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2021 Fellowship Project Report
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Diabetic retinopathy screening in Ecuador: A qualitative study and pilot screening program

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1. How I chose my project?

I chose this project because diabetic retinopathy is a leading visual disease, particularly in working age adults. At Fundación Oftalmológica del Valle, we have seen a growing number of patients with diabetic retinopathy, which could have been prevented through early detection and better control of diabetes. As the prevalence of diabetes and life expectancy in Ecuador grow, this is a disease that will affect more people in the future. Therefore, through my job at the foundation, I would like to take action to prevent the growth of this disease, helping people – especially those most in need – strengthen their eye health and live fulfilling and productive lives.

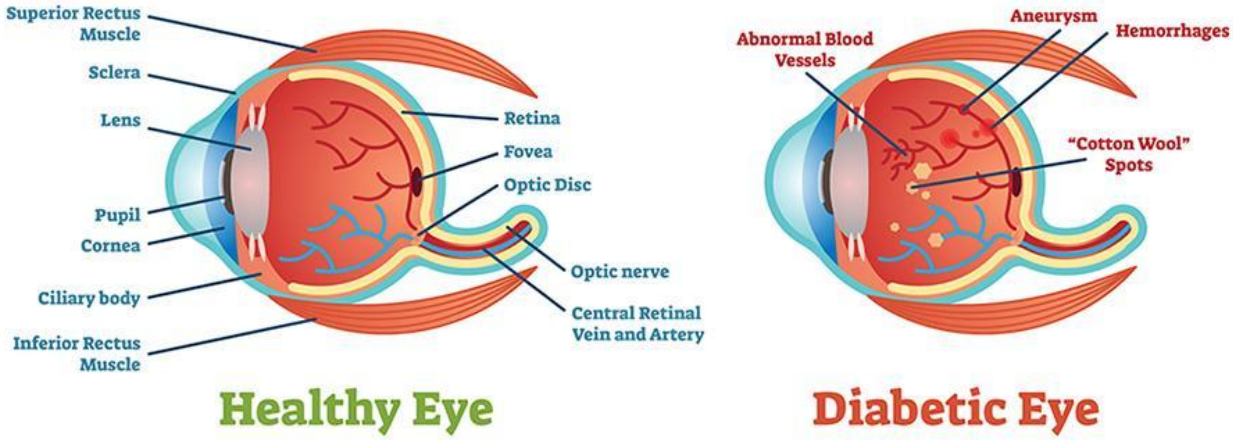
The purpose of this project is to come up with an efficient, cost-effective, and replicable diabetic retinopathy screening program to deploy in Ecuador first. The project will be composed of two parts: the first is a qualitative study where interviews with diabetics, diabetic retinopathy patients, and healthcare professionals are conducted in order to identify prospective barriers to a successful screening program. I chose to include a qualitative study as a part of my project after reaching out to Prof. David Yorston, an ophthalmology consultant at NHS Scotland. Prof. Yorston pointed out the benefits of conducting a qualitative analysis prior to starting a screening program, and provided a paper he co-authored in 2007 with members of the London School Hygiene and Tropical Medicine as a guide.

The second part of this project will be the implementation of a pilot diabetic retinopathy screening program, based out of Fundación Oftalmológica del Valle in Yaruquí, Ecuador. Fundación Oftalmológica del Valle is a non-profit organization founded 26 years ago. Its mission is providing access to high quality eye health treatment with efficiency and a strong work ethic, regardless of economic, social, or religious background. The foundation focuses primarily on prevention of blindness, working along rural communities to conduct screening programs as well as medical brigades. Its main clinic is located in Yaruquí, 20 miles west from Quito, and a satellite clinic is located in the coastal city of Esmeraldas. Since November 2020, I work at this foundation as an operations coordinator.

2. Development Process

2.1 Background

Diabetic retinopathy is a leading cause of vision impairment and blindness in working age adults. It is an eye condition where the back of the eye (retina) is affected due to diabetes. Blood vessels in the retina become blocked or leaky, while abnormal blood vessels can also grow. These cause scarring of the retina and permanent vision impairment or blindness.



American Optometric Association

Most damage caused by diabetic retinopathy is irreversible. It is estimated that around one third of patients with diabetes will develop diabetic retinopathy.[1] The number of people with diabetes is predicted to increase over 50% by 2040, meaning 642 million diabetics. Currently, the NIH estimates that 366 million people worldwide have diabetes.[2] The number of people with diabetic retinopathy is expected to grow from 126.6 million in 2010 to 191 million by 2030, and sight-threatening diabetic retinopathy is expected to increase from 37 million to 56 million if no action is taken.

In Ecuador, 1 in every 10 people over the age of 50 has diabetes. Around 37 thousand new cases of diabetes are registered every year, which has led diabetes to be the second leading cause of death after heart diseases.[3] 98% of new cases are type 2 diabetes, which is due to poor health factors, unbalanced diets, lack of exercise, and genetics. With a growing aging population, rural-to-urban migration, and growing rates of obesity, type 2 diabetes is becoming more common in Ecuador. Moreover, growing numbers of younger diabetics and longer life spans present a big threat, since the duration of diabetes is one of the strongest predictors for development and progression of diabetic retinopathy.[4] The prevalence of any type of diabetic retinopathy among younger diabetic patients is estimated to be 8% at 3 years, 25% at 5 years, 60% at 10 years, and 80% at 15 years. Also, due to underdeveloped public healthcare programs and a lack of information, patients at Fundación Oftalmológica del Valle oftentimes find out they

[1] *WHO Guide to Diabetic Retinopathy Screening*, 2020: https://apps.who.int/iris/bitstream/handle/10665/336660/9789289055321-eng.pdf
[2] Zheng, Y., He, M., & Congdon, N. (2012). The worldwide epidemic of diabetic retinopathy. *Indian journal of ophthalmology*, *60*(5), 428–431. https://doi.org/10.4103/0301-4738.100542
[3] Ecuador's National Institute of Statistics (INEC), 2019
[4] American Diabetic Association (ADA)

could have diabetes after their eye screening, or they seek treatment only after suffering vision loss.

However, it has been demonstrated through studies and clinical trials that diabetic retinopathy can be prevented effectively through tight control of blood glucose and early treatment once detected.

Treatment for diabetic retinopathy depends on the severity of the disease, but will in general involve one of the following options: Mild cases may be treated through careful management of diabetes. More advanced cases will usually require laser treatment to seal off bleeding vessels or remove tissue and control bleeding. Vitrectomy is another surgical procedure, where blood and scar tissue are removed through a small incision in the eye. Finally, vascular endothelial growth factor (VEGF) inhibitors may be injected into the eye to help stop the growth of new blood vessels. Anti-VEGF therapy usually requires more than one injection but the procedure is quick and straightforward.[5]

2.2 Research

A review of existing studies on diabetic retinopathy and screening programs provided useful information to consider for the purpose of this project.

First, the paper on which the first part of this study will be based is a qualitative review of the factors bringing diabetic patients to ophthalmic clinics.[6] This study, done in a rural district general hospital and an urban tertiary teaching hospital in the UK, conducted surveys of both patients and eye care providers. Results from the qualitative surveys showed that lack of awareness was seen as the greatest barrier for both patients and providers. Patients were generally aware that diabetes could affect vision, but not that it could lead to blindness. Endocrinologists and other care providers (not eye-specific) said they mention visual impairment as a possible effect of unregulated diabetes, but they were reluctant to mention blindness. Also, patients were unaware that severe retinopathy could be asymptomatic, but reported fundus images used for diagnostic as valuable educational resources. Finally, patients reported a desire to be "normal," and attending check-ups at a clinic made them feel either sick (despite primary care's strong focus on prevention), or guilty about failing to control their diabetes sufficiently to prevent diabetic retinopathy.

The following studies reviewed focused mainly on the set up of diabetic retinopathy screening programs or the application of new technologies for screening.

For example, a 2020 screening program conducted in India using smartphone-based fundus imaging found that smartphone-based indirect ophthalmoscopy yielded the best image quality,

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[5] "Diabetic Retinopathy", Mayo Clinic: https://www.mayoclinic.org/diseases-conditions/diabetic-retinopathy/diagnosis-treatment/drc-20371617

[6] Lewis K, Patel D, Yorston D, Charteris D. A qualitative study in the United Kingdom of factors influencing attendance by patients with diabetes at ophthalmic outpatient clinics. Ophthalmic Epidemiol. 2007 Nov-Dec;14(6):375-80. doi: 10.1080/09286580701375195. PMID: 18161611.

the largest field of view, but also the longest examination time when compared with three other methods using smartphone-based imaging.[7] Indirect ophthalmoscopy is an optical instrument worn on the examiner's head (which can be replaced by a smartphone), that with the help of a magnifying lens, allows inspection of the back of the eye. This is a commonly used method to screen for diabetic retinopathy, but depends on an examiner (most likely an ophthalmologist) to conduct the exam and grade the level of diabetic retinopathy (if any).

I-Spot Vision, smartphone fundus photography

This study compared four different smartphone-based approaches and concluded that while smartphone-based technology can be useful to meet screening requirements, not all devices are suitable in terms of quality and accuracy. Smartphone-based technology and other innovative approaches towards diabetic retinopathy screening are important since around 80% of people affected by diabetic retinopathy live in low- and middle-income countries (LMICs), where access and resources are limited. Since diabetic retinopathy is the leading cause of visual impairment for working-age adults globally, the effect it has on productivity and economic growth is strongly felt in LMICs.

Another study from 2020 comparing smartphone based retinal imaging for diabetic detection compared four available systems: iExaminer, D-Eye, Peek Retina, and iNview.[8] The data captured through these four systems was analyzed using deep learning to compare their accuracy.

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[7] Wintergerst MWM, Mishra DK, Hartmann L, Shah P, Konana VK, Sagar P, Berger M, Murali K, Holz FG, Shanmugam MP, Finger RP. Diabetic Retinopathy Screening Using Smartphone-Based Fundus Imaging in India. Ophthalmology. 2020 Nov;127(11):1529-1538. doi: 10.1016/j.ophtha.2020.05.025. Epub 2020 May 25. PMID: 32464129.

[8] Karakaya, M., Hacisoftaoglu, R.E. Comparison of smartphone-based retinal imaging systems for diabetic retinopathy detection using deep learning. *BMC Bioinformatics* 21, 259 (2020). https://doi.org/10.1186/s12859-020-03587-2

In conclusion, the field of view of smartphone-based retinal imaging plays an important role in accuracy. Also, none of the smartphone-based retinal imaging systems captures the entire printed retina pattern in comparison to images captured with a fundus camera. The images captured using iNview have the largest field of view in comparison to other systems. Finally, the overall classification accuracy was 61%, 62%, 69%, and 75% for iExaminer, D-Eye, Peek Retina, and iNview images, respectively.

The next paper reviewed is also a case study of a diabetic retinopathy screening program in Mumbai, India, which took place in 2018.[9] Fundus images from 213 study participants were subjected to offline, automated analysis. The sensitivity and specificity of the analysis to diagnose referable diabetic retinopathy were 100.0% and 88.4%, respectively, and the sensitivity and specificity for any diabetic retinopathy were 85.2% and 92.0%, respectively. This study suggests automated analysis might be used to screen for referable diabetic retinopathy using offline artificial intelligence and a smartphone-based, nonmydriatic (without pupil dilation) retinal imaging system. The employment of artificial intelligence in diabetic retinopathy screening becomes even more relevant when we consider one of the biggest constraints to an accessible and scalable screening program is the short supply of ophthalmologists and examiners. Using AI could, therefore, provide an ingenious solution to decrease dependence on ophthalmologists or qualified examiners, especially in rural areas where there might be no qualified personnel.

However, after speaking with Dr. Sobha Sivaprasad, member of the team conducting the previously mentioned study and project leader for the ORNATE India team that implemented a screening policy program in the state of Kerala, some of the positive results presented by smartphone-based retinal imaging and AI were called into question. First, Dr. Sivaprasad pointed out that in LMICs, many of the patients to be screened who have diabetic retinopathy will also have cataract (clouding of the lens of the eye), which impedes non-mydriatic methods from capturing high quality fundus images. Therefore, Dr. Sivaprasad suggested dilating pupils, regardless whether the camera used is non-mydriatic. Her last suggestion was fixing the portable camera to a slit lamp or table, enhancing image quality by decreasing movement.

The conclusions reached by these studies are relevant because they point out effective models as well as barriers to a successful diabetic retinopathy screening program. For example, they show that despite growing interest in smartphone-based retinal imaging, this technology is not yet accurate enough and still depends on a specialist to evaluate the images captured. They also showed that artificial intelligence software presents an ingenious solution for screening purposes worth considering.

2.3 Part one: Qualitative study

The first part of this project is a qualitative study. For this section, we have partnered with Universidad San Francisco de Quito, a leading university in Quito, Ecuador, in order to conduct

[9] Natarajan S, Jain A, Krishnan R, Rogye A, Sivaprasad S. Diagnostic Accuracy of Community-Based Diabetic Retinopathy Screening With an Offline Artificial Intelligence System on a Smartphone. *JAMA Ophthalmol.* 2019;137(10):1182–1188. doi:10.1001/jamaophthalmol.2019.2923

the study. After reaching out to Prof. Ivan Palacios, who leads the university's collaboration program with a network of public primary healthcare centers around Quito, we decided to work together in this study with the end goal of presenting its findings to public healthcare officials.

The study design is the following:

- Investigation type: Observational, qualitative, cross-sectional study
- Study population: patients with diabetes mellitus (both receiving and not receiving treatment for diabetic retinopathy), as well as healthcare professionals directly involved with diabetic patients
- Sample size: Sample size for this study was conveniently chosen using the following criteria:
    - 7 randomly chosen diabetics not previously screened for diabetic retinopathy
    - 7 randomly chosen patients currently receiving diabetic retinopathy treatment
    - 5 healthcare professionals (ophthalmologists, endocrinologists)
    - 5 general practitioners in primary healthcare centers
    - 24 participants in total

- Inclusion criteria
    - Inclusion criteria for patients:
        - Age: 50+
        - Existing health condition: diabetes type 1 or type 2
        - Gender: all
        - Economic background: low economic means
        - Residing in Pifo, Yaruquí
        - Having agreed to participate in this study and having signed the consent form

    - Inclusion criteria for healthcare professionals:
        - Doctors specializing in ophthalmology or endocrinology
        - Treating patients at Fundación Oftalmológica del Valle
        - Having agreed to participate in this study and having signed the consent form

    - Inclusion criteria for general practitioners in primary healthcare centers:
        - General doctors treating diabetic patients at the primary healthcare center located in Pifo, Ecuador
        - Having agreed to participate in this study and having signed the consent form

- Variables analyzed
    - Variables analyzed for patients:
        - Diabetes type
        - Diabetes duration

        - Primary information source regarding diabetes and its management
        - Knowledge about diabetic retinopathy
        - Logistical barriers to attending a screening program in person

    - Variables analyzed for healthcare professionals and general practitioners:
        - Medical experience
        - Professional relation to patients with diabetes
        - Volume of diabetic patients treated
        - Information shared with diabetic patients regarding diabetic retinopathy
        - Frequency of ophthalmological check-ups

- Data analysis: Data will be analyzed following Lewis, Patel, Yorston, and Charteris' methodology ("A Qualitative Study in the United Kingdom of Factors Influencing Attendance by Patients with Diabetes at Ophthalmic Outpatient Clinics", Ophthalmic Epidemiology, 14:6, 375-380, 2007). This method separates responses per question and groups them into four categories: attitudes, beliefs, enabling factors, and social norms.
    - Attitudes: a product of an individual's education, experience, culture, or values
    - Beliefs: supposed consequences of the person performing a behavior, or supposed consequences of influence of other people over performing a behavior
    - Enabling factors: employment, health services, income, transportation
    - Social norms: influence of family, community, or social networks

- Transcribed data will be analyzed using SPSS and Microsoft Excel
- Protocol Formulation: Participating investigators will analyze and apply the recorded data in order to formulate a protocol for setting up a diabetic retinopathy screening program focused in rural areas of Ecuador

2.4 Part two: Screening pilot program

For the second part of this project, which is the implementation of a pilot diabetic retinopathy screening program, the idea is to take into consideration the findings from the qualitative study and apply them to the program design. Using these insights and leveraging our partnership with Universidad San Francisco de Quito, we would design a schedule of planned visits to several primary healthcare centers around the outskirts of Quito. We would also plan to conduct screenings at Fundación Oftalmológica del Valle. All screenings would be conducted by trained personnel from Fundación Oftalmológica del Valle, including ophthalmologists and ophthalmic assistants.

Based on research and previous experience with screening programs in Ecuador, we think that for a screening program to be successful in providing access to those most in need, it ought to be consistent, free of charge, and mobile. Some issues with traditional screening methods include the high dependency on ophthalmologists, time per screening, and low scalability. According to Ecuador's National Institute of Statistics (INEC), in 2014 there were 345 ophthalmologists in the country, with 215 concentrated in the two largest cities and only 7 specialists located in the Amazon region (the population of Ecuador is approximately 17 million people).

Given these constraints, we chose to look into new technologies that can facilitate screening. In the past few years, a handful of companies have applied artificial intelligence to diabetic retinopathy screening. Results have been positive, showing how artificial intelligence software can be a powerful tool in screening for diabetic retinopathy. Below I review two leading software programs after looking at their publications and meeting with their representatives.

	EyeArt	**DART**
Origin	California, USA	Chile (used by the Chilean Ministry of Health since 2018)
Specificity and Sensitivity	91.1% and 91.3%, respectively[10]	74.3% and 94.6%, respectively[11]
Results	Autonomous reports produced in 60 seconds, exported as PDF (internet connection required)	Semi-automatic: positive results are reviewed by an ophthalmologist through telemedicine, results are reported to the patient the day after the screening
Cost	US$ 5 per exam (both eyes) or US$ 5,000 for yearly license	US$ 2 per exam (both eyes) or US$ 7,000 for yearly license
Additional Info	• Low number of non-screenable encounters (1%) • Validated with most hand-held portable cameras	• 20.2% false positives • Open to collaborating and doing a trial program

Based on this review, the preferable screening method would be a mobile design, composed of a portable fundus camera and EyeArt software, which can reduce the dependency on ophthalmologists, the need for pupil dilation, and can increase the number of screenings conducted (especially in remote areas). Plus, patients can receive an immediate diagnosis and their case can be followed up accordingly. Portable fundus cameras would be required compared to smartphone-based imaging due to image quality required by artificial intelligence software.

3. *Findings & Contributions*

Thus far, significant progress has been made with regards to the action plan. First, all the necessary documentation was filled and presented to Universidad San Francisco de Quito's Bioethics Committee on June 18, 2021. A second version was requested on July 17, 2021 and a third version was submitted on August 18, 2021. We received an email on August 27 notifying

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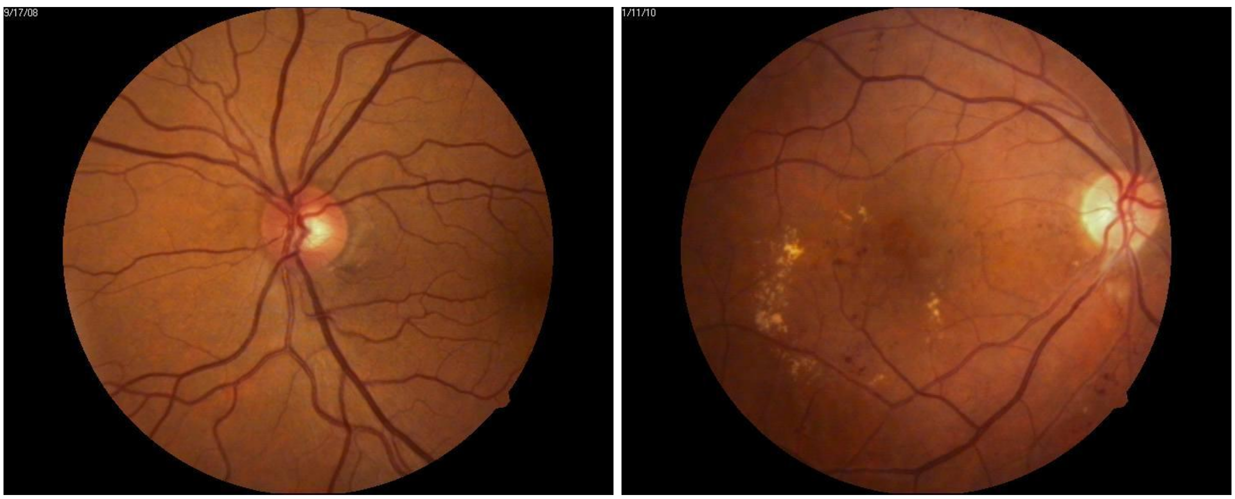
[10] Bhaskaranand. Et.al. "The Value of Automated Diabetic Retinopathy Screening with the EyeArt System: A Study of More Than 100,000 Consecutive Encounters from People with Diabetes." Diabetes Technology & Therapeutics, July 23, 2019. https://doi.org/10.1089/dia.2019.0164.

[11] Arenas-Cavalli, J.T., Abarca, I., Rojas-Contreras, M. *et al.* Clinical validation of an artificial intelligence-based diabetic retinopathy screening tool for a national health system. *Eye* (2021). https://doi.org/10.1038/s41433-020-01366-0

us that all documents submitted are satisfactory and the Bioethics Committee will now draft an approval letter. Interviews are planned to start the first week of September.

A study design and survey questionnaires have already been developed, and we have also established contact with a doctor in a primary healthcare center who will help us identify prospective participants for the study. I also completed a Bioethics certification course online, which is required by the Bioethics Committee for investigators involved in the study.

With regards to prospective equipment and technology to be used in the screening program, we have focused on two handheld portable fundus cameras: the first is the Visuscout 100, manufactured by Zeiss. This camera has not been reviewed by EyeArt yet to determine if it is compatible with its AI software. However, we received some fundus images from an engineer at Zeiss and shared those with EyeArt, so they can evaluate if the camera is compatible with their software. These images are currently under review.



Sample fundus images, provided by Zeiss

The second camera we have looked into is Topcon's Signal hand held camera. This camera is already approved by EyeArt as being compatible with their software. We have reached out to a Topcon representative in Ecuador, and they will have a camera arriving in Quito by mid-September so we can conduct our pilot program. A representative from EyeArt has already agreed to facilitate the necessary technology so we can test both the camera and the AI software.

Topcon Signal Handheld Retinal Camera, Topcon

Ideally, we will manage to conduct the pilot program without incurring any costs thanks to the collaboration of Topcon and EyeArt in providing a trial version for their equipment. Any additional costs will be covered by Fundación Oftalmológica del Valle. We have also identified a number of potential funding sources for an ongoing screening program once the pilot program concludes.

4. *Future Directions & Open Questions*

Next steps for this project include completing the qualitative study, coming up with a protocol summarizing the key findings from the study, and applying these findings to a pilot screening program. The qualitative study is expected to be completed by November, including interviews, results analysis, and protocol formulation.

Following these results, the plan is to collaborate once again with Universidad San Francisco de Quito and the public primary healthcare centers in the outskirts of Quito. This collaboration would involve formulating a schedule of planned visits to these healthcare centers to conduct diabetic retinopathy screenings for the center's diabetic patients primarily.

A successful pilot program would be useful evidence to be shared with public authorities at the Ministry of Public Health, with the goal of scaling up screening programs at the national level. It would also be useful to look for synergies with other organizations, build partnerships, and seek external funding.

Expected costs for a diabetic retinopathy screening program would be the following:

Fixed costs	
Handheld retinal camera (1) [12]	US$ 10,416
Variable costs (per year)	
EyeArt software license (1)	US$ 5,000
Logistics (internet access, transportation)[13]	US$ 360

The estimated budget for such a screening program would be US$ 15,776 for year 1, and US$ 5,360 for subsequent years. This assumes the program is run using one handheld retinal camera.

The whole project is expected to be completed by January 2022. The main obstacle thus far has been the time taken by the Bioethics Committee at Universidad San Francisco de Quito to review our study proposal. Other potential obstacles would be delays in the arrival of necessary equipment for the pilot screening program, including a fundus camera or artificial intelligence software. Finally, due to the ongoing Covid-19 pandemic, we could see the execution of the qualitative study or the pilot screening program delayed if a new wave were to arise. However, based on the country's current high vaccination and low contagion rates, we do not expect there to be any inconvenience with leading all the necessary in-person interactions in a safe manner.

Finally, I would like to thank Glasgow Caledonian New York College, the Center for Social Impact and Innovation, and both Gastón de los Reyes and Sharon Silbermann for their mentorship, guidance, and support. Their openness to review this project's design, provide suggestions, and look into potential synergies and opportunities has contributed great value.

[12] Estimate based on the price of the Topcon Signal Hand Held Retinal Camera

[13] Based on a monthly 10gb internet plan (US$ 10) and US$ 20 for gas or taxi services per month