

# Diabetic retinopathy screening in New Zealand requires improvement: results from a multi-centre audit

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**D**iabetes has become more prevalent worldwide.<sup>1</sup> Diabetic retinopathy is a specific ocular complication of diabetes mellitus, which can cause visual impairment and blindness.<sup>2-4</sup> Timely detection and treatment with laser photocoagulation reduces both progression to and incidence of vision loss.<sup>5</sup> Systematic photographic retinal screening is cost effective compared with no screening or opportunistic screening.<sup>6,7</sup>

Preventing and limiting the impact of diabetes through better services is a key health target in New Zealand (NZ).<sup>8</sup> Initiatives to achieve this goal include implementation of the nationwide primary care based 'Get Checked' program introduced in 2001, and publication of the National Diabetes Retinal Screening Grading System and Referral Guidelines (the Guidelines) in 2006.<sup>9</sup>

Most retinal screening services are provided by District Health Boards (DHBs) which, through contractual service specifications, are directed to adopt the national screening standards. Participation in a retinal screening service is based on referral to the service, principally by general

practitioners. Service outcomes are based on reports of the number of patients screened, the number of screening events, and the number of patients receiving argon laser treatment. However, the quality of fundal photography grading, and referral pathways for screen-detected cases are not monitored nationally.

This study aimed to determine whether four main centre diabetic retinal screening services in NZ comply with the Guideline recommendations for moderate retinopathy (R3) and mild maculopathy (M2B and M3). These grades are the threshold for referral for assessment by an ophthalmologist. Assessment within 4-6 months is recommended to exclude significant peripheral or macular pathology.<sup>9</sup>

## Methods

This study was a retrospective audit of R3, M2B and M3 graded fundal photographs undertaken from May to August 2008. Table 1 shows the grading classification and referral guidelines.<sup>9</sup> Screen-detected grades

## Abstract

**Objective:** To determine whether diabetic retinal screening services and retinopathy referral centres in New Zealand meet the national guidelines for referral and assessment of screen detected moderate retinal and mild macular diabetic eye disease.

**Methods:** Diabetic retinal screening pathways and the data collected at four main centre retinal screening services were described and compared with recommendations in the national diabetes retinal screening guidelines. A retrospective audit of photoscreen detected moderate retinopathy (grade R3), and mild maculopathy (grades M2B and M3) during May to August 2008 was undertaken. Data collected by retinopathy referral centres were used to examine the follow-up of screen detected cases and to make comparisons with the national recommendations.

**Results:** All four screening services used the guidelines for grading, but the recommended dataset was incomplete. Not all recorded data were readily accessible. The retinal photos of 157 (2.4%) patients were graded as R3, M2B, M3 or a combination. The proportion of those screened with these grades varied across the four centres from 1.2% to 3.4%. Follow-up of the 157 screen positive patients did not always comply with guideline recommendations. Seventy five (48%) were referred for review by an ophthalmologist as recommended, 45 (60% of referred) were seen within the recommended six months. Nine patients (15% of the 60 with a documented assessment) were referred for or received laser treatment at 12-months follow-up.

**Conclusion:** Quality diabetic retinal screening data systems and quality assurance programs are required to improve the monitoring and quality of retinal screening in New Zealand.

**Key words:** retinal screening, diabetes, guidelines, monitoring, quality assurance

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R3, M2B and M3 were selected for this audit as appropriate timely referrals as these grades are a measurable indicator of service quality. The Multi-Regional Ethics Committee approved this study (MEC/09/35/EXP).

## Setting

Retinal screening services are delivered by 26 providers in NZ. This study was undertaken at four main centres, two in the North Island and two in the South Island. These four centres were invited to participate as they were organised differently and each screened a substantial number of patients. Two services were provided by the hospital eye department, one by a dedicated hospital diabetes centre and one by a Primary Health Organisation (PHO), which contracted optometrists to undertake initial assessments and fundal photography. One service employed dedicated ophthalmologists to assess screen positive patients; the other three referred screen positive patients to the local hospital eye department for ophthalmology assessment.

At each centre, the retinal screening method, the retinal screening data recorded and where the data were recorded was described, irrespective of whether the national guidelines were used. The professional groups who undertook the primary grading and the secondary grading were recorded. Under the NZ guidelines primary graders can be vocationally registered optometrists familiar with the

national grading system and referral guidelines, or non-ophthalmic medical practitioners and other allied health professionals such as nurses, medical photographers, ophthalmic technologists, who have met specified requirements.<sup>9</sup> Secondary graders can be vocationally registered ophthalmologists familiar with the national grading system and referral guidelines, or optometrists who have who have met specified requirements.<sup>9</sup> There is no national accreditation process for graders, nor is there a national training and accreditation process for photographers.

## Patient Eligibility

Eligible patients were those with diabetes screened between 1 May and 31 August 2008 who had a secondary grading recorded as R3, M2B, or M3. The highest macular or peripheral grade in either eye was used. Where a record of the secondary grade was not found, the primary grading was used. Patients known to be pregnant were excluded.

The process for identifying eligible patients for the audit and obtaining audit data varied between the centres. Electronic appointment or paper records of patients attending screening during the study period were checked to assess eligibility. If retinal screening results or other relevant data were missing from the screening database, paper records were accessed and reviewed to find the missing relevant data. The computerised retinal screening

**Table 1: Summary of the diabetic retinopathy and diabetic macular disease classification and referral guidelines.<sup>9</sup>**

Grade	Brief description	Outcome	Notes	Minimum level of grader*
<b>Retinopathy</b>				
R0	No retinopathy	Biennial photoscreen		Primary grader
R1	Minimal	18 months photoscreen		Primary grader
R2	Mild	12-18 months photoscreen		Secondary grader
R3	Moderate	Refer to ophthalmologist	Review by an ophthalmologist in 4-6 months recommended	Secondary grader
R4	Severe	Refer to ophthalmologist	Review by an ophthalmologist in <4 weeks recommended	Secondary grader
R5	Proliferative	'Fast track' referral to ophthalmologist	Review by an ophthalmologist in <1 week recommended	Secondary grader
RT	Stable treated diabetic retinopathy		Retinopathy may be more difficult to visualise. If there is any uncertainty, refer to an ophthalmologist.	Secondary grader
<b>Maculopathy</b>				
M0	No macular disease	Biennial photoscreen		Primary grader
M1	Minimal	Photoscreen 12 months	Refer if retinopathy requires referral	Primary grader
M2	Mild	Photoscreen 6-12 months or referral to ophthalmologist		Secondary grader
M3	Mild	Refer to ophthalmologist	Review by an ophthalmologist in <6 months recommended	Secondary grader
M4	Moderate	Refer to ophthalmologist	Review by an ophthalmologist in <4 weeks recommended	Secondary grader
M5	Severe	Urgent referral to ophthalmologist	Review by an ophthalmologist in <1 week recommended	Secondary grader
MT	Stable treated macular disease		Biennial photoscreen	Secondary grader

\* The New Zealand guidelines state primary graders can be vocationally registered optometrists familiar with the national grading system and referral guidelines, or non-ophthalmic medical practitioners and other allied health professionals such as nurses, medical photographers, ophthalmic technologists, who have met specified requirements.<sup>9</sup> Secondary graders can be vocationally registered ophthalmologists familiar with the national grading system and referral guidelines, or optometrists who have who have met specified requirements.<sup>9</sup>

database was used to readily identify eligible patients and the audit data at one centre. At another centre, screening appointment lists that recorded follow-up details were examined, and those patients who required follow-up, except for repeat photography in 12-24 months, had their medical notes checked for eligibility. At the third centre, hand-written lists of patients screened at each screening clinic also recorded the primary grading result. These lists were manually checked for potential eligible patients. Eligibility was confirmed by checking the medical notes. At the fourth centre, patients recorded as having mild retinopathy with no maculopathy on the screening database were excluded from a list of patients screened during the study period. The paper medical records were then examined to obtain the screening grade for the remaining patients.

### Audit data

The data collected included: demographics, diabetes type, duration and treatment, date of abnormal retinal screen, date of referral, date of receipt of referral, date specialist appointment made and method of patient notification, whether appointment(s) was attended, co-morbid visual burden and outcome of the clinical review. Hospital patient booking management systems were used to source information pertaining to appointment and referral dates. In all centres, the medical notes (paper or electronic) had to be manually searched for relevant details pertaining to the ophthalmology review appointment.

### Data analysis

Totals were derived, and means and proportions were calculated where appropriate.

## Results

The main features of each of the retinal screening centres are summarised in Table 2.

During the four-month study period there were 6,642 retinal screens, 2,135 by service A, 1,438 by service B, 1,930 by service C and 1,139 by service D.

A total of 157 patients had their retinal photos graded as M2B,

M3, R3 or a combination – 25 (1.2%) in region A, 49 (3.4%) in region B, 62 (3.2%) in regions C and 21 (1.8%) in region D. The demographic details of these patients are shown in Table 3. Details about patients' diabetes, such as type and year of diagnosis, were frequently missing and are not presented. Slightly more than half (52%) of the patients had a best visual acuity in either eye of better than or equal to 6/6, about one-quarter (29%) had a visual acuity worse than 6/6 but better than or equal to 6/10, and 19% had a result worse than 6/10.

Table 3 shows the specific retinopathy grading groups. The proportion of photos reported with each grade or combination of grades varied between the centres. The R3 grade was used most frequently at both service A and service C, and no photos were graded as R3 at service D.

Less than half of the 157 patients identified with R3, M2B, M3 or a combination were referred for review by an ophthalmologist. Referral rates were considerably higher at services A (80%) and D (90%) compared with services B (22%) and C (40%). Of the 75 patients referred, 45 (60%) were seen within the recommended six-month time frame, while 15 had no record of being reviewed before 1 September 2009, which was at least 12 months following the initial abnormal graded screen. Clinical notes were not found for five patients, of whom four had been referred for ophthalmology review in other regions or to private providers.

Of the 60 patients reviewed by an ophthalmologist, nine (15%) received laser treatment before 1 September 2009 for M2B (two) or M3 (six), three of whom also had R3 peripheral retinopathy.

Overall, patients with either an M3 grade or mixed grade had a higher referral rate compared to those with a R3 only or M2B only grade (Table 4). Referral rates for the different grades varied markedly between the four centres (Table 4). Of the 17 patients referred with a R3 grade, 10 (59%) were seen within the recommended six months. This was similar to the 43 patients referred for grades M2B or M3, of whom 27 (64%) were seen within the recommended six months. Of the 16 patients graded as both R3 and M2B/M3 referred for ophthalmology review, eight were seen within the recommended six-month time frame, and five had not been reviewed more than 12 months from the time of referral.

**Table 2: Service features of the four main centre retinal screening services.**

Feature	Screening Centre			
	A	B	C	D
Retinal screening method	Photography	Photography	Photography	Photography
Use of national screening guidelines	Yes	Yes	Yes	Yes
Primary grading performed by	Retinal photographers*	Optometrists	Nil	Retinal photographers*
Secondary grading performed by	Consultant ophthalmologist	Optometrists	Training and non-training ophthalmology registrars	Optometrists or training ophthalmology registrars
Complete recommended dataset collected	No	No	No	No
Dedicated electronic retinopathy screening database	Yes	Yes	Yes	Yes
Direct electronic recording of grades	No	Yes	Yes	No

\* Role not restricted to grading R0, R1, M0 and M1 as specified in the guidelines.

## Discussion

The purpose of the National Diabetes Retinal Screening Grading System and Referral Guidelines<sup>9</sup> in NZ has been to promote a nationally consistent, evidence-based approach for retinal screening. Our audit, the first of its kind in NZ, showed the four retinal screening services used the guidelines to some extent, most notably the recommended grading classification. However, the audit identified some inconsistencies, the most important being that a lower than expected proportion (48%) of patients with screen detected M2B, M3 or R3 diabetic eye disease were referred for ophthalmology assessment as recommended in the guidelines. Moreover, only 60% of these patients were seen within the recommended six months. The importance of referring these patients was highlighted by the fact that at least 15% of those reviewed by an ophthalmologist had laser treatment within twelve months following screening.

During the study period the proportion of screening photographs

graded as M2B, M3 or R3 varied between the four centres from 1.2% to 3.4%. We also found that the two centres with the lowest M2B, M3 or R3 screen detection rate had the highest referral rate. This variation may reflect the relatively short duration of the study (four months) or variation in grading practice. This study was not designed to determine reasons for any variation in grading practices, but we established that the grading process in each centre varied, and different health professional groups with different levels of expertise and experience were grading fundal photographs.

### Retinal screening programs and quality assurance

Evidence for the effectiveness of diabetic retinopathy screening is well established. The objective of diabetic retinopathy screening programs is to identify patients with sight threatening retinopathy and provide timely assessment and treatment to prevent loss of vision. Requirements of retinal screening programs are well

**Table 3: Demographic characteristics, grading and screening outcomes for R3 (moderate retinopathy), and M2B and M3 (mild maculopathy) screen positive diabetic patients, May-August 2008. Data are number (%) unless otherwise stated.**

	Total N=157	A N=25	B N=49	C N=62	D N=21
Male	95 (60.5)	12 (48.0)	28 (57.1)	42 (67.7)	13 (61.9)
Mean age (years)	57	61	58	55	60
European Pakeha	94 (59.9)	5 (24.0)	23 (46.9)	47 (75.8)	18 (85.7)
Other European	10 (6.4)	2 (8.0)	0 (0)	8 (12.9)	0 (0)
Maori	6 (3.8)	1 (4.0)	4 (8.2)	1 (1.6)	0 (0)
Samoan	13 (8.3)	4 (16.0)	6 (12.2)	3 (4.8)	0 (0)
Other Pacific	3 (1.9)	2 (8.0)	1 (2.0)	0 (0)	0 (0)
Asian	17 (10.8)	10 (40.0)	4 (8.2)	2 (3.2)	1 (4.8)
Other Ethnicity	13 (8.3)	0 (0)	11 (22.4)	0 (0)	2 (9.5)
R3	51 (32.2)	11 (44.0)	28 (57.1)	12 (19.4)	0 (0)
M2B	26 (16.6)	1 (4.0)	0 (0.0)	20 (32.3)	5 (23.8)
M3	56 (35.7)	8 (32.0)	12 (24.5)	21 (33.9)	15 (71.4)
Both R3 and M2B/M3	24 (15.3)	5 (20.0)	9 (18.4)	9 (14.5)	1 (4.8)
Referred	75 (47.8)	20 (80.0)	11 (22.4)	25 (40.3)	19 (90.4)
Reviewed within recommended 6 months*	45 (60.0)	14 (70.0)	5 (45.4)	15 (60.0)	11 (57.9)
Reviewed after 6 months*	15 (20.0)	3 (15.0)	1 (9.1)	7 (28.0)	4 (21.1)
No record of being seen before 1 September 2009	15 (20.0)	3 (15.0)	5 (45.4)	3 (12.0)	4 (21.1)
Documented laser treatment before 1 September 09**	9 (15.0)	0 (0.0)	0 (0.0)	5 (22.7)	3 (20.0)

\* Denominator is those who were referred

\*\* Denominator is those who had documented review

**Table 4: Referral rates for R3 (moderate retinopathy), and M2B and M3 (mild maculopathy) and mixed grading screen positive diabetic patients, May-August 2008 for each screening centre. Data are number (%).**

Grading	Total N=157		A N=25		B N=49		C N=62		D N=21	
	Total No	Referred No. (%)	Total No	Referred No. (%)	Total No	Referred No. (%)	Total No	Referred No. (%)	Total No	Referred No. (%)
R3	51	17 (33.3)	11	9 (81.8)	28	6 (21.4)	12	2 (16.7)	0	0/0
M2B	26	8 (30.0)	1	0 (0.0)	0	0	20	4 (20.0)	5	4 (80.0)
M3	56	35 (62.5)	9	6 (66.7)	12	1 (8.3)	21	13 (61.9)	15	15 (100.0)
Mixed R3, M2B, M3	24	16 (66.7)	5	5 (100.0)	9	4 (44.4)	9	6 (66.7)	1	1 (100.0)

documented, and organised programs with good information systems, monitoring and quality assurance activities are features of cost-effective programs. The UK has developed a national retinal screening program with specified standards and monitoring systems, and a strong emphasis on quality assurance.<sup>10,11</sup> The program has not been fully implemented, but good progress has been made and monitoring and evaluation has identified areas requiring improvements.<sup>12</sup> In NZ regional screening programs have been established in a fragmented fashion since the 1980s, and the National Diabetes Retinal Screening Grading System and Referral Guidelines<sup>9</sup> were an initial step to develop an equitable high quality nationally consistent retinal screening program, a need highlighted in the 2008 Diabetes and Cardiovascular Disease Quality Improvement Plan.<sup>13</sup>

### **Fundal photograph grading**

A high standard of grading is critical for an effective retinal screening program. Under-reporting can lead to an unacceptable level of false negative screening photographs and over-reporting can lead to false positive screens, and thus unnecessary referrals to already busy ophthalmology clinics. An expected referral level has not been established, but a recent audit of a regional program in England found the screen positive rate for all grades diabetic eye disease was 3.2%.<sup>14</sup> Our study was not able to determine whether under or over reporting was an issue, but variation in grading practices between the centres was described. Given the lack of national standards, training and accreditation for graders in NZ, this is not surprising, and is in contrast to England where 84% of primary graders are trained retinal screener graders.<sup>15</sup> Our findings support intentions “to define and develop suitable national accreditation and qualifications for primary and secondary graders as part of the ongoing quality assurance work”<sup>9</sup> and to implement intergrader quality assurance initiatives to assess the quality and accuracy of primary grading.<sup>10,16</sup> Intergrader consistency is considered a critical feature of effective retinal screening,<sup>10,17</sup> and relative grading experience does contribute to differences in grading.<sup>18</sup>

### **Diabetic eye disease grading classification**

The grading classification for diabetic eye disease screening is not universal internationally. Classifications vary slightly from country to country.<sup>9,10</sup> In NZ the grades R3, M2B and M3 are the threshold for referral to ophthalmic care.<sup>9</sup> While the guidelines recommend referral, our study found this was not universal practice with only half being referred. Determining reasons for variation in referral patterns was not part of the study design. Possible reasons for non-referral are insufficient clinical capacity to assess these patients, and disagreement with the current guideline recommendations as to which patients are considered to have significant disease. Limited clinical capacity was identified as a significant factor contributing to an inability of services to meet targets in a recent survey of the current state of retinal screening services in the England.<sup>15</sup> About half of retinal screening programs reported waiting lists for screen positive patients who needed further assessment and/or treatment for retinopathy. Moreover about two-thirds of programs reported having

inadequate resources to provide a high quality service. With any screening program, suitable assessment and treatment facilities are necessary requirements so the goals of the program can be achieved. The impact of retinal screening on ophthalmology services should not be underestimated.<sup>19,20</sup>

## **Strengths and Limitations**

The participation, support and co-operation of the four study sites is a strength of the study. However, we only included fairly large main centres and our results may not reflect the situation at other sites, particularly smaller centres. Ideally, a formal national audit would include all retinal screening services in NZ, and indeed if linked national data systems were in place, this would be readily possible, as would a longer audit period. The main limitation of the study was the difficulty obtaining data. We identified that not all centres had a dedicated computerised retinal screening database and the complete recommended minimum dataset was not recorded by all four centres. Also, the details of each retinal screening examination, and follow-up if required, were not readily accessible, and data items had to be manually searched for and checked in patient medical records and different databases. While every effort was made to obtain complete data, some data may have been missed simply because it was recorded in multiple places or not as recommended. Thus, potentially some patients with grades R3, M2B or M3 may not have been identified for the audit. Although the study period was 4 months, this represented a large number of screening events (6,642). Other grades of diabetic eye disease were not examined.

## **Conclusions**

Retinal screening in NZ requires further development to attain a high quality equitable program in order to achieve the goal of reduced visual loss and blindness from diabetes. This study provides evidence to support recommendations made by the Diabetes and Cardiovascular Disease Quality Improvement group to progressively implement a national quality assurance program, based on the national guidelines, that includes appropriate standards for training, competency assurance, technical quality and follow-up.<sup>13</sup>

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