



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executiv

Framework for the Development of a Diabetic Retinopathy Screening Programme for Ireland

October 2008



Irish College of Ophthalmologists

Foreword

It is my pleasure to present the National Framework for Diabetic Retinopathy Screening in Ireland, on behalf of the HSE and the Irish College of Ophthalmologists.

Diabetes is a serious life long disease for individuals. As with other chronic diseases it cannot be cured but only controlled. Control of the complications of diabetes is essential to the quality of life of affected people. The health services spend large amounts of funding on diabetes care, particularly on treating complications. Better management and control of diabetes, together with early detection and treatment of complications will reduce complications, bringing both benefit to the individual and to the health services.

Retinopathy is one of the commonest serious complications of diabetes. This sight threatening condition is preventable by early detection through population screening and treatment. This Framework prepared by the Expert Advisory Group will guide the development of the National Retinopathy Screening Programme for all diabetics in the future.

Professor Brendan Drumm

Foreword

In 2007 the HSE set up the Expert Advisory Group on Diabetes. Diabetic retinopathy screening was immediately identified as a priority service in need of development by the Expert Advisory Group. The Expert Advisory Group set up a sub group called the "National Retinopathy Screening Committee" to develop the plan for a national screening service. This framework document describes the blueprint for the national programme.

Diabetes is a common chronic disease which is getting more prevalent, over 140,000 adults in Ireland suffer from diabetes. One of the serious complications of diabetes is retinopathy, which can lead to blindness. Diabetic retinopathy is the leading cause of blindness in working age individuals. Diabetic retinopathy is preventable by early detection and appropriate treatment.

The National Retinopathy Screening Committee have differentiated between individual patient examination on an ad hoc basis and organised population screening using reproducible quality assured methods.

The most effective method of early detection is by a population based screening programme, which will seek to identify all diagnosed people with diabetes and offer them annual screening, followed by treatment as necessary. The most effective method of screening is by digital photography, which allows for reproducible and quality assurable results.

The Expert Advisory Group on Diabetes (EAG) has approved the development of the National Diabetic Retinopathy Screening Programme and prioritised this for funding and implementation. The Department of Health and Children has made available initial funding to begin roll out of the programme in the HSE West area. Funding is being sought to continue the roll out of the programme in each of the other HSE areas sequentially.

The Expert Advisory Group on Diabetes EAG has approved the development of the National Diabetic Retinopathy Screening Programme and prioritised this for funding and implementation. This Framework Document has been approved by HSE with the endorsement of the Irish College of Ophthalmologists. The Department of Health & Children has made available initial funding to commence the programme. Unfortunately due to financial pressures within HSE it has not been possible to commence implementation as yet. It is anticipated that as economic circumstances allow, this programme will be implemented as a priority, any implementation of diabetic retinopathy screening should follow this framework.

Dr. Orlaith O' Reilly,
Director of Public Health,
Chairperson of the EAG National Retinopathy Screening Committee.

This framework was drafted on behalf of the National Retinopathy Screening Committee, by the Retinopathy Project Team, with contributions from the members of the National Committee.

Members of the group reviewed the literature concerning best practice in retinopathy screening, consulted with the U.K. National Screening Programme, commissioned the English National Screening Co-Ordinator for expert advice, and met with the Association of Optometrists in Ireland and the Irish College of Ophthalmologists. The Expert Committee considered information from the above sources in coming to their conclusions.

A survey of retinopathy detection services around the country was conducted by Ms. Gemma Leane and Dr. Sarah Doyle, Public Health Department, South East, on behalf of the Project Team.

The members of the EAG National Retinopathy Screening Committee are:

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The members of the Project Team are:

Dr. Orlaith O' Reilly	<i>Director of Public Health, National Population Health Lead for Diabetes</i>
Ms. Mairead Gleeson	<i>Project Manager CVD/Chronic Illness</i>
Ms. Gemma Leane	<i>Research Officer</i>
Dr. Sarah Doyle	<i>Specialist in Public Health Medicine</i>

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I am also grateful for the assistance given by Dr. John Devlin, Deputy Chief Medical Officer, Department of Health and Children. Finally thanks to Ms. Caroline Dunlop, Ms. Janet Nolan and Ms. Rita Hayden for administrative support.

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1

Vision of a National Diabetic Retinopathy Screening Programme

1. Vision of a National Diabetic Retinopathy Screening Programme

This will be a national population-based programme of diabetic retinopathy screening offered to all people with diabetes aged 12 years and over and registered with the programme. The programme will be delivered locally and provided to the highest, internationally comparable, quality assured standards. The programme database will be reliable, comprehensive, secure and comply with data protection legislation.

2

Principles of a National Diabetic Retinopathy Screening Programme

2. Principles of a National Diabetic Retinopathy Screening Programme

There will be one national diabetic retinopathy screening programme, with a national office which will set standards, monitor the programme and carry out quality assurance audits. The national programme will be developed for implementation HSE area by area as resources allow. Each HSE area will implement the screening programme as part of the national programme and will report to the national office.

The national office will report to the National Director Primary Community and Continuing Care (PCCC)*** and will appoint appropriate Scientific Advisory Committees for advice.

The following principles of the national diabetic retinopathy screening programme have been adopted by the Diabetes Expert Advisory Group (EAG).

- It will be a population based call-recall programme, delivered on an annual basis.
- Eligible patients will include all those with diagnosed diabetes, aged 12 years and over who are not excluded*.
- It will be accessible to all eligible patients i.e.
 - free
 - wheelchair accessible
 - delivered locally
 - provision will be made for the screening of prisoners and persons in nursing/residential homes who are fit to receive treatment.
- Screening will be carried out using digital retinal photography.
- Screening will be delivered in four area programmes, based on a population of approximately one million and a geographic area corresponding to each HSE area**.
- A database of people with diagnosed diabetes will be established in each area, and collated nationally.
- A grading service will be developed on the basis of each HSE area population, these centres will grade images taken by all photographers in the programme for that area.
- As the national service develops the benefits of four grading centres or one national centre will be assessed.
- The photography model will be mixed i.e. a combination of fixed and mobile clinics and, possibly photography by accredited private practitioners depending on the geographical distribution of the population, public transport links, economies of scale and in compliance with quality assurance standards.
- HSE areas will propose their preferred service model to the National Retinopathy Screening Committee/national office for approval.
- Screening will be carried out in cooperation with appropriate Health Care Staff.
- There will be timely referral, assessment and treatment of abnormalities discovered.
- There will be timely feedback to the screening programme of the result of screening events and of referrals.
- There will be a robust system of clinical governance and quality assurance. The UK National Screening Committee service objectives and English quality assurance standards will be adopted1 (see Appendix 1).

* The following groups of people may be excluded from offers of screening:

- a) a person with diabetes who has made his or her own informed choice that he or she no longer wishes to be invited for screening;
- b) a person with diabetes who is under the age of 12 years (in which case he or she should not have been referred to the programme until they have reached the eligible age);
- c) a person with diabetes who does not have perception of light in either eye;
- d) a person with diabetes who is terminally ill or medically unfit for treatment;
- e) a person with diabetes who has a physical or mental disability preventing either screening or treatment. People with diabetes should not be removed from the list of people offered screening simply because they suffer from a disability which makes it more difficult to provide screening or treatment. However, it may not be possible to screen a small number of people with diabetes due to learning or physical disabilities and this may prove to be an obstacle that cannot be overcome. If it is not possible to screen a person with conventional screening methods, it may still be possible for an ophthalmologist to examine their eyes and in some circumstances to treat the patient (e.g. if the patient is treated under general anaesthetic).

** A critical size population for a retinopathy screening programme is approximately one million.

Service delivery will be reviewed as appropriate if HSE geographical areas are restructured.

*** In a restructured HSE, the National Office may report to the National Clinical Directorate.

3

Summary

3. Summary

Diabetes Mellitus (DM) is associated with the development of a number of complications. One of these is the development of diabetic retinopathy, potentially resulting in blindness. Timely and appropriate care for people with diabetes can significantly reduce visual loss over time, improve patients' quality of life, and reduce the financial burden associated with the complications of visual impairment. Screening, followed by treatment of sight-threatening retinopathy, has been shown to be effective. Effective treatment of diabetic retinopathy may include laser photocoagulation or vitrectomy. Of the population screened and treated, 6% are prevented from going blind within a year of treatment and 34% within ten years of treatment. In addition, the costs of preventing blindness through screening for retinopathy are much lower than those for treatment of advanced lesions.

In 2006 the Department of Health and Children made a number of policy guidance recommendations on the model of care, and services for people with diabetes. They recommended a structured diabetic retinopathy screening programme as a priority.

The diabetes retinopathy project is being led by the Population Health Directorate to establish a national, population-based diabetic retinopathy screening programme. The Diabetes Expert Advisory Group (EAG), which was established in 2007, has recommended the screening programme as a priority for 2008. The Diabetes EAG has formed a sub group for diabetic retinopathy screening called the National Retinopathy Screening Committee. This is the steering committee for the project.

The national programme will be a population-based, call-recall programme of screening for sight-threatening diabetic retinopathy, delivered on an annual basis. Screening will be by digital photography and will be offered to people with diagnosed diabetes, aged 12 years and over, registered with the programme. The programme will be delivered locally and provided to the highest, internationally comparable, quality assured standards. A database of people with diagnosed diabetes will be established in each area, and collated nationally.

The diabetic retinopathy screening programme will be a unified national programme. The structure will be based on the four HSE areas**, with a central grading, administration and management office within each area and a national office to provide national programme leadership, guidance, governance and quality assurance. The national programme will be led by a national clinical lead who will report to the National Director Primary Community and Continuing Care.*** The national office may appoint appropriate Scientific Advisory Committees, as required, and a National Retinopathy Steering Committee will be established to facilitate planning and implementation, followed by quality assurance as the programme develops. Each area will also have their own clinical lead who will report professionally to the national lead. An annual report, providing information relating to performance against national quality standards, will be required from each area programme and from the national programme.

Screening will be delivered in four area programmes, based on a population of approximately one million and a geographic area corresponding to each HSE area.** There will be a mixed model of photography i.e. a combination of fixed and mobile clinics and, possibly, photography by accredited private practitioners in each area. Adherence to quality assurance standards and value for money will be essential in informing which model is adopted in each HSE area. These standards will be set by the National Retinopathy Steering Committee and national office. A grading service will be developed on the basis of each HSE area population and images taken by photographers in that area programme will be graded in the area grading centre. There will be timely referral, assessment and treatment of abnormalities discovered and timely feedback to the screening programme of the result of screening events and of referrals.

Consultation with the English national screening programme for diabetic retinopathy has established the overriding need to procure a national IT system to support the screening programme and quality assurance in Ireland. Approval is being sought for this from the Department of Finance and Department of Health and Children.

Each HSE area will implement the screening programme as part of the national programme and will report to the national office.

Screening will be carried out in cooperation with appropriate Health Care Staff.

There will be a robust system of clinical governance and quality assurance. The UK National Screening Committee service objectives and English quality assurance standards have been adopted (see Appendix 1).

** A critical size population for a retinopathy screening programme is approximately one million.

Service delivery will be reviewed as appropriate if HSE geographical areas are restructured.

*** In a restructured HSE, the National Office may report to the National Clinical Directorate.

4

Introduction

4. Introduction

Diabetes mellitus (DM) is a disorder of multiple causation characterised by chronic hyperglycaemia (high blood glucose levels) with disturbances of carbohydrate, fat and protein metabolism². These result from defects of insulin secretion, insulin action, or a combination of both. Type 1 diabetes is due to a virtually complete lack of pancreatic insulin production, whereas in type 2 diabetes, high blood glucose results from a combination of genetic predisposition, unhealthy diet, physical inactivity, and increasing weight with a central distribution resulting in complex pathophysiological processes².

DM is associated with the possibility of development of a number of specific complications. Some of these are due to abnormalities of large blood vessels (macrovascular complications) or of small blood vessels (microvascular complications). Included among the microvascular complications of DM is the development of diabetic retinopathy, potentially resulting in blindness².

A number of risk factors for diabetic retinopathy have been identified, including some e.g. poor blood glucose control, raised blood pressure, for which better control is associated with improved outcomes in diabetic retinal disease³.

Effective treatment of diabetic retinopathy is available and may include laser photocoagulation or vitrectomy³.

In 2003 it was estimated that there were 194 million people, or 5.1% of the adult population, worldwide with diabetes⁴. With the epidemic of obesity that is currently being experienced in the developed world it is predicted that this figure will rise to 333 million, or 6.3%, by 2025⁴. The actual prevalence of diabetes in Ireland is not known. A report published by the Institute of Public Health in Ireland provides the best available estimates of the population prevalence of diabetes (diagnosed and undiagnosed) in 2005⁵. Just over 141,000 persons in Ireland are estimated to have adult diabetes (type 1 and 2 combined), i.e. 4.7% of all adults, aged 20 years and older. The estimated population prevalence for 2015 is 5.6% (194,000 adults with diabetes), representing an increase of 37% over the ten years⁶. This will be largely due to an increase in the incidence of type 2 diabetes owing to the increases in childhood and adolescent obesity.

The incidence of blindness secondary to diabetes has been reported to be 50-65 per 100,000 people with diabetes per year in Europe⁷⁻⁹, with diabetic retinopathy being the leading cause of blindness in working age individuals¹⁰. This is despite the fact that effective treatment is available. In Ireland it is not known what the incidence of blindness is among people with diabetes. However, one study looked at trends in blindness from 1996 to 2003 by comparing data on those registered blind on the National Council for the Blind in Ireland database over the seven year period¹¹. Numbers registered increased from 5,002 in 1996 to 6,862 in 2003, with a dramatic 120% increase in the numbers registered caused by diabetic retinopathy (from 147 to 323 people). This equates to a rise from 5.2 per 100,000 adults in 1996 to 10.7 per 100,000 adults in 2003. Diabetic retinopathy accounted for 7% of new registrations in 2003 and 11% of new registrations among working adults (16-64 years). This made it the second most common cause of blindness in this group and equates to seven per 100,000 working aged adults.

Due to the growing burden of diabetes over the past number of decades all European countries unanimously agreed the "St. Vincent Declaration" in 1989. The general goals agreed were the sustained improvement in health experience, a life approaching normal expectation in quality and quantity, and prevention and cure of diabetes, and of its complications, by intensifying research effort. A number of five-year targets were agreed, including the reduction of blindness due to diabetes by one third or more¹².

Timely and appropriate care for people with diabetes can significantly reduce visual loss over time, improve patients' quality of life, and reduce the financial burden associated with the complications of visual impairment¹³. The importance of early and adequate retinal screening and subsequent treatment for all people with diabetes is vital^{14,15}. Screening, followed by treatment of sight-threatening retinopathy, has been shown to be effective. Of those screened and treated, the population prevented from going blind is 6% within a year of treatment and 34% within ten years of treatment¹⁶. In 1989, it was estimated that an effectively managed community based screening programme, comprising of detection, referral, treatment, and follow-up could prevent 260 new cases of blindness in people with diabetes every year in those aged under 70 in England and Wales, which would represent over 10% of all cases of blindness in adults in this age group¹⁷. A recent report¹⁸ in 2008 has estimated this figure to have increased in England to at least 427 new cases of blindness.

The expenses involved in preventing blindness through screening for retinopathy are much lower than those involved in unsuccessful treatment of far advanced lesions. It has been estimated that the cost-effectiveness of screening and treatment of diabetic retinopathy, is greater than most commonly provided medical interventions and, indeed, that detecting and treating diabetic eye disease is one of the least costly interventions ever studied¹⁹. In 2000, a study in Liverpool measured the cost effectiveness of systematic photographic screening for sight threatening diabetic eye disease compared with existing opportunistic practice and found systematic screening to be more cost effective²⁰. Evidence to date identifies digital retinal photography as being the optimal and most cost-effective method of performing retinopathy screening²¹.

Screening for diabetic retinopathy fulfils the Wilson and Jungner²² criteria for a screening programme^{17,23}. These criteria have formed the basis of the UK National Screening Committee (NSC) criteria for appraising the viability, effectiveness and appropriateness of a screening programme²⁴. It is recognised that screening for diabetic retinopathy is different from screening for other diseases because screening is to prevent the development of complications in existing patients rather than detection of early disease in healthy populations. However, it still comes under the remit of the NSC. In 2000, Garvican, Clowes and Gillow reported the findings of a group commissioned by the NSC to develop a model and cost estimates for a comprehensive national risk-reduction programme for diabetic retinopathy²⁵. A systematic national programme based on digital photography was proposed. Systematic screening programmes using digital fundus photography are currently being rolled out across England, Scotland, Wales and Northern Ireland.

In 2006 the Department of Health and Children made a number of policy guidance recommendations in relation to the model of care for people with diabetes and recommendations for how services will prevent and manage diabetes in the population²⁶. They recommended a structured retinopathy screening programme as a priority for people with diabetes.

5

Background, Aims and
Progress to Date

5. Background, Aims and Progress to Date

Diabetes Expert Advisory Group (EAG) and National Retinopathy Screening Committee

The diabetes retinopathy project is being led by the Population Health Directorate to establish a national, population-based diabetic retinopathy screening programme. The Diabetes EAG, which was established in 2007, has recommended the screening programme as a priority for 2008.

The Diabetes EAG has formed a sub group for diabetic retinopathy screening called the National Retinopathy Screening Committee. This is the steering committee for the project. The EAG has recommended that the HSE set up a national office to govern the programme ongoing. In the development stage, and in the short term, the National Retinopathy Screening Committee will continue to act as the governing body.

The terms of reference of the National Retinopathy Screening Committee are:

1. To prepare a national framework for the development, implementation, and monitoring of a national screening programme for the detection of sight-threatening diabetic retinopathy.
2. To set out the principles of a diabetic retinopathy screening programme.
3. To set out the monitoring arrangements for the programme.
4. To advise the HSE on the governance and quality assurance standards required.
5. To advise on, and support, implementation of the programme in each of the HSE areas.
6. To advise on, and monitor, implementation of a national diabetic retinopathy screening programme.
7. To advise on the requirement to have diabetic retinopathy screening supported by suitable information technology systems, which are integrated with the rest of diabetes care.
8. To identify workload changes which will occur in ophthalmic services as a result of the introduction of a diabetic retinopathy screening programme.
9. To work with the Diabetes EAG to facilitate diabetic retinopathy screening being fully integrated with all aspects of diabetes care.
10. To invite proposals from each HSE area on the development of services in their area for a diabetic retinopathy screening programme, based on the programme principles set out by the National Retinopathy Screening Committee.
11. To make recommendations to HSE on service developments for diabetic retinopathy screening nationally and within each HSE area.

Following consultation with the English programme the National Retinopathy Screening Committee agreed the aims and principles of a national diabetic retinopathy screening programme.

The **aims** of a national diabetic retinopathy screening programme are to:

- Detect sight threatening diabetic retinopathy which is treatable;
- Detect any diabetic retinopathy that is possible to detect with digital retinal photography;
- Provide screening on a call/recall basis according to best practice guidelines;
- Refer patients in a timely way for ophthalmic assessment and treatment, as required;
- Ensure that there is feedback from the result of clinical examination to the screening service from ophthalmic services

6

Timeframe and Targets

6. Timeframe and Targets

In December 2007 the Diabetes EAG made recommendations to the HSE Leadership Team for the development of diabetes services. The EAG prioritised the roll out of the national diabetic retinopathy screening programme in 2008. The following are the timeframes and targets recommended by the Diabetes EAG.

Timeframe and Targets

1. That funding for the development of a national diabetic retinopathy screening programme be prioritised in 2008.
2. That funding be made available incrementally over the next four years, from 2008 to 2011 to implement the programme in each of the HSE areas, commencing the programme in a new area each year.
3. That the HSE immediately prioritise funding and commence procurement for an eye specific IT system to support a national diabetic retinopathy screening programme.
4. That the HSE set up a formal governance structure for a national diabetic retinopathy screening programme.
5. 95% of registered people with diabetes being invited for screening by Year Five of full national implementation.
6. 70% of registered people with diabetes attending screening by Year Five of full national implementation.

The Liverpool Declaration, 2005, (arising from conference to review progress with St. Vincent Declaration) declares that "European countries should reduce the risk of visual impairment due to diabetic retinopathy by 2010 by: systematic programmes of screening reaching at least 80% of the population with diabetes; using trained professionals and personnel; and universal access to laser therapy".

7

Current Services

7. Current Services

Introduction

A review of current service provision for diabetic retinopathy screening and examination was carried out at the end of 2007. All ophthalmologists, HSE hospital network managers and HSE local health managers were contacted and asked to provide details of diabetic retinopathy screening/examination services in their catchment area. A detailed review of the current service provision is in Appendix 3. The following is a summary of the main findings.

Results

Of the 176 postal questionnaires sent to ophthalmologists there were 66 completed returns and 15 unopened returns, an overall response rate of 41% (66/161). Even though the response rate is low there is sufficient geographical spread in responses received to describe service provision across the four HSE areas. However, there is insufficient information to provide details on community service provision in the former East Coast Area and the South Western Area Health Boards.

Of the 66 returned questionnaires, 48 ophthalmologists provide/oversee routine diabetic retinal screening/examination and 18 do not. Responses from the 48 ophthalmologists, 26 local health managers and seven hospital network managers were analysed. The analysis relates primarily to structure and process questions as there was insufficient response to the outcome sections of the questionnaire to provide meaningful results. The following sections describe the structure and process of diabetic retinopathy screening/examination services in Ireland.

Structure

The structure of the provision of services is presented by the four HSE administrative areas.

HSE South

In the former South Eastern Health Board (SEHB) area the provision of diabetic retinopathy screening/examination services are primarily provided through community care. There are four full-time Community Ophthalmic Physicians (COPs), one assigned to each of the four Local Health Office (LHO) areas, who provide dedicated diabetic retinopathy screening/examination clinics. A digital fundal camera is used for screening/examination in two of the LHO areas. Waterford Regional Hospital also provides a dedicated clinic, using slit lamp biomicroscopy as the screening method.

In the former Southern Health Board (SHB) area screening/examination services are provided through the hospital network, with support from community ophthalmologists. There are two COPs, with one COP serving the four LHO areas that cover Co. Cork. Cork University Hospital (CUH) and Kerry General Hospital (KGH) have dedicated screening clinics, with CUH using digital photography as part of the screening process. The COP in Kerry provides the dedicated clinic in KGH. A digital camera is available but is not used for screening.

HSE West

In the HSE West there are currently two good practice diabetic retinopathy screening services in operation, a population based diabetic retinopathy screening service offered to patients of all 81 general practices in the former North Western Health Board (NWHB) area and a hospital based retinal screening service in University College Hospital Galway.

The North West service covers Donegal, Sligo, Leitrim and the western part of Cavan. All people with diabetes, regardless of medical card status, are screened, including those already attending ophthalmic services. The service commenced in October 2005 and consists of a 'mixed' screening system. Screening, using a digital camera, is provided in one fixed screening site at St Conal's Hospital, Letterkenny. The rural population is serviced by a single mobile unit which visits 39 health centres across the region. A grading and administrative centre for the service is based at St. Conal's Hospital. Image capture, grading and management software is supplied by Prowellness.

Six people are directly involved in the screening programme:

- 1 WTE administrator
- 1 WTE community ophthalmologist/secondary grader
- 2 x 0.5 WTE screeners
- 2 x 0.5 WTE grader/screeners

Currently there are approximately 6,000 people with diabetes registered on the database. More than a quarter of those screened (27%) have been referred to ophthalmic services for further evaluation, and treatment as required. The first round of screening is complete and the second round commenced in May 2007.

In the former Western Health Board (WHB) area a hospital based retinal screening service is offered at the Endocrinology and Diabetes Day Centre at University College Hospital Galway. This service was set up in March 2006 on a pilot basis and is available to patients attending the centre, including other patients from hospital services.

There is a large photography room, which houses the Canon camera and Digital Healthcare computer software system. Fundus photography and primary grading is carried out here. Secondary grading is done in the ophthalmology office. There is also an office for secretarial and administrative duties. The grading criteria used is the National Screening Committee (NSC) retinopathy grading standard that is used in England, Wales and Northern Ireland.

Three people are directly involved in the screening programme:

- 1 photographer/ primary grader/ administrator post that is shared with the general eye clinic
- 0.5 WTE ophthalmologist /secondary grader
- 0.5 WTE secretarial assistant

There are 3,591 persons registered on the database (as of August 2007). In the first year (March 2006-2007) 1,517 persons with diabetes were screened (43% of patients registered).

In the former Mid Western Health Board (MWHB) area there are no community ophthalmology based dedicated diabetic retinopathy screening services. At the Mid Western Regional Hospital Limerick a dedicated diabetic retinopathy clinic is provided by a COP, with a Consultant Ophthalmic Surgeon, on a sessional basis.

HSE Dublin North East

One or two COPs serve each LHO area in the former North Eastern Health Board (NEHB) area and one COP serves the three LHO areas in North Dublin. In the region diabetic retinopathy screening/examination is generally provided as part of routine eye clinics and not in dedicated diabetic eye clinics. However, there is a dedicated diabetic retinal clinic provided in Louth LHO by the COP.

HSE Primary Care Services Dublin North East area have a service level agreement with a company called 'Foresight Eye Care' to provide a mobile retinal screening service to patients in the Diabetes Watch Programme¹. Photographic screening takes place at selected GP practices/suitable health centres. This is a publicly funded, privately provided screening service for 1500 people with diabetes using digital retinal photography and three stage grading with internal and external quality assurance. The programme management software used is Acuitas. The grading criteria used is the NSC retinopathy grading standard. Three people are involved in the screening programme, one ophthalmologist, one photographer (nurse), one primary grader and administrator (optometrist). A random sample of 10% of all images are sent for quality assurance to an external ophthalmologist. The cost of the screening service is €90 per person screened and €45 for each non-attendee. The follow-up examination and treatment on patients deemed to have evidence of diabetic retinopathy of an extent that would require laser photocoagulation is not covered by this programme. However, Foresight assumes the responsibility of assuring referral into the hospital eye service of such patients.

The review identified two hospitals in the region providing dedicated services. A diabetic retinal screening clinic operates once weekly in Drogheda, using slit-lamp biomicroscopy. The Mater hospital operates two clinics each week, a diabetic eye photographic clinic (for no retinopathy, mild retinopathy, new cases) and a diabetic eye specialist clinic (for retinopathy requiring treatment and follow-up). Two nurses, three photographers and one administrator provide some support to this service. People with diabetes are also reviewed in general ophthalmology clinics in other hospitals in the region.

HSE Dublin/Mid Leinster

For the former East Coast Area and the South Western Area Health Boards there was insufficient information to describe diabetic retinopathy services provided in community LHO areas.

In Laois/Offaly LHO a dedicated diabetic retinopathy screening clinic is provided by the COP in the Midland Regional Hospital Portlaoise. Primary screening is carried out by an ophthalmic nurse specialist using a fundal camera. The programme management software used is Acuitas. Secondary screening is performed by the COP. The grading criteria used is the NSC retinopathy grading standard.

A number of hospitals in the region provide diabetic retinopathy screening services. In St. James's Hospital a digital diabetic retinal screening service commenced in September 2005, providing two dedicated clinics per week. Images are taken by a photographer/grader, with images graded by the ophthalmologist, using the Scottish grading system. At St. Columcille's Hospital, Loughlinstown, there is dedicated digital imaging with routine dilation of all patients attending diabetic clinics. Images are taken by a photographer at two dedicated clinics per week. An ophthalmologist grades the images using standard clinical diabetic retinopathy grading criteria.

In the AMNCH Tallaght Hospital diabetic retinopathy screening/examination is provided by two means; patients are referred on an ad hoc basis to the routine eye clinic or patients attend a retinal photography clinic. The latter clinic was established in July 2006 as a pilot clinic and has not been able to move beyond its pilot form due to lack of funding. An orthoptist grades the photographs and any patients with diabetic retinopathy are referred to the ophthalmologists in the diabetic eye clinic.

Photographic screening for diabetic retinopathy, two sessions a month, is carried out in the Royal Victoria Eye and Ear Hospital. However, there is no grading of images. There are dedicated diabetic retinopathy screening/examination clinics held at the Midland Regional Hospital Tullamore. In addition, people with diabetes are also seen at the general ophthalmic clinics at the hospital and also at the Midland Regional Hospital Mullingar. The COP in Laois/Offaly LHO provides a dedicated clinic in the Midland Regional Hospital Portlaoise, as detailed above.

Private Providers

The HSE also contracts services from private ophthalmologists under the Community Ophthalmic Services Scheme, some of whom provide diabetic retinal examination services as part of routine practice surgeries.

Process

Of the 48 ophthalmologists who provide/oversee routine diabetic retinal screening/examination, 23 (48%) provide this service through a dedicated clinic/programme, with 25 ophthalmologists (52%) providing the service as part of routine general eye clinics. For the majority of ophthalmologists (66.7%), patients are introduced into the service by referral from other health professionals only. Some ophthalmologists also proactively invite people with diabetes to have their eyes examined and some accept self-referrals, both are in addition to referrals from other health professionals.

Forty-five of the 48 ophthalmologists (93.7%) routinely dilate their patients' eyes, unless contraindicated. Screening/examination of the patients' eyes is conducted by numerous methods. Almost one third of ophthalmologists (31.3%) who provide a service use slit lamp biomicroscopy only when examining the eyes of people with diabetes. Digital photography, in addition to slit lamp biomicroscopy, is used by 27.1% and 6.3% use digital photography only as the screening method. In total 23 of the 48 ophthalmologists (48%) are using some type of digital photography when screening/examining the eyes of people with diabetes.

Of the 48 ophthalmologists, 26 (54.2%) offer people with diabetes rescreening/re-examination once a year, eight offer rescreening/re-examination less frequently than once a year and five offer rescreening/re-examination more frequently than once a year.

Thirty-six ophthalmologists provide a public funded, public provided screening service model, six provide a public funded, private provided screening service model and 12 provide a private funded private provided screening service model. Seven ophthalmologists did not respond to this question.

Thirteen ophthalmologists (27.1%) report that they audit the service they provide, 30 (62.5%) do not (five ophthalmologists did not respond). When asked if they have plans to start/expand retinopathy screening services in the near future, 28 ophthalmologists (58.3%) responded that they do, 12 (25%) responded no (eight ophthalmologists did not respond).

Conclusion

The responses from ophthalmologists, hospital network managers and local health managers demonstrate that current diabetic retinopathy screening and examination services in Ireland are ad hoc. There is large variability in service provision for diabetic retinopathy screening across the country, but various examples of good practice exist.

The review identifies a variety of methods for the delivery of screening, including a mobile van, static cameras located in healthcare facilities and a mobile camera brought to GP practices. There is no consistency in screening methodology across the country and only some ophthalmologists who responded are using digital photography.

Of those who responded (23 responses) to using digital photography as a screening method, only 14 services are currently grading images. Of the 14, only six responded as using recognised grading standards and only three as having an external quality assurance system.

Lack of funding has been identified as the major reason for non-provision of an adequate screening service.

To date, systematic screening based on retinal photography has been provided on a limited basis within the HSE. Existing services, in general, are not provided on a population-based approach nor do they adhere to best practice quality standards. However, there are examples of good practice based screening services in operation.

8

Screening
Programme Models

8. Screening Programme Models

The UK National Screening Committee¹ has outlined four possible screening programme models:

- Fixed location screening services
- Mobile screening services
- Optometry-based services
- Mixed services.

In Ireland these models will be adopted, but with some adaptation. A mixed model for photography will be adopted. This will include fixed and mobile photography clinics, and possibly photography by accredited private practitioners, depending on the geographic distribution of the population, public transport links, economies of scale and costings of different models. Grading and central administration of the programme will be undertaken at one location in each of the HSE areas.

Fixed Location Retinal Photography Services

This service would be offered through one or more fixed locations, such as a hospital outpatient department, a diabetic centre or a community health centre.

Mobile Retinal Photography Services

This service can be offered at a range of locations. For example, the camera and associated equipment can be taken into a GP surgery or screening can be provided from a mobile screening van. In the latter case the mobile van is taken to a local site (such as a health centre or GP surgery), with patients entering the van to have retinal photographs taken.

Accredited Private Practitioner Photography Services

Accredited private practitioners may carry out digital retinal photography in their practices. Images are then transferred electronically to a central location for grading.

Mixed Photography Services

Mixed services may involve any or all of the above services.

Adherence to quality assurance standards set by the National Retinopathy Screening Committee (adopted from the UK National Screening Committee¹), and, in due course, by the diabetic retinopathy screening programme national office, and value for money will be essential in informing which model is adopted in each HSE area. In particular, software costs will depend on the number of users/sites, the complexity of the model (including customisations to take local working arrangements into account) and the likely support burden. In addition, account should be taken of the likely proportion of people with ungradable images with each of the models and the cost of running dedicated slit-lamp biomicroscopy clinics to review these people.

9

Structure of a National
Diabetic Retinopathy
Screening Service

9. Structure of a National Diabetic Retinopathy Screening Service

The Institute of Public Health in Ireland provides the best available estimates of the population prevalence of diabetes (diagnosed and undiagnosed). In 2005, just over 141,000 persons in Ireland were estimated to have adult diabetes (type 1 and 2 combined), i.e. 4.7% of all adults, aged 20 years and older⁵.

The most realistic estimated population prevalence for 2015 is 194,000 adults with diabetes (5.6%)⁶. Allowing for an estimate of 25% undiagnosed² it seems reasonable to plan for approximately 120,000 people with diabetes, or 30,000 people per HSE area aged 12 years and over, being on the database within the first five years of operation of a diabetic retinopathy screening programme (this assumes excellent completeness of the database). These are figures for planning purposes. They will vary somewhat by HSE area and detailed planning by area will need to be conducted accordingly. It is recognised that this figure will rise with the rising incidence of diabetes currently happening in Ireland and the Western World.

It is assumed, for planning purposes, that all 30,000 people with diabetes (i.e. 100% of people on the database) will be offered screening yearly in each area at full programme implementation. Allowing for an approximate 20% final non-attendance at screening²⁰, planning is on the basis of 24,000 screen events per year at full programme implementation. In reality the population of people with diabetes varies by area and this will have to be taken into account when each area is working out their requirements for resources. Equally, allowance will have to be made for geographical factors and infrastructure within each area. Planning is also on the basis of a seven hour day and 44 week year.

The diabetic retinopathy screening programme will be a unified national programme. The structure will be based on the four HSE areas**, with a central grading, administration and management office within each area and a national office to provide national programme leadership, guidance, governance and quality assurance. The whole national programme will be led by a national clinical lead who will report to the National Director Primary Community and Continuing Care. Each area will also have their own clinical lead who will report professionally to the national lead.

An annual report, providing information relating to performance against national quality standards, will be required from each area programme and from the national programme. It will be the responsibility of the area clinical lead for each programme to provide this each year to the national office six months retrospectively. The national clinical lead will collate this information and publish an annual report.

It has been agreed by the National Retinopathy Screening Committee that a mixed model for photography will be adopted in each of the four HSE areas (Chapter 8). This will include fixed and mobile photography clinics, and possibly photography by accredited private practitioners, depending on the geographic distribution of the population, public transport links, economies of scale and costings of the different models. If a mixed model comprising fixed and mobile units is adopted there will be a number of screening units throughout the area. The mobile units will download their images at networked locations, including fixed clinics.

National Office

The national office will be located in the Primary Community and Continuing Care Directorate *** of the HSE and will have the following objectives:

- To ensure that the programme offers people with diabetes, aged 12 years and over, regular eye examinations for diabetic retinopathy;
- To ensure that all persons with diabetes are identified securely and included in a screening programme;
- To ensure that the programme detects a high proportion of sight-threatening retinopathy at the appropriate stage during the disease process;
- To ensure that there is appropriate training and accreditation available for the individual competencies needed by personnel involved in the programme, so that they can develop their skills, demonstrated through accreditation;
- To ensure diabetic eye disease is treated effectively and within an appropriate timescale;
- To ensure cost-effectiveness of the programme by best use of resources;
- To set standards and to develop a quality assurance system to allow programme monitoring;
- To review evidence regularly in order to make recommendations for improvements in standards;
- To ensure that screening and treatment for diabetic retinopathy are integrated with other aspects of diabetes care (e.g. hyperglycaemia, hypertension and hyperlipidemia) in order to ensure optimal management of diabetes;
- To involve patients individually and collectively in the development and evolution of the programme;
- To develop patient information and support patient education programmes so that they can understand the strengths and weaknesses of the screening programme and the process involved;
- To monitor the programme on a regular basis and produce regular reports on programme performance and progress;
- To generate and mobilise knowledge from the data collected and from the experience of patients and clinicians in order to make continual improvements to the programme; and
- To identify areas where evidence is lacking and to facilitate research in these areas.

These objectives will be achieved by:

- Establishing and maintaining programme guidelines;
- Developing a national quality assurance structure, including production of an annual report;
- A communication strategy (in conjunction with communications function within the HSE), including development of programme literature and media campaigns;
- Financial governance;
- Oversight of staff training and accreditation programmes.

*** In a restructured HSE, the National Office may report to the National Clinical Directorate.

It will be staffed by the following people:

- Programme lead - Ophthalmologist – 0.5 WTE
- Programme manager – 1 WTE
- Quality assurance and communication lead - Specialist in Public Health Medicine – 1 WTE
- IT / Database manager – 0.5 WTE
- Administration staff (Grade IV) – 1 WTE

The clinical lead will be the line manager. The specialist in public health medicine and the programme manager will report to the clinical lead. The database manager and administrative support will report to the programme manager.

A National Retinopathy Screening Committee will be established to facilitate planning and implementation, followed by quality assurance as the programme develops. The National Retinopathy Screening Committee will act as this National Retinopathy Steering Committee for the programme and will facilitate planning, programme oversight and quality assurance. In addition, the national office may set up specific Scientific Advisory Committees as the need arises.

Area Management Structure

Each area will have a central grading, administration and management office**. The area lead is accountable to the national lead for programme, financial performance and quality assurance of their area programme. The area programme will be led by the area clinical lead, who will be an ophthalmologist. The other ophthalmologists in the area programmes will report to this area clinical lead. The area programme manager will line manage the area staff i.e. photographers, graders, IT, database and administrative staff, and will report to the area clinical lead.

The area programme will be responsible for delivering the screening programme to all eligible patients within their area. This will include identifying eligible patients, achieving a high uptake rate and ensuring effective treatment within appropriate timescales. The area programme will manage their resources cost effectively to meet the programme objectives.

The area office will be responsible for the following:

- offering people with diabetes, aged 12 years and over, regular eye examinations for diabetic retinopathy;
- ensuring that all persons with diabetes are identified securely and included in a screening programme;
- detecting a high proportion of sight-threatening retinopathy at the appropriate stage during the disease process;
- ensuring that there is appropriate training and accreditation available for the individual competencies needed by personnel involved in the programme, so that they can develop their skills, demonstrated through accreditation;
- treating diabetic eye disease effectively and within an appropriate timescale;
- ensuring feedback from ophthalmic services to the screening services on the result of clinical examination of patients referred from the screening service;
- ensuring cost-effectiveness of the programme by best use of resources;
- adhering to national quality assurance standards and reporting to the national office;

** A critical size population for a retinopathy screening programme is approximately one million.

Service delivery will be reviewed as appropriate if HSE geographical areas are restructured.

- reporting to the national office as required on programme and financial performance;
- generating and mobilising knowledge from the data collected and from the experience of patients and clinicians in order to make continual improvements to the programme;
- supporting the national office in developing patient information;
- integrating screening and treatment for diabetic retinopathy with other aspects of diabetes care (e.g. hyperglycaemia, hypertension and hyperlipidemia) in order to ensure optimal management of diabetes.

Area Service Structure

Planning of staff resources required for a mixed model of photography, based on a combination of fixed and mobile clinics, is provided below. Areas which also use private practitioners for photography services will adjust these figures accordingly. There will be a number of networked locations throughout each HSE area from which photographs will be downloaded and transferred to the grading centre in each area. Each fixed clinic must have the facilities for this. The photographers in the mobile clinics will travel to the networked locations or the grading centre to download and transfer images taken.

All staff involved in screening will be appropriately accredited and trained.

Each area screening programme should be provided by a multidisciplinary team comprised of:

Staff	WTE
Ophthalmologists - 1 clinical lead ophthalmologist - 3 screening programme ophthalmologists	4
Area programme manager (CNM3)	1
Database staff	2
IT manager	1
Photographers – - 5 Basic - 1 Senior	6 5 1
Graders – - 5 Basic - 1 Senior	6 5 1
Administrative staff	3
Total	23

Clinical Lead Ophthalmologist

The clinical lead ophthalmologist will be responsible for the overall delivery of the screening programme in their area in an efficient and effective manner ensuring that the quality standards are achieved. They will also have a clinical role as a screening programme ophthalmologist (see below).

Screening Programme Ophthalmologists

The functions of the screening programme ophthalmologists will be:

- Arbitration level grading;
- Referral level grading;
- Biomicroscopy for people with unassessable images;
- Biomicroscopy for those unsuitable for photography;
- Clinical assessment of patients with newly diagnosed referable diabetic retinopathy;

- Laser treatment and follow up of patients with newly diagnosed diabetic retinopathy;
- Referral of people with non diabetic pathology to the local ophthalmology services;
- Liaison with local ophthalmic services for feedback of results of retinal examination of all people with diabetes.

All ophthalmologists in the programme will carry out all of the above functions so that there is capacity for cross cover in the event of annual leave, sickness etc. The lead ophthalmologist will be based in the area grading, administration and management centre. The role of the ophthalmologists will be reviewed according to the programme needs.

Area Programme Manager

The area programme manager, reporting to the area clinical lead, will be responsible for the operational delivery of the screening programme in an effective and efficient manner ensuring that the quality standards are achieved. Advice from the UK National Screening Programme is that it is beneficial that this person has a clinical background.

Database Staff

A working group of the National Retinopathy Screening Committee is developing a mechanism for creation and maintenance of a database to support diabetic retinopathy screening (see chapter 10). One of its terms of reference is to estimate the resource that this will require in each area. In the interim, planning is based on the need for two WTE database staff.

IT Manager

The IT manager will be responsible for operating and supporting the ICT infrastructure and software to support the area diabetic retinopathy screening programmes, reporting requirement and quality assurance.

Photographers

Mobile clinics

On the basis of 12 minute appointments (allowing for set up time between patients) and approximately 4.5 hours of screening per day (which allows for travel time, van and equipment maintenance and transfer of images to the grading centre) there would be 23 booked appointments per day. With an approximate 20% final non-attendance rate this would result in about 18 screen events per day. This equates to about **4,000** screen events in a 44 week year. Account has been taken of opt-outs, second round invites to those who do not attend following the first round invitation and of those who will require a second visit within a year in the planning figures presented. Therefore, it is estimated that one WTE photographer, working in a mobile clinic, will be required to cover **5,000** registered people with diabetes per year.

Fixed clinics

On the basis of 12 minute appointments and six hours of screening per day (allowing for transfer of images each day) there would be 30 booked appointments per day. With an approximate 20% final non-attendance rate this would result in about 24 screen events per day. This equates to approximately **5,300** screen events in a 44 week year. Account has been taken of opt-outs, second round invites to those who do not attend following the first round invitation and of those who will require a second visit within a year in the planning figures presented. Therefore, it is estimated that one WTE photographer, working in a fixed clinic, will be required to cover approximately **6,600** registered people with diabetes per year.

Therefore, based on a 44 week year the clinics and photographers required will be as follows. Four and a half clinics per week (and therefore **4.5 WTE**) for a programme with only fixed clinics to six clinics (and therefore **6 WTE**) for a

programme with only mobile clinics for **24,000 screen events** (30,000 invited patients) per (44 week) year. It is likely that most fixed clinics will be operational less than full time to ensure adequate geographic spread of clinics. Planning for the areas with a well spread population geographically is likely to be on the basis of a clinic day of 4.5 hours (as for the mobile clinics) even for fixed clinics as it is likely that the photographers will have to travel between clinics.

Graders

Approximately 50% of all graded images will have to be regraded (includes 10% of normal images and all disease images, but not unassessable images). Therefore, for a programme with 24,000 screen events per year there will be 36,000 grading events per year performed by graders. This does not include arbitration level grading which may be done by an expert grader. This is taken into account above in the role of the ophthalmologist.

Calculations are based on six hours actually worked in a seven hour working day (allowing for breaks, which are required hourly for graders). It is estimated that it will take 10 minutes per imageset for first level grading and 20 minutes per imageset for second level grading. Therefore, a grader will grade, on average, 18 first level images and nine second level images each day. This equates to **5,940 grading events (or 3,960 screen events)** per 44 week year. Advice from the English national screening programme for diabetic retinopathy suggests that one grading station is required for 6-7,000 grading events per year. This suggests that the above estimate is realistic.

This equates to **6 WTE graders** for a programme with **24,000 screen events** (and 36,000 grading events) per year. However, it is recommended that graders work no more than half time on grading due to tiredness and consequent risk of error and it is, therefore, likely that all graders will work less than full time on grading.

Administrative Staff

The office needs to be manned five days a week all year round. It is suggested that two WTE administrative staff could handle the administration of appointments and letters for a programme for 12-20,000 registered people with diabetes¹.

Therefore, for a programme with 30,000 registered people with diabetes a team of administrative staff of at least three WTE is recommended.

10

Diabetic Retinopathy
Screening Database

10. Diabetic Retinopathy Screening Database

Establishing an Irish diabetes database for the initial purpose of diabetic retinopathy screening The Department of Health and Children has recommended that a diabetes register should be developed, starting at local/regional level 26.

Diabetic Retinopathy Screening (DRS) Database Working Group

A multidisciplinary database working group of the National Retinopathy Screening Committee has been established with the following terms of reference:

- To recommend a methodology of forming a database for diabetic retinopathy screening;
- To identify the aims and the objectives of the diabetic retinopathy database;
- To identify appropriate sources of data for the database;
- To establish an algorithm for establishing a diabetic retinopathy screening database;
- To recommend a method of updating the database;
- To recommend a method of quality assuring the database;
- To make the above recommendations based on practical considerations of current Irish health service systems;
- To identify resources required to formulate a diabetic retinopathy database;
- To make the above recommendations based on evidence based literature and the result of testing the accuracy and completeness of proposed data sources, in the chosen test site (see below);
- To create the database in compliance with data protection legislation.

A pilot project to establish a diabetic retinopathy screening database has commenced in the former Mid-Western Health Board (MWHB) area. This will be used to inform the recommendations of the working group, above. The database established will be compatible with any future national diabetes register and may be used to populate it. The results of the pilot will inform the specific recommendations on the database algorithm and the method of formulating and updating the database.

Purpose of a DRS Database

The purpose of the database will be to identify all people with diabetes mellitus, by HSE area, initially to support a diabetic retinopathy screening programme and with capability to expand to support other aspects of diabetes care. In compiling a population-based database, an attempt is made to identify and collect data on all cases of a disease (in this case diabetes mellitus) or other health condition within a defined population.

Features of a DRS Database

- The minimum data set will be agreed in line with the purpose of the database.
- The dataset will be complete and standardised.
- Patient names and addresses or equivalent unique personal identifiers will be required to avoid double counting of individuals and to enable follow-up data (e.g. from death certificates) to be correctly linked to previously registered cases.
- Security and confidentiality are fundamental to the success of the database.
- The database will be flexible, timely and will support upgrading and modification as necessary.

Processes

Systems will be in place to:

- Maintain a reliable notification or identification of cases within the population served;
- Ensure comparability of inclusion criteria onto the database, for diagnosis strict rules will be needed to identify the studied condition within an agreed classification;
- Minimise under-coverage;
- Ensure that duplication of cases does not occur;
- Keep the database updated, removing those who have died or moved out of the area.

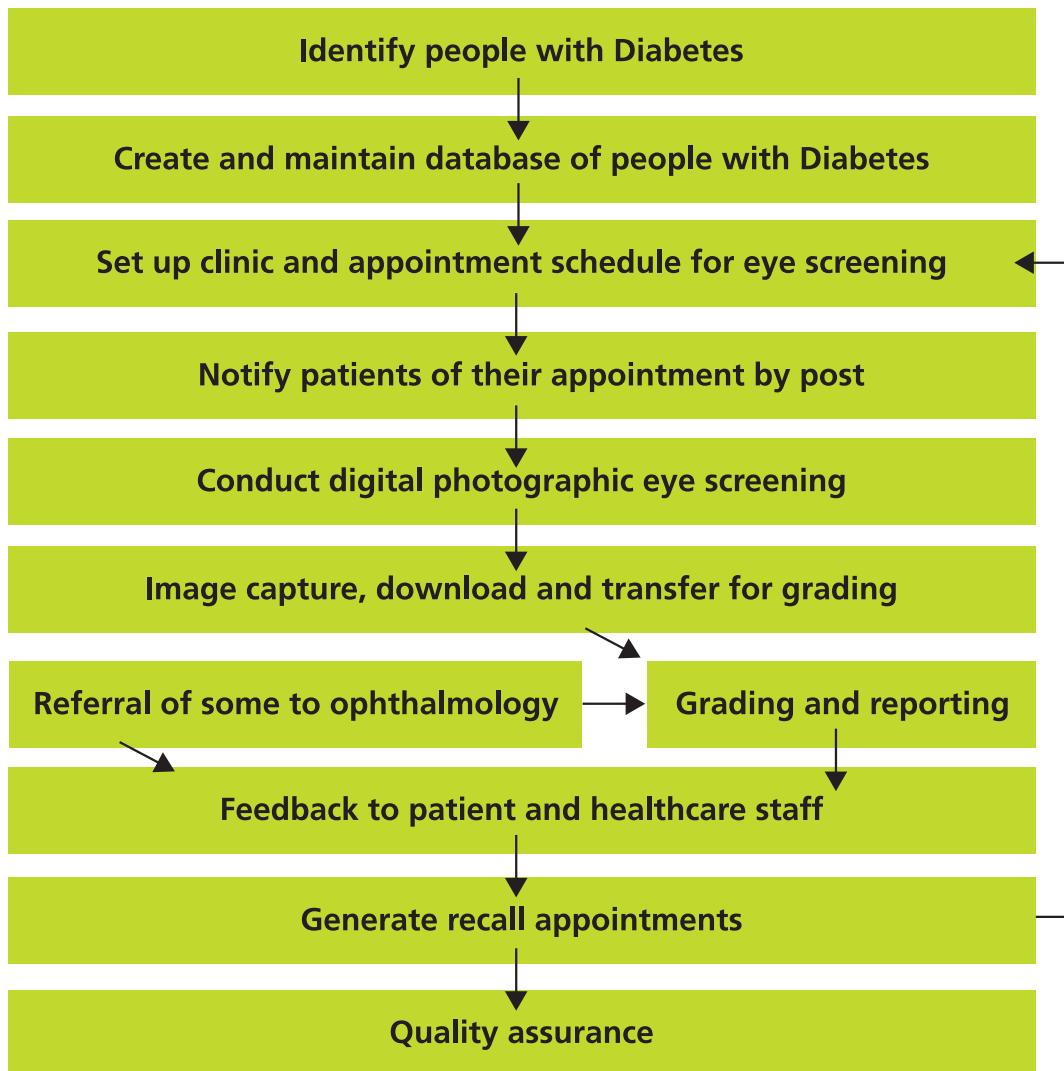
11

Screening Process,
Follow-up and Feedback

11. Screening Process, Follow-up and Feedback

The diagram below outlines the screening process for people with diabetes.

Figure 1: Screening process



Identification of cohort

A single collated list of all people with diabetes in the programme area will be required. Disease progresses as much through a failure to identify those who should be invited to screening and other administrative failures as through clinical failures. The manner in which this will be done will be determined by the database working group of the National Retinopathy Screening Committee (See Chapter 10).

Invitation to patients

Patient information leaflets will be developed for use in the national programme. Patients will be invited by letter to participate in the programme. It is recommended that these letters will be generated by the area programme office and will be sent on behalf of their own GP, as currently done in the North West, in order to comply with data protection legislation. Patients will be asked to inform the programme office if they wish to opt-out of screening. The office will inform their GP. In the case of opt-out, the patient will be sent an opt-out form. Approximately a week after their initial letter the patient will receive a letter with an appointment for the screening service, including contact details should they wish to change their appointment time. Depending on the local area, provision may be made for appointments outside of normal working hours.

The invitation will include information on mydriasis and the use of the patient's data for quality assurance. The patient will be asked to sign a consent form at their first appointment. If patients fail to attend further invitations will be sent.

Photography of patients

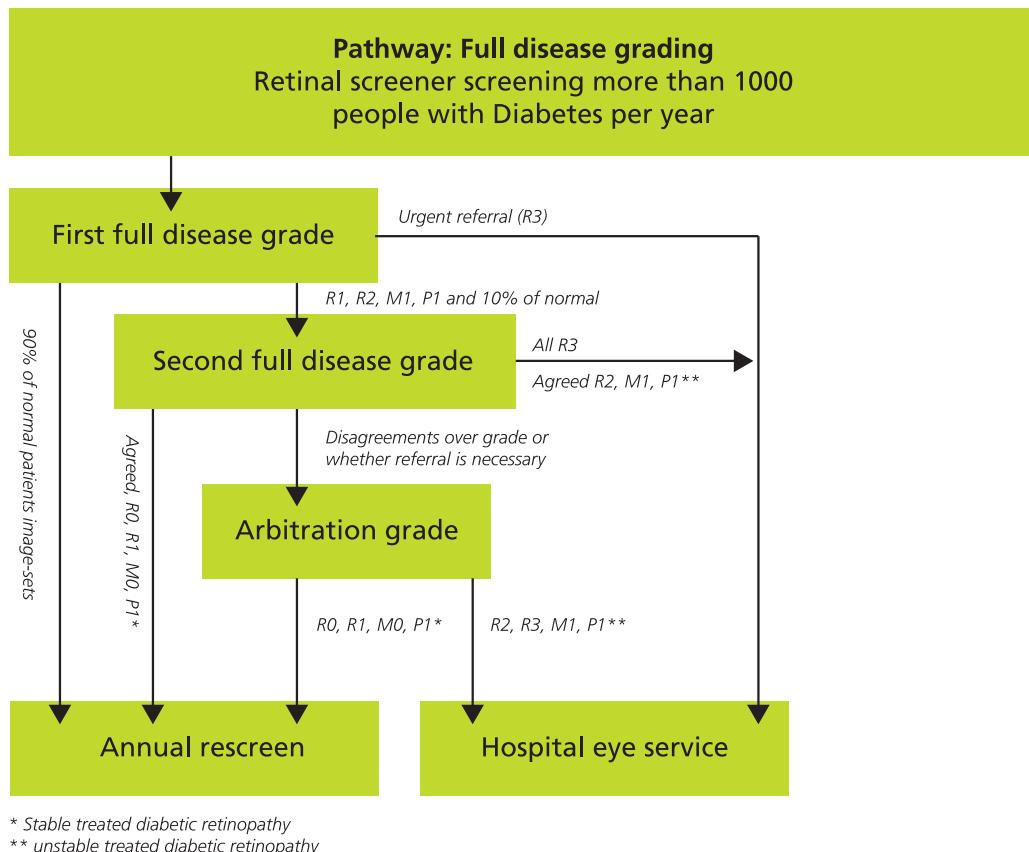
Photography will be carried out by appropriately trained staff. On arrival the process of screening will be explained to the patient and consent sought. A brief medical history and demographic details will be taken and verified. Dilating drops will be instilled unless contraindicated. Two field digital images of each eye will be taken. The images will be stored for transfer to the grading centre at the end of the clinic. The results of screening will be given to the patient and GP by letter following the full grading process. Provisional results will not be given verbally by the photographer at screening.

Grading

Grading will take place at the area grading centre using the National Screening Committee retinopathy grading standard (See Appendix 4). All graders will be specifically trained and will need to see a minimum number of patient imagesets to ensure that they see sufficient elements of disease each year, thus maintaining expertise. These minimum standards are set out in the NSC service objectives and quality assurance standards (Appendix 1).

The following diagram outlines the grading pathway for images.

Figure 2: Grading pathway for images



Assessment of ungradables

Up to 10% of imagesets are likely to be ungradable for reasons such as the existence of cataracts. These patients will have to be assessed by slit-lamp biomicroscopy by an ophthalmologist.

First full disease grade

All imagesets must undergo this procedure.

Second full disease grade

10% of normal imagesets must be re-graded and ALL 'abnormal' imagesets. Because of the way the human eye scans images some disease will be missed and the second grade increases the chances of secure disease identification.

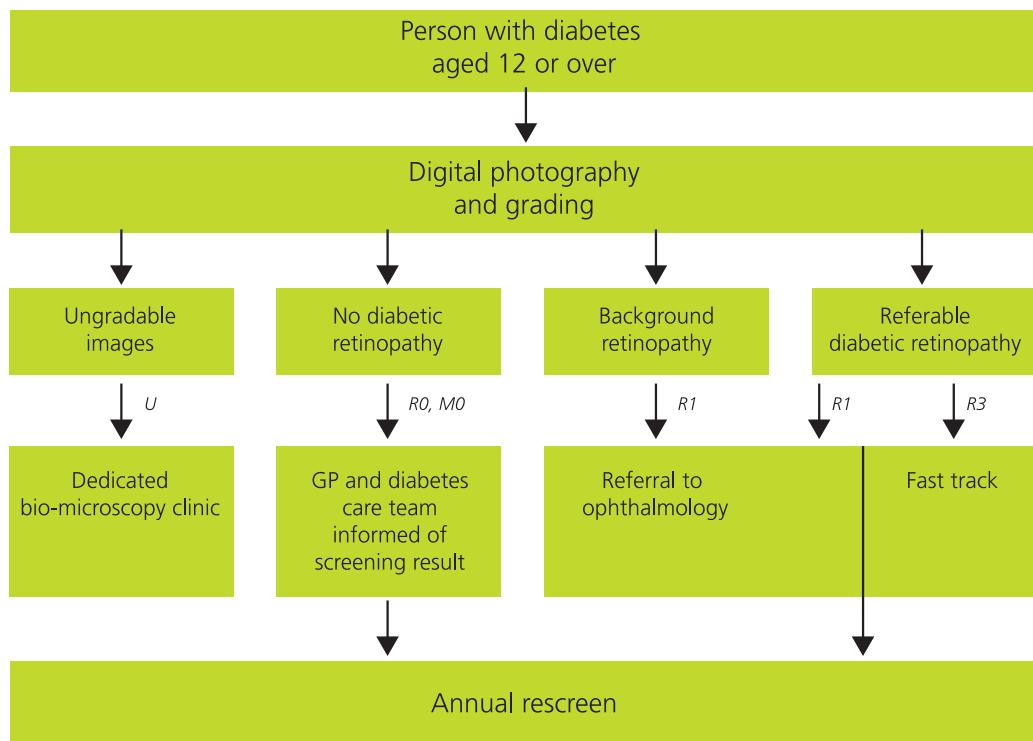
Arbitration level grade

This should be carried out by a specialist ophthalmologist or a senior and very experienced grader who has been tested for reliability of performance against the ophthalmologists. The purpose of this is to enable differences of opinions between first level grading and second level grading to be resolved thus avoiding unnecessary referrals and identify early training issues.

Referral level grade

An ophthalmologist reviewing all referrals can reduce significantly the numbers of patients that actually have to attend the eye clinic. This can reduce costs and also anxiety to patients. Refer to Appendix 4 for an explanation of grades.

Figure 3: Patient care pathway



Results to patients and referral process for sight threatening diabetic retinopathy and ungradable images

Patient information leaflets will be developed for use in the national programme for both results to patients and referral. Local referral pathways to ophthalmologists will be developed with outcomes being fed back into the screening service. There will be referral of people with non diabetic pathology to the local ophthalmology services.

Treatment

Laser treatment is the method of treating diabetic retinopathy. Timescales for assessment and treatment of screen positive patients are dealt with in the quality assurance standards. Visual outcomes of laser treatment will also be monitored. Laser treatment and follow up of patients with newly screening diagnosed diabetic retinopathy will be done by the programme ophthalmologists.

Monitoring of visual outcomes

A system will be set up to monitor blindness registrations from the population of people with diabetes as the aim of the screening programme is to reduce the risk of sight loss among people with diabetes.

Software

The nationally approved ICT software system will be used.

12

Information and
Communications
Technology

12. Information and Communications Technology

The National ICT Retinopathy Project Team was set up in December 2007 to formulate a business proposal and business case in line with national IT requirements. Consultation with the English national screening programme for diabetic retinopathy has established the overriding need to procure a national IT system to support a national diabetic retinopathy screening programme and quality assurance in Ireland.

A national systematic diabetic retinopathy screening programme will require the following IT system components:

- A database of people with diabetes, linked to the programme management software;
- Appropriate programme management software. This will require the following functionality:
 - Capture and grading of digital images
 - Clinic and appointment scheduling
 - Generation of appointment, referral letters and result letters
 - Recording of feedback from Ophthalmologists
 - Call and recall system
 - Generation of reports
 - Quality assurance
 - Generation of standard electronic messages;
- Interfaces with the standard digital cameras selected for diabetic retinopathy screening
- Appropriate infrastructure and support

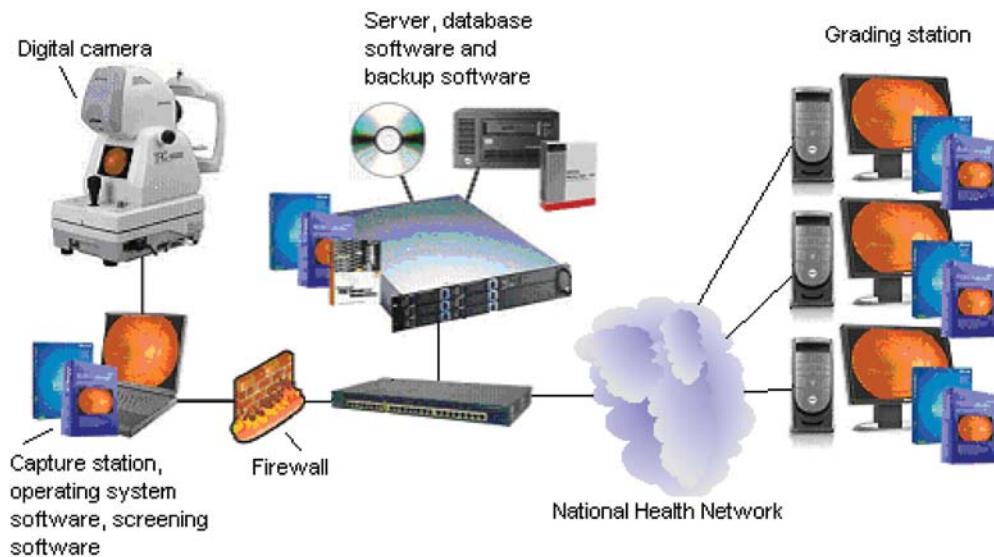
Chapter Ten outlines the requirement for a database of people with diabetes for the national diabetic retinopathy screening programme.

Robust programme management software with capacity for audit, quality assurance and risk management will be an essential element of the programme. Suitable software exists in the marketplace. The national diabetic retinopathy screening information system will provide a single national screening retinopathy record for clients with diabetes across the country. It will support the HSE area services. It will support the operation of the service by managing clinic scheduling, call/recall, generation of letters, reports and messages and facilitating the management and central grading of images. A predefined suite of reports to support operational, statistical and quality assurance (UK standards) will be required. The system will support reporting at both an area and national level.

The Diabetes EAG has prioritised, for 2008, the seeking of approval for, and commencement of procurement of an ICT system for the national diabetic retinopathy screening programme. A business case has been prepared by a multidisciplinary team to procure and implement programme management software and the server/storage hardware for the full national programme rollout and, also, the local network, hardware and desktop software to support rollout to all HSE areas. The members of the national ICT retinopathy project team are in Appendix 2. Separate bids will be submitted for the remaining HSE areas for local infrastructure when required and in line with service development in these areas. The business case was submitted to the ICT Directorate in May 2008 and approved. It has been submitted to both to the Department of Health and Children and the Department of Finance for approval prior to proceeding to tender.

The diagram below (Figure 4) illustrates the hardware and software components of the proposed system.

Figure 4: Hardware and software components of the proposed IT system



Roll-out of the diabetic retinopathy screening programme will be on a phased basis, by HSE area. The implementation phase of the ICT project will occur in parallel with service implementation in each area.

The diabetic retinopathy screening ICT information system will need to be intuitive and user-friendly.

Screening will be offered annually and each person will have four images taken (at least) and stored at each visit. It is estimated that annual screening for 120,000 people with diabetes (i.e. 480,000 images) will require approximately 2.4TB storage capacity over five years. There will be a requirement for transfer of images from fixed sites to the national central image store, and from there to the grading stations, for grading, and back again.

As an example, in a HSE area, a mixed model with fixed and mobile clinics is planned. Each of these will require a camera and a capture station with operating system software and screening software. The area will require storage capacity of about 0.6TB data over five years (600,000 images) on the national image store. The images will be transferred from the local fixed sites to the national image store and graded at the area programme office.

A fast response time is required for graders based in each area grading centre. The UK National Retinopathy Screening Service recommends that there be a minimum of 100Mbs bandwidth availability for grading stations. Upload of images from fixed clinics to the national image store will be scheduled to occur once a clinic is finished. A similar process will be used to upload images from mobile clinics. Retrieval of previous images is not required for screening clinics.

The diabetic retinopathy screening information system will have a single national database residing on a central server to be located in the HSE National Data Centre. This will result in a single configuration and simplify support and maintenance. The server hardware will support live test and training database environments with built in resilience for power, network etc and will be linked to a storage area network (SAN). The diabetic retinopathy screening system should use a standard relational database management system (RDBMS).

The UK procurements for diabetic retinopathy screening programme management software have been based on the number of clients to be screened rather than on the numbers of users. The diabetic retinopathy screening programme management software to support the programme in Ireland must be capable of supporting annual screening for 120,000 people with diabetes nationally.

Grading station PCs will be configured with 4 GB of Random Access Memory and 21" LCD screens supporting resolution of 1600 X 1200. Laptops at screening clinics will support resolution of 1400 X 1200.

Network topology proposed is based on recommendations from the UK National Retinopathy Screening Service and experience to date of the existing system in use in the HSE North West. It is proposed taking both of these into account to provide a National Health Network link of 100Mbs to each of the area grading centres. The National Data Centre has a 1Gb link to the National Health Network. A minimum bandwidth of 1Mb will be provided to fixed sites. Fixed clinic sites are generally on either a hospital or a Primary Community and Continuing Care health centre site.

There are a number of different digital cameras currently owned by the HSE, however these are also used for other ophthalmic purposes besides diabetic retinopathy screening and will be continued to be used as such. There will be one type of camera procured for the national programme. The procurement for these cameras has already been carried out (see Chapter 15).

Creation of the database for the purpose of diabetic retinopathy screening is likely to require intermittent data feeds from other databases and ideally, a facility for internet self registration for people with diabetes. Information will be communicated to primary and secondary physicians through the post, initially, and subsequently by standardised electronic messaging systems.

Data and images on existing systems will need to be evaluated for possible migration to the national diabetic retinopathy screening database.

13

Education, Training and
Accreditation

13. Education, Training and Accreditation

Introduction

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

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

Accreditation of Competence

Accreditation is a one-off measure of current competence. It recognises that the learner has been assessed against the standards set for the profession and has achieved the required standard. Principally it is designed to protect the patient but also protects the worker and employer. It is not a measure of continuing competence. Continuing competence is achieved through continuing professional development and is measured by performance indicators (internal and external quality assurance) in the national screening programme and appraisal.

An accreditation qualification for diabetic retinopathy screening based on English national occupational standards was originally developed in conjunction with the National Health Service University (NHSU) in the UK. The UK City & Guilds are the awarding body. The Certificate in Diabetic Retinopathy Screening has been developed as an accreditation of the minimum level of competence required by ALL personnel involved in the identification of sight-threatening diabetic retinopathy in the English national screening programme. The Irish Programme will adhere to these standards.

14

Programme Governance
and Quality Assurance

The setting up of a national screening programme involves planning according to the following public health screening principles:

- population coverage
- screening interval
- quality: commitment to quality improvement.

International best practice dictates that external quality assurance reviews should be separated from performance management processes.

There are six types of management common to all screening programmes:

- service management;
- programme management;
- population coverage;
- performance management;
- quality assurance system management;
- national co-ordination.

In the Irish national diabetic retinopathy screening programme it is proposed to address these functions through the following method; service management, programme management and population coverage will primarily be the responsibility of the area programme. Performance management and national co-ordination will primarily be the responsibility of the national office. Quality assurance is the responsibility of the area programme internally and the national office for internal quality assurance standards and monitoring, and for external quality assurance.

Service management

Diabetic retinopathy screening programmes consist of a co-ordinated set of services:

- invitation and recall service;
- digital photographic service;
- grading service;
- treatment service.

Each area service needs to have someone clearly identified as responsible for managing the part that service plays in the screening programme. For some this will be a whole-time job, for others screening will be only one of a number of services that their facility, for example an ophthalmology department offering treatment facilities. The area programme manager, in conjunction with the area clinical lead is responsible for organising and managing the operational delivery of the screening programme in an effective and efficient manner.

Programme management

A screening programme is a co-ordinated set of services and the job of the programme manager is:

- to ensure good co-ordination of the services;
- to be accountable for the programme as a whole, including its quality.

The prime responsibility for quality within the programme rests with the area clinical lead and programme manager.

Population coverage

Each area programme is responsible for ensuring the completeness and accuracy of its database, in order to ensure that the population for which they are responsible is covered by the programme.

Performance management

Performance management is the action taken at a higher level than either programme management or population coverage to ensure that each area service responsible for population coverage and programme management are carrying out their functions effectively. Performance management consists of monitoring the performance of a range of different programmes, taking action only when it is felt that there is a problem that is not being adequately addressed by those responsible for programme management and population coverage. This is the responsibility of the national programme lead.

Quality assurance

Each area programme lead is responsible for meeting the quality assurance standards set by the national office and for returning the appropriate statistics. The national quality assurance lead, a Specialist in Public Health Medicine is responsible for developing and implementing both internal quality assurance systems and external quality assurance reviews.

National Co-ordination

The national office will be responsible for assuring consistency of operations between the four area programmes. There will be common programme guidelines, communication methods, education and training standards, and quality assurance standards. The national office will financially govern the full programme.

The national quality assurance lead, in conjunction with the National Retinopathy Steering Committee will oversee the internal quality assurance of the programme, will be in receipt of the external quality assurance reviews and will make recommendations to each area regarding necessary service improvements.

The national office will work with the National Retinopathy Steering Committee and Scientific Advisory Committees to update guidelines, evidence based practice and quality standards.

Quality Assurance

Introduction

The quality of programme is the degree to which it conforms to preset standards of "goodness". Standard setting follows the following processes:

- Setting the objectives of the programme.
- Identifying valid and reliable criteria to be used to measure the progress of the programme towards its objectives. These criteria must be feasible to measure.
- Setting the values which are to be achieved.

In screening, values for the standards are set in two ways;

1. Minimum acceptable and achievable standards that can be used to compare services or programmes and as a basis for setting targets for improvement.
2. Upper and lower rates of some aspect of performance e.g. referral rates, to allow every service to examine its performance and identify opportunities for improvement.

Quality assurance of all health services is essential, but particularly so for a screening service, where a test is applied to people who are asymptomatic for a condition (in this case diabetic retinopathy), to detect those who may have it (and who will benefit from further intervention) and to rule out those who do not. It is inevitable that there will be both false positives and false negatives when a screening test is applied, as that is the nature of screening (and why follow-up with further tests is sometimes necessary) but these must be minimised, monitored and be at an acceptably low level. The national screening programme has deemed that the requirement for screening for diabetic retinopathy is that it should be at least 80% sensitive and 95% specific.

The objective of quality assurance is to help clinicians, service and programme managers reach higher levels of quality. In screening, quality assurance has four aims:

- to reduce the risk of errors;
- to identify and manage errors effectively and sensitively;
- to help professionals and organisations continually improve their performance;
- to set and re-set standards.

A wide range of interventions play a part in quality assurance, namely:

- the development work required to set up the new programme;
- professional development;
- organisational development;
- the management of information systems to give feedback to service and programme managers and public health professionals;
- programmes to help professionals whose perceptions play a part in screening, for example, improve their performance and standardise the way in which they interpret terms and definitions.

All of these activities are quality assurance activities and have to be organised in a way that allows area screening programmes to work together because comparison is one of the key elements in quality improvement. Quality assurance should be a continuous process of improvement which involves all stages of the screening pathway and all professional groups.

Quality Assurance for the National Diabetic Retinopathy Screening Programme

The national diabetic retinopathy screening programme will have two elements to its quality assurance (QA) programme:

1. Internal QA involving the everyday processes of the screening programme
2. External QA which will involve an independent objective assessment of the programme and comparison with other, similar, programmes elsewhere.

The National Retinopathy Screening Committee has decided to adopt the English national screening programme service objectives and quality assurance standards for the Irish diabetic retinopathy screening programme. These are included in Appendix 1. They encompass objectives and standards relating to all areas of the screening service:

- outcomes
- database
- administrative
- photography

- grading
- communication and referral
- follow-up and treatment.

Standards are set at two levels, a minimum level and an achievable level (the latter being the level considered achievable by the top quartile of programmes in England and which the National Retinopathy Screening Committee believe should be aspired to by the Irish programme). There will be a requirement to make minor changes to the standards to ensure that they are appropriate for the Irish programme (e.g. Objective 1, criteria 1 will need to be relevant to Irish rates of blindness predominantly due to diabetic retinopathy and also to the fact that severe visual impairment/visual impairment is not recorded here, unlike in England). It will be the responsibility of the national office to do this. The national office should also consider setting Irish standards where none exist for objectives in the English programme e.g. Objective 6, to ensure that grading is accurate.

The programme software that is procured to support the programme will have to support the adopted English quality assurance standards. It is envisaged that the data required to support the quality assurance programme will be collected as part of the screening process in each area and will be accessible in the national office. Each area programme will have to have a mechanism in place to ensure that they can collect all the information required to support analysis of the programme in relation to the standards. Particular issues that will need attention include monitoring of levels of blindness due to diabetic retinopathy and feedback from ophthalmologists on follow-up of screen positive patients. Analysis of the data and oversight of the quality assurance programme will be the responsibility of the national office. This will be done in close communication and cooperation with the area programmes.

Internal Quality Assurance

Internal quality assurance will consist of the following components:

- Independent re-grading of 10% of disease negative cases by a second accredited grader;
- Independent review of all disease positive cases by a second accredited grader prior to issue of a referral appointment;
- All grading disagreements related to referral to be subject to an arbitration level grade by a higher level grader e.g. ophthalmologist. Consideration will need to be given by the national office (according to resources and results of the quality assurance programme) about whether arbitration level grading is required at all levels of disagreement between graders. If this is not possible such disagreements should be monitored closely, and audited to determine whether there are patterns of under- or over-calling;
- Referral level grading i.e. review of all disease-positive imagesets by the ophthalmologist to decide whether he or she feels that referral is required before a patient is actually referred;
- Grading accuracy reports (a report of accuracy against final grading outcome of all full graded imagesets);
- Inter-grader agreement reports for each grader within the programme (a report of grading outcomes against each other grader for imagesets full graded by both graders, divided according to final grading outcome);
- Intra-grader agreement reports will be generated for each grader. This will be achieved by including previously graded image-sets within the normal workflow to ensure consistency of grading.
- Quality assurance of ophthalmologist examination of patients with a percentage being examined by a colleague;
- Ongoing programme monitoring by collection and analysis of performance data from each area service, to ensure that the quality standards are being achieved. This will be achieved by the collection and analysis of the data in the annual report at national level;

- Production of an annual report, by area programme and nationally. The annual report template for the English national screening programme will be adapted for use by the Irish national programme. It will be the responsibility of the area office to produce the annual report from data provided by the area programmes. The national office will also determine the national minimum dataset (with reference to the English national programme minimum dataset);
- Audit of screening failures. This will involve review of the patient's screening history and of their previous images. This will have to be organised in conjunction with ophthalmologists practising within each HSE area, with the data also sent to the national office. Prompt reporting of these patients to the programme will be essential. Screening failures include the following:
 - those patients who present with symptomatic diabetic retinopathy in the interval between screens;
 - those patients who present with symptomatic diabetic retinopathy but were not invited or did not attend for screening;
 - patients in whom there has been a marked and unexpected deterioration in retinopathy since the previous screen. In this case previous images should be reviewed to ensure that misgrading had not occurred.

External Quality Assurance

An external quality assurance programme will need to be established to provide independent, objective assessment of the national programme, and of each of the area programmes. This should be appropriate to this framework and the objectives and standards of the programme. It may be conducted by a suitably qualified professional or multidisciplinary team, in another country e.g. a national diabetic retinopathy screening programme elsewhere in Europe.

The template for external quality assurance developed for the English programme should be used (this is undergoing development currently) to develop a programme for external quality assurance for Ireland. However, a difference from the English programme will be that ongoing programme monitoring and production of the annual report are considered internal, and not external, quality assurance activities.

External quality assurance will have three main elements:

- Visits to the screening programme (nationally and each area programme) to evaluate sufficiency of resources and to ensure provision of a comprehensive service.
- Administration of an external proficiency testing system, for all graders, using test sets of images with previously agreed grades. All of those involved in grading images will be expected to participate in grading these test sets at regular intervals.
- External re-grading of imagesets graded by the tertiary grader to include imagesets where there was a discrepancy between secondary and tertiary graders, imagesets where there was referable retinopathy and imagesets deemed to be ungradable.

15

Procurement

15. Procurement

Introduction

Equipment and ICT for the national diabetic retinopathy screening programme will be procured through the National Procurement Directorate, adhering to nationally set common standards.

The process of establishing diabetic retinopathy screening programmes in each of the HSE areas will include procurement of a number of items of varying value. For each of these items a procurement support request (PSR) will need to be made to the Procurement Directorate.

The PSR provides a structured approach to the management of requests for obtaining procurement support within the HSE. All PSRs are currently sent to the Assistant National Director Procurement, Head of Portfolio and Category Management.

Procurement Process

A budget holder/requestor is required to complete a PSR form, which gives a high-level overview of the requirement. It gathers the basic details (e.g. budget, scope, risks etc.) of the request, while gaining a clear commitment and sign off from a budget holder. The PSR will form the basis for decisions in relation to the appropriate category of expenditure and the assignment of the appropriate procurement resources in connection with the new request.

Key objectives

- To ensure compliance with procurement and national financial regulations and policy.
- To facilitate aggregation of requirements and obtain value for money.
- To provide a mechanism for prioritisation and allocation of procurement resources.
- To provide management information to the HSE Corporate Leadership Team and other directorates in terms of requests and outcomes.
- To assist Procurement in developing a portfolio and category management approach.
- To prepare and assist with the procurement planning process.

National Procurement Completed

In late 2007 the procurement process for mobile vans and digital cameras was completed. The contract approval requests have been signed and mobile vans and digital cameras can now be purchased as the service develops.

Mobile Vans

The HSE invited suitably qualified companies to supply commercial vehicles with conversion for diabetic retinopathy screening services. Screening will be carried out in mobile units in some instances. The conversion will consist of a waiting area and a clinical area with access for clients in wheelchairs.

Tenders were received from eight suppliers and a tender evaluation team (see Appendix 2) was set up which consisted of service users, public health professionals, procurement specialists and technical services specialists.

Applying the agreed weightings the following tenders were identified as the most economically advantageous tenders for the supply of commercial vehicles and conversion for diabetic retinopathy screening services in the HSE.

1. Premier Vehicle Solutions (Dungannon, Co. Tyrone)
2. Primo Coachworks (Ferbane, Co. Offaly)

It was agreed for geographical reasons that Premier Vehicle Solutions would supply the Northern portion of the country and Primo Coachworks would supply the South.

Cameras

This tender was conducted on behalf of the HSE to provide non-mydriatic digital fundus cameras and associated equipment. The units must be capable of interfacing into a complete retinal screening framework/system. It is envisaged that some units will be placed in mobile vans, which will travel, the other units will be installed at fixed clinics. The requirement is for the supply, installation and training of service users of these cameras.

The tender evaluation team (see Appendix 2) consisted of service users of a number of camera types, public health professionals and procurement specialists.

In line with the health sector procurement policy, the award criteria set out in the tender documentation determined the basis of the evaluation. The contract was awarded to the tenderer who was judged to have submitted the most economically advantageous, substantially responsive proposal and who was willing to enter into a service level agreement for the purposes of managing the contract on an ongoing basis.

It is recommended that the contract to undertake the supply, installation and training of non-mydriatic digital fundus cameras for the diabetic retinopathy screening service initially be offered to Haag Streit, providers of Canon cameras.

As the service develops nationally, cameras and mobile vans will be purchased from the aforementioned successful tenders. The tender validity period is 36 months but may be extended if necessary.

ICT Diabetic Retinopathy Screening Software System

Consultation with the English national screening programme for diabetic retinopathy has established the overriding need to procure a national IT system to support a national diabetic retinopathy screening programme in Ireland. A robust IT system with capacity for audit, quality assurance and risk management will be an essential element of the programme. Suitable ICT systems exist in the marketplace. In 2008, a process is underway to seek approval, and commence procurement, for the programme management software for the national programme. A business proposal was submitted to the HSE ICT council in April 2008, and a business case was requested which was submitted in May 2008 and approved by the ICT council on 6th June 2008. Approval was then sought from the Change Management Organisational Development (CMOD) Unit in the Department of Finance and from the Department of Health and Children. This approval was granted in September 2008.

Roll-out of the diabetic retinopathy screening programme will be on a phased basis, by HSE area. The implementation phase of the ICT project will occur in parallel with service implementation in each area.

The hardware and infrastructure required for each area will be procured as each area begins implementation.

16

Communications

16. Communications

The principles of communication must be to:

- identify those who need to know;
- ensure that individuals/groups have access to the knowledge they need;
- deliver to individuals/groups new knowledge where and when they need it.

Communication in relation to the diabetic retinopathy screening programme will need to target a number of individuals/groups including:

- the general public;
- people with diabetes mellitus;
- professionals.

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

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

It will be necessary to ensure that the relevant professionals are aware of the programme and how it operates. They will need to have the information they require to provide services to patients. In addition the programme must ensure that information on referral and treatment is fed back to the programme.

Each area will organise communications for their area programme.

17

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17. References

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Appendices

18. Appendices

- Appendix 1:** English National Screening Committee Service Objectives and Quality Assurance Standard
- Appendix 2:** Membership of HSE West Diabetic Retinopathy Screening Group, National ICT Retinopathy Project Team and Procurement Teams
- Appendix 3:** Review of Diabetic Retinopathy Screening and Examination Services in Ireland
- Appendix 4:** English National Screening Committee Retinopathy Grading Standard
- Appendix 5:** Development of the Service in 2007 and 2008

Appendix 1

English National Screening Committee Service Objectives and Quality Assurance Standards Release 5, January 2007

Taken from the UK National Screening Committee. Essential Elements in developing a Diabetic Retinopathy Screening Programme. UK National Screening Committee. August 200

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

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

Objective	Criteria	Minimum Standard [all programmes]	Achievable Standard [top quartile]
To ensure optimum workload for graders, to maintain expertise.	1. Optometrists / ophthalmologists 2. All other screener/graders	Each optometrist or ophthalmologist should grade a minimum of 500 patient imagesets per annum Each grader should grade a minimum of 1000 patient imagesets per annum	Each grader should grade a minimum of 1500 patient imagesets per annum
To ensure timely referral of patients with R3 (fast-track) screening results (e-mailed or faxed).	Time between screening encounter and issue of referral request: Flagged by screener/grader as R3 fast-track referral, where secondary grading and appropriate referral actioned within 1 week.	95% referred within 1 calendar week 100% referred within 2 calendar weeks	98% referred within 1 week
To ensure GP and patient are informed of all test results	Time between screening encounter and issuing of result letters to GP and patient.	70% <3 weeks 100% <6 weeks	95% <3 weeks
To ensure timely consultation for all screen-positive patients.	Time between notification of positive test and consultation: 1. Proliferative DR/Advanced DED, R3 2. PPDR, R2 3. Maculopathy, M1 4. All retinopathy grades	70% <2 weeks 70% <13 weeks 70% <13 weeks 100% < 18 weeks	95% <2 weeks 95% <13 weeks 95% <13 weeks
To ensure timely treatment of those listed by ophthalmologist.	Time between listing and first laser treatment, following screening: 1. Proliferative DR, R3 2. Maculopathy, M1	90% <2 weeks 70% <10 weeks	95% <2 week 95% <10 week
To minimise overall delay between screening event and first laser treatment.	Time between screening encounter and first laser treatment, if listed at first visit to hospital eye service following screening, does not exceed: 1. For patients referred as R3 2. For patients referred as M1	70% <4 weeks 100% <6 weeks 70% <15 weeks 100% <26 weeks	95% <4 weeks 95% <15 weeks

Objective	Criteria	Minimum Standard [all programmes]	Achievable Standard [top quartile]
To follow up screen-positive patients (failsafe).	Combined cancellation and DNA rate for ophthalmology clinic 1. For PDR [R3] within 1 month 2. For PPDR [R2] within 6 months 3. For maculopathy within 6 months	<10% <10% <10%	<5% <5% <5%
To minimise the anxiety associated with screening due to inappropriate referral.	Monitor inappropriate referrals following screening 1. False positive rate of DR test (photograph) 2. Neither photograph or clinical examination warranted referral	25% of patients referred	20% of patients referred
To ensure timely re-screening.	Time to re-screening compared to annual screening interval.	70% of eligible patients on database re-screened within 12 months of previous screening encounter or 95% of eligible patients on database re-screened within 15 months of previous screening encounter	
To ensure the public and health care professionals are informed of performance of the screening programme at regular intervals	Production of annual report.	Production of annual report, for preceding financial year, according to national standard, by 31st October.	
To ensure the service participates in quality assurance	External quality assurance.	1. Evidence of participation of all graders in external image test set scheme 2. Participation in peer-review visit programme 3. Annual submission of national minimum dataset by 31st October.	

Objective	Criteria	Minimum Standard [all programmes]	Achievable Standard [top quartile]
To optimise programme efficiency and ensure ability to assure quality of service.	Minimum programme size.	Population including 12,000 people diagnosed with diabetes on current patient list	Population including 15,000 people diagnosed with diabetes on current patient list
To ensure that screening and grading of retinal images are provided by a trained and competent workforce	Accreditation of screening and grading staff in accordance with national standards	All staff should be accredited for their role within two years of appointment, or by April 2008 for existing staff in established programmes	

Appendix 2.

Membership of HSE West Diabetic Retinopathy Screening Group, National ICT Retinopathy Project Team and Procurement Teams

Members of the National ICT Retinopathy Project Team

Dr. Orlaith O'Reilly	Director of Public Health, National Population Health Lead for Diabetes
Ms. Mary Cooke	ICT Information Systems Manager
Dr. Sarah Doyle	Specialist in Public Health Medicine
Dr Fidelma Dunne	Consultant Endocrinologist
Ms. Mairead Gleeson	Project Manager CVD/Chronic Illness
Ms. Gemma Leane	Research Officer
Dr. Mai Mannix	Specialist in Public Health Medicine
Dr. Margaret Morgan	Community Ophthalmic Physician

Members of the Mobile Van Procurement Team

Ms. Caitriona Coleman	Diabetes Nurse Service Development Coordinator
Ms. Mairead Gleeson	Project Manager CVD/Chronic Illness
Mr. Tim Laffey	Technical Services Manager
Mr. Kevin McDonnell	Contracts Manager
Dr. Margaret Morgan	Community Ophthalmic Physician
Dr. Ann Shannon	Specialist in Public Health Medicine

Members of the Camera Procurement Team

Ms. Catherine Allen	Procurement Specialist
Ms. Mairead Gleeson	Project Manager CVD/Chronic Illness
Mr. Garrett Hurley	Retinal Screener/Photographer
Dr. Mai Mannix	Specialist in Public Health Medicine
Dr. Margaret Morgan	Community Ophthalmic Physician
Ms. Ann Reynolds	Procurement Specialist

Members of the HSE West Diabetic Retinopathy Screening Group

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Appendix 3.

Review of Diabetic Retinopathy Screening and Examination Services in Ireland

Introduction

A review of current service provision for diabetic retinopathy screening and examination was conducted in the Department of Public Health, HSE South, Kilkenny, at the end of 2007. All ophthalmologists, HSE hospital network managers and HSE local health managers were contacted and asked to provide details of diabetic retinopathy screening/examination services in their catchment area.

Methodology

Letters were sent to the 32 HSE local health managers and eight hospital network managers requesting names and addresses of ophthalmologists and ophthalmic surgeons currently working in their area or network. They were also asked to provide details, including budget allocation, of any diabetic retinopathy screening services currently being funded and details of HSE owned digital fundal cameras and eye clinical management software.

Using the names and addresses supplied a register of all ophthalmologists currently practicing (publicly and privately) in the Republic of Ireland was compiled. In addition, the following organisations/sources were also contacted/used to form the register:

- Irish College of Ophthalmologists
- Medical Council specialist register for ophthalmology and ophthalmic surgery
- Irish Medical Directory list of ophthalmologists
- HSE Primary Care Reimbursement Service list of ophthalmologists contracted under the community ophthalmic services scheme
- HSE Primary Care Units
- Hospital websites
- Department of Social and Family Affairs website

A pilot questionnaire was developed and sent to four ophthalmologists to assess its ease of use and suitability for purpose. Minor changes were made to the questionnaire as a result.

The final questionnaire was sent to all identified ophthalmologists currently practicing (publicly or privately) in community and hospital settings. The final questionnaire covered questions relating to the structure, process and outcomes of screening. A reminder letter and questionnaire was also sent to non-responders.

In addition, an independent external evaluation by Dr Peter Scanlon, the National Coordinator of the English National Diabetic Retinopathy Screening Programme, in 2007, of services provided in the North West region and a hospital service in Galway was used to inform this review .

Results

Of the 176 postal questionnaires sent to ophthalmologists there were 66 completed returns. In addition, seven ophthalmologists had retired, four were unknown at the postal address, there was an insufficient address for three ophthalmologists and one was deceased. The overall response rate was 41% (66/161). Even though the response rate is low there is sufficient geographical spread in responses received to describe service provision across the four HSE areas. However, there is insufficient information to provide details on community service provision in the former East Coast Area and the South Western Area Health Boards.

Of the 66 returned questionnaires, 48 ophthalmologists provide/oversee routine diabetic retinal screening/examination and 18 do not. The responses from the 48 ophthalmologists and responses from 26 local health managers and seven hospital network managers were analysed. The analysis relates primarily to structure and process as there was insufficient response to the outcome sections of the questionnaire to provide meaningful results. The following sections describe the structure and process of diabetic retinopathy screening/examination services in Ireland.

Structure

The structure of the provision of services is presented by the four HSE administrative areas.

HSE South

Synopses of the provision of diabetic retinopathy screening/examination services in the HSE South are presented in Table 1 (PCCC provision) and Table 2 (hospital network provision). There may be some overlap between community and hospital services.

Diabetic retinal screening and examination services in the HSE South are provided by community and hospital based ophthalmologists. In the former South Eastern Health Board (SEHB) area the provision of diabetic retinopathy screening/examination services are primarily provided through community care (PCCC). In the South East area there are four full-time Community Ophthalmic Physicians (COPs), one assigned to each of the four Local Health Office (LHO) areas, who provide dedicated diabetic retinopathy screening/examination clinics. There is no dedicated budget for such screening services. A digital fundal camera is used for screening/examination in two of the LHO areas. Waterford Regional Hospital also provides a dedicated clinic, using slit lamp biomicroscopy as the screening method.

In the former Southern Health Board (SHB) area screening services are provided through the hospital network, with support from community ophthalmologists. In the Southern area there are two COPs, with one COP serving the four LHO areas (South Lee, North Lee, North Cork, West Cork) that cover County Cork. Cork University Hospital (CUH) and Kerry General Hospital have dedicated screening clinics, with CUH using digital photography as part of the screening process. The COP in Kerry provides the dedicated clinic in Kerry General Hospital. While a digital camera is available in the hospital it is not used for screening.

Some of the LHO areas in the HSE South provide screening/examination services to all people with diabetes regardless of medical card status. In addition, a number of ophthalmologists (HSE employed and private providers) have set up their own registers of people with diabetes.

Private Providers

In the HSE South diabetic retinopathy examination services are also provided by private ophthalmologists. It appears that people with diabetes are examined during routine practice surgeries as opposed to dedicated clinics for screening/examination.

An example of an innovative pilot programme, which previously existed in the South East and run by a private provider, involved a mobile unit with a photographic technician and a retinal camera visiting a number of GP practices in the area. This service was offered free to people with diabetes who were registered with the selected GPs. Patients requiring treatment were referred to the hospital eye department and all patients were given an appointment for annual follow-up.

The HSE also contracts services from a number of private ophthalmologists under the Community Ophthalmic Services Scheme. In Kerry it is known that there is a privately provided, publicly funded service offering dedicated digital photography diabetic retinal examination clinics.

Table 1: Diabetic retinopathy screening and examination services by LHO area – HSE South

	Carlow/Kilkenny	South Tipperary	Waterford	Wexford	South Lee, North Lee North Cork, West Cork	Kerry
COP	Y	Y	Y	Y	Y*	Y
Provide any DR screening/examination [^]	Y	Y	Y	Y	Y	Y
Provide dedicated DRS service	Y	Y	Y	Y	N	Y***
Dedicated budget	N	N	N	N	N	N
HSE owned digital fundal camera	Y Topcon TRC NW6S non-mydriatic	Y Topcon TRC NW6S non-mydriatic	Y Topcon TRC NW6S non-mydriatic	N	Y	Y*** Canon
HSE owned eye clinical management software	Y Acuitas	Y Acuitas	Y Acuitas	Y Acuitas	N	N

[^] screening/examination for the purposes of detecting previously undetected disease or monitoring progression of disease (e.g. background retinopathy) that may in future need treatment.

* one COP serves the four LHO areas ** this is provided in Kerry General Hospital by the COP

*** camera not used for screening

Y: yes N: no COP: community ophthalmic physician

DR: diabetic retinopathy DRS: diabetic retinopathy screening

Table 2: Diabetic retinopathy screening and examination services by hospital – HSE South

	Carlow/Kilkenny	South Tipperary	Waterford
Hospital Ophthalmology Department	Y	Y	N
DR screening/examination	Y	Y	Y*
Dedicated DRS service	Y	Y	Y*
Dedicated budget	N	Info not provided	N
HSE owned digital fundal camera	Y** Canon CR6-45 non-mydriatic	Y	Y** Canon
HSE owned eye clinical management software	Y	Y	N

* provided by the Kerry LHO community ophthalmic physician ** camera not used for screening

HSE West

Synopses of the provision of diabetic retinopathy screening/examination services in the HSE West are presented in Table 3 (PCCC provision) and Table 4 (hospital network provision). There may be some overlap between community and hospital services.

In the HSE West there are currently two good practice diabetic retinopathy screening services in operation, a population based diabetic retinopathy screening service in the former North Western Health Board area and a hospital based retinal screening service in University College Hospital Galway.

Currently in the former North Western Health Board (NWHB) area there is a population based diabetic retinopathy screening service offered to all 81 general practices in the area. The service covers the region comprising of Donegal, Sligo, Leitrim and the western part of Cavan. All people with diabetes are screened including those already attending ophthalmic services and the service sees all people with diabetes regardless of medical card status. The service commenced in October 2005 and receives annual revenue provision of approximately €250,000 as part of a Department of Health special project funding.

The service consists of a 'mixed' screening system. Screening, using a digital camera, is provided in one fixed screening site at St Conal's Hospital, Letterkenny. The rural population is serviced by a single mobile unit which visits 39 health centres across the region. The mobile unit is wheelchair accessible and comprises a photographic area and a waiting area.

The mobile service became fully operational in Donegal in May 2006 and in Sligo/Leitrim in June 2006 with 10 minute appointment slots. Fixed clinics commenced in Letterkenny in April 2006.

The grading and administrative centre for the service is based at St. Conal's Hospital.

Six people are directly involved in the screening programme:

- 1 WTE administrator
- 1 WTE community ophthalmologist/secondary grader
- 2 x 0.5 WTE screeners
- 2 x 0.5 WTE grader/screeners

The grader/screeners conduct fixed clinics in Letterkenny. The screeners work alternate weeks in the mobile unit, one covering Donegal and the other Sligo/Leitrim. The programme receives assistance with quality assurance, audit and system support from the local Public Health Department.

Visions are recorded using a Snellen chart at all screening sites. The screening modality is digital imaging using a Canon CR6/DGi camera (10 D back mobile unit and Sligo site, 20 D back Letterkenny site). The image capture, grading and management software is supplied by Prowellness. It is a web-based system consisting of an eye screening and general diabetes module. There is real-time data input at screening and treatment clinics. The mobile clinic uses a laptop which contains a copy of the software with the clinic schedule. Images and screening data captured are uploaded to the server on a daily basis with download of scheduling changes to the laptop. The system is interfaced to the local patient administration systems thus ensuring accurate demographic data and ensuring the system is updated when patients have deceased. The software is located on a server in Sligo and all data is backed up daily to tape. In addition, there is a back-up laptop in the mobile unit which is backed up daily from the screening laptop.

Two-field digital retinal photography (nasal and temporal) without mydriasis is performed for each eye. If there is a technical failure, two-field digital photography will be performed with mydriasis for each eye, using 1% Tropicamide.

Grader training was carried out locally and in Imperial College, London. Screener training was at formal courses based in Newcastle and Ninewells Hospital, Dundee.

Currently there are approximately 6,000 people with diabetes registered on the database. More than a quarter of those screened (27%) have been referred to ophthalmic services for further evaluation, and treatment as required. The first round of screening is complete and the second round commenced in May 2007.

In the former Western Health Board (WHB) area the review did not identify any dedicated community ophthalmology based diabetic retinal screening service. People with diabetes are seen by a COP as part of routine clinics using slit lamp biomicroscopy and/or direct ophthalmoscopy. Retinal cameras are not available to the community ophthalmologists in this region.

A hospital based screening service is offered at the Endocrinology and Diabetes Day Centre at the University College Hospital Galway (UCHG). This service was set up in March 2006 on a pilot basis with allocation of Hospital and University funds. The diabetes retinal screening service is available to:

- Patients attending the Diabetes Day Centre
- Patients referred from in-patient services
- Paediatrics patients with diabetes over 12 years of age
- Pregnant women with pre-gestational diabetes (Type 1 and Type 2)
- All patients with diabetes awaiting eye clinic appointments (they are automatically removed from the waiting list and offered screening)
- All patients with diabetes referred from primary care and on the waiting list for routine diabetes care.

There is a large photography room in UCHG, which houses the Canon six mega pixel non mydriatic fundus camera and Digital Healthcare computer software system. Fundus photography and primary grading is carried out here. Secondary grading is done in the ophthalmology office. There is also an office for secretarial and administrative duties.

The grading criteria used is the National Screening Committee (NSC) retinopathy grading standard that is used in England, Wales and Northern Ireland. The lead Ophthalmic Physician, the lead Diabetologist and the Photographer/Primary Grader have completed the Imperial College retinal screening and grading course.

Three people are directly involved in the screening programme:

- 1 photographer/ primary grader/ administrator post that is shared with the eye clinic, broken down as follows:
 - 3 days screening for diabetic retinopathy
 - 2 days working in the general eye clinic
- 1/2 WTE ophthalmologist /secondary grader
- 1/2 WTE secretarial assistant

There are 3,591 persons registered on the Digital Healthcare computer software system at the Diabetes Day Centre (as of August 2007). In the first year (March 2006-2007) 1,517 persons with diabetes were screened (43% of patients registered).

Table 3: Diabetic retinopathy screening and examination services by LHO area – HSE West

	Donegal	Sligo/Leitrim NW Cavan	Roscommon	Mayo	Galway	Clare	Limerick	North Tipperary/ East Limerick
COP	Y	Y	Y	Y	Y	Y	Y	Info not provided
Provide any DR screening/examination^	Y	Y	Y	Y	N	Info not provided	Info not provided	Info not provided
Provide dedicated DRS service	Y	Y	N	N	N	N	N	Info not provided
Dedicated budget	Y	N	N	N	N	N	N	N
HSE owned digital fundal camera	Y*	N	N	N	N	N	N	N
HSE owned eye clinical management software	Y	Prowellness	N	N	N	N	N	N

[^] screening/examination for the purposes of detecting previously undetected disease or monitoring progression of disease (e.g. background retinopathy) that may in future need treatment.

* 1 fixed camera and 1 mobile camera

Y: yes N: no

COP: community ophthalmic physician

DR: diabetic retinopathy

DRS: diabetic retinopathy screening

Table 4: Diabetic retinopathy screening and examination services by hospital – HSE West

	St Conal's Hospital, Letterkenny	Sligo General Hospital	University College Hospital Galway	Mid Western Regional Hospital Limerick
Hospital Ophthalmology Department	N	Y	Y	Y
DR screening/examination	Y	N	Y	Y
Dedicated DRS service	Y	N	Y	Y
Dedicated budget	Y	N	Y	Info not provided
HSE owned digital fundal camera	Y*	Y	Y	Y
		Canon CR-DGi Heidelberg HRA2 SIO Topcon 50EX	Zeiss	
HSE owned eye clinical management software	Prowellness	Info not provided	Digital HealthCare	N

HSE Dublin North East

Synopses of the provision of diabetic retinopathy screening/examination services in the HSE Dublin North East are presented in Table 5 (PCCC provision) and Table 6 (hospital network provision). There may be some overlap between community and hospital services.

One or two COPs serve each LHO area in the former North Eastern Health Board (NEHB) area and one COP serves the three LHO areas in North Dublin, i.e. North West Dublin, Dublin North Central and North Dublin. In the region diabetic retinopathy screening/examination is generally provided as part of routine eye clinics and not in dedicated diabetic eye clinics. However, there is a dedicated diabetic retinal clinic provided in Louth LHO by the COP.

HSE Primary Care Services Dublin North East area have a service level agreement with a company called 'Foresight Eye Care' to provide a mobile retinal screening service to patients in the Diabetes Watch Programme . Photographic screening takes place at selected GP practices/suitable health centres that meet agreed standards for photographic screening. This is a publicly funded, privately provided screening service for 1500 people with diabetes using digital retinal photography, three stage grading with internal and external quality assurance. The programme management software used is Acuitas. The grading criteria used is the NSC retinopathy grading standard. Three people are involved in the screening programme, one ophthalmologist, one photographer (nurse), one primary grader and administrator (optometrist). A random sample of 10% of all images are sent for quality assurance to an external ophthalmologist. The cost of the screening service is €90 per person screened and €45 for each non-attendee. The follow-up examination and treatment on patients deemed to have evidence of diabetic retinopathy of an extent that would require laser photocoagulation is not covered by this programme. However, Foresight assumes the responsibility of assuring referral into the hospital eye service of such patients.

The review identified two hospitals in the region providing dedicated diabetic retinopathy screening services, Our Lady of Lourdes Hospital Drogheda and the Mater Hospital. A diabetic retinal screening clinic operates once weekly in Drogheda and the screening method used is slit-lamp biomicroscopy. The Mater hospital operates two clinics each week, a diabetic eye photographic clinic (for no retinopathy, mild retinopathy, new cases) and a diabetic eye specialist clinic (for retinopathy requiring treatment and follow-up). Two nurses, three photographers and one administrator provide some support to this service. The two cameras used for screening are privately owned. People with diabetes are also reviewed in general ophthalmology clinics in other hospitals in the region.

Table 5: Diabetic retinopathy screening and examination services by LHO area – HSE Dublin/North East

	Cavan/ Monaghan	Louth	Meath	North Dublin, North West Dublin, Dublin North Central
COP	Y	Y	Y	Y***
Provide any DR screening/examination [^]	Y	Y	Y	Y
Provide dedicated DRS service	Y*	Y*	Y*	N
Dedicated budget	Y**	Y**	Y**	N
HSE owned digital fundal camera	Y Haagstreich/Canon	Y Topcon NW6S	Y Nidek AFC-210 non mydriatic	Y**** Zeiss Visucam
HSE owned eye clinical management software	N	N	N	N

[^] screening/examination for the purposes of detecting previously undetected disease or monitoring progression of disease (e.g., background retinopathy) that may in future need treatment.

* publicly funded dedicated DRS service in provided to patients in the Diabetes Watch Programme by a private company "Foresight".

** dedicated budget for service provided by Foresight, otherwise services are funded through the community ophthalmology budgets.

*** one COP serves the three LHO areas

**** camera located in community care in North West Dublin
COP: community ophthalmic physician
Y: yes N: no

DR: diabetic retinopathy

DRS: diabetic retinopathy screening

Table 6: Diabetic retinopathy screening and examination services by hospital – HSE Dublin/North East

	Our Lady of Lourdes Hospital Drogheda	Mater Misericordiae University Hospital	Beaumont Hospital
Hospital Ophthalmology Department	N	Y	Y
DR screening/examination	Y	N	Y
Dedicated DRS service	Y	N	Y
Dedicated budgets	Y	N	Y
HSE owned digital fundal camera	Y* canon CR-DGi	Y Canon CR-DGi Heidelberg HRA2 SLO Topcon 50EX	Y Info not provided
HSE owned eye clinical management software	Y Prowellness	Info not provided	Y Zeiss Digital HealthCare

* a digital fundal camera has been purchased and the hospital is in the process of identifying a staff member for training on the operation of the camera.

HSE Dublin/Mid Leinster

Synopses of the provision of diabetic retinopathy screening/examination services in the HSE Dublin Mid Leinster are presented in Table 7 (PCCC provision) and Table 8 (hospital network provision). There may be some overlap between community and hospital services.

For the former East Coast Area and the South Western Area Health Boards there is insufficient information to describe diabetic retinopathy service provision.

In Laois/Offaly LHO a dedicated diabetic retinopathy screening service is provided by the COP, which extends outside the LHO catchment area. The dedicated clinic takes place in the Midland Regional Hospital Portlaoise. Primary screening is carried out by an ophthalmic nurse specialist using a fundal camera. The programme management software used is Acuitas. Secondary screening is performed by the COP. The grading criteria used is the NSC retinopathy grading standard that is used in England, Wales and Northern Ireland.

There are some private practitioners who provide diabetic retinal screening/examination in the community, some of whom provide services under the Community Ophthalmic Services Scheme.

A number of hospitals in the Dublin Mid Leinster region provide diabetic retinopathy screening services.

In St. James's Hospital a digital diabetic retinal screening service commenced in September 2005, providing two dedicated clinics per week. Sessions are held in the outpatients department/diabetic day centre. Images are taken by a photographer/grader, with images graded by the ophthalmologist, using the Scottish grading system. If funding is provided they have planned for a full-time grader/photographer.

At St. Columcille's Hospital, Loughlinstown, there is dedicated digital imaging with routine dilation of all patients attending diabetic clinics. Images are taken by a photographer in two dedicated diabetic retinopathy screening clinics per week. An ophthalmologist grades the images using standard clinical diabetic retinopathy grading criteria and patients are offered rescreening every 12 months. There are plans to expand the service to four clinics per week.

In the AMNCH Tallaght Hospital diabetic retinopathy screening/examination is provided by two means; patients are referred on an ad hoc basis to the routine eye clinic or patients attend a retinal photography clinic. The latter clinic was established in July 2006 as a pilot clinic and has not been able to move beyond its pilot form due to lack of funding. An orthoptist grades the photographs and any patients with diabetic retinopathy are referred to the ophthalmologists in the diabetic eye clinic.

Photographic screening for diabetic retinopathy, two sessions a month, is carried out in the Royal Victoria Eye and Ear Hospital. However, there is no grading of images. Patients are offered rescreening in 18 months. They plan to apply to the National Treatment Purchase Fund to provide diabetic retinopathy screening for patients attending hospital-based diabetes clinics who currently do not have any screening examinations for diabetic retinopathy.

There are dedicated diabetic retinopathy screening/examination clinics held at the Midland Regional Hospital Tullamore. In addition, people with diabetes are also seen at the general ophthalmic clinics at the hospital and also at the Midland Regional Hospital Mullingar. The COP in Laois/Offaly LHO provides a dedicated diabetic retinopathy screening clinic in the Midland Regional Hospital Portlaoise,

Table 7: Diabetic retinopathy screening and examination services by LHO area – former Midlands Health Board only

	Longford/ Westmeath	Laois/ Offaly
COP	Y	Y
Provide any DR screening/examination [^]	Y	Y
Provide dedicated DRS service	Info not provided	Y
Dedicated budget	N	N
HSE owned digital fundal camera	N	Topcon TRC NW-100
HSE owned eye clinical management software	Y Acuitas	Y Acuitas

[^] screening/examination for the purposes of detecting previously undetected disease or monitoring progression of disease (e.g. background retinopathy) that may in future need treatment.

Y: yes; N: no
COP: community ophthalmic physician

DR: diabetic retinopathy

DRS: diabetic retinopathy screening

Table 8: Diabetic retinopathy screening and examination services by hospital – HSE Dublin/Mid Leinster

	Royal Victoria Eye and Ear Hospital	St. James's Hospital	St. Vincent's University Hospital	St. Columcille's Hospital, Loughlinstown	AMNCH Tallaght Hospital	Our Lady's Hospital for Sick Children, Crumlin	Midland Regional Hospital Tullamore	Midland Regional Hospital Portlaoise	Midland Regional Hospital Mullingar
Hospital Ophthalmology Department	Y	Y	Y	Y	Y	Y	Y	Y	Y
DR screening/examination	Y	Y	Info not provided	Y	Y	Info not provided	Y	N	Y
Dedicated DRS service	Y	Y	N	Y	Y	Info not provided	Y	Y*	Don't know
Dedicated budgets	N	N	N	N	N	N	N	N	N
HSE owned digital fundal camera	Y Topcon TRC NW-100	Y Canon non-mydratic	N	Y Topcon TRC 50EX	Y Topcon non-mydratic	N	N	Y Topcon TRC NW-100	Y
HSE owned eye clinical management software	Y Acuitas	Y Acuitas	N	N	N	N	N	Y Acuitas	Y Acuitas

* service provided by COP

Process

Of the 48 ophthalmologists who provide/oversee routine diabetic retinal screening/ examination, 23 (48%) provide this service through a dedicated clinic/programme, with 25 ophthalmologists (52%) providing the service as part of routine general eye clinics. For the majority of ophthalmologists (66.7%) their patients are introduced into the service by referral from other health professionals only (Table 9). Some ophthalmologists also proactively invite people with diabetes to have their eyes examined and some accept self-referrals, both are in addition to referrals from other health professionals.

Table 9: How people with diabetes are introduced into the service

How people with diabetes are introduced into the service	Number	Percentage
Referred by other health professionals only	32	66.7
Referred by other health professionals and proactively invited	7	14.6
Referred by other health professionals and self-referral	5	10.4
Other	4	8.4
Total	48	100

Forty-five of the 48 ophthalmologists (93.7%) routinely dilate their patients' eyes, unless contraindicated.

Screening/examination of the patients' eyes is conducted by numerous methods, which are summarised in Table 10.

Almost one third of ophthalmologists (31.3%) who provide a service use slit lamp biomicroscopy only when examining the eyes of people with diabetes. Digital photography, in addition to slit lamp biomicroscopy, is used by 27.1% of ophthalmologists. 6.3% of ophthalmologists use digital photography only as the screening method. In total 23 of the 48 ophthalmologists (48%) are using some type of digital photography when screening/examining the eyes of people with diabetes.

Table 10: How the eyes of people with diabetes are screened/examined

How the eyes of people with diabetes are screened/examined	Number	Percentage
Slit lamp biomicroscopy only	15	31.3
Slit lamp biomicroscopy and digital photography	13	27.1
Direct ophthalmoscopy and slit lamp biomicroscopy	9	18.8
Direct ophthalmoscopy and slit lamp biomicroscopy and digital photography	6	12.5
Digital photography only	3	6.3
Other	2	4.2
Total	48	100

The following paragraph relates to the responses of only the 23 ophthalmologists using digital photography and should therefore be interpreted with caution. Three of the 23 ophthalmologists who are using digital photography did not answer this section. Of the 20 for whom data was available, only 14 currently provide a service in which images are graded. In nine of the 14 services the ophthalmologist only is grading images, with no secondary grading carried out. In three of the services the ophthalmologist and another health professional, such as a nurse, photographer, grader, or optometrist, carry out grading. In two of the cases the ophthalmologist does not report grading the images, with grading carried out by a nurse, grader or orthoptist only. The 12 ophthalmologists who are grading images grade approximately 150 to 1200 images/year. The other health professionals who are grading images grade approximately 400 to 6000 images/year. In five of the 14 services (35.7%) the NSC retinopathy grading standard is the grading criteria used for screening images. In one service the Scottish Diabetic Retinopathy grading scheme is used and in eight services the information is not provided. Of the 14 services, eight (57.1%) have

an internal quality assurance system. Three (21.4%) have an external quality assurance system, 10 (71.4%) do not and information was missing from one responder.

Of the 48 ophthalmologists who provide/oversee routine diabetic retinal screening/ examination, 26 ophthalmologists (54.2%) offer people with diabetes rescreening/re-examination once a year, eight ophthalmologist offer rescreening/re-examination less frequently than once a year and five ophthalmologist offer rescreening/re-examination more frequently than once a year (Table 11).

Table 11: How often, if no further management is required, people with diabetes are offered rescreening/re-examination

How often people with diabetes are offered rescreening/re-examination	Number	Percentage
More frequent than once a year	5	10.4
Once a year	26	54.2
Less frequent than once a year	8	16.7
Missing data	9	18.7
Total	48	100

Thirty-six ophthalmologists provide a public funded, public provided screening service model, six provide a public funded, private provided screening service model and 12 provide a private funded private provided screening service model. Seven ophthalmologists did not respond to this question.

Thirteen ophthalmologists (27.1%) report that they audit the service they provide, 30 (62.5%) do not (five ophthalmologists did not respond). When asked if they have plans to start/expand retinopathy screening services in the near future, 28 ophthalmologists (58.3%) responded that they do, 12 (25%) responded no (eight ophthalmologists did not respond).

Comments

Below are some of the comments received from ophthalmologists, with regard to diabetic retinopathy screening services in Ireland. In general ophthalmologists would like to expand their existing service, however lack of funding and staff availability appear to be blocking the process. Others see a need for a national diabetic retinopathy screening programme to be established, however some do have reservations.

"Within the region and nationally, a database be established in liaison with primary care to identify all people with diabetes within the area. Subsequently a coordinated community based community service be provided where all people with diabetes may be annually screened."

"Within the job criteria of community ophthalmologists and PCCC eligibility criteria to those services, screening is not possible. Screening only possible if the whole population eligible. I attempted to provide a screening service 8-10 years ago and was informed that had to operate within PCCC COP service framework, i.e. only provide services to those eligible, regardless of clinical need. I would feel that there needs to be an extension of the HSE/NWHS service rather than the extension of privately operated ad hoc schemes."

"There is a serious under provision in the current service to people with diabetes. This starts with a lack of knowledge on the part of patients and their GP as to the necessity to access retinal screening services. However, the existing services are so over stretched that they would not be capable of coping. Hence there is a need for a systematic screening programme using a single database derived from a diabetic register."

"I have requested a digital camera for the hospital services - awaiting a reply. I am very keen to develop the diabetic screening that I am providing in the hospital and have a digital system screening locally for a more efficient service."

"Over the past number of years I have made numerous submissions to establish screening for diabetic retinopathy locally and more recently on a national scale. It has never been possible to establish a screening programme because of very poor support from the Department of Health. A screening programme cannot be established without quality assurance and a proper system of recall, in addition to cameras etc. Therefore, we only have a system where patients who attend, have digital photography and images graded."

"We are at a maximum capacity limited by staffing. If we had a full time person to grade and photograph we could increase screening capacity by 50%. The eye nurse is only available one day per week to screen. The service is limited only by lack of personnel."

"Be very very careful of photographic screening, it creates more technical, administrative and archiving work than it claims to solve".

"A large number of people with diabetes in this area undergo no screening for diabetic retinopathy but regularly attend hospital based diabetic clinics".

"When the process is initiated I suggest a nation wide standard be used. Each area currently has different systems. Any planning must include medical ophthalmologists as it is they who deliver the service. The tendency has been for retinal specialists to plan screening services without consultation with medical ophthalmologists."

"I have major reservations about the value of a national or regional retinopathy screening service using cameras and graders. I feel that diabetic retinopathy screening can be managed using the structures that are currently in place."

Conclusions

The responses from ophthalmologists, hospital network managers and local health managers demonstrate that current diabetic retinopathy screening and examination services in Ireland are ad hoc. There is large variability in service provision for diabetic retinopathy screening across the country, but various examples of good practice exist.

The review identifies a variety of methods for the delivery of screening, including a mobile van, static cameras located in healthcare facilities and a mobile camera brought to GP practices. There is no consistency in screening methodology across the country and only some ophthalmologists who responded are using digital photography.

Of those who responded (23 responses) to using digital photography as a screening method, only 14 services are currently grading images. Of the 14, only six responded as using recognised grading standards and only three as having an external quality assurance system.

Lack of funding has been identified as the major reason for non-provision of an adequate screening service.

To date, systematic screening based on retinal photography has been provided on a limited basis within the HSE. Existing services, in general, are not provided on a population-based approach nor do they adhere to best practice quality standards. However, there are examples of good practice based screening services in operation.

Letter to Hospital Network Manager

25th October 2007

Dear ,

I am writing to inform you that a project is being undertaken within the Population Health Directorate to establish a national, population-based diabetic retinopathy screening programme. This is under the HSE Transformation Programme 2007-2010 Programme 4.2.2, led by Dr. Orlaith O'Reilly on behalf of Population Health. In addition, the Diabetes Expert Advisory Group (EAG), which was established this year, has formed a number of subgroups, including one for diabetic retinopathy screening (DRS). This latter group, which has multidisciplinary representation, is facilitating the work of the transformation project. It would be appreciated if you would bear this work in mind if you are considering any service development in this area in the future.

As part of the project a framework for a diabetic retinopathy screening (DRS) programme in Ireland is being developed. To inform the development of the Framework and future development of services a review of current diabetic retinopathy screening and examination services nationally is being undertaken in the Department of Public Health, HSE-South, Kilkenny. This will take the form of a questionnaire survey of all ophthalmologists practicing (publicly or privately) in Ireland. To facilitate this work I would appreciate if you would

- furnish me with names and addresses of all Ophthalmic surgeons and physicians working in hospitals within your network
- provide me with details, including budget allocation, of any diabetic retinopathy screening/examination programme(s) being funded/provided in your network
- inform me of any HSE owned digital fundal cameras within your network
- inform me of any HSE owned eye-specific software within your network by November 9th 2007.

If you have any queries about the work of the project please do not hesitate to contact me.

Yours sincerely,

Dr. Sarah Doyle MB MRCPI MFPHM

Consultant in Public Health Medicine

Letter and Questionnaire to Ophthalmologist

16th November 2007

Re: Review of diabetic retinal screening and examination services nationally

Dear ,

Please find enclosed a short questionnaire which I would appreciate your response to. It will take about fifteen minutes to complete and will provide important information for the development of a national diabetic retinopathy screening programme.

Under the HSE Transformation Programme 2007-2010 Programme Four (Improving the Health of the Population) a project is being undertaken within the Population Health Directorate to establish a national, population-based diabetic retinopathy screening programme. In addition, the Diabetes Expert Advisory Group (EAG), which was established this year, has formed a number of subgroups, including one for diabetic retinopathy screening (DRS). This latter group, which has multidisciplinary representation, is facilitating the work of the transformation project.

As part of the project a framework for a diabetic retinopathy screening (DRS) programme in Ireland is being developed. To inform the development of the Framework and future development of services I am undertaking a review of current diabetic retinopathy screening and examination services nationally.

You may already have provided some information about your service to me via your Local Health Manager or your Hospital Network Manager. If so, thank you. This questionnaire asks for responses in a little more detail.

Please respond to the questionnaire in relation to your own caseload (including that of doctors for whose work you have direct responsibility e.g. non-consultant hospital doctors) for all locations in which you work.

I acknowledge that some of the information requested will not be available for all services but ask that you would indicate where this is the case. In itself this is important information.

Returned questionnaires will be handled only by the research team.

I am interested in receiving any additional documentation e.g. service development or audit reports that you consider relevant to this work.

Please return the questionnaire in the enclosed addressed envelope by December 7th 2007.

If you have any queries about the questionnaire or the work of the project please do not hesitate to contact me.

Yours sincerely,

Dr. Sarah Doyle MB MRCPI MFPHM
Consultant in Public Health Medicine

Survey no.:

Review of diabetic retinal screening and examination services nationally

Name _____ Position _____

1. Do you provide/oversee routine diabetic retinal screening/examination*? Yes No
 If no, finish questionnaire
 If yes, is this provided through a dedicated diabetic retinopathy screening programme? Yes No
2. Please provide an outline of the type of service that you provide (model of service, lead, guidelines, catchment etc.). Please send any service development documents, patient information literature etc. that you may have.
-
-
-
-
3. Have you access to a register of diabetic patients in your area? Yes No Don't know
 If yes, has this been proactively created Yes No Don't know
 (e.g. sought from diabetic clinics/GPs etc.)?
4. Please estimate the proportion of your employment that you spend on:
 - routine diabetic retinopathy screening/examination (not treatment) of public patients? _____ WTE
 - treatment of diabetic retinopathy in public patients? _____ WTE
5. Do you provide/oversee dedicated diabetic retinal screening/examination clinics? Yes No
 If yes, how many sessions (1/2 day) per week? Public _____ Private _____
 Approximately how many patients do you see per session? _____
6. What other HSE-employed staff are involved in diabetic retinopathy screening/examination with you and what proportion of their time do they spend on it?

Staff	Number	Estimated total whole time equivalent (WTE) spent on diabetic retinopathy screening/examination
Example: Nursing 2 nurses, 1 @ 0.8 WTE, 1 @ 0.6 WTE	2	1.4
Non-consultant hospital doctors		
Nursing		
Optometrists		
Photographers		
Graders		
Photographer/graders		
Administration		
Management		
Other staff (please state positions)		

7. Where is the diabetic screening/examination conducted? Tick all that apply

- Fixed clinics, hospital public clinics
- Fixed clinics, community health centres
- Fixed clinics, private consulting rooms, hospital
- Fixed clinics, private consulting rooms, community
- Mobile clinics
- Screening by optometrist(s) in their practices
- Other

Location(s) _____
 Location(s) _____
 Location(s) _____
 Location(s) _____
 If mobile clinic, no. of vans _____
 Practice locations(s) _____
 Please specify _____

8. Have you access to a digital camera(s) for retinopathy screening? Yes No

If yes,

	HSE-owned	Privately-owned
How many?		
What type(s)?		
Where is it located?		
How many other ophthalmologists also use this camera(s) for retinopathy screening?		
Are the cameras used for other work also?	Y/N	Y/N

9. Have you access to eye-specific software? Yes No

If yes,

	HSE-owned	Privately-owned
What is it?		
Please comment on functionality		
Please comment on limitations		

10. How are patients with diabetes introduced to your service? Tick all that apply

Referred by other health professionals (doctors/nurses/optometrists)

Proactively invited

Other, please specify _____

11. Are all patients' eyes routinely dilated, unless contraindicated? Yes No

If not, please describe practice _____

12. How do you currently screen/examine patients with diabetes? Tick all that apply

- a) Direct ophthalmoscopy
- b) Slit lamp biomicroscopy
- c) Digital photography (with biomicroscopy for technical failures and quality assurance)
- d) Non-digital photography (with biomicroscopy for technical failures and quality assurance)
- e) Other, please specify _____

13. If using retinal photography please outline the following in relation to the grading of images:

Where is it done? _____

By whom?

Position	Grading qualifications	Approx. no. images graded/year

What criteria (e.g. National Screening Committee retinopathy grading standard) are used?

What happens for patients with ungradable images? _____

Have you a system of - internal quality assurance Yes No
- external quality assurance Yes No

14. How often, if no further management is required, are patients offered rescreening/re-examination?

15. What is the diabetic retinopathy screening service model? Tick all that apply

- a) Public funded, public provided Number of patients _____
b) Public funded, private provided Number of patients _____
c) Private funded, private provided Number of patients _____
d) Other, please specify _____ Number of patients _____

16. If public funded, public provided is there a dedicated HSE budget for the diabetic retinopathy screening/examination that you provide/oversee? Yes No Don't know

If yes, how much is this per year? _____

If not, from what budget does the HSE fund the screening/testing service? _____

17. If public funded, private provided have you a service level agreement with the HSE? Yes No

If yes, what is the cost of screening to the HSE? _____

18. Do you audit the service that you provide? Yes No

If, yes, how often? _____

19. Please state the latest year for which you have figures on the number of patients screened/ examined for diabetic retinopathy _____

For that year please provide the following data. If the data is not available please answer NA.

- a) Number of patients on your list/register eligible to be called for screening/examination _____
b) Number of patients invited for screening/examination _____
c) Number of patients that attended for screening/examination _____
d) Number of patients that had their eyes dilated _____
e) If photographic screening, number of patients with ungradable images _____
f) Number of patients with newly diagnosed sight-threatening diabetic retinopathy _____
g) Number of patients that had laser treatment _____

20. Have you plans to start/expand retinopathy screening services in the near future? Yes No

If yes, please elaborate:

21. To what service do you refer patients that need treatment? _____

22. If you have any further comments please make them here: _____

Appendix 4.

English National Screening Committee Retinopathy Grading Standard

Retinopathy (R)		
Level 0	None	
Level 1	Background	microaneurysm(s) retinal haemorrhage(s) ± any exudate not within the definition of maculopathy
Level 2	Pre-proliferative	venous beading venous loop or reduplication intraretinal microvascular abnormality (IRMA) multiple deep, round or blot haemorrhages (CWS - careful search for above features)
Level 3	Proliferative	new vessels on disc (NVD) new vessels elsewhere (NVE) pre-retinal or vitreous haemorrhage pre- retinal fibrosis ± tractional retinal detachment
Maculopathy (M)		exudate within 1 disc diameter (DD) of the centre of the fovea circinate or group of exudates within the macula retinal thickening within 1DD of the centre of the fovea (if stereo available) any microaneurysm or haemorrhage within 1DD of the centre of the fovea only if associated with a best VA of $\leq 6/12$ (if no stereo)
Photocoagulation (P)		evidence of focal/grid laser to macula evidence of peripheral scatter laser
Unclassifiable (U)		unobtainable / ungradable

Appendix 5.

Development of the Service in 2007 and 2008

Planning and development of a diabetic retinopathy screening programme was included as a service development in the HSE National Service Plan 2007. Funding of €750,000 was made available in 2007 to commence a national diabetic retinopathy screening programme. There was also approval for eight whole time equivalent (WTE) staff.

The 2007 funding was to be made available for development of services. HSE areas known to have commenced a diabetic retinopathy screening programme in the past (HSE West and Dublin North East) were contacted to develop bids for funding for the development of a programme within their area. These were submitted as part of the EAG estimates bids. They were evaluated and work was commenced with HSE West to develop an area-wide diabetic retinopathy screening programme that would reflect the national framework.

It was decided to commence roll out of the programme across the HSE West, as a population-based screening programme had previously been established in the former North Western Health Board. The funding was, therefore, made available to the HSE West PCCC budget. However, none of this money was spent in 2007 on diabetic retinopathy screening as it was used for the break even plan. Examination of current services show that a national ICT system which supports quality assurance and risk management is required to develop the screening service prior to further implementation.

A multidisciplinary group (see Appendix 2), including clinicians, public health physicians, managers, IT professionals and others from HSE West had already been formed to progress development of diabetic retinopathy screening services. It became the vehicle through which expansion of services was progressed. The National Retinopathy Screening Committee continued to work with the HSE West Retinal Screening Steering Group to set out the quality standards, governance arrangements, monitoring and information systems required.

The €750,000 budget for diabetic retinopathy screening was made available again in 2008. It was decided to revert this money to the Population Health budget. Unfortunately due to financial pressures within HSE it was not possible to use this funding to commence programme implementation.



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