

### **CLINICAL GUIDELINE**

# Examination and management of patients with diabetes

## **Executive Summary**

- Diabetic retinopathy (DR) is a major cause of vision loss and blindness in working age and older Australians. Approximately 1.7 million Australians are estimated to be living with diabetes, and with an additional 280 people developing diabetes every day, this figure is estimated to grow to 2.45 million by 2030.¹ In Australia, the prevalence of diabetes is seven per cent in adult men and five per cent in adult women². Almost everyone with type 1 diabetes and more than 60 per cent of those with type 2 diabetes will develop some form of diabetic retinopathy within 20 years of diagnosis.³ Early detection and prompt treatment can prevent 98 per cent of severe visual impairment. A.5.6 Persons with DR may be asymptomatic until the condition is advanced, and all persons with diabetes are at risk of developing DR.
- All patients with diabetes are at risk of developing diabetic retinopathy. Factors increasing risk include:

- Increased duration of DM - Hyperlipidaemia - Elevated HbA1c

Systemic hypertensionHyperglycaemiaRenal disease

- Two major, well-accepted grading systems exist which classify stages of DR. These are the International Clinical Diabetic Retinopathy and Diabetic Macular Oedema Disease Severity Scale<sup>7</sup> and the Wisconsin System (modified Airlie House classification)<sup>8,9</sup> and are referred to within the body of this guideline alongside recommended referral timeframes. Both of these grading systems are also cited in the National Health and Medical Research Council (NHMRC) guidelines on the assessment of diabetic retinopathy.
- Referral to an ophthalmologist should be urgent if diabetic macular oedema (DMO) or proliferative diabetic retinopathy (PDR) is suspected. If an unexplained reduction in visual acuity is observed, OCT and/or OCT-A may be useful tools to confirm or rule out oedema or macular ischaemia.
- Medicare Item 10915 should be billed for comprehensive eye examinations with the instillation of a mydriatic eye drop, where a patient is known to have DM. Optometrists should report clinical findings back to the diabetes management team including the patient's GP and/or endocrinologist.
- Optometrists must be key players and active participants within a multidisciplinary diabetes health care team. Effective communication of clinical findings and collaboration within the diabetic health care team results in optimum patient care, improved metabolic control, and reduced cardiovascular risk factors. Optometrists have the capacity to increase patient awareness about diabetes, facilitate early detection, and assist in diabetes management and treatment.



## Optometry Australia Guidelines for the examination and management of patients with diabetes

These clinical guidelines provide recommendations to optometrists on the assessment and monitoring of patients with diabetes and referral of patients with diabetic retinopathy for ophthalmologic assessment and management. The guidelines are not intended to be prescriptive and should not be used as a substitute for statutory responsibilities and optometrists must ensure that they comply with State and Federal Laws.

Diabetic retinopathy (DR) is a major cause of vision loss and blindness in working age and older Australians<sup>11</sup> despite well-developed and proven strategies to prevent visual loss from diabetic eye disease. Early detection and prompt treatment can prevent 98 per cent of severe visual impairment<sup>12</sup>. Optometrists can also play a role in detecting clinical signs in those with undiagnosed DM who present for examinations as well as raising public awareness of the disease.

The NHMRC *Clinical Practice Guidelines for the Management of Diabetic Retinopathy* were developed by the Australian Diabetes Society in collaboration with an expert panel and published in 2008 referencing literature published up to September 2007. Since that time, there have been major advancements in imaging technology for the diagnosis of diabetic retinopathy (DR) as well as new treatment for both DM and DR. Optometry Australia (OA) *Guidelines for the examination and management of patients with diabetes* has considered the NHMRC and other national and international guidelines, as well as recent advancements in diagnosis and management, but adopts a more concise format to facilitate convenient consultation as part of typical optometric practice.

Approximately 1.2 million Australians have diagnosed DM.<sup>13</sup> There are two common types of DM, type 1 (T1DM) and type 2 (T2DM) with some overlap in age at onset, together with intermediate forms.<sup>14</sup> Up to half the cases of type 2 DM remain undiagnosed.<sup>15</sup> Impaired glucose tolerance (IGT) and impaired fasting glycaemia (IFG), also known as pre-diabetes or borderline diabetes, are intermediate conditions in the transition between normal glycaemic levels and diabetes. People with IGT or IFG are at high risk of progressing to T2DM though this is not inevitable. Optometrists can potentially play a role in patient education with regards to the strong benefit of exercise and diet in reducing risk of progression to diabetes for those with IFG or IGT.<sup>16</sup> Gestational diabetes is hyperglycaemia with onset or first recognition during pregnancy.<sup>17,18</sup>

T1DM accounts for approximately 9 per cent of Australians with diabetes with 87 per cent having T2DM. The proportion of people with DM in the Indigenous population compared to that in the non-Indigenous population is 3:1.19

#### **Diabetic retinopathy**

Diabetic retinopathy (DR) is defined as the presence of typical microvascular signs in a person with DM. DR is categorised as 'non-proliferative' (NPDR) or 'proliferative' (PDR). The latter stage is associated with a high risk of visual loss. Capillary leak in the macular or peri-macular region results in diabetic macular oedema (DMO) defined as retinal thickening or hard exudates located within two-disc diameters (2DD) of the fovea (centre of the macula). DMO can occur in either stage of DR and is the most common cause of vision loss related to diabetes.<sup>20</sup> Visual acuity may be unaffected even when vision threatening or treatable DR is present. Non-English-speaking background (NESB) may be an independent risk factor for DR, possibly owing to increased difficulty in achieving optimal blood glucose, blood pressure and blood lipid control, and barriers to communicating with health practitioners.



#### Risk factors

Everyone with diabetes is at risk of developing DR and duration of diabetes is the most significant and strongest factor determining DR prevalence<sup>21</sup>. Other risk factors include:<sup>22,23</sup>

- hyperglycaemia<sup>24</sup>
- systemic hypertension (see appendix A)
- elevated HbA1C<sup>25</sup> (see appendix B for conversion chart from percentage [%] to new units [mmol/mol])
- hyperlipidaemia
- renal disease
- Indigenous Australians or those of non-English speaking background<sup>26</sup>
- dependence on insulin
- pregnancy
- nutritional and genetic factors
- retinal arteriolar tortuosity<sup>27</sup>
- the type of diabetes

#### Optometric examination of a patient with diabetes

When examining a patient with diabetes, optometrists should consider the following recommendations (Table 1) and apply them appropriately for individual clinical presentations.

Optometrists might be sent, or may request, a copy of a patient's diabetes care plan (which may be developed by a GP as part of Practice Incentives Program - PIP<sup>28</sup>), which will include information pertaining to a specific patient's medical history. Discussion of a diabetic patient's medical history should include:

- type and duration of diabetes
- blood pressure and cholesterol/lipid status
- current treatment (diet, oral medications, insulin type and dosage, other injectable medications such as exenatide)
- glycaemic control (including recent laboratory values for HbA1C)
- renal (kidney) function: presence of microalbuminuria<sup>29</sup> or overt proteinuria
- presence of peripheral neuropathy (tingling or numbness in extremities)
- adherence, method, frequency, and results of self-monitoring of blood glucose
- practitioners managing the patient's diabetes care (GP, endocrinologist and/or renal specialist)

DR is a sight-threatening complication of diabetes. Ocular and visual complications of DM are listed in Appendix D and optometrists should be aware of these. Examination of a patient with DM may include - but not be limited to - procedures listed in Table 1.

Diabetic macular oedema is important to detect, as it is the most frequent cause of diabetes-related visual loss. DMO is best assessed using fundoscopy with slitlamp funduscopy (with pupil dilation),



grading stereoscopic macular photographs or OCT.<sup>30</sup> The detection of macular ischaemia in moderate to severe DR is also important in potential vision loss from diabetes.<sup>31</sup>

Proliferative retinopathy can result in severe vision loss through pre-retinal haemorrhage, vitreous haemorrhage and/or tractional retinal detachment. PDR is best assessed using dilated fundus examination with slitlamp funduscopy and indirect ophthalmoscopy. Advanced wide-field imaging techniques can also be useful in supplementing funduscopic examination.

Table 1. Recommended examination procedures for examining patients with diabetes

Procedure	Comments
Visual acuity (with correction)	Distance and Near, monocularly, including pinhole acuity if indicated
Pupil reactions	Direct/Consensual and Near pupillary responses
Ocular motility and cover test	Extent, fluency and symmetry of ocular movements in all directions of gaze, ruling out eye movement anomalies. Relevant history taking regarding the onset and direction of diplopia is necessary. If diplopia is manifest, cover test and prism neutralisation is also indicated.
Visual field screening	- Confrontation
	- Note: visual field screening and baseline testing in the absence of actual or suspected pathology of the visual pathways or brain will not attract a Medicare rebate for item 10940 or 10941.
Refraction	On indication     Where patient reports a change in vision or visual function (e.g. increased glare sensitivity) or where a change in habitual visual acuity is measured.
Slitlamp biomicroscopy	- Recommended at every visit
	- Examination for iris neovascularisation (NVI), diabetic cataract, corneal integrity
Tonometry	Pre-dilation; post-dilation as indicated
Stereoscopic fundus examination with pupil dilation	- NHMRC guidelines describe pupil dilation using 0.5 to 1.0% tropicamide as safe (noting dilated ocular fundus examination increases the sensitivity of DR screening) and so consider it mandatory in performing ophthalmoscopy or slitlamp biomicroscopy <sup>32</sup> unless contraindicated by the presence of potentially occludable anterior chamber angles.
	- Gonioscopy may be necessary to evaluate whether narrow angles are potentially occludable. Where potentially occludable angles are detected, the patient should be referred to an ophthalmologist for an opinion on management e.g. suitability for PI.
	- People with diabetes can show a poor response to mydriatic agents. 2.5% phenylephrine hydrochloride, unless contraindicated, may help achieve maximum pupillary dilation in patients with DM, particularly those of Aboriginal and Torres Strait Islander descent and patients with heavy iris pigmentation
	- Optometry Australia pupil dilation guidelines can be viewed here
	- Symptoms of VA reduction or distortion of vision or a significant change of DM control should always prompt dilated pupil examination



Supplementary testing may include<sup>33</sup>:

- colour vision assessment (performed monocularly)
- contrast sensitivity testing
- gonioscopy
- macular function assessments
- optical coherence tomography
- ocular fundus photography
- wide-field fundus imaging

#### Frequency of examinations

Early detection of retinopathy by regular eye examinations is critical to reducing visual loss and blindness from DR. In line with NHMRC Guidelines for the Management of Diabetic Retinopathy, Optometry Australia advises all people with diabetes undergo two yearly eye examinations unless a practitioner recommends more frequent reviews based on observed changes.<sup>34</sup>

NHMRC guidelines advise that patients considered being at particular risk of visual loss and DR (see Risk Factors) should be considered for annual examinations and recommended frequency of examination is outlined in Table 2, which is adapted and modified from NHMRC guidelines.

Table 2. Recommended frequency of eye examinations according to patient classifications<sup>35</sup>

Patient classifications	Frequency of examination
All patients with diabetes (T1DM or T2DM)	At diagnosis and 2 yearly thereafter.  Annually for higher-risk patients: Aboriginal and Torres Strait Islander patients, longer duration of diabetes, poor glycaemic control, blood pressure or blood lipid control. For children with pre-pubescent type 1 diabetes, Optometry Australia advises introducing eye examinations early in the course of diabetes, to assess patient's ocular fundus, measure baseline VA and perform other tests appropriate for child's age and stage of development.  Otherwise, children with pre-pubertal diabetes should undergo annual examinations from puberty.
Patients with non- proliferative diabetic retinopathy (NPDR) Mild NPDR	Depending on level of DR present, 6–12 monthly or annually.  - Mild NPDR without DMO: 6–12 months.  - Mild NPDR with DMO: ophthalmology referral – see Table 3.
Moderate NPDR	<ul> <li>Moderate NPDR without DMO: 3-6 monthly or referral if at high risk of progression.</li> <li>Moderate NPDR with DMO: ophthalmology referral – see Table 3.</li> </ul>
Pregnant women with diabetes	Pregnancy in females with T1DM or T2DM may accelerate the development and progression of DR. Hence, women with diabetes who become pregnant should:  - have a comprehensive eye exam prior to conception if planning pregnancy  - have a comprehensive eye examination in the first trimester



	<ul> <li>base the frequency of examinations during the pregnancy should be based on first trimester exam results and blood glucose control during pregnancy</li> <li>have a comprehensive eye exam 6–12 weeks post-partum.</li> </ul>
Women with gestational diabetes	Women with gestational diabetes do not need ophthalmic surveillance during or after pregnancy, unless diabetes persists.

#### Classification of diabetic retinopathy

The modified Airlie House classification (Wisconsin system)<sup>37</sup> became the basis for detailed grading of DR and was used in all the major studies of risk factors and trials of laser and other treatments.

To simplify classification of DR and standardise communication between health care providers, in 2003 the International Classification of Diabetic Retinopathy and Diabetic Macular Edema was introduced<sup>38</sup>, drawing on evidence-based studies including the Early Treatment Diabetic Retinopathy Study (ETDRS) and the Wisconsin Epidemiologic Study of Diabetic Retinopathy. This describes five clinical levels of DR and two broad levels of DMO, reducing the number of levels of DR, simplifying category descriptions, and eliminating references to the standard photographs of the Airlie House Classification of DR. The International Clinical Diabetic Retinopathy and Diabetic Macular Edema Disease Severity Scales are listed in Table 3 alongside recommended patient referral patterns.

The DR severity scales should be applied at each assessment to determine the need for follow-up, referral and appropriate management.<sup>39</sup>

#### **Ophthalmologic referral**

The main objective of examining diabetic patients is to monitor for the presence and progression of DR to ensure timely referral of patients for treatment.

Optometry Australia recommends that optometrists communicate with ophthalmologists to determine their preferred referral timelines to achieve optimal visual outcomes.

Table 3. International Clinical Diabetic Retinopathy and Diabetic Macular Edema Disease Severity Scales and recommended referral patterns<sup>40</sup>

Retinopathy stage	Findings on ophthalmoscopy	Management and review/referral timeframe <sup>41</sup>
No apparent retinopathy	No abnormalities	In line with NHMRC guidelines, recommend 2 yearly reviews.
		High risk patients to be seen annually: hypertension, poor HbA1c, long duration of diabetes, Indigenous status, non-compliance to follow-up.
Mild NPDR	Microaneurysms (MA) only	Review 6–12 months taking into consideration proximity of MA to fovea.
Moderate NPDR	More than just MA but less than severe NPDR	Refer (see footnote) <sup>42</sup> or closely monitor.
		Depending on level of DR present, 3–6 monthly or referral – see Table 2.



		Communicate level of DR to the GP and endocrinologist and mention the possible benefits of fenofibrate in slowing DR progression for high risk patients with mild or moderate DR.
Severe NPDR	<ul> <li>Any of the following:</li> <li>more than 20 intraretinal haemorrhages in each of 4 quadrants</li> <li>definite venous beading in 2+ quadrants</li> <li>prominent IrMA in 1+ quadrant AND no signs of proliferative retinopathy</li> </ul>	Ophthalmology referral – see footnote. <sup>41</sup>
PDR	One of the following (or unexplained fall in visual acuity*):  • neovascularisation  • vitreous/pre-retinal haemorrhage	Urgent ophthalmology referral (days-weeks).*
Macula oedema		
Absent	No retinal thickening or hard exudates (HEx) in posterior pole	Follow-up or need to refer should be based on the level of NPDR or DR (Table 2)
Present	Mild – some retinal thickening or HEx in posterior pole but distant from the macula Moderate – retinal thickening or HEx approaching the centre of the macula but not involving the centre  Severe – retinal thickening or hard exudates involving the fovea	Ophthalmology referral and management (within 4 weeks for HEx within 1DD of fovea).*
Unexplained vision loss	-	Ophthalmology referral and management.  In the first instance, OCT, OCTA may be useful to rule out diabetic macular oedema or macular ischaemia.

<sup>\*</sup>Optometry Australia recommends that optometrists communicate with ophthalmologists to determine their preferred referral timelines to prevent vision loss

#### **Tele-screening**

MBS item number for diabetic retinopathy screening using retinal photography allows services to reach patients where access barriers exist via tele-screening. One recent Australian study demonstrated that single-field dilated fundus photography in Indigenous Australians meets the minimum screening requirements recommended by the NHMRC, with adequate sensitivities, specificities and repeatability for detecting DR to determine need for referral or repeat screening frequencies. However, sensitivity of digital photography is influenced by pupil size, media opacities, camera resolution and location of retinopathy outside the posterior pole region, and is therefore not equivalent to a comprehensive examination of the ocular fundus.

Optometry Australia advises that tele-screening should not be viewed as a substitute for comprehensive eye examinations. It is regarded as a useful tool for people with DM in rural and remote areas, with no or limited access to an optometrist or ophthalmologist, and to facilitate communication between primary health practitioners and eye care practitioners.



#### **General Practitioner report and recommendations**

Optometry Australia recommends that optometrists inform the patient's GP and endocrinologist of the outcomes of their patient's eye examination.

This correspondence should include, at the minimum, the following:

- a) visual acuities
- b) whether a dilated ocular fundus exam was performed
- c) whether there is presence of retinopathy, and if so, it's classification
- d) the next recommended eye review.

Optometrists may also like to suggest to the GP/endocrinologist (based on the patient's medical history and risk factors) to consider prescribing Fenofibrate in patients with mild or moderate NPDR. According to the FIELD and ACCORD studies, Fenofibrate may slow the progression of diabetic retinopathy in high-risk adults with type 2 diabetes.<sup>46</sup>

Persons with DR may be asymptomatic until the condition is advanced, and everyone with diabetes is at risk of developing DR; regular eye examinations are important for early diagnosis and timely treatment to prevent vision loss and, in some cases, may detect previously undiagnosed cases of DM. Optometrists who familiarise themselves with risk factors for developing DR, different classifications, and review and referral schedules are able to provide optimal patient care.

Optometrists are ideally placed to advocate for optimal diabetes and health management and be an active participant of the multidisciplinary diabetes team. This includes continuous written communication with the patient's primary care giver (e.g. GP) with the results of the eye examination. Working as part of this team, optometrists can play an important role in reducing unnecessary vision loss from diabetic retinopathy.



## Appendix A

#### Blood pressure treatment targets in adults<sup>48</sup>

Patient group	Target (mmHg)
People with proteinuria > 1 g/day (with or without diabetes)	< 125/75
People with associated condition/s or end-organ damage:	< 130/80
<ul> <li>Coronary heart disease</li> <li>Diabetes</li> <li>Chronic kidney disease</li> <li>Proteinuria (&gt; 300 mg/day)</li> <li>Stroke/TIA</li> </ul>	
People with none of the following:  Coronary heart disease	< 140/90 or lower if tolerated
<ul> <li>Diabetes</li> <li>Chronic kidney disease</li> <li>Proteinuria (&gt; 300 mg/day)</li> <li>Stroke/TIA</li> </ul>	

## Appendix B

#### Conversion table for haemoglobin A1C (HbA1C) values<sup>49</sup>

HbA1C as percentage (old units)	HbA1C in mmol/mol (new units)
5.0	31
6	42
6.5	48
7	53
8	64
9	75
10	86
11	97
12	108



## Appendix C

#### Practice Incentives Program (PIP) – Diabetes Incentive Guidelines<sup>50</sup>

Minimum requirements of the annual diabetes cycle of care (to be completed over a period of at least 11 months and up to 13 months)

Activity	Frequency and description
Assess diabetes control by measuring HbA1c	At least once.
Carry out a comprehensive eye examination	The patient must have had at least one comprehensive eye examination over the current and previous cycle of care. The examination isn't needed if the patient is blind or doesn't have both eyes.
Measure total cholesterol, triglycerides and HDL cholesterol	At least once.
Test for microalbuminuria	At least once.
Measurement of the patient's estimated Glomerular Filtration Rate (eGFR)	At least once.
Measure blood pressure	At least twice.
Examine feet	At least twice. This isn't needed if the patient doesn't have both feet.
Measure weight and height and calculate body mass	Measure height and weight, and calculate the BMI on the patient's first visit and weigh them at least twice
Provide self-care education	Provide patient education about diabetes management.
Review diet	Review the patient's diet and give them information on appropriate dietary choices.
Review levels of physical activity	Review the patient's physical activity and give them information on appropriate levels of physical activity.
Check smoking status	Encourage the patient to stop smoking.
Review medication	Review patient's medicine.

Note: activities needed twice in a cycle of care must be performed at least five months apart.



## Appendix D

#### Ocular and visual complications of diabetes mellitus

Functional	Tritan colour vision deficiencies Refractive error changes Accommodative dysfunction Visual field defects Loss of visual acuity
Extraocular muscle anomalies	Mononeuropathies involving third, fourth, or sixth cranial nerves
Pupillary reflexes	Sluggish pupillary reflexes; poor response to mydriasis
Conjunctiva	Bulbar conjunctival microaneurysms
Tear film	Tear film deficiencies resulting in dry eye syndrome
Cornea	Reduced corneal sensitivity Reduced corneal wound-healing ability Basement membrane abnormalities resulting in increased frequency of abrasions or recurrent erosion syndrome Descemet's membrane wrinkling Endothelial cell morphology changes, often resulting in increased corneal thickness Pigment on endothelium
Iris	Depigmentation Rubeosis iridis, possibly with associated ectropion uvea and peripheral anterior synechiae Neovascular glaucoma
Lens	Higher prevalence of cataracts Reversible opacities and snowflake cataracts rarely seen in industrialised countries
Vitreous	Haemorrhage in proliferative retinopathy
Retina	Non-proliferative retinopathy Proliferative retinopathy Macular oedema and/or ischaemia
Optic nerve	Neovascularisation of the disc (NVD) Papillopathy Ischemic optic neuropathy Higher incidence of open-angle glaucoma

From American Optometric Association Optometric Clinical Practice Guideline *Care of the Patient with Diabetes Mellitus* American Optometric Association 2009



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- <sup>38</sup> Global Diabetic Retinopathy Project Group, Proposed international clinical diabetic retinopathy and diabetic macular edema disease severity scales, *Ophthalmology* 2003:110(9):1677-82
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- <sup>42</sup> OAA advises optometrists practice within their scope and note NHMRC guidelines state only that "Patients with any level of DME, severe NPDR, or any PDR require prompt care from an ophthalmologist experienced in DR management. Referral is also needed if there is any unexplained loss of vision, or if a screening examination cannot be performed."
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- <sup>50</sup> PIP Diabetes Incentive Guidelines document October 2013 <u>http://www.medicareaustralia.gov.au/provider/incentives/pip/forms-guides.jsp#N10068</u>