An evaluation of diabetic retinopathy screening models

Ugo Okoli and Kate Mackay

Abstract
Background The aim of the study was to evaluate three models of diabetic retinopathy screening in a North London Health Authority so as to advise on setting up a comprehensive screening programme. The study evaluated the models against their own objectives and standards published by the British Diabetic Association (BDA) and the Royal Colleges for diabetic retinopathy screening, and assessed service user and provider satisfaction.

Methods Methods used were: analysis of the patient database and a case note review on uptake and coverage; follow-up for abnormal findings; comparisons of positive predictive values; postal questionnaire survey of service user satisfaction; semi-structured interviews of service providers.

Results A total of 2230 people with diabetes were screened between March 1998 and August 2000. The general practitioner (GP) led model achieved 63 per cent coverage and the two optometrist models 24 per cent. The detection rate for sight-threatening diabetic retinopathy was 6 per cent and 2.5 per cent for the optometrists and GP models, respectively. Positive predictive values of 94 per cent, 90 per cent and 60 per cent, respectively, were established for the GP-led model, the optometrists using the retinal camera and the optometrists using indirect ophthalmoscopy only. Twenty-eight (45 per cent) of the 62 people with sight-threatening diabetic retinopathy failed to attend for further investigation.

Service user and service provider satisfaction were high for all three models.

Conclusion The evaluation confirmed that all three methods of screening provided an effective service. The implementation of a district-wide diabetic retinopathy screening programme requires the establishment of a systematic call and recall system to achieve attendance for screening. A formal follow-up of people referred for specialist assessment and treatment should be part of the service.

Keywords: diabetic retinopathy, screening, general practitioners and optometrists

Introduction
Diabetes mellitus is the biggest single cause of registered blindness in the United Kingdom amongst working age people. It is an important public health problem, there are diagnostic procedures and adequate screening tests by which it can be identified, and there is an effective treatment. It can also be cost effective, in terms of both long-term health gains and money saved by prevention of visual impairment.

Studies evaluating different methods of retinal screening such as direct and indirect ophthalmoscopy and retinal photography have shown variable results. The National Screening Committee (NSC) published guidance in 2000 stating that yearly screening is appropriate and the quality of screening depends on the skill and degree of training possessed by the screener. General practitioners (GPs) and optometrists are both accessible for retinal screening programmes. The ‘gold standard’ is indirect ophthalmoscopy and a photograph of the retina.

National standards for care of people with diabetes are currently being developed in England, Scotland and Wales. Key interventions include regular surveillance for diabetic retinopathy in adults with diabetes and early laser treatment of those identified as having sight-threatening retinopathy. We carried out a study to compare and evaluate the effectiveness and efficiency of three retinal screening models for people with diabetes. Study results highlight practical issues for the setting up of effective diabetic retinopathy screening programmes.

Background to the pilot schemes
The study took place in a culturally diverse North London Health Authority with a population of 331,458. Twenty-three per cent of local residents are from ethnic groups other than ‘White’, with 7.9 per cent of Indian origin. Three Primary Care Groups (PCGs) were set up in the north, south and west of the borough, in April 1999. At the time of the study, 5616 people with diabetes were on the Health Authority district-wide

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diabetes register. Although the district register reflected a lower than expected prevalence of diabetes for the study population, it did include all people with diabetes currently known to GPs. The low prevalence is likely to reflect the under-diagnosis of diabetes in the population.

The local Diabetes Committee had recognized that retinal screening should be available to all people with diabetes. A local GP was in the process of setting up a screening pilot for his own practice, which he planned to extend to other practices within his PCG. Funding was not available at the time for a comprehensive service for the whole borough and partly to maintain equity of access as well as assessing the most appropriate models of care locally, the pilot was set up with three different models of retinal screening services – one in each PCG. The formal evaluation results were used to develop a comprehensive service for the whole population at the end of the study.

The three diabetic retinopathy screening models were:

1. A GP-led scheme established in the north of the district, using a single-lens reflex (SLR) retinal camera and indirect ophthalmoscopy (slit lamp). An orthoptist carried out the examination and results were interpreted by the orthoptist and a GP. This scheme was operated from a general practice and had been operational for 2 years at the time of the evaluation.

2. An optometrist scheme established in the west of the borough, using the same methods as above with the camera rotating between optometrists and established 18 months at the time of the study. The optometrists interpreted the results.

3. An optometrist scheme established in the south, using indirect ophthalmoscopy only, also functional for 18 months. The optometrists operated from their business premises and interpreted the results.

Invitation to attend for screening was different in the three models. GPs in the south and west were invited to send their patients with diabetes to the accredited optometrists either opportunistically or from their own practice diabetic register. The GP-led model, in the north of the borough, set up its own database for call and recall with the individual registers from each practice in the area. The Public Health Department of the Health Authority managed the database of patients screened by the optometrists. Although data from the three models were sent to the District Diabetes Register, they were used only for the annual recalls for the two-optometrist models.

A protocol classifying the different types of diabetic retinopathy was agreed by all service providers and a local ophthalmologist who also provided training for screening staff. Quality assurance was carried out by the ophthalmologist by randomly sampling and physically re-examining 5 per cent of people with negative screening findings.

Patients received information on the scheme and their details were recorded on a signed consent form.

There were four routes of referral based on the agreed protocol:

1. If no serious abnormality was detected patients were invited to return for annual review;
2. Those with coincidental ocular abnormalities such as cataracts, raised intra-ocular pressure and other non-diabetic findings were referred to their GP for onward referral to an ophthalmologist;
3. Those with early eye abnormalities (maculopathy, pre-proliferative retinopathy and inadequate fundal view) were referred as soon as possible to the ophthalmologist;
4. Those with advanced retinopathy and sight-threatening diabetic retinopathy were referred urgently to the ophthalmologist.

Methods

Uptake and coverage rate

Screening uptake was the proportion of patients attending for screening of all those invited. Coverage was the percentage of patients screened out of the total number of people with diabetes based on the District Register.

Analysis of people screened by the three models over a 13 month period to August 2000

An analysis of these data provided information on known risk factors for diabetic retinopathy such as the age of patients, duration of diabetes, number of patients with Type 1 and 2 diabetes, ethnic group of patients, and details of patients with hypertension. Ethnicity was defined using the Office for National Statistics definition. Results were compared across the three models using $\chi^2$ tests.

For the purposes of the analysis, the ‘worse eye’ was used to classify patients’ retinal status. Findings were categorized into maculopathy, pre-proliferative and advanced proliferative retinopathy, cataracts and other abnormalities. The proportions of various abnormalities detected by each pilot were calculated.

Sight-threatening diabetic retinopathy (STDR) was defined as any of the following: moderate pre-proliferative retinopathy or worse; circinate exudates within the macula; any exudates within one disc diameter of the fovea.

Quality audit and positive predictive value of screening method

To determine the rate of false positive referrals, a case note review was carried out by the ophthalmologist comparing the screeners’ findings with his own, for all patients referred for STDR during the study period.

Assessment of acceptability and accessibility

A postal questionnaire was used to assess patient access, acceptability and experience of the test. A random sample of 200 patients from each of the three models was obtained. Sampling was carried out using Excel statistics software. The sample
size was estimated using the proportion of patients who would be willing to return for further screening in each pilot. The following attributes were used to calculate the sample size: anticipated population proportion = 85 per cent, confidence interval (CI) = 95 per cent, power = 80 per cent and absolute precision = ±5 per cent. Quantitative data from the questionnaires were analysed using the Statistical Programme for Social Sciences (SPSS) package.20

Service provider views

All 12 accredited optometrists and staff from the GP-led scheme were interviewed. Semi-structured interviews were used to seek views on the training and screening programmes, current service provision and administration, links with the ophthalmologist and GPs, feedback required from the programme, screening methods and ideas for a comprehensive service.

Results

Uptake and coverage of the pilot models

A total of 2230 people with diabetes were screened between March 1998 and August 2000. The GP scheme achieved 80 per cent uptake (1424 of 1802 patients invited). The optometrist scheme started in March 1999 and screened 806 people with diabetes, 458 by the retinal camera and 348 by the indirect ophthalmoscopy method. Uptake rates for the optometrist schemes were not available, as most GPs did not keep a record of the patients they invited for screening.

The GP scheme achieved a coverage rate of 63 per cent by screening 1424 of the 2277 people with diabetes who were recorded on the District Diabetes Register. The two optometrist schemes screened 806 people with diabetes out of 3339 who were recorded on the District Diabetes Register, indicating an overall coverage rate of 24 per cent.

Analysis of service users

A total of 1760 people with diabetes were screened between 1 August 1999 and 31 August 2000. The optometrist models screened 515 people with diabetes, 313 with the retinal camera and indirect ophthalmoscopy and 202 with the indirect ophthalmoscopy on its own. The GP scheme screened 1245 people with diabetes in the same period using the retinal camera.

The mean age of patients attending the three pilot schemes was similar (63–65 years) and the mean duration of diabetes onset was between 5 and 7 years. Ninety-six per cent of service users had Type 2 diabetes. There were no significant differences in the prevalence of hypertension in people attending for screening. There was a significant difference between time spent examining patients by the two optometrists’ schemes (p <0.001), with the camera taking more time. Mean chair time was not available from the GP model for comparison (Table 1). Initially ethnicity was not recorded in the optometry models. Recording was introduced 6 months into the scheme and data were completed for 96 per cent of people attending. Ethnicity was completed for 98 per cent of patients in the GP model. For the whole study population 65 per cent of patients were classified as ‘White’ followed by 12 per cent of ‘Indians’.

Clinical findings

Nineteen people (6 per cent of those screened) were diagnosed with STDR and 56 (18 per cent of those screened) with background retinopathy in the optometrist model using the camera and indirect ophthalmoscopy. Twelve (6 per cent of those screened) people were diagnosed as having STDR and 34 (17 per cent of those screened) with background retinopathy by optometrists using the indirect ophthalmoscopy on its own. Thirty-one people (2.5 per cent of those screened) were detected as having STDR from the GP-led pilot and 264 (21.2 per cent of those screened) had background retinopathy.

During the study period, each optometrist-led scheme had referred 28 people to the ophthalmologist; that is, 9 per cent and 14 per cent, respectively, from the optometrist scheme using a camera and the optometrist scheme using the indirect ophthalmoscopy on its own. The GP scheme referred 64 (5 per cent) patients to the ophthalmologist in the same period.

A breakdown of the eye problems detected by each pilot scheme is detailed in the Figure. Both optometry models were more likely to detect patients as having cataracts and other abnormalities, 176 and 125, respectively, compared with the GP pilot with 90 patients having cataracts and 111 with other abnormalities (odds ratio (OR) 1.7, 95 per cent CI 1.2–2.3). Other eye abnormalities detected included glaucoma and optic atrophy.

Quality audit and positive predictive value

Of a total of 15 STDR cases referred by optometrists and seen by the ophthalmologist, the diagnosis was confirmed in 12, an overall 80 per cent true positive: 90 per cent for those using the camera and 60 per cent for those using the indirect ophthalmoscopy method only. The ophthalmologist saw 17 cases referred from the GP scheme and 16 (94 per cent) were confirmed as true positives (Table 2).

Details of the outcome of STDR referrals are presented in Table 3. It shows that 16 (52 per cent of those referred) and 12 (38 per cent of those referred) people from the optometrists and

![Figure](https://example.com/figure.png)

**Figure** Eye problems detected by all three models between 1 August 1999 and 31 August 2000.
GP scheme, respectively, failed to attend the hospital for follow-up and treatment.

A further analysis of the characteristics of patients who did not attend the ophthalmologist showed that they were more likely to be males (64 per cent) than females (36 per cent), with a mean age of 59 years. Forty-three per cent were from ethnic groups other than the ‘White’ population.

To assess the competency of the screeners, a 5 per cent sample of negative results were rescreened by the ophthalmologist, 6 months into the life of the pilot. Eighty-three (5 per cent) people were rescreened. Any disparity was assessed as minor by the ophthalmologist.

**Assessment of acceptability and accessibility**

A total of 445 (74 per cent) questionnaires were returned in response to the patient satisfaction survey. The response rates for the three models were 77 per cent for the GP-led model, 73

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**Table 1** Characteristics of people screened

<table>
<thead>
<tr>
<th>Variables</th>
<th>Optometrist-led pilot: retinal camera and indirect ophthalmoscopy (n = 313)</th>
<th>Optometrist-led pilot: indirect ophthalmoscopy only (n = 202)</th>
<th>GP-led pilot: retinal camera and indirect ophthalmoscopy (n = 1245)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age years (range)</td>
<td>63 (27–89)</td>
<td>65 (23–95)</td>
<td>63 (9.8–99)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Mean duration of diabetes in years (range)</td>
<td>5.7 (0–30) 95% CI 5.10–6.39</td>
<td>5.1 (0–29) 95% CI 4.32–5.86</td>
<td>7.2 (0–49) 95% CI 6.8–7.7</td>
<td>&lt;0.003*</td>
</tr>
<tr>
<td>Diabetes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type 1 (%)</td>
<td>4 (1.3)</td>
<td>12 (5.9)</td>
<td>Diet 324 (26)</td>
<td>&lt;0.01*†</td>
</tr>
<tr>
<td>Hypertension</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes (%)</td>
<td>155 (49.5)</td>
<td>80 (29.6)</td>
<td>583 (47)</td>
<td>0.25</td>
</tr>
<tr>
<td>Unknown (%)</td>
<td>2 (0.6)</td>
<td>12 (5.9)</td>
<td>Oral 140 (11)</td>
<td></td>
</tr>
<tr>
<td>Mean chair time (minutes) (range)</td>
<td>42.2 (25–65) 95% CI 41.48–42.97</td>
<td>36.5 (20–80) 95% CI 35.20–37.95</td>
<td>Oral + insulin 23 (2)</td>
<td>&lt;0.001**</td>
</tr>
</tbody>
</table>

* Statistically significant, p < 0.05.
† Optometrist schemes only.

**Table 2** Comparison of diagnosis from optometrist and GP-led model with the ophthalmologist

<table>
<thead>
<tr>
<th>Ophthalmologist</th>
<th>Optometrists camera</th>
<th>Optometrists indirect ophthalmoscopy</th>
<th>GP-led scheme camera</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetic retinopathy or maculopathy</td>
<td>Diabetic retinopathy or maculopathy</td>
<td>Diabetic retinopathy or maculopathy</td>
<td></td>
</tr>
<tr>
<td>Diagnosis confirmed</td>
<td>9</td>
<td>3</td>
<td>16</td>
</tr>
<tr>
<td>Diagnosis not confirmed</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>PPV</td>
<td>90% (95% CI 71–100)</td>
<td>60% (95% CI 14–100)</td>
<td>94% (95% CI 82.4–100)</td>
</tr>
</tbody>
</table>

**Table 3** Outcome of sight-threatening diabetic retinopathy referrals

<table>
<thead>
<tr>
<th>Outcome of referral</th>
<th>Optometrist-led scheme (total referred = 31) Number (%)</th>
<th>GP-led scheme (total referred = 31) Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seen by the district ophthalmologist</td>
<td>15 (48)</td>
<td>17 (56)</td>
</tr>
<tr>
<td>Awaiting appointment</td>
<td>—</td>
<td>2 (6)</td>
</tr>
<tr>
<td>Did not attend for follow-up</td>
<td>16 (52)</td>
<td>12 (38)</td>
</tr>
<tr>
<td>Under hospital review/treatment planned</td>
<td>12 (39)</td>
<td>16 (52)</td>
</tr>
<tr>
<td>Referred back to screening programme</td>
<td>3 (10)</td>
<td>1 (3)</td>
</tr>
</tbody>
</table>
per cent for the optometrists with a camera and 72.5 per cent for the optometrists using indirect ophthalmoscopy only.

A total of 436 (98 per cent) people were satisfied with the scheme and irrespective of model stated that the process was adequately explained to them. There was no significant difference between the models in terms of access. A total of 437 (99 per cent) service users stated that they would use the diabetic retinopathy screening service again.

Service provider views

All providers found the training sessions required for joining thescheme useful and suggested refresher courses every 6 months to a year. There were problems regarding the practicality of moving the camera between optometrists in the west and having to set aside particular days for screening clients. All optometrists thought a central administration for their scheme would be more efficient.

Discussion

All three models within the pilot fulfilled the standards published jointly by the Royal Colleges of Physicians, Ophthalmologists and General Practitioners, the College of Optometrists and the British Diabetic Association for retinal screening in people with diabetes,12,13 in terms of screening method, interval, positive predictive value, quality control and service user satisfaction.

At the end of the 2 year pilot period, the diabetic retinopathy screening models had screened 40 per cent of the total number of people known to have diabetes in the Health Authority area (2230 out of 5616 on the District Diabetes Register). The coverage reported by other diabetic retinopathy screening programmes ranges from 38 to 87 per cent.1,21 The GP-led model started a year before the optometrist models and both were organized differently, therefore it was not possible to make simple comparisons between the two schemes. The GP-led model had an overall uptake of 80 per cent and coverage of 63 per cent using the GP’s own, locally developed, register for call and recall. The coverage for the optometrist models was 24 per cent. The relatively low numbers screened by the optometrist models were due to varying referral rates of patients by GPs to the scheme. Most GP practices kept no records of the patients they referred to the optometrists for screening and although 89 per cent of practices in the optometry model localities claimed to have diabetes registers, they did not appear to use them for the retinal screening service.

The best response from service users was when everyone on the register was invited with one reminder. The study recommended that a similar system be set up within the comprehensive screening service and that the district register be used to allow a borough-wide co-ordinated system to operate. District registers have been noted by others to be a prerequisite for an effective and coordinated screening programme to be established.7,21

Advice on the use of diabetes registers for call and recall screening, currently out for consultation in England for the National Service Framework for Diabetes,22 advocates registers at GP practice level. Although practice registers will be essential for ensuring high-quality care for people with diabetes in primary care, our study indicates that practice-based registers on their own are not sufficient to secure adequate uptake for a district-wide service such as retinal screening. The model that achieved the best uptake rate in our study used its own register for call and recall and our recommendation for the continuing service was to use the District Diabetes Register for call and recall to ensure adequate uptake of the service. Using a District Register must also take into account issues of patient consent23 and be in full accordance with the Data Protection Act.24

The prevalence of STDR was 2.5 per cent for the GP-led scheme and 6 per cent for the optometrist schemes. The GP-led model result is at the lower end of that reported in the literature.7,25,26 This may be explained by the fact that although the evaluation of the GP-led model officially started in March 1998, the GP had been routinely screening a proportion of people with diabetes in the north for several years previously and would have already identified a proportion of STDR in that population. People with diabetes in the north for several years previously and would have already identified a proportion of STDR in that population. These people would have dropped out of the screening programme and would be followed up, long term, by the local hospital specialist.

The accuracy of screening (positive predictive value) appeared better for the GP-led scheme and optometrists using the camera (94 per cent and 90 per cent) than for the optometrists using the indirect ophthalmoscopy alone (60 per cent), although all three methods were within the accepted range for effective screening.

This differential is in keeping with findings from a recent study, which showed that the same screeners had higher accuracy with photography, compared with ophthalmoscopy alone.27 Other programmes have reported positive predictive value (PPV) ranging from 39 per cent28 for optometrists using ophthalmoscopy to 84 per cent29 for a programme using retinal photography.

A striking finding was that 28 (45 per cent of the 62 people identified as having STDR) people referred to the ophthalmologist did not attend his NHS clinic for further diagnosis and treatment. This result highlights the need for a failsafe mechanism to ensure, as an integral part of a comprehensive screening programme, the follow-up of all people with retinal disease. Although the study was unable to analyse the reason for failure to attend, it highlights the need for central co-ordination of the screening service, preferably with a dedicated administrator co-ordinating call and recall, follow-up of referrals, as well as quality assurance and annual audit.

A number of studies27,29,30 and the National Screening Committee31 recommend digital cameras as the preferred option for screening, together with indirect ophthalmoscopy, although indirect ophthalmoscopy can be used as effectively on its own. In terms of equity, however, our study recommended that the comprehensive service for the district should continue to be pro-
provided by the current service providers but that all people should have access to a retinal camera – a single-lens reflex – in the first instance. Practical issues, such as transporting the camera between optometrists, need to be considered carefully for the comprehensive programme. The study recommended digital cameras as a future option.

Conclusion

The study showed that all three diabetic retinopathy screening models achieved their objectives and were in line with evidence-based standards of care. However, coverage and uptake could be improved by establishing a systematic call and recall system with a dedicated administrator using the District Diabetes Register. A comprehensive programme also needed to incorporate a robust follow-up system to ensure that people who were identified as having sight-threatening diabetic retinopathy attended for further diagnosis and treatment.

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20 Statistical Programme for Social Sciences, SPSS version 9, SPSS manual. Chicago, IL: SPSS, Inc.


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