Early Detection of Diabetic Retinopathy in the Primary Diabetes Care Setting

Only half of all eligible diabetic patients were examined for DR in 2002.

BY NEIL BROOKS, MD

Early detection of diabetic retinopathy (DR) is the key to early sight-saving interventions. Retinopathy can be asymptomatic, even as significant harm is occurring to the retina. While some studies vary, most agree that about half of the individuals who have either type 1 or type 2 diabetes comply with the recommendation for an annual dilated retinal examination.1-3

This recommendation is made in guidelines issued by organizations including the American Diabetes Association, the American College of Clinical Endocrinologists and the American Academy of Ophthalmology.

The importance of this message resonates in The National Diabetes Quality Improvement Alliance (www.nationaldiabetesalliance.org), a body comprising multiple specialty medical societies and patient organizations that endorse a clinical performance measurement set including compliance with an annual eye examination and other critical measures.

2003 REPORT

Its 2003 report suggested that only 8 million of the 16 million eligible individuals were examined for DR in 2002. While many individuals with diabetes see a primary diabetes care physician on a regular basis, they do not have the recommended eye evaluation at visits. Although these patients may be referred to an ophthalmologist,

Figures 1,2. Left, a picture of the EyeTel DigiScope, used during a photographic examination of the retinas. Above, a picture of the EyeTel reading center, used by specialists at The Wilmer Eye Institute at Johns Hopkins.
many do not follow-up on the recommendation to visit an ophthalmologist or retinal specialist.

Vision loss from DR is usually preventable. Improved glycemic, lipid, and blood pressure control are achievable through medication and educational programs. Laser photocoagulation is recommended for eyes with severe disease including proliferative diabetic retinopathy. These represent steps to minimize the risk of further progression of the disease with possible vision impairment and blindness. For example, Vijian et al. studied the efficacy of glycemic control in type 2 diabetes and found that in patients diagnosed before age 50, reducing HbA1c from 9% to 7% would decrease the lifetime risk for blindness due to retinopathy from 2.6% to 0.3%. For onset of type 2 diabetes after age 65, the risk would be reduced from 0.5% to <0.1%.

INEVITABLE PROGRESSION

In addition, there are pharmacological therapies in clinical trials that may slow or stop the inevitable progression of DR. All rely on prevention of progression of retinopathy, prior to the onset of visual loss. Regular retinal examinations are integral to the medical and surgical management of this potentially disabling condition. It is imperative that methods be found that will allow patients with diabetes to obtain necessary retinal evaluations.

There are many reasons why appropriate eye examinations are not performed. Lack of accessibility to eye care professionals, time constraints, cost and inadequate counseling by primary care providers are all potential hurdles. In order to capture the approximately 8 million unexamined individuals, several groups have developed procedures that meet the requirements for screening examinations that can be performed in a primary care, endocrinologist or multispecialty office. This is based on the fact that most individuals with diabetes regularly visit their primary care physician or diabetic specialist.

Several groups have developed procedures for eye examinations that can be conducted in medical office settings without on-site ophthalmologic supervision (Table 1). While procedures differ, they generally operate the same (Table 2). A series of photographic images are taken, recorded digitally, and then sent to qualified readers who assess the images and report their findings back to the primary care physician.

Primary care and medical specialists will need to understand how a photographic examination of the retina fits into the care of the diabetic patient. First, it is considered a reliable screening tool for retinopathy, but it will not evaluate other problems such as glaucoma or cataracts, which occur with increased frequency in diabetic patients. The medical provider will relay the findings of the office-based retinal examination to the patient and refer appropriately. Greater involvement in the ocular health of patients with diabetes will require that primary care providers and endocrinologists understand the stages of retinopathy and the likelihood of vision threatening progression.

While the current standard for care of the patient with diabetes is a dilated eye examination by a qualified optometrist or ophthalmologist, 7-field stereo color photography is the gold standard for clinical studies involving DR. Studies are now available comparing these new procedures to standard 7-field fundus photography. In these new systems, experienced retinal image readers evaluate the digital images under the supervision of ophthalmologists and make a decision regarding the need for referral and further evaluation. For example, staff at the Wilmer-EyeTel Reading Center, under the supervision of retinal specialists at The Wilmer Eye Institute at Johns Hopkins, processes the digitized EyeTel images obtained with the EyeTel DigiScope. Similar procedures are used by other systems.

Both office-based retinal examination methods intend to improve accessibility and convenience for patients with diabetes, and thus increase the rate of recommend-

### Table 1. Groups with new methodologies for DR retinal eye examinations

<table>
<thead>
<tr>
<th>Group</th>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>EyeTel Imaging, Inc</td>
<td>9130 Guilford Road, Columbia, MD 21046 301-483-6167 888-883-9383 <a href="http://www.eyetel-imaging.com">www.eyetel-imaging.com</a></td>
</tr>
<tr>
<td>Inoveon Corporation</td>
<td>800 N. Research Parkway, Suite 370, Oklahoma City, OK 73104 405-271-9025 866-994-7483 <a href="http://www.inoveon.com">www.inoveon.com</a></td>
</tr>
<tr>
<td>Joslin Diabetes Center</td>
<td>One Joslin Place, Boston, MA 02215 617-732-2400 <a href="http://www.joslin.org">www.joslin.org</a></td>
</tr>
<tr>
<td>Vanderbilt University Ophthalmic Imaging Center</td>
<td>Contact: Lawrence Merin, RBP, FIMI, FO PS, FBCA 333 Commerce Street, 2nd flr EDC, Nashville, TN 37201 <a href="mailto:Lawrence.merin@vanderbilt.edu">Lawrence.merin@vanderbilt.edu</a> <a href="http://www.retinopathyscreening.org">www.retinopathyscreening.org</a></td>
</tr>
</tbody>
</table>
ed screening. Initial studies support this assumption. However, there are significant differences between the services offered by these groups, and some are reflected in Table 2. Table 3 suggests questions that might be asked by those considering use of these services.

Vision loss from DR is largely preventable and treatable. Given that nearly all patients with type 1 diabetes and over 60% with type 2 diabetes develop DR, there is a compelling need to change the current pattern of poor compliance with recommendations for regular eye examinations. In-office methodologies will improve accessibility to cost-effective screening examinations and will change the paradigm to a shared responsibility and increased understanding of this devastating microvascular complication among diabetes care providers. A recent United Healthcare of Texas letter summarizes: “Barriers to accessing specialty health care are well known, and translate into low rates of screening eye examinations. Many patients with diabetes never walk into an eye clinic until they are symptomatic, and at that stage, visual outcomes may be compromised. Digital screening programs do not replace comprehensive eye exams, but rather ensure that those patients are identified at a time when diabetic retinopathy is most amenable to treatment. Digital retinal examination performed by the primary physician will capture many more patients not likely to be seen by an ophthalmologist or optometrist. Introducing digital retinopathy exam capability within your physician practice will facilitate the detection of retinopathy in settings more convenient to the patient.” (United Healthcare of Texas, letter, October 19, 2004).

Collaboration in managing DR will be enhanced as primary diabetes care physicians become more involved in the ocular health of their patients. The convenience for patients will enable a larger percentage of patients to reach the goal of annual retinal eye examinations.

Neil Brooks, M.D., is a primary care physician in private practice in Vernon, Conn. He is the chair of the medical/scientific advisory board of EyeTel Imaging, Inc. and is a paid advisor to the company. He is a member of the editorial board of Diabetic Microvascular Complications Today. He can be reached at 860-729-1830 or Nbrooksmd@aol.com.


### Table 2. Characteristics of Services Offered

<table>
<thead>
<tr>
<th>System/Service*</th>
<th>Acquire Images</th>
<th>Ophthalmic Photographer</th>
<th>Automated Focus</th>
<th>University Affiliation</th>
<th>Dilated Pupils</th>
<th>Image Fields</th>
</tr>
</thead>
<tbody>
<tr>
<td>EyeTel DigiScope</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>11</td>
</tr>
<tr>
<td>Inoveon iSite</td>
<td>Yes†</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>7</td>
</tr>
<tr>
<td>Joslin Vision Network JVN</td>
<td>Yes†</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>3</td>
</tr>
<tr>
<td>Vanderbilt VOIC</td>
<td>Yes†</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>2</td>
</tr>
</tbody>
</table>

* Each of these systems provides analysis and reports to primary care physicians
† Integrates off-the-shelf cameras into system

### Table 3. Questions

1. Will the information provided by this examining procedure be adequate for referral decisions? Does the system meet Health Plan Employer Data and Information Set (HEDIS) specifications?
2. What type of space and/or equipment or special facilities will this procedure require?
3. What are staffing requirements? Will staff need additional training? Will additional staff be necessary?
4. How much time will this procedure take? How quickly will results be available?
5. What reaction have patients had with this procedure?
6. How does this procedure compare to procedures presently being used?
7. Is the procedure safe and reliable?
8. Has a validation study been performed comparing the system to the gold-standard 7-field fundus photographs?
Study compared predictive accuracy of screening by family physicians with ophthalmologists’ assessments using retinal diagrams.

Reviewed by James M. Gill, MD, MPH

Family physicians were fairly accurate in screening patients for diabetic retinopathy (DR) when using standardized criteria and a nonmydriatic ophthalmoscope.

Reporting in the *Annals of Family Medicine*, James M. Gill, MD, MPH, and colleagues said that while the nonmydriatic ophthalmoscope is not sufficiently accurate to replace routine referrals for all patients with diabetes, it could be used to improve care for those who fail to get routine eye screenings. Dr. Gill is with Christiana Care Health Services in New Castle County, Del.

“It is widely recommended that all persons with diabetes mellitus should be regularly screened for [DR],” wrote Dr. Gill. “Most adults with diabetes, however, do not receive this screening. One reason is that most persons with diabetes receive their care in primary care settings, and most primary care physicians have neither the expertise nor the equipment to screen accurately for retinopathy.”

Two recent developments have improved the potential for DR screening in primary care to be more accurate and more efficient. A simple prediction rule has been developed that predicts vision-threatening DR by viewing lesions in a limited number of retinal fields, Dr. Gill wrote. Second, a new-generation ophthalmoscope has been developed that allows retinal field viewing without dilation.

Dr. Gill and colleagues conducted a study of 11 family physicians from the Delaware Academy of Family Physicians comparing the predictive accuracy of their screening against an ophthalmologist’s assessments using retinal diagrams. A total of 28 standardized patients from a local ophthalmologist’s practice were used to represent a spectrum of retinal abnormalities.

The family physicians participated in a 4-hour training program in the eye watch screening criteria (EWSC), which are based on the examination of two standard retinal fields. The physicians were also trained to use the PanOptic scope, which provides a view of the retina three to five times that of a standard direct ophthalmoscope without dilation. The physicians used the EWSC and the PanOptic scope to assess seven patients with DR.

The family physicians’ assessments of whether the patients required referral to an ophthalmologist were compared with the reference standard of retinal diagrams. Dr. Gill and colleagues found that the mean sensitivity for the family physicians was 87% (97% CI, 0.83-0.91) with a specificity of 57% (95% CI, 0.46-0.68).

According to the reference standard, 75% of the patients should have been referred for further evaluation; the mean referral rate by the family physicians was 76%, with a range of 41% to 93%. Kappa statistic for the 11 physicians ranged from 0.06 to 0.70, according to Dr. Gill, with a weighted mean of 0.43 (95% CI, 0.39-0.47).

Overall agreement between the ophthalmologists’ assessment using the PanOptic ophthalmoscope and the reference standard retinal diagrams was similar with a κ=0.48.

“This level of accuracy represents an improvement when compared with techniques that are currently used by primary care physicians,” Dr. Gill wrote. “Previous studies have shown that primary care physicians using standard direct ophthalmoscopy correctly identify <50% of serious retinopathy even when they dilate the eyes. When using standard direct ophthalmoscopy without dilation, even those experienced in ophthalmoscopy have rates for correct assessment of only 50%.”

This study shows a promising way to improve screening for DR, Dr. Gill concluded. If results of this study can be replicated in a larger group, this may be one technique that primary care physicians can use to improve care for their patients with diabetes.

James M. Gill, MD, MPH, is from the Christiana Care Health Services in New Castle, Del. He can be reached at jgill@christianacare.org.