INDUSTRY BRIEF

Refractive Ocular Telehealth: Refraction and Visual Acuity Testing

INTRODUCTION

The purpose of this briefing is to provide an update on ocular telehealth modalities; specifically, platforms that test for refractive error and visual acuity for the purposes of eyeglass or contact lens prescribing (hereafter referred to as "refractive ocular telehealth"). It should be noted that other ocular telehealth modalities such as diabetic teleretinal screening, tele-glaucoma, retinopathy of prematurity, and tele-eye screening are more comprehensive in scope and aim to provide diagnostic evaluation of pathologic eye conditions. In contrast, refractive ocular telehealth focuses on correcting visual impairment from refractive error.

As the U.S. faces ever-growing healthcare needs from an aging population alongside a limited supply of healthcare providers, we have an opportunity to leverage technology to ensure that people have access to care when and where they need it and expand the capacity of providers to care for more people. Our collective responsibility is to ensure that these services are safe, effective, and appropriate. In addition, all telehealth programs should be conducted in accordance with all federal and state laws.

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BACKGROUND

Visual acuity testing is a procedure that assesses how well a patient sees the details of a letter or symbol from a specified distance. Refraction testing is used to determine the prescription needed for glasses or contact lens correction to improve visual function. This document uses the term "refractive ocular telehealth" throughout to refer to platforms that test for visual acuity and/or refractive error outside of a traditional eye doctor's office. These platforms are not intended to be methods for measuring eye health status on their own nor do the platforms comprehensively assess the cause of reduced visual function.

Refractive error is the most prevalent form of vision impairment in the United States and prevalence increases with age. In the U.S., 46.3% of adults between 20-39 years of age have some clinically important refractive error and this increases to 62.7% of adults 60 years or older.[1] From a quality of life perspective, surveys have shown that many people rank vision loss as the most feared medical condition, outranking cancer, HIV/AIDS, and Alzheimer's disease.[2,3]

However, access to eye care is limited. A study in 2015 showed that 24% of counties in the U.S. had no ophthalmologist or optometrist.[4] Consequently, ocular telehealth— like other telemedicine

services—provides a viable method to improve access to eye care by remotely connecting patients and providers through virtual interactions.

RECOMMENDATIONS ON FREQUENCY OF EYE EXAMS

Current recommendations for regular eye examinations for ocular health status are based on age and whether a person uses contact lenses. The American Academy of Ophthalmology (AAO), the world's largest association of eye physicians and surgeons, recommends that asymptomatic adult patients without risk factors for eye disease receive a comprehensive in-person eye exam every 5-10 years if they are between the ages of 18-40; 2-4 years for patients age 40-54; 1-3 years for patients age 55-64 years; and 1-2 years for patients age 65 years and older. These examinations are designed to screen for asymptomatic vision-threatening conditions to allow for the initiation of preventative management strategies when indicated.

The American Optometric Association (AOA), which represents more than 44,000 Doctors of Optometry (O.D.), optometric professionals, and optometry students, has established similar guidelines for the recommended frequency of comprehensive eye examination by age. For low-risk adults between the ages of 18 to 65, the AOA recommends comprehensive in-person exam at least every 2 years. For adults over the age of 65, the AOA recommends annual in-person examination.

Among people who wear contact lenses, AAO guidance recommends a "contact lens examination every 1 to 2 years to monitor for adverse effects of contact lens wear and for an update on healthy practices for contact lens wear and care."[5] Though it may be appropriate for some contact lens wearers to receive an annual comprehensive eye exam (in addition to the recommended "contact lens examination"), the AAO has no formal preferred practice guidelines on the frequency of comprehensive eye exams specific to contact lens wearers. The AOA recommends in its preferred practice guideline for contact lens dispensing that a patient have a follow-up exam in 6-12 months after dispensing a new prescription.[6]

It is important to note that both the AOA and the AAO acknowledge the lack of evidence-based clinical guidelines for these frequency recommendations. Rather, the recommendations are the result of provider consensus based on experience and education.

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CURRENT STATE OF OCULAR TELEHEALTH

Ocular telehealth is the delivery of eye and vision care using remote communication between the patient and provider. Care may be delivered synchronously or asynchronously, facilitated by telecommunication technology. Medical care provided using telehealth has been utilized for decades and the use of ocular telehealth continues to grow and expand in scope as technology evolves.

As with all services provided virtually there are several reasons why patients may choose to use an ocular telehealth platform in lieu of an in-person visit, including convenience and timely access.[3] Current ocular telehealth programs, including those that are providing comprehensive services, are not intended to serve as a replacement for an in-person comprehensive eye exam with an eye care provider. Patients should be made aware of the differences between an ocular telehealth evaluation and an in-person comprehensive eye examination.

Most ocular telehealth modalities have focused on screening and diagnoses of ocular pathology (e.g., diabetic retinopathy and retinopathy of prematurity) using asynchronous, store-and-forward technology. This method allows for virtual interactions between patient and physician when convenient for both parties. These programs utilize specialized eye diagnostic equipment and may gather several ocular vital signs such as visual acuity, eye pressure, and retinal images, which together are capable of determining, with high accuracy, the presence or absence of eye disease in a patient. A significant body of evidence has established the safety, validity, and effectiveness of these modalities.

Across the two leading service providers of refractive ocular telehealth noted earlier, 58% of patients were filtered out of the prescription renewal process as a direct result of rigorous risk stratification.[7]

There is growing interest in the use of refractive ocular telehealth to increase access to the correction of refractive error. Refractive error is one of the leading causes of correctable visual impairment through eyeglasses or contact lenses. Two leading service providers of these remote refraction platforms have treated 720,000 patients over the past 4 years with no adverse events reported. Furthermore, from this same patient population, of those who received a prescription for corrective eyewear, 81% were under the age of 40 years.[7] Thus, most customers were from a low risk age group. Further data on the safety and efficacy of these novel methods is an important area for future research.

KEY COMPONENTS OF A REFRACTIVE OCULAR TELEHEALTH PROGRAM

Programs must establish the safety and efficacy of tools that address the refractive ocular telehealth needs of patients. The following components should be considered:

A. Patient History

The provider should obtain a general medical, social and ocular history, and assess for ocular symptoms; clinical data (e.g. online vision testing); and existing prescriptions for contact lenses and glasses.[1] The provider should determine whether the patient has previously had a comprehensive eye health exam and if so, how recently, taking into consideration the AAO and AOA guidelines.

B. Equipment Employed by Patient

An up-to-date mobile or computer-based device with the ability to control volume and brightness levels capable of obtaining an appropriate vision correction, with subjective fine-tuning by the patient.

C. Software Needs

Software should be able to store, recall, display, and provide serial comparison with interval change of clinical data for the same patient. The system should systematically provide quality checks to ensure data integrity, and conform to established standards for interoperable exchange of patient data. Adherence to all applicable federal and state medical regulations and accepted standards, such as HIPAA, Federal Trade Commission (FTC), Centers for Medicare and Medicaid Services (CMS), Federal Drug Administration (FDA), Digital Imaging and Communications in Medicine[8] (DICOM), Integrating the Health Care Enterprise-Eye Care9 (IHE), Systematized Nomenclature of Medicine - Clinical Terms10 (SNOMED-CT), and Logical Observation Identifiers Names and Codes[11] (LOINC) is essential.

D. Personnel Oversight Requirements

As with all medical care, the results of online vision testing programs and the medical care offered because of their use, should be analyzed by a qualified eye care professional. Additionally, to meet regulatory requirements at the time of this publication, data captured should be reviewed by an eye care provider with appropriate licensure.

E. Refractive and Visual Acuity Testing

Online remote refraction should be serially performed, empirically validated, accurate and evaluated for changes over time. Platforms may employ a variety of modalities to collect clinical data, including but not limited to tele-refraction, visual acuity tests, images, and videos, which must then be reviewed by a licensed eye care provider. Platforms would benefit from having a method for detecting or correcting user error (e.g. detecting that the patient is standing too close or too far from the visual target, testing the wrong eye, etc.) which can affect accuracy of vision measurement and resultant prescription.

F. Safe Use Protocols

Platforms should utilize specific inclusion and exclusion criteria to ensure that only appropriate patients can access these tools. These would likely include age-based requirements that align with established clinical guidelines and the evolving body of research in this area (i.e., systems should be reserved for adults only at this time due to safety concerns in children in whom, unlike adults, an incorrect prescription for a child can lead to permanent vision loss from amblyopia). Additionally, patients with pre-existing medical conditions or eye diseases that significantly limit their vision or are unable for any reason to adequately participate solely in refractive ocular telehealth should not use these services (e.g. diabetes mellitus).

Thorough risk stratification is a critical component to the safe deployment of any telehealth program and refractive ocular telehealth is no exception. Appropriate guidelines can proactively identify high-risk patients and route them to a more appropriate form of eye care delivery. Across the two leading service providers of refractive ocular telehealth noted earlier, 58% of patients were filtered out of the prescription renewal process as a direct result of rigorous risk stratification.[7]

G. Advantages

Obtaining appropriate refractive correction in a timely fashion is critical for adequate visual function and physical safety in performing activities of daily living. In addition, poor contact lens hygiene and over-wear is a leading cause of eye infection. Services that provide enhanced, rapid access to new contact lenses might reduce the likelihood of infection from contact lens over-wear.

In addition, a well-developed refractive ocular telehealth program may be able to provide a customized educational message. For example, a patient who has not had a dilated eye examination may be counseled on the value of a dilated exam. The platform could facilitate scheduling the patient for an in-person exam with an eye care provider.

SUMMARY

Uncorrected refractive error is the leading cause of visual impairment worldwide. There is great potential for refractive ocular telehealth to help address the shortage of eye care providers by improving access to the correction of visual impairment from refractive error. Visual acuity testing and prescription renewals via remote refraction platforms in appropriately selected patients may help alleviate the anticipated burden. Anecdotal evidence exists from two U.S. companies that have provided services to over 700,000 patients without reported incident.[7] Further comparative effectiveness studies would be helpful in this area.

As with other ocular telehealth modalities, there are strengths and limitations to these methods. All stakeholders—patients, providers, legislators, health care administrators, etc.—should be aware of these issues to guide the use of refractive ocular telehealth for reducing the burden of uncorrected refractive error. Patients should be aware of the limitations but have access to these technologies when it is safe, effective, and appropriate to reduce the global burden of uncorrected refractive error.

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AMERICAN TELEMEDICINE ASSOCIATION

901 N GLEBE ROAD | STE 850
ARLINGTON, VA 22203
703-373-9600
INFO@AMERICANTELEMED.ORG