Ocular Telemedicine: Enhancing Compliance and Providing Access

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Diabetes Mellitus has become an epidemic in the United States, currently affecting over 20 million American adults[1, 2]. In addition, over 79 million Americans have been diagnosed with prediabetes[3]. If current trends continue, this number is projected to more than double to 48 million by the year 2050; that is, 1 in 3 U.S. adults over age 40 will suffer from diabetes[2, 4]. Diabetic Retinopathy (DR) is the leading cause of blindness among U.S. adults and is the most common microvascular complication of diabetes[5]. Not only is DR a leading cause of blindness, it is the leading *preventable* cause of blindness in the working-age population. Early detection of DR can preserve vision, by identifying those that need close monitoring and/or treatment.

Certain risk factors have been identified to aid clinicians in identifying patients who are more susceptible to developing retinopathy. The number one risk factor for developing diabetic retinopathy is duration of disease. The prevalence of diabetic retinopathy is around 21% in patients having had diabetes for less than 10 years, but drastically jumps to 76% in those having been diagnosed with diabetes for longer than 20 years[6]. As discussed in the November/December article of CE@Home on DR, other risk factors include poor glucose control and co-morbid conditions such as hypertension and high cholesterol. Annual retinal evaluation is the recommended clinical practice for patients with diabetes to help prevent and detect diabetic retinopathy.

Approximately 30% of diabetic patients 40 years and older have some form of DR[6,7,8]. With nearly one-third of the adult diabetic population having DR, early detection is critical in reducing vision loss. Clinical trials such as the Early Treatment of Diabetic Retinopathy Study (ETDRS) show that effective treatment of DR with laser photocoagulation can decrease vision loss by 50 to 60%. However, many of the highest-risk patients with diabetes are constrained socioeconomically or geographically to accessing health care in general, and have even greater barriers to accessing appropriate eye care. Conventional methods of referral for annual eye examination at the request of a primary care physician (PCP) are at an estimated compliance rate of 30 to 60% of the diabetic population[4,9,12]. According to the 2013 report of The Healthcare Effectiveness Data and Information Set (HEDIS), an annual publication by the National Committee for Quality Assurance (NCQA), the compliance rate of *insured* diabetic patients is 58%[10]. Amongst the uninsured, who have the highest risk for diabetes-related vision loss, the compliance rate drops to10-20%[1]. This disparity in screening rates attained by diabetic patients exposes an immense gap in our health care system, leaving many of these patients vulnerable to developing sight-threatening DR that will go unchecked until retinopathy is too advanced for treatment to be effective.

There are many factors that contribute to the low compliance rate of patients receiving recommended annual diabetic retinal evaluations. A common, but often overlooked, barrier is simply a lack of proper patient education[11]. Roughly 50% of diabetic patients are aware of the need to receive annual eye examinations, but only one-third of those patients know why these are important[11]. A lack of patient understanding in the importance of retinal evaluation, and its implications for avoiding vision loss, leads to the perception that annual retinal evaluations are optional or even unnecessary. Another major barrier often seen in community and county health clinic systems is excessively long waiting periods for an appointment with an eye care specialist for initial evaluation or treatment. These wait times are routinely 6 months to one year, even when the patient has been already identified as having sight-threatening retinopathy[11].

In the US DM currently has an annual economic cost estimated to be around $245 billion dollars, of which $69 billion is spent on indirect costs (such as for disability compensation, work loss, premature mortality)[3]. This places a large economic burden on our health care system in treating and managing diabetic patients. In addition, most patients who develop permanent vision loss from DR are unable to work, thus need to rely on federally- or state-funded disability programs as a means of economic survival. This effectively doubles the economic burden. Given the oncoming tidal wave of diabetic patients, new and innovative methods must be developed and introduced to lower costs associated with identifying patients in need. Ocular telemedicine, specifically teleretinopathy screening, provides such a platform, while also decreasing costs and increasing compliance with annual retinal evaluations.

Teleretinopathy screening in a primary care setting using digital imaging is a cost-effective way to improve compliance and capture-rate. It also directly links the eye care provider (who provides the remote consult) with the PCP, who is often responsible for coordinating and managing systemic manifestations and complications of DM. Color fundus photos or scanning laser ophthalmoscopic images (Figure 1) can be captured at the point of contact in the PCP’s office with minimal training, as these technologies are non-invasive and pose no threat to the patient’s ocular health. These images, along with critical pieces of medical information (duration of disease, HbA1c, etc.) can be transmitted to an eye care provider for evaluation. A report can also be returned to the PCP with assessment and recommendations for follow-up care.

There are currently three common modes of telemedicine: interactive services, remote monitoring, and store-and-forward. Interactive telemedicine is a remote examination or consultation that occurs in real-time, often utilizing video conferencing to enhance communication. Remote monitoring, on the other hand, involves gathering and transmitting data to the provider from monitoring devices used by, or implanted, in the patient. Store-and-forward telemedicine takes patient data, transmits it to a storage intermediary, and is then accessed at a later date by the consulting provider. A report of the consult is generated and downloaded by the originating clinic for review by the PCP. Store-and-forward is the most commonly used type of telemedicine in screening for DR. The advantage to using the store-and-forward methods include: decreased chair time for the patient and the doctor, decreased cost, increased access to patients, ease of evaluating the photos, and increased screening rates. These services aim to decrease the financial burden on the U.S healthcare system while simultaneously improving patient's quality of life through blindness prevention.

There are many different telemedicine platforms and systems to detect diabetic retinopathy implemented across the U.S., such as Joslin Vision Network (JVN) and the Eye Picture Archiving and Communication System (EyePACS). UC Berkeley Digital Health, UC Berkeley School of Optometry's telemedicine clinic, utilizes the EyePACS platform in over 70 safety-net, community, and county clinics throughout California to increase compliance rates amongst the highest-risk diabetic patient populations and decrease costs associated with ocular complications.

EyePACS (www.eyepacs.org; EyePACS, LLC, San Jose, CA) is a license-free, web-based program that utilizes non-mydriatic retinal cameras to capture color fundus images, encrypted data transfer and credentialed consultants for review of the images[12]. EyePACS is unique in that it is non-proprietary, and it allows any health care professional or clinic organization to screen for sight-threatening DR. Its keys to success include simplicity and ease of use, and it also increases compliance rates while keeping overhead costs low. With the implementation of teleretinopathy screenings into these primary care settings, many of the patients receiving no formal eye care can obtain much needed access to retinal screening at a low cost.

Multiple studies have been conducted looking at the impact of implementing telemedicine for DR screenings on the percentages of patients screened. Olayiwola, *et. al.* found that by using EyePACS in a Community Health Center, Inc in Connecticut, they were able to screen nearly 20% of their diabetic population in one year compared to 10-12% previously screened[1]. Although the numbers are far from ideal, this clinic was able to nearly double the number of their patients with diabetes receiving some type of eye care in just one year. Taylor, *et al.* looked at the difference between compliance rates when patients were given the choice to have a dilated eye examination with an ophthalmologist or have digital photos taken. The study consisted of 495 patients, with 201 patients opting for imaging and 294 opting for a live examination. Of the 40.6% of the patients that chose imaging over live exam, 100% of them were compliant with receiving imaging[4]. In contrast, of the 59.4% of patients that chose to be referred for a live exam instead of imaging, only 31.3% attended the appointment and received a dilated eye exam[4]. These studies illustrate the issue of non-compliance with live eye exams and strongly suggest that compliance can be greatly increased using imaging and teleretinopathy screening.

The EyePACS platform has established guidelines for the different "moving parts" of a screening program for diabetic retinopathy. First, the identification of clinic personnel can act as photographer(s) is needed. These individuals undergo a training and certification to ensure they are able to successfully capture images deemed acceptable to be graded[12]. The photographer(s) are often recruited from existing clinical staff; this has the advantage of making this program readily available and more feasible, as no new staff must be hired. The imaging protocol for EyePACS includes mydriatic or non-mydriatic image capture with one external image (to determine media clarity) and 3 internal, overlapping 45^{o} fields (corresponding to fields 1-3 of the ETDRS) captured per eye[12] (Figure 2). Once images are acquired, they are uploaded with the patient's demographic and pertinent medical information through the encrypted website via any mainstream web browser. This constitutes an EyePACS "case"[12]. The consultant then assesses the case, evaluates the images, and makes his or her assessment and recommendations (see grading below). Once the consultant has submitted the consult, a report can then be downloaded at the original clinic site, reviewed by the PCP, and incorporated into the patient's chart.

The grading system that EyePACS utilizes is a combination of the International Diabetic Retinopathy Grading Scale and results from the ETDRS. The lesions graded using the system are microaneurysms, retinal hemorrhages with or without microaneurysms, cotton wool spots, intraretinal microvascular abnormalities (IRMA), venous beading, new vessels, fibrous proliferation, vitreous hemorrhage or preretinal hemorrhage, and hard exudates (HE). The presence or absence of laser scars is also graded; these are often indications of previously treated retinal disease. The consultant then utilizes the online template (Figure 3); he or she has the option of selecting "yes, no or cannot grade". For intraretinal hemorrhages, venous beading, and IRMA the lesions are graded in comparison to the ETDRS Standard photographs. Once all the lesions have been adequately graded, a computer algorithm will then give two summary grades: 1. Overall retinopathy severity level and 2. Suspected presence of Clinically Significant Macular Edema (CSME).

There is a need to rely on other indicators of macular edema for diagnosis of suspected CSME since the photos obtained are not stereoscopic, and therefore retinal edema cannot be appropriately evaluated. EyePACs relies on the presence or absence of HE within 1 disc diameter of the center of the macula to calculate the severity level of macular edema. Based on data analysis in the ETDRS and other studies, this method has a sensitivity of 94% and specificity ranging from 54-88.5%[12,13]. The high sensitivity suggests using HE yields very few false negatives ensuring proper diagnosis of most patients who truly have CSME. Although the low specificity may result in a high rate of false positives and over-referrals, this is seen as less of a concern as these patients are still at high risk for developing CSME within 1 year[12].

When considering screening with fundus photos versus referring patients for a dilated eye examination, it is an important to note that imaging has been shown to be superior in detecting diabetic retinopathy. Analysis of the ability of optometrists to detect DR showed a sensitivity of 73% and a specificity of 90%. However, sensitivity was 96% and the specificity was 89% in comparison to manual grading of color photos[14]. This is also observed in studies unrelated to diabetic retinopathy. In the Ocular Hypertensive Treatment Study (OHTS), for instance, four times as many disc hemorrhages were found by image review when compared to same-day live examinations[15]. This demonstrates the advantages that photo review can provide as a diagnostic tool in addition to documentation. Thus fundus photos can play an integral role in detecting DR, and are arguably superior to live fundus examination when screening for retinopathy.

There has been much debate on whether or not yearly retinal examinations for all diabetic patients are prudent. Previous thoughts and clinical practice were that patients with diabetes be screened yearly with a dilated examination. The American Diabetes Association (ADA) recommends that patients with type I diabetes receive an initial dilated examination within 5 years of diagnosis and then repeated annually and patients with type II diabetes receive an initial dilated examination at time of diagnosis, and annually thereafter. Patients who have one or more normal examinations may be considered for less frequent examinations (every 2-3 years) depending on exam findings[16]. One potential undesirable outcome from recommending screenings every 2-3 years is decreased compliance, as patients may begin to feel as if the screenings are not an integral role in their health care. It is therefore even more important to properly educate patients to seek eye care at regular intervals.

In 2012, the ADA guidelines for diabetic retinopathy screening were clarified to state that high quality fundus photos may be used as a screening tool to detect diabetic retinopathy, but should not replace dilated fundus examinations[16]. The use of fundus photos can be used in conjunction with dilated retinal examinations to monitor for DR. For example, a practitioner may opt to have a patient be imaged one year and have a dilated examination the next. The recommendation to utilize retinal photos via telemedicine to monitor DR should be considered in many primary care settings as this will substantially lower the cost and increase compliance of monitoring diabetic retinopathy. At least two major healthcare organizations in the U.S. are currently looking at the efficacy of a hybrid method DR screening; live eye exams are performed every 2-3 years, with annual retinal imaging in the intervening time. This may prove to be an effective way to lower costs while combating patient non-compliance.

Ocular telemedicine is a valuable tool in monitoring for diabetic retinopathy and can also be utilized to screen for other ocular conditions including: cataracts, glaucoma, macular degeneration, retinal emboli, epiretinal membranes and hypertensive retinopathy. Around 40% of diabetic patients have at least one non-diabetic retinopathy finding identified with retinal screenings utilizing fundus photography[17]. This demonstrates how these programs can detect a wide array of ocular disease, and may be implemented in the future for broader prevention of blindness and early detection of ocular disease. This may be especially true as technologies in imaging and disease detection (e.g. optical coherence tomography) continue to advance and become less costly to implement. Currently, the majority of the patients where ocular telemedicine is utilized are in underserved populations who have limited access to eye care. However, it shows great potential in overall public health, and will likely become an integral part of the way optometry is practiced.

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Figure 1. Imaging modalities for detecting diabetic retinopathy. Digital fundus imaging (left) and scanning laser ophthalmoscopy (e.g. Optomap) have been shown to be highly effective in the detection of diabetic retinopathy, as well as many other conditions.

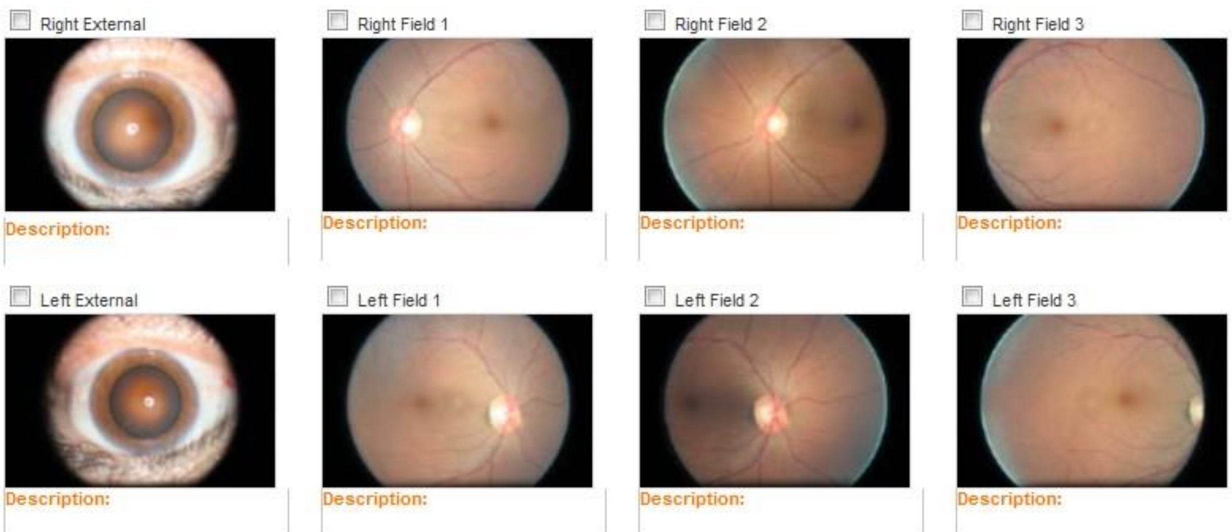

Figure 2. The eight standard fields taken for EyePACS retinal screening. Four images are taken of each eye: one external photo to determine media clarity and 3 overlapping fields of the posterior pole.

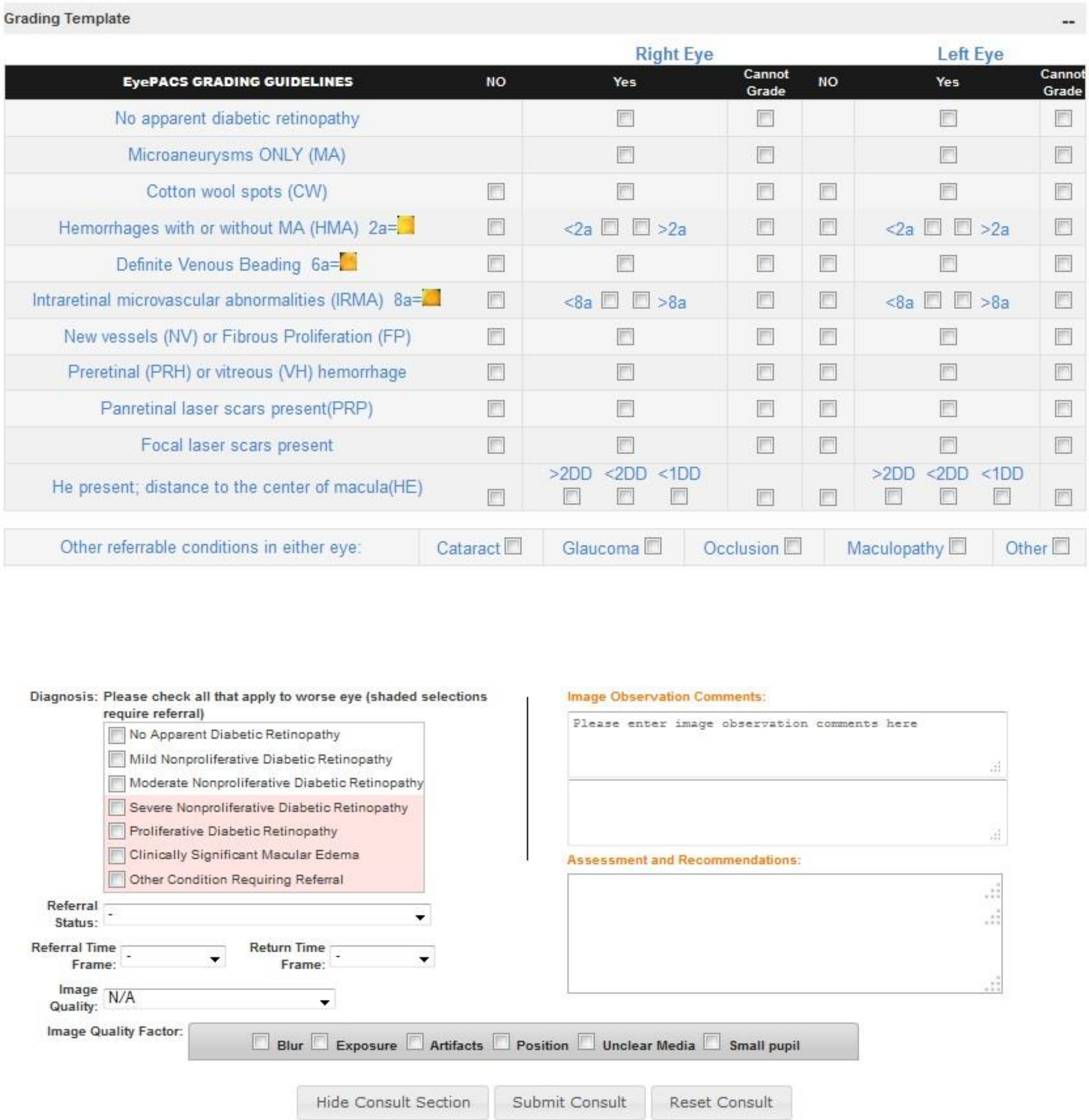

Figure 3. The EyePACS grading template.* Diabetic lesions are graded for their presence or absence in each eye, and the level of retinopathy is automatically determined based on those results. Assessment and recommendations are then made by the consultant based on findings, and a report can be generated for the PCP's review. Note that other common referable ocular conditions are listed at the bottom of the grading matrix, such as cataract, glaucoma, vascular occlusion, and non-diabetic maculopathy.