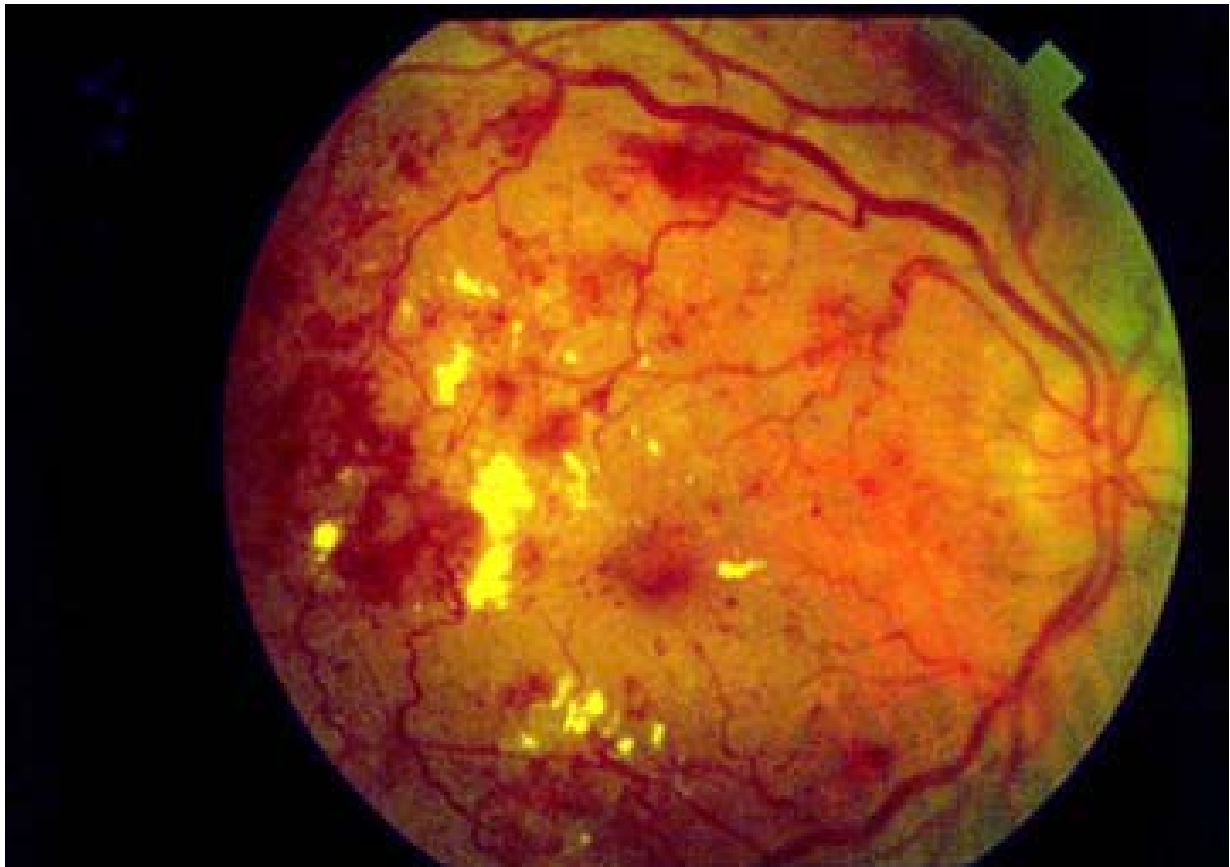


Telehealth Practice Recommendations for Diabetic Retinopathy

A roadmap of technical standards, clinical guidelines and administrative procedures.



Prepared by the American Telemedicine Association, Ocular Telehealth Special Interest Group, and the National Institute of Standards and Technology Working Group*

May, 2004

* A complete listing of the working group follows this article.

Table of Contents

I.	Introduction.....	3
II.	Background.....	3
	A. The Diabetic Retinopathy Study (DRS).....	4
	B. Early Treatment Diabetic Retinopathy Study (ETDRS).....	4
	C. Diabetic Retinopathy Vitrectomy Study (DRVS).....	4
	D. Diabetes Control and Complications Trial (DCCT)/Epidemiology of Diabetes Interventions and Complications (EDIC).....	4
III.	Mission, Vision, Goals, and Guiding Principles of a Telehealth Diabetic Retinopathy Program.....	5
	A. Mission.....	6
	B. Vision.....	6
	C. Goals.....	6
	D. Guiding Principles.....	6
IV.	Ethics.....	6
V.	Communication.....	7
VI.	Qualifications of Personnel.....	7
	A. Imager.....	7
	B. Reader.....	7
	C. Adjudicating Reader.....	8
	D. Information Systems (IS) Specialist.....	8
VII.	Equipment Specifications.....	8
	B. Image Acquisition.....	8
	C. Compression.....	9
	D. Image Analysis.....	10
	E. Data Communication and Transmission.....	10
	F. Computer Display.....	10
	G. Archiving and Retrieval.....	10
	H. Security.....	11
	I. Reliability and Redundancy.....	11
	J. Documentation.....	11
VIII.	Legal Requirements.....	11
	A. Licensure.....	11
	B. Facility Accreditation.....	12
	C. HIPAA.....	12
	D. Privileging and Credentialing.....	12
	E. Liability.....	12
	F. Consent.....	13
IX.	Validation.....	13
	A. Category 1.....	14
	B. Category 2.....	14
	C. Category 3.....	14
	D. Category 4.....	14
X.	Quality Control.....	14
XI.	Financial Factors.....	16
XII.	Figures and Tables.....	17
XIII.	Abbreviations.....	20
XIV.	References.....	21
XV.	Contributors.....	24

I. Introduction

Telehealth holds the promise of increased adherence to evidenced-based medicine and improved consistency of care. Goals for an ocular telehealth program include preserving vision, reducing vision loss and providing better access to medicine. This document includes recommendations for designing and implementing a diabetic retinopathy ocular telehealth care program.

Establishing recommendations for an ocular telehealth program may improve clinical outcomes and promote informed and reasonable patient expectations. This document addresses current diabetic retinopathy telehealth clinical and administrative issues. It also forms the basis for evaluating diabetic retinopathy telehealth techniques and technologies. Recommendations in this document are based on careful reviews of current evidence, medical literature and clinical practice. They do not, however, replace sound medical judgment or traditional clinical decision-making. *Telehealth Practice Recommendations for Diabetic Retinopathy* will be annually reviewed and updated to reflect evolving technologies and clinical guidelines.

II. Background

Diabetes mellitus (DM) is a leading cause of death, disability, and blindness in the United States.^{1,2} It afflicts as much as 8% of the American population³ and the prevalence and incidence of DM is increasing. The World Health Organization (WHO) estimates there are currently 176 million people worldwide with DM and predicts 370 million people with DM by 2030.⁴ The United States Center for Disease Control and Prevention estimates 10.3 million Americans have diagnosed DM and an additional 5.4 million have the disease but have not yet been diagnosed.⁵

Diabetic retinopathy (DR) is a leading cause of new-onset blindness in the United States and many other industrialized countries. DR develops in nearly all persons with DM. The WHO estimates that after 15 years of DM, approximately 2% of people with DM become blind, while 10% develop severe visual handicap⁴. DR is a microvascular complication of both type 1 and type 2 DM. In the Wisconsin Epidemiologic Study of Diabetic Retinopathy (WESDR), 13% of the study population with DM duration less than 5 years and 90% with duration of DM 10-15 years had some level of DR when onset of DM was prior to age 30 years (presumed to have type 1 DM). For those with onset at age 30 years or older (presumed to have type 2 DM), 40% taking insulin and 24% not taking insulin had some level of DR when the duration of DM was less than 5 years. Eighty-four percent taking insulin and 53% not taking insulin had some level of DR when duration of DM was 15-20 years.^{6,7} DR affects over 5.3 million Americans over the age of 18 (2.5% of the US population).⁸ The medical, social, and economic ramifications of the disease are substantial.

Evidence-based treatments demonstrated in clinical studies spanning 30 years provide ways to virtually eliminate the risk of severe vision loss from proliferative diabetic retinopathy. Methods are also available to reduce significantly the risk of legal blindness and moderate vision loss. Unfortunately, DR remains a leading cause of new-onset

blindness in working-aged populations in the United States and other industrialized countries. For a variety of reasons, effective treatments such as laser surgery are underutilized.

Clearly defined clinical standards for evaluating and treating DR have evolved. Five major multi-center clinical trials in the United States and United Kingdom provide the science behind DR clinical management.

A. The Diabetic Retinopathy Study (DRS)

The DRS (1971-1975) demonstrated conclusively that scatter (panretinal) laser photocoagulation reduces the risk of severe vision loss from proliferative diabetic retinopathy (PDR) by as much as 60%.⁹⁻¹¹

B. Early Treatment Diabetic Retinopathy Study (ETDRS)

The ETDRS (1979-1990) demonstrated that scatter (panretinal) laser photocoagulation can reduce the risk of severe vision loss (best corrected vision of 5/200 or worse) to less than 2%. It also found focal laser photocoagulation can reduce the risk of moderate vision loss (a doubling of the visual angle) from diabetic macular edema (DME) by 50%, and that there is no adverse effect on progression of DR or risk of vitreous hemorrhage for patients with DM who take up to 650 mg of aspirin per day.¹²⁻¹⁶

C. Diabetic Retinopathy Vitrectomy Study (DRVS)

The DRVS (1977-1987) provided insight into timing for vitrectomy surgery to restore useful vision in eyes with non-resolving vitreous hemorrhage.^{17, 18}

D. Diabetes Control and Complications Trial (DCCT)/Epidemiology of Diabetes Interventions and Complications (EDIC)

The DCCT (1983-1993) compared conventional blood glucose control to intensive blood glucose control in patients with type 1 DM and little or no DR. The DCCT conclusively demonstrated that for persons with type 1 DM, intensive control of blood glucose as reflected in measurements of glycosylated hemoglobin A1c: reduces the risk of a three-step progression of DR by 54%, reduces the risk of developing severe nonproliferative DR (NPDR) or proliferative DR (PDR) by 47%, reduces the need for laser surgery by 56%, and reduces the risk of diabetic macular edema by 23%¹⁹⁻²⁵. Significantly, the EDIC study showed at seven years after the completion of the DCCT, subjects in the intensive control group continued to show a substantial decrease in risk of progression of retinopathy compared to the conventional control group, despite a near convergence of hemoglobin A1c levels.²⁶

The United Kingdom Prospective Diabetes Study (UKPDS)

The UKPDS (1977-1999) demonstrated similar findings to the DCCT for persons with type 2 DM.^{27, 28}

Because DR is often asymptomatic in its early stages, many people do not seek annual retinal examination as recommended by the American Diabetes Association, the American Academy of Ophthalmology, the American Optometric Association, and other

professional societies. Others may lack care due to socio-economic factors, geographic or travel restrictions, or ignorance of the need for regular retinal examination for DR. It is estimated that 50% of adults with DM in the US do not receive recommended eye care to diagnose and treat DR.²⁹ Studies also show that only 40% of diabetic persons receive adequate eye care and that 60% of those who require sight-preserving laser surgery do not receive treatment.³⁰

Approximately 26% of patients with type 1 DM and 36 percent with type 2 DM have never had their eyes examined.³¹ These patients tend to be older, less educated, and more recently diagnosed than those receiving regular eye care.³¹ They are also likely to live in rural areas and receive health care from a family or general practitioner.³¹ Alarming, 32% of patients with DM at high risk for vision loss never receive an eye examination.³² When examined, almost 61% exhibit DR, cataract, glaucoma, or other ocular manifestations of DM.

The prevalence of DR is high and the incidence is growing in step with worldwide increases in DM. Loss of vision due to DR has a considerable impact on personal and societal resources. In the US, approximately 24,000 persons become blind from DM each year. It is estimated that programs to identify and treat DR could annually save the US healthcare budget nearly \$400 million.^{33, 34}

DR is readily diagnosed by appropriate examination. Film-based retinal imaging has been a mainstay of DR research for many years. Digital retinal imagery is a relatively new tool for assessing patients with DR. Telehealth programs based on digital retinal imagery have the potential to allow increased diagnoses of DR, resulting in timely treatment and preservation of vision.

DM and its eye complications provide an ideal model for telehealth initiatives. DR care has a firm foundation in evidenced-based medicine, is classified by specific retinal lesions, exacts a significant personal and socioeconomic toll, and is a treatable disease. According to the WHO, telehealth programs are “designed to integrate telecommunications systems into the practice of protecting and promoting health,” while “telemedicine programs are designed to integrate telecommunications into diagnostic and therapeutic intervention for the practice of curative medicine.”⁴ Ocular telehealth and telemedicine have the potential of delivering eye care to those without access. They can also provide enhanced care to those with readily available ocular care. Telehealth programs can additionally establish and enforce quality of care by linking to national clinical trial scientific data; offering education modules to health care professionals, patients, and communities; and facilitating recruitment for clinical trials.

III. Mission, Vision, Goals, and Guiding Principles of a Telehealth Diabetic Retinopathy Program

Designing, building and implementing an ocular telehealth DR program requires a clearly defined mission, vision, goals, and guiding principles. The following statements are a guide for leadership and staff to follow in developing coherent, effective and sustainable programs.

A. Mission

Increase access and adherence to demonstrated standards of care among individuals with DM.

B. Vision

Ocular telehealth can be an integral component of primary care for individuals with DM. Ocular telehealth has the potential to expand access to diabetic retinal examinations for individuals with DM consistent with evidence-based recommendations for diabetic eye care (i.e., ETDRS, DCCT, UKPDS).

C. Goals

1. Improve access to diagnosis and management of diabetic retinopathy.
2. Reduce the incidence of vision loss due to DR.
3. Decrease the cost of identifying patients with DR.
4. Promote telehealth to enhance the efficiency and clinical effectiveness of evaluation, diagnosis and management of DR.
5. Promote telehealth to enhance the availability, quality, efficiency and cost-effectiveness of remote evaluation for DR.

D. Guiding Principles

Though ocular telehealth programs offer new opportunities to improve access and quality of care for people with DR, programs should be developed for deployment in a safe and effective manner. Program outcome should be closely monitored to meet or exceed current standards of care for retinal examination.

DM adversely affects most parts of the eye and has a diverse influence on visual function. As a component of informed consent, patients should be aware that a teleophthalmology examination of the retina can substitute for a traditional onsite dilated retinal evaluation, but that it is not a replacement for a comprehensive eye examination. A comprehensive eye examination by a qualified provider continues to be essential.

IV. Ethics

Care for patients using ocular telehealth does not diminish providers' duty to patients. The significance of the doctor-patient relationship does not change.³⁵ Providers that perform or oversee official interpretations of retinal telehealth images are responsible for the quality of reviewed images, evaluation of images and recommendations for appropriate care management. Regardless of an image's origin, providers should ensure the quality of medical images and policies that affect patient care and safety.³⁶⁻³⁸

V. Communication

Communication between eye care specialists and patients is an important component of ocular telehealth.³⁹ Providers interpreting retinal telehealth images should render reports in accordance with relevant jurisdictions and community standards.

VI. Qualifications of Personnel

Telehealth programs for DR depend upon four elements of care: image acquisition; image review and evaluation; patient care supervision; and image and data storage.^{40, 41} Image acquisition personnel are responsible for acquiring retinal images. Image review and evaluation specialists are responsible for grading images for retinal lesions and determining levels of DR. A licensed eye care provider with expertise in evaluation and management of DR should oversee image grading and ultimately be responsible for diagnoses. Patient care and supervisory specialists, image-requesting physicians, optometrists, nurses, nurse practitioners or other credentialed personnel should be responsible for follow-up. Image and data management specialists should be responsible for data integrity and the availability of stored images. Personnel should demonstrate competency as follows:

A. Imager

The nature of ocular telehealth is such that a licensed eye care professional may not be physically available at all times. Imagers should possess a minimum knowledge base and skill set to allow independent imaging with assistance and consultation by telephone. Skills and knowledge should include:

1. An understanding of the basic technology and ocular telehealth principles.
2. Demonstrated technical qualifications for obtaining appropriate image fields of diagnostic quality.
3. A basic understanding of the clinical appearance of the most common retinal diseases requiring immediate evaluation.
4. Communication skills consistent with patients' needs for informed consent and patient education.
5. An understanding of angle closure glaucoma if pupil dilation is performed.

B. Reader

Individuals qualified or specifically trained for the task should perform official grading and interpretation of retinal images. Qualifications may come in part or wholly through academic and clinical training. If a retinal telehealth reader is not a licensed eye care provider, specific training should be undertaken to provide the required knowledge, skills and abilities. Reading skills should take into consideration the ocular telehealth

technology used in the program. Readers should also be under the supervision of a licensed and qualified eye care provider with expertise in DR.

C. Adjudicating Reader

An adjudicating reader makes decisions resolving issues of ambiguous or controversial interpretation. In most cases, an adjudicating reader will be an ophthalmologist with special qualifications in DR by training or experience.

D. Information Systems (IS) Specialist

An IS specialist should be available in case of system malfunction to provide problem-solving input, initiate repair and to coordinate system-wide maintenance.

VII. Equipment Specifications

All elements of a telehealth system used in the United States should conform to Federal Drug Administration (FDA) regulations. Telehealth systems used outside the United States should meet appropriate local standards in that country. Elements include:

1. Image acquisition hardware (computers, cameras and other peripherals).
2. Systems for retinal image transmission, storage and retrieval such as Picture Archiving and Communication Systems (PACS).
3. Software applications for image analysis and clinical workflow management (scheduling follow-up examinations, clinical communication management, and decision support tools).

Equipment specifications will vary depending on individual telehealth program needs and available technology (see Figure 1). At a minimum, equipment should provide image quality and availability appropriate to meet clinical needs and current clinical guidelines. The diagnostic accuracy of any imaging system should be validated prior to being incorporated into a telehealth system.⁴²⁻⁴⁶

Technologies should be Digital Imaging and Communications in Medicine (DICOM) standards compliant. New equipment acquisitions and consideration of periodic upgrades to incorporate expanded features of DICOM standards should be part of an ongoing quality-control program.

B. Image Acquisition

Retinal image datasets should adhere to DICOM standards. DICOM data includes demographic, eye characteristics, retina characteristics, digital image characteristics, and other data linked to image files as metadata. Demographic information includes (parenthetical codes refer to DICOM header metadata):

1. Patient name (0010,0010).
2. Medical ID number (0010,0020).
3. Patient birth date (0010,0030).
4. Gender (0010,0040).
5. Date and time of examination (0008,0020) and (0008,0030).
6. Name of facility or institution of acquisition (0008,0080).
7. Accession number (0008,0050).
8. Modality (0008,0060).
9. Referring physician's name (0009,0090).
10. Manufacturer (0008,0070).
11. Manufacturer model name (0008,1090).
12. Software version (0018,1020).
13. Station name (0008,1010).

Data specific to the retinal evaluation that defines the type of retinal examination and the retinal image set should be included as part of the study information. These metadata includes:

14. Mydriatic (pupil dilation) or non-mydriatic (no pupil dilation) imaging.
15. Image capture modality (digitized analog video, or digital still imaging)
16. Number of retinal fields.
17. Size of field (i.e., 20-degree, 30-degree, 45-degree, 50-degree, 60-degree, and 200-degree).
18. Identification of single retinal field images, simultaneous or non-simultaneous stereo pairs.
19. Identification of stereo pairs.
20. Monochrome gray scale or color bit depth.
21. Orientation of eye (left or right, OD or OS).
22. Retinal region (superior, inferior, nasal temporal).
23. Ratio and type (i.e., wavelet or JPEG) of compression, if used (0028,2112).
24. Spatial resolution of the image (i.e., 640x480, 1000x1000, etc.).
25. Free text field for retinal imager study comments (i.e., presence of media opacities, poor fixation, poor compliance, etc.).
26. Description of any image post-processing.
27. Measurement data and/or pixel spacing (0028,0030).
28. Image magnification factor (mm/pixel).

Additional information such as medical and surgical history, laboratory values, etc. may also be included as metadata associated with an image set.

C. Compression

Data compression may be performed to facilitate transmission and storage of large retinal images. Compression may be used if compression algorithms have undergone clinical validation. Compression types and ratios should be periodically reviewed to ensure

appropriate clinical image quality and diagnostic accuracy. Eye care providers overseeing image grading are responsible for diagnostic accuracy.

D. Image Analysis

Computer algorithms to enhance digital retinal image quality or provide automated identification of retinal pathology are emerging technologies. Retinal image analysis tools for enhancing image quality (histogram equalization, edge sharpening, image deconvolution, etc.) or identifying specific lesions such as hemorrhages or hard exudates can be used to aid retinopathy assessment. Presentation of post-processed images should match the presentation of original retinal imagery. Additionally, image processing tools used for retinopathy assessment should be stated in reports developed for diagnosis of DR level. Image processing algorithms used to assess levels of DR should undergo rigorous validation to assure diagnostic accuracy.

E. Data Communication and Transmission

A variety of technologies are available for data communication and transfer. Each ocular telehealth program should determine specifications for transmission technologies best suited to the program. Transmission systems should have robust error checking mechanisms to ensure no loss of clinical information.⁴⁷ Data communications should be compliant with DICOM standards and a current DICOM conformance statement should accompany ocular telehealth systems.

If ocular telehealth applications are integrated with existing health information systems, interoperability requirements should include DICOM compliance, interfacing with Health Level 7 (HL7) standards, and establishment of appropriate routing for scheduling patients and transmission of reports.⁴⁸

F. Computer Display

Retinal images viewed for non-diagnostic purposes may be viewed in any format on any display. However, retinal images used for diagnosis should be displayed on high quality monitors with a suggested minimum 19" diagonal size. Any display monitor (cathode ray tube, liquid crystal display, gas plasma panel) used for diagnostic purposes should be validated for accuracy of clinical diagnosis. Grading of retinal images should be performed at capture resolution using noncompressed or lossless compressed image files. Lossy compressed and resized/resampled images may also be used if their algorithms are validated for diagnostic accuracy. Display workstation software should provide capabilities for selecting images from an image sequence.

Most display system operating characteristics can be adjusted to meet user preferences. It is recommended that standard or customized settings be validated for clinical diagnostic accuracy. Validation of diagnostic accuracy should be performed if settings are changed. Ambient light levels should be controlled and reduced as much as possible to eliminate reflections.

G. Archiving and Retrieval

Teleophthalmology systems should provide storage capacities in compliance with facility, state and federal medical record retention regulations. Images may be stored at imaging or reading sites and should meet jurisdictional requirements of the storing site. However, if retinal images are stored at the reading site, computer file retention periods must meet jurisdiction requirements of both sites. Prior examination records should also be available based on the facility and medical staff needs.

Each facility should have policies and procedures for archiving digital images equivalent to currently existing facility policies for protecting other digital data and hardcopy records.

H. Security

Teleophthalmology systems should have network and software security protocols to protect patient confidentiality and identification of image data. Measures should be taken to safeguard and ensure data integrity against intentional or unintentional data corruption. Privacy should be ensured through minimum 128-bit encryption and two-point authentication technology. Digital signatures may be used at image acquisition sites. Transmission of retinal imaging studies and study results should conform to Health Insurance Portability and Accountability Act (HIPAA) requirements.

I. Reliability and Redundancy

Written policies and procedures should be in place to ensure continuity of care at levels similar to hard-copy retinal imaging studies and medical records. These policies and procedures should include internal redundancy systems, backup telecommunications links and a disaster plan. Digital retinal images and reports should be retained as part of patient medical records to meet regulatory, facility and medical staff clinical needs

J. Documentation

Readers rendering reports on levels of DR or other ocular abnormalities should comply with guidelines established by the American Academy of Ophthalmology (http://www.aao.org/aao/education/library/ppp/dr_new.cfm). It is recommended that reports be based on software templates or forms compliant with DICOM standards. Forms should allow recording ocular pathology findings to define levels of DR according to accepted standards. It is also recommended that medical nomenclature used in reports conform to Systematized Nomenclature of Medicine (SNOMED <http://www.snomed.org/>) standards. Transmission of reports should conform to HIPAA requirements.

VIII. Legal Requirements

Legal and regulatory issues relating to the practice of ocular telehealth are generally the same as other telemedicine modalities.^{38, 39, 49}

A. Licensure

Licensing regulations vary from state to state. State medical practice acts are being evaluated and modified for specific reference to telemedicine. Some states allow degrees of flexibility but many are fairly restrictive of telemedicine issues.⁵⁰ Licensure may be a

component of other regulatory, financial, and risk management issues. Statutory diversity and rapid changes in state laws suggest telehealth programs should be vetted through appropriate legal counsel. Ocular telehealth programs should also ensure that providers operate within medical practice statutes of all associated state jurisdictions (i.e., jurisdictions of the image capture site and reading center site).

B. Facility Accreditation

Some hospital-based telehealth programs fall within regulatory influences of the Joint Commission for the Accreditation of Healthcare Organization (JCAHO <http://www.jcaho.org/>). Current and planned JCAHO standards suggest this accrediting body will increase attentiveness to telemedicine and ocular telehealth activities, becoming a significant regulatory influence. The Accreditation Association for Ambulatory Health Care (AAAHC <http://www.aaahc.org/>) accredits ambulatory health care. Rules for compliance with JCAHO, AAAHC or other ocular telehealth accrediting bodies exceed the scope of this document. However, the following areas should be considered if an ocular telehealth program determines it falls within the jurisdiction of an accrediting body:

1. Privileging and credentialing⁵¹
2. Peer review⁵²
3. Environment of care⁵³
4. Quality assurance

C. HIPAA

HIPAA rules and their interpretation are evolving. Ocular telehealth programs should obtain professional consultation for HIPAA compliance specific to operations (<http://tie.telemed.org/legal/privacy/>). The following general issues should be considered when constructing clinical, administrative, and technical operation plans:

1. Data privacy and integrity of protected health information.
2. Data security policy and procedures to provide protection against unauthorized access to patient records. Security mechanisms include the use of passwords, secure and high order encryption protocols and audit trails to document file access.
3. Disaster data loss recovery plans with reasonable assurance of continuity of service.
4. Patient consent for release and use of protected health information.

D. Privileging and Credentialing

Providers responsible for official interpretation of retinal telehealth images should be credentialed and obtain appropriate privileges from the imaging institution.^{50, 54} Generally, initial and reappointment privileges criteria are based on reviews of current competency. Ocular telehealth practices should be conducted consistent with bylaws, rules, and regulations for patient care at transmitting sites or transmitting jurisdiction.

E. Liability

Providers engaging in a retinal telehealth practice should consult with their professional liability carrier to ensure coverage in both the initiating and receiving sites.

F. Consent

Patients have the right to autonomous, informed participation in health care decisions.⁵⁵ Informed consent is required for all clinical treatments and procedures including those delivered via telemedicine. For the purpose of informed consent, ocular telehealth is considered part of the treatment or procedure used to deliver health care services.⁵⁶

Patients should be informed that they are free to choose among treatments or procedures that use ocular telehealth and those that do not. Practitioners should provide information about the ocular telehealth program that patients would reasonably want to know, including:

1. Differences between care delivered using ocular telehealth and face-to-face care.
2. Benefits and risks of using ocular telehealth in the patient's situation.
3. Consideration of whether use of ocular telehealth would generally be considered novel or unorthodox.

When treatments or procedures delivered through ocular telehealth are considered low risk and within commonly accepted standards of practice, signature consent may not be required.⁵⁰ Retinal telehealth services for DR may satisfy these criteria.

IX. Validation

Multi-centered, national clinical trials provide evidence-based criteria for clinical guidelines in diagnosing and treating DR. Telehealth programs for DR should clearly define program goals and program performance in relationship to accepted clinical standards. In general, the selection of an ocular telehealth system for evaluating diabetic retinopathy should be based on the unique needs of the health care setting.

ETDRS thirty-degree, stereo seven-standard fields, color, 35 mm slides are an accepted standard for evaluating DR. Unlike film photography, however, no standard criteria have been widely accepted as performance measurements of digital imagery used for DR evaluation. There is yet no consensus on how digital imagery factors influence diagnostic image quality. Until standards for digital imagery are established, telehealth programs for DR should demonstrate an ability to compare favorably with ETDRS film photography as reflected in kappa values for agreement of diagnosis, false positive and false negative readings, positive predictive value, negative predictive value, sensitivity and specificity of diagnosing levels of retinopathy and macular edema.⁴²⁻⁴⁴ Inability to obtain or read images should be considered a positive finding for disease in telehealth programs for DR. Patients with unobtainable or unreadable images should be referred for evaluation by an eye care specialist.

It is recognized that standards other than ETDRS are in use for grading DR. Protocols should state the standards used for validation and relevant datasets used for comparison. *Telehealth Practice Recommendations for Diabetic Retinopathy* recognizes four

categories of validation for telehealth for DR using ETDRS thirty-degree, stereo seven-standard fields, color, 35 mm slides as a reference standard:

A. Category 1

Category 1 validation separates patients into two categories: (a) those who have no or very mild nonproliferative DR (ETDRS level 20 or below), and (b) those with levels of DR more severe than ETDRS level 20. Functionally, Category 1 validation allows identification of patients who have no or minimal DR and those who have more than minimal DR. (See Table 1 for comparisons between ETDRS levels of DR and the Proposed International Clinical Diabetic Retinopathy Disease Severity Scale, and Table 2 for comparisons between ETDRS DME and the Proposed International Clinical Diabetic Retinopathy Disease Severity Scale).⁵⁷

B. Category 2

Category 2 validation indicates a system can accurately determine if sight-threatening DR as evidenced by any level of DME, severe or worse levels of nonproliferative DR (ETDRS level 53 or worse), or proliferative DR (ETDRS level 61 or worse) is present or not present.¹⁴ Category 2 validation allows identification of patients who do not have sight-threatening DR and those who have potentially sight-threatening DR. These patients require prompt referral for possible laser surgery.

C. Category 3

Category 3 validation indicates a system can identify ETDRS defined levels of nonproliferative DR (mild, moderate, or severe), proliferative DR (early, high-risk), and DME 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.

D. Category 4

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.

X. Quality Control

Each program should develop protocols that include policies and procedures for monitoring and evaluating ocular telehealth system performance.⁵⁰ Image acquisition, transmission and reading functions should be evaluated. Like peer review processes used in other clinical settings, formal reviews of retinal telehealth program outcomes are fundamental to sustained quality care. Quality assurance methods should employ a peer review process for outcome review and identification of fallout cases to guide corrective interventions.^{58, 59} The following methods should be considered:

1. Standardized training for imager, imager trainers, and readers.⁶⁰
 - a) Structured, self-study pre-training of imager and reader to provide minimum background knowledge.
 - b) Structured curriculum training with defined endpoints to assure knowledge and skills proficiency.
 - c) Provisional certification followed by full certification based on experience with a minimum number of patients over a minimum period of time. Experience should demonstrate required levels of proficiency documented by formal quality assurance (QA) review of a fixed number of cases.
 - d) Time-limited certification of imagers and readers. Re-certification should be based on the period since last clinical encounter, number of clinical encounters over a period of time, and proficiency as documented by formal QA review. Ocular telehealth programs should create certification methods that are formally defined and relevant to the program.

2. Ongoing sampling of imagers and readers performance by formal criteria based on QA review. A review of trends in fallout from outcome analyses can be used to assess:
 - a) Proficiency.
 - b) Opportunities for program improvement.
 - c) Need for changes in initial or recurring training.
 - d) Need for additional training of an imager or reader.

3. Continuing education (CE) is an important component of any QA/CQI (Continuous Quality Improvement) program and a fundamental method to facilitate current competency⁶¹. CE should be dynamic and sensitive to patient and staff's changing needs. The following are considerations:
 - a) Adjust CE content by end-to-end program testing through data sampling and outcome analysis.
 - b) Adjust CE program to maintain temporal relevance to aggregate and individual clinical populations.
 - c) Deliver CE in formats to achieve desired outcome with maximum efficiency and effectiveness. Format examples include periodic self-study curriculum with pre and post-study testing, newsletters and email "Tips of the Day." A variety of interactive CE sessions using telehealth technology are available such as group-based or one-on-one case reviews, morbidity and mortality (M&M) conferences and conferences patterned on Clinical Pathological Conference (CPC) concepts.

Multiple feedback loops allow CE programs to adapt to changing conditions. Reviews allow CE performance and cost effectiveness to be continuously enhanced (Figure 2).

XI. Financial Factors

Telehealth program sustainability hinges on a well-developed business plan. Reimbursement, remuneration and cost are complex issues. Diagnostic and procedural coding are important considerations in billing and collections. Because of the diversity between regions, payers, and clinical modalities, each program should tailor billing protocols with Medicare, Medicaid, and private insurance intermediaries.

XII. Figures and Tables

Figure 1

Example of a workflow diagram of an ocular telehealth system based on Integrating the Healthcare Enterprise (IHE) infrastructure for radiology. Despite variations between equipment, communications and information systems, a generalized workflow diagram is possible for any ocular telehealth system.

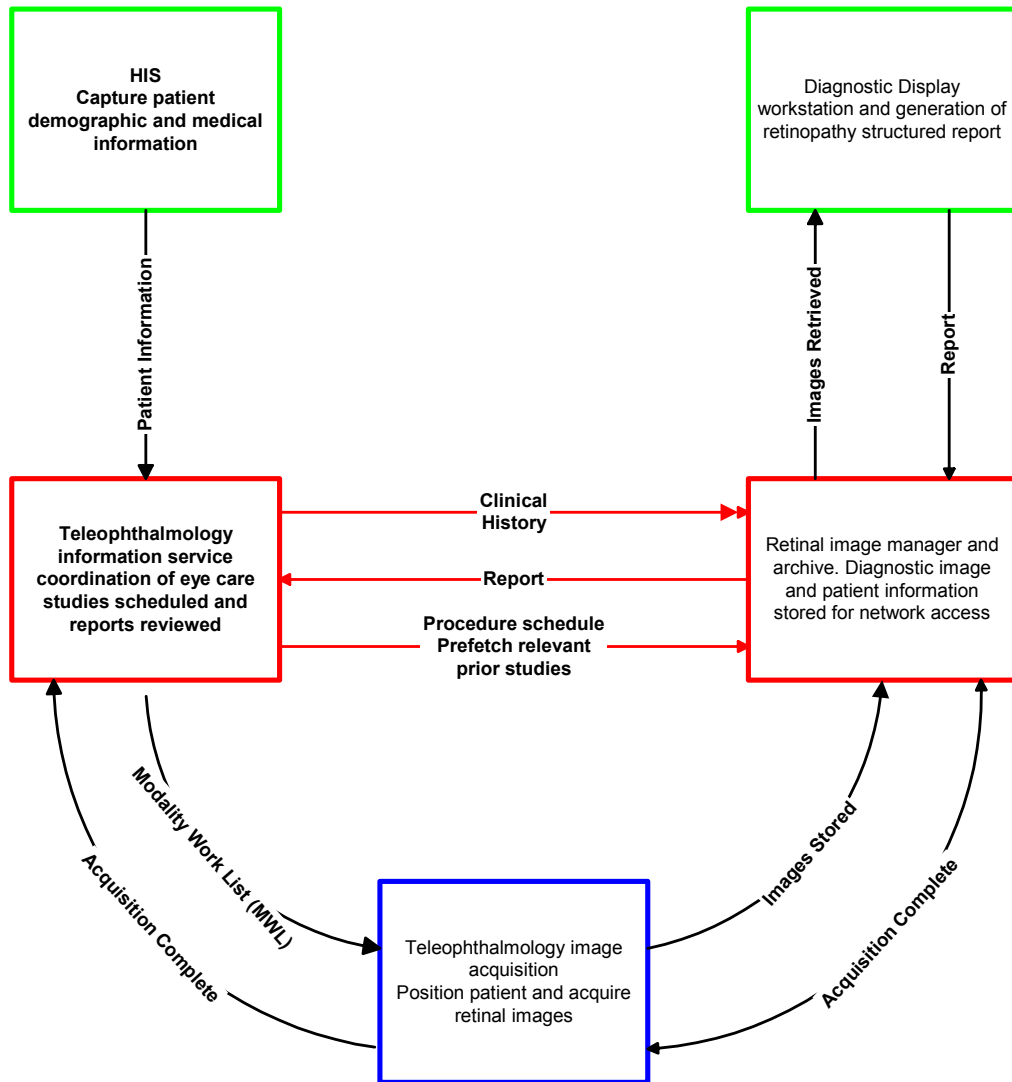


Table 1

International clinical DR scale compared to Early Treatment Diabetic Retinopathy Study (ETDRS) levels of diabetic retinopathy

International Classification Level of DR	ETDRS Level of DR
No apparent retinopathy	Levels 10: DR absent
Mild NPDR	Level 20; very mild NPDR
Moderate NPDR	Levels 35, 43, 47; moderate NPDR
Severe NPDR	Levels 53A-E; severe to very severe NPDR
PDR	Levels 61,65,71,75,81,85; PDR, high-risk PDR, very severe or advanced PDR

DR =diabetic retinopathy; NPDR = Nonproliferative diabetic retinopathy; PDR = Proliferative diabetic retinopathy

Table 2

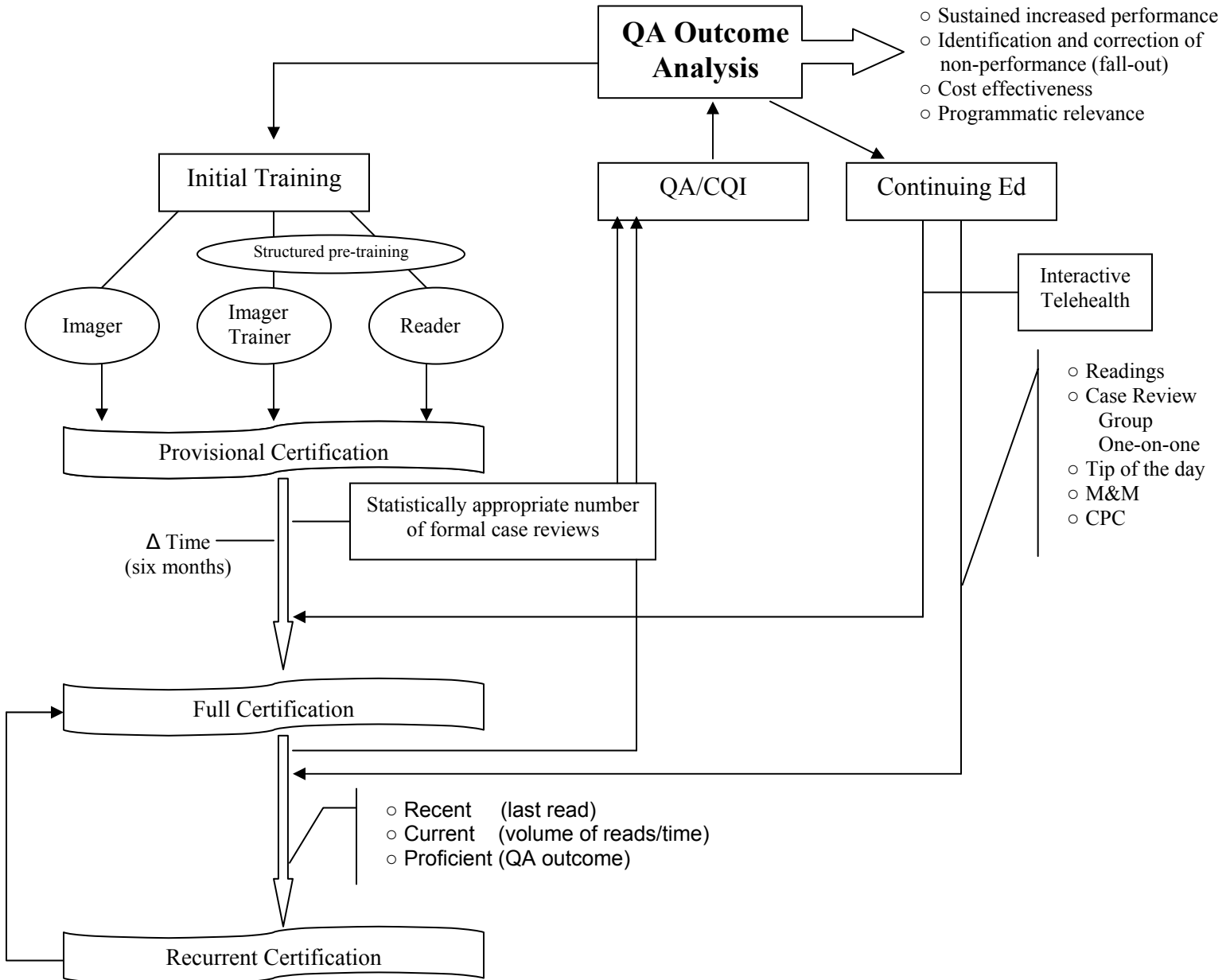
International clinical DME scale compared to ETDRS where noted.

Disease Severity Level	Findings	DME scale
DME apparently absent	No apparent retinal thickening or hard exudates (HE) in posterior pole	
DME apparently present	Some apparent retinal thickening or HE in posterior pole	Mild DME: some retinal thickening or HE in posterior pole but distant from center of the macula (ETDRS: DME but not CSME)
		Moderate DME: retinal thickening or HE approaching the center but not involving the center (ETDRS: CSME)
		Severe DME: retinal thickening or HE involving the center of the macula (ETDRS: CSME)

DME=diabetic macular edema; HE=hard exudates; CSME=clinically significant macular edema

Figure 2

Example of a quality assurance and continuous quality improvement flow diagram.



XIII. Abbreviations

CE	Continuing education
CPC	Continuing Professional Competency
CQI	Continuous Quality improvement
DCCT	Diabetes Control and Complications Trial
DICOM	Digital Imaging and Communications in Medicine
DM	Diabetes mellitus
DME	Diabetic macular edema
DR	Diabetic retinopathy
DRS	Diabetic Retinopathy Study
DRVS	Diabetic Retinopathy Vitrectomy Study
DRVS	Diabetic Retinopathy Vitrectomy Study
EDIC	Epidemiology of Diabetes Interventions and Complications
ETDRS	Early Treatment Diabetic Retinopathy Study
FDA	Food Drug Administration
HIPAA	Health Insurance Portability and Accountability Act
HIS	Hospital information system
HL7	Health Level 7
IHE	Integrating the Healthcare Enterprise
IS	Information specialist
JCAHO	Joint Commission for the Accreditation of Healthcare Organization
JPEG	Joint Photographic Experts Group
M & M	Morbidity and mortality
NPDR	Nonproliferative diabetic retinopathy
OD	Right eye
OS	Left eye
PACS	Picture Archiving Communication System
PDR	Proliferative diabetic retinopathy
SNOMED	Systematized Nomenclature of Medicine
UKPDS	United Kingdom Prospective Diabetes Study
WESDR	Wisconsin Epidemiologic Study of Diabetic Retinopathy
WHO	World Health Organization

XIV. References

1. Harris MI, Hadden WC, Knowler WC, Bennett PH. Prevalence of diabetes and impaired glucose tolerance and plasma glucose levels in U.S. population aged 20-74 yr. *Diabetes* 1987;36:523-534.
2. Kovar MG, Harris MI, Hadden WC. The scope of diabetes in the United States population. *Am J Public Health* 1987;77:1549-1550.
3. Harris M. Diabetes Mellitus: Summary. National Institutes of Health, 1995:1-36.
4. World Health Organization. Diabetes estimates and projections. WHO. 2004. Last copyright date: 2003. Available from: URL: <http://www.who.int/ncd/dia/databases4.htm>.
5. National Center for Chronic Disease Prevention and Health Promotion. Diabetes Public Health Resource: Age-Adjusted Rates of Seeing a Health Professional for Diabetes in the Last Year per 100 Adults with Diabetes, United States, 2001. Center for Disease control and Prevention. 2001. Available from: URL: <http://www.cdc.gov/diabetes/statistics/preventive/fig4g.htm>
6. Klein R. The epidemiology of diabetic retinopathy: findings from the Wisconsin Epidemiologic Study of Diabetic Retinopathy. *Int Ophthalmol Clin* 1987;27:230-238.
7. Klein R, Klein BE, Moss SE. The Wisconsin Epidemiological Study of Diabetic Retinopathy: a review. *Diabetes Metab Rev* 1989;5:559-570.
8. Aiello LP, Gardner TW, King GL, et al. Diabetic retinopathy. *Diabetes Care* 1998;21:143-156.
9. The Diabetic Retinopathy Study Research Group. Photocoagulation treatment of proliferative diabetic retinopathy. Clinical application of Diabetic Retinopathy Study (DRS) findings. DRS Report Number 8. *Ophthalmology* 1981;88:583-600.
10. The Diabetic Retinopathy Study Research Group. Photocoagulation treatment of proliferative diabetic retinopathy: relationship of adverse treatment effects to retinopathy severity. DRS Report Number 5. *Dev Ophthalmol.* 1981;2:248-261.
11. The Diabetic Retinopathy Study Research Group. Four risk factors for severe visual loss in diabetic retinopathy. The third report from the Diabetic Retinopathy Study. *Arch Ophthalmol.* 1979;97:654-655.
12. Early Treatment Diabetic Retinopathy Research Group. Aspirin effects on mortality and morbidity in patients with diabetes mellitus. ETDRS Report Number 14. *JAMA* 1992;268:1292-1300.
13. Early Treatment Diabetic Retinopathy Research Group. Fundus photographic risk factors for progression of diabetic retinopathy. ETDRS Report Number 12. *Ophthalmology* 1991;98:823-833.
14. Early Treatment Diabetic Retinopathy Research Group. Early photocoagulation for diabetic retinopathy. ETDRS Report Number 9. *Ophthalmology* 1991;98:766-785.
15. Early Treatment Diabetic Retinopathy Research Group. Photocoagulation for diabetic macular edema. ETDRS Report Number 1. *Arch Ophthalmol* 1985;103:1796-1806.
16. Early Treatment Diabetic Retinopathy Research Group. Focal photocoagulation treatment of diabetic macular edema. Relationship of treatment effect to fluorescein angiographic and other retinal characteristics at baseline. ETDRS Report Number 19. *Arch Ophthalmol.* 1995;113:1144-1155.

17. The Diabetic Retinopathy Vitrectomy Study Research Group. Early vitrectomy for severe proliferative diabetic retinopathy in eyes with useful vision. Results of a randomized trial. DRVS Report Number 3. *Ophthalmology* 1988;95:1307-20.
18. The Diabetic Retinopathy Vitrectomy Study Research Group. Early vitrectomy for severe vitreous hemorrhage in diabetic retinopathy. Four-year results of a randomized trial: DRVS Report Number 5. *Arch Ophthalmol* 1990;108:958-64.
19. The Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Research Group. Retinopathy and nephropathy in patients with type 1 diabetes four years after a trial of intensive therapy. *N Engl J Med* 2000;342:381-389.
20. Epidemiology of Diabetes Interventions and Complications Research Group. Design, implementation, and preliminary results of a long-term follow-up of the Diabetes Control and Complications Trial cohort. *Diabetes Care* 1999;22:99-111.
21. The Diabetes Control and Complications Trial Research Group. Early worsening of diabetic retinopathy in the Diabetes Control and Complications Trial. *Arch Ophthalmol*. 1998;116:874-886.
22. The Diabetes Control and Complications Trial Research Group. Lifetime benefits and costs of intensive therapy as practiced in the Diabetes Control and Complications Trial. *JAMA* 1996;276:1409-1415.
23. The Diabetes Control and Complications Trial Research Group. The absence of a glycemic threshold for the development of long-term complications: the perspective of the Diabetes Control and Complications Trial. *Diabetes* 1996;45:1289-1298.
24. The Diabetes Control and Complications Trial Research Group. The relationship of glycemic exposure (HbA1c) to the risk of development and progression of retinopathy in the Diabetes Control and Complications Trial. *Diabetes* 1995;44:968-983.
25. The Diabetes Control and Complications Trial Research Group. Progression of retinopathy with intensive versus conventional treatment in the Diabetes Control and Complications Trial. *Ophthalmology* 1995;102:647-661.
26. Writing Team for the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Research Group. Effect of intensive therapy on the microvascular complications of type 1 diabetes mellitus. *JAMA* 2002;287:2563-9.
27. United Kingdom Prospective Diabetes Study Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes. UKPDS 33. *Lancet* 1998;352:837-53.
28. United Kingdom Prospective Diabetes Study Group. Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes. UKPDS 38. *BMJ* 1998;317:703-13.
29. Brechner RJ, Cowie CC, Howie LJ, Herman WH, Will JC, Harris MI. Ophthalmic examination among adults with diagnosed diabetes mellitus. *JAMA* 1993;270:1714-1718.
30. Ferris FL, III, Davis MD, Aiello LM. Treatment of diabetic retinopathy. *N Engl J Med* 1999;341:667-678.
31. Witkin SR, Klein R. Ophthalmologic care for persons with diabetes. *JAMA* 1984;251:2534-2537.
32. Sprafka JM, Fritsche TL, Baker R, Kurth D, Whipple D. Prevalence of undiagnosed eye disease in high-risk diabetic individuals. *Arch Intern Med* 1990;150:857-861.

33. Javitt JC, Aiello LP, Chiang Y, Ferris FL, III, Canner JK, Greenfield S. Preventive eye care in people with diabetes is cost-saving to the federal government. Implications for health-care reform. *Diabetes Care* 1994;17:909-917.
34. Javitt JC, Aiello LP. Cost-effectiveness of detecting and treating diabetic retinopathy. *Ann Intern Med* 1996;124:164-169.
35. Stanberry B. The legal and ethical aspects of telemedicine 3: telemedicine and malpractice. *J Telemed Telecare* 1998;2:72-79.
36. Iserson K. Telemedicine: a proposal for an ethical code. *Camb Q Healthc Ethics* 2000;9:404/6.
37. Mossman K. Medical testing: issues and ethics. *Forum Appl Res Public Policy* 1997;3:90-101.
38. Silverman R. Current legal and ethical concerns in telemedicine and e-medicine. *J Telemed Telecare* 2003;9:7-9.
39. Blum J. Internet medicine and the evolving legal status of the physician-patient relationship. *J Leg Med* 2003;4:413-55.
40. Kasztelowicz P. Security of medical data transfer and storage in Internet Cryptography, antiviral security and electronic signature problems, which must be solved in nearest future in practical contest. *Pol J Pathol* 2003;3:209-14.
41. Brebner E, Bebner J, Ruddick-Bracken H, Wootton R, Ferguson J. The importance of setting and evaluating standards of telemedicine training. *J Telemed Telecare* 2003;9:7-9.
42. Bursell SE, Cavallerano JD, Cavallerano AA, et al. 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;108:572-85.
43. Fransen SR, Leonard-Martin TC, Feuer WJ, Hildebrand PL. Clinical evaluation of patients with diabetic retinopathy: accuracy of the Inoveon diabetic retinopathy-3DT system. *Ophthalmology* 2002;109:595-601.
44. Rudnisky CJ, Hinz BJ, Tennant MT, de Leon AR, Greve MD. High-resolution stereoscopic digital fundus photography versus contact lens biomicroscopy for the detection of clinically significant macular edema. *Ophthalmology* 2002;109:267-74.
45. Lee P. Telemedicine: opportunities and challenges for the remote care of diabetic retinopathy. *Arch Ophthalmol* 1999;117:1639-40.
46. Zeimer R, Zou S, Meeder T, al. e. A fundus camera dedicated to the screening of diabetic retinopathy in the primary-care physician's office. *Invest Ophthalmol* 2002;43:1581-87.
47. Kuzmak PM, Dayhoff RE. Minimizing Digital Imaging and Communications in Medicine (DICOM) Modality Worklist patient/study selection errors. *J Digit Imaging* 2001;14:153-7.
48. Csipo D, Dayhoff RE, Kuzmak PM. Integrating Digital Imaging and Communications in Medicine (DICOM)-structured reporting into the hospital environment. *J Digit Imaging* 2001;14:12-6.
49. Bilimoria N. Telemedicine: laws still need a dose of efficiency. *J Med Pract Manage* 2003;6:289-94.
50. Eliasson A, Poropatich R. Performance improvement in telemedicine: the essential elements. *Mil Med* 1998;8:530-5.

51. Comprehensive Accreditation Manual for Hospitals: The Official Handbook. MS.4.120. MS.4.130.: The Joint Commission on the Accreditation of Healthcare Organizations. 2004.
52. Comprehensive Accreditation Manual for Hospitals: The Official Handbook. Improving Organizational Performance: The Joint Commission on the Accreditation of Healthcare Organizations, 2004.
53. Comprehensive Accreditation Manual for Hospitals: The Official Handbook. EC.6.10. EC.6.20. The Joint Commission on the Accreditation of Healthcare Organizations, 2004.
54. Comprehensive Accreditation Manual for Hospitals: The Official Handbook. MS.4.120. MS.4.130.: The Joint Commission on the Accreditation of Healthcare Organizations, 2004.
55. Stanberry B. Legal ethical and risk issues in telemedicine. *Comput Methods Programs Biomed* 2001;64:225-33.
56. VA. VHA Informed Consent for Clinical Treatments and Procedures: VA, 2003.
57. Wilkinson CP, Ferris FL, 3rd, Klein RE, et al. Proposed international clinical diabetic retinopathy and diabetic macular edema disease severity scales. *Ophthalmology* 2003;110:1677-82.
58. Borkowski W, Mielniczuk H. Telemedical management system of structured clinical documentation-application for quality assurance and multicenter clinical trials. *Pol J Pathol* 2003;3:193-5.
59. McCrossin R. Managing risk in telemedicine. *J Telemed Telecare* 2003;9:6-9.
60. Blignault I, Kennedy C. Training for telemedicine. *J Telemed Telecare* 1999;5 Suppl 1:S112-4.
61. Comprehensive Accreditation Manual for Hospitals: The Official Handbook. EC6.10. MS.5.10. The Joint Commission on the Accreditation of Healthcare Organizations, 2004.

XV. Contributors

American Telemedicine Association, Ocular Telehealth Special Interest Group, and the National Institute of Standards and Technology Working Group

American Telemedicine Association Executive Committee:

Jonathan D. Linkous, Richard Bakalar, MD, Adam Darkins, MD, Col. Ronald K. Poropatich MD

American Telemedicine Association Ocular Telehealth Special Interest Group:

Jerry Cavallerano, OD, PhD (Chair), Mary G. Lawrence, MD, MPH (Vice Chair)

Editorial Committee:

Helen K. Li, MD (Co-chair), Matthew Tennant, MD (Co-chair), Sven Bursell, PhD, Jerry Cavallerano, OD, PhD, Mark Horton, OD, MD, Richard Bakalar, MD

Writing Committees:

Clinical: Jerry Cavallerano, OD, PhD (Chair), Mary G. Lawrence, MD, MPH, Ingrid Zimmer-Galler, MD, COL Wendall Bauman, MD

Technology: Sven Bursell, PhD (Chair), W. Kelly Gardner
Operations: Mark Horton, OD, MD (Chair), Lloyd Hildebrand, MD, Jay Federman, MD

National Institute of Standards and Technology:
Lisa Carnahan

Veterans Administration:
Peter Kuzmak, John M. Peters, Adam Darkins, MD

At Large Group Participants:
Jehanara Ahmed, MD, Lloyd M. Aiello, MD, Lloyd P. Aiello, MD, PhD, Gary Buck,
Ying Ling Chen, PhD, Denise Cunningham, CRA, RBP, MEd, Eric Goodall, Ned Hope,
Eugene Huang, PhD, Larry Hubbard, MAT, Mark Janczewski, MD, J.W.L. Lewis, PhD,
Hiro Matsuzaki, COL Francis L. McVeigh, OD, Jordana Motzno, Diane Parker-Taillon,
Robert Read, Peter Soliz, PhD, Bernard Szirth, PhD, COL Robert A. Vigersky, MD,
COL Thomas Ward, MD

American Telemedicine Association Administrative Contributor:
Catherine Diver