Assessing the Accuracy of the Technology-based Eye Care Services (TECS) Protocol to a Standard Clinical Ophthalmic Exam

Introduction: As patients age, they are more at risk to lose vision. Routine eye exams are critical to detecting diseases but access to eye appointments are a challenge, especially for the elderly and rural patient. Tele-ophthalmology is one solution to this problem but requires more study to ensure it is accurate. This study is a prospective trial comparing the TECS protocol to the face to face eye exam.

Specific Aims/Purpose: This proposal has 3 specific aims: 1. Determine the accuracy of the TECS protocol to detect common ocular disease compared to the face to face ophthalmic exam. 2. Assess inter- and intra-reader variability. 3. Evaluate the quality of care delivered by TECS and how this impacts cost-effectiveness of the program.

Methods: 250-300 patients will be recruited. They will undergo the TECS protocol and a face to face exam on the same day. Two separate reading physicians will interpret each patient independently and the ICD 9 diagnoses will be compared to the face to face exam. They will then read a subset of each of the patients again to assess inter- and intra-reader variability.

Anticipated Results: The TECS protocol will have higher than 90% in four fold table analysis for the detection of common ocular diseases with moderately low inter and intra-reader variability. The quality of care delivered by TECS will therefore be high and make this program cost-effective.

INTRODUCTION

Statement of the Problem: Many people, especially geriatric and rural patients, wait too long to obtain eye care because of access and distance barriers, leading to late diagnoses of potentially blinding conditions.

Background: Vision is absolutely integral to an individual's overall well-being and quality of life. Several large scale prevalence studies have identified diabetic retinopathy (damage to the eyes from diabetes), cataracts, age-related macular degeneration (AMD), and glaucoma as the most common conditions causing visual impairment as people age[1-5].

The Veteran population is more vulnerable than the general US population because of age for potentially blinding diseases[6,7]. According to the Veteran's Health and Reliance on the Veteran Administration (VA) Survey, VA enrollees have an average age of 62 years, with 81.1% of enrollees greater than 50 years old. The general US population has an average age of 33 years. As patients get older, they become less mobile, and they tend to seek eye care even less, which places them at even greater risk for visual impairment[8,9]. Analysis of Georgia data from the Behavioral Risk Factor Surveillance System (BRFSS) showed a high correlation between not seeking eye care services and transportation problems[10]. These findings were also confirmed on a national level[11].

In addition, the rural patient is even *less* likely to have a dilated eye exam within the last year compared to their urban counterparts because lack of access and travel barriers are magnified[19,20]. The VA Office of Rural Health (ORH) estimates that 3.2 million (35.9%) of the 8.9 million enrolled veterans are rural. In the Veteran Integrated Specialty Network #7 (VISN 7) alone, where the Atlanta VA is located, 36 counties in rural sectors are considered medically underserved areas. Furthermore, VISN 7's geriatric rural population is projected to grow 66%-132% in the next 20 years[21,22].

These projections underscore that there will be more enrolled elderly rural veterans; the majority living in a medically underserved area. There may not be enough eye providers available in the VA or even in their general community to give rural veterans, who are the highest risk groups for blindness, the eye care they need. Furthermore, VA eye providers cannot keep up with the growth of geriatric veterans and provide eye care in a timely or convenient fashion.

This problem warrants a solution because visually impaired individuals enter nursing homes three years earlier, have twice the risk of falling, four times the risk of hip fracture, and often become socially isolated with a greater risk for clinical depression or anxiety[12-18]. Preventing visual impairment by increasing access to basic eye care would align with patient priorities and positively impact both the patient and society.

One Solution: Improve access to screening eye care by delivering this care closer to the patient medical care home using tele-medicine methods.

Ophthalmology is an ideal specialty for remote care since diagnosis is often based on pattern recognition and images are already routinely used to care for patients. The Atlanta VA Eye Clinic has established a novel method to deliver screening eye care, Technology-based Eye Care Services (TECS). The TECS program attempts to improve access to care for veteran patients by decreasing the distance/cost barrier and increases access through dedicated new appointments for screening. TECS is located in the patient's community based outpatient clinic (CBOC) and targets patients who need routine eye exams and new eyeglasses. TECS promotes the general health and wellness of veterans

by proactively screening them for the four most common causes of visual impairment and prescribes glasses – a low cost, high-impact item to improve veterans' quality of life and visual function[19].

An overview of TECS: a few pieces of ophthalmic equipment is placed at the veteran's primary care clinic. The veteran, who is seeing their primary physician on any given day, may be evaluated on a walk in or scheduled basis to the TECS where a specially trained licensed practical nurse (LPN) executes the protocol. The protocol involves taking ocular history, vision, eyeglasses, eye pressure, and fundus photos. The data from the intake exam is stored and forwarded to a remote ophthalmologist who interprets the protocol and provides a report for the primary care provider. Patients who have disease are referred to the eye clinic for further evaluation.

Knowledge Gap: A large amount of literature exists on the accuracy of photos for diabetic retinopathy detection but there is not as much data on the use of photos for diagnosis of other ocular disease such as glaucoma or cataract. The principal investigator, Dr. April Maa, and her clinical team at the Atlanta VA has performed some studies on the accuracy of photographs to diagnose multiple eye diseases. A 52 patient pilot study to test feasibility has already been performed and the data published[23], however, the sample size is too small to reliably draw conclusions about the accuracy of the program. Unpublished data (submitted to JAMA Ophthalmology[24]) through a retrospective review of 942 charts suggests that the accuracy of photos for disease diagnoses is very high, greater than 90%. The Eye Clinic has received clinical funds to set up the TECS program, however, those funds **are restricted and cannot be used** to support research on the accuracy of protocol when compared to a face to face exam. The Eye Clinic feels this comparative trial is necessary to determine quality of care and accuracy of the TECS protocol prior to larger, more widespread implementation. HIP funds for a complete grant will be dedicated towards personnel to conduct a prospective trial that compares the TECS protocol with a gold standard, face to face exam.

SPECIFIC AIMS

Specific Aim #1: Evaluate the accuracy of TECS to detect glaucoma, cataract, macular degeneration, and diabetic retinopathy, when compared to the gold standard face to face ophthalmic exam.
Outcome measures: sensitivity, specificity, negative predictive value, and positive predictive value for glaucoma/glaucoma suspect, AMD, cataracts, and diabetic retinopathy will be calculated.

Specific Aim #2: Evaluate the inter and intra-reader variability of the TECS protocol
Outcome measures: Correlation coefficients will be calculated.

Specific Aim #3**:** Evaluate the cost-effectiveness of TECS based on quality of care and on prevention of visual impairment by allowing for early diagnosis.
Outcome measures: protocol referral rate, amount veteran travel distance is reduced, cost savings from reduced travel, and cost of implementing the program.

STUDY METHODOLOGY

The Atlanta VAMC currently runs a "New Comprehensive" eye clinic on Saturdays for new eye patients that are self-referred for a baseline eye exam. These patients have no known acute or chronic ocular issues. 250-300 total patients from these Saturday clinics will be recruited for the study. The study will take place in one visit on the same day the patient comes for their already scheduled Saturday eye clinic appointment.

After informed consent is obtained for each patient, they will be brought to designated study staff who will perform all components of the study protocol except for the actual face-to-face eye exam.

The staff will take a focused ocular history following the TECS protocol and the patient's responses will be documented. The patient will then have distance auto-refraction measurements made on both eyes using the Marco ARK-530A auto-refractor. The distance vision using only the auto-refraction will be checked for each eye through the ARK-530A auto-refractor, and then the auto-refraction and distance vision will be documented. Near add will be calculated from an age-based reference chart, added to the distance auto-refraction, and then the near vision in each eye will be tested. Near add and near vision will be documented.

Then the study staff will refine the auto-refraction with standard manifest refraction techniques. Eye pressure using the iCare tonometer and central corneal thickness (CCT) using the corneal pachymeter will be taken for each eye. These results will be documented and the patient will then be dilated in each eye. Once the patient is finished dilating, the patient will have fundus photos taken following the VA diabetic teleretinal protocol. After photos, the patient will receive a comprehensive face to face ophthalmic exam by an ophthalmologist who is responsible for the medical care of that patient. The examining physician's assessment and plan will go into Medflow, the Eye Clinic EMR and CPRS per usual clinical care routine.

Each participating patient in the study will be assigned a code (e.g. A1) by the study staff. This code will be used to de-identify the patient data. Throughout the interpretation and data analysis process of the study, the patients will be referred to by their code. The data obtained from the study visit (e.g. history, eye pressure, vision) will be entered by the study staff into REDcap, a data management system, under the coded name. The study staff will download de-identified/coded retinal images of the patient into REDcap and upload into REDcap any pertinent de-identified/coded ophthalmology notes, medications, and medical problem lists for the reading physician.

Each patient will be read twice by two different reading ophthalmologists. The reading ophthalmologists will have never seen the patient face to face and will not have access to the patient's medical record or CPRS, thereby eliminating any possibility that they could unintentionally read what the face to face ophthalmologist found. The reading ophthalmologists will also be blinded to the interpretation of the other. The reading ophthalmologists will follow the TECS interpretation guidelines and make diagnoses and referrals based on the information they received through the TECS protocol. A sample of patients will then be re-coded and re-distributed to the reading physicians after a several month delay in order to calculate inter- and intra-reader variability. Reading interpretation is entered into REDcap.

A third reading ophthalmologist will serve as the adjudicator if the two reading ophthalmologists differ in their diagnoses. The face to face ophthalmologist serves as the gold standard. Throughout this study, the data source will be obtained directly from the patient. All information will be obtained through that patient's eye exam, photographs, and medical record.

Statistical Analysis and Sample Size Considerations.

A target of 250-300 patients will be recruited for this study. Given the calculated prevalence of glaucoma suspect (about 25%), testing 250-300 patients would yield a large enough number of patients to power the study for glaucoma detection. The study is powered this way because glaucoma is the most important disease to identify clinically because of its insidious onset and potential for late diagnosis.

Study MetIhods for Specific Aim #1

ICD 9 codes from the 2 reading physicians will be compared to the ICD 9 codes made by the examining physician, with the examining physician serving as the gold standard. Percent agreement, four fold table analysis, positive, and negative predictive value will be calculated.

Study Methods for Specific Aim #2

The reading physicians will have a 'wash out' period of approximately 1-2 months, and then be given a subset of patients to re-read. For intra-reader variability, the first interpretation will be compared to their second interpretation based on ICD 9 codes. For inter-reader variability, the ICD 9 diagnoses made by the two different readers will be compared on the same patients.

Study Methods for Specific Aim #3

The cost of capital, personnel, supplies, and space will be compared between usual care and a theoretical TECS visit (i.e. if the patient could have been seen at their CBOC instead of in the Eye Clinic that particular Saturday). Patient zip codes will be used to estimate travel cost savings. Cost models will be estimated using generalized linear methods while adjusting for patient demographics and comorbidities as well as the TECS. A sensitivity analysis will be conducted by estimating various cost models while adjusting for clinical outcomes to ensure robustness of the results.

ANTICIPATED RESULTS

The anticipated impacts of the proposed TECS program will be:

1. Accuracy of the TECS protocol to diagnose eye disease will be high, with greater than 90% sensitivity, specificity, positive, and negative predictive value.
2. The inter and intra reader variability will be low, with good reproducibility
3. TECS will be cost effective. Quality of care delivered by the TECS protocol will be comparable to the face to face exam, but potentially be more cost-effective because of reduced travel costs and prevention of blindness through early detection.

PROJECT SIGNIFICANCE

This project coincides with the HIP mission statement and HIP Research program goals below:

1. *"Interactions among key components and sub-components of quality, cost, and access. Health care safety and outcomes…"*

   This project aims to specifically and directly study the quality of care provided by the TECS program. This research study is critical to prove the protocol is safe for patients and that it can be used as an effective screening program.

2. *Impact of delivery models on key components e.g. outpatient care, preventative care."*

   TECS is based in the outpatient clinics and represents a novel eye care delivery method. HIP support of this project will generate data that will be used to support the development of a new model of eye care delivery in the patient centered medical home.

3. *"…Enhance the activities of faculty…to create, disseminate…knowledge about health care services…"*

   The data obtained from analyzing the accuracy of TECS will be used to support widespread implementation at the VA and in other health care systems. Private "single payer" groups such as Kaiser Permanente could potentially also use a TECS-type program. We also intend to apply for future funding to implement a similar program targeting the underserved and uninsured population in Georgia through county hospitals such as Grady Memorial Hospital.

4. This project represents T2 translational research because it takes the Atlanta VA eye clinic's experience and preliminary studies on tele-ophthalmology techniques and tests it in an optimally controlled environment. The data generated from this study will provide evidence-based efficacy of the TECS protocol and also allow the eye clinic to improve it prior to widespread implementation.

TIMELINE

The chart below provides an overall timeline of the proposed HIP project, which will span 2 years of patient recruitment and data analysis.

Date	Objective
First Quarter of calendar year 2016 (Jan-Mar)	Hire individual to serve as Research Coordinator Begin recruitment of patients and conduct trial
Second Quarter of 2016 (Apr-Jun)	Continue recruitment and conducting trial Begin reading photographs and collecting data
Third and Fourth Quarter 2017 (Jul-Dec)	Continue recruitment, data collection and analysis
First through Third Quarter 2017 (Jan-Sep)	Finish recruitment, data collection and analysis
Final Quarter 2017 (Oct-Dec)	Complete analysis of data and publish results

BUDGET JUSTIFICATION

1. A Research Assistant will be needed on a part time basis to recruit patients, conduct the study, and organize the data. We estimate that this individual working part time with 50% effort will cost $24,700.00 per year for 2 years.

2. Data for the study will be gathered and entered into REDcap, a data management system. The cost for this system is $25/month for the duration of the project, totaling $300 per year for 2 years.

SUMMARY

The Atlanta VA Eye Clinic has developed a new tele-ophthalmology protocol that screens veterans for the four major vision-impairing conditions at their primary medical care home. This proposal utilizes HIP funds in a T2 study to perform a prospective comparison. The data obtained will be used to support widespread implementation of this novel eye care delivery method. The TECS delivery model may be applied to non-veteran populations such as the medically underserved and indigent in Georgia through county hospitals.