DIABETES RETINAL SCREENING, GRADING AND MANAGEMENT GUIDELINES FOR USE IN PACIFIC ISLAND NATIONS 2010

Based on New Zealand's *National Diabetes Retinal Screening Grading System and Referral Guidelines 2006*

Adapted by the Diabetes Working Group of The Fred Hollows Foundation NZ, Auckland, New Zealand

Foreword

Worldwide, blindness is one of the greatest fears people have. Loss of sight is a real possibility for a person with uncontrolled diabetes.

No country has reliable measures of the incidence of loss of vision from diabetes. However, it is likely to be increasing in the Pacific region as the prevalence of diabetes increases. Recently it has been established that the prevalence of diabetes in persons ≥40 years of age in Fiji is approximately 40% (Personal Communication: GRB). This is likely to continue if diabetes identification and management, including patient education and complications monitoring and treatment, remain under-resourced and of variable coverage and quality.

For individuals and their families, the good news is that diabetic retinopathy can be detected reliably through effective screening programs, and that early intervention can prevent or help reduce loss of vision. For service funders and providers, the benefit is that such screening and treatment are cost-effective and, in the longer term, cost-saving.

Now is the time to set up diabetes retinal screening, referral and treatment systems in the Pacific: so they may be developed into consistent, robust services, better able to handle the profusion of retinopathy that seems will likely eventuate. To help achieve this, these Diabetes Retinal Screening, Grading and Management Guidelines for use in Pacific Island Nations (the Pacific Guidelines) have been developed.

The Pacific Guidelines are a modification of New Zealand's National Diabetes Retinal Screening, Grading System and Referral Guidelines (2006). The Diabetes Working Group of The Fred Hollows Foundation New Zealand is grateful to the National Diabetes Retinopathy Steering Group both for its work in producing the New Zealand guidelines and for its permission to use them. The Diabetes Working Group would also like to acknowledge and thank those Pacific Island-based ophthalmologists and ophthalmic nurses who contributed by reviewing draft documents that eventually became these Pacific Guidelines.

Uniform application of the Pacific Guidelines across the region will ensure consistent services and care that will benefit patients. It will also enable comparison of data and permit standardized training of a workforce that shifts the bulk of the workload away from ophthalmologists, the scarcest human resource, whose training can be better utilized. To facilitate use of the Guidelines, from 2010 the Pacific Eye Institute—the regional ophthalmic nurse and doctor training centre associated with the Fiji School of Medicine and the University of the South Pacific—will be providing a certificate course for nurses and technicians.

The Pacific Guidelines and certificate course are based on the use of non-mydriatic digital retinal photography as the screening tool. This has been a deliberate decision. The Diabetes Working Group believes that the difficulties of procuring and maintaining this equipment in scattered, tropical, low-resource settings are outweighed by the benefits, which include records that enable service monitoring, review and control of clinical decision making, and portability with availability wherever and whenever a patient is reviewed.

Diabetes eye care services based on the Pacific Guidelines will provide service and clinical data from within and across jurisdictions of the region. Analysis of this will produce evidence to support improvement of local services and regional agreement of Guidelines modification.

Gillian Clover
Consultant to the Diabetes Working Group, The Fred Hollows Foundation New Zealand, Auckland, New Zealand

Garry Brian
Medical Director, The Fred Hollows Foundation New Zealand, Auckland, New Zealand

John Szetu
Medical Director, The Pacific Eye Institute, Suva, Fiji
Chair, PACEYES (the professional association of Pacific eye care practitioners), Suva, Fiji

Gordon Sanderson
Chair, New Zealand National Diabetes Retinopathy Steering Group, Dunedin, New Zealand

Contents

1. Introduction

1.1 Aim and Scope

The **aim** of the Guidelines is to provide ophthalmologists and other health professionals involved in retinal screening and the management of diabetes eye disease with:

- a consistent approach to the grading of severity of retinopathy, and referral of persons with signs of diabetic retinopathy for review by an ophthalmologist
- the ability to measure and monitor grading and referrals against an agreed Pacific standard
- retinal screening images (non-mydriatic digital retinal camera photographs where available) for comparison, training, and quality assurance purposes
- data for analysing service performance and trends
- continuity of care for individuals, when they are seen at different times and by different clinicians, regardless of where the person chooses to go.

The **scope** of the Guidelines includes:

- introductory information
- screening recommendations for diabetic retinopathy, including a screening pathway
- a grading system and explanation of the different levels of Grader
- recommendations for recall, referral and other management
- suggested minimum dataset for each patient examination
- quality assurance activities.

The Guidelines are intended to be the basis of Pacific retinal screening and management programs which aim to prevent vision loss due to diabetic retinopathy. They will contribute to improved and consistent care by standardising aspects of diabetic retinopathy management, and providing a basis for quality assurance programs for providers and services.

1.2 Diabetic Retinopathy: The Rationale for Grading

Diabetes damages the small blood vessels in the retina. These then leak or occlude. A clinical picture results that is typical of diabetes damage. Progression of vessel damage is mirrored by progression of clinical features. The progression and link of diabetes damage and clinical findings of this retinopathy are well understood.

When particular features occur, the likelihood of vision loss increases; when others develop, vision loss is inevitable.

Treatments, particularly with laser, are available. Laser, if applied appropriately and in a timely manner, reduces the risk of vision loss.

Therefore, it is important to be able to grade a person's retinopathy such that the likelihood of vision loss is understood, and appropriate management that will reduce the risk of vision loss is provided.

Particular patterns of retinal features occur as diabetic retinopathy progresses. Recognising these patterns can be used to grade the retinopathy.

There are many systems of grading for classifying diabetic retinopathy. Some are now obsolete, although they continue to be used in clinical practice and diabetes literature.

The classification used in The Wisconsin Epidemiological Studies of Diabetic Retinopathy, is linked to a large weight of evidence of retinopathy progression and treatment (Table 1). It is therefore a useful guide to the establishment of safe screening recall intervals, and onward referrals to ophthalmologists for patients with higher-risk retinopathy. However, it is cumbersome to apply in everyday clinical practice.

The system of grading recommended by the Pacific Guidelines is easily applied to a diabetes retinal screening program. Using this grading system on a national and regional basis will:

- provide a consistent approach to retinopathy classification, recall, referral and treatment of people with diabetes
- enable measuring, monitoring, and appropriate levels of service planning and provision
- allow national and regional quality assurance management as a support network for providers and to assist in evaluating quality of service provision.

Table 1: Diabetic Retinopathy: Grading and Risk of Progression (Based on The Wisconsin Epidemiological Studies of Diabetic Retinopathy)

Retinopathy Grade	Definition	Rate of Progression (%)			
		to PDR		to High-risk Grade	
		1 year	3 years	1 year	5 years
Minimal (level 20)	MA only	Not documented			
Mild (level 30)	MA and one or more of: retinal H, HEx, CWS, but not meeting Moderate definition	5	14	1	15
Moderate (level 40)	H/MA > standard photo 2A in at least one quadrant and one or more of: CWS, VB, IRMA, but not meeting Severe NPDR definition	12-26	30-48	8-18	25-39
Severe Pre-proliferative [Severe NPDR] (level 50)	Any of: H/MA > standard photo 2A in all four quadrants, IRMA > standard photo 8A in one or more quadrants, VB in two or more quadrants	52	71	15	56
Proliferative [PDR] (level 60)	Any of: NVE or NVD < standard photo 10A, vitreous/preretinal H and NVE < ½ disc area without NVD			46	75
High-risk PDR (level 70)	Any of: NVD > ¼ to ⅓ disc area, or with vitreous/preretinal H, or NVE > ½ disc area with vitreous/preretinal H	Severe visual loss (VA< 5/200) develops in 25-40% within 2 years			
Advanced PDR	High-risk PDR with traction detachment involving macula or vitreous H obscuring ability to grade NVD and NVE				
Macular Oedema	Retinal thickening within 2 disc diameters of macular centre	Can occur at any stage of diabetic retinopathy			
Clinically Significant Macular Oedema [CSMO]	Retinal thickening within 500 um of macular centre or hard exudates within 500 um of macular centre with adjacent thickening	Can occur at any stage of diabetic retinopathy			

MA	Microaneurysms	Hex	Hard Exudates
CWS	Soft Exudates	H	Haemorrhages
VB	Venous Beading	IRMA	Intraretinal Microvascular Abnormalities
NVD	Neovascularisation and Fibrous Proliferation involving the optic disc	NVE	Neovascularisation and Fibrous Proliferation involving other areas of the retina

1.3 Risk of Retinopathy

All people with diabetes are at risk of developing retinopathy.

There is evidence that the prevalence of diabetes in the Pacific region is higher than elsewhere. However, local variability is determined by the like of ethnic diversity and the rural/urban mix of populations (e.g. in New Zealand, diabetes is about three times more common in Pacific than Caucasian people).

Generally, in developed countries such as New Zealand:

- approximately 30% of people with diabetes have retinopathy at any given time
- retinopathy threatens the vision of approximately 10% of people with diabetes at any one time.

Although unknown for most of the Pacific, the percentage of adults with diabetes who have retinopathy may be higher than 50% in some countries.

The duration of a person's diabetes is one of the more important factors determining the presence of diabetic retinopathy. Some grade of retinopathy is almost universal after fifteen years of diabetes. However, the precise timing of onset of diabetes in the individual is often difficult to determine.

Duration of diabetes and poor metabolic control with elevated blood glucose are the two principal risk factors causally linked to the development and progression of diabetic retinopathy. Other risk factors include (also see Section 3.5.1):

- hypertension
- elevated blood lipids
- pregnancy
- nephropathy.

Given the effect of these factors on the development and progression of diabetic retinopathy, diabetes eye services should not be provided in isolation. A holistic approach, integrated with comprehensive services for diabetes and other chronic conditions, is required to ensure the best possible outcomes for individuals.

1.4 Retinal Screening of People with Diabetes

There is substantial evidence that retinal screening helps prevent avoidable loss of vision caused by diabetes. It has also been shown to be cost-effective and cost-saving.

The objectives of diabetes retinal screening are to:

- screen every person with known diabetes as soon as possible after diagnosis for the onset of clinically significant diabetic retinopathy, and then at regular intervals in accordance with the Pacific Guidelines
- identify people with early retinal microvascular disease, and inform the individual, primary care providers and/or the local diabetes team to ensure optimum diabetes and hypertension control
- refer those at risk of visual impairment (i.e. with severe grades of retinopathy, or with established maculopathy or proliferative disease) for management and treatment by ophthalmologists, before avoidable loss of vision occurs.

Diabetes retinal screening using photography will allow comparison:

- of the retinopathy of the same person examined at different times or by different professionals
- between different groups of people with diabetes.

1.5 Development of the Pacific Guidelines

The Pacific Guidelines have been developed after an extensive review of the current diabetic retinopathy literature, grading systems and management guidelines in use, particularly in New Zealand.

The retinopathy screening, grading and management systems reviewed are based on available current evidence, but have been developed to suit local conditions. The same is true of the systems outlined in the Pacific Guidelines. However, it is important to note that necessary local modifications often weaken the association with the evidence base. For example, the non-mydriatic digital retinal photography screening images of the Pacific Guidelines cannot be directly compared to the standard photographs of the current evidence base. Therefore, the evidence that is derived from studies such as the Early Treatment Diabetic Retinopathy Study (ETDRS), which may imply a grade of retinopathy and risk of progression, cannot be assumed from the more limited and more easily achieved photography screening of the Pacific Guidelines. Nevertheless, in the absence of Pacific-based data, produced using the Pacific Guidelines photography screening methodology, the Wisconsin epidemiological studies of the natural history of diabetes and associated retinopathy (WESDR) are an internationally accepted guide to risk assessment. They have been used to inform the Pacific Guidelines.

Of necessity, the Pacific Guidelines are a compromise. There are the demands of low-resource environments with limited availability and training of their workforces; the need for systems that enable monitoring of service and clinical activities spread across often remote geography and a disparate workforce. In addition to service delivery constraints, cognisance was taken of the difficulty of maintaining optimal glycaemic control of persons with diabetes in the Pacific Islands, such that more frequent screening than elsewhere is required because the progression of retinopathy can be rapid in poorly controlled diabetes. Until further local evidence and experience are available, the Diabetes Working Group believes the Pacific Guidelines achieve a workable balance between best evidence and implementation.

1.6 Flexibility and Review of the Pacific Guidelines

This is a “living” document. The Pacific Guidelines are a flexible tool that may be adjusted as data from well-run programs within the Pacific become available, practical experience suggests a problem, or new evidence is published. Although it is expected that these Guidelines will be formally reviewed at least every three years by a Pacific-based ophthalmic forum, amendments and additions may be made by this forum at any time during that period. (see Section 6.3)

The Pacific Guidelines are intended for local, national and regional implementation. Therefore, to maintain standardisation across the Pacific, with the benefit of consistent good quality patient care and the production of data comparable across jurisdictions, the aim should be to keep the implementation of these Guidelines as uniform as possible. This is especially so for the grading system recommended. However, it is recognised that circumstances vary across the region. This being the case, the Lead Ophthalmologist may need to make some local modifications. For example, based on the experience of the Graders used, some of the referral recommendations may require adjustment.

2. Screening Recommendations

2.1 Introduction to Retinal Screening

It is recommended that retinal screening occur routinely every year for people with diabetes who do not have retinopathy. (refer Section 1.4)

People with diabetic retinopathy should have the interval between screening episodes adjusted, based on the recommendations of the Guidelines and reflecting:

- the severity (grade) of retinopathy
- glycaemic control
- blood pressure control
- pregnancy
- other modifiers of the disease
- the risk of progression.

However, in some circumstances (e.g. remoteness of the person's domicile), the professional may need to use clinical judgement to modify the interval recommended by the Guidelines.

Diabetes retinal screening should be performed using non-mydriatic digital retinal photography.

People with diabetes who are unsuitable for screening by retinal photography (e.g. have media opacities such as cataracts) should have clinical assessment in lieu of photography screening.

2.2 Method of Retinal Examination

Currently, the two most sensitive methods for detecting diabetic retinopathy are slit-lamp biomicroscopy through dilated pupils and mydriatic retinal photography. Both depend on interpretation by an appropriately trained eye health professional.

For a diabetes retinal screening program to function effectively, the technique used for retinal examination must have sufficiently high sensitivity and specificity—around 80% is deemed satisfactory by the British Diabetic Association.

There is still some debate about the best strategy to achieve effective screening. Direct ophthalmoscopy alone is inadequate because it consistently fails to meet the 80% target. Indirect ophthalmoscopy is effective in trained hands. However, even with a trained practitioner and red free illumination, small microvascular abnormalities may be difficult to detect in dark fundi. Both ophthalmoscopy techniques are less effective than slit-lamp biomicroscopy through dilated pupils.

Seven-Field stereoscopic $30^0/35^0$ retinal photography using colour film and dilated pupils probably remains the gold standard for retinal imaging. However, the use of film makes it impractical as a screening technique. This has been overcome by the use of high resolution mydriatic digital retinal cameras that match the performance of film. Digital retinal cameras have become less expensive, more portable, and capable of quality images through undilated pupils. These are now used extensively for screening for diabetic retinopathy.

Recent comparative studies of screening modalities involving digital non-mydriatic retinal cameras are very promising. Also, experience in Fiji, New Zealand and Australia suggests that digital non-mydriatic retinal photography performed and interpreted by trained personnel is at least as effective as indirect ophthalmoscopy and slit lamp biomicroscopy, except in patients with media opacities. In Fiji, screening using non-mydriatic photography has a failure rate of about 20% due to media opacities (usually cataract), small pupils and a few rarer conditions. When small pupils are the problem, pupil dilation generally permits satisfactory photography. For the remainder, a clinical examination by an ophthalmologist is required.

An advantage of retinal photography is that, unlike ophthalmoscopy and biomicroscopy, it provides an objective record of the examination—the retinal images. These can be used as a patient education tool, giving immediacy and personal relevance as the patient's retinopathy and management are discussed. They can also be easily catalogued and stored for the long term, and readily recalled for comparative purposes, for evaluation of screener performance, for audit of grading, and be a record of retinopathy progression, regression and laser treatment.

It is recognised that these cameras are relatively expensive, need to be operated by trained personnel, appreciate an air conditioned environment, and may require maintenance. However, the advantages of their use currently seem to outweigh any disadvantages.

Therefore, the Guidelines recommend mobile non-mydriatic digital retinal photography as the standard technique for diabetes retinal screening programs in the Pacific.

There may be occasions on which a camera is unavailable. The preferred substitute screening technique would be that of a dilated-pupil fundus examination using slit-lamp biomicroscopy. However, particularly in remote locations, a slit-lamp may not be available either. So, if a camera is unavailable, or if satisfactory photographs cannot be obtained, the default should be use of the less effective but mobile technique of indirect ophthalmoscopy through dilated pupils.

2.3 Practicalities of Retinal Screening

Diabetes retinal screening requires:

- assessment of the visual acuity
- identification and grading of diabetic retinopathy
- taking of a history focussed on diabetes and its modifiers.

Assessment of the visual acuity and identification and grading of retinopathy should occur for each eye separately.

2.3.1 Visual Acuity Assessment

Presenting distance visual acuity (with correction if worn) should be assessed and recorded for all eyes.

Pinhole visual acuity should be assessed and recorded for all eyes with presenting visual acuity ≤6/12.

2.3.2 History taking

A history should be obtained and recorded for all patients, which should include known duration of diabetes, and blood glucose levels to assess metabolic control. The following values are considered to represent, good, moderate and poor levels of control

HbA1c	Good: ≤ 7%	Moderate: > 7% ≤ 9%	Poor: ≥ 9%
Blood Glucose	Good: ≤ 7 mmols/l	Moderate: > 7 ≤ 9 mmols/l	Poor: ≥ 9 mmols/l

2.3.3 Retina Assessment

Retinal photography using a 45 degree non-mydriatic digital retinal camera should be performed on all eyes.

Initially and as a routine, retinal photography should be performed without mydriasis. However, if the retinal image produced does not meet the "quality of image" criteria (Section 3.2), then the pupil should be dilated and the photography repeated. If the image is still unsatisfactory, a slit-lamp biomicroscope examination is required, usually by an ophthalmologist.

A "Standard Retinal Image" (Table 2) should be taken of each eye.

Table 2: Standard Retinal Image

Retinal Image	Description	Extent of Image
Standard Retinal Image	Nasal margin of the optic disc positioned 1 disc diameter from the nasal edge of the image	Image extends temporally at least 3 disc diameters from the temporal disc margin

If photography with less than a 45 degree field is used, then extra images will need to be taken to provide the same extent of retinal cover as that of the Standard Retinal Image.

If there is **ANY** evidence of diabetic retinopathy in the Standard Retinal Image, then the Supplementary Nasal Retinal Image (Table 3) **MUST** be taken. All images must meet the "quality of image" criteria (Section 3.2).

If the retinopathy visible in these macula and nasal images is **graded >R1** (Section 3.2), then a Supplementary Superior Retinal Image and Supplementary Inferior Retinal Image (Table 3) **MUST** be taken. Both of these images must meet the "quality of image" criteria (Section 3.2).

Table 3: Supplementary Retinal Images

Retinal Image	Description	Extent of Image
Supplementary Nasal Retinal Image	Centre of the optic disc positioned 2 – 3 disc diameters from the temporal edge of the image	Image extends nasally at least 3 disc diameters from the nasal disc margin
Supplementary Superior Retinal Image	Centre of the optic disc positioned 1 disc diameter from the inferior edge of the image	Image extends superiorly at least 3 disc diameters from the superior disc margin
Supplementary Inferior Retinal Image	Centre of the optic disc positioned 1 disc diameter from the superior edge of the image	Image extends inferiorly at least 3 disc diameters from the inferior disc margin

Note: The use of non-mydriatic retinal photography is advocated as the platform for a well organized and managed diabetes retinal screening service. It permits objective information storage, quality assurance activities and data analysis. However, in some circumstances diabetes retinal screening may need to be performed using slit-lamp biomicroscopy or indirect ophthalmoscopy. These have the disadvantage of having to dilate every pupil to permit screening. Diabetes retinal screening using slit-lamp biomicroscopy or indirect ophthalmoscopy should only be done by those competent in these examination techniques. It should entail detailed observation of the macula and all four retinal quadrants.

2.3.3 Use of Pupil Dilation

In a well darkened room, acceptable photographic screening is possible even for some people who initially have small pupils. Only about 20% of people need pharmacological pupil dilation to permit retinal photography to a standard that meets the “quality of image” criteria (Section 3.2)

Tropicamide 1% alone may produce satisfactory dilation. Sometimes adding Phenylephrine 2.5% is helpful in achieving more rapid onset and more complete dilation, but only one drop in each eye is advised in patients with hypertension.

Pupil dilation is safe. The precipitation of angle closure glaucoma is extremely uncommon. The use of Tropicamide and Phenylephrine during pregnancy is unknown but is likely to be of very small or no risk to the mother and foetus. Occasionally, recording of informed consent for pupil dilation is advisable if it is perceived that this may carry some risk to the patient (see below).

Where possible, before attending screening, people should be informed that short-term pupil dilation may be necessary. They should be warned that, if this is the case, until the effect of the drop has worn off in a few hours’ time they may experience:

- lack of tolerance to bright light or sunlight, thus using sunglasses is recommended
- distorted vision
- poor vision
- impaired balance

The following may thus be hazardous activities which carry some risk following pupil dilation

- driving a vehicle from the appointment venue
- undertaking any task requiring precise visual accuracy, e.g. using machinery.

2.4 People Ineligible for Routine Retinal Screening

The following people should not be allocated to routine photography screening, unless otherwise agreed by the Lead Ophthalmologist:

- individuals previously graded (Sections 3.3 and 3.4) as R3, R4, R5 and/or M3, M4 (unless subsequently re-graded lower by an ophthalmologist)
- individuals who have had laser photocoagulation treatment for peripheral or macular diabetic retinopathy within the last two years.

2.5 Retinal Screening Intervals

Retinal screening helps prevent diabetes-related loss of vision. Screening must be timed appropriately to achieve this cost-effectively and with savings because of a reduction in the need for services for endstage disease, screening must be timed appropriately.

This requires that the first occasion on which people with diabetes are screened should occur in a timely manner. (Section 1.4) Then, repeated screenings should take place at intervals in which the timing of the next screening is determined by the presence and severity of any diabetic retinopathy found at the previous screening.

People with retinopathy of a type and severity known to place them at risk of losing vision should be removed from regular screening and referred to an ophthalmologist for assessment and treatment.

Recommendations for the timing of the first screening, the intervals between screening episodes and the criteria for referral should be based on knowledge of the natural history of the disease and the outcomes of intervention. Although there is considerable evidence of these in some populations (Section 1.2), this is not the case for the Pacific region.

Therefore, the recommendations (Table 4, and Sections 3.3, 3.4 and 3.5) in these Pacific Guidelines are based on the limited experience available, and adaptation of evidence from similar populations.

When well-run Pacific screening, referral and management programs generate data, these recommendations will be modified according to this local evidence. (Section 1.6)

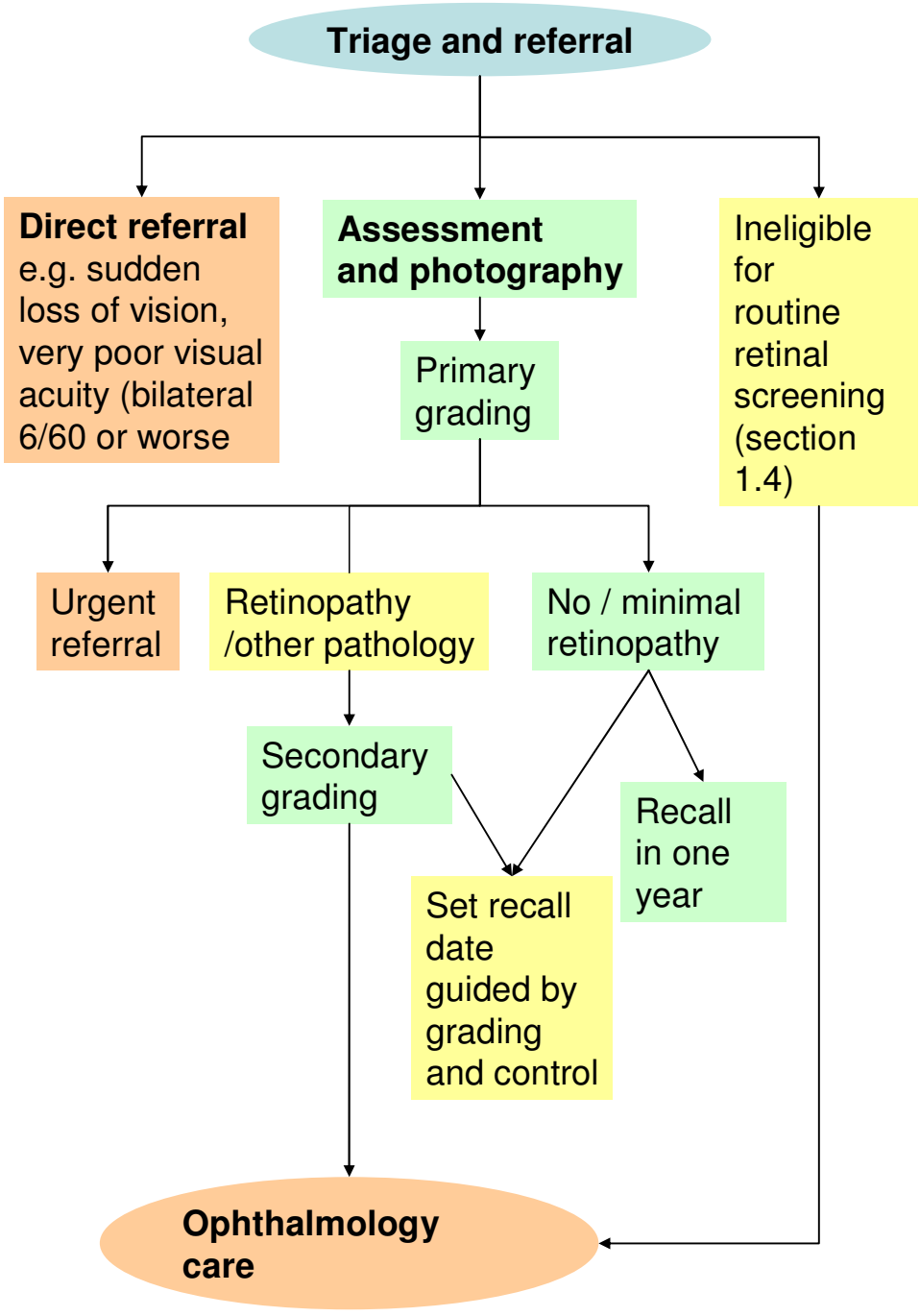
Table 4: Timing of Initial and Intervals for Ongoing Retinal Screening

Retinal Screening	Type 1 diabetes	Type 2 diabetes
Initial Retinal Screening	Adults: • initiate screening when the duration of diabetes is more than 5 years • if the date of onset is unknown, assume that the duration of diabetes is more than 5 years Children: • initiate screening 5 years after diagnosis of diabetes is made, or at puberty, whichever is the earlier	All patients: • initiate screening as soon as possible after diagnosis of diabetes
Ongoing Retinal Screening	All patients: • conduct regular ongoing screening at least every year if no abnormality is detected • once any diabetic retinopathy is detected, the frequency of the assessments may need to be increased depending on the severity of the retinopathy and the risk factors for progression to vision-threatening disease (Sections 3.3, 3.4, 3.5)	
Retinal Screening During Pregnancy	Pregnant women who have diabetes (Section 3.5.1): • regardless of the previous history of screening, conduct a screening early in the first trimester of the pregnancy • if no retinopathy (P0) and no clinical modifiers (Section 3.5.2) are present, annual screening can continue as usual • if minimal retinopathy (P1) is present, frequent screening throughout the pregnancy is indicated • if retinopathy more advanced than minimal (P2) is present, referral to an ophthalmologist is required for ongoing review during the pregnancy	

2.6 Retinal Screening Pathway

An overview of the retinal screening pathway is shown in Figure 1.

Figure 1: Retinal Screening Pathway



3. Grading and Management Recommendations

3.1 Introduction to Diabetic Retinopathy Screening, Grading and Management

3.1.1 Screening

When retinal photography is used to screen for diabetic retinopathy, for the image produced to be useful, it must capture the desired location and extent of retina (Tables 2 and 3), and be of sufficient clarity. An image is suitable for determining the presence and severity of retinopathy if it satisfies pre-determined "quality of image" criteria (Section 3.2).

3.1.2 Grading

The presence and severity of retinopathy are used to determine the grade of retinopathy.

- Each eye is graded separately.
- For each eye, the macula and peripheral retina are graded separately.
- An individual with diabetes is assigned a single grade for each of the macula and the peripheral retina. These equate to the grade of the worst of the two maculae and the worst of the two peripheral retinae.

3.1.3 Management

- The grade of retinopathy has implications for the management of the individual.
- Both the person's peripheral retinal grade and macula grade are used to determine the management of that person (Section 3.3 and 3.4)
- Management of a particular eye or person may, however, require modification depending on the risk of progression and the presence of other conditions (see Section 3.5.1 for the complete list of clinical modifiers and values)

3.2 Quality of Retinal Photography Image

A retinal photograph image must meet "quality of image" criteria before it can be used to determine the grade of diabetic retinopathy. These criteria concern the location, extent and detail clarity of the retina imaged (Table 5).

Table 5: Quality of Image Criteria for Determining Suitability of Retinal Photographs for Retinopathy Grading

Image Quality	Quality Criteria	Action
Adequate	**Clarity:** • Small retinal vessels visible over the majority of the field(s), including at the macula **Location and Extent of Retinal Image:** • As per Table 2 for Standard Retinal Image • As per Table 3 for Supplementary Retinal Images taken for patients with retinopathy	Proceed with grading
Inadequate	Does not meet all of the above criteria	If screening has been performed through an undilated pupil, repeat after mydriasis • If the image is still inadequate after mydriasis: refer the patient to an ophthalmologist, unless indirect ophthalmoscopy screening is available and the clarity and field size are adequate with this technique • If the image is poor, but clear enough to establish the presence of retinopathy: refer the patient to an ophthalmologist, who will allocate a grade if the retina is visible using biomicroscopy

3.3 Peripheral Diabetic Retinopathy: Grading and Management

The peripheral retina is that retina beyond 2 disc diameters from the foveola.

This equates to the retina that is:

- nasal to the optic disc
- at and above and below the large retinal arteries and veins that arch above and below the central vision area temporal to the optic disc
- beyond approximately 4 disc diameters from the temporal edge of the optic disc.

3.3.1 Grading

- The peripheral retina in each eye is graded separately.
- An individual with diabetes is then assigned a single grade for the peripheral retina. This grade is the worst of the grades given the peripheral retina in each of that person's eyes.

3.3.2 Management

The person's peripheral retina grade and macula grade are then used to determine the management of that person.

The person is managed according to the recommendation for the most urgent intervention for either of the peripheral retina or macula grades.

When the features of the retinopathy are such that the grade is borderline Mild/Moderate, modifiers (Section 3.5.1) should be taken into account when considering recall interval for re-screening, or referral for ophthalmic clinical review.

Groups or clusters of microvascular abnormalities

Groups or clusters of microvascular abnormalities confined to a small area of retina may be counted as one lesion in photographic images that overall show Mild disease.

Cotton-wool Spots:

Cotton-wool spots are no longer felt to correlate with retinopathy severity or be predictive of progression. They are therefore no longer used in the determination of retinopathy grade. However, their presence should prompt a search for other features of diabetic retinopathy such as venous beading or IRMA (intra-retinal microvascular abnormalities), and for systemic hypertension.

Table 6: Peripheral Diabetic Retinopathy (Retina Peripheral to the Macula)

Grade	Description	Clinical Signs	Outcome	Action
R0	No retinopathy	No abnormalities	Screen again in 12 months	
R1	Minimal	< 5 microaneurysms and/or dot haemorrhages	Screen again in 12 months	
R2*	Mild	> 4 microaneurysms and/or dot haemorrhages ***and/or*** Exudates > 2 disc diameters from the centre of the macula ***If*** more than 20 microaneurysms and/or haemorrhages per photographic image, ***then upgrade to R3***	Screen again in 6 months	
R3**	Moderate	Any features of R2 Mild ***plus*** Up to 3 quadrants of blot or larger haemorrhages ***and/or*** Up to 1 quadrant of venous beading	Refer to ophthalmologist	Review by an ophthalmologist in less than 6 weeks Ophthalmologist to check peripheral retina for unusual proliferative changes: if none, then continue screening at 6 month intervals or continue with ophthalmologist follow-up
R4	Severe	***One or more of:*** Definite IRMA 2 quadrants or more of venous beading 4 quadrants of blot or larger haemorrhages	Refer to ophthalmologist	Review by an ophthalmologist in less than 4 weeks
R5	Proliferative	***One or more of:*** Neovascularisation Sub-hyaloid or vitreous haemorrhage Traction retinal detachment or retinal gliosis	"Fast Track" referral to ophthalmologist	Review by an ophthalmologist in less than 1 week (preferably on the same day as screened)
RT***	Stable, treated diabetic retinopathy		Screen again in 6 months***	See notes on Laser Scars***

***R2 Mild:** If haemorrhages are principally large, then referral for ophthalmic clinical review is suggested. (Graders should liaise with the Lead Ophthalmologist to decide how these types of cases should be managed.) This does not preclude subsequent return to photography screening if deemed appropriate.

****R3 Moderate:** R3 is the threshold for referral to ophthalmologic care but some programs may elect to keep these patients within photoscreening. However, it is recommended that patients receive ophthalmic clinical examination to exclude significant peripheral disease beyond the photographic fields before continuing photoscreening. If deemed safe to continue photoscreening, this should be undertaken at least 6-monthly and the patient referred to the ophthalmologist again when there is evidence of deteriorating retinopathy.

*****Laser Scars:** When a person has been discharged from ophthalmic care with STABLE retinopathy following laser treatment, the treated eye may generally be viewed as grade RT for the two years following the last treatment. During this time screening may be organised as for grade R2. However, Graders should be aware that retinopathy may be more difficult to visualise in the presence of laser scars, and that reactivation of retinopathy is possible. After the two years following last laser treatment, the eye may be re-graded according to features present. If there is any uncertainty, repeat referral should be made to an ophthalmologist.

3.4 Diabetic Macular Disease: Grading and Management

The macula is that retina within 2 disc diameters of the foveola.

This equates to the retina that:

- extends approximately 4 disc diameters temporally from the temporal edge of the optic disc
- is bordered by large retinal arteries and veins that arch above and below.

3.4.1 Grading

- The macula in each eye is graded separately.
- An individual with diabetes is then assigned a single grade for the macula. This grade is the worst of the grades given to the macula in each of that person's eyes.

3.4.2 Management

The person's macula grade and peripheral retina grade are then used to determine the management of that person.

The person is managed according to the recommendation for the most urgent intervention for either of the macula or peripheral retina grades.

Table 7: Diabetic Macular Disease (Retina Within 2 Disc Diameters of the Foveola): Grading and Management

Grade	Description	Clinical Signs	Outcome	Action
M0	No macular disease	No microaneurysm, haemorrhage or exudate within 2 disc diameters (DD) of centre of the macula	Screen again in 12 months	
M1*	Minimal	Microaneurysms and/or haemorrhages within 2 DD of the centre of the macula No exudates No retinal thickening No reduction in visual acuity	Screen again in 6 months unless Peripheral Diabetic Retinopathy requires referral to ophthalmologist	
M2**	Mild	Exudates and/or retinal thickening within 2 DD of the centre of the macula, but outside 1 DD of the centre	Refer to ophthalmologist	Review by ophthalmologist in less than 2 months
M3	Moderate	Exudates or retinal thickening within 1DD of the centre of the macula Foveola not involved No reduction in visual acuity	Refer to ophthalmologist	Review by ophthalmologist in less than 1 month
M4	Severe	***Either*** Microaneurysms and/or haemorrhages within 1 DD of the centre of the macula Reduction in visual acuity ***or*** Exudates and/or retinal thickening involving the foveola Reduction in visual acuity	Urgent referral to ophthalmologist	Review by ophthalmologist in less than 1 week (preferably on the same day as screened)
MT	Stable, treated Macular Disease		Screen again in 12 months unless Peripheral Diabetic Retinopathy requires otherwise	

*** M1** In the event that there is mild macular disease (M1) but no detectable peripheral retinopathy, the overall classification for that retina is R1, M1. This is permitted because macular classification is a subsection of retinopathy grading derived from the ETDRS grading system. It was established by ETDRS as effective in assessing threat to sight by macular disease and need for laser treatment

****M2 Mild:** Retinal photography and ophthalmoscopy do not allow accurate assessment of retinal thickening. When grading of an eye as M2 depends solely on the presence of retinal thickening, referral of that patient may be deferred if techniques such as slit-lamp biomicroscopy are available to rule out its presence on the day the patient is screened (i.e. an ophthalmologist is present to undertake this examination).

3.5 Variations in Recommended Management

3.5.1 Clinical Modifiers: Identification and Management

Diabetes eye disease and its management do not occur in isolation. The development and progression of diabetic retinopathy may be modified by patient characteristics such as behaviour (e.g. compliance with medications) and concurrent health problems (e.g. hypertension). Therefore, when these recognised clinical modifiers occur, the management of the person and the diabetes eye disease may also need to be altered to maximise the likelihood of retaining vision.

Table 8: Clinical Modifiers: Identification and Management

Clinical Modifier	Note	Outcome
Poor compliance (e.g. "did not attend" screening twice or more)		Consider reducing screening interval or referral of patient
Very poorly controlled diabetes: blood glucose ≥9mmols/l ***or*** HbA1c ≥9%		
Poorly controlled hypertension: >144/82 (evidence UKPDS)		
Long duration of Type 2 diabetes		
Duration of Type 1 diabetes >15 years (Insulin Dependent Diabetic Mellitus [IDDM] >15 years)	May have peripheral retinal ischaemia without significant changes in the areas covered by screening photography Peripheral neovascularisation or features of R4 or R5 retinopathy may be present beyond the field of view	Refer for clinical examination of the peripheral retina by biomicroscopy If this retina is satisfactory, the patient may be returned to routine screening

3.5.2 Women who have Diabetes and are Pregnant: Grading and Management

Women who have diabetes and become pregnant are at risk of experiencing an accelerated worsening of diabetes retinal disease. Therefore, these women should be screened for retinopathy as early as possible in the first trimester.

The grading (P0, P1, P2) then applied at this baseline screening has particular significance while that woman is pregnant.

Management decisions determined by this grading will be different from those for the same retinopathy in a non-pregnant stage.
When the woman is no longer pregnant, grading should revert to the standard scheme for peripheral retina and macular disease.

Table 9: Women who have Diabetes and are also Pregnant: Grading and Management

Grade	Description	Clinical Signs	Outcome
P0	No peripheral retinopathy or macular disease	No peripheral retinopathy and no macular disease (R0 M0)	Screen again in 12 months ***or*** If clinical modifiers indicate increased risk, retinal screen at 2 monthly intervals for the remainder of the pregnancy
P1	Minimal	Minimal retinopathy with no macular disease (R1 M0)	Retinal screen at 2 monthly intervals for the remainder of the pregnancy
P2	Greater than Minimal	More than minimal retinopathy and/or macular disease (>R1 >M0)	Review by ophthalmologist Inform obstetrician and/or health centre

3.5.3 Non-diabetes Pathology and Anatomical Aberrations: Grading and Management

Patients should be informed that diabetes retinal screening is not a complete eye examination. Its purpose is to identify, grade and inform management of diabetic retinopathy alone. However, when screening for diabetic retinopathy, normal anatomical variations and non-diabetes pathology will be found. The diagnosis and implications of most of these findings will be unknown to the Screener/Grader. Therefore, any non-diabetes pathology should be graded as such (NDP), and the patient referred for assessment according to guidelines determined by the local ophthalmic service.

Table 10: Non-diabetes Pathology (NDP): Grading and Management

Grade	Pathology	Outcome
NDP	• Cataract • Myelinated Nerve Fibres • Naevi • Glaucomatous Cupping • Age Related Macular Degeneration • Epiretinal membrane • Venous Occlusions • Hypertensive changes • Other pathology • Signs detected but not understood by Screener/Grader	According to local guidelines, either discuss with or refer to an ophthalmologist

4. Diabetes Retinal Screening Program: Personnel

4.1 Lead Ophthalmologist

All diabetes retinal screening programs should have a Lead Ophthalmologist. Where possible, this person should have medical retina subspecialty training that is appropriate for Pacific-based practice and recognised within the region. (Section 6.3)

The Lead Ophthalmologist should be responsible for the conduct, oversight, quality and safety of the entire service.

Only the Lead Ophthalmologist should be authorised to amend aspects of the program to accommodate local circumstances. However, this should not extend to making changes to the grading classifications, which should only occur at a regional level, after consultation. (Section 1.6)

The Lead Ophthalmologist should be satisfied that all ophthalmologists, Screeners and Graders involved have adequate Pacific-based training and qualifications, and actively supervise the performance and ongoing training of all personnel.

The Lead Ophthalmologist should ensure that quality assurance activities (Section 6), including peer review, are undertaken regularly so that high standards are maintained.

4.2 Ophthalmologists

It is preferable that all ophthalmologists in diabetes retinal screening programs have some relevant medical retina training and experience.

Ophthalmologists provide advice and supervision for Screeners and Graders, and accept referrals of patients who require more complete clinical examination, assessment and/or treatment.

4.3 Screeners and Graders

Generally, Screeners and Graders in diabetes retinal screening programs are nurses and other allied / mid-level health professionals.

The appropriate qualification for Pacific-based Screeners and Graders is the Pacific Eye Institute's Certificate Course in Diabetes Eye Care. This is awarded by the Fiji School of Medicine and is recognised by PACEYES, the professional association of Pacific eye care practitioners.

A Screener measures the visual acuity and examines the retinae of persons with diabetes. This requires the use of non-mydriatic digital retinal photography or, if necessary, indirect ophthalmoscopy. A Screener is usually not trained or competent in the use of slit-lamp biomicroscopy, which remains in the domain of ophthalmologists.

A Grader documents the severity of diabetic retinopathy according to the grades outlined in the Pacific Guidelines. A Grader is required to work in full collaboration with the Lead Ophthalmologist, who should ensure that no grading is undertaken independently by anyone whom they deem has had inadequate experience in this, has failed to reach or sustain grading standards, or who has only recently joined the program team.

At graduation from the Pacific Eye Institute's Certificate Course in Diabetes Eye Care, Graders are:

- competent at recognising grades R0, R1; M0, M1; and P0
- **NOT** to be expected to reliably grade R2, R3, R4, R5, RT and M2, M3, M4, MT.

It takes considerable time in active practice for a Grader to gain sufficient experience with photography image assessment to achieve competency in grading, and maintain efficiency and safety.

Therefore, for at least six months after graduation, the Grader:

- is called a Primary Grader
- may immediately commence independent grading, with appropriate supervision
- may organise routine re-call and screening for patients with retinopathy grades R0, R1, M0 and P0
- should trial grade any retinopathy worse than R1 and M0, and have this checked by the Lead Ophthalmologist, or appropriate delegated practitioner (who may be an experienced Secondary Grader), who will then confirm the appropriate management of the patient
- should frequently review the PEI Evaluative Grading Image Sets
- should regularly discuss with the Lead Ophthalmologist, or appropriate delegated person, any queries
- should submit to regular audit of the screening images and grading the Grader generates in everyday practice.

After six months of work experience, the Lead Ophthalmologist may authorise a Primary Grader to proceed to grading all levels of retinopathy severity, and be designated a Secondary Grader. It should not be considered the right of any Grader to proceed to more advanced grading at this time. Instead, it must be recognised that:

- progression is dependent on consistent and accurate performance at less severe grades of retinopathy
- the Lead Ophthalmologist has to take full responsibility for errors or generally poor performance by any Grader, and so must be satisfied with the competency of a Grader before allowing progression to more advanced grading
- a longer duration of continued intense supervision is needed by some Primary Graders before reaching sufficient competency to progress.

A Secondary Grader commencing independent grading of more severe retinopathy should do so with full ophthalmologist support. This should include frequent and regular audit/corrective and discussion sessions. If there are several Graders, such sessions may be enhanced by meeting as a team with the Lead Ophthalmologist to review grading and associated recalls and referrals which have taken place over a prescribed period. This provides an opportunity for review of procedures, training, and checking adherence to agreed standards. It also ensures collaborative reading outcomes and better communication with patients and other providers.

Some Primary Graders are not able to progress reliably to grade patients with more severe retinopathy, or may not wish to do so. That situation should be recognised by the Lead Ophthalmologist, and no Grader should be pushed beyond their capabilities.

To maintain proficiency, all Graders should grade a minimum number (500 or greater) of patient image sets per annum.

Whilst the roles of the Screener and the Grader are here described separately, in most cases, a single individual will be both Screener and Grader. This professional completes full documentation of each patient visit to the diabetes retinal screening service and determines the immediate management of the patient, being either recall for subsequent screening or onwards referral to an ophthalmologist.

5. Clinical Examination Information Requirements

The Houston Medical Diabetic Retinopathy Management and Medical Records Software possesses all the information that is required for a diabetic retinopathy screening service.

A copy of the screens used in this software is provided to all candidates attending the PEI Postgraduate Certificate in Diabetes Eye Care Course.

Candidates are required to familiarise themselves with this software program and to utilise it during the practical component of the Course.

Data Reports on a screening program can be generated by this software.

6. Quality Assurance

6.1 Continuous Quality Improvement for Pacific diabetes screening services

Quality Assurance (QA) is an integral component of any screening program, to ensure that the program achieves the highest possible standards. This should be a continuous process of improvement, across all stages of the screening pathway and all professional groups. It will involve the monitoring of performance against a set of QA Standards and Criteria (see Section 6.2)

Any screening program will inevitably have both false negatives and false positives as no screening test can achieve 100% sensitivity and specificity.

The **aims** of QA for the Retinal Screening Programs are to:

- Reduce the probability of error
- Ensure that errors are dealt with competently and sensitively
- Help screening and hospital eye department providers, managers, and IT systems, improve year on year
- Set, refine and Re-Set Standards
- Involve the whole service in each area in QA which involves standards for all staff involved in retinal screening programs

To establish QA the following are needed:

1. A Minimum Data Set which can supply two broad categories of information:
    - Patient Information and Appointments/Referral systems
    - Screening and Eye Clinic Outcomes (i.e. seamless system)
2. Time, funding and staff allocated to QA activities. Internal and External audit.
3. IT facilitation of integrated data systems for community and hospital providers, and of data analysis.

These requirements will be difficult for some Pacific Island Diabetic Retinopathy Screening programs to achieve. Nevertheless, the above should aim to be achieved in time and as funding permits. Communication between providers and achievement of high standards in service delivery are vital to the success of screening programs. Analysis of data helps to document activity and to reveal strengths and weaknesses of the program. Governments and other funders need this information to be able to continue to justify funds for screening programs.

Participation in QA is important to minimise the chance of poor performance at both an individual and service process level which can ultimately lead to poor outcomes for patients.

6.1.1 Improving individual performance

There are many activities which need to be monitored and the following are only some of them. For example, for Retinal Screening Providers specifically, QA systems seek to identify and improve performance of screeners/graders who are:

Screening process

- Undertaking more frequent screening of patients than is recommended for their Grade of retinopathy, and "modifiers"
- Failing to record a complete and accurate clinical record of each patient
- Failing to achieve quality images

Accuracy of grading and referral

- Missing clear disease by simple error
- Inaccurate grading
- Missing certain subtle patterns of disease which require referral to the Ophthalmologist for management
- Over referring patients to ophthalmologists and hence swamping their outpatient clinics
- Failing to complete timely and accurate referrals to Ophthalmologists

6.1.2 Improving the performance of the diabetes services

Efficiency of the system

- Timely referral of patients, timely examination by ophthalmologist of patients referred, and timely treatment of those listed for laser
- Report annual New and Follow Up attendance rates

Quality improvement

- Communicate results of patient screening and of performance of the program
- Service participates in Quality Assurance: maintain standards, audits and reports

6.2 Recommended Pacific Island Quality Assurance and Standards

OBJECTIVE	CRITERIA	MINIMUM STANDARD	ACHIEVABLE STANDARD
Performance of graders			
To ensure optimum workload for graders.	Non-medical graders	Each grader to read a minimum of 500 patients per annum*	400 Unshared or Shared grading with O'mologist
To ensure accuracy and completeness of entries to the Minimum Data Set	All screeners/photographers monitored by Designated Ophthalmologist	< 5 errors per patient entry	No errors or omissions
To ensure photographs are of adequate quality	Percentage of upgradeable images (excluding cataract) due to poor quality images or poor field definition or clarity	< 10%	3%
Accuracy of grading and referrals			
To ensure grading is accurate and Pacific Islands Classification 2009 is adhered to. To ensure accuracy of recall times	Credentialed Primary Graders (Ro,R1, Mo,M1, P0) Credentialed Secondary Graders (All Grades of retinopathy)	90% 90%	95% 95%
To ensure clear disease is not missed by simple error, or that certain subtle patterns of disease that require referral are not missed	Audit of photographs, grading and referrals by the ophthalmologist		
To ensure timely, and not excessive, re-screening in relation to Grade of retinopathy and clinical modifiers	Time to re-screening for grade of retinopathy compared to recommended re-screening intervals.	70% within 1 month of recommended recall date	95% within 1 month of recommended recall date
Communication			
To ensure hospital diabetes clinic and other shared providers are informed of screening results	Ensure examination summaries are a complete documentation of each examination, including management plan where applicable	80% complete	95% complete
Ensure clinical records of follow-up patients are updated at each attendance	Monitor completeness and accuracy of all notes, summaries and tick boxes	80% complete	95% complete
To ensure health care professionals are informed of the performance of the screening program	Communication with Hospitals and Health Centres Communication with local diabetes team	Annual Report to Ministry of Health	More frequent Reports on request MoH
Attendance rates			
To maximise the number of invited persons attending for DR screen.	Percentage of eligible persons attending:		
	1Initial Screen	70%	90%
	2. Repeat Screen	80%	95%
To follow-up screen positive patients	Combined cancellation and DNA rate for ophthalmology clinic: For: R3, R4, R5, M2, M3, M4.	<10%	<5%
Quality Assurance			
To ensure the service participates in Quality Assurance	Internal and External Quality Assurance	▪ Evidence of participation of all graders in QA audits. ▪ Occasional External QA audit	On request submission of QA and Standards data to MoH

6.3 Recommended Pacific Island Program Outcomes

The following is information that could be collected and used to improve the outcomes of diabetes services

Visits per annum		
No. of patient visits for **photo-screening**	▪ *New ▪ Follow up	Ethnicity
No. of patient visits for **ophthalmologists' clinic**	▪ New ▪ Follow up	Ethnicity
No. of patient visits for **laser**	▪ New ▪ Follow up	Ethnicity
** NB No. of new patients in photos is an indication of referral rate to service*		
Did Not Attend rates		
Photo-screening		
Clinic		
Laser		
Grade of DR		
No. of patients in **photo-screening**	▪ New ▪ Follow up	Grade: Peripheral Macula
No. of patients in **ophthalmologists' clinic**	▪ New ▪ Follow up	Grade: Peripheral Macula
Advanced DR		
No. of patients with advanced DR (R6; M4,1&2)		
≅ vision impaired or blind (best eye)		
Adequacy of screening		
No. of screenings of clinic patients in relation to presumed prevalence of diabetes in populations being served		
NB above statistic should be available for all base-hospital services and for outreach clinics		
Laser treatments per annum		
Outcomes of laser treatments (completed) per annum	***For best eye*** No. retaining presenting VA No. with vision decline No. with vision improved	
Average no. treatments per person	▪ **R** – Severe or PDR ▪ **M** - M3 – M4 (1& 2)	
NB Above should be done by ophthalmologist when they deem a course of treatment complete		
No. of patients in the process of treatment		
Cataract surgery		
No of patients who have had cataract surgery	▪ One eye ▪ Both eyes	

6.4 Overall Responsibility for Retinal Screening Program

The Lead Ophthalmologist is responsible for the management of the program and ensuring:

- quality and standards are upheld.
- data are routinely collected and reported to management and other funders.
- compliance with the Pacific Island Guidelines for Diabetic Retinopathy Screening.
- any difficulties encountered with the Guidelines are reported to the Chair of PACEYES
- recommendations for changes to the Guidelines are proposed.
- Whilst interim changes may be made PacEyes will formally review the guidelines every three years

7. Glossary of Terms

Cataract

Opacity of the crystalline lens of the eye, associated with age and many other risk factors. The most frequent age-related cataract types are nuclear, cortical and posterior subcapsular (PSC). Early onset of cortical and PSC cataract occurs in people with diabetes.

Clinically significant macular oedema (CSMO)

Accumulated leakage of fluid from capillaries in the macular or peri-macular region causes retinal thickening. When present within 2 disc diameters of the centre of the macula, it is termed macular oedema. When present within 1 disc diameter of the centre of the macula, it is sometimes termed clinically significant macular oedema (CSMO). CSMO is imprecise terminology and has been discarded in these Guidelines. It is recommended that the Classification of Macular Disease (Grades M0-M4) used in these Guidelines be adopted. In this classification Grades M3 and M4 are significant and vision threatening. Oedema (often associated with exudate) is best assessed using stereo slit-lamp biomicroscopy (with a fundus lens). If visual acuity is impaired fluid may be in the foveola (M4).

Clinical practice guidelines

Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.

Cotton-wool spot (CWS)

An ill-defined white patch in the retina due to a microvascular infarction affecting the retinal nerve fibre layer and causing a blockage of axoplasmic flow. The affected nerve fibres swell and become opaque. Hence, CWS have an irregular, or feathery edge. They are common in diabetes and hypertension. CWS are no longer believed to correlate with diabetic retinopathy severity or be predictive of progression.

Diabetes mellitus

Diabetes mellitus is a chronic metabolic disorder characterised by raised blood glucose. It is classified by differences in aetiology, clinical presentation and natural history. Type 1 diabetes is an autoimmune disorder leading to absolute insulin deficiency. Type 2 diabetes is a much more common and complex disorder of variable insulin resistance and insulin deficiency.

Diabetic retinopathy (DR)

Diabetic retinopathy may be defined as the presence of typical retinal microvascular lesions in an individual with diabetes. Microaneurysms, haemorrhages, hard exudates, intraretinal oedema, cotton-wool spots, venous loops and beading, new vessels and fibrous tissue comprise the clinical features of diabetic retinopathy. However, none of these individual lesions is specific for diabetes. They may occur in other disease processes such as hypertension, blood hyperviscosity, retinal vascular occlusions, inflammation and radiation damage.

It is the pattern, symmetry and evolution of the retinal lesions that characterises the appearance as diabetic retinopathy. Diabetic retinopathy is first evident ophthalmoscopically as non-proliferative retinopathy. This is characterised by microaneurysms, haemorrhages (dot, blot and/or flame), hard exudates, intraretinal oedema, intraretinal microvascular abnormalities (IRMA) and venous beading.

The proliferative stage of diabetic retinopathy is characterised by the growth of abnormal new vessels and fibrous tissue in response to retinal ischaemia, and the development of pre-retinal or vitreous haemorrhage. If

new vessels appear on the disc or within one disc diameter of the disc margin, they are known as new vessels on the disc.

Leakage from the capillaries in the macula results in retinal thickening or macular oedema (defined as thickening located within two disc diameters of the centre of the macula). When this is present within 1 disc diameter of the foveola, it is sometimes collectively termed Clinically Significant Macular Oedema (CSMO). However, it is preferable that Grades M3 and M4 be used to describe the location of oedema and exudate in the central macula.

Evidence-based guidelines

Clinical practice guidelines based on a systematic review of scientific data and publications.

Exudate

See Hard Exudate.

Florid diabetic retinopathy (FDR)

A particular type of retinopathy occurring in young Type 1 patients. Features include marked capillary dilatation and a rapid, bloody progression to Severe proliferative retinopathy and visual loss. Now seen rarely, florid retinopathy was shown, in the period before the introduction of laser treatment, to respond to pituitary ablation.

Fluorescein angiography

A valuable means of documenting the retinal capillary bed, the presence and features of macular oedema, or to confirm the presence of new vessels not otherwise seen. The test is conducted following an intravenous dye injection (sodium fluorescein solution) and requires special filters in a mydriatic fundus camera. It is a useful investigation in the management of macular oedema, but the recently developed technique of Ocular Coherence Tomography (OCT) is now more useful in the assessment of retinal thickening.

Foveola

The centre of the central vision area (macula) of the retina. It is located about 2 disc diameters temporal to the optic disc.

Gestational diabetes mellitus

Development of diabetes or elevated blood glucose in women during pregnancy. It usually regresses spontaneously in the post-partum period, but may persist. Type 2 diabetes may develop in later years.

Glaucoma

An optic neuropathy in which characteristic visual field defects occur in association with abnormal cupping of the optic disc. Glaucoma is frequently associated with elevated intraocular pressure and is frequently undetected until significant visual loss has occurred.

Grading of diabetic retinopathy

An assessment system developed to differentiate the severity of diabetic retinopathy. Grading allows comparison between different groups of patients, or of the same patient examined at different times.

Hard exudate

Well-defined, irregular, yellowish retinal deposits (lipid and proteinaceous material), often at the margin of oedematous retina. These are derived from leaking retinal capillaries and breakdown of retinal cells. They are termed “hard exudates” and are differentiated from cotton-wool spots (once called “soft exudates”), which are retinal nerve fibre layer infarcts.

Hypertension

A systemic disease characterised by abnormally elevated blood pressure. It is associated with an increased risk of many diseases, including vascular events, as well as early mortality.

Retinal vascular abnormalities occur with hypertension: arteriovenous nipping, flame and blot haemorrhages, cotton-wool spots, and, when the blood pressure elevation is very severe and prolonged, papilloedema and macular exudate and oedema.

Macula

The central vision area of the retina. It extends from the temporal edge of the optic disc, within the large retinal vessels that arch above and below. It is roughly circular, with a diameter of approximately 4 disc diameters. The foveola is at the centre of the macula.

Macular oedema

Macular oedema is abnormal retinal thickening located within two disc diameters of the centre of the macula (the foveola). It is caused by leakage from capillaries in the macula or peri-macular region. In addition to retinal thickening, macular oedema may be associated with are exudates near the foveola and a reduction in visual acuity. The presence of macular oedema is best assessed by stereo slit-lamp biomicroscopy (with or without a contact lens), or from stereo photographs of the macula. Biomicroscopy is the superior technique. Newer adjunct tests may assist when these are available (e.g. Ocular Coherence Tomography).

The Early Treatment Diabetic Retinopathy Study (ETDRS) classification uses the term Clinically Significant Macular Oedema (CSMO). It is recommended that the term CSMO not be used even though it occurs in the literature. It is better to use the macula grading terminology provided in these Guidelines.

It is important to note that macular oedema is the most frequent cause of decreased vision associated with diabetes. It occurs principally in people with Type 2 diabetes. It is important to detect and assess macular oedema, which can occur at any stage of retinopathy from Mild (R2) to Proliferative (R5).

Microaneurysm

Small saccular dilatations of capillary vessels, which appear as a round small red dot within the retina. These are one of the earliest lesions visible in diabetic retinopathy.

Mydriasis

Pupil dilation from short-acting eye-drops such as Tropicamide (Mydriacyl) 0.5% or 1%. Mydriasis is essential for ophthalmoscopic screening for diabetic retinopathy, but is mostly not needed when using a non-mydriatic camera.

Nephropathy

A renal complication of diabetes. This is the result of microangiopathy similar to that which occurs in diabetic retinopathy. Initially nephropathy is manifest by micro-albuminuria. This may progress to macro-proteinuria and end-stage renal failure.

Non-mydriatic retinal camera

Camera by which retinal photography can be performed satisfactorily either with or without dilating the pupils.

Non-proliferative diabetic retinopathy (NPDR)

Non-proliferative Diabetic Retinopathy (NPDR) is also known as “background retinopathy” and includes all stages of diabetic retinopathy prior to the development of proliferative retinopathy. Features include retinal microaneurysms, haemorrhages, hard exudates, intraretinal oedema, intraretinal microvascular abnormalities (IRMA) and venous beading. In the absence of other retinal changes, signs of macular oedema are also classified as NPDR.

Panretinal photocoagulation (PRP)

Application of photocoagulation burns (usually laser) to retinal areas outside the vascular arcade. PRP is the principal treatment technique for proliferative diabetic retinopathy. PRP is usually applied in more than one treatment session. PRP may occasionally be painful and require the use of peribulbar or retrobulbar local anaesthesia. It is also termed “scatter” photocoagulation.

Photocoagulation (laser treatment)

Surgical technique in which laser light is used to treat ischaemic or oedematous retina of patients with diabetic retinopathy. The value of laser treatment has been proven by large randomised clinical trials. Drugs that inhibit the formation of new vessels (e.g. AntiVEGF) are now used as adjunct to laser treatment, but clinical trial outcomes are awaited regarding best practice for their use.

Proliferative diabetic retinopathy (PDR)

Proliferative Diabetic Retinopathy (PDR) is an advanced stage of diabetic retinopathy. It is characterised by the growth of abnormal new vessels and then fibrovascular proliferation on the retinal surface. These changes are in response to retinal ischaemia caused by widespread retinal capillary occlusion. PDR may co-exist with macular disease, especially in people with Type 2 diabetes. New vessels are fragile and tend to bleed, causing pre-retinal or vitreous haemorrhage. Late contraction of the new vessels and fibrous bands produces retinal traction. This may lead to traction retinal detachment. PDR virtually always requires prompt laser therapy to ablate the ischaemic tissue.

People presenting clinically with evidence of new vessels, pre-retinal and/or vitreous haemorrhage should be referred urgently to an ophthalmologist. Some of these people may be asymptomatic. Others may present with a sudden deterioration in visual acuity either on history or examination, a sudden onset of flashes or floaters, or an inability to visualise the retina because of suspected blood in the vitreous.

Risk factors

Factors which indicate a higher risk of having a particular disease than in the general population. The distinction between a risk factor and a disease, however, is not always clear-cut, as illustrated by hypertension or nephropathy as risk factors for diabetic retinopathy.

Screening

Examination of a group of asymptomatic people considered at risk for a particular disease, with the aim of detecting any pre-clinical disease. People detected during screening as likely to have disease are investigated further to arrive at a final diagnosis. Screening is conducted on the basis that early detection can improve quality of life or survival rate with respect to the disease being screened for.

Sensitivity

The ability of a test to designate people with pre-clinical disease as “positive” is referred to as the sensitivity of the test. The sensitivity of a screening test is thus the ratio of the number of people with pre-clinical disease who are positive on testing, to the total number of people tested who have pre-clinical disease. Detected cases are termed “true positives”. Cases of disease with a negative test result are termed “false negatives”.

Specificity

The specificity of a test is its ability to designate as “negative” those people who are not diseased. The specificity of a test also determines whether the frequency of false positives will be low enough for a screening program to be useful.

Type 1 diabetes

Type 1 diabetes has a rapid onset in the young, in whom it is more common. People with Type 1 diabetes are insulin deficient and dependant on insulin therapy to sustain life. 10% of people with diabetes have Type 1.

Type 2 diabetes

Type 2 diabetes is a progressive disorder of variable insulin resistance and insulin deficiency, with an insidious onset. It is associated with hypertension, central obesity, and dyslipidaemia. It is more common in Māori and Pacific peoples than Caucasians. Management includes diet, exercise, and weight control. Oral medications and/or injected insulin therapy are needed by many people with Type 2 diabetes to maintain glycaemic control. 90% of people with diabetes have Type 2.

8. Reference Material

American Association of Clinical Endocrinologists. 1994. Why the DCCT applies to NIDDM patients: AACE guidelines for management of diabetes mellitus. Clinical Diabetes 12: 141-44.

American Diabetes Association. 2001. Clinical practice recommendations 2001. Diabetes Care 24 Suppl 1: S1-133.

Anonymous. 1991. Early photocoagulation for diabetic retinopathy: ETDRS report number 9. Early Treatment Diabetic Retinopathy Study Research Group. Ophthalmology 98(5 Suppl): 766-85.

Anonymous. 1985. Photocoagulation for diabetic macular edema. Early Treatment Diabetic Retinopathy Study report number 1. Early Treatment Diabetic Retinopathy Study research group. Archives of Ophthalmology 103(12):1796-806.

Bursell SE, Cavallerano JD, Cavallerano AA, et al. 2001. Stereo non-mydriatic digital video color retinal imaging compared with Early Treatment Diabetic Retinopathy Study seven standard field 35-mm stereo color photos for determining level of diabetic retinopathy. Ophthalmology 108(3):572-85.

Department of Health. 1988. Diabetes mellitus: a model for health maintenance: service planning guidelines for Area Health Boards. Wellington: Department of Health.

Diabetic Retinopathy Working Party of the National Health and Medical Research Council, Australian Diabetes Society Retinopathy Sub-Committee. Retinopathy Chart.
URL: http://www.eyesondiabetes.org.au/article/9 Accessed 14 September 2006.

The Diabetes Control and Complications Trial Research Group. 1993. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. New England Journal of Medicine 329(4): 977-86.

Fonseca V, Munshi M, Merin LM, et al. 1996. Diabetic retinopathy: a review for the primary care physician. Southern Medical Journal 89(9): 839-50.

Fong DS, Ferris FL, Davis MD, et al. 1999. Causes of severe visual loss in the early treatment diabetic retinopathy study: ETDRS report no. 24. Early Treatment Diabetic Retinopathy Study Research Group. American Journal of Ophthalmology 127(2): 137-41.

Health Funding Authority. 2000. BreastScreen Aotearoa Data Management Manual, Breast Screen Program, Version 2.12. Wellington: Health Funding Authority.

Health Funding Authority. 2000. Diabetes Referral Guidelines and Prioritisation Criteria. Wellington: Health Funding Authority.

Health Funding Authority. 2000. Diabetes 2000. Wellington: Health Funding Authority.

Health Funding Authority. 2000. Interim Operational Policy and Quality Standards for the National Cervical Screening Program. Wellington: Health Funding Authority.

Javitt JC. Aiello LP. 1996. Cost-effectiveness of detecting and treating diabetic retinopathy. Annals of Internal Medicine 124(1 Pt 2): 164-9.

Klein R, Klein BE, Moss SE, et al. 1984. The Wisconsin Epidemiologic Study of Diabetic Retinopathy. II. Prevalence and risk of diabetic retinopathy when age at diagnosis is less than 30 years. Archives of Ophthalmology 102(4): 520-6.

Klein R, Klein BE, Moss SE, et al. 1984. The Wisconsin Epidemiologic Study of Diabetic Retinopathy. III. Prevalence and risk of diabetic retinopathy when age at diagnosis is 30 or more years. Archives of Ophthalmology 102(4): 527-32.

Klein R, Klein BE, Moss SE, et al. 1989. The Wisconsin Epidemiologic Study of Diabetic Retinopathy. IX. Four-year incidence and progression of diabetic retinopathy when age at diagnosis is less than 30 years. Archives of Ophthalmology 107(2): 237-43.

Klein R, Klein BE, Moss SE, et al 1989. The Wisconsin Epidemiologic Study of Diabetic Retinopathy. X. Four-year incidence and progression of diabetic retinopathy when age at diagnosis is 30 years or more. Archives of Ophthalmology 107(2): 244-9.

Klein R, Klein BE, Moss SE, et al. 1994. The Wisconsin Epidemiologic Study of Diabetic Retinopathy. XIV. Ten-year incidence and progression of diabetic retinopathy. Archives of Ophthalmology 112(9): 1217-28.

Lee SC, Lee ET, Kingsley RM, et al. 2001. Comparison of diagnosis of early retinal lesions of diabetic retinopathy between a computer system and human experts. Archives of Ophthalmology 119(4): 509-15.

Ministry of Health. 2001. National Service Specification Tier 2: diabetes retinal screening. Wellington: Ministry of Health. URL: http://www.newhealth.govt.nz Accessed 14 September 2006.

Moss SE, Klein R, Kessler SI, et al. 1985. Comparison between ophthalmoscopy and fundus photography in determining severity of retinopathy. Ophthalmology 92: 62-7.

National Health and Medical Research Council, Australia. 1997. Management of Diabetic Retinopathy: A guide for general practitioners. Canberra: National Health and Medical Research Council, Australia.

National Health and Medical Research Council, Australia. 1997. Management of Diabetic Retinopathy: Clinical practice guidelines. Canberra: National Health Medical Research Council, Australia.

National Health and Medical Research Council, Australia. 1997. Preserving Vision in Diabetes: A quick reference guide for optometrists, nurses and other health practitioners. Canberra: National Health and Medical Research Council, Australia.

Prasad S. 1999. Screening for Diabetic Retinopathy: An overview.
URL: http://www.priory.co.uk/med/eye.htm Accessed 14 September 2006.

Rand LI, Prud'homme GJ, Ederer F, et al. 1985. Factors influencing the development of visual loss in advanced diabetic retinopathy. Diabetic Retinopathy Study (DRS) Report No. 10. Investigative Ophthalmology & Visual Science 26(7): 983-91.

Reda E, Dunn P, Straker C, et al. 2003. Screening for diabetic retinopathy using the mobile retinal camera: the Waikato experience. New Zealand Medical Journal 116(1180): U562.

Rudinsky CJ, Hinz BJ, Tennant MT, et al. 2002. High resolution stereoscopy digital fundus photography versus contact lens biomicroscopy for the detection of clinically significant macular oedema. Ophthalmology 109: 267-74.

Taylor R. Lovelock I, Turnbridge WMG, et al. 1990. Comparison of non-mydriatic retinal photography with ophthalmoscopy in 2159 patients: mobile camera study. British Medical Journal 310: 1243-7.

UK Prospective Diabetes Study Group. 1998. Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes: UKPDS 38. British Medical Journal 317(7160): 703-13.

Vijan S, Hofer TP, Hayward RA. 2000. Cost-utility analysis of screening intervals for diabetic retinopathy in patients with type 2 diabetes mellitus. Journal of the American Medical Association 283(7): 889-96.

Wilkinson CP. Ferris FL, Klein RE. et al. 2003. Proposed international clinical diabetic retinopathy and diabetic macular edema disease severity scales. Ophthalmology 110(9):1677-82.

The Wisconsin Diabetes Advisory Group. 2001. Essential Diabetes Mellitus Care Guidelines. Rev. Ed. Madison, Wisconsin: Wisconsin Diabetes Control Program, US Department of Health and Family Services.

Zoorob RJ, Hagen MD. 1997. Guidelines on the care of diabetic nephropathy, retinopathy and foot disease. American Family Physician 56(8): 2021-8, 2033-4.