

# Addition of Primary Care–Based Retinal Imaging Technology to an Existing Eye Care Professional Referral Program Increased the Rate of Surveillance and Treatment of Diabetic Retinopathy

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**OBJECTIVE** — Digital retinal imaging is a relatively new technology that can be used to assess patients for diabetic retinopathy. We evaluated the impact of adding a primary care–based retinal imaging technology to an existing eye care professional referral process on the rate of surveillance and treatment of diabetic retinopathy in a large, well-defined patient population over a 5-year period.

**RESEARCH DESIGN AND METHODS** — We performed systematic performance evaluations using a computerized patient information system and a comprehensive procedure log to describe annually the patient population, the number of patients with diabetes, and the proportion of patients with diabetes who received appropriate eye care services, including surveillance and laser treatment for diabetic retinopathy before and after implementation of a digital retinal imaging system at the Phoenix Indian Medical Center Primary Care Medical Clinic.

**RESULTS** — The rate of annual retinal examinations increased from 50% (95% CI 44–56%) to 75% (70–80%;  $P < 0.000001$ ), representing a 50% increase in the retinal examination rate. The rate of laser therapy increased from 19.6 per 1,000 patients with diabetes in 1999 to 29.5 per 1,000 in 2003 for a 51% increase in the laser treatment rate.

**CONCLUSIONS** — Implementing retinal imaging technology in a primary care setting resulted in a significant increase in the rate of diabetic retinopathy surveillance and a proportional increase in the rate of laser treatment for diabetic retinopathy for a large patient population. Application of this technology in primary care settings holds the potential to extend sight-preserving care by increasing access to appropriate retinal care.

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**D**iabetic retinopathy develops in nearly all persons with diabetes and is a leading cause of new-onset blindness in the U.S. (1). The medical, social, and economic impact of diabetic retinopathy is substantial, but the impact can be lessened significantly through early intervention (2,3). Diabetic retinop-

athy is readily diagnosed by appropriate examination, but because the disease is typically asymptomatic in its early stages and for a variety of socioeconomic, geographic, or logistic reasons, as many as 50% of adults with diabetes in the U.S. do not receive the recommended frequency of examination, thus limiting the ability to provide effective early intervention treatment (4).

Digital retinal imaging is a relatively new technology that allows assessment of patients for diabetic retinopathy. Combined with telehealth programs, digital retinal imaging has the potential to extend sight-preserving care by increasing access to retinal evaluation. Although the clinical accuracy of several digital retinal imaging technologies has been validated (5–7), it is not known whether the use of such technology in community practice will result in an increase in the delivery of appropriate diagnostic and interventional services. We evaluated the impact of supplementing an existing referral program for diabetes eye care with a primary care–based retinal imaging technology in a large, well-defined patient population by reviewing systematically gathered data on the rate of retinal surveillance and laser treatment of diabetic retinopathy over a 5-year period.

## RESEARCH DESIGN AND METHODS

— The Phoenix Indian Medical Center (PIMC) is operated by the Indian Health Service (IHS), an agency of the U.S. Department of Health and Human Services. Eligible American-Indian and Alaska-Native people receive the available health care services without direct out-of-pocket health care expense. This evaluation was carried out at the Primary Care Medicine Clinic at PIMC. This clinic provides diabetes care with a staff that includes family practice and internal medicine physicians, nurse practitioners,

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**Abbreviations:** IHS, Indian Health Service; JVN, Joslin Vision Network; PIMC, Phoenix Indian Medical Center; SRC, Salt River Clinic.

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

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and diabetes nurse case managers. Eye care for people with diabetes is provided by referral to the eye clinic located on the same campus and staffed by professionals who deliver a broad range of optometry and ophthalmology services, including surveillance for diabetic retinopathy. Before implementation of retinal imaging technology, the eye clinic staff provided all diabetic retinopathy surveillance services.

We also analyzed the annual diabetic retinopathy surveillance rate using the same computerized audit process at the Salt River Clinic (SRC), a separate satellite clinic of PIMC. The SRC has an approximate primary care population of 850 people with diabetes. This satellite has comparable primary care services and referral process including scheduled on-site eye care but did not implement the Joslin Vision Network (JVN) imaging technology until a later date. Thus, the annual diabetic retinopathy surveillance rate at the SRC over the same time period served as a comparison against which to evaluate the impact of primary care–based imaging technology.

The JVN is a digital store and forward teleophthalmology system designed by the Joslin Diabetes Center (8). Briefly, the JVN is composed of a stereoscopic, non-mydiatic, digital video, color retinal imaging acquisition system. Digital images of the retina and pertinent patient health data are forwarded to an image reading center where a diagnosis and treatment plan tailored to the patient's level of diabetic retinopathy can be made. A validation study has shown substantial agreement ( $\kappa = 0.65$ ) between the clinical level of diabetic retinopathy assessed from the JVN images and assessment of 35-mm photographic images of the seven standard fields used in the Early Treatment Diabetic Retinopathy Study obtained through dilated pupils. Importantly, there was excellent agreement ( $\kappa = 0.87$ ) for findings that suggested referral to ophthalmology specialists (5).

In 2000, PIMC added the JVN program to its existing disease and case management programs. The image acquisition system was located in the primary care clinic and staffed by a full-time technician. Both actively scheduled imaging appointments timed to coordinate with primary care visits and opportunistic walk-in imaging opportunities were used to obtain retinal images for people with

diabetes. After implementation of the JVN program, referrals to eye clinic staff for both diabetic retinopathy surveillance and treatment continued, but the JVN program supplemented the eye care process by integrating a diabetic retinopathy surveillance and detection capacity into the Primary Care Medicine Clinic process.

### Evaluation and measurement

Since 1999, we have performed systematic performance evaluations using the computerized patient information system to describe, on an annual basis, the patient population, the number of people with diabetes, and the proportion of the diabetic patient population who receive appropriate medical services as measured against standards of care. The clinic population is defined as the total count of American-Indian and Alaska-Native people who have accessed the health care system within the preceding 3 years and who, at registration, listed their community of residence within a geographically defined administrative area of central Arizona known as the Phoenix Service Unit. From the clinic population, people with diabetes are identified by the presence of at least one ICD-9 code for diabetes (range 250.00–250.93) within a 1-year period of study. This use of an ICD-9 code to identify people with diabetes has been validated in this population and is consistent with the method used to define prevalence of diabetes within the IHS (9,10). The use of an audit to measure the standards of care for people with diabetes, including an annual diabetic retinopathy surveillance, has been used for many years (11,12). Either a retinal image or an appropriately documented examination by an eye care professional is credited as evidence of diabetic retinopathy surveillance. A computer application within the facility's information system allows for a completely electronic auditing process of an abstract of the clinical encounter.

To measure the use of laser treatment for diabetic retinopathy, we reviewed a well-maintained hand-tallied procedure log used by the ophthalmology staff to document laser treatments for diabetic retinal disease. We then matched the patients on the procedure log to patients from the population to ascertain the proportion of patients receiving laser treatments per year.

### Human subject protection

All data were collected as a part of routine care of the patient. Personal identifiers were not used in the analysis portion of the evaluation. The project was reviewed and publication approved by the Phoenix Area Institutional Review Board.

### Statistical analysis

Rates of diabetic retinopathy surveillance and laser treatment services were determined on an annual basis. Because the calculated prevalence of diabetes and the rate of laser treatment represent a full census of the population meeting our criteria, we did not calculate CIs for these rates. The annual audit of the standards of care was performed on a random sample of 322 patients at the Primary Care Medicine Clinic each year who met systematic inclusion and exclusion criteria, which provided an estimate of attainment of the performance measure at the facility within 10% of the true rate with a power of  $\geq 90\%$  (13,14). At the satellite clinic, records from 267 randomly selected patients who met the same criteria were audited. CIs for the annual rates of diabetic retinopathy surveillance were calculated using Epi-Info version 6.04 (Stone Mountain, GA).

**RESULTS**— Between 1999 and 2003, the number of people with diabetes within the geographic region who had at least one health care encounter in a year increased from 2,910 to 4,068, which corresponded to an increase in all-ages prevalence from 5.5 to 6.6% ( $\chi^2$  test = 80.9; trend  $P = 0.000001$ ) or a 20% increase in the rate of diabetes in the population.

The rate of annual diabetic retinopathy surveillance at the Primary Care Medical Clinic among people who met inclusion criteria started at 50% (95% CI 44–56%) in 1999. The annual rate increased as follows: 55% (50–60%) in 2000, 70% (65–75%) in 2001, to 68% (63–73%) in 2002, and 75% (70–80%) in 2003 ( $P < 0.000001$ ). This represents a 50% increase in the diabetic retinopathy surveillance rate among people with diabetes. The annual diabetic retinopathy surveillance rate at the satellite care clinic where the imaging technology was not available remained stable at 52% (46–58%), 59% (52–65%), 55% (49–61%), and 51% (45–57%) ( $P = 0.22$ ) during these same evaluation years. Multiplying

Table 1—Annual population census and retinal examinations and laser treatments at PIMC

	1999	2000	2001	2002	2003
Clinic population	52,991	55,566	58,233	59,963	61,871
Patients with diabetes seen in the year (n)	2,910	3,183	3,581	3,829	4,068
Patients with JVN images (n)	0	183	1072	1272	1605
Patients with diabetic retinopathy surveillance examination (mid-range of calculation) (n)	1455	1751	2507	2604	3051
Patients with laser treatments (n)	57	58	67	102	120
Rate of laser treatment rate per 1,000 diabetic people with diabetic retinopathy surveillance	39.2	33.1	26.7	39.2	39.3
Rate of laser treatment rate per 1,000 diabetic people receiving care at PIMC	19.6	18.2	18.7	26.6	29.5

the diabetic retinopathy surveillance rate by the diabetic patient population, the calculated number of people with diabetic retinopathy surveillance in 1999 was 1,455 (range 1,280–1,630) and increased to 3,052 (2,848–3,254) in 2003. The number of patients imaged in the primary care setting increased annually reaching 1,605 per year in 2003.

During this time, the number of individuals from the study population who received laser treatment within any year increased from 57 to 120. The rate of laser treatment among those who received any form of diabetic retinopathy surveillance remained relatively stable over this time. In 1999, the rate was 39 per 1,000 diabetic people screened, and in 2003 the rate was 39.3 per 1,000 diabetic people screened. However, in proportion to the 50% increase in the surveillance rate in the diabetic population, the rate of laser therapy among the diabetic population increased 51% from 19.6 per 1,000 people with diabetes in 1999 to 29.5 per 1,000 people with diabetes in 2003. These data are shown in Table 1.

**CONCLUSIONS**— In this large, geographically defined patient population, supplementing an existing eye care referral program by implementation of a primary care–based retinal imaging technology resulted in a significant increase in the surveillance rate for diabetic retinopathy. During this same time period, the rate of laser treatment for diabetic retinopathy in the diabetic patient population increased in proportion to the increase in the surveillance rate, suggesting that the combined use of the JVN technology and an eye care referral pro-

gram to improve surveillance resulted in an appropriate application of early intervention treatment. Implicit in this observation is that the diabetic patient population that previously did not have any surveillance activity did have pathology that would have otherwise not been identified without increased surveillance. To our knowledge, this is the first evaluation to demonstrate that supplementing a referral program for eye care by use of primary care–based retinal imaging technology in a community practice does result in an increase in the delivery of interventional services.

Several features of the setting for this study should allow the findings to be generalized to other health systems; however, some caution is appropriate. In the U.S., current evidence suggests that ~50% of the people with diabetes do not obtain the recommended periodic retinal examination, and 60% of individuals with diabetic retinopathy requiring sight-preserving laser surgery do not receive treatment (4). Despite differences in the structure of the health care system, the IHS experience is similar. As assessed by the annual Diabetes Care and Outcomes Audit, only ~50% of the IHS diabetic patient population receives such an examination. The examination rate at our facility before the intervention was identical to this historical IHS rate. Limited information is available about the level of adherence with treatment recommendations within the IHS system. However, similar to other studies, a 1993 study in an American-Indian community found that ~40% of people who were found to have proliferative diabetic retinopathy did not follow up for treatment (15). In that study, lim-

ited transportation was the major barrier to adherence. Thus, in this IHS setting, the pattern of adherence with eye care recommendations for surveillance and treatment was similar to most other settings in the U.S. This supports the ability to generalize the outcomes from this setting to other health care settings. However, this setting provided services to a unique ethnic population with special disease management programs tailored to their special health care needs; so, whether the outcomes will be similar in other populations with or without comparable disease management programs will require further study.

The methods used in this study have both strengths and weaknesses. To assess the change in delivery of services over time, our study used consistent, validated, annual assessments of the population and of the services provided. The prevalence of diabetes and rates of diabetic retinopathy surveillance are similar to those previously identified in the IHS (11,16). Also, the delay in implementation of the technology at the satellite clinic allowed for a very comparable comparison clinic. The diabetic retinopathy surveillance rate at this satellite clinic was the same at baseline as the clinic with the intervention but did not increase with time. This temporal observation supports our assertion that the implementation of the imaging technology resulted in the increased diabetic retinopathy surveillance rate. The rate of use of laser treatment in this particular population has not previously been reported. A number of factors influence the rate of laser treatment within a population, including the rate of retinal pathology and a variety of patient

and physician-related factors. Assuming that the laser treatment represents the prevalence of identified sight threatening diabetic retinopathy, the observed treatment rate of 39 per 1,000 people with diabetes is remarkably similar to the observed prevalence of proliferative diabetic retinopathy in a report of an American Indian patient population with type 2 diabetes (17). On the other hand, the use of a single facility's annual laser treatment log may incorrectly estimate the utilization of laser treatments. For example, we were not able to account for treatments provided at other facilities. Nor did our methods allow us to distinguish between incident versus repeated laser treatment. However, because we used consistent methods over the 5-year time period, the year-to-year comparisons should be valid. Furthermore, because of the unique setting and capacities of this IHS medical center, we feel it is likely that a large proportion of diabetic retinopathy surveillance and treatment for this population has been captured by the methods used in our evaluation. Our retrospective analysis also does not allow us to know definitively how frequently the retinal imaging technology was used as the principal surveillance modality. Given the number of images performed in 2003, retinal imaging could have provided as much as 53% of all diabetic retinopathy surveillance events in that year. However, whether retinal imaging technology alone could replace an eye care professional program cannot be known from this evaluation. Prospective studies should be designed to formally test whether digital retinal imaging could replace eye care professional surveillance programs.

After deployment of the JVN technology in our primary care setting, we observed a substantial increase in diabetic retinopathy surveillance that we did not see in the comparable satellite clinic. This result suggests that location of the acquisition system in primary care is a key factor in increasing surveillance. The location may have made access more efficient, or its presence may have affected patient awareness or provider recommendations for eye care. While such explanations logically link the location of the image acquisition system with increased surveillance, it does not necessarily explain the observed increase in therapeutic interventions. Several questions remain unanswered. Was the proportional in-

crease in the laser treatment rate a simple function of increased surveillance? Did the use of this technology influence a patient's decision to receive treatment, or did the availability of added technology alter the workload capacity or practice patterns of the eye care professional staff? Why was there a lag period between an increase in surveillance activities and an increase in interventions? Was a period of acceptance of the new technology required by professionals or patients? While these questions are not answerable in the current retrospective evaluation, they may be important issues to understand before the full public health potential of this technology can be translated into the many different health care systems and diverse patient populations that exist in the U.S. and around the world.

In summary, we have shown that implementation of digital retinal imaging technology in a primary care setting resulted in a significant increase in the rate of diabetic retinopathy surveillance and a proportional increase in the rate of laser treatment for diabetic retinopathy for a large patient population. Continued study of the application of this technology in a variety of health care systems and of the changes it makes in the behaviors and work processes of patients and health care professionals alike should help assure that advances in technology will translate into a promise of preservation of sight for people with diabetes.

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