

Telemedicine for Ophthalmology Information Statement

Task Force on Telemedicine in Ophthalmology: American Academy of Ophthalmology

I. Introduction

This statement is intended to 1) provide an overview of telemedicine for ophthalmology (incorporating features of telehealth) and 2) highlight issues that we anticipate will shape the development and implementation of telemedicine for ophthalmology in the near future. As new technology is developed and incorporated into patient care, additional information on validity and reliability is generated and payment systems evolve, we anticipate that future guidance will be incorporated into this summary.

Telehealth describes health care delivery over distance or time using electronic communication technologies and serves to enhance health care access, quality and patient satisfaction. Telemedicine is used to describe provision of a traditional clinical service delivery using electronic communication technology, often in a live format. The term telehealth adds diagnosis, management, education and administration well beyond traditional health care delivery. The rapid improvement of electronic imaging capability and biometric data acquisition in ophthalmology, combined with parallel advancements in health information technology and widely available broadband connectivity, has created new pathways for delivery of eye care services. These pathways improve access by extending the reach of medical eye care services, improve clinical outcomes by providing care in a timely fashion, and enhance patient satisfaction by providing care in a setting and at a time convenient for the patient.

Telehealth includes four primary domains:

- Live audio-video (synchronous) telemedicine: Real-time, bidirectional communication between a patient and provider using audiovisual telecommunications and data collection technology.
- Store-and-forward (asynchronous) telemedicine: Electronic transmission of health care data (e.g., images, text, or other digital data) to a provider for evaluation and service delivery using methods other than real-time interaction with the patient.
- Remote patient monitoring (RPM): Health data collection directly from the patient, typically during their usual activities of daily living, with transmission to a provider for analysis and possible action (e.g., tele-intensive care)
- Mobile Health (mHealth): Health care, patient communication, and education based on mobile communication platforms, e.g. fitness tracker, cell phones, tablet computers, etc.

These domains employ different technologies - optimized for a particular clinical process, setting, and disease or condition - to improve clinical and public health outcomes. Use of telehealth tools should occur in the context of established clinical practices and evidence-based standards of care. The best features of telehealth are derived through integration with traditional processes to improve current practices (sustaining innovation) and creation of new workflows and clinical settings to allow new approaches (transformational innovation). To ensure safe and effective patient care, evidence of effectiveness and safety is required to validate telehealth practices, including the technology to create new standards of health care. These strategies will require new risk management practices, reimbursement strategies, and approaches to regulatory oversight. The secure exchange and storage of telehealth data between devices, systems and providers is required to protect patient privacy, but also ensures data availability for appropriate patient care.

A related and emerging area of telehealth is the use of decision analytics and artificial intelligence for the interpretation of images and other patient care data collected electronically. A complete discussion is outside the scope of this document. Future reports will be needed to describe the validation and introduction of these approaches to clinical care, many of which may move the analysis to the point of care.

II. Telemedicine for Ophthalmology

Ophthalmology has multiple opportunities for utilizing telemedicine.² Two mature domains, diabetic retinopathy (DR) and retinopathy of prematurity (ROP), illustrate how telemedicine can be deployed to improve access and quality of health care. Successful use of telemedicine in these domains has delivered benefits to patients, providers, health care systems and society. Telemedicine for remote surveillance of DR is an established use. Research has demonstrated clinical, public health and economic benefits.^{3, 4} Although effective treatments for high-risk DR have existed for more than four decades, DR remains a leading cause of blindness among working-age adults. The inability of half the population to access retinal examinations in a timely fashion is a major contributor to vision loss from diabetes. Telemedicine programs can improve patient access to the annual DR screening through patient imaging in a primary care setting.⁵ These programs have led to improved clinical outcomes.⁶ Given the high proportion of patients currently unable to obtain a retinal screening or an eye examination at the appropriate frequency, expansion of telemedicine for ophthalmology programs would likely result in earlier provision of eye care for DR and non-DR eye conditions.⁷

Telemedicine for ROP has a proven ability to improve access to eye care for premature infants at high risk for ROP to eye care.^{8,9} Timely diagnosis and treatment of ROP is key for successful outcomes. There are shortages of examiners skilled in indirect ophthalmoscopy and trained in retinopathy of prematurity screening who can provide care for low birth weight infants. Telemedicine provides an attractive alternative, especially in more remote areas. In addition, imaging could improve documentation over a retinal drawing.

These two clinical areas demonstrate that telemedicine can successfully improve and extend ophthalmic care with the use of imaging technology. Other areas of telemedicine within ophthalmology such as intraocular pressure monitoring, optic nerve analysis, macular disease monitoring, visual field analysis and anterior segment diagnosis are being organized. In addition, the capacity to perform remote, yet face to face, exams and consults in regular and emergent clinical situations is advancing with improved two-way communication technologies.

III. Validation

Telemedicine programs for ophthalmology must ensure that quality of care and long-term outcomes are not compromised by insufficient performance of the technology or the system. Validation of clinical performance against an accepted standard is necessary, as is instituting an ongoing quality assurance program. These assessments need to be conducted in the clinical setting where these technologies will be deployed and with the devices and clinical and technical staff in place. For instance, telemedicine programs for DR should be assessed in primary care settings. Programs for ROP need to be assessed in neonatal intensive care units. Additional validation challenges include assessing the available imaging devices, the image field of view, the use of eye drops for pupillary dilation, and the training of imagers and readers.¹⁰⁻¹²

One example of a validation standard is the Early Treatment Diabetic Retinopathy Study (ETDRS), which uses 7 standard field stereoscopic color photographs as the reference standard for detection of diabetic retinopathy. Based on this standard, the American Telemedicine Association (ATA) describes four categories for telemedicine programs based on their capability of detecting DR. 14

- Category 1 differentiate the presence or absence of none or very mild non-proliferative diabetic retinopathy (NPDR) from mild NPDR or more severe DR.
- Category 2 distinguish sight-threatening disease (greater than moderate NPDR, proliferative DR, or diabetic macular edema) from less severe disease
- Category 3 identify defined levels of diabetic retinopathy and macular edema and may be used to remotely manage the disease
- Category 4 match or exceed the accuracy of ETDRS imaging; can replace the 7-field reference standard in a clinical or research setting.

The selected validation category for DR evaluation should be based on the program's goals. To assess performance in a category, performance thresholds for sensitivity and specificity need be established. Importantly, the validation program needs to evaluate all the components of image acquisition, compression, transmission, and review. Equipment cost, technical difficulty, operational complexity and training requirements generally increase with increasing program performance.

Another validation standard for telemedicine programs could be a clinical exam by ophthalmologists with varied levels of training. For ROP, the reference standard is dilated pupil bedside indirect ophthalmoscopy for the detection of moderate or severe stages of ROP.¹⁵ Of note, validation standards may change over time. For instance, recent studies have suggested that detection of ROP with imaging may be more accurate than bedside examination. Thus, there is the potential for a new reference standard to be adopted for detection of moderate or severe ROP which may be a combination of wide-field fundus imaging and indirect ophthalmoscopy.¹⁶

IV. Clinical

A. Equipment

There are two broad categories of equipment used in a telemedicine for ophthalmology program: 1) information acquisition devices (cameras, optical coherence tomography machines, tonometers, autorefractors, visual field machines, etc.), and 2) image communications devices (computers, servers, network devices, etc.) for sending the data. These devices should have the following characteristics:

- FDA-approval of medical devices
- Underwriters Laboratory/ISO standards met
- Adherence with local, state, federal and international guidelines for health care information acquisition, transmission and retention
- Health Insurance Portability and Accountability Act of 1996 (HIPAA)-compliant
- DICOM compatible (if applicable)
- Ability to interface with widely-available electronic health records (EHR) and picture archiving and communication systems (PACS), preferably using standards based interoperability protocols
- Performance necessary to conduct the ophthalmology evaluation.

Imaging and other diagnostic acquisition device performance should be periodically confirmed according to the manufacturers' recommendations, and diagnostic displays

periodically checked for normal function and recalibrated as needed. Proper data security, integrity, and availability (including back-up and archive) should be confirmed in an ongoing fashion by information technology staff.

B. Setting and space requirements

The setting, whether a medical office, urgent care, emergency room or community health care center, should have the ability to monitor test-appropriate vital signs, take a detailed clinical history and review of systems, conduct and transmit the telemedicine for ophthalmology examination and organize appropriate follow-up care.

Telemedicine examinations will have differing space requirements based upon their use of synchronous versus asynchronous technology. Synchronous visits will require space for the patient, the local provider and the remote provider to privately conduct the exam and discuss findings. Synchronous visits typically require audio and video equipment, a computer to transmit necessary examination information and devices and technologies to conduct a remote eye exam. Asynchronous visits require space for the necessary imaging equipment, other devices being used and space for image and data preparation and submission. Typically, a small footprint within an existing clinical space is adequate for telemedicine examinations and consultations.¹

C. Personnel

There is little regulatory guidance regarding the personnel who are acquiring, transmitting and interpreting telemedicine data. Each member of the team should meet necessary qualifications established by the program, have those verified initially and provide for ongoing evidence of excellence. A task-based (or "function-based") assessment of personnel requirements is conducted. Furthermore, the reading method for image analysis should be transparent to the requestor, whether a trained reader supervised by a physician or a physician reader. It should be understood that the reading center is liable for errors in reading.

The following are basic requirements for the staff involved in telemedicine for ophthalmology at a remote imaging site:

- Familiarity with the eye, the diagnostic equipment, the risks and clinical stigmata of ocular complications of pupillary dilation (if mydriatic imaging performed), universal precautions and antiseptic technique and with HIPAA and informed consent
- Training for safe and proper contact with patients in a clinical setting as outlined by applicable hospital and facility standards.
- Training on the specific devices and equipment, obtaining necessary certifications, and adhere to quality control metrics established for the instrument by the program (for example, percentage of gradable images or missing data from clinical encounters).
- Periodic reevaluation of competence.

The following are requirements for the supervising physician of the reading center and the readers:

- Ophthalmologists serving as the remote physician should receive initial training and periodic re-evaluation to meet quality standards for the tasks being performed.
- The reading physician should confirm medical malpractice liability coverage for this activity from their insurer.

• Reading physicians must meet state licensure requirements in the state where the patient resides (or have appropriate alternative permissions as state laws evolve).

D. Data Acquisition

Much of current telemedicine for ophthalmology is based upon a store-and-forward model with acquisition of images for subsequent evaluation by a trained reader under physician supervision. Newer applications may involve at-home testing with transmission and webbased interactions on the part of the patient.

Diabetic Retinopathy

Many DR surveillance systems use one, two or three central field photographs to detect the presence or absence of any significant retinopathy. These systems must be validated against the 7-field ETDRS standard or clinical exam across the full spectrum of diabetic retinopathy. As data is developed about the performance of more limited field of view devices, new imaging systems can be adopted for use in appropriate settings. In addition, there is ongoing work to assess the performance of non-mydriatic ultra-wide-field imaging (with or without concurrent optical coherence tomography). Similarly, these new systems should be validated against appropriate standards. There are tradeoffs between performance and accessibility, as well as costs versus usefulness. These will help determine which approaches are best in a setting or for a desired clinical outcome.

Retinopathy of Prematurity

ROP telemedicine evaluations are generally performed in the neonatal intensive care unit (NICU). If a NICU is performing these, the neonatal nurse, photographer or other individual needs to be trained to obtain the necessary images.^{5, 6} In all cases, the baby's medical status shall be monitored throughout the evaluation by a nurse not performing the imaging. This imager should be trained by the imaging platform vendor in conjunction with oversight by the ROP screening physician(s) working with the nurse.^{6, 17} An ophthalmologist with expertise in treatment of ROP needs to be available in a timely manner.

Anterior Segment Disease

While much less common, technology for two-way video-audio examinations is expanding to include the use of slit-lamp and indirect ophthalmoscope imaging for anterior segment disease. One intermediate step has been acquisition of exam information by a technician with subsequent physician review, leading to the decision to conduct or not conduct a face-to-face examination.¹⁸

Home Monitoring and Automated Refraction

Home monitoring of chronic ophthalmologic disease is just beginning, but is expected to grow because of interest in its ability to expand access to care with remote reporting to the physician. IOP measurements and macular visual field testing are early uses of this approach. These programs may provide timely warnings to patients and physicians of the need for an office visit. Web-based refraction systems have entered the market offering increased access and convenience for prescription updates. These systems should be validated, may need to meet regulatory concerns with respect to FDA clearance for health care use, and should include disclosure that a refraction does not replace a comprehensive examination of the eyes. Multiple digital applications are being developed and will need validation on multiple hardware and software configurations. Advice from the FDA will be necessary in most cases.¹

E. Data Transmission

Patient data transmission should occur in strict compliance with all regulatory and patient care requirements, including the following:

- HIPAA compliant: Privacy and Security
- Standards-based verification of successful transmission and storage of text (HL7) and images (DICOM) automated protocols using appropriate IHE-Eye Care frameworks preferred.
- Alternative mode of information transfer in the event of primary system failure (system failover and disaster recovery)

All systems should affirmatively acknowledge the status of transmitted data. However, the originating site staff should have a low threshold for suspecting failed transmission in the event of a delayed response or customary report from the reading center. Appropriate procedures should be outlined to manage this occurrence.

F. Reading

An ophthalmologist or team of image readers under ophthalmologist supervision should perform image grading, image reading with recommendations, and results reporting. All personnel require sufficient training, expertise, and the privilege to make an accurate, timely diagnosis. Qualifications of image or other data reviewers should be determined for each application.

G. Communication of results

The goal of a telemedicine encounter is to identify pathology that may need to be managed. It is inherent in this goal that communication of results from the reader to the physician should include the following minimal criteria:

- Timely reporting (within medically-defined guidelines or any applicable local, state, or federal regulatory standards, as applicable, for the underlying disease processes, with a goal to expedite interpretation as appropriate to the circumstances)
- HIPAA-compliant (privacy and security)
- Verifiable transmission and receipt
- Secure and persistent storage of the data report
- Timely availability to imaging site and reading center
- An ungradable image should include the recommendation for referral.

H. Quality Control and Continuous Systems Improvement

Quality assurance (QA) programs monitor the operational process and clinical outcomes to ensure ongoing compliance with the program's goals. As highlighted above, equipment, personnel and clinical outcomes should meet established quality control metrics and be evaluated periodically. Quality assurance programs will include rereads, as well as assessment on inter- and intra-reader variability of readings.

Process and workflow metrics of the application should be specified to assess program quality. For screening services, the rate of a referred patient completing any follow up examinations/treatments and the proportion of patients being tested with the ophthalmology application compared with those eligible in a community or other group is an example of a program quality metric. Telemedicine services should attempt continuous improvement that addresses failures and technology advances in order to improve quality and access to care.

I. Data Security

Telemedicine programs should address all data security and integrity concerns including: patient privacy and confidentiality, data availability and data recovery. Patient privacy for telemedicine examinations shall comply with HIPAA. All image or video transmissions should be transmitted with proper security measures, including encryption.

V. Telemedicine Impact on Ophthalmology Practice

Some patients, typically those with lower disease burden, may be shifted away from traditional practices to telemedicine programs. However, programs designed to improve access to care using telemedicine often serve people not currently obtaining care. The improved access means more patients with pathology are identified and enter the health care system. For some patients the findings will be specific to the telemedicine model (e.g. severe diabetic retinopathy in DR monitoring programs), while for others opportunistic identification of abnormalities may occur outside of the telemedicine model (e.g. retinal tumor found during a DR monitoring programs). In aggregate, telemedicine can lead to increases in (1) patient volume and (2) disease severity at the traditional clinics affiliated with telemedicine programs.

VI. Legal Considerations in Telehealth

Legal considerations include typical issues such as malpractice, informed consent, patient privacy (HIPAA) and agency concerns, but also extend to new areas based on the separation in distance and time of the physician and patient.²⁰ State by state information on legal and regulatory issues can be found at a website developed by the Center for Connected Health.²¹ First and foremost, as a patient care delivery mechanism, patient interactions in telemedicine are subject to the same considerations as face-to-face interactions. Once a patient and physician are in contact about an aspect of medical care, a physician-patient relationship is established and all standard tort (malpractice) and informed consent requirements are applicable. To the extent a physician assumes oversight or supervises telemedicine services, such a physician will be responsible for the quality of care provided to the patient. Thus, errors of omission or commission will be the basis of any legal malpractice action. While the concern for "missing" a finding is present, the presence of photographic documentation is itself a strong indicator - perhaps even a presumption - of what was or was not present at the time of the exam. Similarly, to the extent that a patient has submitted or had photos submitted on their behalf by another care provider, informed consent is likely to be presumed if not explicitly authorized by the appropriate documentation. However, several states require specific informed consent for the use of telemedicine in addition to general consent requirements for care.

This document will not review the use of devices that are not approved by the FDA or not exempt from FDA approval. Similarly, the use of approved or exempt devices in ways not approved by the FDA is allowed under the "practice of medicine" and will not be discussed in this paper. However, it is important to note that there should be sufficient scientific support for the use of any device or approach and should be supported by a "respectable minority" or more of fellow practitioners.

Specific areas of concern related to telehealth include 1) its use of intermediate systems (agents) in many cases to acquire and transmit images, 2) the fact that the patient is not physically in the physician's office in most cases, 3) how images obtained are interpreted and 4) the separation of feedback of results from the acquisition of the data.

First, to the extent that a patient's data is being evaluated by someone outside a physician's practice, appropriate "business associate" agreements need to be in place to ensure compliance with HIPAA rules. Second, if a patient is located in a state outside of the state where the physician has a valid medical license, issues of appropriate state licensure (and the authorized or unauthorized practice of medicine) of the physician arise. The simplest approach is for the physician reading telemedicine images to have a license in every state in which a patient image they are reviewing is generated. Lacking that, it's critical to note that the applicable laws and regulations have undergone significant change in many states over the last few years. Physicians should review the laws and state medical board regulations in their state and those of the states in which the patient's images are being acquired or where the video exam is taking place. Patterns of law include unlimited ability (states that view the practice site as in the state where professional judgment is being rendered), authorization (in the majority of states) if a patient is explicitly referred by a licensed physician in the state where the image is generated (often with a numerically limited number per year as "exceptions"), the issuance of special certificates or licenses specifically for telemedicine, and a prohibition without an active license in the state where the activity is originating. The recent adoption (April 2017) of an Interstate Medical Licensure Compact by 18 states, with more joining, provides an opportunity for physicians to more readily meet the licensing requirements for allowed practice across state lines among compact states. (see http://www.cchpca.org/ for updated information - accessed December 26, 2017)

The third issue is liability regarding the interpretation of images if not performed by a licensed physician, such as by technicians in a reading center. In such cases, there should be a physician who is ultimately responsible for interpreting the images to avoid charges of the unauthorized practice of medicine by the readers. Further, while there is a question of what the applicable standard of care for interpretation will be - that of a specialist versus a general physician - it is likely that legal analysis will hold the standard to be that of a specialist. It is unclear whether the standard will be that of a general ophthalmologist specialist or a retinal specialist. Such a decision may turn on how the service is represented to patients and other physicians who use the telemedicine service.

Fourth, the result of the telemedicine service needs to be communicated back to the requesting health care provider and the patient. Failure to communicate test results is the foundation of numerous malpractice suits and adverse awards. Issues regarding miscommunications and errors due to technical problems are also yet to be clearly defined in this field. To the extent that a system is more under the control of a physician, that system is more likely to be deemed the responsibility of the physician. Contractual indemnification clauses and other arrangements may be potential approaches as well.

VII. Coverage Policies and Limitations

One of the hurdles for telemedicine to overcome to be able to achieve its potential has been infrequent and inconsistent coverage by healthcare insurance, both commercial and government. The absence of wide-spread coverage has made it difficult for these programs to become self-sustaining. Coverage lags improvement and availability of telehealth, especially among government payers.

Medicare

There is Medicare Part B coverage for synchronous services provided by two-way real-time audio and video communication. However, this coverage is limited to those patients residing in a rural county or rural physician shortage area as determined by CMS and who receive the service in a medical office or similar site, but not, for instance, while at home. These services

are billed using evaluation/management codes, telehealth codes subsequent hospital care codes, among others (claim submitted with -95 modifier (formerly -GT)). The originating site bills the Medicare contractor with HCPCS code Q3014.²² CPT includes a list of acceptable codes in Appendix P. Medicare Part B carriers make individual determinations. Unfortunately, even this very limited coverage does not yet include eye codes (CPT[®] 92002-92104).

Asynchronous telehealth services (store and forward) are covered under a Federal demonstration project for Alaska and Hawaii (claim submitted with -GQ modifier) for medical remote opinions as in the covered synchronous services. There are two CPT® codes for asynchronous imaging and review of images for detection of retinal disease (CPT® 92227) or monitoring and management of active retinal disease (CPT® 92228). However, because of statutory language they are non-covered services except where specifically allowed by CMD. Once these codes were established, the use of CPT® 92250 was no longer allowed for retinal imaging when used for remote evaluations as described in CPT®.

Remote monitoring has been payable for few activities by some Medicare Carriers. In ophthalmology, one covered application by some contractors has been visual field monitoring for macular degeneration (CPT® 0378T, 0379T). CMS for 2018 approved payment for CPT code 99091 Collection and interpretation of physiologic data (e.g., ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician requiring a minimum of 30 minutes of time.

Medicare Advantage (Part C)

This program is run by commercial carriers who must provide all of the services covered in traditional Medicare (Part B). They are free to provide non-covered services, including telehealth services, in addition to all allowed services provided under Part B that fit company and patient interests. Some companies are beginning to consider inclusion of coverage of these programs to improve their health care quality indicators.

Medicaid

Medicaid is administered by each state, the District of Columbia and Puerto Rico using local and federal funds. Each jurisdiction chooses what telehealth services it will cover. At the end of 2017, forty-eight states and DC provide coverage for live video encounters, but with site of service restrictions.²³ Only 13 states currently reimburse for store and forward telehealth, while 21 states provide some coverage for remote monitoring.

Commercial coverage

The decision to allow telehealth services, including synchronous consultations and asynchronous retinal imaging, is carrier specific. Many commercial carriers have embraced synchronous consultations and e-consultations for minor problems as patient friendly and provider efficient. They have also adopted remote retinal imaging coverage to improve their ability to provide care for their diabetic patients, often with the imaging taking place in primary care offices.

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