Diabetic retinopathy is the leading cause of new blindness among Americans 20 to 74 years of age. Yet it is estimated that timely treatment of diabetic retinopathy can decrease blindness and visual impairment by 90 percent. Screening has been demonstrated to be of great potential benefit for this condition. Annual dilated ophthalmic examination of diabetics at risk for ocular complications has been shown to be a highly cost-effective means of identifying treatable diabetic retinopathy. However, national studies indicate that only 50 percent of at-risk diabetic patients undergo annual dilated examination as suggested by American Diabetes Association guidelines. Preventive ophthalmic surveillance of high-risk diabetic individuals is even worse in urban underserved communities. Baker and colleagues demonstrated that 62 percent of diabetics presenting for the first time to an inner-city public hospital eye clinic had clinically apparent ophthalmic disease; 40 percent had advanced ocular disease, including 6.8 percent of the sample who were legally blind on presentation.

Clinical investigations evaluating the use of 45° nonmydriatic fundoscopic cameras—with selective pupillary dilation for documenting the status of diabetic retinopathy—indicate that this modality may provide reliable onsite photodocumentation in the primary care setting. Through use of a telemedicine linkage and digital image capture of the fundus, an ophthalmic specialist can screen for diabetic retinopathy and triage patients accordingly in the primary care setting, thereby averting the chance of the patient being lost to followup using the traditional referral mechanism. To test this hypothesis, we set out to investigate the relative accuracy (sensitivity and specificity) of a telemedicine-based strategy for diabetic retinopathy screening.

All type I or type II diabetic subjects 18 years of age or older attending one of three remote telemedicine clinic sites were recruited to participate in this study. Each study participant underwent nonstereoscopic 45° retinal photographs through undilated or pharmacologically dilated pupils using a nonmydriatic digital retinal camera. The desired 45° fundoscopic image included an area above and below the temporal arcades, as well as areas just nasal to the disk and temporal to the macula. The nonmydriatic digital retinal cameras were linked to desktop personal computer (PC) workstations (CPU Intel 200 MHz) equipped with Flashpoint 3030 video capture cards (Integral Technologies, Indianapolis, IN). The PC workstations used to capture the retinal images at the remote telemedicine clinical sites were linked via a switched asynchronous transfer mode network to a central file server at Drew University via a T1 connection. The patient data directory on the central file server was mapped to the client PC telemedicine workstations at the remote clinics. Thus, all patient data (i.e., retinal images) captured at the remote clinics were stored directly on the central file server and retrieved for review by the consulting ophthalmologists from this central location. Hierarchical password assignment and 128-bit data encryption were used to maintain data security and patient confidentiality. Data security and patient confidentiality were further enhanced by conducting all telemedicine interactions over a closed network. Telemedicine interactions were conducted predominantly in a store-forward format. In some instances, real-time interactions were used in conjunction.

Digital retinal images were evaluated with respect to six standard grading criteria for diabetic retinopathy. Because the focus of this project was to evaluate digital retinal imaging as a screening tool, the unit of analysis for the primary objective of this project was the patient. The primary outcome measure was the assigned referral status of the patient on the basis of the level of retinopathy detected on the digital retinal image. Any patient found to have moderate-to-severe nonproliferative diabetic retinopathy, proliferative diabetic retinopathy, or suspected clinically macular edema in either eye met the criteria for referral. The reviewer was asked to assign a patient referral status on the basis of the level of retinopathy inferred from the digital retinal images.

A total of 375 eyes of 185 diabetic patients underwent digital retinal photography. Of these 185 diabetic patients, 87 (47 percent) underwent both digital photography and in-person evaluation.
The majority of study participants reported never having a dilated fundus examination (56 percent). Of the 86 patients who reported having had a previous eye examination, 38 (44 percent) reported that their last examination occurred more than 2 years ago. Twenty-three patients (12 percent) reported never having an eye examination.

Of the 87 patients who underwent digital retinal photography in conjunction with in-person evaluation, digital retinal photography exhibited a detection rate for threshold diabetic retinopathy essentially equivalent to that of in-person evaluation. Using the referral criteria established for the purposes of this study, 25 (29 percent) of the 87 patients who underwent dual evaluation met the criteria for referral on the basis of evaluation of the digital retinal images, whereas 29 (33 percent) of the 87 patients met the criteria for referral based on in-person evaluation.

When compared with in-person evaluation for identifying the level of retinopathy present, digital retinal imaging showed relatively low sensitivity for detecting early nonproliferative diabetic retinopathy and high sensitivity for detecting moderate-to-severe and proliferative diabetic retinopathy. With respect to identifying any level of retinopathy, digital retinal photography demonstrated a sensitivity of 81 percent and a specificity of 98 percent. In patients manifesting early nonproliferative diabetic retinopathy on in-person evaluation, digital retinal photography demonstrated a significantly lower sensitivity of 52 percent. The specificity, however, remained high at 94 percent. In patients manifesting moderate-to-severe or proliferative diabetic retinopathy on in-person evaluation, digital photography demonstrated 86 percent sensitivity and 100 percent specificity. In patients identified with clinically significant macular edema, the sensitivity and specificity of digital retinal imaging were 83 percent and 95 percent, respectively.

The findings from this study suggest that onsite digital photodocumentation in the primary care setting—coupled with telemedicine linkage to an ophthalmologist—appears to be an effective strategy for diabetic retinopathy screening, but additional evaluation is needed. On the basis of the referral criteria established for the purpose of conducting this study, we found that digital retinal photography yielded similar results to in-person evaluation for detecting threshold diabetic retinopathy. Although the findings of this study offer a potential solution for improving ophthalmic surveillance of diabetics, several factors must be considered before the findings of this study can be generalized to other populations and other settings. First, review of the digital images was conducted using a well-structured clinical protocol that was designed to have a low threshold for referral. The grading criteria used in this study to categorize the various levels of diabetic retinopathy were more stringent than criteria utilized in previous studies to evaluate the efficacy of nonmydriatic fundoscopic photography for diabetic retinopathy screening. The more stringent grading criteria were designed to minimize the referral threshold and thereby increase the sensitivity of digital retinal imaging for detecting visually significant diabetic retinopathy. Other aspects of the study design used to enhance the disease detection rate included intensive training of the remote-site personnel recruited to take the photographs and the liberal use of pharmacologic dilation to increase the photographic yield and enhance image quality.

In summary, the transmission of digital retinal images from the primary care setting to an ophthalmic specialist through a telemedicine linkage appears to be a viable solution for increasing the ophthalmic surveillance of at-risk diabetic patients, particularly among medically underserved populations that lack appropriate access to eye care, such as the inner-city population we serve.

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