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Alabama Screening and Intervention for Glaucoma and Eye Health through Telemedicine (AL-SIGHT): Study Design and Methodology

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Abstract

Purpose—To describe the study rationale and design of the Alabama Screening and Intervention for Glaucoma and eye Health through Telemedicine (AL-SIGHT) project.

Methods—The study will implement and evaluate a telemedicine-based detection strategy for glaucoma, diabetic retinopathy, and other eye diseases in at-risk patients seen at federally qualified health centers located in rural Alabama. The study will compare the effectiveness of the remote use of structural and functional ocular imaging devices to an in-person exam. Study participants will receive a remote ocular assessment consisting of visual acuity, intraocular pressure, visual field testing, and imaging of the retina and optic nerve with spectral domain optical coherence tomography, and the data will be reviewed by an ophthalmologist and optometrist. It will also compare the effectiveness of financial incentives along with a validated patient education program versus a validated patient education program alone in improving follow-up adherence. Finally, cost

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and cost-effectiveness analyses will be performed on the telemedicine program compared to standard in-person care using effectiveness measured in numbers of detected eye disease cases.

Conclusions—The study aims to develop a model eye health system using telemedicine to prevent vision loss and address eye health among underserved and at-risk populations.

Précis:

This paper presents the methods and protocol of a community-based telemedicine program to identify glaucoma and other eye diseases.

Keywords

Glaucoma; Diabetic Retinopathy; Cataract; Health disparities; Telemedicine; Teleophthalmology; Vision impairment; Eye health education; Financial incentives

Introduction

Glaucoma, diabetic retinopathy (DR), and cataracts are eye diseases that have the potential to cause considerable visual disability when not diagnosed early in the disease course. Glaucoma is one of the most common eye diseases of aging and the leading cause of irreversible vision loss and blindness in older African Americans. Ocular complications from diabetes are the leading cause of new cases of blindness in adults age 20–74 years in the US,[1–3] and African Americans are twice as likely to have DR as whites.[4,5] Cataracts are another major cause of preventable visual impairment and blindness, especially in African Americans, with over 24 million people in the US having cataracts.[4,6] Finally, as the aging population increases, there is an expected increase in the prevalence of all of these eye diseases and the potential for visual impairment and blindness.[7,8]

Inadequate access to and utilization of eye care delays diagnosis and increases visual disability.[4,9] Factors underlying lower utilization of eye care include inadequate knowledge of risk factors, early symptoms, and available treatments; reduced financial resources; and limited transportation.[10–12] Alabama has one of the highest prevalence rates of diabetes in the nation (~12%), and African Americans there have a diabetes mortality rate 1.6 times greater than whites.[5] In Alabama, ophthalmologists rarely practice in rural areas, where African Americans represent the majority of the population.[13] The relative lack of specialists in communities with high concentrations of African Americans, combined with the high glaucoma and diabetes prevalence, offers an opportunity to create an innovative, proactive, and community-based approach to increase access to and utilization of eye care.

Telemedicine is a potential strategy to improve eye disease detection and management. By using current technologies, telemedicine transmits patient data from a primary care clinic to another remote site for review by specialist physicians and thus, the standards of specialty care are more accessible to patients who live where no specialists practice. There has been a dramatic increase in the use of telemedicine across numerous areas of medicine due to the COVID-19 pandemic.[14] Telemedicine is well suited for the detection and management of certain eye conditions since there have been great strides made in the development of non-

invasive ocular imaging devices that provide high levels of diagnostic reliability, ease of training of testing personnel, and electronically transmissible results.[15]

In the past 20 years, there has been a growing interest in using telemedicine in the detection and management of glaucoma.[16–26] Previous attempts at using telemedicine in glaucoma care primarily used transmission of optic disc photos at times combined with visual field testing. However, several problems arise such as issues with the quality of transmitted stereoscopic images as well as the highly variable nature of the reviewer's subjective evaluation of photos.[17,20,27–30] Portable cameras and smartphone-based fundus imaging can potentially make optic nerve photography simpler and less expensive in glaucoma telemedicine programs.[31] Detection of glaucoma has greatly improved with non-invasive spectral domain optical coherence tomography (SDOCT). The increased accuracy of this instrument for detecting glaucoma results from a sensitivity and specificity appropriate for glaucoma detection in high-risk populations such as African Americans over age 40.[32,33] Unfortunately, few telemedicine programs have utilized SDOCT in their protocols in order to define its additive utility and cost-effectiveness.[22]

Ensuring appropriate follow-up for patients diagnosed with an eye disease through telemedicine is a challenge, particularly in rural, underserved populations. Financial incentives are a possible way to increase adherence levels. A study by Tan et al. found improved adherence to tertiary eye care services after community-based screenings in low socio-economic areas by providing a one-time transportation allowance to the eye care appointment and a subsidy for the first tertiary eye care consultation.[34]

Our goal is to improve the accessibility of glaucoma and other eye disease detection and management among a vulnerable and at-risk population using a telemedicine model. We would also like to evaluate methods to improve patient adherence to follow-up appointments such as an evidence-based glaucoma education program to improve knowledge, attitudes, and beliefs about glaucoma and the importance of routine eye care as well as the use of financial incentives. We designed and implemented a glaucoma detection and management program entitled Alabama Screening and Intervention for Glaucoma and eye Health through Telemedicine (AL-SIGHT). It uses advanced eye imaging technology to remotely assist in the detection of glaucoma, DR, cataract, and refractive error in an underserved, predominantly African American community receiving primary care through federally qualified health centers (FQHC's) in rural counties of Alabama.

Methods

Study Setting

The study is performed in FQHC's, which are community-based health care centers that receive federal funding from the Health Resources and Services Administration Health Center Program for the provision of primary care services in underserved locations.[35] FQHC's are located in urban and rural areas and operate on a sliding fee scale based on the ability of the patient to pay for services. The study sites are three FQHC's that are part of the Cahaba Medical Care Foundation, an Alabama-based FQHC. With a total of nine FQHC clinics located in both urban and rural counties of Alabama, Cahaba's rural clinics serve an

area with the highest poverty rate in the US. Cahaba has over 16,000 active patients per year seen in its clinics, including 58% African American, 38% white, and <3% Hispanic patients. Cahaba serves a large proportion of Medicaid (25% of patients) and uninsured (20%) populations as well as Medicare patients (30%) and private insurance (25%). The clinic locations for the study are Centreville (Bibb County, AL), Maplesville (Chilton County, AL), and Marion (Perry County, AL) (Figure 1). We have selected a geographic region with a population of socioeconomically disadvantaged individuals having significant barriers to receiving high-level eye evaluations who are also at the greatest risk from glaucoma and DR as detailed above. The Institutional Review Board of the University of Alabama at Birmingham (UAB) reviewed and approved the study's protocol.

Eligibility and Recruitment

Patients attending the selected FQHC study sites are eligible to participate in the study if they have one or more of these risk factors: (1) African American or Hispanic ≥40 years; (2) white ≥50 years; (3) anyone ≥ 18 years with diabetes, (4) anyone ≥ 18 years with a glaucoma associated diagnosis (GAD) (glaucoma suspect [GS], ocular hypertension [OHT], and primary open-angle glaucoma [POAG]); (5) anyone ≥ 18 years with a family history of glaucoma. All participants must be able to speak and understand English. The enrollment period is from November 2020 through September 2023 with a goal of recruiting 1500 participants (Figure 2).

Study participants are recruited through several methods. The electronic medical record of Cahaba is searched monthly by Cahaba staff using the study eligibility criteria and potential participants are mailed recruitment letters. Also, the primary care providers and clinic staff at the FQHC sites refer patients meeting the eligibility criteria directly to the research coordinator. All participants receive compensation for study enrollment in the form of a UAB ClinCard, a secure, pre-loaded participant payment card used as a debit or credit card.

COVID-19 Safety Precautions

In order to protect participants and research staff from COVID-19 infection, guidelines issued by UAB, in accordance with recommendations from the Centers for Disease Control and Prevention (CDC), are followed. All participants are called the day before the scheduled study day and asked if they have a positive COVID-19 diagnosis or if they have COVID-19 symptoms. In the event of a positive response to the screening call, the participant will be re-scheduled for the research visit and will be instructed to contact his/her primary care physician at the FQHC. Upon arrival at the FQHC study site, the participant's temperature is checked by FQHC staff, the presence of the above COVID-19 symptoms are asked again, and if the screening is negative, a mask is given to the participant and the visit proceeds. The research coordinator wears a mask throughout the study visit, maintains 6 feet of distance when not performing necessary ocular testing, thoroughly cleans each ocular instrument before and after use, and practices hand hygiene with hand sanitizer. The costs of the personal protection equipment will be calculated due to their increased use during the COVID-19 pandemic.

Protocol

Once written informed consent is obtained, the study protocol is completed in one session. The research coordinator administers a series of surveys to collect demographic data such age, race, gender, marital status, education level, employment status, insurance status, and contact information. Three questions are asked about cost being a potential barrier to eye care (Table 1). Seven questions are asked in an effort to understand the participant's knowledge, attitudes, and beliefs about eye health (Table 1). The coordinator also collects family history of glaucoma or blindness, medical history including smoking history, and ocular history. Family history of glaucoma will be considered positive if the participant reports a first-degree relative (parent, sibling, or child) diagnosed with glaucoma. The ocular history includes questions about previous eye exams and the reason for not having had an eye exam if the last exam was greater than 2 years ago or never. Next, the Abbreviated National Eye Institute Visual Function Questionnaire (NEI VFQ 9) is administered (Table 2).[36] Questions regarding the participant's education level, employment, and reason for not having had an eye exam in the past 2 years represent social determinants of health.[37] The eye health education program is then administered to the participant by the research coordinator (see below for more details).

A telemedicine remote ocular assessment (ROA) protocol is implemented as follows. Presenting distance visual acuity is measured, with correction if present, followed by refractive error measurement with an autorefractor. Intraocular pressure (IOP) is measured with a portable rebound tonometer (Icare USA, North Carolina, USA). If the IOP is >21 mmHg, a second measurement is taken. If the IOP differs by more than 2 mmHg, a third measurement is taken. If the IOP was measured more than once, then the median IOP is recorded. If the IOP is measured > 30 mmHg, participants are given a referral with a provider, as outlined below, within two weeks. If the IOP is > 35 mmHg, a referral is made for within 1 week. If the IOP is > 40 mm Hg, the participant is given an urgent referral within one day.

Structural and functional assessment of the optic nerve and fundus occurs through undilated pupils. Using a combined SDOCT and fundus camera device (Maestro2, Topcon Medical Systems, New Jersey, USA), the retinal nerve fiber layer thickness of the optic nerve head and the macular thickness is measured. The fundus, capturing both the optic nerve and macula together, is photographed with two different imaging modalities in order to allow for comparison between the two techniques: a traditional fundus photo from the Maestro2 device; and a 5 second video from a smartphone with an adapter to image the fundus (D-EYE, Padova, Italy). Functional assessment of the optic nerve is achieved through perimetry testing using three different types of testing: a traditional Humphrey Field Analyzer screening strategy SITA-FAST (Carl Zeiss Meditec, California, USA) and a tablet-based perimetry application (Melbourne Rapid Fields application, M&S Technologies, Illinois, USA[38]).

At the completion of the ocular testing, a satisfaction survey is administered to the participant (Table 3).

ROA Interpretation

The ROA data is shared electronically with the investigators at the Department of Ophthalmology and Visual Sciences at the UAB Callahan Eye Hospital and Clinics in Birmingham, AL for reading, interpretation, and report generation. At UAB, the ROA data is interpreted by a comprehensive ophthalmologist with subspecialty training in glaucoma as well as by an optometrist who both make independent ocular diagnoses using their clinical judgement in addition to the glaucoma case definitions in Table 4. Additionally, factors such as whether the participant has been previously treated for glaucoma (e.g. already taking glaucoma medications or previous glaucoma surgery) based on history or has a family history of glaucoma will inform the diagnosis. The ROA data is evaluated for the presence of DR in participants with a diagnosis of type 1 or type 2 diabetes based on the National Health Service Grading Classification System (Table 5).[39]

In cases of poor data quality, such as uninterpretable photos or low reliability indices on perimetry or SDOCT, that are inadequate to determine a definitive diagnosis, the participant is contacted for repeat evaluation and diagnostic testing at the FQHC by the research coordinator at a future date. The UAB ophthalmologist's interpretation of the ROA data is then used to create reports for the participant and FQHC primary care provider, as well as to determine appropriate follow-up care. The report is generated and electronically returned to the primary care provider at the FQHC within 14 days of the participant's research visit and includes the visual acuity, IOP, and ocular diagnoses possibly identified such as glaucoma, DR, cataract, refractive error, and other, for each eye. The recommended treatment course and frequency of follow-up is included in the report to facilitate a team approach to patient care. The report is also mailed to the participant and if referral for an in-person eye exam is needed, the participant is contacted by the research coordinator to schedule this appointment as described next.

Participant Referral

For the evaluation of the structural and functional optic nerve testing, the UAB ophthalmologist defines the participant as normal, glaucoma suspect, ocular hypertensive, glaucoma, or other. Those participants judged to be normal are recommended to return in a year for a repeat ROA. In participants who have glaucoma suspect status, ocular hypertension, or glaucoma, considered GAD, the recommendation is a referral for in-person exam with either a community-based optometrist who is partnered with the FQHC in Centreville, AL or with an ophthalmologist at the Glaucoma Service at UAB or the Lions Eye Clinic at UAB in Birmingham, AL. UAB is between 50–80 miles from the individual FQHC locations. The choice of referral to the local optometrist or UAB ophthalmologist is made by the participant. If the participant chooses a referral with a UAB ophthalmologist and it is determined after the in-person exam that laser or surgical treatments are not needed to control the disease, then the participant may be referred to the community-based optometrist if the participant wishes. An individualized care plan is communicated to the community-based optometrist by the ophthalmologist, which includes recommendations for treatment, the target IOP, the visit frequency, and interval testing frequency.

In participants with diabetes, after the images are graded based on Table 5, those participants judged to have normal findings (a diabetic retinopathy grade of R0) are recommended to return in a year for a repeat ROA. For participants positive for DR (diabetic retinopathy grades of R1-R3, M, or P), the recommendation is a referral for in-person exam following the same protocol as above for the GAD referral.

As the ROA data is reviewed, the presence of other eye diseases is also notated such as cataract, other optic nerve pathology, or other retinal pathology. Depending on the severity of the other eye diseases identified, the participant is contacted for a referral appointment to either the community-based optometrist or UAB. Participants found to have significant refractive error from the autorefraction performed by the coordinator are referred to the community optometrist's office for manifest refraction and glasses prescription.

Regardless of participant insurance status, all referral care is supervised by attending ophthalmologists of UAB. No participant needing referral care in Birmingham at UAB is refused care on the basis of being uninsured. Those with health insurance receive care through UAB; those without health insurance receive care by the same UAB ophthalmologists at the UAB Lions Eye Clinic, which receives financial support from the Alabama Lions Clubs and the EyeSight Foundation of Alabama to deliver care to the uninsured. Attending ophthalmologists at UAB, including glaucoma and retina specialists, supervise the Lions Eye Clinic, providing equal quality of care to all patients. Alternatively, if the participants prefer not to travel to UAB, a referral is made to the community-based optometrist that is partnered with the FQHC. The participant is seen on the same sliding fee schedule at the optometrist's office as at the FQHC.

Outcomes and Analysis: ROA

The effectiveness of ROA to detect GAD in participants seen in rural FQHC's compared to a standard in-person exam will be evaluated by having a subset of the enrolled participants return for an in-person exam by the same ophthalmologists reviewing the ROA data. Thus, once per quarter per year during enrollment, an ophthalmologist from the UAB Glaucoma Service that has been participating in reviewing the ROA data will travel to the community optometrist's clinic that has partnered with the FQHC. At the clinic, the ophthalmologist will perform a comprehensive dilated eye exam on a subset of participants who have already been enrolled and imaged by the telemedicine program within the past 3 months. These participants will be selected to represent a range of diagnoses from normal to glaucoma and normal to DR and will be called by the research coordinator to ask for their participation with the in-person exam. The ophthalmologist will be blinded to the participant's previous ROA diagnosis but will be permitted to view the structural and functional testing that was previously obtained. This in-person exam by an ophthalmologist will provide gold standard optic nerve and retinal diagnoses against which the previous ROA diagnosis can be compared. Our aim will be to examine in-person 100 of the target 1500 participants in the first year of the study. Participants will receive an additional compensation for participating in the in-person exam, separate from the previous payment described above.

The kappa statistic will be used to compare the agreement between the specialist's in-person gold standard diagnosis, the ROA-based diagnoses by both the ophthalmologist and

optometrist, and the automated SDOCT diagnosis of each eye of each patient who received an in-person exam by the ophthalmologist. Additionally, the optometrist's ROA diagnosis will also be compared against the ophthalmologist ROA diagnosis in order to assess for agreement using the kappa statistic. Using the in-person gold standard diagnosis as the reference standard, the sensitivity and specificity of the ability of ROA to detect GAD and DR will be calculated. Finally, the kappa statistic will also be used to evaluate the intraobserver agreement of the reviewers of the ROA data comparing the initial ROA-based diagnosis with the diagnosis made after review of the same data 12 months later.

The evaluation of the performance of the individual structural and functional imaging devices in remote eye disease detection will be assessed using statistical analyses that compare the effectiveness of the devices' diagnoses against a standard diagnosis. The diagnosis of a normal or GAD diagnosis that will be the standard against which each functional device will be compared will be based on a structural assessment of ROA optic disc photographs by two graders using the criteria in Table 4. If these graders disagree, a third grader will serve as an adjudicator. Such approach has been used by others when investigating and comparing the diagnostic accuracies of multiple visual function tests for glaucoma. One group reported receiver operating characteristic (ROC) curve areas ranging from 0.60 to 0.80 for different perimetry parameters when detecting glaucoma based on assessment of optic disc photographs.[40] The analysis of the diagnostic accuracy of the functional testing by traditional and tablet-based perimetry will be determined by comparing each device against each other using ROC curves. The area under the ROC curve will be used to summarize the diagnostic accuracy of each parameter. The analysis of the visual function devices will include the continuous variable of mean deviation for traditional and tablet-based perimetry.

In order to compare the structural devices of a traditional fundus camera and smartphone-based camera against each other in diagnosing glaucoma, the photos from each device for each patient will be graded as normal, glaucoma suspect, glaucomatous optic neuropathy, or other by two graders. The agreement between the devices will be compared using a kappa statistic similar to Bastawrous et al.[41] The percentage of unreadable photographs for each device will also be determined.

Intervention: Eye Health Education and Financial Incentives

The eye health education consists of specially structured and targeted educational messages about glaucoma and eye care conveyed to at-risk patients. The educational strategy is evidence-based both in terms of format and targeted messages and has been previously shown to successfully improve knowledge, attitudes, and beliefs in patients.[42] All research staff are trained using web-based instruction in culturally aware and educationally appropriate approaches to counsel patients on the importance of maintaining follow-up eye care for glaucoma and other eye diseases including strategies for minimizing barriers to care.[43,44] The educational materials for participants are based on our previous work and have several formats[11,45–47]: (1) based on what they learn in the online training above, research staff engage in key eye disease prevention dialogues and conversations with participants; (2) the research coordinator shows engaging and brief (< 1 minute) videos to patients on an iPad

on glaucoma and diabetic eye problems and the importance of routine eye care to prevent vision loss; (3) there are culturally and educationally appropriate brochures in the waiting rooms of the Cahaba study sites which are also provided to each participant at the end of the visit with the research coordinator; (4) posters on glaucoma and diabetic eye problem prevention are also situated throughout the Cahaba study sites.

For the first 750 participants enrolled in the study there is no financial incentive offered for completing the scheduled referral visit if one is recommended upon review of the ROA data. For the next 750 participants enrolled in the study, all participants needing referral will be notified that they will receive a payment upon the completion of their referral visit with the local optometrist or ophthalmologist at UAB. If a participant in this second group requires multiple visits with the optometrist or UAB ophthalmologist, the participant will receive a payment for each completed visit.

Outcomes and Analysis: Eye Health Education and Financial Incentives

We will evaluate strategies to overcome the barriers to patient adherence with referral and follow-up appointments by comparing the effectiveness of financial incentives along with a validated patient education program versus a validated patient education program alone in the following ways.

1. Knowledge, attitudes, and beliefs about glaucoma, the importance of routine eye care, and eye health: participants answer 7 questions addressing these items in regard to glaucoma, its management, and the importance of routine care (Table 1) prior to exposure to the education video and discussion with research staff. Then at one-month, six-months, and 12-months after the enrollment visit, we will repeat the questionnaire by telephone, in order to assess changes in knowledge, attitudes, and beliefs following the visit. McNemar's test will be used to assess differences in knowledge, attitudes, and beliefs between the baseline and follow-up patient responses. Multivariate logistic regression models will be used to assess the independent association of patient characteristics (age, sex, race, prior glaucoma diagnosis, employment status, education level, comorbidities, visual acuity, and visual field mean deviation) with improvement in knowledge, attitudes, and beliefs.

2. Participant adherence to recommended referral and follow-up appointments after their enrollment visit: This information will be obtained from the medical record of the provider the participant was scheduled to see. Once the participant's scheduled referral visit date is passed, the research coordinator contacts the office of the scheduled visit to log if the visit occurred or was re-scheduled. Appointments that are cancelled or "no-shows" are also noted. Data from the referral visit such as exam findings, assessment and plan are collected. By comparing the number of participants who adhere to their referral and follow-up appointments in the group with the patient education program alone to the group with the education plus financial incentives, it can be determined if financial incentives are more successful at maximizing patient adherence to referral and follow-up appointments than an education program alone. Descriptive statistics

will be used to compare patient level characteristics between these two groups. Models will include temporal effects for patients seen more than once during the follow-up period.

Cost and Cost-effectiveness Analyses

From a healthcare payer perspective, we will conduct the cost analysis (including ROA costs, financial incentives and eye health education intervention costs) using the micro-costing approach.[48] The cost per case of detected GAD will require summing all associated program costs and dividing by the number of GAD cases. Cost per case of other conditions (refractive error, cataract, DR, and other eye disease) will be summarized similarly. The cost per case detected will also include the proportion of participants who adhered to recommended referral appointments. Program costs will include variable and fixed costs such as personnel time, equipment, medical and study supplies, participant incentives, and staff travel to study sites which will be captured from the start of the study. Staff time costs will be calculated using actual wage rates plus fringe benefits costs. All surveys administered have a start and end time recorded for analyses on the time costs of the study. We will log the total amount of time the research coordinator spends performing the ocular testing with each participant. The costs of ocular testing and other applicable procedures will be derived based on Medicare reimbursement rates current procedural terminology codes.[49] Sensitivity analyses will be conducted to examine changes in costs against uncertainties. Examples of uncertainties include variation in personnel costs, medical procedure costs, and COVID-related costs (e.g., enhanced safety measures like personal protective equipment[50] and an additional phone call for COVID screening). We will calculate the total cost of the financial incentives distributed during the intervention as well as the costs of the eye health education materials. The results will be adjusted to 2024 United States Dollars using the consumer price index for medical care.[51]

A cost-effectiveness analysis will be performed on the telemedicine program compared to standard in-person care by a glaucoma specialist at the conclusion of participant enrollment. A standardized method from the healthcare payer perspective will calculate an incremental cost-effectiveness ratio comparing the cost per additional case detected between the two models of care. In this analysis, the telemedicine program with and without financial incentives will be deemed two interventions. Thus, we will report the incremental cost-effectiveness ratios comparing each of the telemedicine interventions compared to standard in-person care, and the incremental cost-effectiveness ratio comparing the two telemedicine interventions. Our effectiveness measure will be the number of detected cases of GAD, refractive error, cataract, and DR as well as the proportion of participants that adhere to recommended referral appointments. The cost measure will be derived from the above-mentioned cost analysis.

Discussion

With an expected boom in the number of patients with glaucoma, DR, and other eye diseases and the relatively limited number of ophthalmologists in rural Alabama, it is vital to evaluate alternative models of care, such as telemedicine, that are effective and low cost. Testing the

hypotheses of the AL-SIGHT project will inform the development of a telemedicine system that can be deployed within a widespread, existing clinical infrastructure that has access to underserved populations and can be generalized to other primary care clinics. We expect that our study results will be able to inform: (1) whether a telemedicine system in rural FQHC's performed on at-risk patients will detect glaucoma at an equivalent rate as traditional in-person examination by a glaucoma specialist; (2) whether an eye health education program improves adherence to follow-up appointments with or without the addition of financial incentives; (3) whether education improves knowledge, attitudes, and beliefs about glaucoma, its management, and the importance of routine comprehensive eye care. The existence of thousands of FQHC's in the United States can facilitate the scalability of a telemedicine program nationally, should its effectiveness, patient acceptance, and cost-effectiveness be demonstrated with the ultimate goal of preventing visual impairment and blindness in at-risk individuals.

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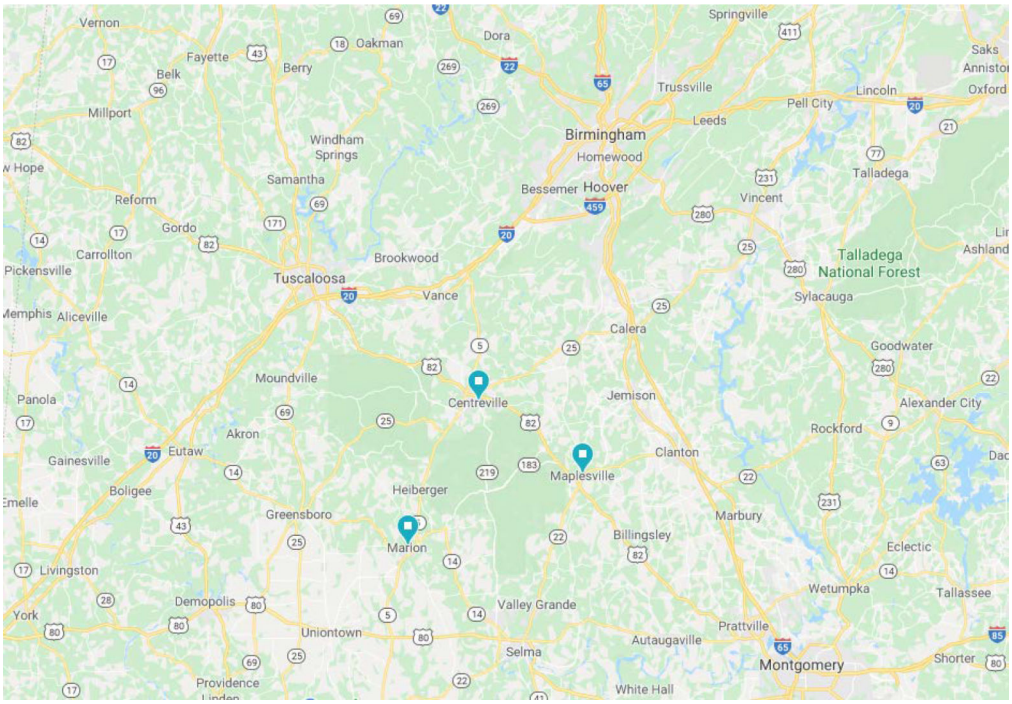

Figure 1.
Map of Study Sites in Alabama

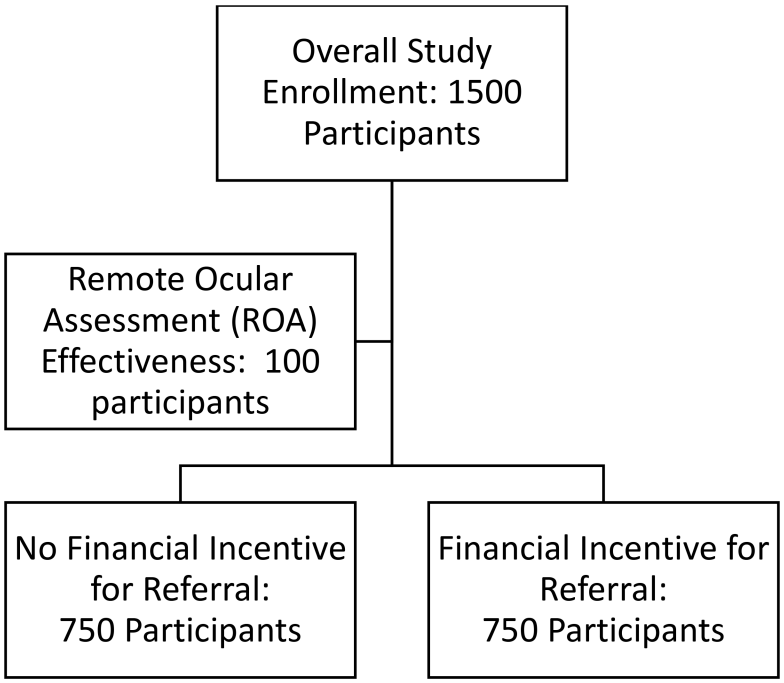

Figure 2.
Goals for Study Enrollment Flowchart

Table 1.

Questions of Cost barriers, Knowledge, Attitudes, and Beliefs about Eye Care

Domain	Item Synopsis
Cost	Is the cost of an eye exam a problem for you?
	Is the cost of buying eyeglasses a problem for you?
	If the doctor prescribed eye drops for you in order to treat an eye problem you have, would the cost of prescription eye drops be a problem for you? (Problem Scale)[1]
Knowledge about glaucoma	A person can have glaucoma and not know it.
	Glaucoma can be controlled.
	Vision lost from glaucoma can be restored.
	A complete glaucoma exam consists only of measuring eye pressure.
	People at risk for glaucoma should have an eye examination through dilated pupils. (True/false)
Attitudes and beliefs about eye care	It is important to go to the eye doctor at least once every two years.
	There is no need to go to the eye doctor if you're not having a problem with your eyes. (Agree/disagree scale)[2]

[1] Problem scale response options: Not a problem at all, A little bit of a problem, Somewhat of a problem, A big problem.

[2] Agree/disagree scale response options: Strongly agree, Somewhat agree, Somewhat disagree, Strongly disagree

Table 2.

National Eye Institute Visual Function Questionnaire 9 (NEI VFQ 9)

Domain	Item Synopsis
1. General vision	At the present time, would you say your eyesight using both eyes (with glasses or contact lenses, if you wear them) is: (Quality scale)[1]
2. Well-being/Mental health	How much of the time do you worry about your eyesight? (Time scale)[2]
3. Near vision, Reading normal newsprint	How much difficulty do you have reading ordinary print in newspapers? (Difficulty scale)[3]
4. Near vision, Seeing well up close	How much difficulty do you have doing work or hobbies that require you to see well up close, such as cooking, sewing, fixing things around the house, or using hand tools? (Difficulty scale)[3]
5. Distance vision, Going downstairs at night	Because of your eyesight, how much difficulty do you have going down steps, stairs, or curbs in dim light or at night? (Difficulty scale)[3]
6a. Do you currently drive	Yes/No
6b. If you are driving	How much difficulty do you have driving during the daytime in familiar places? (Difficulty scale)[3]
7. Role limitation	Are you limited in how long you can walk or perform other activities such as housework, child care, school, or community activities because of your vision? (Time scale)[2]
8. Peripheral vision	Because of your eyesight, how much difficulty do you have noticing objects off to the side while you are walking along? (Difficulty scale)[3]
9. Near vision, Finding objects on a crowded shelf	Because of your eyesight, how much difficulty do you have finding something on a crowded shelf? (Difficulty scale)[3]

[1]Quality scale response options: Excellent, Good, Fair, Poor, Very poor, Completely blind

[2]Time scale response options: None of the time, A little of the time, Some of the time, Most of the time, All of the time

[3]Difficulty scale response options: No difficulty at all, A little difficulty, Moderate difficulty, Extreme difficulty, Stopped doing this because of your eyesight, Stopped doing this for other reasons or not interested in doing this

Table 3.

Satisfaction Survey

Question	Response Options
How satisfied are you with your vision screening?	Very Satisfied, Satisfied, Dissatisfied, Very Dissatisfied
How satisfied are you with the time it took to complete your vision screening?	Very Satisfied, Satisfied, Dissatisfied, Very Dissatisfied
How convenient was it to have your vision screening where you see your primary doctor?	Very Convenient, Convenient, Inconvenient, Very Inconvenient
How likely are you to recommend this vision screening to family, friends, and neighbors?	Very likely, Somewhat likely, Not very likely, Not at all likely
How likely are you to return in 12 months for a follow-up vision screening at this same location?	Very likely, Somewhat likely, Not very likely, Not at all likely
If you are referred to an eye doctor for follow-up of a problem found today, how likely are you to attend this follow-up eye exam appointment?	Very likely, Somewhat likely, Not very likely, Not at all likely
Please make any suggestions on how we can improve this visit in the future.	Open-ended question

Table 4.

Glaucoma Case Definitions

Diagnosis	Definition
Glaucomatous appearing optic disc	Glaucomatous optic disc damage is defined as evidence of excavation, neuro retinal rim thinning or notching, localized or diffuse RNFL defect, disc hemorrhage, or a between eye asymmetry of the vertical CDR > 0.2 where the larger CDR is ≥0.6.
Glaucomatous visual field defect	A reliable SAP Humphrey 24–2 field (defined as < 33% false positives, false negatives, and fixation losses) that exhibits a pattern standard deviation outside the 95% normal limits or a glaucoma hemifield test outside of the 99% normal limits consistent with an RNFL defect pattern based on clinical review.
Glaucomatous SDOCT	Overall RNFL thickness <80 microns or thinning at <1% certainty in the inferior or superior quadrants
Normal	No glaucomatous appearing disc changes, normal visual field, normal SDOCT, statistically normal IOP (<22 mmHg).
Ocular hypertension	No glaucomatous appearing disc changes, normal visual field, normal SDOCT, statistically elevated IOP (≥22 mmHg).
Glaucoma suspect	The presence of glaucomatous appearing disc changes, normal visual field, with or without abnormal SDOCT.
Glaucoma	The presence of glaucomatous appearing disc changes, an abnormal visual field, and an abnormal SDOCT.

Abbreviations: RNFL, retinal nerve fiber layer; CDR, cup to disc ratio; SAP, standard automated perimetry; SDOCT, spectral domain optical coherence tomography; mmHg, millimeters of Mercury

Table 5.

Diabetic Retinopathy Grading and Classification

Grade	Description
R0	NO DIABETIC RETINOPATHY (DR)
	None
	Isolated cotton wool spots (1 or more) in the absence of any microaneurysm or hemorrhage
R1	BACKGROUND DR
	1 or more microaneurysm(s)
	1 or more retinal hemorrhage(s)
	Any exudates caused by DR
R2	PRE-PROLIFERATIVE DR
	Intraretinal microvascular abnormality (IRMA)
	Venous beading
	Venous loop or reduplication
	Multiple deep, round or blot hemorrhages
R3	PROLIFERATIVE DR
	New vessels on the disc (NVD)
	New vessels elsewhere (NVE)
	Pre-retinal or vitreous hemorrhage
	Pre-retinal fibrosis with or without tractional retinal detachment due to DR
M	MACULOPATHY
	Exudate within 1 disc diameter of the center of the fovea
	Circinate or group of exudates within the macula
	Any microaneurysm or hemorrhage within 1 disc diameter of the center of the fovea only if associated with a best visual acuity of 20/40 or worse
P	PHOTOCOAGULATION
	Focal/grid to macula
	Peripheral scatter
U	UNCLASSIFIABLE/UNGRADABLE
	Due to poor photographic location, focus, or contrast