

# Information Statement

## Screening for Diabetic Retinopathy

November 2006. Updated October 2014

### Summary

The American Academy of Ophthalmology recognizes that screening for diabetic retinopathy using validated digital imaging can be a sensitive and effective detection method. Such technology has not been demonstrated to be as effective, however, at detecting and quantifying the spectrum of other ophthalmic pathology that can accompany diabetic retinopathy, including cataract and glaucoma, which are more prevalent in patients with diabetes mellitus. Imaging technology also does not mitigate the need for periodic comprehensive ophthalmic examinations.

### Background

The Preferred Practice Pattern on Diabetic Retinopathy states<sup>1</sup>:

Diabetic retinopathy is a leading cause of visual impairment in working-age adults. While defects in neurosensory function have been demonstrated in patients with diabetes mellitus prior to the onset of vascular lesions, the most common early clinically visible manifestations of diabetic retinopathy would include microaneurysm formation and intraretinal hemorrhages. Microvascular damage leads to retinal capillary nonperfusion, cotton wool spots, increased numbers of hemorrhages, venous abnormalities, and intraretinal microvascular abnormalities (IRMA). During this stage, increased vasopermeability can result in retinal thickening (edema) and/or exudates that may lead to a loss in central visual acuity. The proliferative stage results from closure of arterioles and venules with secondary proliferation of new vessels on the disc, retina, iris, and in the filtration angle. These new vessels then lead to traction retinal detachments and neovascular glaucoma respectively. Vision can be lost in this stage from capillary nonperfusion or edema in the macula, vitreous hemorrhage, and distortion or traction retinal detachment.

Diabetic retinopathy can occur at any age. The primary prevention and screening process for diabetic retinopathy varies according to the age of disease onset. Several forms of retinal screening with standard fundus photography or digital imaging, with and without dilation, are under investigation as a means of detecting retinopathy. Appropriately validated digital imaging technology can be a sensitive and effective screening tool to identify patients with diabetic retinopathy for referral for ophthalmic evaluation and management.<sup>2</sup> Some studies have found that photography is more sensitive in identifying sight-threatening retinopathy than clinical examination with ophthalmoscopy.<sup>3 4 5 6</sup> Digital cameras with stereoscopic capabilities are useful for identifying subtle neovascularization and macular edema.<sup>7 8</sup> At this time, it is not clear that photographic screening programs achieve a greater reduction in vision loss than does routine community care in areas where access to ophthalmologists is straightforward. Studies have found a positive association between participating in a photographic screening program and subsequent adherence to receiving recommended comprehensive dilated eye examinations by a clinician.<sup>9 10</sup> Of course, such screening programs have great value in circumstances in which access to ophthalmic care is limited.<sup>11 12 13 14</sup> Future research should also include establishing standardized protocols and satisfactory performance standards for diabetic retinopathy screening programs.

At this time, these technologies are not considered a replacement for a comprehensive eye evaluation by an ophthalmologist experienced in managing diabetic retinopathy.

### Recommendations for Care

Early detection of retinopathy depends on educating patients with diabetes as well as their families, friends, and health care providers about the importance of regular eye examination even though the patient may be

asymptomatic. Patients must be informed that they may have good vision and no ocular symptoms, yet may still have significant disease that needs treatment, which depends on timely intervention.

The care process for diabetic retinopathy includes a medical history, an ophthalmic examination and screening of high quality retinal photographs of patients who have not had previous treatment for diabetic retinopathy, and vigilant follow-up. An effective screening program can determine who needs referral to an ophthalmologist for close follow-up and possible treatment, and who simply requires annual screening. People with Type 1 diabetes should have annual examinations for diabetic retinopathy beginning five years after the onset of their disease, while those with Type 2 diabetes should have a prompt examination at the time of diagnosis, then at least yearly examinations thereafter. Women who develop gestational diabetes do not require an eye examination during pregnancy, and do not appear to be at increased risk for developing diabetic retinopathy during pregnancy. However, diabetics who become pregnant should be examined soon after conception and early in the first trimester of the pregnancy. The recommended follow-up is every 3-12 months for no retinopathy or moderate nonproliferative diabetic retinopathy (NPDR), or every 1-3 months for severe NPDR.

Ophthalmologists can play an important role in the total care of the patient with diabetes. At the time of the eye examination, patients can be counseled about the importance of maintaining near-normal blood glucose and blood pressure and monitoring serum glycosylated hemoglobin levels, which may lessen the risk of retinopathy developing and progressing. It is recommended that an HbA1c of 7.0% or lower is the target for glycemic control in most patients while in selected patients there may be benefit to setting a target of 6.5%. Aspirin may be used without concern for worsening diabetic retinopathy by patients with diabetes who require aspirin for other medical indications and have no contraindications. Intravitreal injections of anti-vascular endothelial growth factor (VEGF) agents have been shown to be an effective treatment for center-involving diabetic macular edema. Treating physicians should note that the use of betadine antiseptic drops is recommended during intravitreal injections. At this time, laser photocoagulation remains the preferred treatment for non-center-involving diabetic macular edema.

Physicians that care for patients with diabetes, and patients themselves, need to be educated about indications for ophthalmologic referral. Referral to an ophthalmologist is required when there is any non-proliferative diabetic retinopathy, proliferative diabetic retinopathy (PDR), or macular edema. Ophthalmologists should communicate the ophthalmologic findings and level of retinopathy with the primary care physician as well as the need for optimizing metabolic control. It is reasonable to encourage patients with diabetes to be as compliant as possible with therapy of all medical aspects of their disease.

### Imaging

The Ophthalmic Technology Assessment on Single Field Fundus Photography for Diabetic Retinopathy Screening states<sup>15</sup>:

A variety of techniques can be used to detect and classify diabetic retinopathy, including direct and indirect ophthalmoscopy, stereoscopic color film fundus photography, fluorescein angiography, and mydriatic or nonmydriatic digital color or monochromatic photography. Ophthalmoscopy is the most commonly used technique to screen for diabetic retinopathy. However, undilated ophthalmoscopy, especially that done by nonophthalmologists, has poor sensitivity relative to 7-field stereoscopic color photography.<sup>16</sup> Under typical clinical conditions, direct ophthalmoscopy done by nonophthalmologists has a sensitivity of approximately 50% for the detection of proliferative retinopathy.<sup>17</sup> The gold standard for the detection and classification of diabetic retinopathy is stereoscopic color fundus photographs in 7 standard fields, as defined by the Early Treatment Diabetic Retinopathy Study (ETDRS) group.<sup>18</sup> Although this technique is accurate and reproducible, it is labor intensive and requires skilled photographers; skilled photograph readers; and sophisticated photography equipment, film processing, and archiving. The turnaround time from acquisition of the data to interpretation can take weeks in clinical trials. Finally, from the patient's perspective, it can be time consuming and uncomfortable. In short, 7-field stereoscopic fundus photography is not an ideal screening technique, but it can serve as the standard with which to compare other screening technologies.

There is level I evidence that single-field fundus photography with interpretation by trained readers can serve as a screening tool to identify patients with diabetic retinopathy for referral for ophthalmic evaluation and management, but it is not a substitute for a comprehensive ophthalmic examination. The advantages of single-field fundus photography interpreted by trained readers are ease of use (only one photograph is required), convenience, and ability to detect retinopathy. The disadvantage is that reported sensitivity values are less than ideal when compared with 7–standard field photography. When compared with ophthalmoscopy, however, single-field fundus photography has the potential to improve the quality of the evaluation and the numbers of patients evaluated. The use of nonmydriatic fundus photography systems represents a compromise. Although it is apparent that mydriasis improves image quality and sensitivity, particularly in older patients, it is uncertain whether this is outweighed by the disadvantage of dilation related to patient compliance. In other words, the diminished sensitivity of a nonmydriatic photograph may be acceptable if more patients complete the process.

Whether any of the systems discussed can accommodate the tens of thousands of photographs necessary to appreciably improve detection rates for diabetic retinopathy in the general population is unknown. Caution should be exercised in strictly applying the test characteristics from the reported studies; most tests perform less well in the real-world setting. Further studies will be required to assess the implementation of programs that are based on single-field fundus photography in a real clinical setting to confirm the clinical effectiveness and cost-effectiveness of these techniques in improving population visual outcomes. Future research also should include establishing standardized protocols and satisfactory performance standards for diabetic retinopathy screening programs.

## References

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American Academy of Ophthalmology, Quality of Care Secretariat, October 2014

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