Diabetic retinopathy is the leading cause of blindness in adults in the United States, and early screening/treatment may preserve vision. This study examined the feasibility of using non-mydriatic digital retinal imaging (DRI) for retinopathy screening in a busy family medicine residency program at the point of care using a nurse-driven protocol.

**METHODS:** We compared the number of diabetics screened during a 1-year period before and after DRI protocol implementation. We also determined the prevalence of retinopathy, assessed patient satisfaction with the alternative screening process, and tracked ophthalmologic appointment compliance for patients referred because of abnormal screening results.

**RESULTS:** Screening approximately doubled from 161 patients/year before the protocol to 330 patients/year after protocol implementation. However, DRI screening had no impact on ophthalmologic appointment compliance; only 58% of 153 patients referred for ophthalmologic evaluation because of positive screening findings completed their referral appointment. Seven cases needing urgent ophthalmologic treatment were identified. Satisfaction with primary care retinopathy screening was high.

**CONCLUSIONS:** Use of a nurse-driven protocol for digital retinal imaging at the point of care dramatically improves rates of annual retinopathy screening in academic family medicine practice and can identify patients who require subspecialty referral. However, DRI screening does not improve visit compliance rates with ophthalmologists for evaluation and management.

(Fam Med 2012;44(3):159-63.)

Diabetic retinopathy is the leading cause of blindness in US adults, with an estimated 12,000–24,000 new cases of blindness each year due to this disease.1,2 Laser photocoagulation therapy can preserve vision and prevent blindness if retinopathy is caught early.3,5 These studies demonstrate, however, that photocoagulation therapy can only prevent further vision loss, and it does not restore lost eyesight. Therefore, screening is essential to finding sight-threatening retinopathy before permanent vision loss occurs. As the incidence of diabetes increases dramatically, we need improved and efficient mechanisms to screen for diabetic retinopathy that are acceptable to both patients and providers.

Current recommendations are for dilated and comprehensive eye exams by eye care professionals, generally on an annual basis.6,7 There are significant barriers to obtaining the recommended screening. The most recent update of the *Standards of Medical Care in Diabetes* acknowledges the increasing amount of data that support digital retinal imaging (DRI) as an appropriately sensitive screening tool for retinopathy. The sensitivity and specificity of DRI has also been shown to be excellent.7 In certain populations, this process may be more effective than the traditional process of referral for ophthalmologic examination since many barriers to care can be overcome.

Through use of a chronic disease registry in a primary care clinic at a family medicine residency program, the authors identified low diabetic retinal screening (DRS) rates (~20%) in this clinic population. Barriers to the referral process (provider dependent) and to obtaining the eye exam (patient dependent) were found. By specifically addressing these barriers, the overall goal was to improve screening rates in this clinic population and find more retinopathy at early stages, thus enabling early treatment and sight preservation. However the optimal strategy for implementing a point-of-care DRI screening program in a large primary care residency training program with multiple providers and staff remains unclear. There are specific barriers to quality care in academic.
medical centers that undermine appropriate screening practices as well as the provision and intensification of appropriate care. These include a continual influx of new learners, multiple part-time providers due to teaching demands of faculty, and a patient population that is often more chronically ill and that has more varied insurance coverage compared to private practices. The advent of pay-for-performance and financial incentives associated with quality of care have made systematic management of diabetic populations a priority.

The goal of this study was to demonstrate the feasibility of an alternative screening process for a diabetic population in a busy family medicine residency practice in an academic medical center. We hypothesized that this redesigned process would help our practice increase diabetic retinopathy screening rates while training our learners in population management. We also sought to determine the prevalence of retinopathy in the screened population, assess patient satisfaction with the alternative screening process, and determine appointment compliance for subsequent ophthalmologic evaluation of patients with abnormal screening results. Previous studies of DRI have been aimed at measuring sensitivity and specificity or the cost-effectiveness of the procedure and not how the process is implemented in academic primary care. This is the first study to use a nurse-driven protocol for point-of-care testing to both improve overall screening rates as well as find sight-threatening retinopathy in an academic family medicine practice.

Methods
Overall Design
The present study was designed as a before and after comparison of diabetic retinopathy screening (DRS) rates and associated eye findings before and after introduction of a DRI system, used in collaboration with a nurse-driven protocol and standing order system for point-of-care testing in an academic family medicine practice. The study was designed to examine whether this intervention strategy resulted in improvement in the number of diabetic patients with a completed annual DRS. The time periods compared were 1 year prior to introduction of the system/protocol and 1 year following this introduction.

Patients
Inclusion criteria included all active (at least one visit/year) adult patients with an established medical record diagnosis of diabetes mellitus, being seen during the 2-year study period at the academic family medicine center site. There were no exclusion criteria.

Digital Retinal Imaging System and Training
The Retasure® (Digital Healthcare Inc, Wake Forest, NC) DRI System was selected for implementation in this study. This system combines a non-mydriatic digital retinal photography unit with a computerized data capture program and remote evaluation by a retinal specialist. This system allows digital retinal images to be collected in consenting patients without dilation by a trained individual in the primary care office. The system also allows these images to be transmitted in a HIPPA-compliant fashion to a remote retinal specialist for evaluation, and the resulting evaluation report is then included in the electronic medical record system. Patients with identified eye pathology were then referred to a local ophthalmologist for further evaluation and management. Two nurses in the academic practice were extensively trained in the collection of digital retinal images by an experienced technician. Images and findings were also stored for review with residents and students.

Nurse-driven Protocol/IRB
During the 1-year period involving implementation of the DRI system, a standing order was developed by the clinic director that mandated that all staff nurses and medical assistants review the electronic medical record of all diabetic patients at the time of intake and, if no diabetic retinopathy screening examination was documented in the last 12 months, the patient was referred to one of the two trained nurses for DRS during the same office visit. The nurse-driven flow diagram for patient evaluation and management is shown in Figure 1. The study was approved by the University Medical Center IRB and informed consent for participation was obtained by one of the two trained nurses at the time of screening.

Data Collected/Statistics
Data collected from medical records included demographics (age, race, sex, health insurance) and the total number of patients who had completed recommended annual DRS in the year prior to implementation (from June 1, 2007, to May 31, 2008) and in the year following implementation (from June 1, 2008, to May 31, 2009) of the DRI system and protocol. Data on annual DRS during both of these 1-year periods was abstracted from medical record documentation of an eye examination via either the DRI system (during the implementation year) or via a visit to a local eye care professional (during either year). Clinical data abstracted also included the most recent hemoglobin A1c (HbA1c) and blood pressure (BP) values. Among patients who completed an examination via DRI, the proportion of patients with positive eye screening findings was documented. Using reports from the retinal specialist, eye screening findings were categorized as no retinopathy, pre-proliferative retinopathy, proliferative retinopathy using the Early Treatment of Diabetic Retinopathy Scale (ETDRS). Among patients with positive eye screening findings from the DRI system, the proportion referred for evaluation and the proportion who actually completed an initial evaluation by an ophthalmologist was also captured from medical records review.
in both the primary care and ophthalmologist offices. In addition, the satisfaction of patients with being screened in a primary care setting using the DRI system was evaluated using a 10-point Likert scale ranging from 0 being the worst eye examination experience and 10 being the best eye examination experience. Each patient was asked to complete the written satisfaction question following completion of the DRI examination, and responses were collected by the office staff. The brief questionnaire also requested patient-specific comments about their eye examination experience.

**Results**

Demographic characteristics for diabetic patients in both time periods are given in Table 1 and did not differ significantly in the two time periods. In the control period (from June 1, 2007, to May 31, 2008), before implementation of the nurse-driven DRI protocol, approximately 447 diabetic patients (19% of the practice’s diabetics) had documentation of an eye examination in their medical record. During this same time period 283 diabetic patients had a provider-generated referral to an eye care professional in their medical record, and 163 of the 283 patients (57%) actually completed the eye examination at the eye care professional’s office. Findings revealed that 24% of these 163 patients had background retinopathy, and 2.2% had proliferative retinopathy.

In the nurse-driven point-of-care DRI pilot intervention period (from June 1, 2008, to May 31, 2009), a total of 659 diabetic patients had

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**Table 1: Demographic Characteristics of Diabetic Patients in the Two Study Periods**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Control Period</th>
<th>Intervention Period</th>
</tr>
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<tbody>
<tr>
<td>Mean age (year) ± SD</td>
<td>57.2 ± 14.3</td>
<td>58.2 ± 14.8</td>
</tr>
<tr>
<td>Mean systolic BP (mmHg) ± SD</td>
<td>133.2 ± 20.2</td>
<td>131.4 ± 19.6</td>
</tr>
<tr>
<td>Mean HbA1c ± SD</td>
<td>7.6 ± 2.1</td>
<td>7.6 ± 2.6</td>
</tr>
<tr>
<td>% Female</td>
<td>64%</td>
<td>63%</td>
</tr>
<tr>
<td>% African American</td>
<td>65%</td>
<td>66%</td>
</tr>
<tr>
<td>% White</td>
<td>33%</td>
<td>33%</td>
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SD—standard deviation, BP—blood pressure
a documented eye examination in their medical record (29% of the practice’s diabetics). Of these 659 patients, 274 (42%) were screened with the new point-of-care DRI system and constituted our evaluation group. Among those screened with the point of care DRI system (n=274), reports from the retinal specialist revealed that there was no retinopathy in 207 patients (76%), background retinopathy in 52 patients (19%), pre-proliferative retinopathy in 12 patients (4%), and proliferative retinopathy in three patients (1%). Unreadable images were occasionally obtained during the early implementation phase, but this improved with increased experience of the nurses completing the examinations. All patients in whom new diabetic retinopathy findings were identified reported that they had not seen an eye care professional in more than 12 months, and in some cases it had been many years since they had obtained a dilated eye examination despite recommendations from their provider. The mean HbA1c level in this subgroup with positive retinopathy findings was 8.3 compared to 7.6 in the screened patients with normal eye findings.

Of the 274 DRI screened patients, 153 (56%) were identified by the retinal specialist with either diabetic retinopathy or other eye findings requiring subsequent referral to a local ophthalmologist for further evaluation and management. Only 89 of these 153 referred patients (58%) kept the appointment and completed the recommended ophthalmologic examination. Findings at referral ophthalmologic examination revealed seven patients (4.6% of the 153 referred patients, 2.5% of the overall 274 DRI screened patients) with proliferative retinopathy requiring definitive treatment. An additional 136 patients were referred directly to an ophthalmologist without in-house DRI screening, and approximately the same percentage (78/136 (57%)) kept their referral appointment and completed the recommended ophthalmologic examination. Figure 2 summarizes these results from the control and intervention periods.

Figure 2: Diabetic Patients Who Completed Diabetic Retinal Screening in Control and Intervention Periods

<table>
<thead>
<tr>
<th></th>
<th>Control (n=447)</th>
<th>Intervention (n=659)</th>
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<tbody>
<tr>
<td>Eyecare visit without referral</td>
<td>36%</td>
<td>25%</td>
</tr>
<tr>
<td>Direct referral</td>
<td>13%</td>
<td>13%</td>
</tr>
<tr>
<td>DRI then referral</td>
<td>64%</td>
<td>50%</td>
</tr>
</tbody>
</table>

We received 116 complete responses to our patient satisfaction survey (116/274 or 42% response rate) regarding satisfaction with the point of care DRI examination. The average satisfaction score on the 10-point Likert scale was 8.6 ± 3.2. Many favorable comments were made by patients including being impressed with the convenience of getting the procedure done at the point of care without a separate eye appointment. Many commented on the economic benefit to them of obtaining eye screening at their regular diabetes management visit. Several were impressed by the availability of this high tech equipment in the primary care office.

Discussion
This paper demonstrates the feasibility of implementing point-of-care DRI using a nurse-driven protocol in a busy academic family medicine residency program to increase the proportion of diabetic patients receiving recommended DRS. In this study, the number of patients receiving appropriate screening examinations approximately doubled from the control period to the intervention period. Importantly, this primary care-based approach was particularly successful...
in providing screening for individuals who may not get regular dilated eye examinations by an eye care professional. The demographic factors and clinical findings, including higher mean Hba1c levels, among those with positive DRI screening suggest an at-risk population for progressive retinopathy. Data from the ACCORD study\(^1\) have clearly shown that inadequate glycemic and lipid control is associated with greater progression of diabetic retinopathy.

The overall prevalence and distribution of diabetic retinopathy subtypes was similar to that described for the United States by Zhang et al.\(^1\) Similar to Zhang et al we found a significant burden of diabetic retinopathy among rural African Americans with diabetes, and the present point-of-care approach may partially address this by making recommended screening more readily accessible to this vulnerable population.

This approach specifically addresses both patient and health system barriers by providing screening at the same time as the primary care visit with no additional co-payment. Many of our patients with positive DRI screening reported that they had not visited an eye care professional in the last 12 months and, in some cases, for many years, despite provider recommendations to do so. This suggests that the non-mydriatic nature of the DRI screening and the lack of a second trip with an additional co-payment at an eye care professional’s office were valued by these at-risk diabetic patients. However, we note that these same barriers may persist for the subset of patients who were identified as having retinopathy that required ophthalmologist evaluation and management. The percentage of patients who actually showed up for this dilated eye examination (58\%) was almost exactly the same as the visit adherence rate during the control period before the DRI equipment was in use. Of interest, the patients’ knowledge from DRI screening that they were suspected of having an eye condition that required further assessment did not appear to increase the percentage of patients who successfully kept their ophthalmology appointment. This fact underscores the persistent nature of patient and health system barriers to completing recommended diabetic eye care.

The use of a nurse-driven protocol in this study appeared to be an important component of the intervention. Quality improvement initiatives that augment the role of office nursing staff by giving them the opportunity, under protocol and a standing order policy, to facilitate needed care processes, may lead to improved practice-wide care outcomes and may be associated with improved employee satisfaction. In addition, the present study suggests that this point-of-care process was acceptable to patients in that a sample of patients surveyed rated their satisfaction with the DRI process as very high. Comments suggested that sophisticated eye screening equipment of this nature in a primary care office was a surprise to some patients.

This study has a number of limitations. The study did not have a concurrent control group studied during the same time period. However, we did examine similar patients (see Table 1) from two different time periods. In addition, we studied unselected patients that may not have been representative of the entire diabetic population and used a simple one-question satisfaction instrument without demonstrated reliability and validity. This study did not examine the cost-effectiveness of this intervention. Despite these limitations, the study is the first to demonstrate the feasibility of using DRI technology in an academic family medicine setting in conjunction with a nurse-driven protocol.

In conclusion, DRI can be successfully used in busy academic family medicine residency practice environments, and, when combined with a nurse-driven protocol for use, results in improved screening and disease detection rates. However, DRI screening and even knowledge of positive eye findings does not appear to impact visit compliance rates for subsequent ophthalmologic evaluation and management.

**Acknowledgments:** This paper was presented at the 2010 Society of Teachers of Family Medicine Annual Spring Conference, Vancouver. The authors acknowledge the assistance of Amy Shipley and JacQuetta Foushee.

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