

PROOF OF CONCEPT STUDY 2020 - 2022

EXECUTIVE SUMMARY

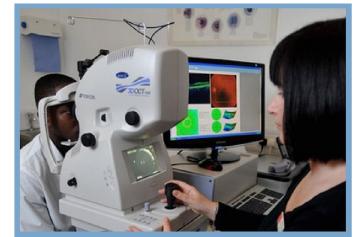


Introduction

Established in 2020, the Scottish Collaborative Optometry-Ophthalmology Network e-research (SCONe) is a pioneering project to build a world-leading, retinal image resource for innovation in eye research, healthcare, and education.

In Scotland, community optometrists collect millions of retinal images every year during eye examinations. Many have been doing so for more than a decade. SCONe's goal is to harness the power of these community-acquired retinal images.

SCONe successfully engaged with community optometry practices across Scotland and seven independent optometry practices participated in our initial two-year Proof of Concept (PoC) study. During this study, processes were developed to securely transfer retinal images from optometry practices to the Public Health Scotland (PHS) National



Safe Haven. Over 120,000 optometry-acquired retinal images have been delivered to the National Safe Haven so far.

This is the first time that a retinal image repository of this scale has been developed using data from primary care. This resource could lead the way to develop new technologies for detecting eye diseases such as age-related macular degeneration (AMD) in the earliest stages.

The first phase of research enabling early detection of AMD, the UK's most common cause of blindness has been completed. The need for early detection of sight-threatening conditions such as AMD is imperative, as experts have warned that the number of people with sight loss in Scotland will rise to over 200,000 in the next decade.¹

Data Collection and Governance

The SCONe team performed a practice visit to each of the seven independent PoC practices, carefully finding and extracting all relevant data. This included a patient list from the Practice Management Software (PMS) and fundus photographs for patients aged 60+ years old. From this initial experience, SCONe researchers were able to develop a semi-automated procedure for the linkage of images to patient data within optometry practices with high rates of accuracy.

The data were securely transferred to the National Safe Haven, at which point further links were made to hospital inpatient and day case records (SMR01) and the General Ophthalmic Services dataset (GOS) to provide details of diagnoses, procedures and other health data for those patients. This linkage of retinal images to routinely-acquired NHS healthcare datasets creates the opportunity to discover new information about retinal manifestations of both ocular and systemic diseases.

Within the National Safe Haven, the images were pseudonymised so that no personally-identifiable data is visible to researchers. In order to access the transferred images and conduct analysis on them, SCONe team members must go through the Safe Haven's formal application process to become approved users, with all the technical restrictions and governance requirements which that entails. In the future, it is envisaged that external researchers may be able to apply to use the SCONe dataset for additional research, but this was beyond the scope of the initial PoC study.

Governance Protocols:

- NHS Scotland Public Benefit and Privacy Panel for Health and Social Care (PBPP) authorisation for the use of unconsented healthcare data for research, October 2021 (Ref: 1920-0121 Tochel)
- Data Privacy Impact Assessment (DPIA) approved by the University of Edinburgh Data Protection Officer, September 2021
- Co-sponsorship from University of Edinburgh and NHS Lothian, following a review by ACCORD²
- Data Sharing Agreements signed by each practice Data Controller and both sponsors before any images are extracted
- eDRIS National Safe Haven ethical approval³

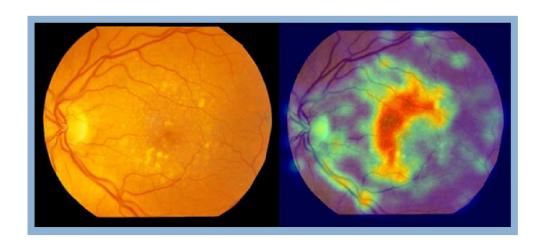
^{2.} www.accord.scot

^{3.} www.isdscotland.org/Products-and-Services/eDRIS/FAQ-eDRIS/#d4)

Image Analysis

One of the initial aims of SCONe was to develop algorithms for the analysis of retinal images using Artificial Intelligence (AI), specifically for early detection of AMD. The earliest phase of AMD is typically observed as the presence of (asymptomatic) macular drusen (yellow deposits that build up at the back of the eye), which are often incidentally found on routine examination or retinal imaging. Drusen frequently occur in normal ageing, but an increase in the number and size of drusen increases the risk of progression to visually symptomatic AMD.

SCONe researchers have successfully developed new methods for drusen detection and for the measurement of vascular changes in the eye. The potential of these methods for early detection of disease can now be assessed using the SCONe dataset. A data quality assurance framework will be established to ensure insights obtained and algorithms developed from SCONe data are reliable and meaningful, in line with the use of real-world data and all of its unavoidable challenges.



One of the great benefits of utilising images from community optometry practices comes from the presence of many patients' images without or before clinical diagnoses. Having multiple images from lots of healthy people is extremely valuable for determining how our current vascular/drusen measures change over time, and prior to the development of symptomatic disease, so that thresholds can be established and crucial time points in the clinical care pathways can be refined where monitoring, referral and intervention are required.

The Next Phase

The SCONe project is now moving into its second phase, building on the work conducted in the PoC study to scale up engagement with community optometrists across Scotland, expand the retinal image repository, extend governance and regulatory applications to support this, and develop a prototype diagnostic tool for image analysis and disease screening.

SCONe has the backing of the Scottish Government, including the Cross-Party Group for Visual Impairment and Dr Janet Pooley, Chief Optometric Advisor. In December 2022, the Scottish Government published a memorandum which "strongly encouraged" optometrists across Scotland to participate in the SCONe project.⁴

As more practices get involved, the SCONe retinal image research repository will soon represent one of the largest community-acquired retinal image repositories in the world, creating a unique opportunity to advance biomedical research and help with the diagnosis, care and treatment of both ocular and systemic disease.

The SCONe team would like to thank the following organisations for their support:















Optometry practices can register their interest in joining SCONe <u>online</u> or by emailing scone@ed.ac.uk.

Further information about the project can be found on the SCONe website: www.ed.ac.uk/clinical-sciences/ophthalmology/scone