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A Look into the Impacts of Tele-Optometry Expansion

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Departmental Honors Thesis The University of Tennessee at Chattanooga Integrated Studies: General Business and Pre-professional Biology

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Abstract

Objective

This study aims to assess the health and economic costs and benefits to society and patients resulting from the expansion of telemedicine into online refractive exams and to determine the likelihood of potential consumers to utilize such services.

Methods

A paper survey was distributed at the Inaugural Cempa Health Fair in October of 2019 to both vendors and participants. 105 responses were used to evaluate personal perceptions, practices, and likelihood across a diverse range of demographics. Responses were then entered and analyzed using descriptive statistics and percentages/frequencies. *Results*

Results showed respondents were most attracted to online refractive exams due to cost and convenience factors; however, the majority would still prefer to use in-person exams if costs were the same but were less likely to seek out comprehensive exams when accurately priced.

Implications

Tele-optometry, per the AOA, can be useful in a variety of mediums unless they are being used as substitutes. Both the survey and literature show interest in expansion, especially in populations which may be susceptible to missed diagnoses. Cost-benefit analysis is positive for patients but may have more negative implications for society and the economy as a whole. Further modifications should be made within the vision field to ensure proper education, access, safety, and insurance opportunities are made a priority.

Keywords: Optometry, Tele-medicine, Refractive Eye Exams, Economy of Tele-health

Introduction

The goal of this study is to determine the health and economic impacts of the expansion of tele-eye care for patients. As telemedicine coverage continues to grow and cover more health sectors, patients' awareness of and confidence in telehealth services also grows, especially when looking at more routine procedures such as a refractive eye exam [1]. Though the World Health Organization (WHO) outlines four elements of telemedicine (provide clinical support, overcome geographic barriers and connect users, involve various technologies and information, and improve health outcomes), telemedicine remains controversial because not all platforms adhere to all elements [2]. This study aims to understand the impact of patients' decisions to use or not use tele-optometrical services through the following research questions:

- What are the impacts of receiving screening not otherwise received?
- What are the impacts of replacing comprehensive exams?
- What are the short and long term costs and savings of tele-eye care, from both economic and health standpoints?
- How do patients weigh travel and wait time considerations in their decisions?
- What are patient perceptions of tele-eye care?

Eyecare Definitions, Prevalence, and Recommendations

Thirty-eight million Americans aged 40 years and older are blind, visually impaired, or have age related eye diseases, and this number has been predicted to reach 50 million by 2020 [3]. Vision impairment is determined by using the best-corrected visual acuity (BCVA) of the better seeing eye. Despite the lack of an adopted universal definition of vision impairment, most define the ranges of: 20/40 to 20/63 as mild impairment, 20/80 to 20/160 as moderate impairment, and 20/200 or worse as severe impairment. Legal blindness as determined by the U.S. government is 20/200 or worse, and WHO defines it as 20/400 or worse [4].

Glaucoma is characterized by optic nerve damage, nerve layer fibre defects, and visual field loss. It is most commonly associated with high intraocular pressure (IOP). As of 2012, glaucoma was estimated to affect over 2 million people in the United States and predicted to increase to 3 million by 2020. There are two types of glaucoma: open angle and angle closure [5]. This condition occurs most often in people over 40 and is the second leading cause of blindness. Primary open-angle glaucoma, while it cannot be prevented, usually develops slowly and is initially asymptomatic, and if diagnosed early enough, it can be better controlled. Vision lost in the progression of this disorder cannot be restored [6]. Interventions to this condition include miotic agents, epinephrine drops, α 2-adrenoceptor antagonists, β -adrenoceptor antagonists, carbonic anhydrase inhibitors, prostaglandins, and combination products. Surgical and laser procedures can also be utilized [5].

Cataracts are another common eye condition in which the lens of the eye becomes cloudy or opaque. The lens is responsible for focusing light on the retina at the back of the eye which sends an image through the optic nerve to the brain, but with the presence of

cataracts, light becomes scattered. This leads to blurry vision, reduced intensity of colors, increased sensitivity to light glare, and difficulty seeing at night. Doctors may alter lens prescriptions or recommend surgery [6].

Macular degeneration, or age-related macular degeneration (ARMD), is the leading cause of severe vision loss in adults over the age of 50. This eye disease affects the macula, which is the center of the retina at the back of the eye, which in turn causes the loss of central vision. The CDC has estimated that 1.8 million people have ARMD and another 7.3 million are at substantial risk. Depending on the type, wet or dry, there may or may not be responses to treatments of diets or injections. Wet ARMD has better responses to injection treatments when caught early, but the early stages often go unnoticed by patients. Vision loss caused by this disease cannot be restored; however, low-vision devices may be utilized in order to maximize remaining vision [6].

Diabetic retinopathy is a condition within those with diabetes that causes progressive damage to the retina. Diabetes damages small blood vessels throughout the body, including in the retina, which leads to fluid leakage and retinal swelling. A comprehensive eye exam is the only way to determine if a person's diabetes will cause blindness. Early detection and treatment may limit the potential for significant vision loss, but if left untreated, blindness can occur. Treatments may include laser surgery, injection, or vitreous surgery. Preventative measures for this condition are careful controlling of diabetes [6].

Professionals recommend having eye checkups with pupil dilation every 2-4 years for those aged 40-64 and every 1-2 years for those 65+. This recommendation supports early detection of diseases, such as cataracts or glaucoma, because physiologic

compensation by contralateral eye delays patient recognition until the diseases have come to a point of irreversible vision loss. Early detection of glaucoma reduces the intraocular pressure and can slow or halt vision impairment [7]. This recommendation varies depending on medical history and risk-factors. Three-fourths of vision loss is avoidable [8].

Vision and the Economy

Depending on source, the annual total cost of vision problems to the United States ranges from \$51.4 billion to \$67.6 billion dollars a year [3]. The annual total direct cost to the United States government and its taxpayers from blindness or vision disorders for those aged 40 years or older is about \$35.4 billion. Medicaid accounts for \$13.7 billion of this, or 38.7% [7]. If common ocular conditions such as conjunctivitis, strabismus, trauma, and uveitis were included, this overall direct medical cost would likely rise by 15%. As for the non-direct costs, \$16 billion is estimated to be from medical care expenditures, informal care costs, and loss in value of quality of life. Breaking down the spending even more, cataract costs are \$6.8 billion, refractive error costs \$5.51 billion, glaucoma costs \$2.86 billion, age-related macular degeneration costs \$570 million, and diabetic retinopathy costs \$490 million. These vision costs are greater when problems are able to progress to an advanced stage, so these long term costs can be reduced by providing preventative measures or interventions during earlier stages [3]. In 2008, \$357 billion, or 12% of federal expenditures, was spent on disability related expenses. In 2009, 17.2% of total disabilities were vision related. Only 38.3% of vision-disabled working age adults were employed. Meanwhile, 11.6% of the working age population aged 40 years or older has glaucoma, age-related macular degeneration, and/or cataracts [7].

Insurance

Vision insurance is an add-on benefit and typically not covered by employment insurance plans. It's also one of the first benefits individuals or employers eliminate in order to lower costs [7]. As seen in the comprehensive list of East Tennessee vision insurance options (see Appendix A), many plans offer varying discounts on vision services, often including routine eye exams and possibly eyewear purchases as well. In person comprehensive exams aren't typically broken down into refractive and health elements because these services are often given at the same time. However, according to Dr. John Rumpakis, CEO of Practice Resource Management, Inc., if practices showed the breakdown and price-by-price comparison, for instance:

'... a comprehensive exam at an average Medicare reimbursement of \$120 to \$150, the line-item for the refraction aspect of the exam averages between \$20 and \$25, says Dr. Rumpakis. Specifically, 'The 2017 National Average Allowable from CMS for 92015 (Determination of Refractive State) is \$20.13.' [9]

His statement puts online exams comparably priced to in person refraction portions of the exam. However, both the aforementioned comprehensive list of insurances and Dr. Rumpakis notes no insurer currently covers online refractive exams [9].

Other than affecting how much a patient will pay, vision insurance has an impact on incidence rates of various eye complications. Insured populations have higher incidences of glaucoma and cataracts. This is due to the fact that those with insurance are more likely to seek health care professionals, and therefore there is an increase in detection. Lack of detection then leads to the higher incidence of vision loss in uninsured populations [10]. Many of these conditions can be initially asymptomatic, and the longer an individual waits

to receive medical attention, the more detrimental the condition can be to the individual's vision and wallet, as well as to the economy as a whole.

Telemedicine, Tele-eyecare

Telemedicine, in a general sense, is the process of evaluating, diagnosing, and/or treating patients from a remote location using telecommunication technology. This technology gives users access to medical expertise quickly and efficiently without the requirement of travel [11]. Telemedicine has been in the works since the 1700-1800s when electrical inventions first allowed for expansion of near instantaneous long distance communication. With the introduction of the radio into people's homes in 1924, there was talk of a "radio doctor" that could be on the horizon featuring audio and live pictures. This idea was further provoked with the introduction of live television transmissions in 1927. The first references to telemedicine in medical literature appeared in 1950, while medical video communications and diagnostic consultations in the United States date back to 1959. In 1967, there is evidence of telemedicine applications in the transmission of ECG and cardiac rhythm information being transferred from fire-rescue units to emergency departments. Ten years later, there was a medical project working on one-way television visuals and two-way audio. The high cost of such transmissions discouraged interest in telemedicine later in the 1980s [12]. Current literature, as well as medical and technological advancements, show that interest and implementation of telemedicine has again risen to an all-time high.

Telemedicine use in the eye care field, like other specialties, requires certain parameters. In order for this implementation to be successful and beneficial, the tele-

eyecare should improve coordination and communication between patients and different eye specialists. There are different techniques utilized in such services. For synchronous telehealth, there must be adequate lighting and matching levels of high resolution at both the originating and the distant site. If video-conferencing, transmission works best with high speed connections. Due to privacy laws, all transmissions that occur over the internet must establish secure encryption and multi-factor authentication [13].

There have been successful uses and developments of tele-evecare through the management of diseases such as glaucoma and diabetic retinopathy. Looking at a study that follows patients at risk for glaucoma in rural Canada, teleglaucoma services were successful by increasing referral rate by 20% and by reducing patient travel time by 61 hours, wait times by 30%, and costs by 80% [14]. Another study follows a teleretinal diabetic retinopathy program in Los Angeles shows an eliminated need for more than 14,000 unnecessary visits to specialists. The successful goal of this program was also to reduce wait times and costs, as well as increase annual screening rates and referral rates [15]. As diabetes becomes a more prevalent issue, telemedicine access could help prevent complications as most diabetic patients are worried about other more symptomatic health issues. Additionally, most diabetic care is given by primary care physicians, but eves are a look into the microvascular system and should be managed from early diagnosis. Such programs as teleretinal diabetic retinopathy increase access and care from an earlier point in diagnosis and show the successful utilization of telemedicine as an expansion of care and not a substitute [16].

More recently, tele-eyecare has expanded into refractive exams. Opternative is the frontrunner of these tele-optometrical companies. Founded in 2015, Opternative is a

Chicago based company that offers online eye exams from approximately \$40-\$60 depending on the services selected. Ultimately, this organization, and many others like it, offer such services as a way to receive glasses or contact prescriptions from the comfort of home. Opternative has a disclaimer that its services do not include a comprehensive health exam and recommend users to still get checked in person. The site even prohibits patients from using the online refractive exam more than four consecutive years without a confirmation of an outside eye health exam [9].

The joint commision (TJC) has standards for telemedicine in which practitioners who render care may need to be credentialed in both the originating and distant site for live interactions, or they can just have distant credentials and be viewed as a consultant in store forward systems, but licenses are still typically by state. This explains why online refractive prescriptions originate from ophthalmologists instead of optometrists, since these medical professionals are permitted to practice across state lines [13].

Online refractive tests, regardless of which company is running it, have similar testing processes requiring both a cell phone and a computer. Consumers are asked for a phone number, which enables the consumer to use their phone as a remote control for computer testing. They are asked for their shoe size in order to determine how many steps away from the computer they need to move. The service then proceeds to ask several hard stop questions that will end the testing including several about systemic diseases and the consumer's state of residence. The system will not allow consumers to complete the test if they have specific conditions or diseases, such as diabetes, glaucoma, pain in the eye, or cataracts. Online tests are barred in 11 states. The test then begins after the consumer has confirmed that they are the instructed distance away from the screen [9]. Some services

use microphones to answer questions, while others solely rely on the cell phone. The test may include testing that covers visual acuity, color blindness, refractive error, and contrast sensitivity. (See Appendix B for online test references from the Essilor Group and Opternative)

Other companies have also expanded the use of tele eye services. Warby Parker is a disruptor company launched in 2010 that was founded to overcome the optical shop monopoly. Disruptors are companies that subvert established business models through the use of modern technology. By utilizing this strategy, Warby Parker provides lower-priced, stylish glasses for consumers to either buy in a traditional brick and mortar store or online fronts which ship to their home. They also have developed the option to have trial frames delivered to consumers' homes for free. By 2014, Warby Parker was ranked number 2 on the top 50 disruptor list. Several other companies have entered the market including 1-800 Contacts, Eyenatra, GlassesOn, Essilor, and SimpleContacts [9].

AOA Stance

The American Optometric Association (AOA) has stated their support of telemedicine as a supplement to high value and quality eye and vision care. The AOA finds tele services to be appropriate in the use of basic data acquisition, confirmation of expected results and stability, and notification of changes in chronic conditions as between face-toface visit data transfers. However, they have also stated these services are not appropriate for initial diagnosis, a replacement for face to face exams, or for the substitution of partial or entire categories of eye care [13]. Per AOA claims, online refractive exams rely on subjective testing alone, while comprehensive in-person exams use both subjective and

objective measures. These online tests are unable to provide prismatic corrections, even if their spherical and cylindrical powers are correct. They also are unable to account for cyclorotation and accommodative spasm [9]. The AOA also does not support these services that offer prescriptions without an adequate history, exam, diagnosis, and/or known proper doctor-patient relationship. This doctor-patient preexisting relationship allows for better communication between care teams and establishes an integrated health delivery system. Additionally, the AOA requests that services have protocols for local referrals within the patient's area for both urgent and emergency services [13].

All in all, optometrists fear that patients will skip in person doctor and optician visits altogether by utilizing online prescription services and then ordering contacts and/or glasses from companies such as 1-800 contacts or Warby Parker. In order to combat these concerns, the AOA has launched education campaigns regarding the risks of online exams. They have reached out to reporters for Politico, Medscape Medical News, and have also had their suggestions published in The Hill. Additionally, the California Optometric Association has created educational YouTube videos, and the AOA as a whole, along with Vision Council has launched an informative website: www.thinkaboutyoureyes.com. As a way to directly fight refractive and dispensing tele services, the AOA also collects stories from doctors in which a patient has suffered due to the use, or misuse, of such services. These stories are collected at stopillegalcls@aoa.org [9].

FDA and Controversy

On top of launching educational programs, the AOA has filed formal complaints about Opternative to the FDA's office of compliance, center for devices and radiological

health in April of 2016. The AOA complained due to Opternative's lack of premarket approval (PMA) and formal FDA review of their product's safety and efficacy. Opternative was not compliant with federal medical device and patient safety laws per the AOA. The association claims substantial equivalency between Opternative's app and a visual acuity chart, color-vision tester, and medical device data; however, Opternative's March 2014 patent application states otherwise [17].

Through investigative measures taken by the FDA Opternative's mobile app is considered a "device" under section 201(h) of the FDCA, 21 U.S.C. § 321(h), "intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body." The app was also found "adulterated" under section 501(f)(1)(B) of the FDCA, 21 U.S.C. § 351(f)(1)(B), because it did not have an FDA-approved PMA in effect, or an approved application for an investigational device exemption. Lastly, the app was labeled "misbranded" under section 502(o) of the FDCA, 21 U.S.C. § 350(o), because the company did not notify the FDA of its intent to introduce the device into commercial distribution [17].

As a result of the violations of the FDCA, the FDA issued a warning letter to Opternative in 2017 requesting them to "immediately cease activities that result in the misbranding or adulteration of the On-Line Opternative Eye Examination Mobile Medical App device, such as the commercial distribution of the device through your online website." Following allegations, Opternative changed its name to Visibly in December of 2018 to try and alleviate tension surrounding its connotation as an optometry alternative [18]. A recall, or a voluntary action that removes or corrects products in violation of FDA laws, was ordered due to the failure to submit a PMA and lack of 510(k) clearance, assuring it was

safe, effective, and substantially equivalent. Opternative was no longer available after a notice in August 2019 made by the FDA [19].

Methodology

In the fall of 2019, a paper survey was designed and conducted to determine the likelihood of potential consumers' use, interest, and awareness of tele-optometrical services. This survey was the most efficient method for measuring patterns in a wide range of respondents. Since there was no existing survey instrument available in the literature, a survey had to be designed. The survey aimed to determine opinions regarding optometric practices, as well as obtain information regarding experiences, qualities, and demographics from varying populations in a target sample. Using several binary and multi-categorical questions, a space for open-ended comments, and one visual-analog scale question, respondents were asked about their current eye care practices, as well as their thoughts and impressions of tele-eye care.

The survey (see Appendix C) was designed to determine responses to such questions as:

- Do you have vision insurance?
- Do you have a regular optometrist?
- How often do you go to the eye doctor?
- Have you heard of tele-optometrical services?
- If costs were the same, how would you prefer your exam to be administered?
- How likely are you to switch to an online eye exam?

This survey was translated to Spanish (see Appendix D) in order to be inclusive to those at the health fair who did not speak English. 150 surveys were printed in each language. The translation process was done by providing the English survey to two native speakers for

translation and checking. The same process was applied to the consent sheet used to obtain consent by assent, which informed participants of the estimated time the survey would take, the requirements, and that the survey was voluntary and optional (see Appendix E). This consent option was chosen in order to keep respondents' anonymity.

Initially consideration was given to sampling those who attended the University of Tennessee Chattanooga annual wellness fair for students, staff, and faculty. However, due to the similar levels of education and salary levels among those employed at the University of Tennessee Chattanooga as well as the homogenous student demographics (income and age), it was dismissed as a potential respondent pool. The decision was to seek a survey respondent sample outside of this environment for a more diverse response set. In order to reach a target audience of those over 18, of varying race, ethnicity, age, gender, and income level, this survey was conducted at the Inaugural Cempa Health Fair in October 2019 at Howard High School in Chattanooga, TN. Target respondents included 100 to 200 responses from both fair attendants and vendors.

Upon completion of the survey design, translations, and approval from Cempa, an exempt application was submitted to the Institutional Research Board and given the approval number of #19-128 (see Appendix F). The survey recruitment and collection as well as the analysis were completed by CITI trained researchers. Paper survey data was initially coded by hand, with measurements added to the visual analogue responses. In cases where more than one answer was marked or respondents made comments, the two coders would each separately come to a decision about the response intention. After individual coding, those ambiguous responses were then discussed and in all cases both independent reviews resulted in consistent response coding with no discrepancies. Prior to

data entry, an excel collection sheet was created with drop down menus and field constraints.

Collected data was hand entered and organized into excel sheets and then double checked for accuracy. Outliers were marked to the most similar answer, the scaled question was measured and quantified, and the missing components were accounted for by using the term "missing." Upon completion of data verification by a second coder, app open fields were cleaned to ensure synchronicity for data analysis. This data was then analyzed using excel pivot tables and Tableau software to cross analyze questions and create graphs. This data was analyzed utilizing descriptive statistics and percentages/frequencies. Since the goal of this study was descriptive analysis of sample opinions, statistical significance testing was not appropriate. Data was stored in a password secured OneDrive available only to the aforementioned CITI trained volunteers.

Results

One hundred and five responses were collected at the health fair. Of these 105, 60% reported that they had a regular eye doctor, while a portion of these respondents, 47.6% and 15.2% respectively, reported they visited the eye doctor every year or every other year. 23.8% only visited when they had problems, and 6.7% had never visited.

To identify the reasons the people might not be visiting their eye doctors, the respondents were asked to identify all that applied for why they dislike eye doctor visits. **Figure 1** illustrates respondents' dislikes regarding visiting the eye doctor. Respondents selected combinations of dislikes including: commuting, cost, hard to schedule, how long the visit takes, nothing, or other. Of the 47 who reported "nothing," 10.6% of them were part of the 6.7% who had never been to the eye doctor. The majority complaint of respondents revolved around the cost, which was later referenced again when asking about preferred methods of testing.

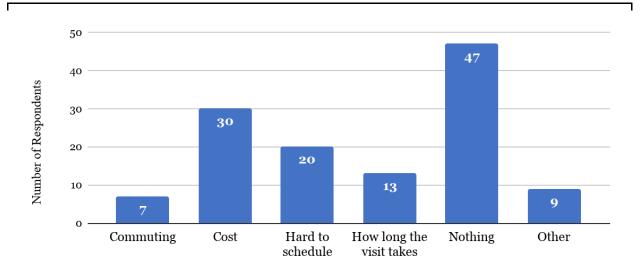


Figure 1: Respondent Dislikes Regarding Eye Care Visits (N=103)



Figure 2 demonstrates a cross reference between respondents' preference if costs were equal and how often they would actually be willing to go to an in-person comprehensive exam and pay the approximate \$100 exam cost versus the \$40 refractive only online fee. This figure shows preferences in a matched alternative, but eliminates discrepancies and bias by comparing responses with cost realities.

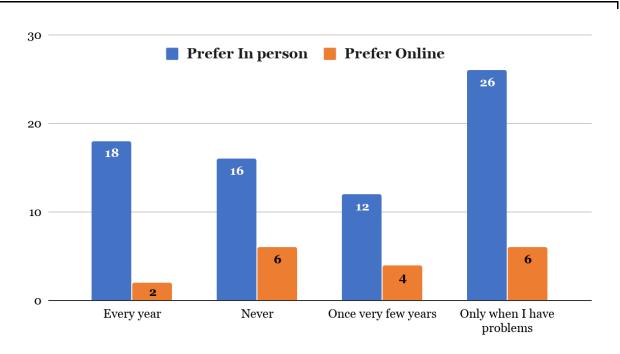


Figure 2: Respondent Preferred Method versus Willing to Pay (N=97)

74.4% reported that they would rather have an in person eye exam compared to the 19.1% who stated that they would choose an online exam, regardless of whether or not there was a price difference. Respondents were asked to mark on the visual analogue scale how likely they would be to try an online eye exam. Markings ranged from 0.0 to 5.0, with 0.0 being not at all likely and 5.0 being very likely. The average value was 2.4 with the minimum at 0.0 and maximum at 5.0. When broken down into interval groups (0.0-0.9, 1.0-

Willing to Pay in Person

1.9, 2.0-2.9. 3.0-3.9, and 4.0-5.0), there was an approximate inverted bell curve distribution with more people siding towards extremes.

Respondents were also asked if they would go in for a comprehensive eye health exam after receiving the online prescription. A majority of the respondents (76 of 105) said they would go in. In a different question presented in the survey, 46.1% of these particular respondents were actually willing to pay the additional rates for the in person exam either every year or every other year.

At survey initiation, 89.3% of the sample population had not heard of online eye exams. Of the 105 respondents, only one person had used an online eye exam previously. Looking at a more general stance on telemedicine, 16.2% of respondents reported having used some form of online health services. Despite interest, not all respondents had access to or were eligible for these online exams. When asked about access to a phone and computer in which one would be comfortable entering personal information and performing the refractive exam, 77.1% reported that they did have access to both a phone and a computer. 16.2% and 2.9%, respectively, stated they either only had access to a phone or no access at all. In addition to access, the online refractive exams required that consumers have no history of specific diseases or symptoms such as diabetes, glaucoma, pain in the eye, cataracts, etc. When asked about eligibility, 45.7% reported they were eligible, 34.3% stated they were not, and 11.4% and 8.6%, respectively, were either unsure of eligibility or had skipped the question.

The sample was also asked about contact and glasses use. 73% of respondents reported they wear glasses, and 30.5% reported wearing contacts. Of the 30.5% of contact wearers, 43.8% report they do not change contacts as directed. This may include sleeping

in contacts, wearing for extended hours in the day, not properly cleaning and storing contacts, or wearing contacts past intended use time (ex. dailies, monthlies, or biweeklies). Those between the ages of 18 and 24 and between 60 and 69 were the groups least likely to follow contact wear directions, with 25.0% and 20% following directions respectively. Comparing exam visit frequency with contact lens care, 65.5% of those that don't change contacts as directed report visiting every year or every other year compared to 75.0% of those that properly change their contacts that reported the same frequencies.

Demographics were requested of respondents to determine if there was any correlation between these factors and their responses. Of the 105 respondents, 69.5% were female, 25.7% were male, and under 1% preferred not to disclose that information.

Respondents' race characteristics are shown in **Table 1** (below). Ethnicity of respondents was also recorded. 56.2% recorded "Not Hispanic or Latino" and 14.29% recorded they were. 25.7% skipped the question, and 3.8% reported that they would prefer not to answer. Age ranged from 18 to over 70 years, with groups making up the demographics as 18-24 yr (11.4%), 25-29 yr (6.7%), 30-39 yr (20.0%), 40-49 yr (19.1%), 50-59 yr (13.3%), 60-69 yr (15.2%), and 70+ yr (8.6%).

| Variable | Frequency | Percentage |
|-------------------------|-----------|------------|
| Race White/Caucasian | 44 | 41.9% |
| Black/African American | 41 | 39.1% |
| American/Alaskan Native | 3 | 2.86% |
| Asian | 2 | 1.90% |
| Two or more | 1 | 0.95% |
| Prefer not to answer | 3 | 2.86% |
| Missing | 11 | 10.5% |

| Table 1: Respondent | acial Demographic | Information (N=105) |
|---------------------|-------------------|---------------------|
|---------------------|-------------------|---------------------|

Concerning respondents' financial and insurance statuses, **Table 2** demonstrates the distribution of income levels ranging from under \$20,000 to over \$100,000. Within the 105 respondents, 68.6% stated that they had vision insurance, and the other 31.4% did not. Cross referencing income levels with vision insurance, shows a correlation between higher incomes with higher probability to have vision insurance. Within those that make \$100,000 or more (14.3% of respondents), 93.3% of them have vision insurance. Comparatively, those that make less than \$20,000 (also 14.3% of respondents), 46.7% had vision insurance. To average it out, those in the top three income brackets (\$50,000 to over \$100,000), respondents averaged 87.5% having vision insurance. In the bottom three income brackets (\$49,999 and below), respondents averaged 56.1% having vision insurance. Of the total respondents that do have vision insurance, 73.6% reported going to

the eye doctor either every year or every other year compared to the 39.4% of those without insurance who reported the same frequencies.

| Table 2. Respondent nousenoid meome Level Demographic information (N-105) | | | | |
|--|-----------|------------|--|--|
| Variable | Frequency | Percentage | | |
| Income | | 1 | | |
| \$100,000 or more | 15 | 14.3% | | |
| \$75,000- \$99,999 | 10 | 9.52% | | |
| \$50,000-\$74,999 | 23 | 21.9% | | |
| \$35,000-\$49,999 | 13 | 12.4% | | |
| \$20,000-\$34,999 | 13 | 12.4% | | |
| Less than \$20,000 | 15 | 14.3% | | |
| Prefer not to answer | 8 | 7.62% | | |
| Missing | 8 | 7.62% | | |

Table 2: Respondent Household Income Level Demographic Information (N=105)

Discussion and Further Implications

Survey Discussion and Society Perception

As tele-optometry continues to expand into more general use and access of refractive exams for the public, society perceptions on tele services, in-person services, and vision as a whole must be assessed. According to an outside survey of 2,044 people, respondents had varying levels of awareness for common eye conditions: 65.8% were aware of cataracts or glaucoma. 50.0% were aware of ARMD. 37.3% were aware of diabetic retinopathy, 25.0% were not aware of any of these conditions, and 4.8% were not sure. These same respondents ranked losing vision as equal to or worse than losing hearing, memory, speech, or a limb [20]. These results show a lack of education on diseases of the eve and their impacts. Some of these conditions can cause gradual and irreversible vision loss if not detected. Without being fully aware, that percentage of society may assume eye professionals are only useful for prescriptions and obvious issues. These professionals, however, are responsible for pre/post-operative care, prescriptions, injections, vision therapy, and diagnosing a large range of systemic diseases, including those within the categories of congenital, traumatic, vascular, neoplastic, autoimmune, idiopathic, infectious, metabolic or endocrine, and drugs or toxins [21]. Ultimately, visiting eye professionals for in-person exams is important in preserving both overall health and vision.

Despite the importance of in-person exams, several respondents in this study as well as outside studies have reported reasons for avoiding or disliking in-person exams. Looking at data from the BRFSS Vision Impairment and Access to Eye Care Module, or a state based, random digit dialed phone survey, which collected answers from a sample of

11,503 adults at least 40 years old that had reported some level of visual impairment who hadn't visited an eye care professional in the year prior, shows four different categories for why people didn't visit an eye care professional [22]:

- 1. Cost or lack of insurance
- 2. Haven't thought of it; No reason or problems
- 3. Don't have an eye doctor; No transportation; No appointment; Too far
- 4. Other

The above reasons are consistent with those found in this study, with the addition that those aged 65 or older may see no need as they expect vision changes to occur as a normal part of aging [22].

Vision insurance has been shown to affect society's likelihood to receive comprehensive exams and incidence rates. Approximately 40% of the population and subsample of an outside survey were found to have no vision insurance, while 86-88.6% reported having a form of general health insurance [7]. In this particular study, 31.4% of respondents reported not having vision insurance. This data shows consistency when considering the sample was selected within a minority health fair, many of whom were among the lower income brackets. As mentioned earlier, those with vision insurance are more likely to receive exams and, therefore, have diseases caught early. This preserves both health and vision. Due to vision insurance plans' lack of coverage for online eye exams, which don't catch systemic or eye diseases, preventative eye care could be better and more desirable if health plans included mandatory vision insurance components. Those who had visual screenings during physical examinations from their primary doctors were also found to have better eye health due to physician reminders to seek care from an eye care

professional [22]. These modifications may help those subsamples who are otherwise more likely to be susceptible to using online exams as substitutions due to cost differences and lack of education.

Costs and Benefits to Society

Some of the main challenges when attempting to evaluate the economics of telemedicine are the constantly changing technology, lack of appropriate study design to manage inadequate sample sizes, the need of a nonconventional technique, and the valuation of health and non-health outcomes. Telemedicine may be more cost effective to society when considering monetary and time costs/benefits for patients, such as cheaper up-front exams and convenience factors [23]. If considering the working class of patients, if appropriate refractive correction is given, there could be at least a 2.5% increase in productivity [24]; however, missed or incorrect astigmatisms during online refractive exams are not uncommon and can increase symptoms of discomfort for patients [9]. When live consultations and similar services are considered, there are increases in the cost of care due to the additional requirements and costs of equipment, transmission lines, and additional personnel and administration necessary for scheduling and preparing services [23].

On top of all the costs and benefits directly related to expansion of tele-optometry, indirect effects must also be considered. These costs would most often be found in missing the early detection of vision altering conditions such as glaucoma, cataracts, diabetic retinopathy, or ARMD, as well as several other systemic diseases which may be caught due to ocular manifestation. Missing these diseases early on may not only impact patients'

vision capabilities, but it may also impact the amount of money required to treat or accommodate vision losses. As mentioned earlier from the AOA's recommendations, teleoptometry services should be used as a supplement and not as a replacement [13].

Costs and benefits apply to those under the age of 40 as well, especially when considering those who may over wear and abuse contacts. Jeffrey Sonsino, OD, chair of Contact Lens and Cornea Section of the AOA, recounts a story of a 30 year old patient who came to his office due to eye irritation. His patient had reordered contacts online for 3 years without an in-person exam and had developed a Pseudomonas ulcer caused by Acanthamoeba that ate through his cornea. The patient required a 10.5 mm diameter corneal transplant, and such treatment will need to be repeated until the patient's eye is unrecoverable [9].

Moving Forward

As tele-optometry continues to expand from disease monitoring to refractive exams to the next phase, certain steps should be implemented. An important consideration in telemedicine is asking what should be done instead of what can be done. Standards written and expected by the AOA should be fulfilled as their instructions lead to the best possible valuations of health outcomes, which may in turn result in a reduction in direct and indirect medical costs to the U.S. economy. Tele-optometry expansion into refractive exams should also introduce security measures to ensure multi-factor authentication and secure encryption are utilized. Loop-holes should be analyzed and removed so that consumers may not change state of residence or specific medical history responses which would allow them to bypass preventative and legal hard stop measures. Furthermore, education

programs regarding the importance of comprehensive health exams and impacts of early versus late detection should continue to be developed, simplified, and distributed to the masses, especially in susceptible communities.

Future research on this topic should consider possible expansions within vision insurance, both within general health coverage and on a tele-health service basis. Another point of research would be covering successful education programs and their implementation. Data within this study's research topic should also be further broken down into racial and ethnic demographics, as certain demographics are more genetically susceptible to different ocular conditions. Lastly, this research should further its costbenefit analysis as more contemporary methods are made available to keep up with changes in technology and development of proper valuation of outcomes.

Appendix

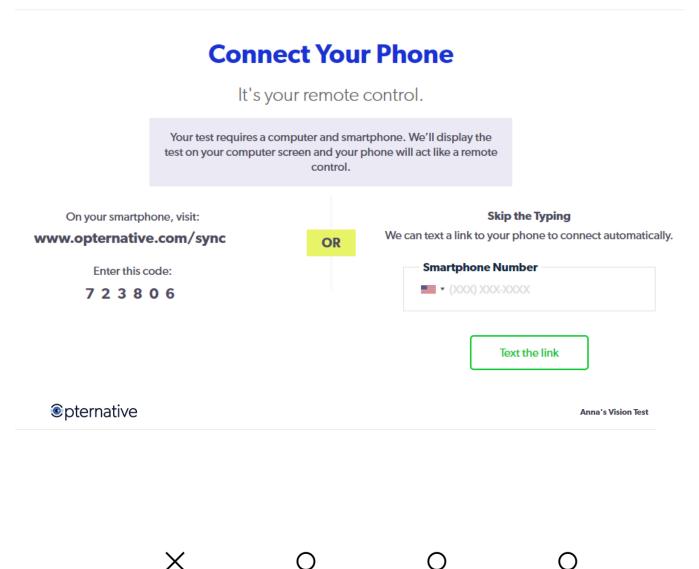
| Insurer | Vision Insurance Comments | Cost of Coverage Per Year Per Person | Application fee (one time only) | Copay for Comprehensiv e | Cover online? |
|---------------------------------------|---|--|---------------------------------------|---|------------------|
| Aetna® Vital Savings [25] | Addition to traditional coverage - covers dental, RX and Eye with a Plus plan; a savings card for services | \$95 | \$15 | \$42 | No |
| Aetna Vision™ Preferred [26] | Federal Employee Benefits | \$82.68 - \$150 | \$0 | \$0 | No |
| Cigna® [27] | Addition to traditional coverage, can be added to self insured | No data available | \$0 | No data available | No |
| Blue Cross Blue Shield [28] | Addition to traditional coverage - discounts through EyeMed Advantage Vision Discount | \$0 | \$0 | \$50 | No |
| Blue Cross Blue Shield [28] | Addition to traditional coverage - discounts through Davis Vision | \$0 | \$0 | discount off cost of services 10%-40% | No |
| VSP Vision Care [29] | Standard and Enhanced | \$153.24 - \$359.16 | \$0 | \$15 | No |

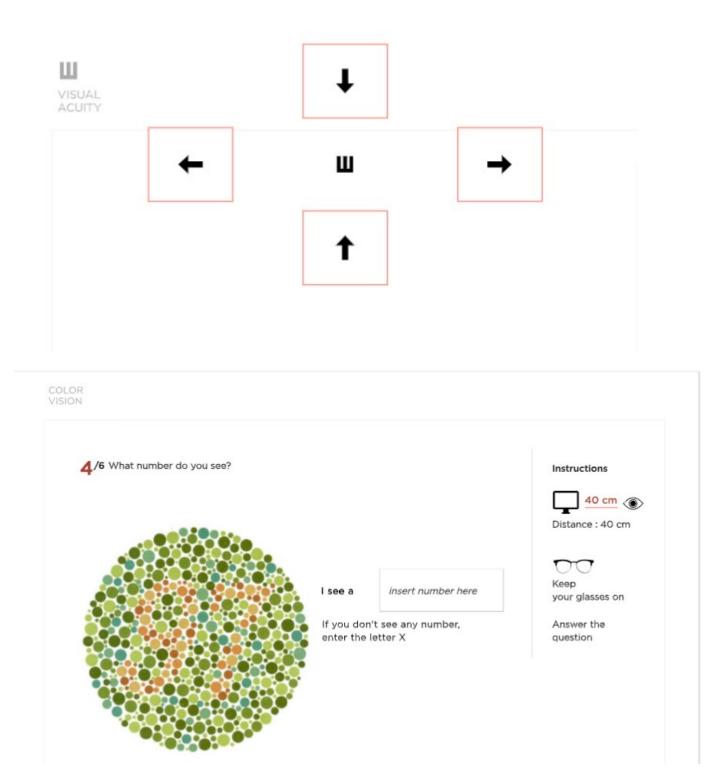
Appendix A: Vision Insurance Policies and Costs in East Tennessee

| | programs for individual consumer | | | | |
|-------------------------------|---|------------------|-------|--|----|
| United Healthcare® [30] | Uses Golden Rule Insurance Company vision insurance | \$1060.92 - 1200 | \$0 | \$10 | No |
| | | Supplemental H | Plans | | |
| Medicare Part C [31] | BCBS Blue Advantage Plan for TN - costs related to region of the state (southeast) as well as income of individual and coverage plan options | \$0-\$2,505.60 | \$0 | \$30-\$35 | No |
| Humana [32] | | \$480 - \$840 | \$0 | \$40 [\$0 for diabetes and glaucoma] | No |
| Medicaid Tenncare [33] | Vision benefits administered through Amerigroup | \$0 | \$0 | \$0 | No |

Appendix B: Screenshots of Online Testing from Opternative and Essilor Groups

[34]; [35]







Some guidelines for the test

1 Place yourself 1 meter from the screen.



2 If you have glasses for distance vision or glasses with progressive lenses, keep them on.

3 Without pressing on the eyelid, cover your left/right eye with your hand.



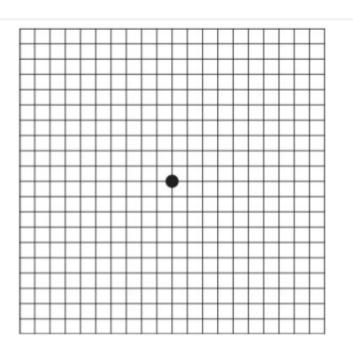
4 Indicate which way the open side of the **u** is facing with your keyboard or mouse.

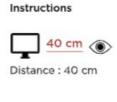


No

Concentrate on the central point in the grid without moving your gaze. Do you see any strong distortions in certain lines?

Yes





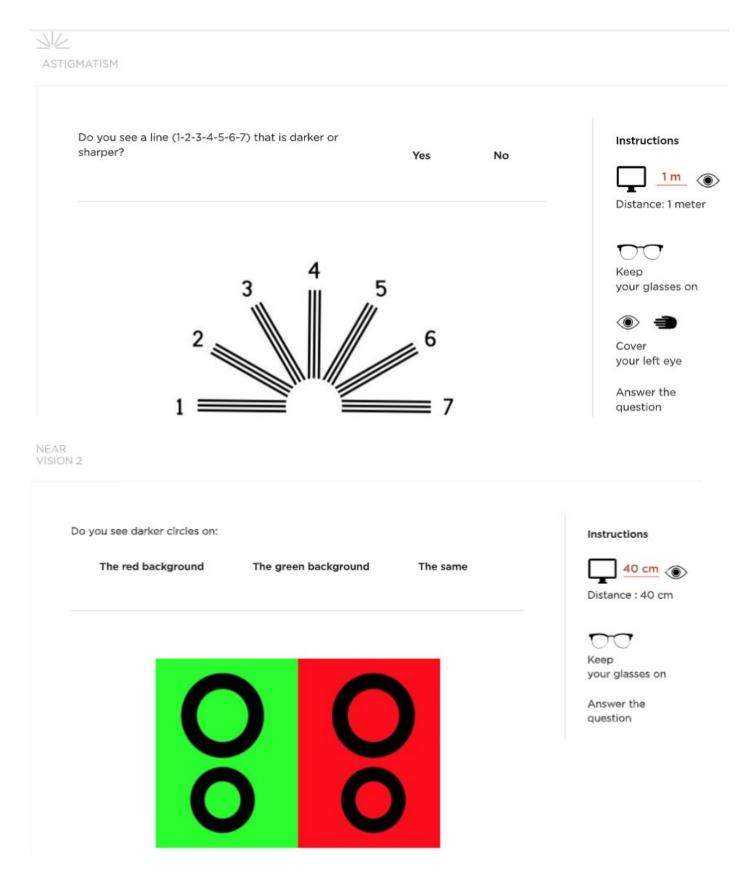


Keep your glasses on



Cover your left eye

Answer the question



Appendix C: English Survey (FRONT)

This survey is a research project at University of Tennessee at Chattanooga about eye exams. You make skip any questions that make you do not wish to answer.

Online eye exams - using a computer and phone, test your eyes over the internet for glasses or contact lenses

In person eye exams - checks for eye related diseases and tests your eyes in a clinic for glasses or contact lenses

1. The following questions are about eye care:

| Please mark the box that applies | Yes | No |
|---|-----|----|
| Do you have eye care (vision) insurance? | | |
| Do you have a regular eye doctor? | | |
| Do you wear glasses? | | |
| Do you wear contacts? | | |
| Have you heard of online eye exams? | | |
| Have you used an online eye exam? | | |
| Have you used any online health services? | | |

2. Do you change your contact lenses as often as your doctor says you should?

I do not use contact lenses Yes No

- 3. How often do you visit the eye doctor?
 - Never been
 - Only when I need to
 - Every year
 - Every other year
 - Other: _____

4. What do you dislike about visiting your eye doctor? Mark all that apply

- Commuting
- Cost
- How long the visit takes
- It is hard to schedule at times I can easily make it
- Nothing
- Other: _____

Online Vision Survey

University of Termessee at Chartencoge Institutional Review Roard Approval # 19-128

English Survey (BACK)

| Only a phone | | | |
|--|---|--|---|
| | Only a computer | No pho: | ne or computer |
| | eurological issues, brain ot take an online eye ex | | laucoma, cataracts |
| | Yes | No | I don't know |
| | exam once at least eve Yes | ry other ye No | ar even after gettin |
| - | ou are to try an online e | ye exam: | |
| | - | - | Not at all likely |
| an eye exam if they we | ere the same cost? | Online | In person |
| g to pay \$100 for an in p | oerson exam versus a \$4 | 40 online ey | ye exam? |
| m I have problems | Once every few year | is I | Every year |
| Race (check all t American Indi Asian Black/African Native Hawaii White | hat apply) an/ Alaskan Native American an/Other Pacific Islander | Ethnic His No: Pre | |
| Household Annu: | al Income 00 | 4 | l hank you |
| | the online eye exam? ve an in person full eye glasses or contacts? a line with how likely ye an eye exam if they we g to pay \$100 for an in p en I have problems to share about the ide Race (check all t American Indi Asian Black/African Native Hawaii White | the online eye exam? Yes ve an in person full eye exam once at least eve glasses or contacts? Yes a line with how likely you are to try an online e an eye exam if they were the same cost? g to pay \$100 for an in person exam versus a \$4 en I have problems Once every few year e to share about the idea of online/ over the pl Race (check all that apply) American Indian/ Alaskan Native Asian Black/African American Native Hawaiian/Other Pacific Islander | ve an in person full eye exam once at least every other ye glasses or contacts? Yes No e line with how likely you are to try an online eye exam: an eye exam if they were the same cost? Online g to pay \$100 for an in person exam versus a \$40 online eye en I have problems Once every few years I e to share about the idea of online/ over the phone health the base of online over the phone health american Indian/ Alaskan Native I His American Indian/ Alaskan Native I His Asian I No Black/African American I Pre Native Hawaiian/Other Pacific Islander White |

Appendix D: Spanish Survey (FRONT)

Esta encuesta es un estudio de investigación en la Universidad de Tennessee en Chattanooga sobre los exámenes de ojos. Usted puede omitir cualquier pregunta que no desee responder.

Examenes de la vista en linea- usando un computador y celular, evalúe sus ojos en el internet por anteojos o lentes de contacto

Examenes de la vista en persona – verifica si hay enfermedades relacionadas con los ojos y examina sus ojos en una clínica en busca de anteojos o lentes de contacto

| preguntas son soore er culdado de los ojos. | | |
|---|----|----|
| Por favor marque la casilla que corresponda | Si | No |
| ¿Tiene seguro de cuidado de la vista (visión)? | | |
| ¿Tiene un oftalmólogo habitual? | | |
| ¿Usas lentes? | | |
| ¿Usas lentes de contacto? | | |
| ¿Has oído hablar de los exámenes oculares en línea? | | |
| ¿Has utilizado un examen de la vista en línea? | | |
| ¿Has utilizado algún servicio de salud en línea? | | |
| | | |

Las proxinas preguntas son sobre el cuidado de los ojos:

2. ¿Cambia sus lentes de contacto tan a menudo como su médico le dice que debería?

No uso lentes de contacto Si No

3. ¿Con qué frecuencia visita al oftalmólogo?

- Nunca he estado
- Solo cuando necesito
- Todos los años
- Cada dos años
- Otro: ______

4. ¿Qué no le gusta de visitar a su oftalmólogo? marque todo lo que corresponda

- Commuting
- Desplazamientos
- Costo
- Cuánto dura la visita
- Es difícil programarlo en momentos en que puedo hacerlo fácilmente
- 🗆 Nada
- Otro: _____

Online Vision Survey

University of Tennesses at Chattanooga Institutional Review Board Approval # 19-128

Spanish Survey (BACK)

5. ¿Tiene acceso a un teléfono y una computadora con internet donde se sentiría cómodo tomando un examen de la vista en línea?

| Tanto un teléfono como una computadora | Solo un telefono | Solo una comput | | No hay teléfon ii computador: | |
|--|---|---------------------|----------------|----------------------------------|----------------|
| | s, presión arterial alta, pro ento de retina o dolor ocu | _ | | _ | |
| ¿Podrías usar el exa | amen de la vista en línea? | Si | No | No lo s | é |
| | un examen completo de l ener una receta en línea p | - | | | os años, No |
| 8. Coloque una marca o | en la línea con la probabil | idad de que se ha | ga un examer | 1 de la vista e | n línea: |
| Muy probable | | | | | No es probable |
| 9. ¿Cómo preferiría hao | cerse un examen de la vist | a si tuvieran el m | ismo costo? | En línea | En persona |
| 10. ¿Cuándo estaría dis línea de \$ 40? | puesto a pagar \$ 100 por u | in examen en per | sona versus u | n examen de | la vista en |
| Nunca So | olo cuando tengo problemas | i Una vez o | ada pocos año | 5 | Todos los años |
| ¿Algún comentario que (telesalud)? | e le gustaría compartir sob | ore la idea de aten | ción médica (| en línea/por | teléfono |
| Género | Raza (marqu | e todo lo que cor | responda) | Etnicidad | |
| Femenina | | ricano/nativo de A | | 🗆 Hispan | o o latino |
| Masculino | Asiático | | | - | pano o Latino |
| No binario | Negro/afr | roamericano | | Prefier | o no contestar |
| Prefiero no contesta | ar 🗆 Nativo de | Hawai/Otro isleñe | o del Pacífico | | |
| Prefiero | Blanco car | ucásico | | | |
| autodescribirme: | Prefiero n | o contestar | | | |
| Edad | Ingresos anua | des del hogar | | | |
| 18-24 | 🔲 Menos de 🖇 | - | | <u> </u> | |
| 25-29 | □ \$20,000 - \$ | | | Gracia | as por su |
| □ 30-39 | \$35,000 - \$ | • | | - | uda! |
| 40-49 | □ \$50,000 - \$ | - | | ay | uuai |

Online Vision Survey

50-59

60-69

70 años o más

Prefiero no contestar

University of Terreneues at Chartencoge Institutional Review Board Agencyal # 19-128

\$75,000 - \$99,999

Prefiero no contestar

\$100,000 o más

Appendix E: English and Spanish Letter of Consent (COMBINED 1 PAGE)

IRB # 19-128

INFORMED CONSENT A LOOK INTO THE IMPACTS OF TELE-OPTOMETRY EXPANSION

You are being invited to participate in a research study about eye exams done online with a computer. You are being asked to offer your opinions about eye exams. The survey does not include an eye exam. This study is being conducted by Annie Hulsey and her faculty advisor Dr. Deborah Mullen (phone: 423.425.4116; email: <u>deborah-mullen@utc.edu</u>) at the University of Tennessee at Chattanooga.

The survey will take about 5 minutes to complete.

This survey is anonymous. Do not indicate your name or other personal contact information on the survey. No one will be able to identify you or your answers, and no one will know whether or not you participated in the study.

Your participation in this study is voluntary. By filling in the survey, you are voluntarily agreeing to participate and you are acknowledging that you are <u>18 years of age or older</u>. You are free to stop answering questions at any time or to decline to answer any particular question you do not wish to answer for any reason. If you are younger than 18, do not proceed.

Research at the University of Tennessee at Chattanooga involving human participants is carried out under the oversight of the Institutional Review Board. Address questions or problems regarding these activities to Dr. Amy Doolittle, UTC IRB Chair, gmail; amy-doolittle@utc.edu; phone: (423) 425-5563.

CONSENTIMIENTO INFORMADO

UNA MIRADA A LOS IMPACTOS DE LA EXPANSION DE TELEOPTOMETRIA

Usted está siendo invitado a participar en un estudio de investigación sobre exámenes de la vista realizados en línea con una computadora. Se le pide que ofrezca sus opiniones sobre los exámenes de la vista. La encuesta no incluye un examen de la vista. Annie Hulsey y su asesora de facultad, la Dra. Deborah Mullen (teléfono: 423.425.4116; correo electrónico: <u>deborah-mullen@utc.edu</u>) de la Universidad de Tennessee en Chattanooga, están llevando a cabo este estudio.

La encuesta tardará unos 5 minutos en completarse.

Esta encuesta es anónima. No indique su nombre u otra información de contacto personal en la encuesta. Nadie podrá identificarlo a usted ni a sus respuestas, y nadie sabrá si usted participó o no en el estudio.

Tu participación en este estudio es voluntaria. Al completar la encuesta, acepta voluntariamente participar y reconoce que tiene <u>18 años de edad o más</u>. Puede dejar de responder preguntas en cualquier momento o negarse a responder cualquier pregunta en particular que no desee responder por ningún motivo. Si es menor de 18 años, no continúe.

La investigación en la Universidad de Tennessee en Chattanooga con participantes humanos se lleva a cabo bajo la supervisión de la Junta de Revisión Institucional. Dirija las preguntas o problemas relacionados con estas actividades a la Dra. Amy Doolittle/Presidenta de UTC IRB, correo electrónico: amy-doolittle@utc.edu; teléfono: (423) 425-5563.

IRB # 19-128

Appendix F: IRB Approval Letter



Institutional Review Board Dept 4915 615McCallie Avenue Chattanooga, TN 37403 Phone: (423)425-5867 Fax: (423)425-4052 instrb@utc.edu http://www.utc.edu/irb

| TO: | Anna Hulsey Dr. Deborah Mullen | IRB # 19-128 |
|-------|--|--------------|
| FROM: | Lindsay Pardue, Director of Research Integrity Dr. Amy Doolittle, IRB Committee Chair | |
| DATE: | 10/7/2019 | |

SUBJECT: IRB #19-128: A Look into the Impacts of Tele-Optometry Expansion

Thank you for submitting your application for exemption to The University of Tennessee at Chattanooga Institutional Review Board. Your proposal was evaluated in light of the federal regulations that govern the protection of human subjects.

Specifically, 45 CFR 46.104(d) identifies studies that are exempt from IRB oversight. The UTC IRB Chairperson or his/her designee has determined that your proposed project falls within the category described in the following subsection of this policy:

46.104(d)(2)(i): Research only includes educational tests, surveys, interviews, public observation and recorded information cannot readily identify the subject (directly or indirectly/linked)

Even though your project is exempt from further IRB review, the research must be conducted according to the proposal submitted to the UTC IRB. If changes to the approved protocol occur, a revised protocol must be reviewed and approved by the IRB before implementation. For any proposed changes in your research protocol, please submit an Application for Changes, Annual Review, or Project Termination/Completion form to the UTC IRB. Please be aware that changes to the research protocol may prevent the research from qualifying for exempt review and require submission of a new IRB application or other materials to the UTC IRB.

A goal of the IRB is to prevent negative occurrences during any research study. However, despite our best intent, unforeseen circumstances or events may arise during the research. If an unexpected situation or adverse event happens during your investigation, please notify the UTC IRB as soon as possible. Once notified, we will ask for a complete explanation of the event and your response. Other actions also may be required depending on the nature of the event.

The University of Tennesses of Chaltanooga is a comprehensive, community-engaged campus of the University of Tennesses System.

1 of 2

Please refer to the protocol number denoted above in all communication or correspondence related to your application and this approval.

For additional information, please consult our web page http://www.utc.edu/irb or email instrb@utc.edu/irb or email instrb@utc.edu/irb or email

Best wishes for a successful research project.

The University of Tennesses of Chattanoogo is a comprehensive, community-ongogod campus of the University of Tennesses System.

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