Importance. The use of a nonmydriatic camera for retinal imaging combined with the remote evaluation of images at a telemedicine reading center has been advanced as a strategy for diabetic retinopathy (DR) screening, particularly among patients with diabetes mellitus from ethnic/racial minority populations with low utilization of eye care.

Objective. To examine the rate and types of DR identified through a telemedicine screening program using a nonmydriatic camera, as well as the rate of other ocular findings.

Design, Setting, and Participants. A cross-sectional study (Innovative Network for Sight [INSIGHT]) was conducted at 4 urban clinic or pharmacy settings in the United States serving predominantly ethnic/racial minority and uninsured persons with diabetes. Participants included persons aged 18 years or older who had type 1 or 2 diabetes mellitus and presented to the community-based settings.

Main Outcomes and Measures. The percentage of DR detection, including type of DR, and the percentage of detection of other ocular findings.

Results. A total of 1894 persons participated in the INSIGHT screening program across sites, with 21.7% having DR in at least 1 eye. The most common type of DR was background DR, which was present in 94.1% of all participants with DR. Almost half (44.2%) of the sample screened had ocular findings other than DR; 30.7% of the other ocular findings were cataract.

Conclusions and Relevance. In a DR telemedicine screening program in urban clinic or pharmacy settings in the United States serving predominantly ethnic/racial minority populations, DR was identified on screening in approximately 1 in 5 persons with diabetes. The vast majority of DR was background, indicating high public health potential for intervention in the earliest phases of DR when treatment can prevent vision loss. Other ocular conditions were detected at a high rate, a collateral benefit of DR screening programs that may be underappreciated.
Diabetes Eye Screening in Minority Populations

Original Investigation Research

The Innovative Network for Sight (INSIGHT) study was approved by the institutional review boards of The Johns Hopkins University, University of Alabama at Birmingham, University of Miami, Wake Forest University, and Wills Eye Hospital (WEH) and followed the tenets of the Declaration of Helsinki. Participants provided informed consent, written at some sites and oral at other sites. Participants did not receive financial compensation. The protocol has been described in detail (A. Murchison, MD, MPH, written communication, October 8, 2014); our focus in the present study was on the rates of DR and other ocular findings identified through the screening. Of the 4 study sites, 3 were based in outpatient clinics serving uninsured or underinsured populations with high representation of persons from ethnic/racial minorities. The fourth site was an outpatient pharmacy setting in an urban environment. Persons aged 18 years or older with a diagnosis of diabetes mellitus (type 1 or 2) were invited to participate in a DR screening. Birmingham, Alabama (University of Alabama at Birmingham), was one clinical site. The Cooper Green Mercy Health Service’s internal medicine clinic is a county-operated safety-net clinic serving county residents regardless of their ability to pay or insurance status. English-speaking patients with diabetes were invited to participate from January 26 to July 24, 2012. The second clinic site was in Miami, Florida (University of Miami). The Jessie Trice Community Health Center is a federally qualified health center serving the uninsured or underinsured population in the county. Participants were recruited via flyers and by referral from local physicians. Participants spoke English, Spanish, or Creole. Screening was conducted from March 2, 2012, to April 11, 2013. The third clinic site was in Winston-Salem, North Carolina (The Johns Hopkins University). The Downtown Health Plaza affiliated with Wake Forest School of Medicine, serves low-income persons residing in the downtown area. Physicians and staff invited English-speaking individuals with diabetes to participate in the screening, which was conducted from May 5, 2013, to November 14, 2014. The pharmacy site was in Philadelphia, Pennsylvania (WEH). The outpatient pharmacy at Thomas Jefferson University Hospital is located in an urban environment. English- or Spanish-speaking persons with diabetes were invited for screening by pharmacy personnel when picking up medications for diabetes, by family practice physicians in nearby offices, and with flyers or advertisements in newspapers. The screening program took place from December 5, 2011, to March 29, 2013.

Participants completed a questionnaire providing contact information, demographics, age when first told by a physician that they had diabetes, whether they knew their hemoglobin A₁c level, when they had received their most recent dilated eye examination, smoking status, and health insurance status. They were asked if they needed assistance in making an eye appointment once their DR screening results were available.

Ocular imaging was performed by trained technicians using a nonmydriatic camera with autofocus (model AFC-230, Nidek Inc). Dark fabric was draped over the participant’s head and/or...
The intrarater κ coefficient for other ocular pathology (A. Murchison, MD, MPH, written communication) viewed by an ophthalmologist; none was found to have signs of age-related macular degeneration, and glaucoma. A 10% random sample of images labeled as diabetic retinopathy (DR) was graded according to a protocol using anterior segment photographs. Established algorithms were used to identify other ocular disease including hypertensive retinopathy, age-related macular degeneration, and glaucoma. A 10% random sample of images labeled normal by the readers with respect to DR findings was 0.72 with 88.8% agreement. The interrater κ coefficient for DR findings was 0.62 (95% CI, 0.51-0.73) with agreement of 84.1%. Readers assigned preliminary grades within 48 hours of image upload.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>R0</td>
<td>None of the signs listed for the other grades</td>
<td>Reevaluate in 12 mo with either eye care specialist or photographic screening</td>
</tr>
<tr>
<td>R1</td>
<td>Background DR</td>
<td>Refer to eye care professional</td>
</tr>
<tr>
<td>R2</td>
<td>Preproliferative DR</td>
<td>Refer to ophthalmologist promptly</td>
</tr>
<tr>
<td>R3</td>
<td>Proliferative DR</td>
<td>Refer to ophthalmologist promptly</td>
</tr>
<tr>
<td>M</td>
<td>Maculopathy</td>
<td>Refer to ophthalmologist promptly</td>
</tr>
<tr>
<td>P</td>
<td>Photocoagulation</td>
<td>Refer to eye care professional</td>
</tr>
<tr>
<td>U</td>
<td>Unclassifiable/ungradable</td>
<td>Refer to eye care professional</td>
</tr>
</tbody>
</table>

Table 1. Classifications Used to Grade DR Presence and Severity Based on the National Health Service Grading Classification System

Abbreviations: DD, disc diameter; DR, diabetic retinopathy.

* Adapted from Harding et al.42
+ The American Academy of Ophthalmology’s recommendations for diabetic patient follow-up.43

the room was darkened. Technicians were trained in camera use by the WEH telemedicine reading center staff and followed the manufacturer’s standard operating instructions. Three photos were taken per eye: anterior segment, nasal fundus, and temporal fundus. If the images were blurry, additional images were taken to achieve satisfactory quality. Images were generated using NAVIS-Lite software (Nidek Inc) and uploaded to a Health Insurance Portability and Accountability Act (HIPAA)-compliant secure website at WEH. Trained/certified readers at WEH read the images. A HIPAA-compliant proprietary software program (Diabetic Retinopathy Disease Management, version OTM1; Ocular Telehealth Management) was used for image management and report generation. Readers evaluated images using the National Health Service’s DR grading classification system (Table 1).47 Cataracts were graded according to a protocol using anterior segment photographs. Established algorithms were used to identify other ocular disease including hypertensive retinopathy, age-related macular degeneration, and glaucoma. A 10% random sample of images labeled normal by the readers was reviewed by an ophthalmologist; none was found to have signs of ocular pathology (A. Murchison, MD, MPH, written communication, October 8, 2014). The intrarater κ coefficient for

Results
A total of 1894 persons participated in screening (Table 2), with 31.7% of the sample from Birmingham, 32.1% from Miami, 26.7% from Philadelphia, and 9.5% from Winston-Salem. The participants’ mean age at each site was similar, ranging from 53 to 55 years. There were more women (63.1%) than men (36.9%). Most individuals screened were of ethnic/racial minorities (88.0%); however, there were site differences. In Birmingham, most participants were African American (84.3%); in Philadelphia and Winston-Salem, approximately 68% of the participants were African American with a larger percentage of whites than in Birmingham, whereas in Miami 63.6% were Hispanic, Haitian, or Cuban American and 33.9% were African American, with very few whites screened.

Abbreviations: DD, disc diameter; DR, diabetic retinopathy.

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Results from the reading center’s review of images were summarized in a screening report sent electronically to the participant’s site. The coordinator mailed a letter to participants describing the results and recommended follow-up care based on the findings; the recommendations were derived from the American Academy of Ophthalmology’s guidelines42 for DR follow-up and were based on the presence and degree of DR (Table 1). The letter to participants whose reports recommended normal (nonurgent) referral or follow-up (grades R0, R1, or P) encouraged them to seek an appointment for a dilated eye examination on an annual basis. For abnormal results for grade R1 or P DR, the letter encouraged the participant to seek an appointment for a dilated eye examination “within the next few months.” For individuals whose reports recommended prompt referral to an eye care professional owing to DR or maculopathy (grades R2, R3, or M), the coordinator telephoned the participant within 48 hours of receiving the report from the reading center, informed the participant of the recommendation, and offered to schedule an appointment with an ophthalmologist. Up to 5 telephone attempts were made to reach a participant. A letter was also mailed to the participant with results and recommendations. Patients with images deemed to be ungradable due to poor quality were advised to return for a dilated examination. Results were sent to the patient’s primary care physician upon patient request.

Data Management and Statistical Analysis
Each site oversaw its own data entry and securely transmitted the information to the data coordinating center at the University of Alabama at Birmingham, where a multisite database was constructed and data analysis was performed. Analysis of variance and χ² tests were used to compare continuous and categorical data, respectively, across groups. P ≤ .05 (unpaired, 2-tailed test) was considered statistically significant.

Results
A total of 1894 persons participated in screening (Table 2), with 31.7% of the sample from Birmingham, 32.1% from Miami, 26.7% from Philadelphia, and 9.5% from Winston-Salem. The participants’ mean age at each site was similar, ranging from 53 to 55 years. There were more women (63.1%) than men (36.9%). Most individuals screened were of ethnic/racial minorities (88.0%); however, there were site differences. In Birmingham, most participants were African American (84.3%); in Philadelphia and Winston-Salem, approximately 68% of the participants were African American with a larger percentage of whites than in Birmingham, whereas in Miami 63.6% were Hispanic, Haitian, or Cuban American and 33.9% were African American, with very few whites screened.
The mean age at diabetes diagnosis by self-report was 44.5 years (Table 2). The mean duration of diabetes was approximately 8 to 10 years in Birmingham, Miami, and Philadelphia but longer (14.6 years) in Winston-Salem. Approximately 25% of the sample reported smoking or using other tobacco products. The percentage of patients with health insurance was wide, ranging from 22.6% in Miami to 79.2% in Philadelphia. There was site variability for when participants reported receiving their last dilated eye examination. About half of the Birmingham participants reported having a dilated eye examination within the past year, but at other sites, those reporting eye care within the past year ranged from 25.5% to 32.4%. In Miami, almost half (45.0%) of the participants reported receiving a dilated examination 2 or more years ago, and 11.2% reported never having a dilated examination. Approximately 30% to 42% of the participants at Miami, Philadelphia, and Winston-Salem indicated that they knew their hemoglobin A1c level compared with only 13.5% in Birmingham.

Across the sample, 21.7% of the participants had DR (background, proliferative, and/or maculopathy) in either eye: Birmingham, 23.5%; Miami, 24.1%; Philadelphia, 15.8%; and Winston-Salem, 24.3%. Figure 1 shows the percentage of participants with specific types of DR in either eye. At Birmingham, Miami, and Winston-Salem, background DR was present in 22.2% to 23.7% of the participants, but the percentage was lower in Philadelphia (14.4%). Among patients with DR, the vast majority had background DR (94.1%), with rates of preproliferative and proliferative DR ranging from 0% to 11.4% depending on the site. The proportion of participants with maculopathy in the overall sample was 9.3%. The rate of maculopathy was similar in Birmingham, Miami, and Winston-Salem, ranging from 9% to 11%, but was approximately half that rate in Philadelphia (5.4%). Depending on the site, no or very few participants displayed evidence of having had photocoagulation treatment. Twelve percent of the patients had at least 1 ungradable image in 1 or both eyes.

The prevalence of DR (regardless of type) was similar for whites vs the combined ethnic/racial minority groups (22.6% vs 21.6%, *P* = .74) and was unrelated to time since the last dilated eye examination (*P* = .44), smoking or other tobacco product use (*P* = .46), health insurance status (*P* = .21), or knowledge of hemoglobin A1c level (*P* = .82). Participants with DR had a longer duration of diabetes than did those without DR (mean [SD], 13.7 years [9.8] vs 8.8 [10.4], *P* < .001).

Almost half of the participants (44.2%) had ocular findings other than DR, with variability across the sites. Miami had double the prevalence of other ocular findings (61.1%) compared with Birmingham (29.7%), with Philadelphia and Win-
stion-Salem falling between the 2 extremes. Table 3 lists the percentage of other ocular findings in either eye by type in the overall sample. The most common other finding was cataract, present in almost one-third of the participants. Hypertensive retinopathy, followed by cotton-wool spots, glaucomatous or optic nerve findings, and age-related macular degeneration, were also noted. Pterygium notations were much less common, and nevus was rare. Figure 2 displays the types of other ocular findings stratified by site.

Discussion

One in 5 patients with diabetes screened positive for DR using a telemedicine screening program in 4 urban settings in the United States serving predominantly ethnic/racial minority populations. This rate is similar to that reported in 2 previous US studies also using telemedicine reading centers. Three of our sites based at primary care clinics had very similar rates of DR (23.5%-24.3%), but the Philadelphia site (a pharmacy) was lower (15.8%), which could result from many factors. Patients who fill prescriptions may be more medically adherent and less likely to have diabetes complications. Philadelphia had a higher percentage of participants with health insurance (79.2%) compared with other sites (34.6%). Patients with diabetes having health insurance are more likely to have better glycemic control and lower rates of diabetic eye disease compared with those lacking health insurance. Given the lower DR rate in the pharmacy cohort, it may be that screening in this setting will have lower yield than in outpatient clinics, which is an issue for further study.

The majority (94.1%) of persons with DR had background DR, which is similar to the percentage determined in screening programs in primary care settings in the United States and Canada. Patients with proliferative disease were rare at all sites. From a public health perspective, our finding that most patients with DR had background DR, with almost 10% of persons with diabetes screened having maculopathy, indicates a high potential for intervention in DR’s earliest phases when treatment can prevent vision loss. In contrast to a UK report, the rate of DR detected in our program was not higher among ethnic/racial minorities compared with the rate in whites of European origin. At first glance, this finding may seem paradoxical since the prevalence of DR among African Americans and Hispanics in the United States is higher than that in whites of European descent. However, only 12% of the participants in our study were white; this small sample size may have made it difficult to evaluate white vs ethnic/racial minority differences in our screening program.

Diabetic retinopathy was unrelated to smoking status, health insurance status, and knowledge of one’s hemoglobin A1c level. These findings highlight the potential benefit of a DR screening program for the general population of people with diabetes rather than a more narrow approach for a selected subpopulation. However, DR was more likely to be present in persons with longer durations of diabetes, which is a well-established risk factor. This finding underscores the importance for screening programs to target individuals with long-standing diabetes.

The rate of self-reported dilated eye care use in the past year was low for the overall sample (32.2%), suggesting that DR screening in these settings could fulfill a critical role for patients with diabetes not routinely accessing annual dilated eye examination care. There were interesting differences across sites in the reported dilated examination rates. In Birmingham, more than half (52.8%) of the participants reported having a dilated examination within the past year, whereas at the other sites, the dilated examination rate was considerably lower (25.5%-32.4%). Unlike the other sites, Birmingham’s county-operated health system has an ophthalmology clinic. The other primary care sites did not have on-site eye services. This distinction may have contributed to a higher eye care utilization rate among Birmingham patients since care was accessible on site. The situation was inverted in Miami, where almost half (45.0%) of those screened reported not having a dilated eye examination in 2 or more years, and 11.2% reporting never having one. Previously, the clinic had an on-site optometrist, but that service was closed prior to the start of the present study. It remains to be determined whether these factors influenced the lower rate of eye care utilization.

Almost half of the participants had other ocular findings. This finding is an important collateral benefit of DR screening.
programs since many ocular findings detected are potentially sight-threatening conditions (eg, cataract, glaucoma, and macular degeneration) that are amenable to vision-preserving treatments. The most common other ocular finding was cataract. Glaucomatous/optic nerve findings were the most commonly noted conditions in Birmingham, which is not surprising given the high percentage of African Americans in the sample (84.3%), who have a 4- to 5-times greater risk for glaucoma-associated disorders compared with whites.\(^5\) Pterygium occurred in more than 10% of the persons screened in Miami but was rare at other sites, which may reflect the higher risk of pterygium for persons residing closer to the equator or with prolonged UV light exposure.\(^5\) The rate of other ocular findings differed substantially among sites, with Miami having the highest rate at greater than 60%. In contrast, Birmingham had half the rate (approximately 30%). Although DR screening has the additional benefit of identifying other potentially sight-threatening conditions, the particular lesion types and their frequency in the population screened depends on demographics, lifestyle, and utilization of comprehensive eye services.

Study strengths include a focus on evaluating a DR screening program in urban settings that predominantly serve patients with diabetes from ethnic/racial minorities and uninsured or underinsured populations, an approach receiving only scant attention previously.\(^5\) Our target populations have among the lowest comprehensive eye care utilization rates in the United States, thus being at high risk for undetected DR. Screening incorporated a nonmydriatic camera that is rapid and less burdensome and a central reading center through telemedicine. Multiple sites allowed us to implement the program in diverse geographic locations. Study limitations include selection bias during enrollment; it is unknown whether those who participated vs those who did not were systemically different. Information is unavailable on the percentage of persons who declined participation. Although inclusion of 4 different sites enhances generalizability, the sites differed in many ways; factors contributing to site differences cannot be precisely determined but can be addressed in future research. One site had fewer participants than the others because of delayed startup. Although we have not focused on patient follow-up for recommended eye appointments, acuity screening, and patient satisfaction in this article, these issues will be addressed in subsequent reports.

### Table 3. Number and Percentage of Patients With Other Ocular Findings

<table>
<thead>
<tr>
<th>Other Ocular Findings</th>
<th>Total, No. (%) (N = 1894)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cataract</td>
<td>581 (30.7)</td>
</tr>
<tr>
<td>Hypertensive retinopathy</td>
<td>316 (16.7)</td>
</tr>
<tr>
<td>Cotton-wool spots</td>
<td>211 (11.1)</td>
</tr>
<tr>
<td>Glaucomatous or optic nerve findings</td>
<td>197 (10.4)</td>
</tr>
<tr>
<td>Age-related macular degeneration</td>
<td>174 (9.2)</td>
</tr>
<tr>
<td>Pterygium</td>
<td>90 (4.8)</td>
</tr>
<tr>
<td>Nevus</td>
<td>11 (0.6)</td>
</tr>
<tr>
<td>Miscellaneous*</td>
<td>101 (5.3)</td>
</tr>
</tbody>
</table>

*Miscellaneous findings are those that were noted on the screening reports in 5 or fewer participants at all sites. These included retinal scar, epiretinal membrane, myelinated nerve fibers, vitreous opacity, asteroid hyalosis, corneal findings, embolic material, glia, macular hole, choroidal folds, peripapillary atrophy, vein or artery occlusion, iris findings, melanocytoma, horizontal folds, retinal striae, and posterior vitreous detachment.

### Figure 2. Types of Other Ocular Findings in Either Eye

Percentage of the sample having other ocular findings in either eye stratified by site. AMD indicates age-related macular degeneration; Cat, cataract; CWS, cotton-wool spots; Glau ON, glaucomatous/optic nerve findings; Hyp Ret, hypertensive retinopathy; Misc, miscellaneous; and Pterygm, pterygium.
Conclusions

In a DR telemedicine screening program in urban clinic and pharmacy settings in the United States serving predominantly ethnic/racial minority populations, 1 in 5 persons with diabetes screened positive for DR. Most had background DR, suggesting a high potential for intervention in DR’s earliest phases when management can prevent vision loss. Other ocular conditions were detected in almost 50% of the patients screened, a potentially underappreciated feature of DR screening programs for preventing vision loss.

REFERENCES


