Diabetic retinal screening in the UK

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Diabetic eye disease is the most common cause of preventable visual loss in people of working age in the UK[1]. Diabetes mellitus now affects over two million people in England and Wales, with certain ethnic groups (for example, Asian and Afro-Caribbean populations) at particular risk[2,3]. Furthermore, by 2010 the prevalence of type 2 diabetes is expected to be twice what it was in 1997[4].

DIABETIC RETINOPATHY

Sustained hyperglycaemia induces pathological changes to retinal blood vessels. Microvascular occlusion combined with leakage results in development of the microaneurysms, intraretinal haemorrhages, exudates and oedema that characterize background diabetic retinopathy. Involvement of the fovea by such changes, termed maculopathy, is the most common cause of visual impairment in diabetic patients.

Secondary ischaemia, initiating the production of vasoproliferative factors, can result in and drive the progression to proliferative diabetic retinopathy which is typified by the growth of fragile abnormal new vessels on the retina, at the disc, or into the vitreous cavity. Subsequent haemorrhage and retinal detachment lead to blindness.

British surveys suggest that around 5–10% of all people with diabetes have sight-threatening retinopathy and up to 40% have some retinopathy at diagnosis[5]. The incidence of retinopathy requiring ophthalmological follow-up or treatment has been reported to average 1.5% after one year[6]. Twenty years from onset, over 90% of patients with type 1 and more than 60% of those with type 2 diabetes will have some retinopathy. In the UK Prospective Diabetes Study cohort of people with newly diagnosed type 2 diabetes, retinopathy was present in 39% of men and 35% of women[7].

CRITERIA FOR SCREENING

The cardinal principles of screening for human disease, defined by the World Health Organization in 1968, form the basis of the National Screening Committee's existing criteria for a screening programme[8].

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First, the condition in question should present an *important health problem*. This is true of diabetic retinopathy.

Second, there must be an *effective preventive therapy*. For every 100 patients with treatable disease, 55 would become blind or severely visually impaired in ten years without treatment, compared with 13 if all were treated in the same period. The beneficial effect of argon laser photocoagulation on proliferative retinopathy and macular oedema has been established in randomized controlled trials. The most important of these are the Diabetic Retinopathy and the Early Treatment of Diabetic Retinopathy studies, which included patients with both type 1 and type 2 diabetes. Laser photocoagulation for proliferative retinopathy with high-risk characteristics was shown to be associated with a 52% reduction in relative risk of severe visual loss. Early treatment of clinically significant macular oedema reduced severe visual loss by 50% at five years and lowered the need to treat at two years to only 8%[9,10]. Severe visual loss curtails independent living, and even moderate visual loss impairs quality of life. The protective effect of laser treatment lasts over ten years in two-thirds of laser patients[11]. Data from epidemiological studies indicate that each successful treatment will give at least ten years of preserved sight[12].

Third, screening must be *cost-effective*. The cost-effectiveness of retinal screening compares well with that of other screening programmes. The social cost of blindness, in terms of loss of earning capacity in working-age people and the need for social support, is substantial. A pilot study in the west of Scotland put the cost of treating each patient at risk of blindness at £387, against average savings in social benefits of £3375 per annum[13]. An analysis by the Liverpool Eye Group confirms the case for replacing local programmes with systematic screening[14].

Finally, *safe, simple validated screening methods* are available.

Diabetes UK audit standards

Diabetes UK has set some additional criteria in relation to a national screening programme for diabetes[15]:

- Annual examination after the age of twelve
- Screening test to have sensitivity $>80\%$, specificity $>95\%$ and failure rate $<5\%$

- All individuals found to have sight-threatening retinopathy to be referred to an ophthalmologist
- Incidence of visual impairment and blindness to be recorded
- Local system of audit and quality control to be set up.

Current screening practice is inadequate and inconsistent, both in quality of screening and in coverage of the diabetic population. Services range from well-structured programmes employing the latest cost-effective technology, to *ad-hoc* provision without central administration. In a Bristol survey, 50% of patients registered as having lost their sight from diabetes had not had regular eye checks[16]. The proportion of people with known diabetes screened each year ranges from 38% to 85% across the UK[17], and the haphazard nature of the current arrangements has led to worries over litigation. Already there have been medico-legal claims for compensation because of inadequate screening[18].

According to the estimate, systematic screening for diabetic retinopathy in England and Wales could prevent 260 cases of blindness each year in people over 70. With the predicted increase in the prevalence of diabetes this estimate may be too low[4].

ISSUES FOR A NATIONAL PROGRAMME

In Europe as a whole an impetus to improve screening was the St Vincent Task Force Declaration (1989) which stated that blindness due to diabetes should be reduced by one-third in five years[19]. An advisory panel convened by Diabetes UK compiled a report at the request of the National Screening Committee, and its recommendations for a national diabetic retinopathy screening programme will be linked to the National Framework for Diabetes, which aims to improve the quality of care for people with the disease.

Frequency of screening

The Diabetes UK audit criteria specify annual screening, but in type 2 diabetes this has been challenged. Of those patients in the UK Prospective Diabetes Study with no retinopathy at baseline, none required laser in the first three years[7]; and in the Wisconsin study only 1 of 271 patients who had no retinopathy at baseline went on to develop proliferative retinopathy at three years[20]. Patients at low risk of sight-threatening disease could be screened less frequently, though this might be complex to administer.

Population

All individuals with diagnosed diabetes over the age of 12 or post-puberty are eligible for screening. The age at which screening stops is at the discretion of the general practitioner and will depend on other aspects of health.

Quality assurance

The National Screening Committee requires a coherent, coordinated approach to quality assurance to be in place. Quality cannot be taken for granted, as indicated by recent events in the world of cervical screening[21]. All staff will be expected to take part in internal and external appraisal.

Criteria for quality assurance include:

- Continual training and accreditation of screeners
- Audit by ophthalmologist to determine false-positive rate
- Collection of adverse event data
- Regrading by camera or ophthalmoscopy to detect false negatives—a crucial issue since 90% of tests for sight-threatening retinopathy will be negative. A photographic method has the advantage of providing a hard record.

Modality

The two main screening approaches are ophthalmoscopy and retinal photography. Research is underway to determine whether a combination of methods might be most effective in preventing visual loss.

Photography

Slide and polaroid media have been overtaken by digital photography. Although digital operates at lower resolution than conventional colour photography, the clinical information is not inferior[22]. A minimum of 1300×1000 pixels is required to detect most microaneurysms in a 45° image. Advantages of digital over colour include image storage and transmission, ease of acquisition, potential for review with patients for educational purposes and greater patient comfort because of the lower flash intensity. With use of mydriatics, sensitivity is reported to increase and a technical failure rate of less than 5% is achievable[23].

Ophthalmoscopy

Direct ophthalmoscopy, even when performed by consultant ophthalmologists after mydriasis, does not reach the 80% sensitivity required by the Diabetes UK audit standards[24]. Alone it is not an acceptable retinal screening technique.

Indirect ophthalmoscopy, performed at the slit lamp with a hand-held fundus lens, is a viable alternative. Advantages are the low capital cost of slit lamps, convenience for patients (who can make appointments locally to suit themselves), feasibility of a service for housebound patients, ease of detecting other ocular disease, especially glaucoma and cataracts, and widespread participation by optometrists. Disadvantages are that there is no permanent retinal image, so that quality assurance may

involve time-consuming re-examination of patients, and that optometrists who see few patients may be unable to maintain adequate skills.

EXISTING MODELS OF RETINAL SCREENING

Across the UK several exemplary schemes are already in operation—based either on optometry with slit lamp biomicroscopy or on retinal photography. An example is the programme implemented in 1995 as part of a diabetic shared-care scheme at the Whittington Hospital in North London[25]. Trained accredited optometrists in the community examine patients by indirect slit lamp biomicroscopy. The programme has expanded to include 3400 patients resident in the population areas of three North London hospitals. A local protocol has been implemented which sets out criteria for dilated fundoscopy and referral to the ophthalmologist and the optometry training and accreditation now extends across four London health authorities. A quality audit of this screening programme showed a sensitivity of 100% and a specificity of 96%, thus satisfying the nationally defined standards[25].

It is important that introduction of a national scheme should not disadvantage the local schemes but rather allow their enhancement, if necessary, to the approved specifications. The schemes must begin to collect data for quality assurance—information that can be shared with health authorities and with the general practitioners responsible for continuing care of diabetic patients. The method of choice is likely to be digital photography, because of the ease of quality assurance. High-resolution digital cameras will soon become cheap enough for use in optometry practices; and this method provides the ideal combination of patient convenience, quality assurance and diagnosis of other ocular disease.

THE FUTURE

Some obstacles remain to be overcome, but the principles of a national screening programme will be submitted to Government as an essential part of the national framework for diabetes scheduled for April 2001.

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