Automated Detection of Retinal Disease

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Given the rapidly growing prevalence of a number of common chronic conditions, especially diabetes, it is difficult to conceive how the resulting sharp increase in the demand for recurring diagnostic and therapeutic services can be met without significant increases in physician productivity. Information technology (IT) in particular has been advanced as a potential source of productivity increases in healthcare.[1] Another approach centers on the implementation of electronic health records (EHRs). Yet, some healthcare providers remain hesitant to adopt EHR systems because these typically entail large upfront costs of installation, training, and work flow redesign; can be difficult to use[2,3]; and to date, reports of the success of EHRs in increasing productivity have been mixed.[4,5] Another approach centers on the increased use of computer-aided diagnostics, which involves sophisticated computer algorithms that analyze a patient's medical images and mark suspicious elements of the images, thereby assisting the examining physician's detection of disease.[6] Because these systems continue to require image interpretation and data entry by physicians, however, their productivity potential is limited.[7]

Automated Detection of Retinal Disease

The current standard for detection of diabetic retinopathy is a dilated retinal examination by an ophthalmologist or optometrist, using indirect ophthalmoscopy and a handheld lens (Figure).[8] A patient's typical visit takes about 2 hours to allow time for pupil dilation, consultation with the ophthalmologist or optometrist, the patient's recovery, and documentation of the results in the patient's medical chart or EHR.

By contrast, automated image-based detection of disease takes less than 2 minutes[9] and does not require the labor-intensive interpretation of medical images and data entry by ophthalmologists or optometrists. Low-cost, compact retinal imagers have been prototyped that allow patients to perform retinal scans on their own.[10] Moreover, "smart" retinal imagers are equipped with image-analysis algorithms

ABSTRACT

Nearly 4 in 10 Americans with diabetes currently fail to undergo recommended annual retinal exams, resulting in tens of thousands of cases of blindness that could have been prevented. Advances in automated retinal disease detection could greatly reduce the burden of labor-intensive dilated retinal examinations by ophthalmologists and optometrists and deliver diagnostic services at lower cost. As the current availability of ophthalmologists and optometrists is inadequate to screen all patients at risk every year, automated screening systems deployed in primary care settings and even in patients' homes could fill the current gap in supply. Expanding screens to all patients at risk by switching to automated detection systems would in turn yield significantly higher rates of detecting and treating diabetic retinopathy per dilated retinal examination. Fewer diabetic patients would develop complications such as blindness, while ophthalmologists could focus on more complex cases.

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that evaluate the camera-generated digital images for retinal abnormalities and automatically flag patients for a follow-up assessment by a physician, including a confirmatory dilated retinal examination and possibly treatment by an ophthalmologist.[11] To date, patient-operated "smart" retinal imagers have only been used on an experimental basis in research settings. Once approved by the FDA, however, these devices could be made available for sale, for lease, or even for free in primary care offices, minute clinics, pharmacies, and other healthcare facilities, where trained personnel could instruct patients on how to use them properly. The widespread availability of a device that enables patients to screen themselves for retinal abnormalities will offer the potential of reaching more persons with diabetes more frequently than is possible by following the current practice of relying exclusively on dilated retinal examinations.

Although the precise integration of results from automated disease-detection devices into existing work flow designs remains to be determined, one option would follow the model of current diagnostic home-use tests for HIV or pregnancy: patients would periodically screen themselves for retinal abnormalities and save both the images and their automated interpretation, possibly following the Continuity of Care Document standard[12] as required for meaningful use.[13] Patients will be able to access the results electronically and share them with an ophthalmologist for further examination and for inclusion in their EHRs. Analogous to the follow-up care for positive HIV and pregnancy tests, if the device detected a retinal abnormality, patients would first consult with their primary care physicians who in turn might refer them to an ophthalmologist for a confirmatory dilated retinal examination and possibly treatment.

Take-Away Points

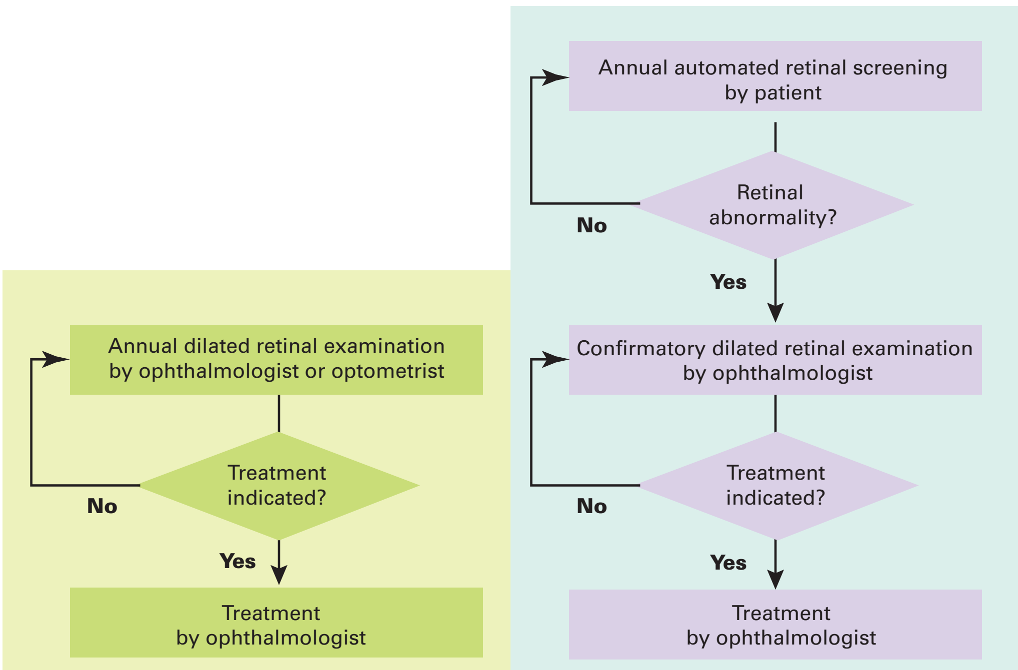
Automated image-based detection of retinal disease is rapid and can obviate the labor-intensive method of image interpretation and data entry by physicians.

- Low-cost retinal imagers that reliably detect diabetic retinopathy and are designed for use by patients have been prototyped and may soon aid in the early detection of other conditions.
- By raising the number of retinopathy cases detected per office visit, automated screening systems could compensate for the emerging shortfall in office-based retinal exams.
- The significantly higher number of retinal abnormalities that automated systems can help detect, coupled with the rising prevalence of diabetes, will largely sustain the demand for ophthalmology services.

The Public Health Potential of Automated Diagnostics

Although diabetic retinopathy can be detected early and

Figure. Retinal Disease Detection Under Current Practice (Panel A) and Automated Screening (Panel B)



A. Current Screening Practice **B.** Hypothetical Screening Practice treated effectively, it remains a serious and widely feared complication that accounts for more than 24,000 largely preventable new cases of blindness and nearly 50,000 new cases of vision loss annually in the United States.[14]

Although current guidelines recommend that all persons with diabetes in the United States undergo a retinal exam every year, in 2010 ophthalmologists and optometrists examined only about 63% of the 25.8 million Americans with diabetes, or about 16.25 million patients.[14,15] Potential causes include the limited number and availability of ophthalmologists and optometrists, many of whom operate at full capacity; the limited number of and access to high-quality digital retinal cameras[16]; patients' ignorance of screening recommendations; and the reluctance of asymptomatic patients to incur the monetary and time costs associated with an examination.[17]

Automated retinal imaging could be used to screen all persons with diabetes annually and thereby identify those who require further examination and possibly treatment. To assess the impact of such automated detection systems on patient health and the cost of care, it is useful to compare their sensitivity and specificity statistics to those achieved by ophthalmologists and optometrists. As with any screening process, minimizing false negatives (high sensitivity) is vital to ensure that patients excluded from further assessment as a result of the screen will not suffer from the lack of indicated treatment, which in this case would prevent vision loss and improve the patient's quality of life.

More reliable early detection of the disease could also reduce the risk of a professional liability claim arising from a missed diagnosis. On the other hand, by minimizing false positives, highly specific detection systems reduce unwarranted dilated retinal examinations by ophthalmologists or optometrists, thus lowering the cost to patients without the disease (and their insurers). The sensitivity levels of detecting referable retinopathy achieved by ophthalmologists, optometrists, and retinal specialists have been reported to range from 34%[18] to 91%,[9] with specificity levels reaching 98%.[9] By comparison, in a recent study the sensitivity and specificity levels achieved by an automated system reached 97% and 59%.[9] The burden and cost implications are discussed next.

As ophthalmologists and optometrists currently examine only 63% of all persons with diabetes, or about 16.25 million, at a sensitivity level as high as 91% they are currently identifying 63% × 91% = 57.3% of all patients who require treatment, for a Likelihood Ratio Positive (LR+) of 45.50 and a Likelihood Ratio Negative (LR–) of 0.43 (**Table**). By contrast, if all persons with diabetes underwent an initial retinal exam using an automated detection system, the number referred to an ophthalmologist for a confirmatory dilated retinal examination and possibly treatment would drop to 12.02 million; these systems would flag 97% of the estimated 2.58 million persons with diabetes who every year develop retinopathy that requires clinical management,[19] or about 2.50 million, and 100% – 59% = 41% of the remaining 23.22 million patients who do not require treatment, or 9.52 million. In combination with the follow-up examinations by ophthalmologists, this hypothetical screening practice would, in assessing the overall process, yield both a higher Likelihood Ratio Positive (108.00) and a lower Likelihood Ratio Negative (0.12) than the current screening practice. Screening all persons with diabetes for retinal abnormalities using automated detection systems would cut in half the typical patient's number of office-based dilated retinal examinations per annum. Perhaps most important, it would raise the proportion of patients requiring treatment who receive it from 57% to 88%, thereby preventing 54% more cases of partial vision loss or blindness.

If the adoption of automated detection systems left the proportion of persons with diabetes undergoing screening unchanged at its current level of 63%, the number of referrals to ophthalmologists would drop from 16.25 to 7.57 million, while the proportion of patients requiring treatment who receive it would decline minimally from 57% to 56%. Thus, automated detection systems would yield a significantly higher rate of detecting and treating diabetic retinopathy per dilated retinal examination. A full cost-effectiveness analysis of universal automated screening is beyond the scope of this report.

Even at the comparatively lower levels of specificity, automated screening allows patients to avoid on average every other office-based dilated retinal exam they would be scheduled to undergo under the current testing recommendations. At the same time, the relatively high rate of false positives under automated screening might lead some patients to discount a positive test result and discourage them from promptly seeking a confirmatory dilated retinal examination, even if they knew that a delay in treatment might result in impairment or total loss of vision. Educational campaigns, reminders, and possibly modifications to the patient's health insurance benefit could be considered to minimize the risk that a patient will ignore a positive test result.

A Complement to Current Screening Practice

Automated image-based disease detection could complement the important role that ophthalmologists and optom-

Table. Number (in millions) of Adults With Diabetes Examined and Treated for Diabetic Retinopathy, by Screening Practice, United States, 2010

A. Current Screening Practice in 2010: Dilated Retinal Examinations Only

	Adults With Diabetes	Annual Dilated Retinal Examination	Treatment Offered	No Treatment Offered
Treatment indicated	2.58	1.63	1.48 (57% sensitivity)	
	1.10			
No treatment indicated	23.22	14.63	0.29	22.93 (99% specificity)
Total	25.80	16.25	1.77	24.03
			LR+ = 45.50	LR– = 0.43

B. Hypothetical Screening Practice: Automated Screening Plus Confirmatory Dilated Retinal Examinations

	Adults With Diabetes	Annual Automated Screening	Confirmatory Dilated Retinal Examination	Treatment Offered	No Treatment Offered
Treatment indicated	2.58	2.58	2.50	2.28 (88% sensitivity)	0.30
No treatment indicated	23.22	23.22	9.52	0.19	23.03 (99% specificity)
Total	25.80	25.80	12.02	2.47	23.33
				LR+ = 108.00	LR– = 0.12

"Current Screening Practice" assumes that 63% of the estimated 25.8 million adults with diabetes in 2010 were examined by an ophthalmologist or optometrist. "Hypothetical Screening Practice" assumes that 100% of adults with diabetes would undergo automated retinal screening. Both practices assume a 10% annual incidence rate of retinopathy requiring clinical management ("treatment indicated"). The sensitivity and specificity levels reported in the table refer to all adults with diabetes. LR+ and LR– denote likelihood ratio positive and negative, respectively.
Sources: CDC (2012) and authors' calculations described in the text.

etrists currently fill in diagnosing diabetic retinopathy: it could reduce the time required of these specialists to interpret medical images, automatically add the results to the patient's record, and overcome possible biases that may skew the clinical assessments. Once approved by the FDA, such an initial examination could be performed by anyone with the device, including patients themselves, which would reduce the cost of universal automated screening even more. More frequent detection of retinal abnormalities would not just prevent substantially more cases of blindness; it would also help identify patients with badly managed diabetic disease more generally and could eventually aid in the early detection of cardiovascular disease, macular degeneration, glaucoma, malaria, and Alzheimer's disease.[20-23]

Given that the prevalence of diabetes in the United States is projected to increase by 50% over the coming decade[24] and given the expected increase in insurance coverage as provisions of the Affordable Care Act are implemented, automated initial screening may represent an attractive low-cost option to meet the growing demand for routine diagnostic services.

Paradoxically, greater use of automated detection systems, coupled with the rising prevalence of diabetes, could largely sustain the demand for ophthalmologist services. Even if automated detection systems replace all initial retinal examinations currently performed by ophthalmologists and optometrists, expanding these screens to all persons with diabetes implies that ophthalmologists will continue to perform about three-fourths of the current volume of examinations. Moreover, the significantly higher number of retinal abnormalities that automated systems help detect implies that patients seeking a follow-up exam will now be much more likely to require treatment, thus allowing ophthalmologists to concentrate on more complex, and possibly more rewarding, tasks.

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