Tele-ophthalmology Screening for Proliferative Diabetic Retinopathy in Urban Primary Care Offices: An Economic Analysis

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BACKGROUND AND OBJECTIVE: To determine whether tele-ophthalmology screening for proliferative diabetic retinopathy (PDR) can be cost-saving.

PATIENTS AND METHODS: Adults with diabetes presenting for routine medical care underwent nonmydriatic fundus photography with remote grading. Direct medical costs were estimated using the Medicare fee schedule in the base case, with Medicaid and commercial insurance rates used for low and high values, respectively. One-way and probabilistic sensitivity analyses were performed.

RESULTS: Of 99 participants, at least mild retinopathy was found in 24 (24.2%). Urgent consultation was recommended for eight participants (8.1%) for possible vision-threatening diabetic retinopathy, including two participants (three eyes) with PDR. In the base case, screening saved $36 per patient. A Monte Carlo simulation indicated that screening saved a median of $48 per patient.

CONCLUSION: A substantial burden of diabetic retinopathy was identified, most of which was undiagnosed. In a closed system, tele-ophthalmology screening for PDR is likely to be cost-saving across the range of scenarios explored.

INTRODUCTION

Diabetic retinopathy (DR) is the most common microvascular complication of diabetes mellitus. In the United States, approximately 40% of people with diabetes over the age of 40 years have DR, and 8% have vision-threatening disease. Early DR is often asymptomatic, so detection of disease is either incidental or by deliberate screening. Screening for DR has been proven to be valuable and cost-effective. Unfortunately, rates of adherence to published guidelines are poor, with only 35% to 60% of diabetic individuals receiving an annual dilated fundus examination in the U.S. As a way to increase adherence, nonmydriatic fundus photography and remote interpretation have become increasingly utilized for DR assessment, particularly in rural and remote settings. Tele-ophthalmology assessments are being widely studied in the U.S., with a particular emphasis on primary care or endocrinology offices as the site of photo acquisition, which may help improve systemic management.

Tele-ophthalmology may also be a way to control provider, payer, and societal costs. Depending on the structure of the intervention, a tele-ophthalmology assessment may prevent a separate physician encounter, pupillary dilation, and the associated travel and lost work time. The purpose of the present study was to evaluate a tele-ophthalmology assessment program in an urban primary care office, with special attention to economic considerations.
PATIENTS AND METHODS

In the first phase of the study, consecutive adult patients with diabetes presenting for routine medical care at an urban internal medicine practice were recruited to participate. Consenting participants underwent three-field nonmydriatic fundus photography following a standardized protocol using the Canon DGi Digital Imaging System (Canon USA, Lake Success, NY). Photographs were taken by medical technicians who received training from ophthalmic photographers. Photograph acquisition took approximately 7 to 10 minutes for each patient. Age, ethnicity, glycosolated hemoglobin level, insulin status, and time since last eye examination were also recorded.

The images were transmitted to a remote expert reader (RCS) via the Optolite secure telemedicine system (Digital Healthcare, Wake Forest, NC). Images were graded according to the United Kingdom (UK) National Screening Committee grading criteria. Image grading and report generation took approximately 5 to 6 minutes. Nondiabetic findings such as suspected cataract or glaucoma were also noted. Vision-threatening DR was defined as evidence of PDR or suspected macular edema due to hard exudate formation. Following the recommendations of Li et al., the medical provider receiving the report was then free to refer the patients for subspecialty care according to preexisting referral patterns.

The study was approved by the institutional review boards of the Wills Eye Institute and Thomas Jefferson University School of Medicine. All subjects provided written consent and Health Insurance Portability and Accountability Act authorization prior to enrollment. The study was conducted in adherence to the tenets of the Declaration of Helsinki.

In the second phase of the study, decision-tree analysis was used to estimate the costs of screening for PDR compared to no screening from a third-party payer perspective using six main parameters: (1) the cost of tele-ophthalmology screening per patient; (2) the prevalence of PDR; (3) the probability of a patient receiving any treatment given the presence of PDR in the screening and no-screening study arms; (4) the probability of receiving pan-retinal photocoagulation (PRP) given the presence of PDR; (5) the costs of treatment (ie, PRP, pars plana vitrectomy with endolaser PRP [PPV-EL], and pars plana vitrectomy repair of tractional retinal detachment with membrane peeling [PPV-MP]); and (6) the effectiveness of PRP. One-way and probabilistic sensitivity analyses were performed to explore the robustness of study findings.

Screening costs were assumed for the base case using the 2013 Medicare fee schedule for metropolitan Philadelphia for Current Procedure and Terminology (CPT) Code 92227 (“Remote imaging for detection of retinal disease”): $14.96 per patient. We also used low ($11.97) and high ($17.95) estimates of screening costs in sensitivity analyses, reflecting 80% and 120% of the Medicare rate, respectively. Per-patient treatment costs for the base case and high and low estimates for the sensitivity analysis were determined in a similar fashion and are presented in Table 2 (page 559). The base case estimate of the prevalence of PDR was derived from our study, with low (2%) and high (15.5%) estimates derived from the literature.

The probability of receiving any treatment given a diagnosis of PDR was 100% in both the screening and no-screening arms in the base case scenario. Based on the rate of 50% severe vision loss in the control arm of the Diabetic Retinopathy Study over 5 years, we examined the impact of reducing the probability of treatment in the no-screening arm to 50% in sensitivity analyses.

In the base case, we assumed that early diagnosis of proliferative retinopathy would result in the initiation of PRP and would obviate PPV-EL or PPV-MP. We also assumed participants would present for care in the no-screening arm only when symptomatic from either vitreous hemorrhage or tractional retinal detachment. Therefore, our base case estimate reflected that 100% of patients screened and found to have PDR would receive PRP; we assumed that 100% of patients with PDR in the no-screening arm would be
evenly distributed between PPV-EL and PPV-MP. In sensitivity analysis, we explored the impact assuming up to 25% of screening subjects present with more severe disease, requiring PPV-EL or PPV-MP. We also varied the probability of PRP from 0% to 20% in the no-screening arm to reflect the reality that some patients may only require PRP if they were to present with mild vitreous hemorrhage.

In the base case, we assumed that PRP was 100% effective. To account for efficacy results from the Early Treatment of Diabetic Retinopathy Study, we varied the effectiveness of PRP between 95% and 100% in sensitivity analyses, assuming that the 5% requiring additional treatment after PRP would be evenly distributed between receiving PPV-EL and PPV-MP.

Probabilistic sensitivity analysis was conducted using Monte Carlo simulation in TreeAge Pro 2009 Suite to estimate the mean cost of screening compared to no screening and the 95% uncertainty interval (UI) after 100,000 trials. The distributions selected for each parameter are noted in the table of input parameters (Table 2). Due to the sources of data for the sensitivity analyses, we could not assume normality of many parameters, and use of uniform and triangular distributions resulted in different expected values for many of the parameters than used in the base case scenario (Table 2).

### RESULTS

Phase 1 enrollment included 102 subjects (204 eyes). No images were received for three subjects, who were subsequently excluded (Table 1). One hundred seventy-eight of 198 of the eyes (89.9%) had images transmitted that were gradable.

At least mild DR was found in 24 of 99 subjects (24.2%). Of these, 21 (87.4%) reported “no retinopathy” or “unknown status.” The interpreting ophthalmologist recommended urgent consultation for eight subjects (8.1%, 12 eyes) for possible vision-threatening DR, including two subjects (three eyes) with suspected PDR. In addition to diabetic findings, five subjects (six eyes) were referred for pathology including suspected glaucoma and macular degeneration. The resulting prevalence of PDR in our study population was 2.02% (two cases in 99 subjects).

Figure 1 (page 557) depicts the decision tree developed to assess the economic impacts of diabetic retinopathy tele-ophthalmology screening compared to no screening in the base case scenario. In the base case, DR tele-ophthalmology screening resulted in $38 in costs per patient compared to $74 in the no-screening arm, thereby saving $36 per patient. Sensitivity analysis of the base case indicated that the most influential parameter in the model was the prevalence of PDR and that increased prevalence would correspond to greater cost savings in the screening compared to no-screening arm. After adjustment of the base case scenario to account for a 50% reduction in the probability of treatment in the no-screening arm, screening was associated with a $1 cost per patient.

Results from a Monte Carlo simulation model with 100,000 iterations varying our input parameters indicated that screening saved a median of $48 per patient compared to no screening, with a 95% UI, ranging from $–8 to $210. This represents a greater cost savings than found in the base case, likely due to changes in the mean (expected) values generated by the model as a result of distributions chosen (Table 2). Figure 2 (page 560) presents the histogram of results across all trials, with 93% of the estimates indicating that screening saved costs compared to no screening and also showing the 10th and 90th percentile values at $4 and $144 saved per patient, respectively.

### DISCUSSION

Our results demonstrate that tele-ophthalmology screening for PDR in a primary care office can be effective and potentially cost-saving. In the clinical phase of the study, the prevalence of PDR was 2%, and prior adherence to annual screening was 59.6%, both in line with published reports. Critically, the vast majority of images captured and transmitted were of sufficient quality to interpret. This result was despite only minimal training in fundus photography for the medical technicians, and despite acquisition through a nonmydriatic pupil. A substantial burden
of DR was identified, most of which was previously undiagnosed and one-third of which was possibly vision-threatening.

Assuming Medicare reimbursement rates for this catchment area, screening saved $36 in health care–related costs compared to no screening in our base case. Results from a Monte Carlo simulation supported these findings, with a median of $48 in costs saved in the screening arm. Ninety-three percent of 100,000 trials in this simulation study indicated that tele-ophthalmology screening was cost-saving compared to no screening.

Tele-ophthalmology retinal assessment for DR is being used with increasing frequency in rural and remote areas. Additionally, such systems have been adopted in the U.S. Veterans Administration and throughout the United Kingdom. The poor adherence rates to screening guidelines throughout the U.S. highlights the fact that nongeographic barriers to care are equally important in areas without an overt shortage of eye care providers.

Situating the DR assessment encounter in the primary care office is attractive for several reasons. First, this eliminates the burden of an additional visit for the patient, with associated travel costs, expenses, lost work time, etc. Additionally, the primary care provider may benefit from more immediate feedback in a consistent format from the screening, such that the results of the fundus photography would be available on the same timeline as the results of any other ancillary testing ordered at the encounter. Finally, telemedicine may give the primary care provider more control over an important health metric being used by the National Committee on Quality Assurance to determine incentives and future reimbursements. As with screening performed by a provider who does not treat the target condition, telemedicine can create a lag between the diagnosis of possible retinopathy and the treatment thereof. This issue is certainly not unique to telemedicine, but robust systems to prevent loss to follow-up need to be in place for any program.

As with other pilot studies, grant funding was used to acquire equipment and software. In order to scale up tele-ophthalmology programs, they will need to be self-sustaining. In programs designed like ours, the investment in the fundus camera is the major determinant of the overall cost of the project. In many health care environments in the U.S., the party who would make the investment in a fundus camera (ie, a physician, practice, or hospital) would not be the same party to realize of the cost savings associated with avoiding vitrectomy surgery (ie, the insurance company). It was for this reason that we chose a hypothetical closed system to be the perspective for our simulation. This decision is supported by the fact that closed or semi-closed systems such as the U.S. Veter-

<table>
<thead>
<tr>
<th>Description</th>
<th>Low Estimate</th>
<th>Base Case Estimate</th>
<th>High Estimate</th>
<th>Distribution Type</th>
<th>Expected Value</th>
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<td>Prevalence of PDR</td>
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<td>0.155</td>
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<td>Not varied</td>
<td>Uniform</td>
<td>1</td>
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<tr>
<td>Probability of screened patients receiving PRP</td>
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<td>0.875</td>
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<td>987.85</td>
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<td>Cost of PPV with laser</td>
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<td>3491.71</td>
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<tr>
<td>Cost of PPV with membrane peel</td>
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* Reflects assumptions of probabilistic sensitivity analysis.
ans Administration and the U.K. National Health System are leaders in the field of tele-ophthalmology. The results of our study indicate that tele-ophthalmology screening for PDR is likely to be cost-saving across the range of scenarios explored in our simulation. Because each screening saves $36 in the base case, the cost of a basic fundus camera ($10,000) could be recovered after 278 screenings. Economic analyses from other perspectives are needed to more fully characterize the costs to providers, patients, and society.

Because most tele-ophthalmology interventions rely solely on interpretation of fundus photographs, there is still a need for comprehensive eye services, so tele-ophthalmology cannot replace ophthalmic examination by an eye care specialist. In a real-world urban setting with adequate eye care resources, some individuals would seek eye care, and therefore may have PDR diagnosed, independent of tele-ophthalmology screening. Because our model is very sensitive to the prevalence of PDR in the population, if those seeking care were enriched for those with PDR, and the screening population likewise depleted of PDR, this could decrease the cost savings of tele-ophthalmology.

Our economic simulation used local reimbursement rates as inputs, which may reduce generalizability, but we believe the relative costs of the procedures will be fairly similar in many settings. The Medicare reimbursement for the telemedicine screening in particular ($14.96) for this newly recognized CPT code may not reflect the true costs for providing this service. As this reimbursement evolves, new analyses may be needed. This notwithstanding, high, medium, and low estimates for cost were varied randomly at each node in the Monte Carlo simulation, such that a high-cost PRP and low-cost PPV might be compared in one iteration, and vice versa in a subsequent iteration, increasing generalizability. We used prevalence data from our study for the base case in our simulation but incorporated well-established epidemiologic data into the model, increasing the generalizability of our result. Our model assumed one charge for PRP, but some payers may reimburse a reduced rate for subsequent treatments. Because Medicare and some commercial payers will allow for only one session to be billed in a 90-day “global period,” we chose to limit the cost in our model in this fashion. In other settings, full or reduced reimbursement for multiple sessions within a global period could alter the outcome of the cost-saving threshold.

In the present study, we limited the analysis to the screening for and treatment of PDR, which at present has a straightforward treatment algorithm dictated by decades-old clinical trials. An economic simulation allowing for the possibility of intravitreal anti-VEGF would be much more complex; intravitreal anti-VEGF was not included as it is not yet the standard of care for PDR. Likewise, a model concerning the treatment of diabetic macular edema would be of interest but also rather complex due to the various pharmacologic options, both FDA-approved and “off-label,” which can be performed at various frequencies in addition to macular laser photocoagulation. Moreover, in the Diabetic Retinopathy Study, PDR was the major cause of severe vision loss (defined as 20/800 visual acuity for 4 or more months), supporting our choice to focus on PDR for this simulation.

Tele-ophthalmology has primarily been applied in rural and remote areas with insufficient eye care resources. The present study supports a role for tele-ophthalmology in primary care offices in urban areas, where barriers to eye care are more complex. Moreover, this study supports the notion that the large start-up costs of tele-ophthalmology screening programs might be offset by the earlier detection of disease in some circumstances.
REFERENCES


