SMC desk using existing resources.

Appendix 20

VARIABLE COSTS

Mydriatic, Mobile, GP-based, one Staff Member, Digital Camera						
Item	**Number**	**Lifespan**	**Unit cost**	**Year 1**	**Recurrent**	**Annualised**
Capital Equipment						
TRC50EX Fundus Camera	1	5	17,813	17,813		4,231
JVC scsi Capture	1	5	9,185	9,185		2,182
Video relay lens	1	5	2,779	2,779		660
Camera trolley	1	10	3,000	3,000		408
Laptop computer	1	3	2,000	2,000		749
Van purchase	1	5	17,500	17,500		4,157
Consumables and Recurrent						
Van maintenance	1		720	720	720	720
Fuel	514		4	2,057	2,057	2,057
GP Room Rental	1,000		6.1	6,100	6,100	6,100
Flash tubes	1		716	0	367	367
Sundries	2,565		0.2	513	513	513
Staffing						
MTO Grade 3	1		20,958	20,958	20,958	20,958
Training	1	5	13,025	13,025		3,094
Equipment Maintenance				1,739	1,739	1,739
Total				**97,388**	**32,454**	**47,934**
Cost per Screen				37.97	12.65	18.69

Mydriatic, Mobile, GP-based, two Staff Members, Digital Camera						
Item	**Number**	**Lifespan**	**Unit cost**	**Year 1**	**Recurrent**	**Annualised**
Capital Equipment						
TRC50EX Fundus Camera	1	5	17,813	17,813		4,231
JVC scsi Capture	1	5	9,185	9,185		2,182
Video relay lens	1	5	2,779	2,779		660
Camera trolley	1	10	3,000	3,000		408
Laptop computer	1	3	2,000	2,000		749
Van purchase	1	5	17,500	17,500		4,157
Consumables and Recurrent						
Van maintenance	1		720	720	720	720
Fuel	514		4	2,057	2,057	2,057
GP Room Rental	1,000		6.1	6,100	6,100	6,100
Flash tubes	1		716	0	490	490
Sundries	3,420		0.2	684	684	684
Staffing						
MTO Grade 3	1		20,958	20,958	20,958	20,958
Nurse Grade D	1		18,656	18,656	18,656	18,656
Training	1	5	13,025	13,025		3,094
Equipment Maintenance				1,739	1,739	1,739
Total				**116,215**	**51,404**	**66,884**
Cost per Screen				33.98		19.56

Mydriatic, Mobile, Van-based, one Staff Member, Digital Camera						
Item	**Number**	**Lifespan**	**Unit cost**	**Year 1**	**Recurrent**	**Annualised**
Capital Equipment						
TRC50EX Fundus Camera	1	5	17,813	17,813		4,231
JVC scsi Capture	1	5	9,185	9,185		2,182
Video relay lens	1	5	2,779	2,779		660
ATE 600 table top	1	10	661	661		90
Laptop computer	1	3	2,000	2,000		749
Van purchase	1	5	26,310	26,310		6,249
Consumables and Recurrent						
Van maintenance	1		720	720	720	720
Fuel	514		4	2,057	2,057	2,057
Flash tubes	1		716	0	381	381
Sundries	2,662		0.2	532	532	532
Staffing						
MTO Grade 3	1		20,958	20,958	20,958	20,958
Training	1	5	13,025	13,025		3,094
Equipment Maintenance				1,622	1,622	1,622
Total				**97,661**	**26,271**	**43,525**
Cost per Screen				36.69	9.87	16.35

Non-Mydriatic, Mobile, Van-based, one Staff Member, Digital Camera						
Item	**Number**	**Lifespan**	**Unit cost**	**Year 1**	**Recurrent**	**Annualised**
Capital Equipment						
TRCNWS6S digital	1	5	16,673	16,673		3,960
JVC scsi capture	1	5	9,185	9,185		2,182
ATE 600 table top	1	10	661	661		90
Laptop computer	1	3	2,000	2,000		749
Van purchase	1	5	19,500	19,500		4,632
Consumables and Recurrent						
Van Maintenance	1		720	720	720	720
Fuel	600		4	2,400	2,400	2,400
Flash tubes	1		716	0	404	404
Sundries	5,358		0.15	804	804	804
Staffing						
MTO Grade 3	1		20,958	20,958	20,958	20,958
Training	1	5	13,025	13,025		3,094
Equipment Maintenance			1,426	1,426	1,426	1,426
Total				**87,350**	**26,711**	**41,418**
Cost per Screen				16.30		7.73

Mydriatic, Static, Hospital-based, one Staff Member, Digital Camera						
Item	**Number**	**Lifespan**	**Unit cost**	**Year 1**	**Recurrent**	**Annualised**
Capital Equipment						
TRC50EX Fundus Camera	1	5	17,813	17,813		4,231
JVC scsi Capture	1	5	9,185	9,185		2,182
Video relay lens	1	5	2,779	2,779		660
AIT 15 Table Top	1	10	860	860		117
Furniture	1	10	1,500	1,500		204
PC Computer	1	3	2,000	2,000		749
Consumables and Recurrent						
Flash tubes	1		716	0	551	551
Sundries	3,848		0.2	770	770	770
Staffing						
MTO Grade 3	1		20,958	20,958	20,958	20,958
Training	1	5	13,025	13,025		3,094
Equipment Maintenance				1,532	1,532	1,532
Hospital Overheads	3,848		4	15,390	15,390	15,390
Total				**85,810**	**39,200**	**50,437**
Cost per Screen				22.30	10.19	13.11

Mydriatic, Static, Hospital-based, two Staff Members, Digital Camera						
Item	**Number**	**Lifespan**	**Unit cost**	**Year 1**	**Recurrent**	**Annualised**
Capital Equipment						
TRC50EX Fundus Camera	1	5	17,813	17,813		4,231
JVC scsi Capture	1	5	9,185	9,185		2,182
Video relay lens	1	5	2,779	2,779		660
AIT 15 Table Top	1	10	860	860		117
Furniture	1	10	1,500	1,500		204
PC	1	3	2,000	2,000		749
Consumables and Recurrent						
Flash tubes	1		716	0	735	735
Sundries	5,130		0.2	1,026	1,026	1,026
Staffing						
MTO Grade 3	1		20,958	20,958	20,958	20,958
Nurse Grade D	1		18,656	18,656	18,656	18,656
Training	1	5	13,025	13,025		3,094
Equipment Maintenance				1,532	1,532	1,532
Hospital Overheads	5,130		4	20,520	20,520	20,520
Total				**109,853**	**63,426**	**74,663**
Cost per Screen				21.41		14.55

Non Mydriatic, Static, Hospital-based, one Staff Member, Digital Camera						
Item	**Number**	**Lifespan**	**Unit cost**	**Year 1**	**Recurrent**	**Annualised**
Capital Equipment						
TRCNWS6S digital	1	5	16672.5	16,673		3,960
JVC scsi capture	1	5	9184.5	9,185		2,182
ATE 600 table top	1	10	661.05	661		90
Furniture	1	10	1500	1,500		204
PC	1	3	2,000	2,000		749
Consumables and Recurrent						
Sundries	7,695		0.15	1,154	1,154	1,154
Flash tubes	1		716	0	551	551
Staffing						
MTO Grade 3	1		20,958	20,958	20,958	20,958
Training	1	5	13,025	13,025		3,094
Equipment Maintenance				1,326	1,326	1,326
Hospital Overheads	7,695		4	30,780	30,780	30,780
Total				**97,261**	**54,769**	**65,047**
Cost per Screen				12.64		8.45

Mydriatic, Static, Hospital-based, two Staff Members, Slit Lamp						
Item	**Number**	**Lifespan**	**Unit cost**	**Year 1**	**Recurrent**	**Annualised**
Capital Equipment						
SL75 Slit Lamp	1	10	7,470	7,470		1,015
Ocular 90D Indirect Lens	1	10	128	129		17
W-A Coaxial Scope	1	10	315	316		43
Snellen Chart	1	10	409.5	410		56
Perkins tonometer	1	10	900.9	901		122
Furniture	1	10	1,500	1,500		204
PC	1	3	2,000	2,000		749
Consumables and Recurrent						
Sundries	7,695		0.2	1,539	1,539	1,539
Staffing						
Staff Grade Doc	1		35,731	35,731	35,731	35,731
Nurse Grade D	1		18,656	18,656	18,656	18,656
Equipment Maintenance				461	461	461
Hospital Overheads	7,695		4	30,780	30,780	30,780
Total				**99,893**	**87,167**	**89,374**
Cost per Screen				12.98	11.33	11.61

Training	Days/No	Unit Cost	Total
MTO Grade 3 (trainee)			
Residential training	15.00	104.79	1,572
Accommodation	15.00	50.00	750
Travel	3.00	30.00	90
Supervised training	36.00	104.79	3,772
Consultant (res training)	1.88	328.83	617
MTO 5 (supervised training)	36.00	154.83	5,574
Room hire (per trainee)	1.88	80.00	150
Materials (per trainee)	1.00	500.00	500
Total			**13,025**

Mydriatic Grading Costs, two Fields per Eye						
Item	**Number**	**Lifespan**	**Unit cost**	**Year 1**	**Recurrent**	**Annualised**
Capital Equipment						
PC	11.0	3	2,000	22,000		8,240
Printers	4	5	800	2,933		697
Furniture	11.0	10	1,500	16,500		2,242
ISDN Connection	7.0	5	80	560		133
Consumables and Recurrent						
Sundries	169,483		0.15	25,422	25,422	25,422
ISDN Rental	7.0		200	1,400	1,400	1,400
Staffing						
A&C Grade 5	1		23,114	23,114	23,114	23,114
Grader MTO 3	7		20,958	146,706	146,706	146,706
Grader MTO 5	2.3		30,965	71,721	71,721	71,721
Consultant Ophthalmologist	1.1		65,766	73,794	73,794	73,794
Equipment Maintenance				2,072	2,072	2,072
Office Rental and Overheads	320		11.00	3,523	3,523	3,523
Total				**389,745**	**347,752**	**359,063**
Cost per Grading				3.34		3.08

Non-mydriatic Grading Costs, one Field per Eye						
Item	**Number**	**Lifespan**	**Unit cost**	**Year 1**	**Recurrent**	**Annualised**
Capital Equipment						
PC	6.0	3	2,000	12,000		4,494
Printers	2	5	800	1,600		380
Furniture	6.0	10	1,500	9,000		1,223
ISDN Connection	8	5	80	640		152
Consumables and Recurrent						
Sundries	176,244		0.15	26,437	26,437	26,437
ISDN Rental	4.0		200	800	800	800
Staffing						
A&C Grade 5	1		23,114	23,114	23,114	23,114
Grader MTO 3	4		20,958	83,832	83,832	83,832
Grader MTO 5	1.2		30,965	37,043	37,043	37,043
Consultant Ophthalmologist	0.6		65,766	39,378	39,378	39,378
Equipment Maintenance				1,130	1,130	1,130
Office Rental and Overheads	190		11.00	2,093	2,093	2,093
Total				**237,067**	**213,827**	**220,076**
Cost per Grading				2.10		1.95

Appendix 21

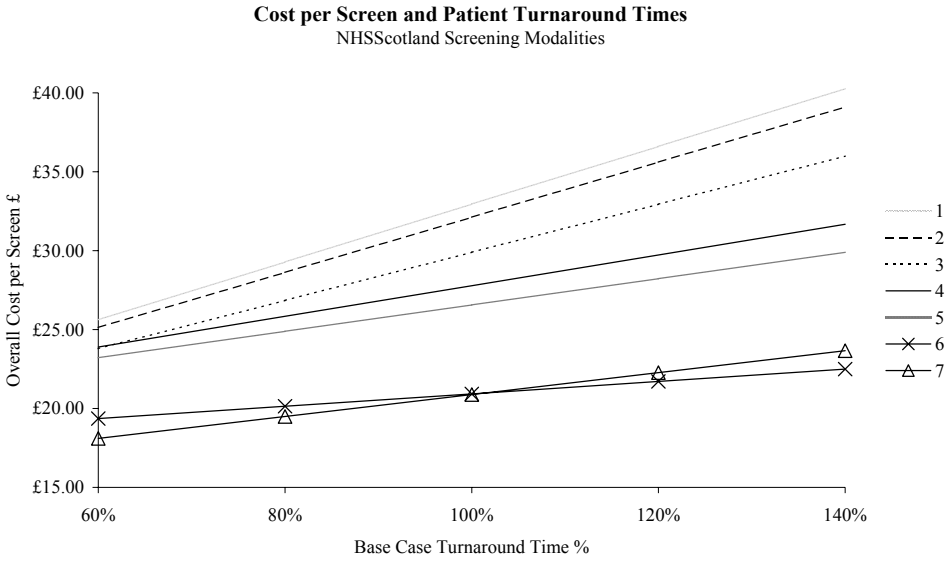
OVERALL COST PER SCREEN AND PATIENT TURNAROUND TIMES

Sensitivity analysis of the effect of different patient turnaround times as a percentage of the base case upon the overall cost per screen for screening modalities:

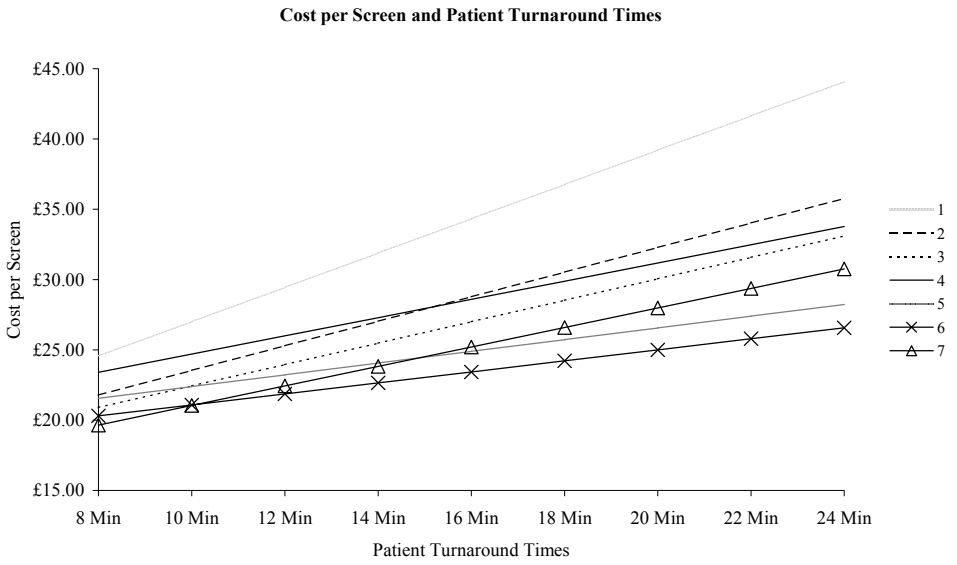
1. mydriatic, mobile, GP-based, double staffed (15 min);
2. mydriatic, mobile, GP-based, single staffed (20 min);
3. mydriatic, mobile, van-based, single staffed (20 min);
4. mydriatic, static, hospital-based, double staffed (15 min);
5. mydriatic, static, hospital-based, single staffed (20 min);
6. non-mydriatic, static, hospital-based, single staffed (10 min); and
7. non-mydriatic, mobile, van-based, single staffed (10 min).

Base case turnaround times in parentheses.

% of Base Case Turnaround Time	60%	80%	100%	120%	140%
Modality 1	£25.78	£29.44	£33.11	£36.76	£40.42
Modality 2	£25.29	£28.78	£32.28	£35.77	£39.26
Modality 3	£23.95	£27.00	£30.06	£33.10	£36.15
Modality 4	£24.05	£26.00	£27.94	£29.88	£31.83
Modality 5	£23.22	£24.89	£26.56	£28.23	£29.90
Modality 6	£19.52	£20.30	£21.09	£21.87	£22.65
Modality 7	£18.26	£19.65	£21.04	£22.43	£23.82



A similar analysis can be performed to show the cost per screen of the different screen modalities for absolute turnaround times, as shown below.



Appendix 22

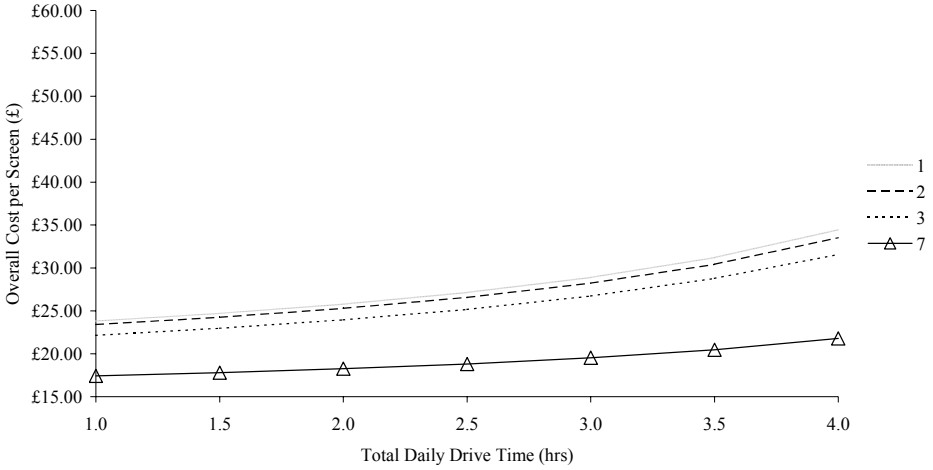
OVERALL COST PER SCREEN AND TOTAL DAILY DRIVE TIMES

Sensitivity analysis of the effect of different total daily drive times upon the overall cost per screen for mobile screening modalities:

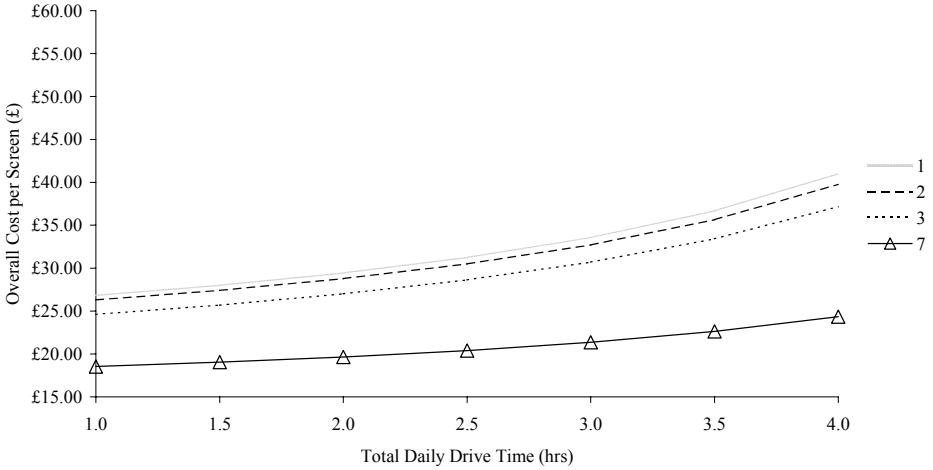
1. mydriatic, mobile, GP-based, double staffed;
2. mydriatic, mobile, GP-based, single staffed;
3. mydriatic, mobile, van-based, single staffed; and
7. non-mydriatic, mobile, van-based, single staffed.

60% of base case turnaround time							
Drive Time	1.0 hr	1.5 hrs	2.0 hrs	2.5 hrs	3.0 hrs	3.5 hrs	4.0 hrs
Modality 1	£23.81	£24.70	£25.78	£27.14	£28.88	£31.20	£34.45
Modality 2	£23.42	£24.26	£25.29	£26.57	£28.23	£30.43	£33.52
Modality 3	£22.16	£22.97	£23.95	£25.17	£26.73	£28.77	£31.58
Modality 7	£17.42	£17.80	£18.26	£18.82	£19.54	£20.48	£21.78
80% of base case turnaround time							
Drive Time	1.0 hr	1.5 hrs	2.0 hrs	2.5 hrs	3.0 hrs	3.5 hrs	4.0 hrs
Modality 1	£26.82	£28.00	£29.44	£31.25	£33.57	£36.67	£41.00
Modality 2	£26.29	£27.41	£28.78	£30.50	£32.70	£35.64	£39.76
Modality 3	£24.61	£25.69	£27.00	£28.63	£30.70	£33.42	£37.17
Modality 7	£18.53	£19.04	£19.65	£20.40	£21.36	£22.62	£24.34
100% of base case turnaround time							
Drive Time	1.0 hr	1.5 hrs	2.0 hrs	2.5 hrs	3.0 hrs	3.5 hrs	4.0 hrs
Modality 1	£29.82	£31.30	£33.10	£35.36	£38.26	£42.13	£47.55
Modality 2	£29.16	£30.56	£32.28	£34.42	£37.18	£40.85	£46.00
Modality 3	£27.06	£28.41	£30.05	£32.08	£34.67	£38.08	£42.76
Modality 7	£19.65	£20.27	£21.04	£21.98	£23.18	£24.75	£26.90
120% of base case turnaround time							
Drive Time	1.0 hr	1.5 hrs	2.0 hrs	2.5 hrs	3.0 hrs	3.5 hrs	4.0 hrs
Modality 1	£32.82	£34.60	£36.76	£39.47	£42.95	£47.60	£54.10
Modality 2	£32.03	£33.71	£35.77	£38.34	£41.65	£46.06	£52.24
Modality 3	£29.51	£31.13	£33.10	£35.54	£38.47	£42.73	£48.35
Modality 7	£20.76	£21.51	£22.43	£23.56	£25.00	£26.88	£29.47
140% of base case turnaround time							
Drive Time	1.0 hr	1.5 hrs	2.0 hrs	2.5 hrs	3.0 hrs	3.5 hrs	4.0 hrs
Modality 1	£35.83	£37.89	£40.42	£43.58	£47.65	£53.06	£60.65
Modality 2	£34.90	£36.86	£39.26	£42.27	£46.13	£51.27	£58.47
Modality 3	£31.96	£33.85	£36.15	£39.00	£42.62	£47.39	£53.94
Modality 7	£21.87	£22.75	£23.82	£25.14	£26.81	£29.01	£32.03

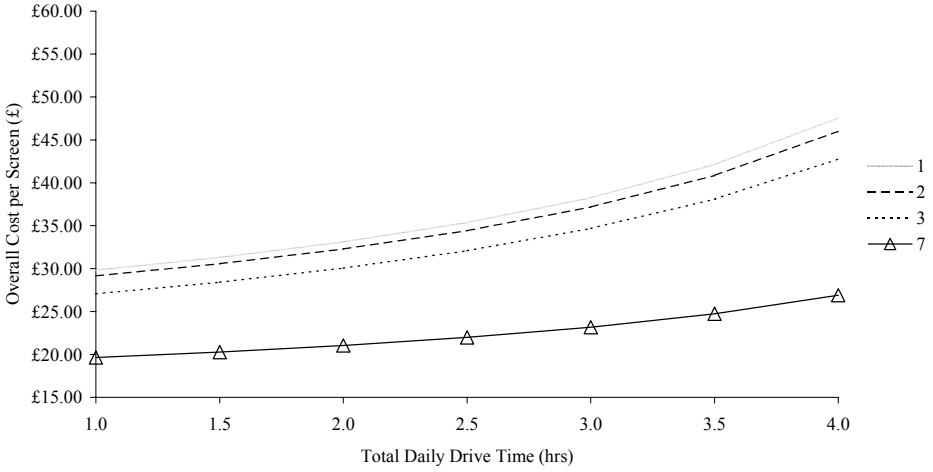
Cost Per Screen and Drive Times
60% of Base Case Turnaround Times



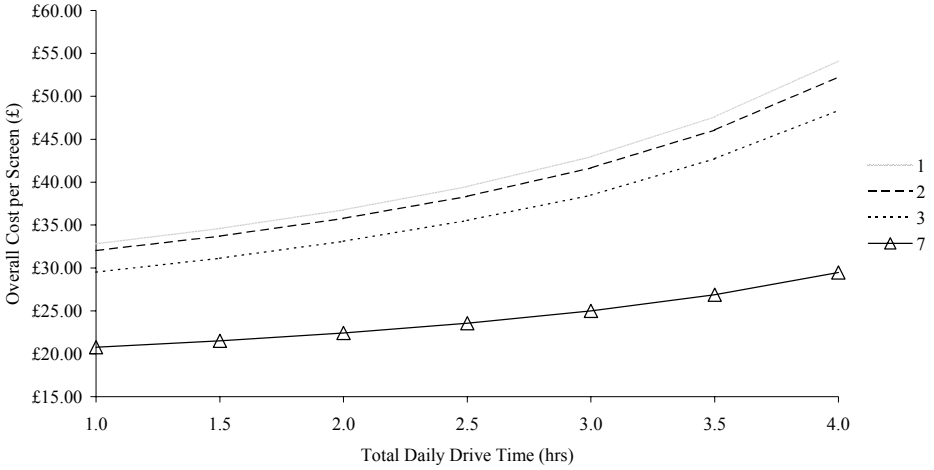
Cost per Screen and Drive Times
80% of Base Case Turnaround Times



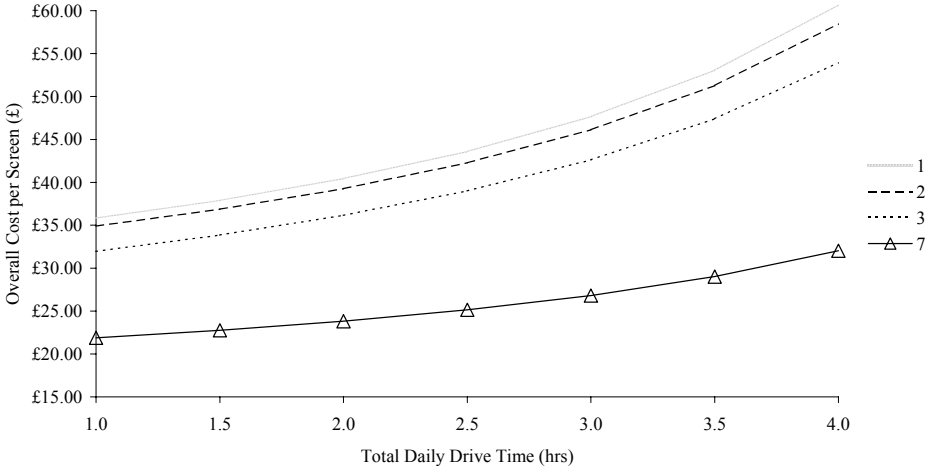
Cost per Screen and Drive Times
100% of Base Case Turnaround Times



Cost per Screen and Drive Times
120% of Base Case Turnaround Times



Cost Per Screen and Drive Times
140% of Base Case Turnaround Times



Appendix 23

COST OF REFERRALS TO OPHTHALMOLOGY

True +ves						
Item	**Number**	**Lifespan**	**Unit cost**	**Year 1**	**Recurrent**	**Annualised**
Capital Equipment						
Haag Streit Slit Lamp	1	10	8,000	8,000		1,087
Ocular 90D Indirect Lens	1	10	129	129		17
W-Allen Scope	1	10	316	316		43
Snellen Chart	1	10	410	410		56
Perkins tonometer	1	10	901	901		122
Furniture	2	10	1,500	204		408
PC	1	3	2,000	2,000		749
Consumables						
Sundries	3,500		0.2	700	700	700
Angiograms	700		50	35,000	35,000	35,000
Staffing						
Consultant Opthalmologist	1		65,766	65,766	65,766	65,766
Nurse Grade D	1		18,656	18,656	18,656	18,656
Equipment Maintenance				488	488	488
Hospital Overheads	3,500		16	56,000	56,000	56,000
Total				**188,569**	**176,610**	**179,092**
Cost per Referral				53.88		51.17

Item	**Number**	**Lifespan**	**Unit cost**	**Year 1**	**Recurrent**	**Annualised**
Capital Equipment						
Haag Streit Slit Lamp	1	10	8,000	8,000		1,087
Ocular 90D Indirect Lens	1	10	129	129		17
W-Allen Scope	1	10	316	316		43
Snellen Chart	1	10	410	410		56
Perkins tonometer	1	10	901	901		122
Furniture	2	10	1,500	204		408
PC	1	3	2,000	2,000		749
Consumables and Recurrent						
Sundries	5,500		0.2	1,100	1,100	1,100
Angiograms	1,100		50	55,000	55,000	55,000
Staffing						
Consultant Opthalmologist	1		65,766	65,766	65,766	65,766
Nurse Grade D	1		18,656	18,656	18,656	18,656
Equipment Maintenance				488	488	488
Hospital Overheads	5,500		16	88,000	88,000	88,000
Total				**240,969**	**229,010**	**231,492**
Cost per Referral				43.81		42.09

Appendix 24

ASSUMPTIONS AND BASE CASE COST-EFFECTIVENESS ACCEPTABILITY CURVES

Annual transition probabilities and mortality multipliers are as summarised in the following table.

	Nil		BDR1		BDR2		Prolif.		Blind	
IDDM	a	b	a	b	a	b	a	b	a	b
Mortality Multiplier	0	1	0	2	0	2	0.004	5	0.0012	15
Progression Probability	13%		14%		6.8%		7.5%		..	
Remission Probability	..		3%		0%		..		..	
NIDDM	a	b	a	b	a	b	a	b	a	b
Mortality Multiplier	0	1.01	0	1.5	0	1.5	0	2.2	0	2.2
Progression Probability	7%		12%		4.5%		7.5%		..	
Remission Probability	..		5%		3%		..		..	

Mortality risk takes the form a + (b * all cause Scottish mortality). Two values are listed by the School of Management for the mortality risk among people with IDDM and proliferative retinopathy, reflecting an increase in the risk of death as the time spent with proliferative retinopathy lengthens. Unfortunately, it has not been possible to model this within Crystal Ball and a mid point has been taken. No progression probability is listed from proliferative retinopathy to blindness, with only a common progression probability for those who have been treated being noted. The figure used is taken from the paper by Davies *et al.,* 1996[1] who lists a value for those with IDDM. Note that the post treatment transition probability from PDR to blindness listed by the School of Management is the same for IDDM and NIDDM.

Patients are grouped into the age cohorts for which incidence and prevalence data is reported, the patient impact being estimated from the median age within each cohort. For incident cases of IDDM there is assumed to be no background retinopathy, while among incident cases of NIDDM there is taken to be 20% BDR but no PDR. The incidence and prevalence figures for IDDM and NIDDM are taken as:

[1] Davies, R., 1996

IDDM									
Age Range	<15	15-19	20-24	25-29	30-34	35-44	45-54	55-64	65+
Median Age	14	17	22	27	32	39	49	59	69
Incidence/100,000	16.5	16.3	11.1	7.2	2.7	0.0	0.0	0.0	0.0
Prevalence/1,000	1.0	2.9	3.3	3.1	2.8	2.8	1.9	1.6	0.9
Prevalence BDR	18%	52%	57%	57%	50%	51%	51%	51%	51%
Prevalence PDR	0%	0%	2%	17%	29%	33%	33%	33%	33%

NIDDM							
Age Range	20-29	30-39	40-49	50-59	60-69	70-79	80-89
Median Age	25	35	45	55	65	75	85
Incidence/1,000	0.2	0.6	1.4	2.3	3.1	3.4	3.5
Prevalence/1,000	0.7	2.3	8.9	21.3	36.1	65.4	60.4
Prevalence BDR	0%	24%	35%	38%	41%	41%	41%
Prevalence PDR	0%	4%	7%	9%	5%	5%	5%

Note that both incidence figures and prevalence figures are likely to be slightly dated, prevalence figures in particular giving an overall prevalence of somewhat less than the 3% assumed throughout this report. However, this will not affect the assessment of patient impact[2] within cohorts. It only affects the aggregation of cohort patient impacts to yield overall average patient impact. The current distribution of incidence and prevalence may now tend to be within younger cohorts, particularly for those with NIDDM. This may lead the stated overall patient benefits to be slight underestimates.

The relative risk reduction (RRR) in the likelihood of blindness from treatment is subject to a considerable degree of uncertainty. The NSC reports an RRR of 50% with this benefit extending over ten years in two-thirds of patients, though how this latter figure is arrived at is unclear. Blankenship *et al.,* 1991 reports an RRR of 84% while Javitt *et al.,* 1994 reports a re-analysis of primary data showing an RRR in excess of 90%. Informal enquiries[3] suggest an RRR of between 50% and 80%. As a consequence, both an RRR of 50% and an RRR of 70% are explored as plausible estimates for the effectiveness of laser treatment, with an RRR of 70% being taken as the base case.

For systematic screening, a random 80% of diabetics are assumed to present for screening each year, with a 60:40 split between mobile and hospital-based screening. This does not address the issue of non-attendees within the diabetic population, though there will still be a small percentage within the modelling who are not screened over a number of years due to the properties of cumulative probabilities. Persistent non-attendees are in a sense outside the system, and are extremely difficult to model. As a result, modelling only relates to those imperfectly disposed to attend screening, this also applying to the modelling of opportunistic screening. The degree of persistent non-attendance is assumed to be the same under systematic screening as under opportunistic screening.

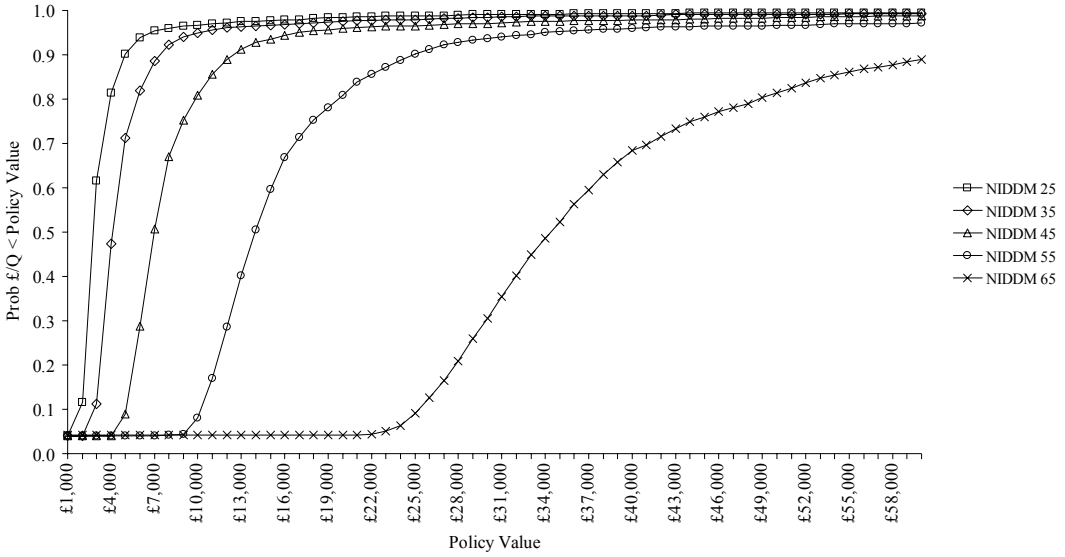
[2] Neither is cost-effectiveness affected, due to the application of unit costs.
[3] Dr. R. Davies, University of Southampton.

The NSC reports opportunistic screening as being 30% by optometrists, 20% by hospitals and 50% by GPs. The NSC also reports that in health authorities with opportunistic screening 60% of diabetics are screened annually, with 80% having been screened at least once within a two-year period. This suggests that a random 60% of diabetics present each year for opportunistic screening.

For both systematic screening and opportunistic screening, those presenting for a screening method are assumed to continue to present for and be amenable to it. For instance, under opportunistic screening those with diabetes are taken to divide into those who present to optometrists, those who present to hospitals and those who present to GPs. Within those presenting to optometrists, a random 60% are assumed to be screened by optometrists each year. This is felt likely to better reflect the experience of those with diabetes than the alternative modelling assumption that those with diabetes present to different screening methods randomly.

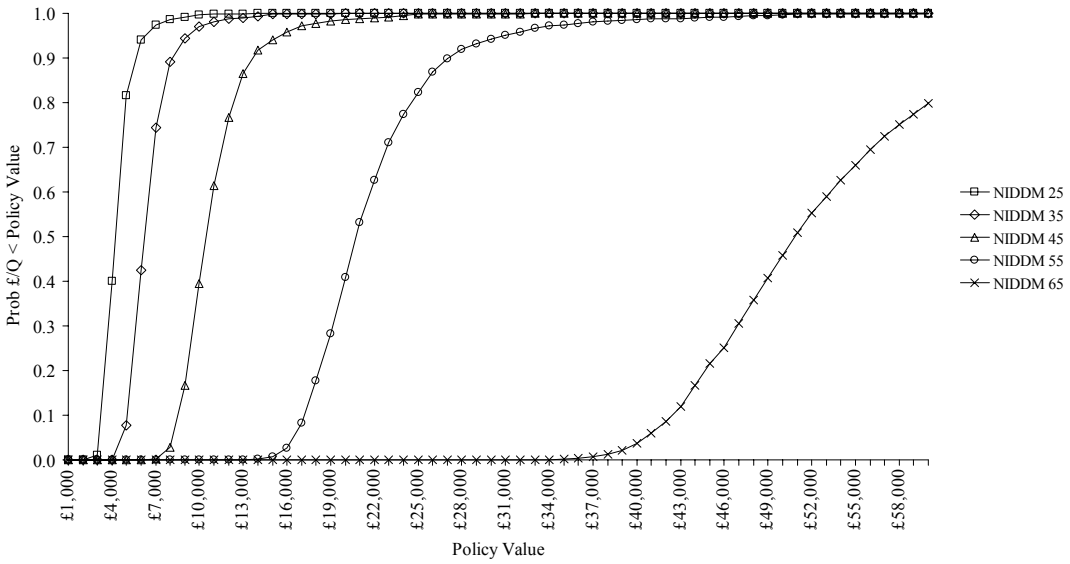
Opportunistic to Systematic Non Mydriatic: RRR 70% Benefit DR 1.5%

NIDDM Incidence



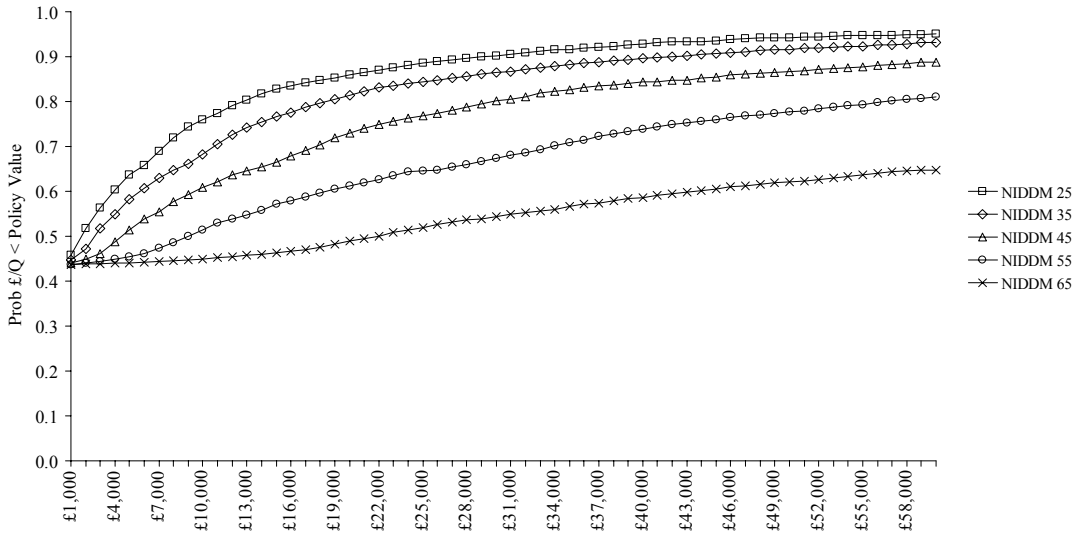
Opportunistic to Systematic Mydriatic: RRR 70% Benefit DR 1.5%

NIDDM Incidence

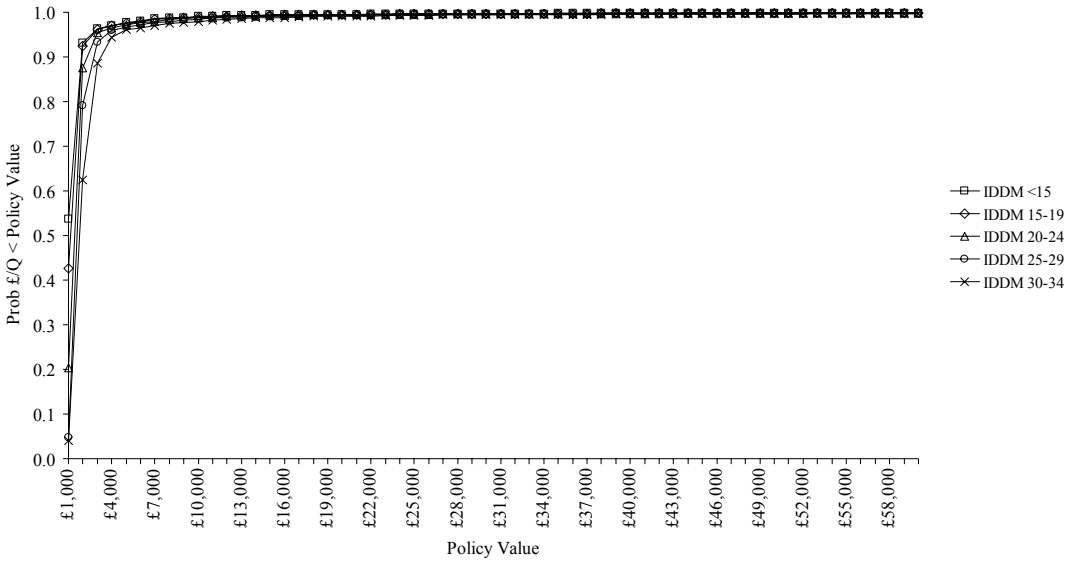


Systematic Non Mydriatic to Systematic Mydriatric: RRR 70% Benefit DR 1.5%

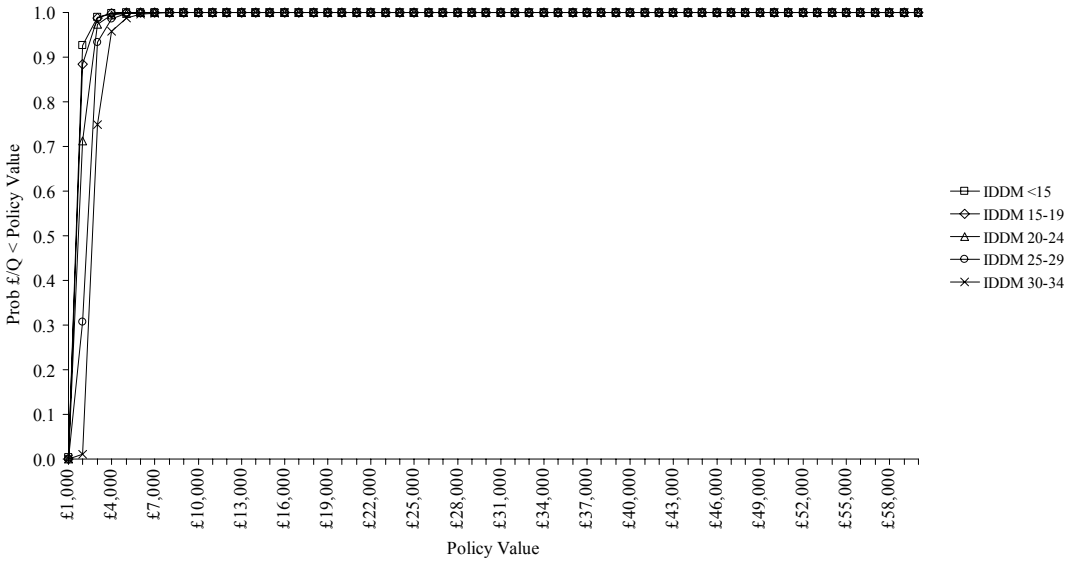
NIDDM Incidence



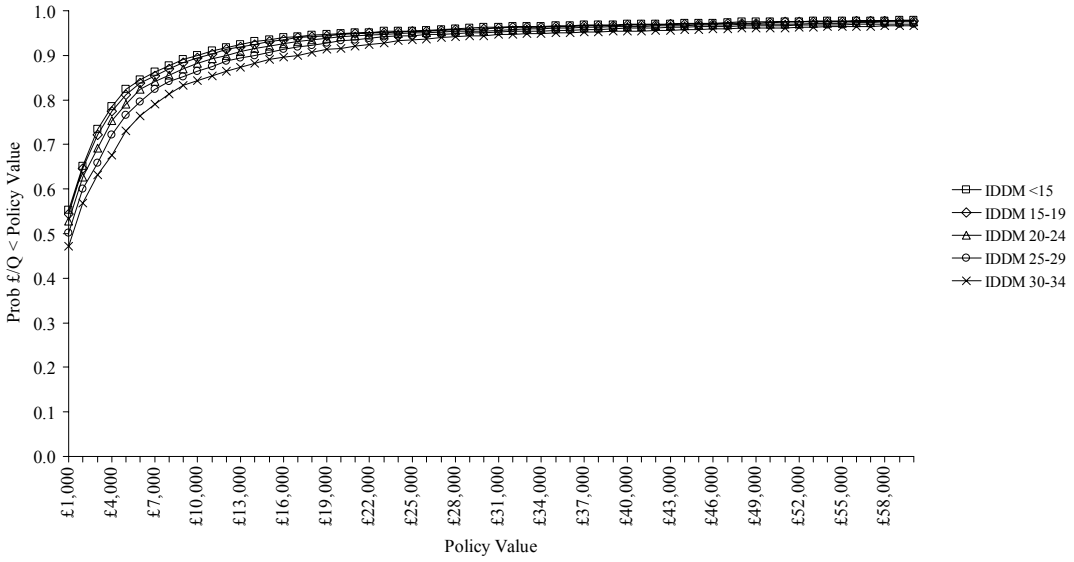
Opportunistic to Systematic Non Mydriatic: RRR 70% Benefit DR 1.5%
IDDM Incidence



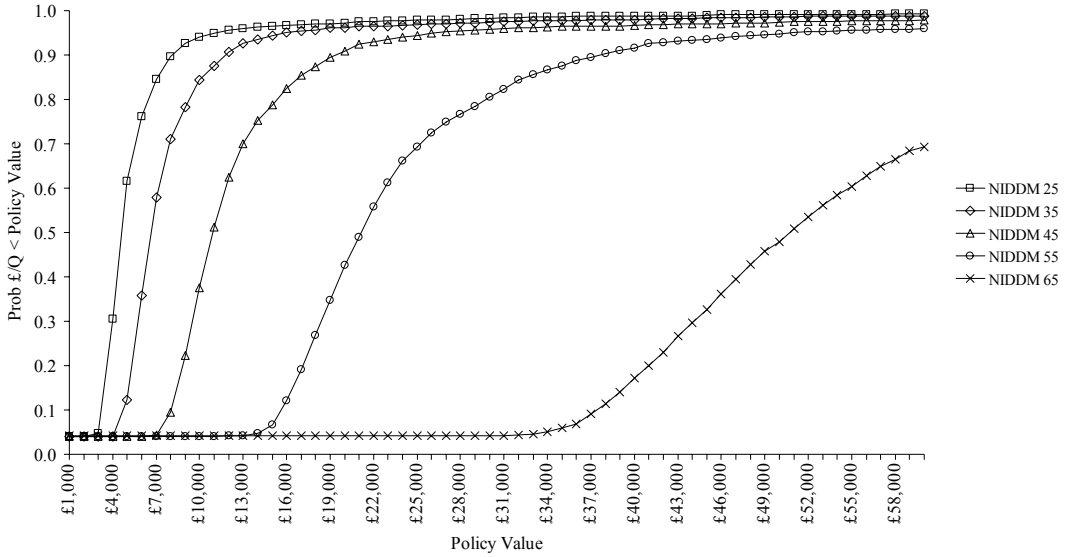
Opportunistic to Systematic Mydriatic: RRR 70% Benefit DR 1.5%
IDDM Incidence



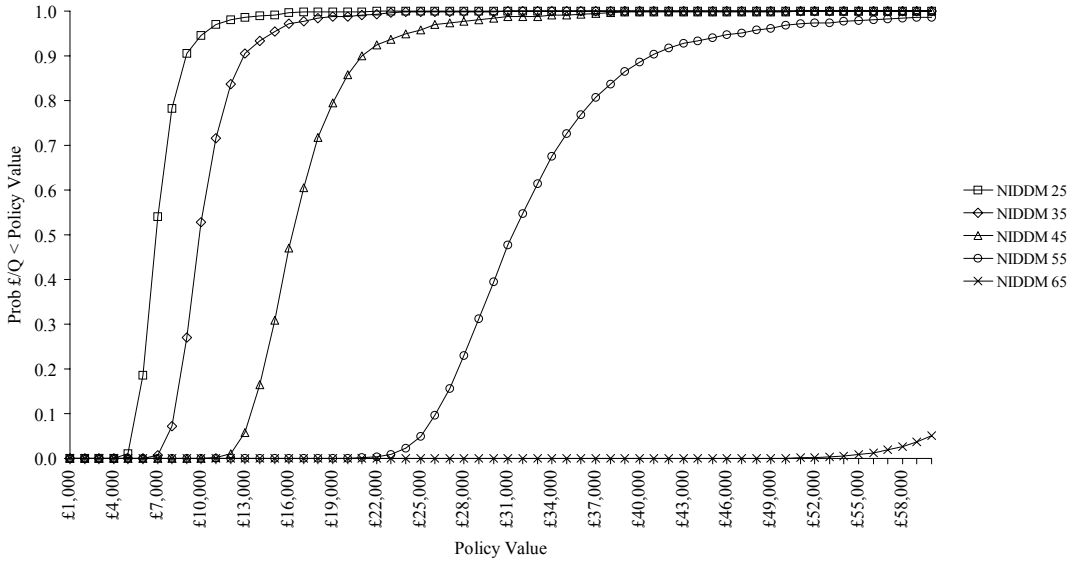
Systematic Non Mydriatic to Systematic Mydriatic: RRR 70% Benefit DR 1.5%
IDDM Incidence



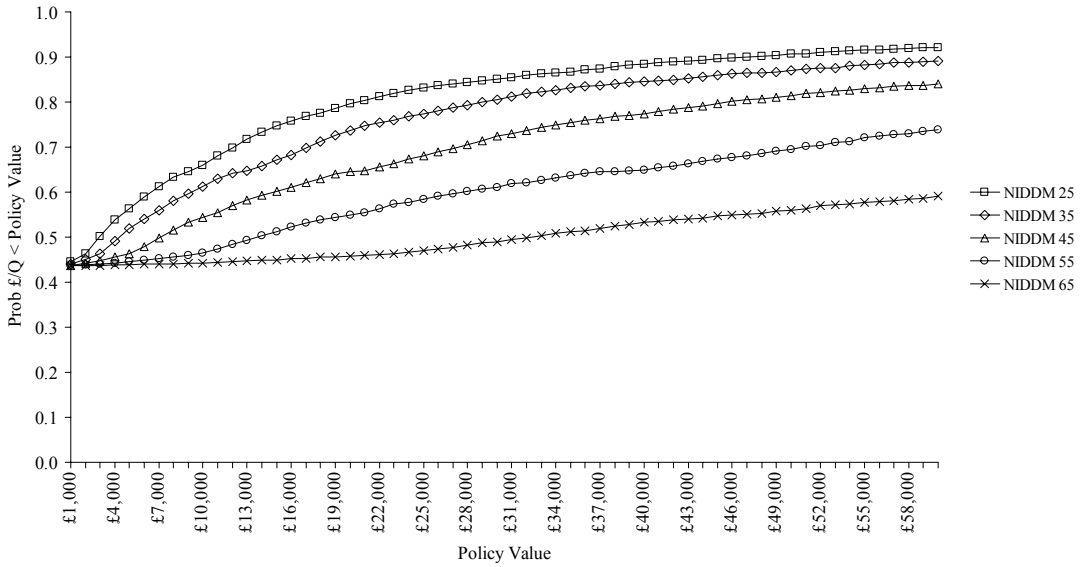
Opportunistic to Systematic Non Mydriatic: RRR 50% Benefit DR 1.5%
NIDDM Incidence



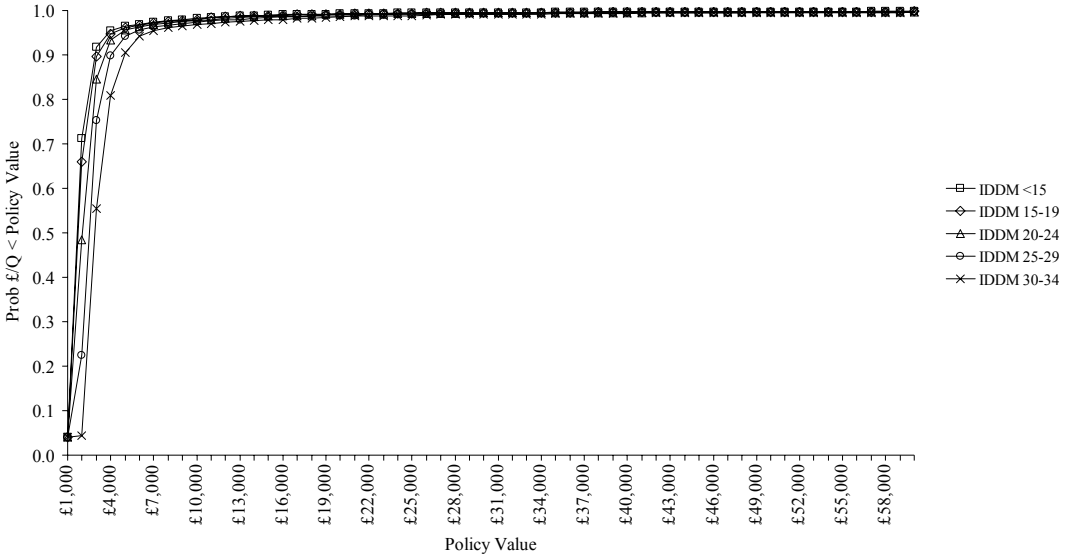
Opportunistic to Systematic Mydriatic: RRR 50% Benefit DR 1.5%
NIDDM Incidence



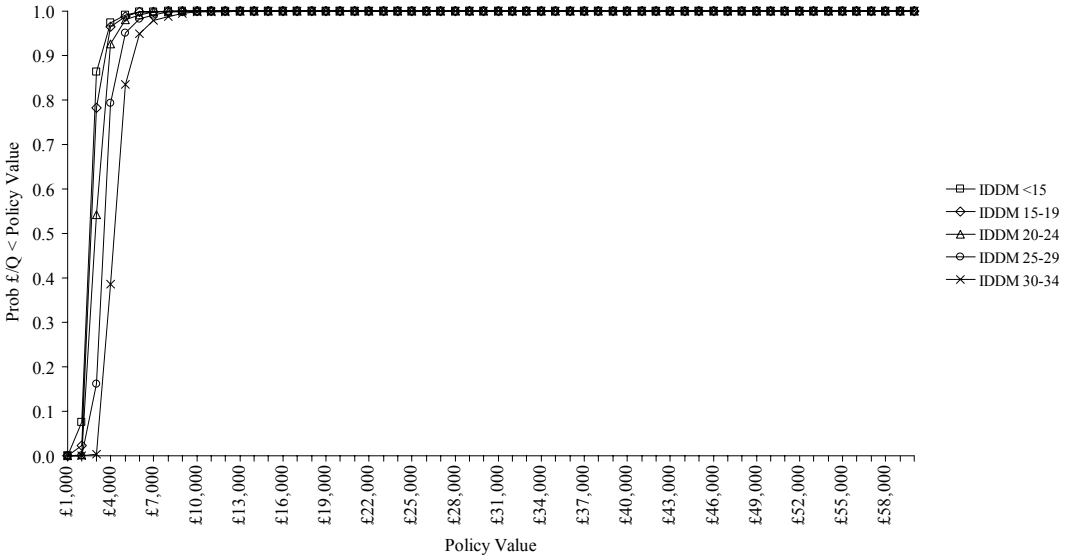
Systematic Non Mydriatic to Systematic Mydriatric: RRR 50% Benefit DR 1.5%
NIDDM Incidence



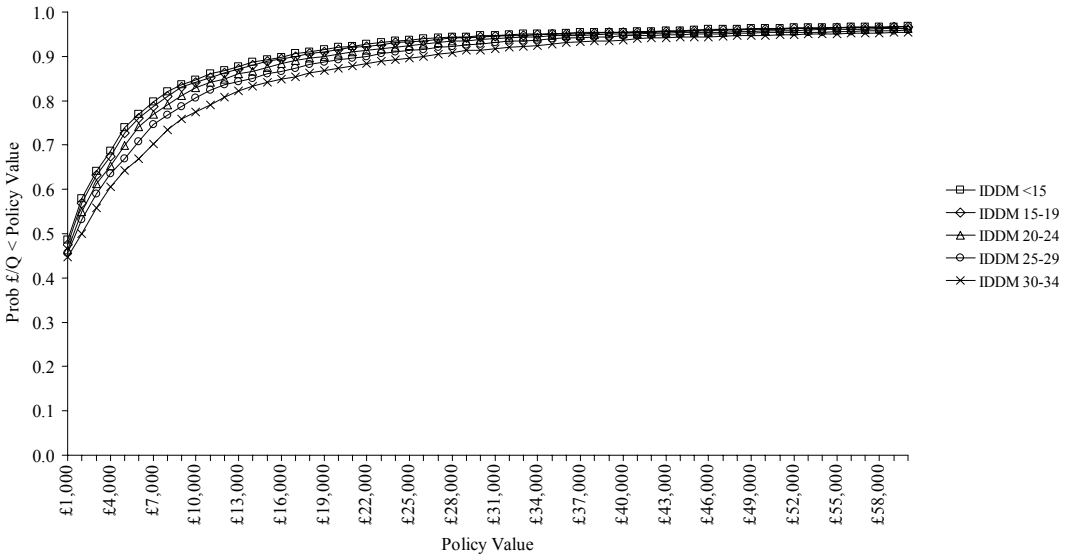
Opportunistic to Systematic Non Mydriatic: RRR 50% Benefit DR 1.5%
IDDM Incidence



Opportunistic to Systematic Mydriatic: RRR 50% Benefit DR 1.5%
IDDM Incidence



Systematic Non Mydriatic to Systematic Mydriatic: RRR 50% Benefit DR 1.5%
IDDM Incidence



Appendix 25

PATIENT IMPACT SENSITIVITY ANALYSIS

Mydriasis and Attendance Rates

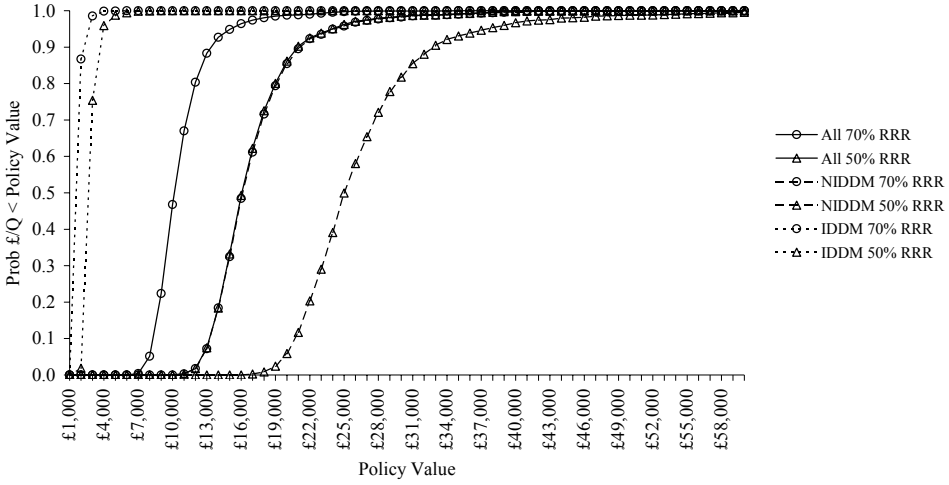
As noted in the patient issues section, mydriasis is likely to reduce the percentage of patients willing to attend systematic screening. It may reduce the numbers willing to attend systematic screening by 5% (Klein *et al.,* 1992). Those deterred from screening by mydriasis seem to be similarly unlikely to have previously attended opportunistic screening that requires mydriasis. Consequently, this 5% is assumed to fall back to opportunistic screening by GPs. This results in the anticipated increase in the average number of days spent with sight as below.

Increase in Sight Days	Opp to Sys Myd		Sys Non-m to Sys Myd	
	RRR 50%	RRR 70%	RRR 50%	RRR 70%
All	15	24	1	1
NIDDM All	11	17	1	1
NIDDM 25	70	114	4	7
NIDDM 35	43	69	3	4
NIDDM 45	23	35	1	2
NIDDM 55	9	14	1	1
NIDDM 65	3	4	0	0
IDDM All	85	138	5	8
IDDM <15	130	213	8	13
IDDM 15-19	118	192	7	11
IDDM 20-24	98	157	6	9
IDDM 25-29	78	123	5	7
IDDM 30-34	60	93	4	6

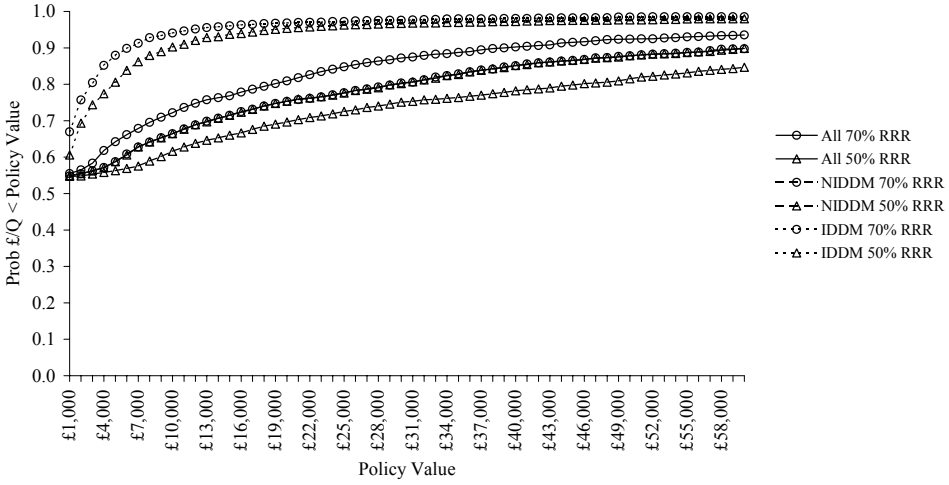
As would be anticipated, there is a small fall in the increase in days spent with sight as a result of a move from opportunistic screening to systematic mydriatic screening. More important are the results relating to a move from systematic non-mydriatic screening to systematic mydriatic screening. The effect of 5% of those with diabetes being deterred from systematic screening by mydriasis is to give a near equivalence between the anticipated patient benefits from non-mydriatic and mydriatic systematic screening. The effect of a lower patient attendance rate upon cost-effectiveness ratios is as below.

Cost per	Opp to Sys Myd		Sys NonM to Sys Myd	
QALY	RRR 50%	RRR 70%	RRR 50%	RRR 70%
All Patients	£16,327	£10,287	£79,014	£50,239
NIDDM All	£25,461	£16,393	£122,362	£79,403
NIDDM 25	£6,998	£4,244	£34,892	£21,634
NIDDM 35	£10,071	£6,293	£49,469	£31,447
NIDDM 45	£16,486	£10,618	£79,442	£51,768
NIDDM 55	£31,861	£21,114	£150,243	£100,242
NIDDM 65	£76,331	£51,867	£352,219	£240,092
IDDM All	£2,686	£1,621	£12,840	£7,972
IDDM <15	£2,484	£1,484	£11,962	£7,371
IDDM 15-19	£2,645	£1,597	£12,666	£7,869
IDDM 20-24	£2,996	£1,842	£14,181	£8,935
IDDM 25-29	£3,499	£2,191	£16,331	£10,437
IDDM 30-34	£4,244	£2,707	£19,490	£12,634

Opportunistic to Systematic Mydriatic 75%Attend: Benefit DR 1.5%
Incidence



Systematic Non Mydriatic 80%Attend to Systematic Mydriatic 75%Attend: Benefit DR 1.5%
Incidence



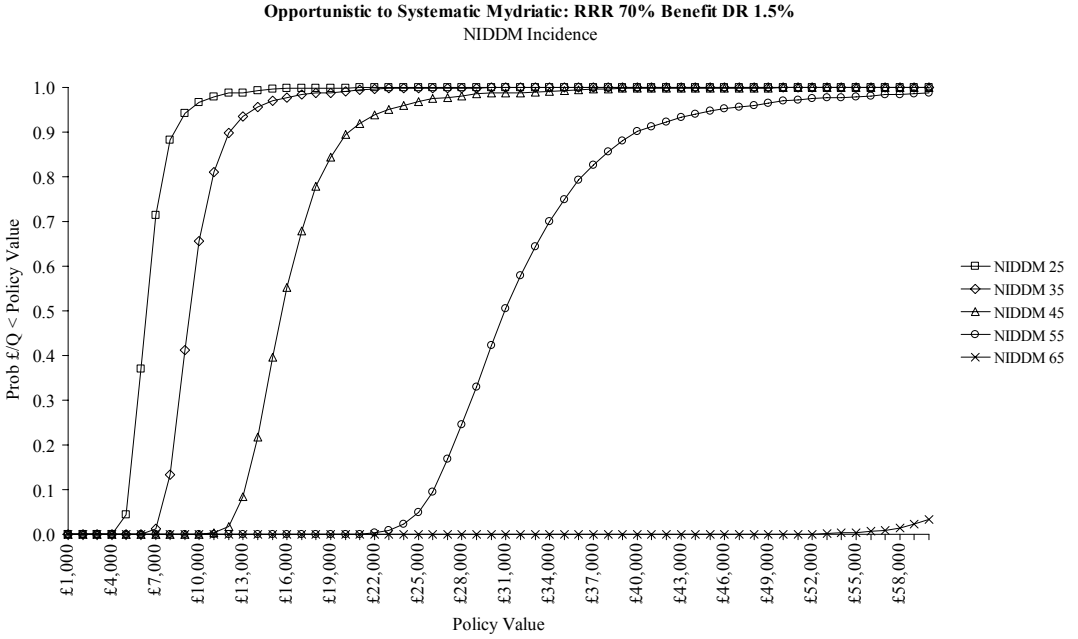
As can be seen from the table and the upper graph of CEACs, even with a reduction in attendance rates under systematic mydriatic screening, a move from opportunistic screening to mydriatic screening remains highly cost-effective. But the cost-effectiveness of a move from non-mydriatic screening to mydriatic screening becomes increasingly uncertain. There is a rough balance between the probability of the patient impact being the same under either systematic screening programme. This leads to flat CEACs and considerable uncertainty as to the likelihood that a move from systematic non-mydriatic screening to systematic mydriatic screening is cost-effective.

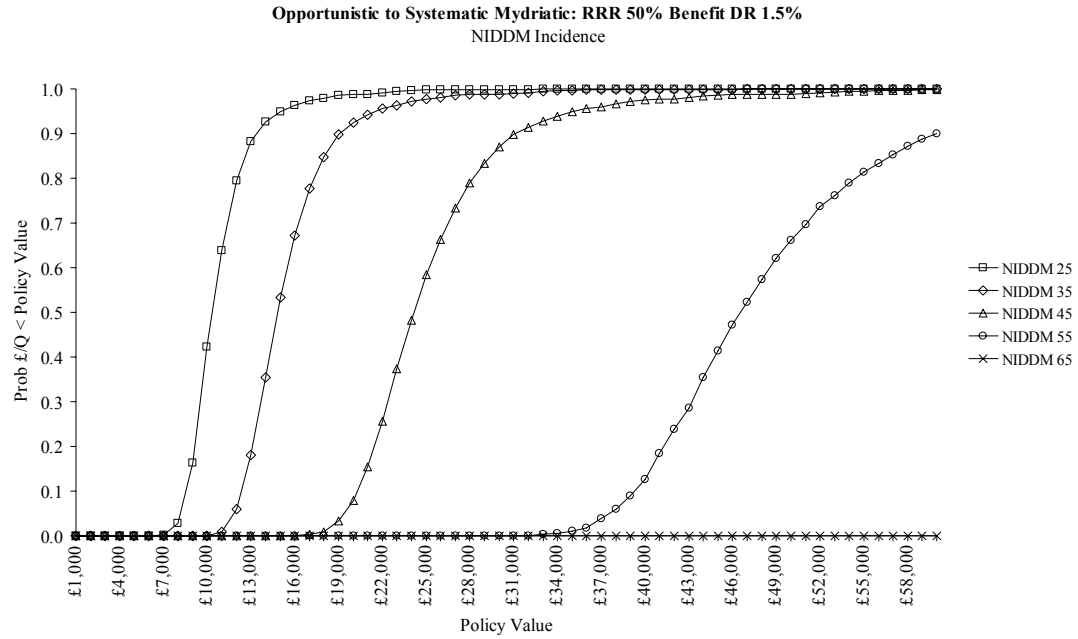
Cost per Screen

Within the costing data it is possible that the cost per screen will prove to be an underestimate; for instance, capacity utilisation rates may fall significantly below those assumed. This has been explored by the addition of an arbitrary £10.00 to the cost per screen within systematic screening, which is roughly equivalent to the fixed costs of the programme being imposed upon screen costs a second time.

Cost per QALY	Opp to Sys Non-m		Opp to Sys Myd	
	RRR 50%	RRR 70%	RRR 50%	RRR 70%
All Patients	£21,053	£13,299	£24,267	£15,349
NIDDM All	£32,867	£21,209	£37,880	£24,471
NIDDM 25	£9,061	£5,531	£10,475	£6,413
NIDDM 35	£13,022	£8,178	£15,034	£9,464
NIDDM 45	£21,284	£13,755	£24,536	£15,883
NIDDM 55	£41,106	£27,297	£47,319	£31,453
NIDDM 65	£98,609	£67,073	£113,412	£77,177
IDDM All	£3,434	£2,089	£3,948	£2,411
IDDM <15	£3,180	£1,916	£3,659	£2,214
IDDM 15-19	£3,383	£2,058	£3,890	£2,377
IDDM 20-24	£3,825	£2,367	£4,393	£2,728
IDDM 25-29	£4,458	£2,807	£5,113	£3,229
IDDM 30-34	£5,395	£3,456	£6,179	£3,967

The cost per QALY necessarily rises with the cost per screen of systematic screening. Despite the cost increase being large, the anticipated cost-effectiveness of systematic screening is not seriously called into question, save possibly for those with NIDDM onsetting later in life. Scottish costs and patient data should be collected, following implementation of the national screening programme, to inform on the cost-effectiveness of screening those with NIDDM onsetting in their sixties.





CEACs for those with IDDM have not been presented as these lie well within the bounds of acceptable cost-effectiveness ratios.

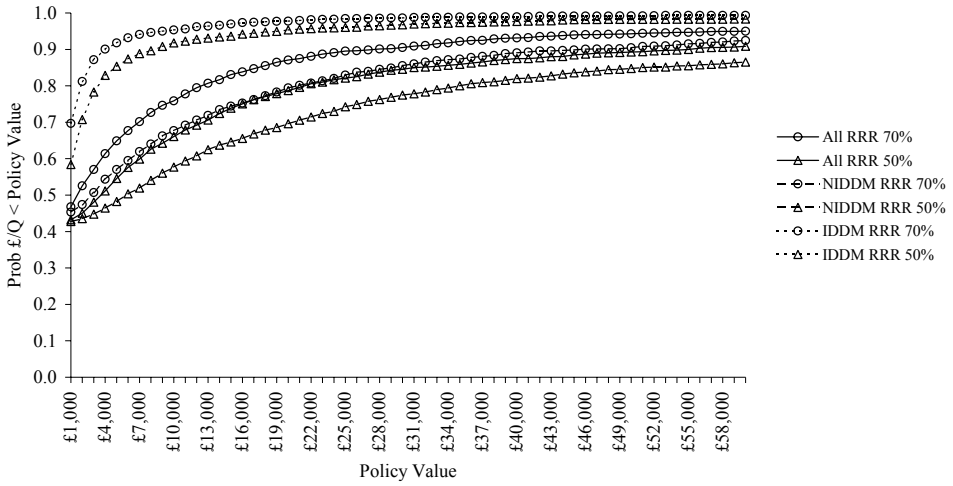
Results for the impact of an arbitrary addition of £10.00 to the cost per screen have not been presented for the move from systematic non-mydriatic screening to systenatic screening. Rather, the impact of a reduction in the difference in their respective costs per screen is explored through a reduction in the patient time for mydriatic screening to 15 minutes.

Cost per QALY	Benefit DR 0.0%		Benefit DR 1.5%		Benefit DR 6.0%	
	RRR 50%	RRR 70%	RRR 50%	RRR 70%	RRR 50%	RRR 70%
All Patients	£16,251	£10,836	£27,001	£15,211	£78,965	£55,264
NIDDM All	£27,000	£18,457	£42,065	£24,190	£106,269	£75,250
NIDDM 25	£6,626	£4,288	£11,708	£6,378	£40,877	£27,859
NIDDM 35	£10,161	£6,780	£16,760	£9,390	£50,112	£34,731
NIDDM 45	£17,703	£12,169	£27,260	£15,709	£69,101	£48,780
NIDDM 55	£36,317	£25,678	£52,351	£30,968	£112,222	£80,686
NIDDM 65	£92,092	£66,796	£124,841	£75,518	£226,975	£165,892
IDDM All	£2,425	£1,562	£4,401	£2,402	£16,862	£11,466
IDDM <15	£2,209	£1,409	£4,082	£2,207	£16,318	£11,035
IDDM 15-19	£2,393	£1,543	£4,337	£2,368	£16,668	£11,325
IDDM 20-24	£2,790	£1,831	£4,890	£2,715	£17,489	£11,990
IDDM 25-29	£3,355	£2,242	£5,679	£3,209	£18,770	£12,998
IDDM 30-34	£4,191	£2,850	£6,846	£3,935	£20,795	£14,553

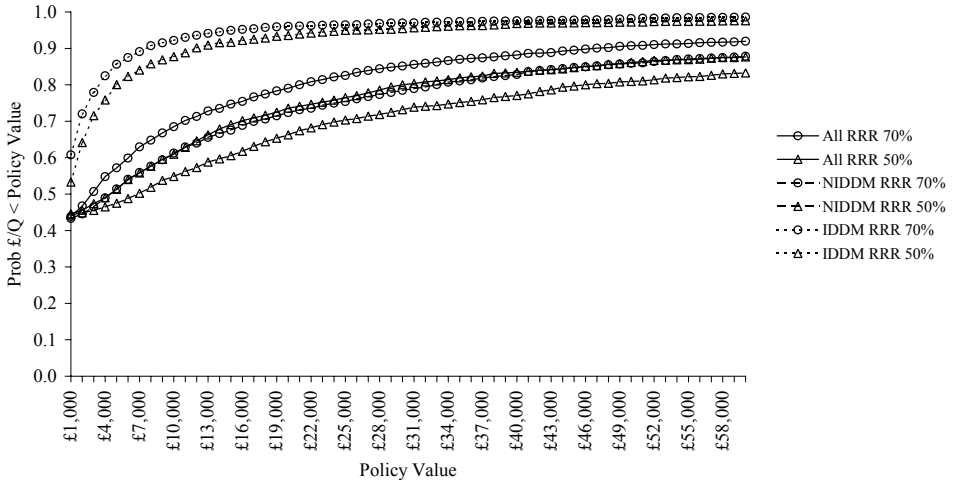
With higher patient throughputs for mydriasis then it is unlikely that a move from systematic non-mydriatic screening to systematic mydriatic screening is likely to be cost-effective, particularly among those with NIDDM. This is further underlined by the CEACs overleaf, which even for the base case benefit discount rate of 1.5% show a rough balance in probabilities between;

- mydriatic screening conferring no additional patient benefits but being more expensive;
- mydriatic screening conferring additional patient benefits, with cost-effectiveness ratios within acceptable bounds; and
- mydriatic screening conferring additional patient benefits, but with cost-effectiveness ratios outside acceptable bounds.

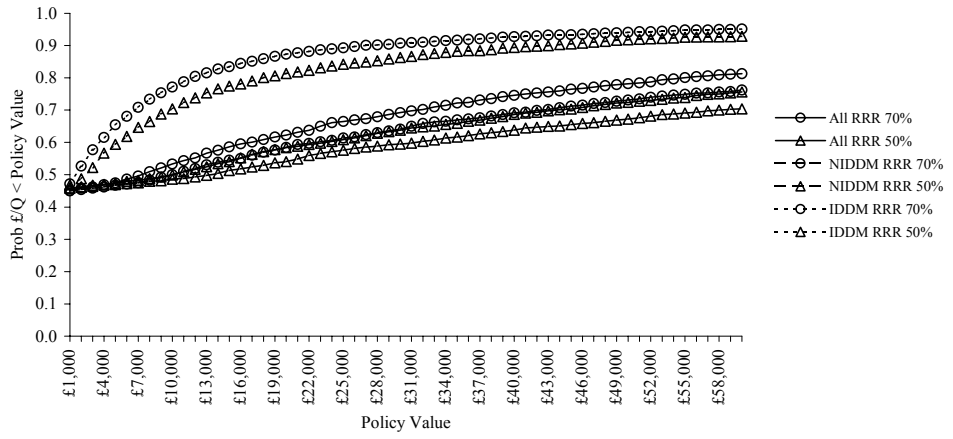
Systematic Non-Mydriatic to Systematic Mydriatic: Benefit DR 0.0%
Incidence



Systematic Non Mydriatic to Systematic Mydriatic: Benefit DR 1.5%
Incidence



Systematic Non Mydriatic to Systematic Mydriatic: Benefit DR 6.0%
Incidence



Costs of Blindness

The values used for the cost of incident and ongoing cases of blindness only relate to inpatient costs, and there are likely to be additional outpatient and social services costs. Within these, the annual average inpatient cost of £280 arising from ongoing cases of blindness seems most likely to be an underestimate of the overall costs of blindness to NHSScotland and the social services. It has proved difficult to arrive at an estimate of what these costs are, this being explored through an arbitrary addition of £1,000 to the £280 base case.

Cost per QALY	Opp to Sys Non-m		Opp to Sys Myd		Sys Non-m to Sys Myd	
	RRR 50%	RRR 70%	RRR 50%	RRR 70%	RRR 50%	RRR 70%
All Patients	£11,211	£6,675	£15,236	£9,241	£44,423	£27,847
NIDDM All	£17,699	£10,869	£23,985	£14,957	£69,448	£44,525
NIDDM 25	£4,178	£2,122	£5,944	£3,224	£18,799	£11,244
NIDDM 35	£6,321	£3,481	£8,838	£5,090	£27,118	£16,768
NIDDM 45	£10,952	£6,519	£15,028	£9,185	£44,519	£28,473
NIDDM 55	£22,325	£14,186	£30,130	£19,406	£86,335	£56,992
NIDDM 65	£55,638	£37,114	£74,291	£49,846	£207,713	£140,903
IDDM All	£1,533	£731	£2,175	£1,133	£6,848	£4,058
IDDM <15	£1,375	£626	£1,973	£997	£6,326	£3,703
IDDM 15-19	£1,499	£710	£2,132	£1,106	£6,743	£3,994
IDDM 20-24	£1,774	£898	£2,484	£1,349	£7,649	£4,626
IDDM 25-29	£2,173	£1,174	£2,993	£1,701	£8,944	£5,528
IDDM 30-34	£2,765	£1,582	£3,746	£2,222	£10,856	£6,854

It is unclear how realistic the arbitrary addition of £1,000 is as an estimate of the wider health care costs of blindness. But its addition has relatively little effect upon the anticipated cost-effectiveness of a move to systematic screening among most cohorts. Incident cases of NIDDM are only likely to become blind some years after the onset of diabetes, and any savings realised within the health service from reductions in the occurrence of blindness will be also be some years into the future. Discounting costs at 6.0% reduces the significance of these.

There is a more marked effect upon cost-effectiveness ratios among those with IDDM, but the effect is still relatively minor and unlikely to materially affect any decision as to how screening should be organised.

Call/Recall in Isolation

The move to a systematic screening programme is composed of two elements; the establishment of systematic call/recall and the use of digital cameras. It is conceivable that systematic call/recall could be established to raise the attendance rate of opportunistic screening, without any investment in digital photography.

To explore this, the fixed costs of a national screening programme are imposed upon those of opportunistic screening programme. This is then coupled with an increase in attendance rates for opportunistic screening to the 80% assumed for systematic screening.

Comparing opportunistic screening with call/recall to systematic screening yields the anticipated gain from the investment in digital photography, as outlined below.

Cost per QALY	Opp to Sys Non-m		Opp to Sys Myd	
	RRR 50%	RRR 70%	RRR 50%	RRR 70%
All Patients	..	..	£4,625	£2,828
NIDDM All	..	..	£7,112	£4,463
NIDDM 25	..	..	£1,885	£1,056
NIDDM 35	..	..	£2,758	£1,623
NIDDM 45	..	..	£4,587	£2,837
NIDDM 55	..	..	£8,923	£5,775
NIDDM 65	..	..	£21,039	£14,129
IDDM All	..	..	£834	£464
IDDM <15	..	..	£762	£415
IDDM 15-19	..	..	£818	£454
IDDM 20-24	..	..	£943	£540
IDDM 25-29	..	..	£1,123	£665
IDDM 30-34	..	..	£1,391	£849
Anticipated negative cost effectiveness ratios have not been reported				

Cost savings result from the move from opportunistic screening to systematic screening based upon non-mydriatic photography, because the average cost per opportunistic screen exceeds that of the cost per systematic screen. Systematic screening based around mydriatic photography remains more costly than opportunistic screening, but the expected cost per QALY from investment in digital photography remains well within acceptable limits.

The above strongly suggests that if systematic call/recall is established the resultant systematic screening programme should be based around digital photography. This conclusion is unaffected by the balance between the different screening modalities within opportunistic screening. CEACs are not presented for this, as the result appears relatively robust.

Opportunistic Screening Characteristics for those with IDDM

The pattern of opportunistic screening for those with IDDM may differ considerably from those with NIDDM. Currently, those with IDDM may tend to be more likely to present to opportunistic screening, and this screening may be based less upon examinations by GP and more upon slit lamp examinations within hospital and optometrist practices.

The cost-effectiveness of a move to systematic screening can be examined assuming an 80% attendance rate among those with IDDM, with only 20% of opportunistic screening carried out by GPs and the remainder split equally between hospital and optometrist provision. The results are given below.

Cost per QALY	Opp to Sys Non-m		Opp to Sys Myd	
	RRR 50%	RRR 70%	RRR 50%	RRR 70%
IDDM All	£3,096	£1,873	£4,702	£2,879
IDDM <15	£2,876	£1,723	£4,372	£2,653
IDDM 15-19	£3,051	£1,846	£4,635	£2,839
IDDM 20-24	£3,429	£2,110	£5,205	£3,239
IDDM 25-29	£3,965	£2,484	£6,014	£3,803
IDDM 30-34	£4,752	£3,031	£7,203	£4,630

While the anticipated cost-effectiveness ratios for the moves from opportunistic screening to systematic screening programmes increase, they remain well within acceptable bounds for both the move to systematic non-mydriatic screening and systematic mydriatic screening.

Patient impact of screening using prevalence data

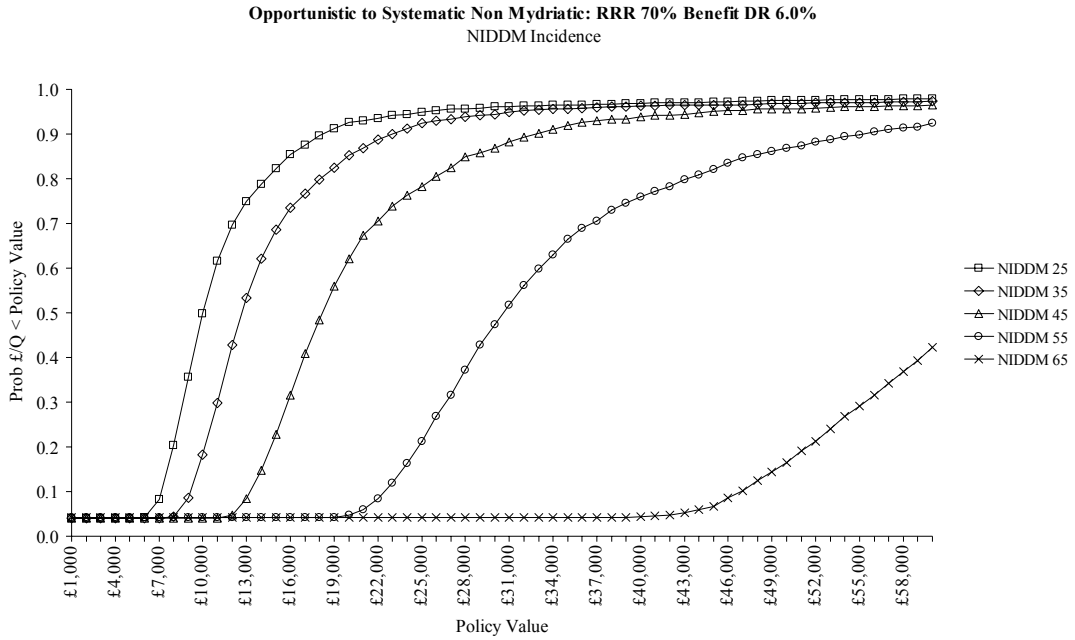
In order to identify the short-term impact of a move to systematic screening, prevalence data of NIDDM, IDDM, BDR and PDR yields a number of cohorts for flowing though the model. Flowing these cohorts through the model yields the anticipated patient impact for the current diabetic population. Since these cohorts will have been living with diabetes and opportunistic screening for some time, a move to systematic screening is likely to detect a relatively high number of cases of PDR for treatment. But as this population prevalence of PDR is worked through and treated, in the medium term the number of cases of PDR detected among these cohorts will fall. The table below presents the estimated patient impact for the prevalence data as reported by the University of Southampton.

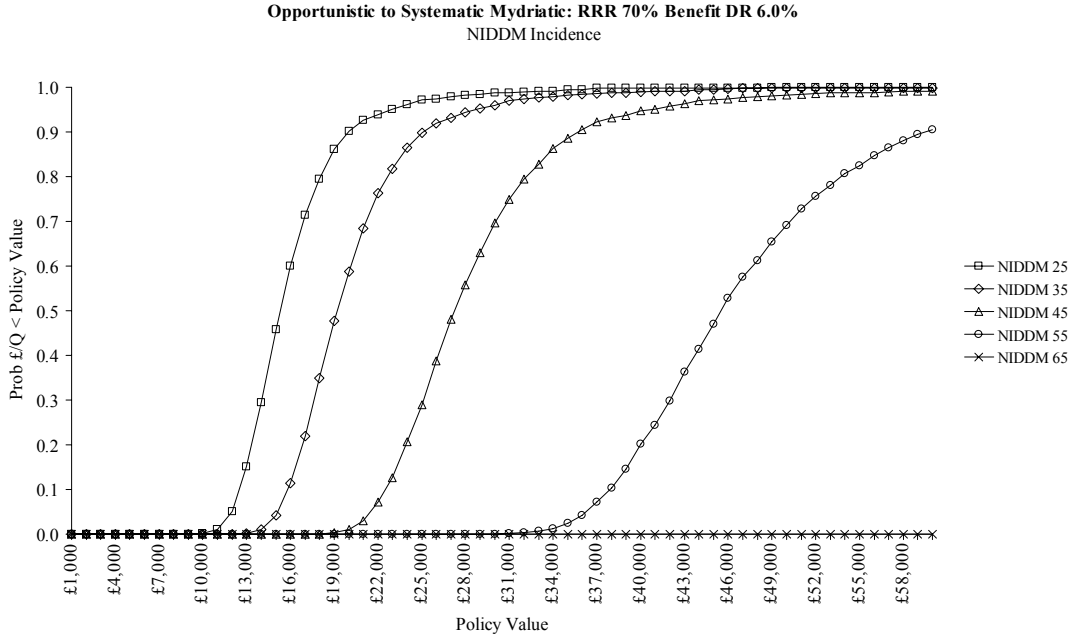
Increase in Sight Days	Opp to Sys Non-m		Opp to Sys Myd		Sys Non-m to Sys Myd	
	RRR 50%	RRR 70%	RRR 50%	RRR 70%	RRR 50%	RRR 70%
All	28	44	31	50	4	6
NIDDM All	14	22	16	25	2	3
NIDDM 25	22	35	25	40	3	5
NIDDM 35	21	34	24	38	3	5
NIDDM 45	25	39	28	45	3	5
NIDDM 55	22	33	25	38	3	5
NIDDM 65	9	14	11	16	1	2
IDDM All	249	403	283	459	34	55
IDDM <15	75	124	85	141	10	17
IDDM 15-19	231	383	263	436	32	53
IDDM 20-24	401	667	456	758	55	91
IDDM 25-29	504	824	573	937	69	113
IDDM 30-34	1,185	1,923	1,347	2,188	163	264

Immediately striking is the large gain in sight years among those with IDDM in the older age groups. However, for reasons already discussed this seems likely to be something of an overestimate. The base case prevalence simulations for these groups assume that around a third have proliferative retinopathy, which would imply an annual incidence of blindness among them of around 1.5%. This seems unlikely, particularly since these groups are among the most likely to be receiving ongoing care for their diabetes within hospital. Unfortunately, it appears that the prevalence data used may have limited relevance to the current Scottish population with diabetes. As a consequence, it is difficult to estimate what latency effect will be observed in the move to a systematic screening programme.

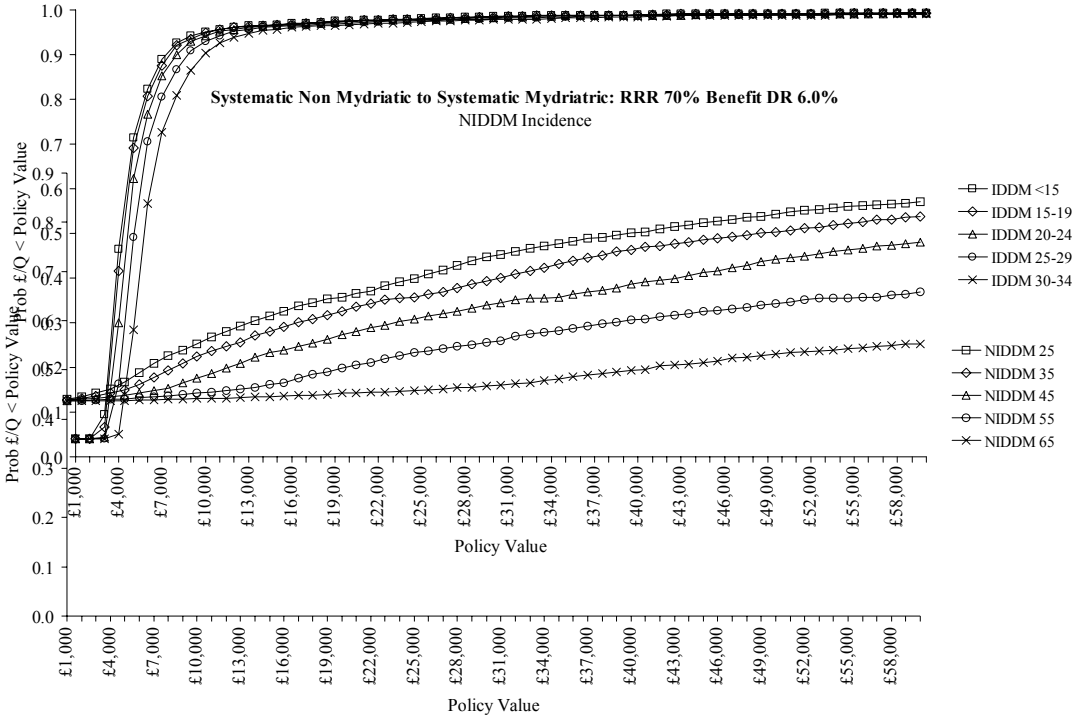
Appendix 26

SENSITIVITY TO BENEFIT DISCOUNT RATES

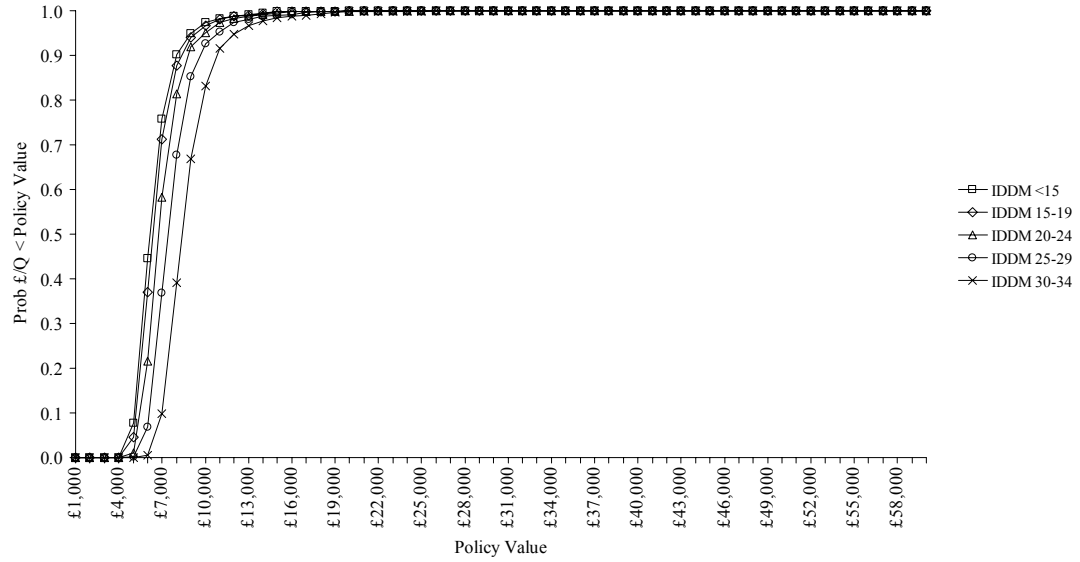


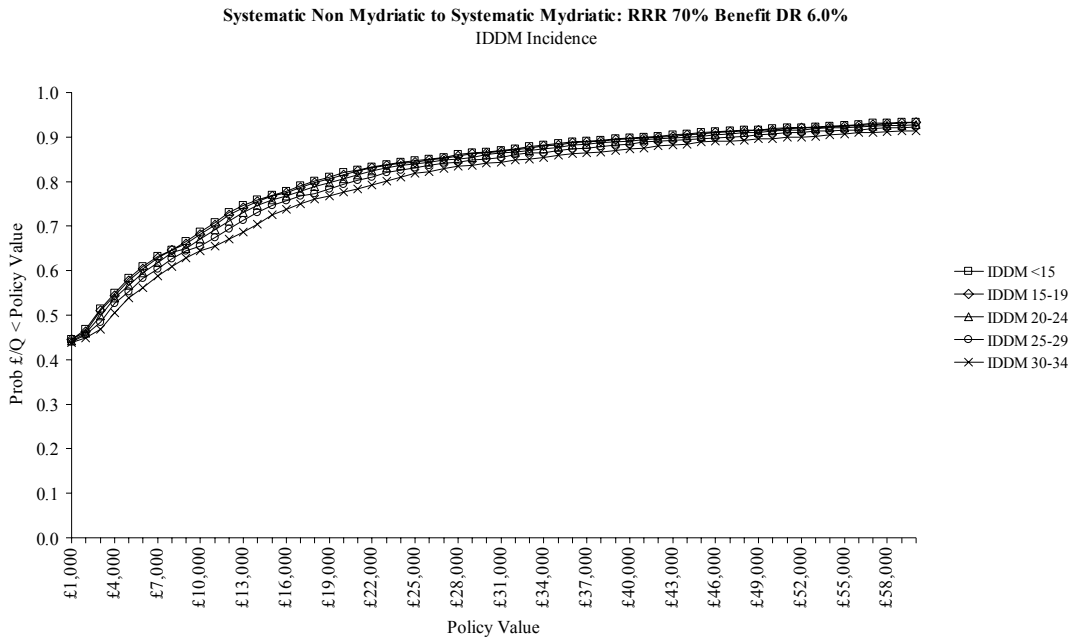


Opportunistic to Systematic Non Mydriatic: RRR 70% Benefit DR 6.0%
IDDM Incidence

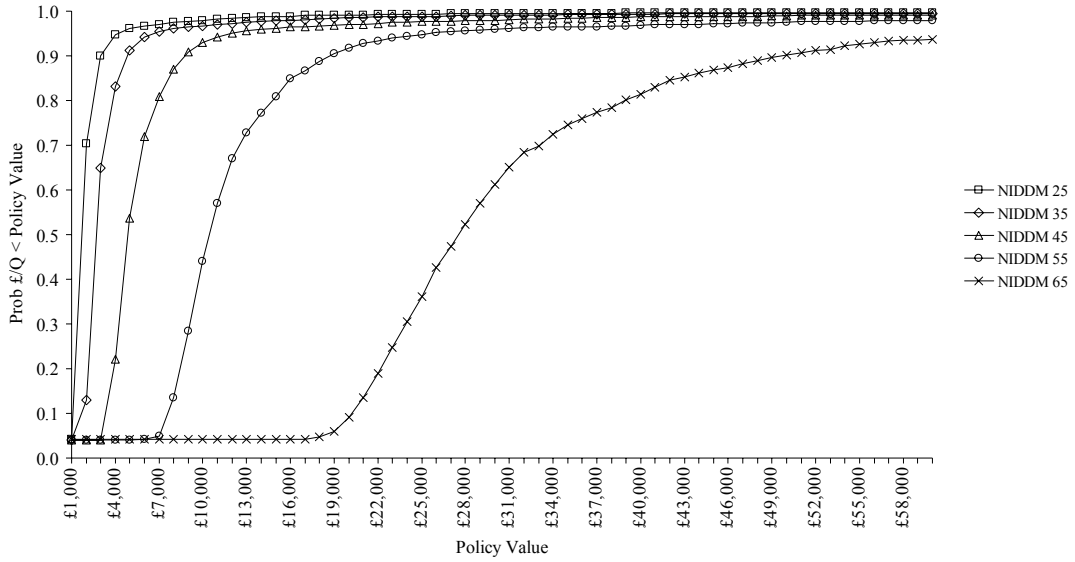


Opportunistic to Systematic Mydriatic: RRR 70% Benefit DR 6.0%
IDDM Incidence

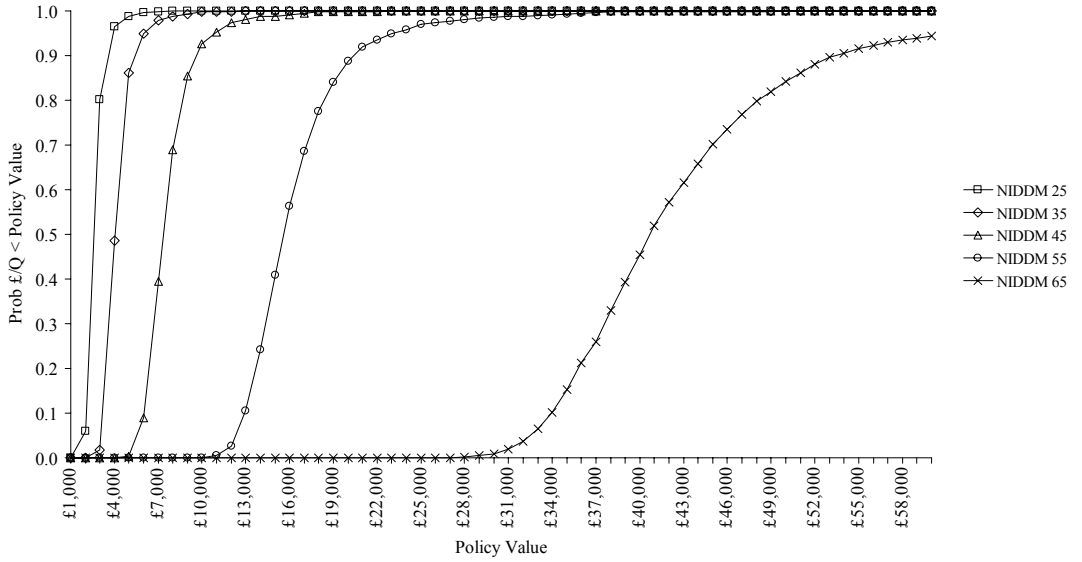



Systematic Non Mydriatic to Systematic Mydriatic: RRR 70% Benefit DR 6.0%
IDDM Incidence
Prob £/Q < Policy Value
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
£1,000
£4,000
£7,000
£10,000
£13,000
£16,000
£19,000
£22,000
£25,000
£28,000
£31,000
£34,000
£37,000
£40,000
£43,000
£46,000
£49,000
£52,000
£55,000
£58,000
Policy Value
IDDM <15
IDDM 15-19
IDDM 20-24
IDDM 25-29
IDDM 30-34

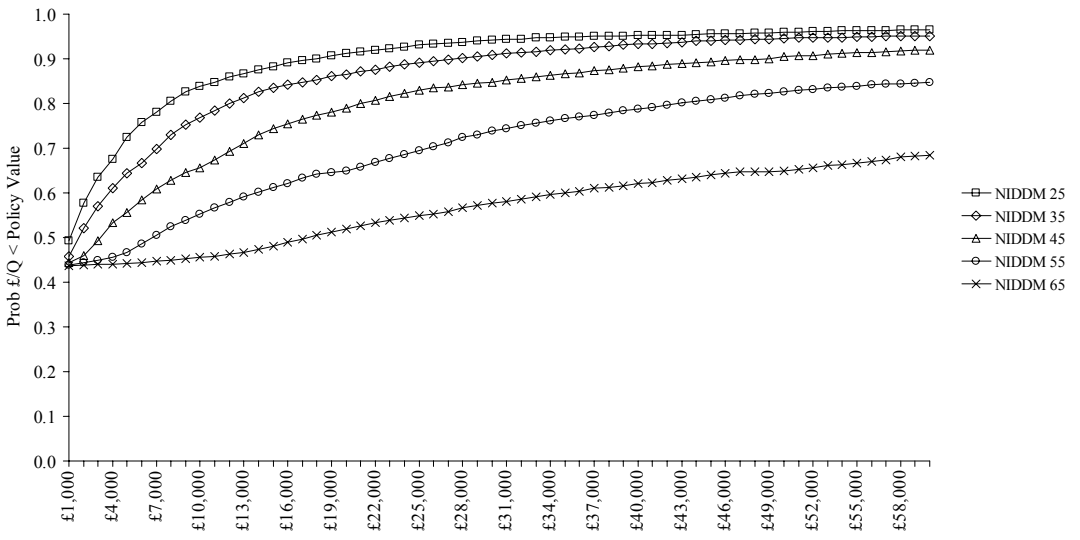
Opportunistic to Systematic Non Mydriatic: RRR 70% Benefit DR 0.0%
NIDDM Incidence



Opportunistic to Systematic Mydriatic: RRR 70% Benefit DR 0.0%
NIDDM Incidence

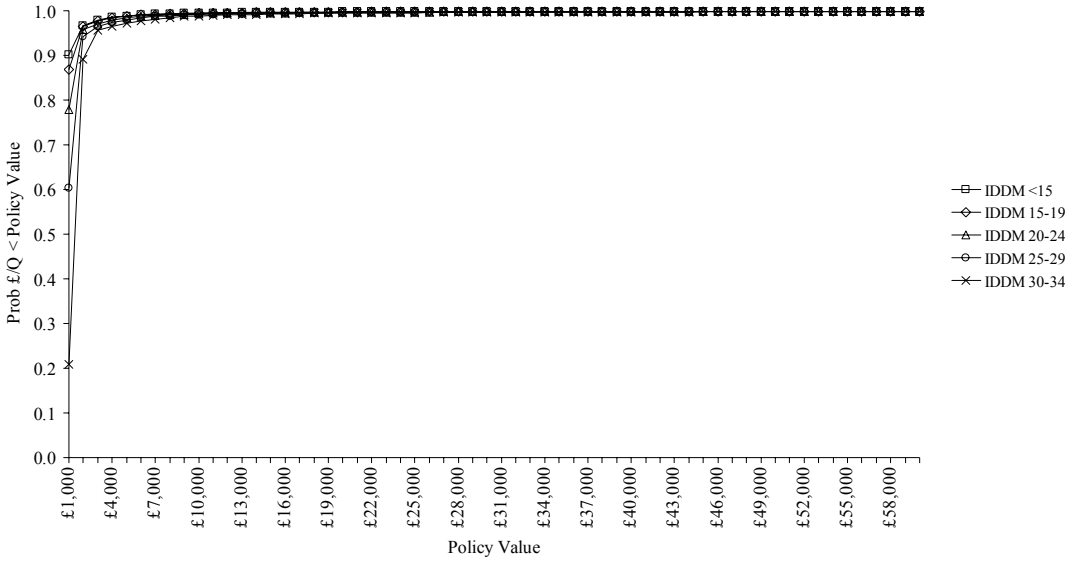


Systematic Non Mydriatic to Systematic Mydriatric: RRR 70% Benefit DR 0.0%
NIDDM Incidence



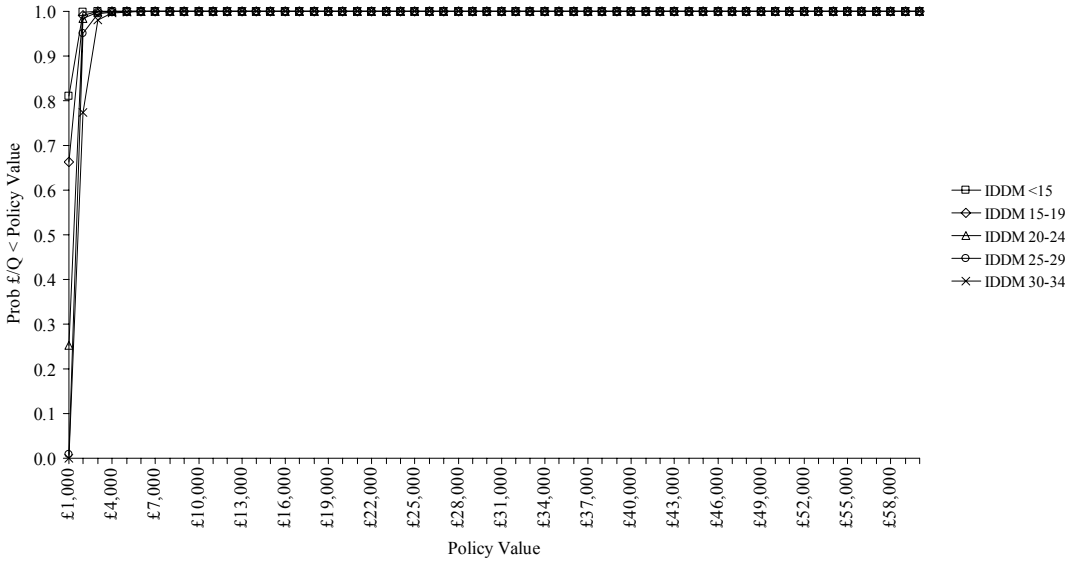
Opportunistic to Systematic Non Mydriatic: RRR 70% Benefit DR 0.0%

IDDM Incidence



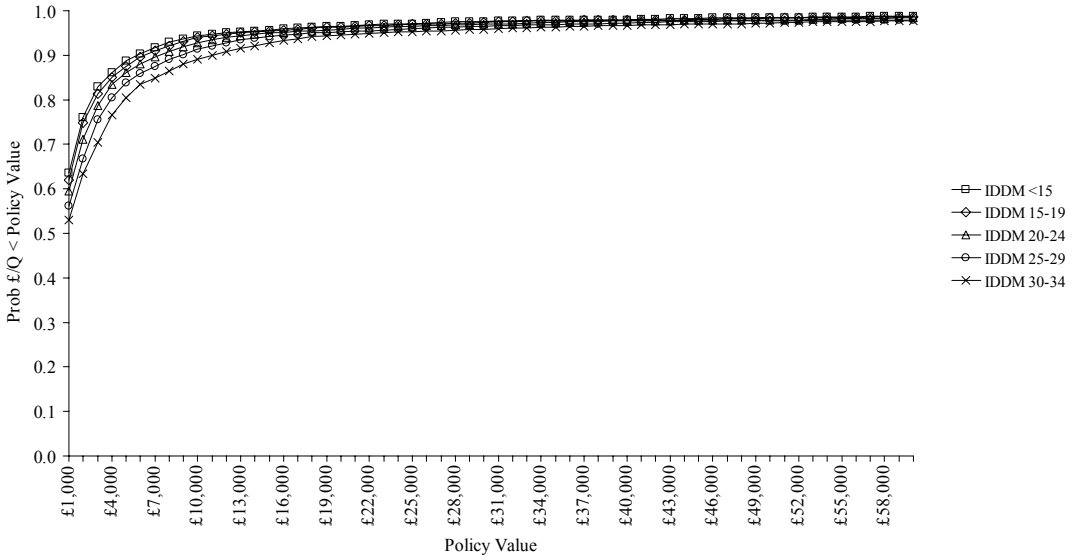
Opportunistic to Systematic Mydriatic: RRR 70% Benefit DR 0.0%

IDDM Incidence



Systematic Non Mydriatic to Systematic Mydriatic: RRR 70% Benefit DR 0.0%

IDDM Incidence



Appendix 27

DOWNSTREAM TREATMENT COSTS

The net effects of a move from opportunistic screening in steady state to systematic screening are outlined below for an incidence of sight-threatening retinopathy of 1.3%.

Net Effect: Opportunistic to Systematic				
Year	False +ve	Treatment	ST Prev	Cost
1	-3,036	1,139	0.00%	£1,271,249
2	-2,995	424	-0.66%	£394,136
3	-2,983	228	-0.84%	£153,599
4	-2,980	174	-0.89%	£87,634
5	-2,979	159	-0.90%	£69,544
6	-2,979	155	-0.91%	£64,584
7	-2,979	154	-0.91%	£63,223
8	-2,979	154	-0.91%	£62,850
9	-2,979	154	-0.91%	£62,748
10	-2,979	154	-0.91%	£62,720
11	-2,979	154	-0.91%	£62,712
12	-2,979	154	-0.91%	£62,710
13	-2,979	154	-0.91%	£62,709
14	-2,979	154	-0.91%	£62,709
15	-2,979	154	-0.91%	£62,709
16	-2,979	154	-0.91%	£62,709

The derivation of these figures is presented in the following table, along with an exploration of the effects of an annual incidence of sight-threatening retinopathy of 1.0%, 1.3% and 1.6%.

	Opportunistic				**Systematic**				**Net Effect**
Year	False +ve	Treat	ST Prev	Cost	False +ve	Treat	ST Prev	Cost	Cost
1	9,166	1,378	2.08%	£2,080,670	6,110	2,254	2.08%	£3,028,071	£947,401
4	9,166	1,378	2.08%	£2,080,670	6,153	1,512	1.39%	£2,117,604	£36,934
7	9,166	1,378	2.08%	£2,080,670	6,154	1,496	1.38%	£2,098,826	£18,156
10	9,166	1,378	2.08%	£2,080,670	6,154	1,496	1.38%	£2,098,439	£17,768
13	9,166	1,378	2.08%	£2,080,670	6,154	1,496	1.38%	£2,098,431	£17,760
16	9,166	1,378	2.08%	£2,080,670	6,154	1,496	1.38%	£2,098,431	£17,760
ST Incidence 1.00%									

	Opportunistic				**Systematic**				**Net Effect**
Year	False +ve	Treat	ST Prev	Cost	False +ve	Treat	ST Prev	Cost	Cost
1	9,107	1,791	2.70%	£2,586,009	6,072	2,931	2.70%	£3,857,258	£1,271,249
4	9,107	1,791	2.70%	£2,586,009	6,127	1,965	1.81%	£2,673,644	£87,634
7	9,107	1,791	2.70%	£2,586,009	6,128	1,945	1.79%	£2,649,232	£63,223
10	9,107	1,791	2.70%	£2,586,009	6,128	1,945	1.79%	£2,648,729	£62,720
13	9,107	1,791	2.70%	£2,586,009	6,128	1,945	1.79%	£2,648,718	£62,709
16	9,107	1,791	2.70%	£2,586,009	6,128	1,945	1.79%	£2,648,718	£62,709
ST Incidence 1.30%									

	Opportunistic				**Systematic**				**Net Effect**
Year	False +ve	Treat	ST Prev	Cost	False +ve	Treat	ST Prev	Cost	Cost
1	9,049	2,204	3.32%	£3,091,346	6,033	3,607	3.32%	£4,686,432	£1,595,086
4	9,049	2,204	3.32%	£3,091,347	6,101	2,419	2.23%	£3,229,683	£138,336
7	9,049	2,204	3.32%	£3,091,347	6,102	2,394	2.21%	£3,199,638	£108,291
10	9,049	2,204	3.32%	£3,091,347	6,102	2,394	2.20%	£3,199,018	£107,671
13	9,049	2,204	3.32%	£3,091,347	6,102	2,394	2.20%	£3,199,006	£107,658
16	9,049	2,204	3.32%	£3,091,347	6,102	2,394	2.20%	£3,199,005	£107,658
ST Incidence 1.60%									

The previous tables assume that opportunistic screening, as characterised in the NSC report, has reached a steady state. However, this leads to a background prevalence of sight-threatening retinopathy below that commonly reported. The following tables explore the effect of a background prevalence of 5.5% and annual incidences of 1.0%, 1.3% and 1.6%.

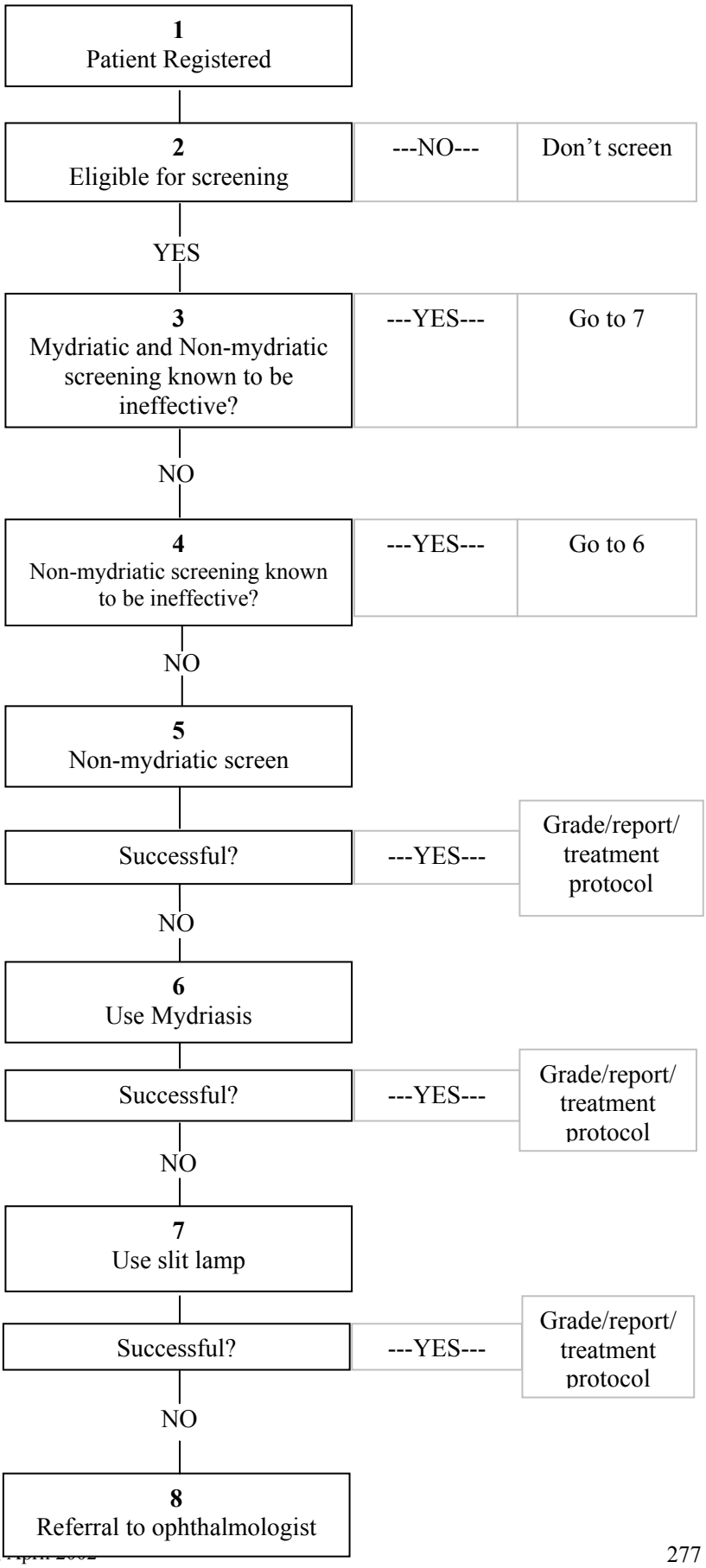
	Opportunistic				**Systematic**				**Net Effect**
Year	False +ve	Treat	ST Prev	Cost	False +ve	Treat	ST Prev	Cost	Cost
1	8,845	3,650	5.50%	£4,858,505	5,897	5,972	5.50%	£7,586,059	£2,727,555
4	9,121	1,694	2.55%	£2,467,542	6,149	1,588	1.46%	£2,211,610	-£255,932
7	9,159	1,422	2.14%	£2,134,550	6,154	1,498	1.38%	£2,100,765	-£33,786
10	9,165	1,384	2.09%	£2,088,174	6,154	1,496	1.38%	£2,098,479	£10,304
13	9,166	1,379	2.08%	£2,081,715	6,154	1,496	1.38%	£2,098,432	£16,716
16	9,166	1,378	2.08%	£2,080,816	6,154	1,496	1.38%	£2,098,431	£17,615
ST Incidence 1.00%									

	Opportunistic				**Systematic**				**Net Effect**
Year	False +ve	Treat	ST Prev	Cost	False +ve	Treat	ST Prev	Cost	Cost
1	8,845	3,650	5.50%	£4,858,505	5,897	5,972	5.50%	£7,586,059	£2,727,555
4	9,071	2,050	3.09%	£2,902,502	6,123	2,028	1.87%	£2,750,548	-£151,953
7	9,102	1,827	2.75%	£2,630,087	6,128	1,947	1.79%	£2,650,818	£20,731
10	9,107	1,796	2.71%	£2,592,148	6,128	1,945	1.79%	£2,648,761	£56,614
13	9,107	1,792	2.70%	£2,586,864	6,128	1,945	1.79%	£2,648,719	£61,855
16	9,107	1,791	2.70%	£2,586,128	6,128	1,945	1.79%	£2,648,718	£62,590
ST Incidence 1.30%									

	Opportunistic				**Systematic**				**Net Effect**
Year	False +ve	Treat	ST Prev	Cost	False +ve	Treat	ST Prev	Cost	Cost
1	8,845	3,650	5.50%	£4,858,505	5,897	5,972	5.50%	£7,586,059	£2,727,555
4	9,021	2,406	3.63%	£3,337,461	6,098	2,467	2.27%	£3,289,486	-£47,975
7	9,045	2,233	3.36%	£3,125,624	6,102	2,395	2.21%	£3,200,871	£75,248
10	9,049	2,208	3.33%	£3,096,121	6,102	2,394	2.20%	£3,199,044	£102,923
13	9,049	2,205	3.32%	£3,092,012	6,102	2,394	2.20%	£3,199,006	£106,994
16	9,049	2,205	3.32%	£3,091,440	6,102	2,394	2.20%	£3,199,005	£107,565
ST Incidence 1.60%									

Appendix 28

HTBS MODEL FOR DIABETIC RETINOPATHY SCREENING



Appendix 29

THE NHS BOARD TRANSITIONAL ISSUES TO MOVE TO THE HTBS MODEL

Argyll and Clyde

Argyll and Clyde NHS Board has proposed an evolutionary path building upon existing optometrist systems. They have a bid in the local health plan for the digital camera technology and an implementation person. The plans are to obtain:

- hospital cameras and associated technologies at two hospitals to enable diagnostic, treatment, training and QA aspects and brokerage;
- non mydriatic cameras to be used in semi mobile settings - Health centre, GP surgery and / optometrist - either two or four to enable evolution and to test linkages to relevant hospital based services and LHCC activities;
- an implementation person - grade 5 for one year.

With this, registers will be better established and it will be possible to work through the issues and the ground rules locally both for call/recall and QA.

Glasgow

In the past, Greater Glasgow NHS Board has provided no funding to establish any form of retinal screening, so any ongoing 'good work' was very local and not performed to the quality standards recommended by HTBS. However, this means that there is no existing system to dismantle, or to persuade people to move away from.

The Board has now committed recurring funding to fully implement the recommendation produced by a local working group in 2000 to establish city-wide retinal screening using four digital cameras. The proposed system has been modified during development to ensure that HTBS recommendations are incorporated. However fully implementing HTBS recommendations will incur costs which were not anticipated in the original proposal, and for which funding has yet to be secured. The draft procurement document can be seen in Appendix 14.

Glasgow's other current problem is that by being among the first to introduce a screening programme which incorporates HTBS recommendations they are having to do much of the detail development work themselves. This has delayed the implementation of the local screening service. By involving individuals from other NHS Board areas (Grampian and Tayside) in some of that planning the Glasgow group is gaining from their expertise - hopefully other areas will in turn gain from lessons learned during this implementation.

Had this process not been underway in Glasgow, and they were required to implement the HTBS recommendations locally, the main things which would have been required to facilitate the change would have been the will and resource to establish a broad-based project management team to:

- design and get local agreement on the new service;
- cost and secure funding for the new service;
- produce a schedule for progressing towards the new service;
- oversee and coordinate the implementation through to its completion.

Orkney

The population served by NHS Orkney includes about 800 people with diabetes, who also require retinal screening. At present this is provided by direct ophthalmoscopy, either by a consultant physician or diabetologist in training at periodic visiting hospital diabetic clinics or by the patients' GP. Some patients may also attend the single optometrist practice on the islands, but this practice does not participate in any formal scheme.

There is no QA for any form of retinal screening. The optometrist practice does possess a digital retinal camera, although its technical specification is unknown.

From this low baseline it is clear that rather than a transition there is a need for a complete introduction of a retinal screening service to meet the HTBS recommendations.
Options include:

- Utilise optometry-based camera for image capture and contract for off-island image grading and reporting with another centre;
- Contract for a visiting mobile service to come to the islands from elsewhere for a few weeks per year, to include all technical provision and QA;
- Purchase dedicated camera for use from a fixed base in Kirkwall, with off-island grading and reporting. Although the Orkney Islands comprise 17 inhabited islands, the majority live on mainland Orkney, and almost all would have occasion to visit Kirkwall at least once per year;
- Full on island service comprising retinal photography and grading, with possible external quality assurance;
- Whatever option is chosen there will be a need for locally (within NHS Orkney) coordinated call/recall and integration of the results into the patient record and diabetes register which is in the early stages of construction.

Tayside

At present there is a non-mydriatic retinal camera housed in a mobile unit, driven and operated by a Technician Photographer. Approximately 5,000 patients are sent appointments each year and approximately 4,000 patients are photographed without mydriasis (i.e. 20% failure to attend). Digital images are graded and then loaded onto the DARTS website (available on Tayside NHSNet) and are available to all clinicians involved in the patients' care (GPs, diabetologists and ophthalmologists).

The requirements to implement the HTBS recommendations would be:

1. Retinal photography facility for additional 6,000 patients (and rising):
   - either using trained optometrists, of which 6 in Tayside are keen to be involved;
   - present mobile unit would need to be exchanged for a larger van (waiting area);
   - or using a further two cameras, one static and one mobile, or two static;
   - legal clarification is required about the use of eye drops by retinal photographers;
   - need to upgrade resolution on present retinal camera.

2. Need to identify individuals to perform slit lamp examination in those failing photography:
   - this would most appropriately be either community-based or hospital-based optometrists.

3. Increased administration time:
   - needs to be increased from present 0.2 wte to 1.0 wte;
   - extra time needed for audit (to be determined, could be approximately 0.2 wte).

4. Grade images:
   - needs 0.5 wte for image grading once established;
   - needs recognised training course for non-medical graders.

5. Quality control:
   - needs 0.1wte medical time for quality control and overall administration;
   - needs 0.1wte ophthalmologist time to help with "level 3" grading.