



Diabetic Retinopathy Screening

Practice Guide

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Christine Martin, Executive Director

Prepared by:

Jorge Cuadros, O.D., Ph.D.
Director of Informatics Research
University of California Berkeley Clinical Research Center,
School of Optometry

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About the Author: Jorge Cuadros, OD, PhD, is Director of Informatics Research, University of California Berkeley Clinical Research Center, School of Optometry. Starting in 1994, Dr. Cuadros has developed several programs for remote clinical diagnosis and distance learning, including programs in China and Latin America. Dr. Cuadros' EyePACS system was developed at the UC Berkeley School of Optometry as an open access system for clinical communication in eye care, and has been used for teleconsultation, retinopathy screening, nursing home care, education, digital grand rounds, and research. He is also co-editor of an international collaborative book, "Teleophthalmology" which was published in February 2006.





Introduction

By far, the most common use of telemedicine in eye care is detection of diabetic retinopathy using asynchronous or store-and-forward (SAF) telemedicine. This has proven to be a viable and less expensive alternative to real-time telemedicine in ophthalmology and has been increasingly used for diabetic retinopathy screening for nearly two decades. Thousands of sites across the United States are now performing diabetic retinopathy screening remotely via several varieties of SAF.

This guide presents the practical aspects of developing a diabetic retinopathy screening (DRS) program along with general guidelines and recommendations for performing DRS based on experiences in community clinics in California. A comprehensive set of guidelines describing requirements and recommendations for DRS is available from the American Telemedicine Association's (ATA) Ocular Telehealth Special Interest Group.¹

The Need for Diabetic Retinopathy Screening Programs

Diabetic retinopathy (DR) is a microvascular complication of diabetes where leakage and blockage of small vessels in the retina cause swelling of retinal tissue, abnormal blood vessel growth, cell death, and retinal detachments. DR is the leading cause of blindness among working age adults in the United States. Vision loss can be prevented in most cases by performing retinal laser photocoagulation in a timely manner.² Although early detection and treatment of sight-threatening DR can prevent blinding complications, less than half of all diabetics receive recommended yearly eye examinations.³

Primary health care providers have traditionally referred their patients to eye care providers for the annual diabetic retinal exam. Patients often fail to visit referred eye care providers for timely eye exams because of geographic, social, economic, and other barriers. Failed visits lead to preventable complications, including blindness from diabetes, glaucoma, and other diseases. DRS via telemedicine can effectively detect sight-threatening DR in the primary care setting, and can often detect other previously undetected diseases, but it does not yet take the place of a comprehensive eye examination. Problems such as cataracts and refractive errors have not been proven to be adequately assessed via DRS; therefore all patients are encouraged to continue with their routine eye care. Future advancements and experience with remote monitoring and diagnostic technology will facilitate the development of comprehensive blindness prevention programs in primary care through telemedicine.

Screening Feedback⁵

Patricia Andrade, Age 32, Diabetic

Patient: I didn't know I could go blind from diabetes until I visited my [primary care] doctor...I had never had an eye exam before, and her assistant took pictures of my eyes with a special camera, and I learned how my eyes could end up and how they were already bleeding inside.

Lyn Berry, MD, Director of the Diabetes Clinic of Alameda County Medical Center:

We found that our compliance rate with diabetic retinal exams went from around 25% up to the high 90's. We feel that we've actually been able to prevent advanced eye disease and blindness, and it's really been an enormous quality tool for our clinic.

David Martins, MD, Medical Director

T.H.E. Clinic: My patient recently went blind waiting for a routine eye exam. I could not take that any more, so I instituted diabetic retinopathy screening in my clinic to identify our patients who are at risk, and prevent diabetic blindness.

Guidelines for Referring Patients

The following guideline summary is presented for better understanding of the screening process. Diabetic retinopathy screening does not take the place of a comprehensive eye examination by an optometrist or ophthalmologist. The guidelines are derived from the Position Statement of the American Diabetes Association in cooperation with the American Optometric Association (Michael Duneas, OD), and the American Academy of Ophthalmology (Donald S. Fong, MD, MPH).⁴ Readers are advised to view the complete position statement.

1. Patients with type 1 diabetes should have a retinal examination 3–5 years after the onset of diabetes. In general, evaluation for diabetic eye disease is not necessary before 10 years of age. However, some evidence suggests that the prepubertal duration of diabetes may be important in the development of microvascular complications; therefore, clinical judgment should be used when applying these recommendations to individual patients.
2. Patients with type 2 diabetes should have a retinal examination shortly after diabetes diagnosis because the onset of the disease may occur several years before the diagnosis. Subsequent examinations for both type 1 and type 2 diabetic patients should be repeated annually. Examinations will be required more frequently if retinopathy is progressing.
3. When planning pregnancy, women with preexisting diabetes should have a retinal examination and should be counseled on the risk of development and/or progression of diabetic retinopathy. Women with diabetes who become pregnant should have a retinal examination in the first trimester and close follow-up throughout pregnancy. This guideline does not apply to women who develop gestational diabetes, because such individuals are not at increased risk for diabetic retinopathy.



Referring Patients with Sight-threatening Diabetic Retinopathy

Patients with any level of macular edema, severe nonproliferative diabetic retinopathy (NPDR), or any proliferative diabetic retinopathy (PDR) require prompt care of an ophthalmologist who is knowledgeable and experienced in the management and treatment of diabetic retinopathy. Referral to an ophthalmologist should not be delayed until PDR has developed in patients who are known to have severe nonproliferative or more advanced retinopathy. Early referral to an ophthalmologist is particularly important for patients with type 2 diabetes and severe NPDR, since laser treatment at this stage is associated with a 50% reduction in the risk of severe visual loss and vitrectomy.

4. Patients who experience vision loss from diabetes should be encouraged to pursue visual rehabilitation with an ophthalmologist or optometrist who is trained or experienced in low-vision care.

Program Validation – Defining Program Goals and Performance

The Ocular Telehealth section of the American Telemedicine Association defined four categories of performance of DRS programs using the Early Treatment Diabetic Retinopathy Study (ETDRS) film-based retinopathy diagnosis system as the gold standard⁶ :

- Category 1 validation indicates a system can separate patients into two categories: those who have no or very mild nonproliferative and those with more severe levels of DR. This level generally identifies patients who may potentially require the care of an ophthalmologist within a year.
- Category 2 validation indicates a system can accurately determine if sight-threatening DR as evidenced by any level of macular edema or severe diabetic retinal changes. This category of validation allows identification of patients who do not have sight-threatening DR and those who have potentially sight-threatening DR. These patients with sight-threatening DR generally require prompt referral for possible laser surgery.
- Category 3 validation indicates a system can identify ETDRS defined levels of nonproliferative DR (mild, moderate, or severe), proliferative DR (early, high-risk), and macular edema with accuracy sufficient to determine appropriate follow-up and treatment strategies. Category 3 validation allows patient management to match clinical recommendations based on clinical retinal examination through dilated pupils.
- Category 4 validation indicates a system matches or exceeds the ability of ETDRS photos to identify lesions of DR to determine levels of DR and DME. Functionally, Category 4 validation indicates a program can replace ETDRS photos in any clinical or research program.

The cost and complexity of performing DRS generally increases with higher category of validation. DRS program administrators must determine the appropriate program goals and performance and select a service that matches these expectations.

Program Models for Diabetic Retinopathy Screening

Organizations must consider how to adapt telemedicine-based diabetic retinopathy screening to their clinicians' workflow without disrupting their work while ensuring that all patients who require screening are attended to. Three predominant strategies have emerged to manage screening:

1. **Appointments for Retinopathy Screening.**

The most obvious and intuitive option is to set up appointments for diabetic patients to return for retinal imaging. An appointment schedule is set up when screening personnel process patients to be screened. Unfortunately, many patients fail to return for the retinal imaging, just as they often fail to attend an eye exam.

2. **Integrating Screenings into Clinic Workflow.**

The success of any clinical program depends on how well it is integrated into the workflow of the care process. One straightforward way to ensure that this happens is to create a simple set of clinical scenarios and then map out suggestions for a modified workflow, including alerts and reminders for all the people involved with the patient. For diabetic retinopathy screening, there are a few basic scenarios:

a. Clinical Scenarios

- i. Current diabetic patient visiting the clinic for a regular exam or unrelated issue. The key is for physicians and case managers to have retinopathy screening at the front of their minds. They should be making referrals for retinopathy screening to all diabetic or borderline diabetic patients.
- ii. Current diabetic patient who is not scheduled for a clinic visit. Many diabetics have never had a

retinopathy screening and do not know that it is necessary. Others may have received a retinopathy screening more than a year ago and are due for another screening. Patient outreach – mailings and phone calls – can educate these patients and motivate them to schedule a visit. Electronic registry systems can help simplify identification of patients needing screens and outreach.

- iii. New diabetic patient who visits the clinic specifically for retinopathy screening. One result of community outreach is that new patients may come to the clinic just to have their eyes tested for retinopathy. Since retinopathy screening is part of a whole program of diabetes management, it is critical to provide these patients with a more comprehensive care program.
3. DRS Events. Diabetic patients are gathered at an event where they can be screened for retinopathy. Diabetes education seminars, health fairs, or other community events are often excellent locations for performing DRS. Care should be taken to include all patients, not just the compliant patients who are most likely to attend these events.

Typical Diabetic Retinopathy Screening Workflow⁷:



Tip for Workflow Integration:

Use charts and notes as reminders for referrals. If possible, make retinal screenings available without an appointment so that a patient who is already in the clinic does not have to schedule a return trip for the screening. (Many patients do not comply with scheduled return visits.) If electronic registry systems are available, set up alerts and reminders for annual eye exams.

Program Personnel and Operations

In addition to the technical requirements, a successful retinopathy screening program must have organizational features in place.

Personnel involved in the screening include:

- primary care clinicians who refer patients for DRS
- photographers who acquire and transmit retinal images
- reviewers who interpret images and generate assessments of retinopathy
- administrators who oversee the process
- technical personnel that develop and maintain the technical components of the system

DRS programs also require policies and procedures including:

- templates and protocols to manage data
- procedures for interfacing with medical records, billing, and administrative tasks.

A DRS requires a primary care provider, photographer, clinical consultant, administrator, and technical support. The following are recommendations for ensuring adequate assignment of personnel for DRS.

1. Primary Care Providers

Primary care providers are usually in charge of coordinating the care of their chronic disease patients so it is crucial that they understand and agree about the importance of on-site DRS. Any DRS program should include meetings with all providers and staff to present the rationale for the program, address any concerns, and develop the processes and protocols for referring patients for screening and subsequent care. These meetings should occur early in the program development process.

Five typical concerns of primary care providers are:

- Duplication of services with regular eye exams with eye care providers. Why perform DRS if patients are already getting eye exams? Review of a clinic's own compliance level with yearly eye exams (usually less than 50%) can effectively address this concern, given that high risk patients are often the least likely to receive yearly eye exams. Furthermore, eye exams reported by patients are often not accurate. Patients often state that they have had a DR exam when they have only had a simple eye exam for eyeglasses or visual acuity. Patients sometimes misunderstand the results of their retinal exams or can't effectively relay the pertinent information to their primary care provider. Often the reports from the eye care providers are not available in the patients' records. It is important to emphasize that DRS does not take the place of a regular eye exam, whereas, DRS is more effective for detecting retinopathy.

- DRS requires the participation of high level clinicians, taking resources away from other necessary services (lost opportunity cost). The DRS process requires minimal to no active participation by physicians. The photography and communication can be managed by medical assistants, interpreters, volunteers, and others (see section on photographers below).
- Insufficient resources for treating patients with detected retinopathy. Providers are sometimes concerned that patients that are found to have sight-threatening retinopathy will not have access to treatment. This is a real concern (discussed further in the section on follow-up), however, the rationale for screening at the primary care site is to refer only those patients with sight-threatening conditions to the local retinal specialists, thereby preserving retinal specialist resources for treatment, rather than using their time to see diabetic patients that don't have serious retinopathy. Furthermore, it is usually better for the patient to be aware of sight-threatening retinopathy rather than to think that the eyes are normal.
- Inadequate follow up on referrals. Who will refer the patient in the event of a positive finding on the screening? The clinic and off-site retinal consultants must have a mechanism for ensuring that patients can be contacted and referred to appropriate eye care providers in the event that serious retinopathy is found. Primary care providers should use their regular specialty referral mechanisms to follow up with patients.
- Inadequate validation of DRS and reading consultants. Several landmark studies have validated the use of digital retinal imaging, summarized by John Whited⁹ for the US Veterans Administration. Ensuring that the proposed DRS is validated

against the standard programs should effectively address this concern.

2. Photographers

Digital retinal photography is generally much easier to learn than film-based retinal photography. Personnel at all levels can usually be trained to perform adequate digital photography in a matter of hours. Sites that perform DRS have designated medical assistants, x-ray techs, interpreters, volunteers, medical and pre-medical students, optometric interns, diabetic care coordinators, diabetic educators, nurses, and doctors to acquire retinal images. High level personnel (e.g. nurses and educators) may use retinal images to educate patients and to assess their general microvascular status; however, all levels of photographers can acquire adequate images for DRS.

Individuals that are well-suited as retinal photographers have the following qualities:

- Familiarity and comfort with technological devices, such as digital cameras, video games, and computers.
- Patience in working with patients.
- Attention to detail. Consistently high quality images are important for the success of DRS.
- Dedicated time for performing the photography. If the photographer has too many other assigned activities, then DRS may be avoided.
- Enthusiasm for DRS. Most photographers soon become enthusiastic about performing DRS, which creates motivation to overcome the changes to clinic activities that are necessary during the initial phase of the DRS program.

Certification of photographers is important to ensure consistently adequate images. Certification programs for photographers are available through the University of Wisconsin Fundus Photograph Reading Center

(<http://eyephoto.opth.wisc.edu/>) as well as the University of California, Berkeley Retinal Reading Program (<https://www.eyepacs.org>). Continuous quality improvement should also be implemented by tying quality assessment of retinal images with the remote clinical consultation. The clinicians that interpret the images should provide feedback to the photographers regarding the quality of their images. Retraining and remediation can then follow the consultants' feedback.

3. **Clinical Consultants**

The professionals that read transmitted retinal images for DRS programs are varied and can be anywhere in the world. DRS programs have used retinal specialist ophthalmologists, general ophthalmologists, optometrists, or trained non-clinical staff. Most programs, including Kaiser Permanente and the Veterans Administration, have employed both ophthalmologists and optometrists to read images, while others, like the University of Wisconsin Fundus Photograph Reading Center, have employed trained non-clinical staff to interpret images using a highly developed lesion detection protocol.

Following are qualities of clinical consultants that should be considered when selecting and contracting with appropriate consultants:

- Experience
- Capacity
- Availability
- Cost
- Liability
- Turnaround time

Certification and quality assurance of clinical consultants is of utmost importance. Inconsistent assessments and recommendations among consultants can cause uncertainty regarding the disposition of screened patients. A certification program “calibrates” consultants and allows for better

quality assurance of the DRS program. Certification programs for consultants are available through the University of Wisconsin Fundus Photograph Reading Center (<http://eyephoto.opth.wisc.edu/>) as well as the University of California, Berkeley Retinal Reading Program (<https://www.eyepacs.org>).

An adjudicating consultant makes decisions resolving issues of ambiguous or controversial interpretation. In most cases, an adjudicating consultant will be a retinal specialist ophthalmologist. Adjudicating consultants may also perform quality control by reviewing a sub-sample of cases that have been reviewed by other clinical consultants.

4. **Administrators**

In most retinopathy screening programs, high-level administrators participate in the initial interactions to review the expected benefits and costs of the program. Once the decision has been made to incorporate retinopathy screening in a clinic, the administration will usually assign a project manager who will perform the following on-going administrative duties:

- Manage schedules and duties of photographers and assistants involved in the day-to-day processing of encounters
- Coordinate billing for services
- Manage referrals for treatment of patients by retinal specialists
- Act as liaison between retinal consultants and the clinic
- Communicate technical difficulties to retinal camera vendors
- Ensure compliance with DRS policies and procedures
- Generate reports on performance of program

A Note to CEOs, Operations Directors, and Clinic Managers

There are a few key ways that administrators can ensure a successful diabetic retinopathy screening program:

1. Communicate your support for the program at its inception and on an ongoing basis – your buy-in is absolutely essential in motivating the clinic staff. Ask for updates at staff meetings, and promote the clinic’s goals, milestones and successes.
2. Take a team approach to integrating screening into clinic workflow, enlisting the support of case managers, providers, photographers, and support staff. This may require the flexibility to accept walk-in appointments for people who were not aware at the time of making their appointment that they should be having retinopathy exams.
3. Emphasize the critical role of primary care in overall management of diabetic eye health. Make sure that everyone at the clinic understands that screening is part of every diabetic’s care management program at the normal site of care, not something performed only by specialists.
4. Embrace telemedicine as a new model of care, communicate with IT professionals to ensure their support, and educate your clinic team about the key benefits of this approach, including speed of service, ease of process, lower costs, and better patient care.
5. Provide training, support, and recognition for staff to fit retinopathy screening into a comprehensive diabetes management plan. Make sure that participation in the program is reflected in performance measures.

Policies and Procedures

The success of a diabetic retinopathy screening program can be measured by the percentage of diabetic patients who receive annual retinal examinations. Close attention to identifying diabetic patients who have not had a retinal examination within one year will ensure that all patients will receive appropriate care. The following are recommendations about identifying patients for retinal screening that have proven effective to ensuring a high level of compliance with yearly retinal exams:

- Identify and screen diabetic patients without requiring a referral from the primary care provider. Providers are often very busy and will neglect to initiate the referral for screening. Diabetic registries or electronic medical records are often effective in identifying patients that need DRS.
- Screen all diabetic patients regardless of previous eye exams. Patients often report having had a regular eye exam, but a report of the findings is not available in the patient record. Patients are sometimes mistaken when they receive a simple eye examination for eyeglasses, thinking that a thorough view of the retina was performed.
- Closely follow patients that fail the screening and are referred for retinal treatment. Diabetic retinopathy is often asymptomatic, even in the late stages, and patients will often neglect to obtain treatment. It is incumbent upon the primary care staff, as well as the retinal consultants, to ensure that the patient actually receives proper treatment.

Three sample protocols on screening services, photography review and pupil dilation can be found in the Appendix.

Technical Requirements

Diabetic retinopathy screening programs generally use store and forward technologies (SAF). A SAF telemedicine program generally relies upon a similar set of concepts and components, regardless of specialty, and a typical DRS program follows this similar format.

First, there must be a device used to capture imagery or data from the patient at a point in time. For DRS, there are a number of digital retinal imaging devices in common use. These vary significantly in both cost and features, and any prospective screening site should consider their needs, the needs of the referral specialist, and the capabilities of their staff when choosing a device.

Second, there must be access to an imaging and archival system for storing the images and clinical data, as well as a communications system for transmitting the images and data between the patient care site and consulting specialists. In many SAF disciplines, some systems are based on a central data repository referred to as “PACS” (Picture Archiving and Storage Systems). In other cases, PC-based image management and communications software systems concentrate on secure transmission of patient information from point to point, without the additional investment in central archiving. The example illustrated in this guide, EyePACS, is an open source transmission and archiving system.

Finally, there must be a system in place on the consultant’s side which allows review and analysis of the imagery and data at an appropriate resolution and format. In the case of DRS, a viewing station is required for the consultants to view and interpret cases.

Connectivity

Because a DRS is an asynchronous program by nature, the connectivity requirements are generally more modest than those required for live interactive telemedicine protocols, and even less than those required by other SAF protocols which generate huge files, such as echocardiography for example. A successful DRS program can operate within the following connectivity and configuration parameters:

- Allows upload of image files to a trusted site
- Allows Secure Socket Layer (SSL) encryption at 128 bit strength in web browser
- Allows connections via VPN to imaging computer through network (for managing computer)
- 128 Kbps minimum connection to Internet

If the clinic will assign its own computers for the program then it must meet these minimum specifications:

- CPU: 2 GHz
- Hard Drive: 40 Gb – 5400 rpm
- RAM: 512 MB
- Two standard USB2 inputs
- Video Card: 128 Mb vRAM; supports 1152 X 864 resolution in 24-bit color
- Network Interface Card: 10 Mbps minimum
- Latest virus protection and operating system updates
- Monitor: 15” Flat screen or flat panel; 60 Hz refresh rate
- A printer for printing retinopathy reports (just text) can either be connected directly to imaging computer, or connected via the network.

The room used for DRS must be able to be darkened so that patients' pupils will dilate. Completely dark is preferable. There should be at least four electrical outlets available for imaging devices and computer. The maximum electrical requirement for all devices is approximately 5 Amps. There should also be a plain telephone line and telephone installed at the work station available for service calls, troubleshooting, and patient consults.

A comprehensive review of all retinal imaging modalities is well beyond the scope of this guide. Moreover, new imaging devices are quickly appearing on the market at an accelerating rate. Below are considerations that may be helpful in determining which devices are appropriate for a particular DRS program. Many diverse retinal imaging products are sold to eye clinicians. Prices for retinal imaging devices vary greatly and the quality of the acquired images also varies greatly.

Retinal imaging devices generally work by shining light (plain or laser) through the pupil of the eye to illuminate the retina. Lenses inside the device focus light from the retina onto camera sensors that convert the light into signals that are interpreted by a computer and rendered onto a viewing monitor or stored in computer files. The quality of the images that are viewed by the eye consultant depends on each link in this chain of events. The various factors that ultimately affect the quality of the displayed images include resolution, color, stereopsis (depth perception), image compression, and pupil dilation. These factors are discussed in the following sections.

Resolution

The optimum image resolution has been actively debated since the beginning of digital retinal imaging. Resolution of a digital retinal image is the number of pixels (the smallest elements of a

digitized image) that are assigned to represent a given area of retina. High resolution images have finer detail, but they also require larger files for storage and more time for processing and transmission. Early digital retinal imaging devices (circa 1990) used video cameras mounted to adapters on the camera ports of film based retinal cameras. Images were acquired using video capture cards inside computers that digitized analog video still frame signals. The typical image resolution was 640 X 480 pixels over a 30 to 45 degree circular field of the retina. Many clinicians felt that these images were sufficient to detect retinal abnormalities. Clinical studies, however, showed poor correlation with face-to-face examinations or film transparencies. Since then, image resolution has steadily increased. Most of today's retinal cameras have one million or more pixels of resolution on the image sensors. Jensen and Scherfig⁹ found that 3 million pixels was the minimum resolution required for a digital camera to capture images comparable to slide film. Tom Cornsweet explains in "The Great Pixel Race"¹⁰, however, that a camera sensor's resolution is not equivalent to the acquired retinal image resolution. He notes that there is a limit to the benefit of adding more pixels to a sensor. This limit is set by the optical quality of the eye that is being photographed. The size of the captured field in the retina also greatly affects the resolution. A 45 degree field requires more than twice as many pixels as a 30 degree field. Cornsweet also indicates that most digital cameras have rectangular sensors. A third or more of the space on rectangular sensors is wasted because retinal images are round. A square sensor would require less resolution than a rectangular one because less space would be wasted. Lastly, resolution is greatly affected when capturing color vs. grayscale ("black and white") images. More than twice as many pixels

are needed to capture a color image than to capture a grayscale image because color pixels must be divided among the different wavelength sensors in order to get color images, whereas grayscale pixels match the image point for point. This leads to the question of whether color is necessary for retinal imaging in diabetic retinopathy, or is grayscale adequate for image interpretation.

Color

Rendering retinal images in color or grayscale, and how to do it, is open to debate. Although there are many different ways to analyze color, a color retinal image is typically separated into three components or channels: red, green, and blue. A more detailed discussion of digital color image theory can be found in Ken Davies' discussion of digital color models. Investigators generally agree that the green channel of a retinal image contains most of the important information regarding diabetic retinopathy. Clinicians often use green filters to isolate the green channel in order to enhance retinal lesions when viewing the retina with biomicroscopy. Many clinicians, however, prefer to view color images of the retina, perhaps because they are more accustomed to it. Hence, designers of monochrome retinal imagers often "colorize" the grayscale images in order to provide a more normal appearance for the display. Ultimately, the choice of grayscale vs. color imaging will be a matter of preference. Grayscale sensors may be more frugal in their use of pixels, but greater numbers of pixels are rapidly becoming easier to manage and cheaper to make and purchase.

Several parameters affect the appearance of digital color images. The color depth is one of the most important parameters that affects how well subtle differences in colors and shading are rendered. Images should be captured in a

minimum of 24-bit color (16 million possible colors) and displayed as well with a minimum of 24-bit color. The hue, saturation, and brightness are other parameters that can be adjusted both on the acquisition side and on the display side; however, there is no standard guidelines as to how these should be set. Color matching products are available to insure that displays match the original image, however, these may not be so important since the human eye readily adapts to changes in surrounding colors. Moderate mismatching of colors among different computer monitors and display devices does not greatly influence the ability to detect lesions.

Stereopsis

Stereopsis (depth perception) allows observers to perceive variations in the thickness of the retina. Stereopsis is useful for evaluating edema, the accumulation of fluid in the retina. Edema comes from leaky blood vessels and damaged tissue, which in turn disrupts sensory cells. Detection of edema that is in and around the macula, the central most sensitive area of the retina, is particularly important since this is one of the main causes of blindness from diabetes. A stereoscopic image is actually composed of two images, one for the observer's right eye and one for the observer's left eye. The observer perceives stereopsis when the two images are combined in the observer's brain. To acquire a stereoscopic pair from an ordinary retinal camera, the photographer takes one picture of the retina, then rotates the camera slightly and takes another picture of the same field. Alternatively, with some cameras, stereoscopic images are rendered by combining overlapping areas of different fields. Some retinal cameras, such as the Nidek 3DX, Visual Pathways ARIS, and the Clarity Pathfinder, can acquire both right and left stereoscopic images simultaneously

There are a few different ways to view digital stereoscopic images once they are acquired. The simplest is to place the stereoscopic pair side by side on a computer screen (or screens), then cross the eyes or use prisms or mirrors to overlay the image in the observer's right eye onto the image in the observer's left eye. After some practice fusing images becomes easier and it often becomes unnecessary to use prisms or mirrors. This method requires no special software and can be viewed on any monitor. At UC Berkeley, the retinal reading stations have dual computer monitors where the stereoscopic pair is rendered over the span of the two monitors allowing a larger area to be viewed in stereo. Another way to view images in stereo is to use special "shutter" eyeglasses that are connected to the computer's video card. Right and left stereoscopic images are alternately displayed at 60 times per second or faster while the eyeglasses are synchronized to alternately block the view of one eye. Disadvantages are that the images may be dimmer and it is necessary to use proprietary software and eyeglasses to create and view the images on the observer's work station. Still another option is to use recently released computer monitors that can render stereoscopic images without having to use special eyeglasses to view them. These monitors display the two images in alternating vertical strips which are then directed alternately to either the observer's right or left eye. The disadvantages of this strategy includes costly monitors for all viewing stations, special software to render the images, and only one observer can view stereoscopic images at a time.

UC Berkeley's DRS photography protocol uses three overlapping fields which contain images of the optic nerve and macula that can be combined for stereoscopic viewing.

Although stereoscopic viewing of the retina is the gold standard for diabetic retinopathy detection, many, if not most, screening programs do not use stereoscopic viewing. Retinal edema is a significant finding for assessing diabetic retinopathy; however, many clinicians feel that it does not affect their referrals to specialists unless the edema is in or around the macula. Bresnick et al¹¹ found that the presence of hard exudates (fatty protein leakage from damaged blood vessels) within about 1500 microns of the macula detected clinically significant macular edema (CSME) with a sensitivity of 94% and specificity of 54%. This means that almost all patients with CSME will be detected and about half of those patients who are found to have CSME will not actually have it. Many clinicians feel that the 2-to-1 over-referral rate caused by using this guideline is acceptable because the consequence of a false positive result is simply an eye examination.

Compression

Compression allows digital images to be stored in small computer files. Smaller files make it more efficient to store, retrieve, and transmit images. Without compression some retinal images would be too large to be practical for telemedicine. There are many ways to compress images. Some methods, such as JPEG and PNG, are standard compression formats and the programs necessary to display these images are already in any typical computer or Internet browser. Some compression methods are proprietary and users are required to install or download special programs in order to view images in these formats. Some compression methods are "lossless", which means that they are exactly like the original uncompressed image when they are displayed. Others are "lossy", meaning that they may look like the original image, but some fine detail and image information may be lost. Some diabetic retinopathy screening programs use

only uncompressed images due to concerns that misinterpretation of compressed retinal images may create legal liability. Some studies have compared graders viewing retinal images with lossless compression and “lossy” compression. Although they may not be definitive, the results generally indicate that compression up to about 15 to 1 level (i.e. the compressed image is roughly one fifteenth the size of the original) does not significantly affect the grading of retinal images.¹² Significant image degradation occurs, however, when images are enhanced or modified after they are compressed.

A system using a fiber optic network with no limitation on data storage would perform well with uncompressed retinal images. Many primary clinics, however, have far more modest bandwidth connectivity and must transmit images in the most efficient way possible. The UC Berkeley Retinal Reading Center allows transmission of uncompressed images, but encourages the use of compression no greater than 15 to 1. UC Berkeley uses the JPEG format for compressed images because it provides adequate image quality and is widely accessible through almost all imaging programs and web browsers.

Enhancement

Some developers of retinopathy screening programs recommend that images should be stored as “raw” images for medico-legal

reasons in order to ensure that detected lesions are actually present and are not artifacts of the enhancement. A typical digital image, however, goes through several image processing steps before it is rendered on a display, so it becomes unclear at what stage is an image still “raw.” In addition, a significant number of popular applications do not support direct display of .RAW image files. In practice, high quality JPEG images have proven more than adequate for the screening process.

Pupil Dilation

Many retinal cameras, such as the Canon DGi, and the Topcon NW-200, do not require pupillary dilation for retinal photography. Even with these cameras, however, images are often of better quality when they are taken through dilated pupils. Approximately 10% of images that are acquired without pupillary dilation with non-mydratic retinal cameras can not be appropriately interpreted by clinicians due to poor image quality. Two factors that affect image quality are small pupil size and media opacities, such as cataracts. These limitations can be overcome by temporarily increasing the pupil size with pharmacological agents. Better images can be acquired more quickly when pupils are dilated, particularly in older patients, since they are more likely to have small pupils and media opacities. Pharmacological dilation, however, can have adverse effects. The most common adverse effects are photophobia (sensitivity to light) and cycloplegia (inability to change focus, usually causing near blur). Other adverse effects are much less common, and include hypersensitivity, which can cause conjunctival and corneal inflammation and ocular infection from contact with contaminated eye drops. Pupillary dilation has occasionally been reported to cause acute angle closure glaucoma, a painful sight-threatening condition. The use of





two dilating agents used in combination for full pupillary dilation has been reported to potentially cause angle closure in approximately one out of five thousand individuals. There have been no reported cases of angle closure caused by using a single dilating agent.¹³ One drop per eye of 1% tropicamide can be used as a single agent to provide adequate dilation for retinal photography. Onset of pupillary dilation is approximately 15 minutes and photophobia and cycloplegia will typically last from two to four hours, although a few individuals may experience pupil dilation for up to three days.

A specific protocol for pupil dilation should be followed if eye care professionals are not available to instill eye drops. An example protocol is found in the Appendix.

Program Assistance and Support

CTEC is available to provide assistance to organizations interested in developing or expanding telemedicine programs. CTEC is a leading source of expertise and comprehensive knowledge on the development and operation of telemedicine and telehealth programs. CTEC has received national recognition as a federally designated Telehealth Resource Center. Please contact us to discuss your needs.

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Glossary of Teleophthalmology Terms

Diabetic Retinopathy (DR) - Diabetic retinopathy is a microvascular complication of diabetes where leakage and blockage of small vessels in the retina cause swelling of retinal tissue, abnormal blood vessel growth, cell death, and retinal detachments. Diabetic retinopathy (DR) is the leading cause of blindness among working age adults in the United States. Vision loss can be prevented in most cases by performing retinal laser photocoagulation in a timely manner.¹⁴ A detailed discussion of prevention, early detection, evidence-based recommendations, clinical trials, and grading scales is presented in the American Academy of Ophthalmology's Diabetic Retinopathy Preferred Practice Pattern¹⁵ Although early detection and treatment of sight-threatening DR can prevent blinding complications, less than half of all diabetics receive recommended yearly eye examinations.¹⁶

ADA Guidelines Terms:

Macular Edema – Fluid from leaky blood vessels accumulating around the macula (the center of vision in the retina). Clinically significant macular edema is defined by the ETDRS to include any of the following features:

- Thickening of the retina at or within 500 microns (about one third of the optic nerve head diameter) of the center of the macula.
- Hard exudates at or within 500 microns of the center of the macula, if associated with thickening of the adjacent retina (not residual hard exudates remaining after the disappearance of retinal thickening).
- A zone or zones of retinal thickening one disc area or larger, any part of which is within one disc diameter of the center of the macula.

Severe NPDR – Severe Non-Proliferative Diabetic Retinopathy: The cutoff of severe NPDR is derived from the “4-2-1 rule” where presence of the following would qualify for this level if no PDR is present:

- 4 quadrants of hemorrhages or microaneurysms greater than ETDRS standard photograph 2A (> 20 retinal hemorrhages); or
- 2 quadrants of venous beading; or
- 1 quadrant of IRMA equal or greater than ETDRS standard photograph 8A (prominent, easily visible abnormal blood vessels)

PDR – Proliferative Diabetic Retinopathy: Neovascularization (new blood vessel growth) and/or vitreous/preretinal hemorrhage (blood in front of the retina).

IRMA – Intra-Retinal Microvascular Abnormalities: dilated abnormal capillaries, which are often leaky, and lie in the plane of the retina. They usually occur in areas of widespread capillary occlusion, often associated with occlusion of larger vessels and cotton-wool spots.

Vitrectomy - The vitreous is a normally clear, gel-like substance that fills the center of the eye. Advanced diabetic retinopathy may require a vitrectomy, or surgical removal of the vitreous. After a vitrectomy, the vitreous is replaced as the eye secretes aqueous and nutritive fluids.

A vitrectomy may be performed to clear blood and debris from the eye, to remove scar tissue, or to alleviate traction on the retina. Blood, inflammatory cells, debris, and scar tissue obscure light as it passes through the eye to the retina, resulting in blurred vision. The vitreous is also removed if it is pulling or tugging the retina from its normal position.

ETDRS¹⁷ (Early Treatment of Diabetic Retinopathy Study) - A large NIH sponsored study which measured the effectiveness of early diabetic retinopathy treatment with laser and created a widely accepted scale for staging diabetic retinopathy.



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Appendix

Sample Protocol 1: Diabetic Retinopathy Screening Services

University of California, Berkeley Retinal Reading Center

PROCEDURE FOR DIABETIC RETINOPATHY SCREENING SERVICES (DRS)			
Department	DIABETES CARE FACILITIES	Effective Date	June 28, 2005
Campus		Date Revised	
Unit		Next Scheduled Review	
Manual		Author	Jorge Cuadros
Replaces the following Policies:		Responsible Person	

Policy

1. All appropriate consents must be obtained for Diabetic Retinopathy Screening Services.
2. All patients must be referred by the primary care physician (PCP) for DRS services based on the following guidelines:
 - a. Diagnosed diabetic patients who have not had a retinal exam within the last year.
 - b. Completed pinhole test (visual acuity).
 - c. Has recent lab results (within the last 6 months), including Cholesterol, Triglycerides, and Hemoglobin A1C.
3. All appropriate documentation must be sent with the referral prior to the DRS services appointment.
4. All photographers providing DRS services must complete Diabetic Retinopathy Screening Photography Training and complete 10 satisfactory sets of images prior to providing DRS patient services.

Background

According to the American Diabetes Association, up to 21% of people with type 2 diabetes have retinopathy when they are first diagnosed with diabetes, and most will eventually develop some degree of retinopathy. Diabetes is responsible for 8% of legal blindness, making it the leading cause of new cases of blindness in adults 20-74 years of age. Through the findings of the 2002 Behavioral Risk Factor Surveillance System, the CDC reports that each year, 12,000–24,000 people in this country become blind because of diabetic eye disease. Regular eye exams and timely treatment could prevent up to 90% of diabetes-related blindness. However, only 60% of people with diabetes receive annual dilated eye exams as recommended by the American Diabetes Association guidelines. Some studies have also indicated that preventive ophthalmic surveillance of high-risk diabetic individuals is even worse in urban underserved communities. (Flowers, et al.)

Seven out of every 100 people in California are estimated to have diabetes, a 2.3 per every 100 people increase from 1994. African American, Hispanic, American Indian, and Alaska Native adults are about 2–3 times more likely than white adults to have diabetes. It is estimated at 15% of adult American Indian/ Alaska Native have diabetes, 13% of African American, 10% of Latinos, and nearly 8% of Whites. The prevalence of diabetes has increased steadily over the past 20 years, most notably among African Americans. Recent increases have also occurred among Latinos. (CDC)

Dilated comprehensive eye examinations have been demonstrated to be of great potential benefit for diabetic retinopathy. However, with national studies indicating that only 60% of diabetics actually undergo annual dilated examinations and urban underserved communities exhibiting even worse numbers have driven diabetic retinopathy screening models via digital fundus photography into the forefront of diabetes management.

With the introduction of digital fundus cameras, high capacity computers, and the internet, the medical and financial implications of a telemedicine retinopathy screening model has been explored in the past decade. DRS, however, is not a substitute for regular comprehensive eye examinations.

Procedure

1. Patients may be appointed for DRS services for same day appointments or for future appointments when same day appointments are not available.
2. The photographer(s) will follow steps in image capture as outlined in EyePACS DRS Photography Manual.
3. Three standard fields and fundus reflex photographs will be captured.
 - a. Field 1M – Disc
 - b. Field M – Macula
 - c. Field 3M – Temporal to Macula
4. Documentation of the service will be inserted in the patient chart by photographer.
5. All images are transmitted via Internet to the EyePACS image server at UC Berkeley.
6. All pictures are stored for transmission for review and consult by credentialed UC Berkeley reviewers. Reports of the retinal screening cases will be appended to digital case presentation usually within one hour, but not more than five days after image capture.
7. Patients needing further retinal services will be referred by photographer to appropriate eye care specialist as indicated in EyePACS report.
8. The photographer assures that all electronically transmitted information is printed and the hardcopy report is placed in patient's chart or sent to Medical Records for processing according to existing procedures for consult reports.

In the event that adequate images cannot be acquired:

1. If the photographer determines that clear images can't be acquired, then the patient will be encouraged to go to their general eye exam appointment.

References

ADA Guidelines on Diabetic Retinopathy Screening.

Basu A, Kamal AD, Illahi W, Khan M, Stavrou P, Ryder RE. Is digital image compression acceptable within diabetic retinopathy screening? *Diabet Med.* 2003 Sep;20(9):766-71.

Bursell SE, Cavallerano JD, Cavallerano AA, Clermont AC, Birkmire-Peters D, Aiello LP, Aiello LM; Joslin Vision Network Research Team. Stereo nonmydriatic digital-video color retinal imaging compared with Early Treatment Diabetic Retinopathy Study seven standard field 35-mm stereo color photos for determining level of diabetic retinopathy. *Ophthalmology.* 2001 Mar;108(3):572-85.

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Approvals

(This area can be changed depending on approvals needed. Signatures are required on all new policies)

Departmental	Date:
Administrative Team	Date:
Board	Date:



Sample Protocol 2: Diabetic Retinopathy Photography Review

University of California, Berkeley Retinal Reading Program

PROCEDURE FOR DIABETIC RETINOPATHY PHOTOGRAPHY REVIEW			
Department	COMMUNITY CLINICS AND DIABETES CENTERS	Effective Date	July 28, 2005
Campus	UC Berkeley Optometric Eye Center	Date Revised	
Unit	EYE – TELEMEDICINE	Next Scheduled Review	
Manual		Author	Jorge Cuadros, OD, PhD
Replaces the following Policies:		Responsible Person	

Policy

1. Optometrists will review digital DRS cases at a web terminal and report to PCP and to tertiary care providers as needed. Optometrists will follow the ADA guidelines for referral.

Background

According to the American Diabetes Association, up to 21% of people with type 2 diabetes have retinopathy when they are first diagnosed with diabetes, and most will eventually develop some degree of retinopathy. Diabetes is responsible for 8% of legal blindness, making it the leading cause of new cases of blindness in adults 20-74 years of age. Through the findings of the 2002 Behavioral Risk Factor Surveillance System, the CDC reports that each year, 12,000–24,000 people in this country become blind because of diabetic eye disease. Regular eye exams and timely treatment could prevent up to 90% of diabetes-related blindness. However, only 60% of people with diabetes receive annual dilated eye exams as recommended by the American Diabetes Association guidelines. Some studies have also indicated that preventive ophthalmic surveillance of high-risk diabetic individuals is even worse in urban underserved communities. (Flowers, et al.)

Seven out of every 100 people in California are estimated to have diabetes, a 2.3 per every 100 people increase from 1994. African American, Hispanic, American Indian, and Alaska Native adults are about 2–3 times more likely than white adults to have diabetes. It is estimated at 15% of adult American Indian/Alaska Native have diabetes, 13% of African American, 10% of Latinos, and nearly 8% of Whites. The prevalence of diabetes has increased steadily over the past 20 years, most notably among African Americans. Recent increases have also occurred among Latinos. (CDC)

Dilated comprehensive eye examinations have been demonstrated to be of great potential benefit for diabetic retinopathy. However, with national studies indicating that only 60% of diabetics actually undergo annual dilated examinations and urban underserved communities exhibiting even worse numbers have driven diabetic retinopathy screening models via digital fundus photography into the forefront of diabetes management.

With the introduction of digital fundus cameras, high capacity computers, and the internet, the medical and financial implications of a telemedicine retinopathy screening model has been explored in the past decade. Although the quality of fundus photography has not been proven to be a suitable substitute for a dilated comprehensive eye exam done by an ophthalmologist or optometrist, there have been some examples of beneficial outcomes.

Procedure

1. Attending optometrist receives notification of cases to review.
2. Attending optometrist reviews images and case information and follows the ADA guidelines for referral of sight-threatening retinopathy.
3. Attending optometrist generates a report in EyePACS usually within one hour, but not more than 14 days from date of e-mail notification. Report indicates findings, impressions, and advice.
4. Notification that report has been generated is sent to referring clinic.

In the event that adequate images cannot be reviewed:

1. If the images that are transmitted are not of sufficient quality to make an assessment, then e-mail notification will be sent back to referring clinic recommending that patient be encouraged to attend their general eye exam appointment.

In the event that patient needs referral for tertiary care:

1. If the reviewing optometrist determines that patient requires a referral to ophthalmology services, notification will be sent along with report indicating need for further study or treatment with appropriate specialist.
2. Primary care clinic staff will follow regular referral procedure to refer patient to ophthalmology clinic.

References

ADA Guidelines on Diabetic Retinopathy Screening.

Basu A, Kamal AD, Illahi W, Khan M, Stavrou P, Ryder RE. Is digital image compression acceptable within diabetic retinopathy screening? *Diabet Med.* 2003 Sep;20(9):766-71.

Bursell SE, Cavallerano JD, Cavallerano AA, Clermont AC, Birkmire-Peters D, Aiello LP, Aiello LM; Joslin Vision Network Research Team. Stereo nonmydriatic digital-video color retinal imaging compared with Early Treatment Diabetic Retinopathy Study seven standard field 35-mm stereo color photos for determining level of diabetic retinopathy. *Ophthalmology.* 2001 Mar;108(3):572-85.

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Lin DY, Blumenkranz MS, Brothers RJ, Grosvenor DM. The sensitivity and specificity of single-field nonmydriatic monochromatic digital fundus photography with remote image interpretation for diabetic retinopathy screening: a comparison with ophthalmoscopy and standardized mydriatic color photography. *Am J Ophthalmol.* 2002 Aug;134(2):204-13.

Wilkinson CP, Ferris FL 3rd, Klein RE, Lee PP, Agardh CD, Davis M, Dills D, Kampik A, Pararajasegaram R, Verdaguer JT; Global Diabetic Retinopathy Project Group. Proposed international clinical diabetic retinopathy and diabetic macular edema disease severity scales. *Ophthalmology.* 2003 Sep;110(9):1677-82. Review.

Approvals

(This area can be changed depending on approvals needed. Signatures are required on all new policies)

Departmental	Date:
Administrative Team	Date:
Board	Date:

Sample Protocol 3: Pupil Dilation Before Diabetic Retinopathy Photography

University of California, Berkeley Optometric Eye Center

PROCEDURE FOR PUPIL DILATION BEFORE DIABETIC RETINOPATHY PHOTOGRAPHY			
Department	DIABETES CLINICS	Effective Date	November 16, 2005
Campus	UC Berkeley Optometric Eye Center	Date Revised	
Unit	EYE – TELEMEDICINE	Next Scheduled Review	
Manual		Author	Jorge Cuadros, OD, PhD
Replaces the following Policies:		Responsible Person	

Policy

Patients will undergo pharmacological pupillary dilation with one drop per eye of 1% tropicamide solution when retinal images are of insufficient quality for interpretation and no risk factors exist for complications from pupillary dilation.

Background

Approximately 10% of images that are acquired without pupillary dilation with non-mydratic retinal cameras can not be appropriately interpreted by clinicians due to poor image quality. Two factors that affect image quality are small pupil size and media opacities, such as cataracts. These limitations can be overcome by temporarily increasing the pupil size with pharmacological agents. Better images can be acquired more quickly when pupils are dilated, particularly in older patients, since they are more likely to have small pupils and media opacities. Pharmacological dilation, however, can have adverse effects. The most common adverse effects are photophobia (sensitivity to light) and cycloplegia (inability to change focus, usually causing near blur). Other adverse effects are much less common, and include hypersensitivity, which can cause conjunctival and corneal inflammation and ocular infection from contact with contaminated eye drops. Pupillary dilation has occasionally been reported to cause acute angle closure glaucoma, a painful sight-threatening condition. The use of two dilating agents used in combination for full pupillary dilation have been reported to potentially cause angle closure in approximately one out of five thousand individuals. There have been no reported cases of angle closure caused by using a single dilating agent. One drop per eye of 1% tropicamide can be used as a single agent to provide adequate dilation for retinal photography. Onset of pupillary dilation is approximately 15 minutes and photophobia and cycloplegia will typically last from two to four hours, although rare individuals may experience pupil dilation for up to three days.

Procedure

In the event that adequate images cannot be acquired without pupillary:

1. Photographer or qualified health care personnel determines that patient does not:
 - a. have a history of glaucoma
 - b. have significant redness, irritation, or discharge from eyes

- c. have previously had significant adverse reactions to pupillary dilation
 - d. is not pregnant
 - e. is not wearing contact lenses
 - f. has not had a previous adverse reaction to papillary dilation
2. Explain to patient that one drop will be instilled in each eye to increase pupil size. Blurred vision and light sensitivity may be experienced for two to four hours. Care should be taken when driving or performing other potentially dangerous activities until the effect of the drops goes away. In rare instances the effects may last for two days.
 3. The bottle of drops should be discarded if the nozzle appears discolored or contaminated. Do not use expired eye drops.
 4. Hold the bottle a half inch to one centimeter from the eye while instilling drop. If simultaneous contact occurs with the drops, the eye and the bottle, then the drops should be discarded due to contamination.
 5. Patient can then pat eyes dry with a tissue without vigorously rubbing eyes.
 6. Wait between 15 to 30 minutes for drops to take effect.
 7. After photography, give the patient plastic sun shields before leaving the clinic in order to avoid light sensitivity.

References

ADA Guidelines on Diabetic Retinopathy Screening.

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Pandit R, Taylor R. Mydriasis and glaucoma: exploding the myth. A systematic review. *Diabet Med* 17, 693-699 (2000).

Approvals

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