Improving Diabetic Retinopathy Screening Ratios Using Telemedicine-Based Digital Retinal Imaging Technology

The Vine Hill Study

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OBJECTIVE — To evaluate the impact of a telemedicine, digital retinal imaging strategy on diabetic retinopathy screening rates in an inner-city primary care clinic.

RESEARCH DESIGN AND METHODS — This retrospective cohort study included all diabetic patients aged ≥18 years (n = 495) seen at Vine Hill Community Clinic between 1 September 2003 and 31 August 2004. Patients were offered ophthalmology referral or digital screening. Patients choosing referral received the next available (within 3 months) appointment at the Vanderbilt Eye Clinic; patients choosing digital screening were screened during the visit.

RESULTS — Retinal screening was documented for 293 (59.2%) patients, a significant improvement compared with the 23% baseline rate. Of 293 patients screened, 92 (31.4%) were screened in ophthalmology, and 201 (68.6%) were digitally screened. Among the 201 digitally screened patients, 104 (51.7%) screened negative and were advised to rescreen in 1 year, 75 (37.3%) screened positive and were nonurgently referred to ophthalmology, and 22 (11.0%) screened positive for sight-threatening eye disease and were urgently referred for ophthalmological follow-up. Digital imaging technical failure rate was 0.5%. Referral status was associated with race/ethnicity (χ^2 = 7.9, $P < 0.02$) with whites more likely to screen negative than non-whites (62.4 vs. 47.8%, respectively). Sight-threatening disease among non-whites (14.7%) was more than double that observed for whites (5.9%).

CONCLUSIONS — Digital imaging technology in the primary care visit can significantly improve screening rates over conventional methods, increase access to recommended diabetic eye care, and focus specialty care on medically indigent patients with greatest need.

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Diabetic retinopathy (DR) is a leading cause of adult blindness in the U.S. despite the availability of treatments that postpone or prevent most diabetes-related vision loss (1,2). The Centers for Disease Control and Prevention (1) report that 21 million Americans have diabetes, which is a 14% increase in prevalence from 2003 to 2005, and estimates link as many as 24,000 new cases of blindness to DR per year. Increases in DR-related disabilities are anticipated due to population aging and the rapid increase in prevalence of diabetes. Future forecasts are not encouraging, as 41 million Americans have pre-diabetes, and 1 of 3 Americans born in the year 2000 are expected to be diagnosed with diabetes during their lifetime. The increasing incidence of diabetes is expected to be even greater among minority subgroups (e.g., one of two Hispanic Americans born in 2000) with concurrent increases in comorbid conditions such as DR. Increasing prevalence of type 2 diabetes among younger age groups may exacerbate these predictions (3).

DR denotes a spectrum of microvascular changes associated with hyperglycemia. It is typically asymptomatic before the onset of vision loss but is detectable with the standard annual dilated retinal examination and visual acuity assessment recommended by the American Diabetes Association (4). Yet, using the traditional approach to detecting diabetic eye disease, which involves referral to an ophthalmologist by the patient's primary care provider, only about half of all diabetic patients in the U.S. receive the recommended annual screening for DR and, by extension, access to effective treatment (5,6). Racial/ethnic minorities and other groups with limited access to care are less likely to receive screening or treatment, disproportionately higher rates of diabetes-related vision loss among these population subgroups are well documented (2,7,9), and elimination of health disparities is a major public health goal in the U.S. Thus, there is a clear and growing need for innovative population-based strategies for early DR detection.

The majority of diabetes care is delivered within a primary care system ill-equipped to manage chronic care needs but amenable to redesign to more effectively address gaps such as those observed for DR screening (10). At Vine Hill Community Clinic (VHCC), we instituted clinical improvement initiatives (provider education and clinical reminders) to increase DR screening rates during 2001 and 2002; however, despite our efforts, data abstracted from medical records of 400 diabetic patients during this time revealed a screening rate of only 23%.

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Abbreviations: DR, diabetic retinopathy; VHCC, Vine Hill Community Clinic; VOIC, Vanderbilt Opthalmic Imaging Center.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

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Digital retinal imaging is a promising and efficacious technology designed to identify patients with retinopathy in nonspecialty settings such as primary care (11,12). The technology has vastly improved patient access to DR screening in the U.K. (13,14) and in Australia (15,16), but it is used less frequently in the U.S. We hypothesized that offering telemedicine-based, digital retinal imaging during the primary care visit as an alternative to ophthalmology referral would increase DR screening rates at VHCC and provide actionable information about patient needs previously unavailable because of suboptimal screening rates. In this study, we evaluate the impact of offering such a choice in a primary care clinic serving medically indigent patients. We also assess the relationships between demographic characteristics and patients' screening and follow-up status.

RESEARCH DESIGN AND METHODS

— A retrospective cohort design was used, and the sample consisted of all ($n = 495$) adult patients (aged ≥18 years) diagnosed with diabetes as designated by *International Classification of Diseases* (ICD-9 code 250), who were seen for any care at VHCC between 1 September 2003 and 31 August 2004. VHCC is a nurse-managed primary care clinic located in inner-city Nashville, Tennessee. For 15 years, the clinic has provided community-based health care and outreach services to vulnerable citizens. Supported by Vanderbilt University School of Nursing, advanced practice nurse faculty at the clinic manage care for a population of 10,000 patients, 90% of whom are TennCare (Tennessee's Medicaid-managed care program) recipients, and provide an annual average of 13,000 patient visits. Patients' self-reported race/ethnicity is 45% white, 45% black, and 10% other at the clinic. About one-quarter of adult visits are related to diabetes. After we determined the 23% baseline DR screening rate in 2002, a telemedicine-based, digital retinal imaging program was implemented at the clinic in June 2003. Approval for this study was obtained from Vanderbilt University's Institutional Review Board.

Subjects in the study were 60.6% female ($n = 330$), 43.6% white ($n = 216$), 40.0% black ($n = 198$), 6.9% other ($n = 34$), and 9.5% unknown ($n = 47$). Mean ± SD age of the sample was 52.1 ± 11.8 years. For analytic purposes, we dichotomized race/ethnicity into white and non-white groups and categorized age into groups of patients aged 18–44 years, 45–64 years, and ≥65 years.

The retinal imaging system comprised a Canon CR6-45NM with Canon EOS D-30 camera back, a Dell Latitude D-600 laptop computer, and software designed to manage digitized clinical information (Digital Healthcare EyeQ Lite). The computer was connected via T-1 broadband link to the Vanderbilt Ophthalmic Imaging Center (VOIC) reading center, a division of the Vanderbilt Eye Institute supervised by a retinal specialist. A desktop visual acuity testing machine (Stereo Optical Optec 800X with ETDRS test target and pinhole accessory) standardized visual acuity testing. Clinic support staff (medical assistants) received 4 h of instruction on the screening process (pharmacologic dilation, patient education, and photography) followed by 2 h of training on equipment use and digital image production. A concurrent quality assessment program was implemented to report quality of image focus, field definition, selection of correct retinal fields, and avoidance of lash artifacts to the screening staff. This feedback produced consistent, gradable images.

All patients underwent standardized visual acuity testing using the Optec 800X and were offered a choice of either digital retinal screening during their visit or referral to ophthalmology. Patients choosing referral to ophthalmology received the next available appointment (within 12 weeks) at the Vanderbilt Eye Clinic. For patients choosing digital retinal screening, one drop of 1% tropicamide was instilled into each eye for dilation. Each patient's identifying information was entered into the computer and two digital photos (one fovea centered and one optic nerve centered) of each eye were obtained. At the end of the clinic day, clinic personnel uploaded all patient images obtained during the day to VOIC.

Each morning, the previous day's images were extracted at VOIC and examined for signs of diabetic changes by expert technical graders using a masked, two-reader process. We used gradability criteria set forth in the National Health Service's Diabetic Retinopathy Screening Workbook (17). Ungradable images included those in which vessels were not clearly detectable within one-disc diameter of the center of the fovea, small vessels were not clearly visible on the optic nerve, or vessels could not be clearly seen in more than one-third of the total field. Markers for diabetic eye disease included microaneurysms, dot-blot hemorrhages, lipid exudates, and other vascular changes. The number and distribution of markers were evaluated for severity, and standard recommendations for rescreening in 1 year or for more urgent ophthalmology follow-up care were generated using the Diabetic Retinopathy and Diabetic Macular Edema Disease Severity Scales (18) as a guide. Referral guidelines were also standardized for decreased visual acuity and increased cup-to-disc ratios: *1*) negative or subclinical rescreen in 1 year (no retinopathy, mild nonproliferative diabetic retinopathy [NPDR], or moderate NPDR without central macular involvement); *2*) nonurgent, i.e., referral to ophthalmology within 8 weeks (visual acuity ≤20/50 with pinhole, cup-to-disc ratio ≤0.6); or *3*) urgent, i.e., ophthalmological referral within 30 days (moderate NPDR with exudates within one-disc diameter of fovea, severe NPDR, proliferative DR with neovascularization and no history of previous laser therapy) or within 7 days for high-risk proliferative DR (disc neovascularization, preretinal or vitreous hemorrhage, or history of previous laser therapy). All recommendations were entered into the patient's electronic medical record within 24 h. A VOIC retinal specialist arbitrated on the one occasion when the two readers disagreed on image interpretation.

An advanced practice research nurse abstracted data from electronic medical records of 495 diabetic patients seen at VHCC for any care during the 12-month study period. Data included age in years, patient-reported race/ethnicity (black, white, other, unknown, or not reported), sex, documented evidence of dilated retinal screening within 12 months (either digital image or ophthalmology report), and results of retinal screening. Interrater reliability was assessed in a randomly selected sample of 25 records, which were resurveyed on all data by the project director. Discrepancies were identified in <1% of the data values reviewed, and these discrepancies were corrected.

Postintervention screening rate and 95% CIs were calculated and compared with the baseline rate. χ^2 analysis was used to compare characteristic differences between screened and nonscreened groups for the entire sample and to compare characteristic differences among follow-up screening status groups for patients receiving the digital retinal screening. Data were analyzed using SAS

Table 1—*Documented retinal screening rates associated with patient's choice of retinal screening method* (n = 495)

Patient's choice of screening method	Number of patients	Documented screening
Digital screening during the primary care visit	201 (40.6)	201 (100)
Referral for ophthalmologic examination	294 (59.4)	92 (31.3)

Data are *n* (%).

Version 9.1 for Windows statistical software package (SAS Institute, Cary, NC).

RESULTS — Of 495 patients offered the choice of either digital retinal screening or referral to an ophthalmologist, 40.6% ($n = 201$) chose digital screening, all of whom received that screening; 59.4% ($n = 294$) chose referral to an ophthalmologist, of whom only 31.3% ($n = 92$) subsequently received retinal examination as documented in their medical records (Table 1). Thus, results of digital retinal screening or formal ophthalmologic examination were documented for 293 (59.2%) patients. The 95% CI was 54.7–63.6%, which was a significant improvement compared with the baseline screening rate (23%). There were no age, race/ethnicity, or sex differences between screened and nonscreened groups. Follow-up information was not available for the 40.8% ($n = 202$) of patients who chose ophthalmology referral but subsequently had no documented screening in the record.

Of the 201 digitally screened patients, 104 (51.7%) were evaluated as screen negative or as having subclinical microvascular changes and were advised to be rescreened in 1 year (Table 2). Seventy-five patients (37.3%) were evaluated as screen positive and were referred for nonurgent ophthalmological examination within 8 weeks. Of these, two-thirds ($n = 50$) were referred because of decreased visual acuity, and one-third ($n = 25$) were referred because of possible glaucoma (based on cup-to-disc ratio measurements) or other microvascular changes. Twenty-two patients (11.0%) were evaluated as screen positive and in need of urgent referral based on disease severity. These patients were referred for ophthalmological evaluation within 7–30 days.

Follow-up status of digitally screened patients was not associated with sex or age, but follow-up status was significantly associated with race/ethnicity ($\chi^2 = 7.87$, $P < 0.02$) (Table 2). Whites were more likely to have a negative screen (62.4%) than non-whites (44.0%), and non-whites were more likely to need urgent referral (14.7%) than whites (5.9%).

Initial retinal images obtained for 1 (0.5%) of the 201 digitally screened patients were evaluated as not fully gradable because of technical error (pupil misalignment) and not associated with media opacities (cataract, corneal problems, or vitreous hemorrhage). This patient was included in the nonurgent referral group, the primary care provider was notified, and the patient was successfully referred and rescreened by an ophthalmologist.

CONCLUSIONS — DR is the most common and preventable contributor to vision loss experienced by persons with diabetes. To reliably identify patients who have crossed the threshold between early, non-vision-threatening microvascular changes and serious changes that occur in more advanced disease, annual dilated retinal examination is recommended and is considered the standard of care (4). With digital retinal screening, patients with often asymptomatic DR (including retinal neovascularization and macular edema) can be identified and triaged to ophthalmic care for laser photocoagulation and other therapeutic modalities to slow disease progression. Left undetected, the disease worsens and treatment becomes more complex, less effective in maintaining vision, and more costly. Patients can be unaware of vision loss until the disease is sufficiently advanced such that complex interventions such as vitrectomy and retinal detachment surgery may be required.

The digital DR imaging program implemented in our study meets screening criteria for disease established by the World Health Organization (19). Successful screening must address an important health problem with a prolonged latent stage for which reliable and effective strategies for detection and treatment are available. The screening must be cost-effective and reach the target population with minimum inconvenience to patients. The screening and treatment for DR is one of few interventions linked to measurable health benefits and cost-savings (20,21).

Table 2—*Patient characteristics, digital DR screening results, and follow-up recommendations* (n = *201*)

	Negative or subclinical rescreen in 1 year	Positive/nonurgent referral: ophthalmology follow-up in 8 weeks	Positive/urgent referral: ophthalmology follow-up in 7–30 days	χ^2 (df)	*P*
Patients	104 (51.7)	75 (37.3)*	22 (11.0)		
Sex					
Female	69 (56.56)	40 (32.78)	13 (10.66)	3.12 (2)	0.21
Male	35 (44.30)	35 (44.30)	9 (11.40)		
Race					
White	53 (62.36)	27 (31.76)	5 (5.88)	7.87 (2)	0.02
Non-white	51 (43.97)	48 (41.37)	17 (14.66)		
Age (years)					
18–44	31 (57.41)	18 (33.33)	5 (9.26)	1.70 (4)	0.79
45–64	62 (50.82)	47 (38.52)	13 (10.66)		
≥65	11 (44.00)	10 (40.00)	4 (16.00)		

Data are *n* (%) unless otherwise indicated. *Includes one patient with ungradable digital image rescreened by ophthalmology.

Sensitivity and specificity for DR detection by digital retinal imaging range between 80 and 100% and consistently exceed those of routine ophthalmoscopy (14,22–24). Digital retinal imaging has been adopted as the DR screening standard in the U.K. (25), but digital DR screening applications in the U.S. are sparse. Our findings suggest that the application of digital imaging technology, in conjunction with established population-based strategies for reaching a greater proportion of diabetic patients, is an efficient strategy to overcome traditional barriers to diabetic eye care.

Alleviation of health disparities is a major public health initiative in the U.S. In the present study, non-whites were significantly more likely than whites to require urgent ophthalmic treatment. Others have also reported higher rates of severe diabetes-related eye disease among minority racial and ethnic groups. Kirk et al. (26) reported consistent suboptimal diabetic eye examination rates for all groups in a review of 27 studies published between 1993 and 2003; however, disparities were pronounced among African Americans and Hispanics, with these groups significantly less able to access specialty care. Additionally, Wong et al. (27) recently reported significantly higher rates of DR among black and Hispanic patients compared with both white and Chinese patients in a national sample of 778 individuals participating in the Multi-Ethnic Study of Atherosclerosis. We believe digital DR screening within the context of the primary care visit is an appropriate intervention for improving access to care for these high-risk groups.

Inclusion of visual acuity testing and pharmacological pupil dilation are characteristic of good fundus photography screening program fidelity and thus strengthen our findings. The primary limitations of this study are related to external and internal validity. Because patients at only one inner-city primary care clinic were assessed, generalizability is limited. The lack of a comparison group limits definitive cause-and-effect statements, but we know of no historical events that occurred between the baseline survey and our outcome measure that could account for the magnitude of the effect found (23–59%). It is also highly unlikely that the provider education and reminders introduced before this intervention could have produced delayed effects of this magnitude. Further, we acknowledge that establishing the effectiveness of a screening program requires evaluation of impact on treatment and patient outcomes. Regrettably, we did not have access to other clinical markers for diabetes (e.g., A1C and blood pressure) in this study, and, while it is possible that some patients sought follow-up care elsewhere, we believe this to be highly unlikely due to their indigent circumstances. These measures should be included in future research. Nevertheless, this study demonstrates the usefulness of the technology for improving access to care and generating data on service use and resource needs for diabetic eye screening and treatment heretofore unavailable for underserved populations. Given the promise of our findings of significantly improved screening rates and the <1% technical error rate, we believe more controlled studies are warranted.

Vision loss and blindness from DR are significant and growing public health problems in the U.S. Notwithstanding existing shortcomings in our capacities for DR screening and treatment, even greater challenges are ahead. The traditional, specialty-based model often does not meet chronic diabetes-related eye care needs, particularly for the medically vulnerable. There are multiple barriers associated with delivering care to indigent patients, and DR screening addresses one of many complex care needs of patients with diabetes. Mobility of the population, resource constraints, and funding pressures also must be addressed if effective systems of care for the underserved are to be developed.

Despite the rapidly increasing prevalence of diabetes, there is surprisingly no nationwide DR-screening initiative in the U.S. (28). This study demonstrated that in a primary care setting serving medically indigent patients, a telemedicine-based digital imaging strategy using commercially available equipment and software can significantly improve DR screening rates. Secondary prevention of vision loss and population-based triage to appropriate levels of care can address increasing demands for limited resources and contribute to improved patient outcomes in our most vulnerable populations.

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