Assessing the Effect of Informative Photo Referral Cards on Access to Eye Care Services Within a Community-Based Program in Kwale County: A Randomized Controlled Trial

Abstract

The Vision Impact Project (VIP) is a major community-based eye screening programme running in Kenya with the aim of promoting eye health for all. Previous studies embedded within the programme in Kwale County have found that a third of people who are screened require care for an eye problem, however only half of these people manage to access outreach treatment clinics. Access varies between sociodemographic groups: only 29% of individuals aged 18-34 years managed to access care. In previous mixed-methods work our team conducted interviews and surveys with non-attenders from this 'left-behind' group to explore what could be done to improve access. This group suggested individual and clinic level interventions that are likely to improve attendance rates. This protocol is based on the individual level intervention, which involves an informative photo referral card. We will assess whether attendance rates are higher among those randomised to receive this informative photo referral card compared to those who receive standard care.

This is a randomised controlled trial that will be embedded within the VIP Project that is currently underway in Kwale County. We aim to recruit adults who have been identified as having an eye problem during screening and referred to local treatment outreach clinics for further assessment and treatment. The eligibility criterion is 18 years and above and willingness to participate in the trial. Intervention arm participants will receive an informative photo referral card at the point of referral. The control arm will receive usual care, which involves counselling at the point of referral and SMS reminders. The primary outcome will be the proportion of people from the left-behind group who attend the ophthalmic outreach clinic. Our secondary analysis will examine attendance among individuals aged 35 years and above. The findings will be shared with the programme managers and written up for peer-reviewed publication. If the trial is effective, it will inform policy and practice on the use of informative photo referral cards to improve clinic attendance. We will recommend the introduction of these cards across the entire VIP programme and as other eye screening programmes in Kenya.

Lay Summary

The Vision Impact Project (VIP) is a large community-based eye screening programme running in Kenya to promote eye health for all. Previous studies running within the VIP programme have found that half of the people referred to outreach clinics do not manage to access these clinics. Access varied among groups, with the lowest clinic attendance reported among young people, especially male. We conducted additional interviews and surveys to find out why these individuals were not going to the eye clinics. They had some ideas on how to get more people to attend the outreach clinics. These ideas included providing areferral card that includes a photo of the patient, and gives information about the importance of attending the clinic, services available, costs, opening hours, location, and contact details of the person who screened and referred the participant. We want to test if this referral card actually helps more people go to the clinic.We are conducting a test in which some people receive the referral card with additional information about services available at the outreach clinic, along with a participant's photo attached on it and others don't. We are recruiting adults who have eye problems and are referred to local clinics. The ones receiving the referral card will also receive the counselling at the point of referral and text reminders. The other group will get the counselling at the point of referral and text reminders but not the referral card. The main outcome we are assessing is how many people from the left-behind group (18-34 years) actually go to the clinic. We will also assess the attendance for individuals who are 35 years and above. We're going to look at the numbers to see if these referral cards with pictures help more people come to the clinic. The results will help figure out if giving people thesereferral cards can help more people go to clinics when they need eye care. If it works, this information could help change how we encourage people to visit clinics. We will also recommend introducting these referral cards in eye screening programmes in Kenya.## Keywords

Eye care, access, health services research, embedded trial, equity, referral card, photo card

1. Reporting guidelines

This protocol has been prepared in line with the SPIRIT checklist and incorporates relevant elements from the CONSORT extensions for equity-oriented and pragmatic trials.

2. Trial registration

This trial will be registered with ISRCTN (International Standard Registered Clinical/soCial sTudy Number).

3. Protocol version

Version 3_05/08/2025

4. Funding

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5. Roles and responsibilities

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5c. Role of sponsor and funders

The study sponsor and funders will not have any role in or ultimate authority over the study design, data collection, management, analysis, and interpretation, report writing, or decision to submit the report for publication.

5d. Team composition

	Coordinating Centre	Trial Steering Committee	Data management team
1.	Sarah Karanja	James Carpenter (chair)	Sarah Karanja
2.	Luke Allen	Malebogo Tlhajoane	Luke Allen
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Common terms used in the protocol

Table 1: Common terms used in the protocol

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Access and attendance	We are interested in **access to services**, which is driven by complex supply and demand factors. We will use **attendance** as the primary indicator of access. We note that access and attendance are both proximal outcomes in that they do not automatically lead to the receipt of good quality care and improved health outcomes.
Eye care need	We are concerned with whether those with an **eye care need** access service. This includes near or distance vision impairment and non-visually impairing eye conditions, included but not limited to uncorrected / under-corrected refractive errors, cataract, a red eye, eye discomfort or pain, or any other eye-related issue identified by screeners.
Left behind population groups.	We focus on the **population groups** with the worst access to services, aligning with the UN Agenda for Sustainable Development's "central, transformative promise" to 'leave no one behind' and 'reach the furthest behind first'. Further UN guidance states that "leaving no one behind means moving beyond assessing average and aggregate progress, towards ensuring progress for all population groups at a disaggregated level." The UN uses the terms 'worst-off' and 'left-behind' groups interchangeably(1). Multiple population subgroups and domains can be used for disaggregation, such as age, sex, ethnicity, occupation, income, socioeconomic status etc.
Informative photo referral card	The informative referral photo card is an initiative designed based on feedback from service beneficiaries from the left-behind group. This card is given to individuals referred for eye care services and contains crucial information about the importance of attending the outreach clinic, the services offered, clinic hours, and any associated costs. The card also features a photo of the individual who has been referred for eye care services. This photo is taken by the screener at the time of referral using a smartphone and then printed with a wireless mobile photo printer that connects to the smartphone via Bluetooth. The printed photo is attached to the referral card.

6. Introduction/Background

An estimated 1.1 billion people worldwide live with vision loss, primarily due to limited access to eye care services, making eye health a significant global burden. Additionally, approximately 2.2 billion people globally suffer from uncorrected poor vision, with a substantial proportion residing in low- and middle-income countries (LMICs)(2–4). Consequently, this burden impacts individual quality of life and also has broader economic implications, with an estimated annual global productivity loss of $410.7 billion due to vision impairment (2,5). Subsequently, the increasing prevalence of eye conditions necessitates urgent attention to eye health as a critical component of public health.

The prevalence of vision impairment is estimated to be four times higher in low- and middle-income countries compared to high-income countries. However, many individuals in these countries face barriers to accessing necessary eye care, including financial constraints, lack of awareness, and inadequate healthcare infrastructure (3). Ramke et al. highlight that, despite the presence of national eye care plans, the integration of eye health services into broader health systems is often insufficient, resulting in inequities in access(6). Notably, the shortage of trained eye care professionals worsens the situation, as many communities struggle to offer essential services like screenings and treatments for common eye conditions.

Considering this, the World Health Organization has advocated for integrating eye care into Universal Health Coverage (UHC) to ensure that everyone has access to vital eye health services without experiencing financial hardship (7). This integration is crucial for achieving Sustainable Development Goal 3, which aims to ensure healthy lives and promote well-being for all at all ages. The WHO's Package of Eye Care Interventions aims to provide evidence-based strategies for enhancing eye health services worldwide. This package includes interventions that address common eye conditions and promote early detection and treatment, essential for reducing the prevalence of avoidable blindness and vision impairment(8). Notably, collaboration among governments, healthcare providers, and communities is essential to successfully implement these interventions and overcome the systemic barriers that limit access to eye care services.

Access to care is a critical component of healthcare systems, influencing patient outcomes and satisfaction. Specifically, in Kenya, the Vision Impact Project (VIP) focuses on screening individuals for eye problems at the community level, referring them to appropriate care, and facilitating treatment for eye conditions. Our research collaborative group, which includes LSHTM, Peek Vision, the Ministry of Health, and the Kenya Medical Research Institute, is focused on identifying the population groups with the least access to eye care services in two of the seven counties where VIP is implementing its project: Kwale and Meru counties. With regards to this, the evidence from this work indicates that access to essential eye services is low. Specifically, in Kwale, only 42% of individuals screened and referred accessed eye care services.

Consequently, our collaborative team is using the Improvement Studies for Evidence-based Equitable Innovation (IM-SEEN) model to improve access to eye health services(9). The model focuses on three primary objectives. Firstly, the collection of sociodemographic data from individuals who have been screened and referred for eye care services in order to identify groups that are least likely to access eye health services. Secondly, engagement with left-behind groups to ascertain barriers to care as well as potential solutions. Thirdly, the implementation of randomized controlled trials to test these solutions, followed by the scaling-up of evidence-based interventions within existing community-based eye screening programs. Ultimately, this study aims to evaluate solutions proposed by left behind groups and validated by eye-screening stakeholders, including members of the community advisory group in Kwale County.

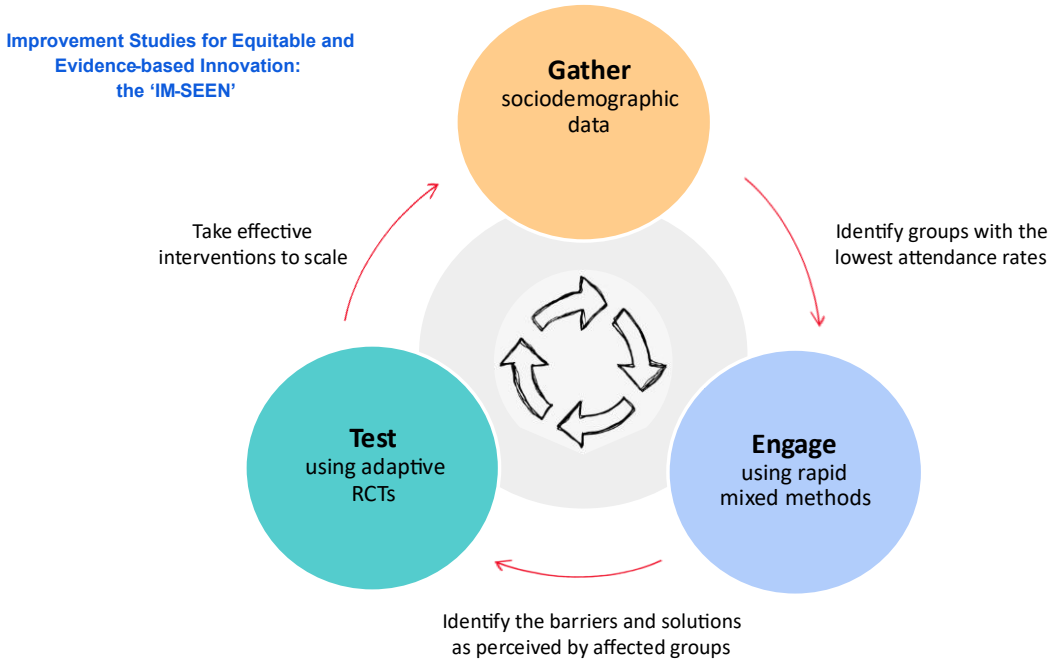


Figure 1: The Improvement Studies for Equitable and Evidence-based Innovation (IM-SEEN) model

Problem statement

In Kwale County, we have concluded the IM-SEEN model's first and second primary objectives (we are currently writing the findings for publication). The first aim of identifying groups least likely to access care revealed that the sociographic characteristics strongly associated with clinic non-attendance were gender and age. Hence, in the next objective, we engaged the groups least likely to attend the clinics (young men and women aged 18-34) in a sequential mixed methods study. After this, we first conducted a qualitative assessment to identify barriers and solutions as perceived by individuals aged 18 to 34 who were screened and referred for eye care but did not attend the clinic. Afterward, we engaged a representative sample from the same group to rank the solutions identified by those interviewed using qualitative methods, and finally, we discussed the ranked solutions with eye health stakeholders, including members of the community advisory group. Ultimately, we asked the

stakeholders to select solutions that should be prioritized for testing based on impact, feasibility, and cost-effectiveness.

Overall, the barriers identified by left-behind groups included the perceived cost of spectacles and eye drops, lost wages, distance to the referral clinic, transportation costs, long wait times at the referral clinic, dissatisfaction with screening services, competing work and social commitments, fear, forgetfulness, and a lack of clear information regarding appointment dates, times, locations, available services, and service costs. Consequently, suggested solutions included adding more clinic locations to minimize travel distances, extending outreach clinic hours to cover more weekdays and weekends, clearly specifying clinic opening and closing times, hosting mop-up clinics for those who missed their appointments, reducing wait times, establishing multiple outreach clinics to decrease queue sizes, implementing separate queues for older adults, women, children, and young people, ensuring clinics are fully stocked, and increasing awareness of services available at the outreach clinics.

Under those circumstances, the stakeholder engagement workshop concentrated on prioritizing interventions for testing. Regarding this, they emphasized both individual-level and clinic-level interventions. First, at the individual level, stakeholders recommended an informative photo referral card at the point of referral. Second, at the clinic level, they suggested involving experienced patients who have participated in similar community eye screenings, triage, and treatment to deliver health talks at the outreach treatment clinics. Moreover, these talks would cover what to expect at the outreach treatment clinics, available services and associated costs, as well as the possibility of referrals to higher-level or secondary facilities, among other topics. Additional recommendations at the clinic level included enhancing the overall quality of interaction between patients and healthcare professionals during the outreach treatment clinics, conducting mop-up clinics, and extending the outreach clinics to more weekdays and weekends.

Justification

This protocol is based on the individual-level intervention derived from the stakeholder workshop. The intervention focuses on providing an informative photo referral card at the point of referral. By introducing an informative photo referral card, we aim to enhance patients' understanding of where to access necessary eye care services, the importance of attending the outreach clinic, the services available, and whether there are any associated costs. This will ensure that referred individuals are fully aware of their appointment and treatment options, reducing confusion and the likelihood of missing their appointments. It also acts as a tangible reminder of what was verbally discussed at the time of referral and provides individuals with a reference point for future questions or clarifications. On the other hand, including a person's photo on the referral card can enhance personalization and promote engagement and follow-through. This study aims to evaluate whether informative photo referral cards can enhance access to eye health services for individuals identified with an eye problem during community screenings and referred for care.

Informative referral cards can be a useful tool in promoting healthcare services by improving patient adherence and streamlining referral practices.(10,11)Providing patients with essential information about their condition, treatment plan, and follow-up appointments can empower them and lead to greater satisfaction(10–13). There is limited evidence on the use of patients' photographs on referral cards to improve access to health services. However, one study examined the association between displaying patient photographs on electronic health records and the reduction of wrong-patient order entry errors. The study observed a significant decrease in such errors after implementing the display of patient photographs, highlighting the potential of visual identifiers in enhancing patient safety (14).

7. Research questions

Primary research question: What is the effect of informative photo referral cards on improving attendance at the outreach clinic among left-behind groups (ages 18-34)?

Secondary objective: What is the effect of an informative photo referral card on improving attendance at the outreach clinic for individuals over 35 years old?

8. Objectives

Primary objective: To assess whether informative photo referral cards improve attendance rates among left-behind groups (18-34 year-olds) compared with the standard of care in the Vision Impact Project screening programme in Kwale County

Secondary objective: To assess whether informative photo referral cards improve attendance for individuals over 35 years old. compared with the standard of care in the Vision Impact Project screening programme in Kwale County.

It is important that we check attendance among the left-behind group as well as the overall population to guard against adopting an intervention that improves access for the left-behind group but leads to a significant overall fall in attendance across the entire programme. We will use absolute percentage differences in attendance for comparisons between the left-behind and general populations exposed to the intervention.

9. Methodology

9a. Trial design

This will be a two-arm randomised controlled superiority trial. Participants who are referred to onward care will be randomised to one of two groups

1) Standard care
2) Standard care + provision of an informative photo referral card

The outcome of the trial is attendance at an ophthalmic outreach clinic on the appointed date. The proportion of participants who attended their appointment will be compared between arms.

9b. Study setting

The trials will be embedded within the VIP community-based screening programme currently underway in Kwale County. The programme uses integrated screening and patient management software developed by Peek Vision. Our platform trial will use data routinely gathered using Peek software.

This study marks the third phase of our ongoing continuous improvement investigations, which are being conducted in Meru and Kwale Counties. We have previously presented SERU 4571 (phase one), 4765 (phase two) and 4919 (Meru phase three). The rationale for conducting this phase three study in Kwale is grounded in the fact that the data used to inform the intervention was collected from Kwale County. Specifically, this includes information on groups with the lowest attendance rates, as well as the barriers, solutions, and most practical interventions likely to make an impact.

9c. Study population

The study population is adults in Kwale country, screened by the vision impact project.

Participants will be all individuals aged 18 and over, screened by the Vision Impact Project during the 12-week study period, who have been identified as having an eye problem during screening and referred to local treatment outreach clinics for further assessment and treatment.

Our primary analysis focuses on those aged 18-34. This age range was chosen as a previous equity analysis conducted in Kwale County showed that those aged 18-34 were less likely to attend outreach clinics following referral than those aged 35 or over. (The study also showed that young men were less likely to attend than young women, but local eye health stakeholders in Kwale County felt that it would be better to focus on all young people aged 18 to 34 rather than exclusively on males.)

9d. Eligibility criteria

The only eligibility criteria are being 18 years or older and willing to participate in the trial. The only exclusion is the lack of intention to stay in the area screened for at least one month. There are no specific exclusions for pregnant women, individuals living with HIV, or other vulnerable groups.

10. Intervention

10a. Intervention and administration

The intervention is an informative referral photo card that has been developed in line with suggestions from intended service beneficiaries from the left-behind group. During interviews with 41 non-attenders from the left-behind group, 19 different potential service modifications

were suggested. We then asked 399 additional non-attenders from the left-behind group to ascribe a simple score to each suggestion, ranging from 'likely to make a large difference' to 'likely to make a small/no difference' on a three-point Likert scale. The top-ranked suggestions were discussed at a workshop with representation from the VIP programme implementing partners (Kwale Eye Center), the programme funder (Christian Blind Mission), the county health management team, the community advisory board and Ministry of Health ophthalmic services unit. This group unanimously agreed that it would be feasible to implement and test an informative photo referral card intervention. The card has been translated into Swahili and back-translated into English to ensure that meaning has not been lost. Each participant can choose whether to communicate in English or Swahili during screening. This decision is recorded on the Peek app and determines the language in which the verbal and SMS interventions are delivered.

At the point of referral, screeners will read out the standard referral counselling script

> *"I have found a problem with your eyes. I am referring you to the outreach treatment clinic that will be held at [location] on [date] between [time] and [time]. At the clinic, eye care professionals will perform a specialist assessment free of charge and provide medicines. Individuals who require spectacles will be referred to a place where they can purchase them. Note that a small proportion of people who attend the clinic will be found to have complex eye problems that require onward referral for hospital assessment and specialist glasses which may not be free.*
>
> *With treatment, you will be able to see more clearly. This will help with your work, reading, viewing screens, and many other things. It is important that you attend the clinic or your eye problem may get worse. The outreach clinic will only be running from [day] to [day], so if you don't manage to attend, you may not be able to reschedule the appointment. However, you may visit any public health facility or Kwale Eye Center for similar services."*

After reading these messages, the screener will take a photo of the participant using the Vision Impact Project a smartphone. The photo will be printed using a wireless mobile photo printer linked to the smartphone via Bluetooth and attached to the referral card (see below) then deleted from the device after printing. The plan is to provide the intervention group with the standard referral information (in-person counselling and SMS), along with a card containing key information and a personalized photo of the individual. Individuals in the control group will not receive an informative photo referral card; instead, they will receive the standard in-person counselling mentioned above, along with an SMS reminder containing similar information. The card consists of two pages (front and back), and participants can choose between an English or Kiswahili version. The card measures A5 and is in portrait orientation.

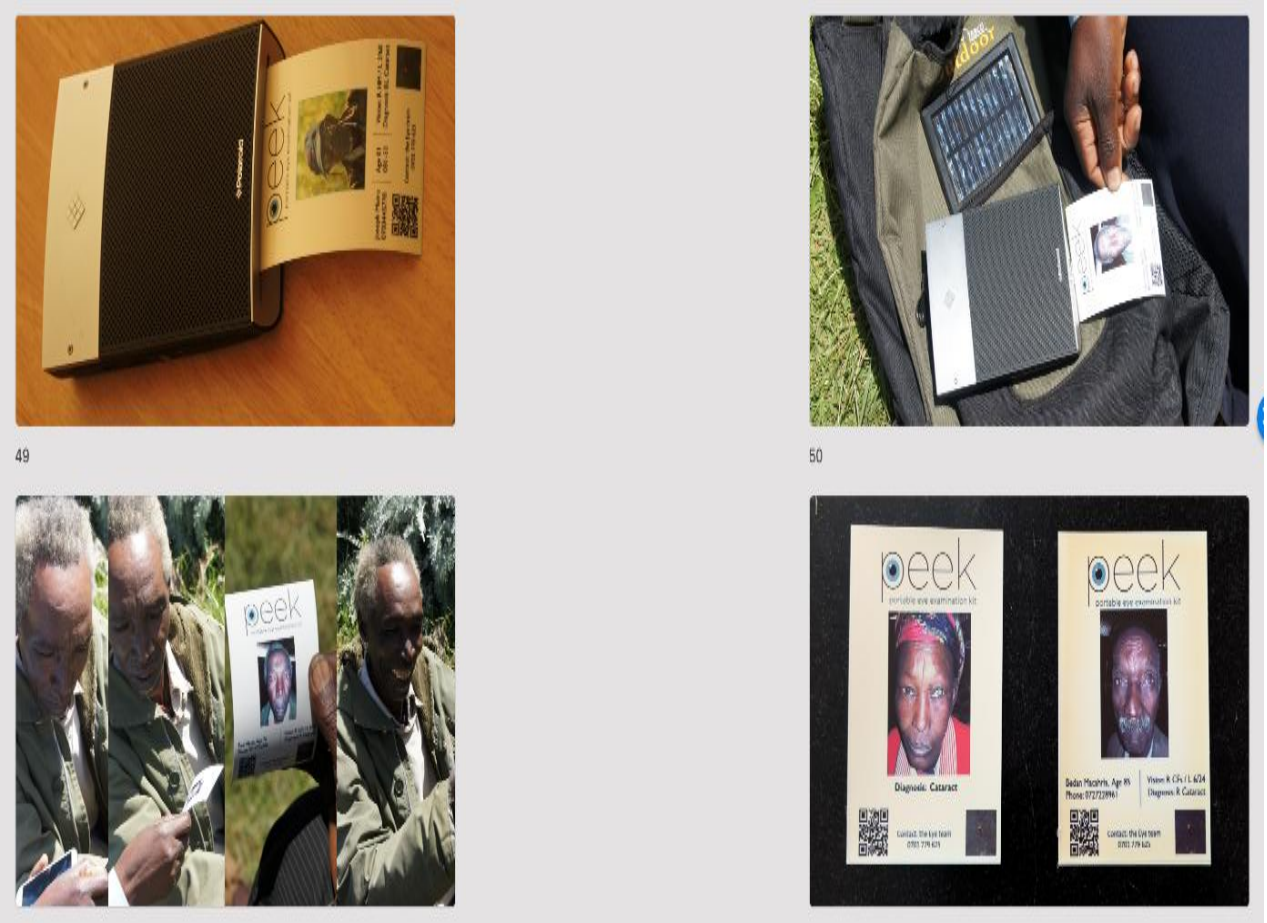
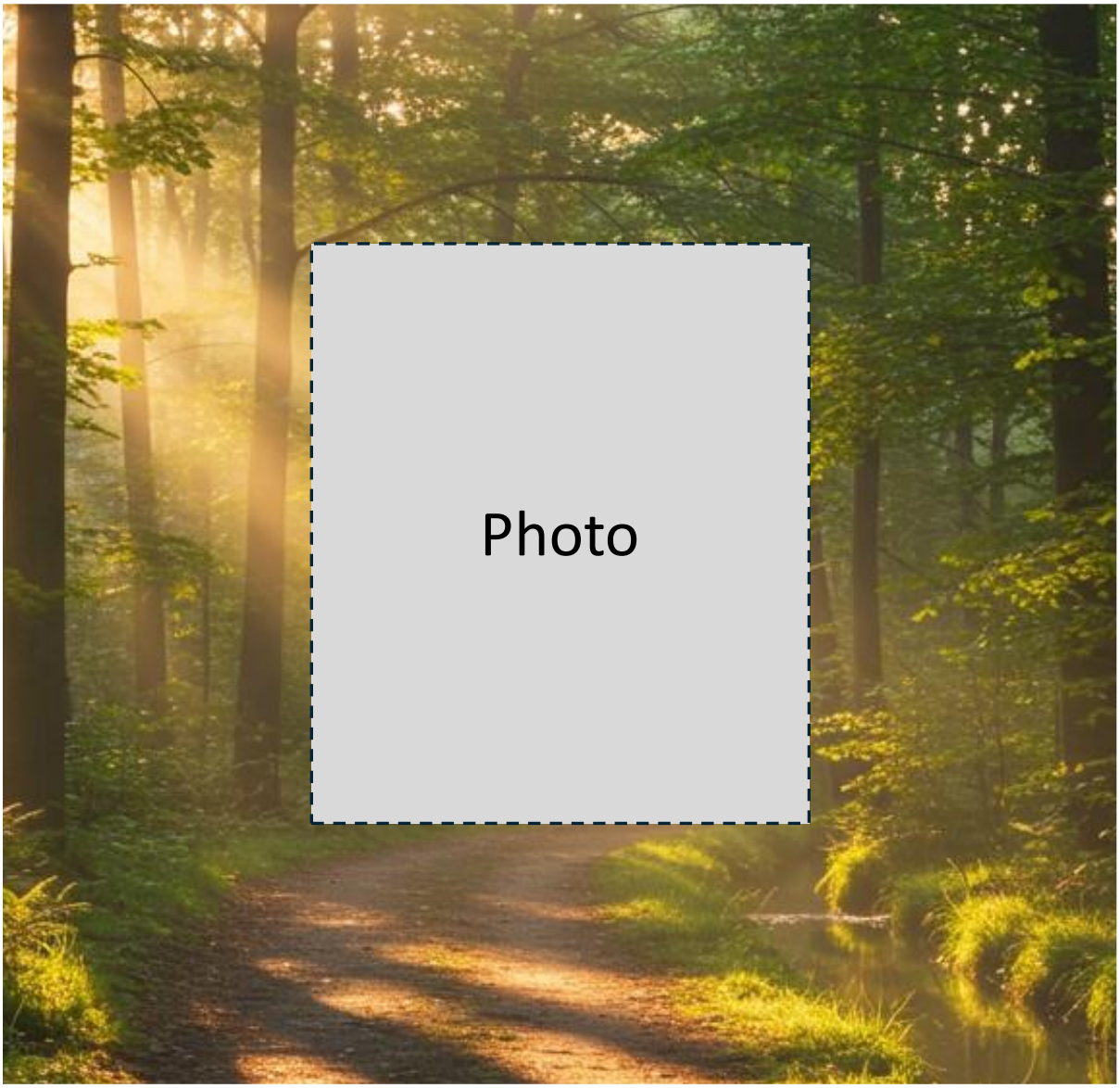


Figure 1: Image of a photo printer and printed photos courtesy of Peek Vision

Front side – informative photo referral card



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INTERNATIONAL CENTRE FOR EYE HEALTH

cbm
christian blind mission

peek vision

Backside – Informative Photo Referral Card (English)

KWALE EYE CENTRE INFORMATIVE REFERRAL CARD

PATIENT NAME: _____

CLINIC NUMBER (refer to the Peek platform): _____

DATE OF THE APPOINTMENT:_____

TIME: _____

LOCATION: _____

REFERRED BY: _____ _____

PHONE NUMBER: _____

Referral Information

I have found a problem with your eyes. I am referring you to the outreach treatment clinic that will be held at _____ on date _____ between _____ and _____. At the clinic, eye care professionals will perform a specialist assessment free of charge and provide medicines. Individuals who require spectacles will be referred to a place where they can purchase them. Note that a small proportion of people who attend the clinic will be found to have complex eye problems that require onward referral for hospital assessment and specialist glasses, which may not be free.

With treatment, you will be able to see more clearly. This will help with your work, reading, viewing screens, and many other things. It is important that you attend the clinic, or your eye problem may get worse. The outreach clinic will only be running from _____ to _____, so if you don't manage to attend, you may not be able to reschedule the appointment. However, you may visit any nearby health facility or Kwale Eye Center for similar service".

Backside – Informative Photo Referral Card (Kiswahili)

KWALE EYE CENTRE INFORMATIVE REFERRAL CARD

JINA LA MGONJWA: _____

NAMBA YA KLINIKI (refer to the peek platform): _____

TAREHE YA KLINIKI:_____

MUDA: _____

MAHALI PA KLINIKI: _____

ALIYEKUCHUNGUZA: _____

NAMBARI YA SIMU: _____

Taarifaza Rufaa

Nimegundua tatizo kwenye macho yako. Ninakuelekeza kwenye kliniki ya matibabu itakayofanyika huko _____ tarehe _____ kuanzia saa _____ hadi saa _____. Kwenye kliniki, wataalamu wa huduma za macho watafanya uchunguzi zaidi bila malipo na pia kukupa madawa. Watu wanaohitaji miwani wataelekezwa mahali ambapo wanaweza kuzinunua. Tafadhali fahamu kwamba kuna idadi ndogo ya watu watakaogundulika na matatizo makubwa ya macho watakaoelekezwa kwenye hospitali kuu kwa uchunguzi zaidi na miwani maalum. Hii inaweza kuhusisha gharama.

Baada ya matibabu, utaweza kuona kwa uwazi zaidi. Hii itasaidia katika kazi yako, kusoma, kutazama skrini, na mambo mengine mengi. Ni muhimu kuhudhuria kliniki, au tatizo lako la macho linaweza kuwa mbaya zaidi. Kliniki itakua inafanya kazi tu kuanzia _____ hadi_____, hivyo kama hautaweza kuhudhuria, huenda usiweze kupanga upya mpango huu. Hata hivyo, unaweza kutembelea kituo chochote cha afya kilicho karibu au Kwale Eye Center kwa huduma kama hiyo.

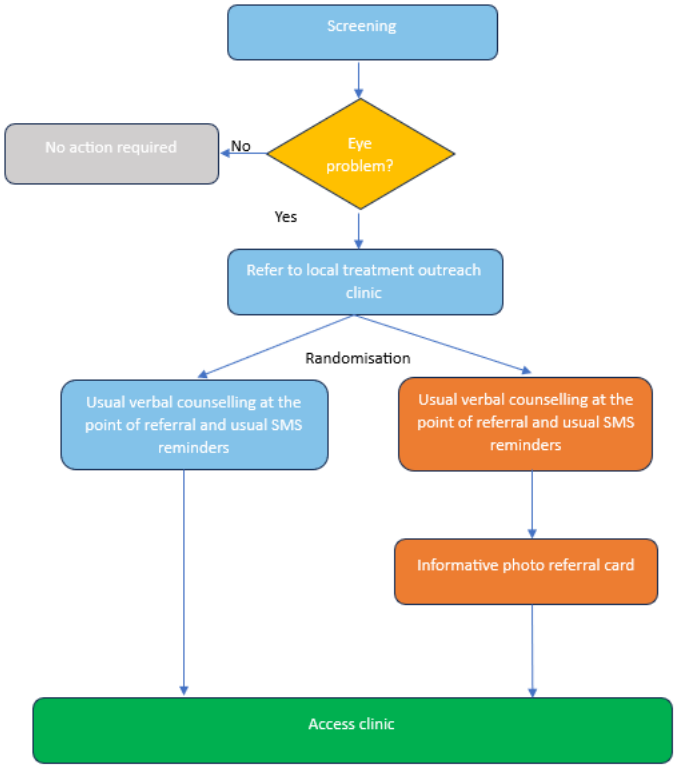

Figure 2: Patient flow in this RCT

10b. Discontinuing or modifying interventions.

The intervention arm will be discontinued (or modified to remove the risk) if there is evidence that the informative photo referral card is harming exposed individuals. We acknowledge that the risk of harm has been previously assessed and found to be low or negligible during the intervention selection stage by a group of researchers, program managers, and lay representatives.

10c. Adherence

There are no *a priori* strategies to improve adherence.

10d. Concomitant interventions

As our trials will be embedded within routine service delivery, we cannot exclude the possibility that local teams will introduce other initiatives before, during, or after individual trials. We will report all programmatic changes that take place during individual trials that could bias our findings. Additionally, since our trial is individually randomized and is of a reasonable size, we would expect that any initiatives would be balanced across our trial arms.

11. Outcomes

This trial focuses on testing an intervention to improve equitable access to eye services among those identified with a need during screening. We will use attendance as a proxy for access. Our primary outcome analysis focuses on adults aged 18-34 (the group found to have lowest attendance in a previous study).

Primary outcome: The proportion of adults aged 18-34 that are referred to a ophthalmic outreach clinic who attend the ophthalmic outreach clinic on their appointed date.

Secondary outcome:

The proportion of adults aged 35 years and above who are referred to an ophthalmic outreach clinic and who attend the clinic on their appointed date.

When a participant is referred, it is recorded within the Peek app and stored in the central database (which holds records of each participant's eye care needs and sociodemographic characteristics) alongside their ophthalmic outreach clinic appointment date and the trial arm to which they have been allocated.

When referred participants check in at ophthalmic outreach clinics, their attendance status is recorded by administrative staff using the Peek app, which automatically updates a central database. Once a participant's clinic appointment date has passed, their outcome status resolves to state whether they attended or not.

12. Participant timeline

This trial is embedded within a routine screening programme. From the individual participant's perspective, they will flow through the screening programmes as normal: participants will have their eyes checked by a first-line screener either in their own home or at a community meeting place, depending on how screening is being run in their location. The screener will ask a series of sociodemographic questions and perform a 'tumbling E' visual acuity assessment, all using the Peek smartphone app. Those who screen positive will be referred to a local outreach treatment centre where their eyes will be re-checked by a more highly skilled practitioner and treatment will be delivered. At the point of referral, those in the intervention arm will receive an informative photo referral card.

13. Sample size

The trial will run for 12 weeks, during which we expect to screen approximately 60,000 individuals, of whom we expect 21,600 to be referred. In the pilot study, about 25% of those referred were aged 18-34, so we expect about 5,400 to be aged between 18 and 34 (16,200 aged 35+). If we assume 80% consent to participate, then we would expect a sample size of approximately 4,320 for the primary analysis (12,960 for the secondary).

In the pilot study, attendance following referral among those aged 18-34 was approximately 30%. So, using this as our expected attendance in the control arm, a sample size of 4,320

participants (2,160 per arm) will give 80% power (at a significance level of 5%) to pick up an improvement of 4.0% (up to 34.0% attendance) in those aged 18-34, and 90% power to pick up an improvement of 4.6%.

Expected attendance (taken from the pilot study) in the control arm of those aged 35+ is 46%. A sample size of 12,960 (6,480 per arm) provides 90% power to pick up an improvement of 2.8% (up to48.8%) in the secondary analysis.

14. Recruitment

As the trial is pragmatic, the VIP programme screeners and data collectors will recruit participants. The screeners will identify potential participants at the point of referral for further assessment and care and inform them about the study. If an individual expresses interest in the study, the screener will assess the individual for eligibility; eligible individuals will be invited to participate in the study, and informed consent will be sought. The Peek Capture app will maintain a recruitment log to document screened individuals and report the number of participants recruited. During the consenting process, participants will be informed that they are free to withdraw from the study at any time without affecting the medical care they would receive from the VIP project.

15. Community engagement

Community health promoters (CHPs) will play a vital role in engaging local communities and ensuring they are well-informed about the study. Before the study begins, CHPs will receive close supervision from Community Health Assistants (CHAs) to sensitize the community about the eye screening program and the research study. Local CHPs will visit the households to sensitize them about both activities before the onset of screening and recruitment into the study. Additionally, the sub-county community health focal person, CHAs, and CHPs will encourage community members to participate in the screening and research during public meetings, such as barazas and other social events. This will help the community understand the research's purpose, benefits, and their roles in it. Regular updates will be provided through various channels, including community meetings and household visits by health promoters.

We also have an established community advisory board that was involved in deliberating the intervention to be implemented. The board, along with CHPs and CHAs, will serve as points of contact for any community concerns related to the study and will assist in disseminating the study findings. Research findings will be shared with this team, who will then relay this information to the community through community action days, barazas, and other local gatherings.

16. Allocation

16a Sequence generation

The randomisation will be restricted to balance the arms in terms of

1) Mean number of referrals per screener
2) Mean attendance rate per screener

The restriction will be based on routine data collected from screeners over the months leading up to the study. Based on this pre-study data, 10,000 suitable random allocations that ensure balance will be generated numbered 0000-9999. From this a four digit number will be selected at random to choose the final allocation.

We will use computer-generated random numbers to generate the allocation sequence and assign all consented, referred participants to intervention arms, with equal numbers of participants in each arm. A simple algorithm embedded in the Peek app will perform this function at the point where the screener records in the Peek Capture app that the patient needs a referral.

16b Allocation concealment mechanism

The allocation is done in a single shot as described above, so there is no need for allocation concealment.

16c Implementation

When the random allocation algorithm within the Peek app assigns a patient to the intervention arm, the Peek app will display a notice to the screener that reads, 'Please take a photo of the participant, print it, and attach it to the referral card. Provide the informative photo referral card to the participant.' The control arm will not receive the card. Both groups will receive the usual counseling at the point of referral, along with SMS reminders on the day of the referral, the day before the appointment, and on the day of the appointment.

17 Masking

17a Who and how

Once assigned by the algorithm, each participant's online record will automatically update to display which arm they have been allocated to. Participants and screeners will not be masked to assignment. Screeners will see allocation status as they are required to deliver the intervention.Outcome assessment will be performed by a different group - those responsible for checking-in participants at outreach clinics. No steps will be taken to mask these staff to participant allocation status.

17b Unmasking

Human investigators and programme managers will not be able to access data on participant allocation to specific arms unless they are involved in delivering an intervention.

The Data Safety and Monitoring Committee (DSMC) will have access to all data at any point and for any reason, including to unmask assignments if required. The trial steering committee

members will only be able to access these data as per the adverse event protocol outlined below.

18. Data Collection

18a Data collection methods

As stated above, outcome assessment (attendance at the clinic) will be recorded when participants check in at the clinic on their appointed date. The central Peek electronic database will record each participant's attendance status. Peek Vision is a leading provider of eye screening software worldwide. The 'Peek Capture app is used to screen participants for vision impairment, capture observations by screeners and health practitioners, and gather demographic data, as well as link participants to a referral system that tracks each of their progression through the local eye health system. The same app is used to collect data on visual acuity, socioeconomic status, referral status, and attendance status (our primary outcome).

19. Retention

There are no plans to promote participant retention and complete follow-up.

20. Data management

All data entry will be performed by programme staff as part of routine screening and clinical care. See the data management plan for further information about coding, security, and storage.

20a Data storage

The data is stored on a Peek managed server hosted in a Virtual Private Cloud (VPC) utilising the Amazon Web Services (AWS) Cloud. Each Peek powered programme is hosted on its own dedicated server and a VPC that will reside in the UK/EU ensuring all of the data privacy safeguards as governed under the GDPR. All data collected is securely stored in AWS data centers which are state of the art, utilising innovative architectural and engineering approaches. More information, including a virtual tour, can be found by visiting this link https://aws.amazon.com/compliance/data-center/.

The hardware and software that will be used in this research include:

Software:

- Peek Capture - is an application that runs on Android devices that supports eye health screening and referral pathways to treatment
- Peek Admin - is a web-based data platform application that is used to view the data collected by Peek Capture, it tracks the Programme progress, provides insights and helps ensure no one is left behind.
- STATA and R, and Excel will be used to analyse the data exported from Peek Admin

Hardware:

- Peek servers are hosted on Amazon Elastic Compute cloud-based virtual machines running Amazon Linux.
- Android devices, locally managed by Peek's implementing partners, Kwale Eye Centre.

Any participants' identifiable data collected by the Study Coordination Centre will be stored securely and their confidentiality protected on Peek Vision servers in accordance with the UK Data Protection Act 1998 and Kenya Data Protection Act 2019. Data and all appropriate documentation will be stored for a minimum of 12 months after the completion of the study, including the follow-up period.

All analyses will be performed on anonymised data (name, date of birth, and address removed), held on encrypted and password-protected servers at LSHTM. Each participant will be given a unique identifier and the data that will be extracted for research purpose will not have names, date of birth, addresses, phone numbers or any other identifying information.

Data will be collected by eye care programme providers using Android devices with access to the Peek Capture application. Peek Capture enforces security controls that include strong device passcodes and native Android encryption. Data stored is time limited, the device syncs via an encrypted connection with a Peek managed server, the data is then deleted to minimise the risk of data stored on the device.

20b Statistical methods

Baseline characteristics of all participants will be described as mean (SD) or median (IQR) for categorical variables, or as frequencies and proportions for continuous variables.

The proportion attending in each arm will be reported, along with the p-value (and odds ratio) from a logistic regression with the outcome as attendance (yes/no) and the exposure as trial arm (intervention/control). For the primary analysis this will be restricted to all those aged 18-34 with the secondary analysis including all participants aged 18+.

20c Equity analyses

The primary aim of the platform trial is to improve equity. We focus on the intervention effect in the left-behind group (those aged 18-34) and also examine how this effect may differ in those outside of this group (those aged 35+). We will do this by checking for effect modification by age group in the logistic regression including all individuals aged 18+ with attendance as the outcome, trial arm as the exposure of interest, and adjust for age group (18-34, 35+) along with an interaction between trial arm and age group.

20d Non-adherence and missing data

Missing data is not considered a great problem because those for whom no attendance was recorded are considered non-attendees. The research officer will supervise the data collection

teams to ensure that participants in the intervention arm receive the informative photo referral card. We will use intention-to-treat analysis.

21 Data Monitoring

21a. Data management team

KEMRI/MOH will be responsible for implementing the study in Kenya, including training and supervising screeners, ensuring data quality, and supporting data analysis and interpretation. All data management will be conducted in accordance with MOH and KEMRI guidelines. Dr. Michael Gichangi, the head of the Ophthalmic unit at MOH, and Sarah Karanja, a research scientist from KEMRI, are the investigators in this study.

Eye care programme providers will collect data using Android devices with access to the Peek Capture application. Peek Capture enforces security controls that include strong device passcodes and native Android encryption. Data stored on the device is time limited. The device syncs via an encrypted connection with a Peek-managed server, and the data is then deleted to minimise the risk of data stored on the device.

From the UK, Dr. Luke Allen, Dr. David Macleod (data analyst), Min Kim (data analyst), and Dr. Nigel Bolster (PEEK engineer) will have access to all data. In Kenya, Sarah Karanja and Dr. Michael Gichangi (Co-Principal investigators) will also have access to these data. David and Min Kim will conduct data analysis and share it with all investigators.

22 Ethical considerations

22a. Ethical review

We will seek ethical approval from the LSHTM ethics committee and the Scientific and Ethics Review Unit, Kenya Medical Research Institute. We will also apply for a research permit from the National Commission for Science, Technology, and Innovation (NACOSTI) and seek permission to conduct the research from the Kwale County health department.

22b. Consent

Informed consent will be sought by screeners during screening - at the point that participants are identified as having an eye care need and referred for further care. At the time of consenting, participants will receive detailed information about the research project, including the objectives and measures taken to respect the confidentiality of the data collected. The participant can either read or have the screener read the consent form. Consent will be recorded digitally using an electronic tick box (as appropriate for low-risk trials). To confirm participation, the participant needs to indicate their choice by ticking either 'Yes' or 'No' themselves. The consenting process and the provision of participant information will be delivered through EpiCollect, a mobile phone data gathering tool with an associated web application, providing two-way communication between multiple data gatherers and a project

database. This platform will be used solely for the digital consenting process and will be used alongside the Peek Capture App that is used during screening. A hard copy of the participant information leaf will be provided to all participants. Participants will be free to leave the trial at any time. There will be no remuneration for participants.

22c. Patient and public involvement

Lay people and a community advisory board have reviewed and contributed to the development of this protocol and all preceding work on identifying the left-behind group and potential service improvements. Lay representatives will assist with interpreting and disseminating the trial findings.

23. Adverse event reporting and harms

An adverse event (AE) is defined as any untoward medical occurrence in a patient or study participant. A serious adverse event (SAE) is defined as any untoward medical occurrence that:

- Results in death
- Is life-threatening.
- Requires inpatient hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability/incapacity
- Consists of a congenital anomaly or birth defect

Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences.

All adverse events will be reported. Depending on the nature of the event the reporting procedures below will be followed. Any questions concerning adverse event reporting will be directed to the study coordination centre in the first instance. The flow chart below has been provided to aid the reporting of adverse events.

Non-serious AEs

All non-serious AEs will be reported to the study coordination centre and recorded in a dedicated AE log within 72 hours. The entry must state the patient ID, date and time of the AE, nature, and relation to the intervention, if any. The AE should also be reported to the data and safety monitoring committee within 72 hours. AE logs will be stored in a secure, password-protected file on an KEMRI computer.

Serious AEs

Serious Adverse Events (SAEs) will be reported to the PI and study coordination centre within 24 hours of the local site being made aware of the event (Figure 5). The PI will report the event to the data safety monitoring committee and ethics committee within 48 hours and include it in the study safety report.

An SAE form will be completed and submitted to the PA and study coordination centre with details of the nature of event, date of onset, severity, corrective therapies given, outcome and causality. All SAEs whether expected, suspected or unexpected will be reported to regulatory bodies and the trial DSMB within 48 hours of occurrence. The responsible investigator will assign the causality of the event. All investigators will be informed of all SAEs occurring throughout the study. If awaiting further details, a follow up SAE report should be submitted promptly upon receipt of any outstanding information.

Any events relating to a pre-existing condition or any planned hospitalisations for elective treatment of a pre-existing condition will not need to be reported as SAEs.

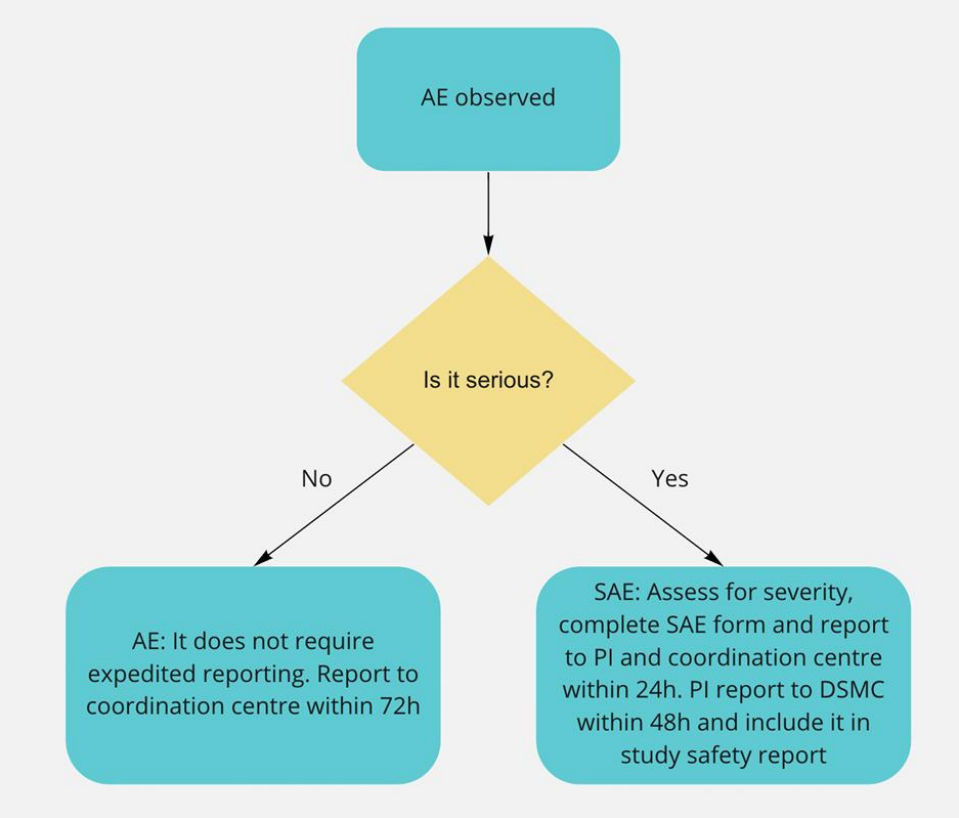

Figure 2: Approach for managing adverse events

Contact details for reporting SAEs

SAE forms will be sent to: mgichangi@yahoo.com and luke.allen@lshtm.ac.uk using the title 'Urgent - SAE'

Tel: Dr. Michael Gichangi: +254 733 343 012 (Mon to Fri 09.00 - 17.00, Nairobi)

Tel: Dr Allen +44 (0) 20 7958 8316 (Mon to Fri 09.00 – 17.00, London)

Responsible Personnel

Chief Investigator (CI)

- The PIs are responsible for the study's conduct and the ongoing safety and evaluation of any interventions being used in the trial.
- Promptly notifying all investigators, Institutional Review Board (IRB) or Independent Ethics Committee (IEC) and Competent Authorities (CAs) of each concerned member state of any findings that may affect the health of the trial participants.
- Keeping detailed written reports of all AEs/ARs identified in the protocol as critical to the evaluation of safety within the agreed timeframes specified in the protocol.
- Accurate production and submission of the Development Safety Update Reports and progress reports to CAs and IRB/IECs.
- Collate all AR/AEs/SAEs/SARs and report to the Sponsor annually.
- Ensure that the PIs report all SAEs/SUSARs immediately to the Sponsor and to the CAs, IRB/IECs and any other relevant parties within agreed timelines (
- Supplying the Sponsor and IRB/IEC with any supplementary information they request.

CO-Principal Investigators (CO-PIs)

- The CO-PIs are responsible for the research performed at the local site, handling and managing the intervention, and informing the CI, Sponsor, Ethics, regulatory bodies, and the trial coordinating team of all adverse events that occur at their site.
- Safety responsibilities:
    - Ensure trial participant safety and the swift and adequate management of trial participants with any type of AE/AR as per the management protocol described below.
    - Reporting all SAEs/SUSARs immediately to the Sponsor and to the CAs, IRB/IECs and any other relevant parties within agreed timelines (i.e. LSHTM, EFMHACA, ORHB, FMOST).
    - Assessing each event for causality, severity, and expectedness. (Note: a medical decision which must be made by the investigator directly involved with the care of the patient/participant experiencing the AE)
    - Ensure adequate archiving of AE records and reports in the local trial office along with the trial master files.
    - Collate all AR/AEs/SAEs/SARs biannually and present to the CI.
    - Guide and supervise the field research team on accurate recording, reporting of all adverse events.

Field Research Team Members (Coordinators, Nurses, Examiners, Recorders)

- All field research team members are responsible for identifying, recording, and reporting any AE or AR to the PIs regardless of severity or causality.
- Assessing each event for causality, severity and expectedness. (Note: a medical decision which must be made by the investigator directly involved with the care of the patient/participant experiencing the AE).
- Ensure that the participant has received the necessary management. This includes advice/reassuring, referral, offering transport, paying for management, making follow-up visits.
- Report to the PIs/Project manager AEs/ARs based on the specified timeline and file all AE/AR recorded forms in the trial master file.

Frequency and plans for auditing trial conduct

The London School of Hygiene & Tropical Medicine, under its remit as sponsor, the Study Coordination Centre, KEMRI Scientific, Ethics and Research Unit, and other regulatory bodies, may subject the study to an audit to ensure adherence to Good Clinical Practice.

Limitations

We have chosen to use a prioritarian approach that focuses on left-behind population groups. This prevents a situation where we accept an intervention that improves the overall mean but is associated with a decline among left-behind groups. This approach does not hedge against the slope of inequality worsening. Unfortunately, using a proportionate approach where we assess whether gains in each group are proportionate to their initial need would risk attributing success to our intervention rather than the more likely detection of regression toward the mean.

We use attendance as a proxy for access. Whilst this is the closest hard indicator available, the semantic implication of the term places responsibility on people rather than clinical systems or societal structures. We will counterbalance this in the language that we use to talk about barriers and in the framing of interventions. We also note that we focus on a proximal indicator that does not always correlate well with receipt of high-quality care, or good clinical outcomes. We decided to focus on access for three main reasons; first it aligns with the conceptual narrative of Universal Health Coverage and ‘leaving no one behind’, second attendance data are already routinely collected and available for every single person who is referred, and third, internal Peek data suggests that the ‘fall off’ gap between those who are referred but do not attend is much larger than other gaps e.g. the proportion of those who attend but do not receive appropriate care, or the proportion of those who receive appropriate care but do not experience improved health outcomes.

Dissemination

The findings will be shared with the programme managers and written up for peer-reviewed publication. No participant names or identifiable information will be used in any of the write-ups. The study findings will be disseminated during quarterly and annual review meetings with implementing partners and representatives from the county health management committee, including community advisory members and county and sub-county community health focal persons.We will also publish our findings in peer-reviewed journals and present abstracts at national, regional, and/or international conferences If the trial proves to be effective, it will guide policy and practice regarding the use of informative photo referral cards to enhance clinic attendance. We will recommend introducing these cards throughout the entire VIP program and other eye screening initiatives in Kenya.

Timelines

Year	2025												2026		
Activities	**Jan**	**Feb**	**Mar**	**April**	**May**	**June**	**July**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**	**Jan**	**Feb**	**Mar**
Proposal development															
CSC approval															
SERU and NACOSTI for approval															
County permission															
Training of research assistants/screeners and pilot															
Mobilization, recruitment, intervention and data collection															
Data analysis															
Manuscript writing															
Dissemination including publication															

Budget

KWALE FIELD BUDGET						
No.	**Budget Items**	**Quantity**	**Cost**	**Duration**	**Total**	**Budget notes**
			Per Unit		**Amount (KES)**	
1	Training of screeners and pilot testing					
	Flight	3	40,000.00	1	120,000.00	Transport for 3 people
	. Transport reimbursement for screeners	65	2,000.00	3	390,000.00	Transport reimbursement for screeners. 65 screeners will require 2000/- transport reimbursement per day for 3 days.
	. Conference package	74	4,500.00	3	999,000.00	Conference package for 65 screeners, Kwale eye centre officers, CHMT representative, KEMRI, and PEEK.
	. DSA for 3 people	3	5,000.00	4	60,000.00	DSA for 3 people for 4 days
	. Accomodation for 3 people	3	20,000.00	4	240,000.00	Accommodation for 3 people for 4 days
	. Transport to the pilot-testing location	74	1,000.00	1	74,000.00	Hire 4 mini vans to transport the team to the pilot testing location
	. Printing and laminating intervention and	140	100.00	1	14,000.00	Print and laminate intervention and control scripts
	. Printing participants information leaf	2000	20.00	1	40,000.00	Print PIL for 2000 participants at 20 KES per PIL (each PIL has 3 pages)
	. Printing of informative referral cards	10000	50.00	1	500,000.00	Print informative cards for 10000 participants at 20 per IC
	. Mobilization of participants (CHP allowance)	20	800.00	1	16,000.00	CHP allowance for mobilizing participants and guiding screeners to participants homes
	Sub-total training and pilot testing				**2,453,000.00**	
2	Recruitment of participants					
	Incentives for Vision Impact Project screeners	65	5,000.00	1	325,000.00	Will cover Vision Impact Project screeners incentive @ 5000 KES per screener
	Sub-total recruitment of participants				**325,000.00**	
3	**Monitoring Visits**					
	Ground transport	1	100,000.00	1	100,000.00	Ground transport for the study coordinator
	Flight	3	40,000.00	2	240,000.00	Flight for 3 people on 2 different visits
	Accommodation	3	20,000.00	10	600,000.00	Accommodation for 3 people for 10 days (2 visits)
	DSA	3	5,000.00	10	150,000.00	DSA for 3 people for 10 days (2 visits)
	Sub-total monitoring/supervisory visit				**1,090,000.00**	
4	**Dissemination meeting**					
	Flight	4	40,000.00	1	160,000.00	Flight for 4 people
	Accommodation	4	20,000.00	3	240,000.00	Accommodation for 4 people for 3 days
	DSA	4	5,000.00	3	60,000.00	DSA for 4 people for 3 days
	Ground transport	1	15,000.00	1	15,000.00	Ground transport in Kwale
	Printing of evidence briefs	25	50.00	1	1,250.00	Print evidence briefs and programme
	Transport reimbursement for county officials	15	2,500.00	1	37,500.00	Transport reimbursement for 15 county officials at 2,500 per person
	Transport reimbursement for CAB members	3	4,000.00	1	12,000.00	Transport reimbursement for 3 CAB members at 4000 per person
	Tea and refreshments	26	1,000.00	1	26,000.00	Tea and refreshments for 26 people @ 1000/ per person
	Sub-total dissemination meeting				**460,000.00**	
	Total Budget				**4,328,000.00**	

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Appendices

Appendix I: Description of Vision Impact Project and Peek Vision

Table 2: Vision Impact Project (VIP)

Vision Impact Project in Kenya: This is a four-year project funded by the Christian Blind Mission (CBM). The project aims to reduce the prevalence of visual impairment and avoidable blindness in seven counties in Kenya by 2025 through:

1. Conducting a Rapid Assessment of Avoidable Blindness (RAAB) survey in selected counties to provide data for informed decision-making and subsequent planning for eye health services.
2. Offering eye screening opportunities to an estimated eight million individuals in the targeted counties, both within communities and schools. Those identified as having eye issues are referred to various levels of care, starting from the primary level.
3. Providing eye health equipment to primary and secondary healthcare facilities.
4. Addressing the shortage of human resources in eye health through training programs for healthcare workers in eye health-related specialties.
5. Enhancing governance frameworks at both the county and sub-county levels.
6. Upgrading infrastructure and ensuring the availability of medical supplies.

The activities implemented are as follows:

1. Screening eye problems in schools and community locations, where both children and adults are evaluated and referred for additional care if any issues are detected.
2. Primary eye care services are provided at primary healthcare facilities. Patients are assessed and sent to hospitals for further treatment if necessary.
3. Patients are referred to secondary hospitals, where they undergo diagnosis, treatment, and rehabilitation.
4. Tertiary hospitals offer specialized treatment and surgical procedures for patients.

*Glasses are provided to patients as needed at optical shops.

Table 3: Peek Vision

PEEK Vision: This is a social enterprise spin-off from London School of Hygiene & Tropical Medicine (LSHTM). Peek provides a rigorously validated eye screening app that is used in 13 countries to enable non-specialist teams to perform large-scale community screening programmes. Programmes follow two main formats: the first is a mobile school- and/or house-to-house programme, where a team works its way through an entire population. In both cases, screeners use the Peek app to deliver 'tumbling E' visual acuity assessments, identifying those whose vision falls below a pre-determined threshold. These positive cases are then referred to local triage and treatment centres where they are offered eye medication, spectacles, cataract surgery, or referral for specialist care as required. Peek also provides the patient referral and flow management software that tracks patients through these systems and can identify 100% of patients who do not attend. Peek is collaborating with LSHTM, the Botswana Ministry of Health, the Kenyan Ministry of Health, Kenya Medical Research Institute, College of Ophthalmology of Eastern Central and Southern Africa, Nepal Netra Jyoti Sangh, Shroff Eye Centre, and the University of Botswana to improve attendance rates and improve equity in screening programme outcomes.

Appendix 2: Data Management Plan

Data and Data Collection Process

The data will be collected in Peek powered Eye Health School and Community Programmes using Peek's Capture application. During the Programmes initial screening process only basic and non-personal identifying data is collected.

Data Fields Collected During the Initial Screening Process:

- Age
- Gender
- Awareness (optional)
- Spectacle status
- Diabetes status (optional)
- Visual Acuity or pass/fail threshold.
- Eye Condition

All those identified as requiring referral will also be asked to provide sociodemographic data to enable us to monitor the equity performance of our programmes e.g. are certain ethnic groups more likely to be screened? The additional sociodemographic indicators are:

- Ethnicity
- Language
- Marital Status
- Religion
- Migrant/refugee status
- Health insurance status
- Disability
- Occupation
- Education
- Food adequacy
- Housing
- Asset ownership

Based on the visual acuity threshold set prior to screening the Peek Capture automatically informs the data collector whether the attendee may potentially need onward treatment. For

those screened negative no further data is collected. Only for those screened positive is further information collected. This ensures data collection is kept to an absolute minimum maintaining privacy and ensuring compliance with data protection regulations.

For those screened positive additional information is collected, but the data is always minimised to ensure only the required data is collected at each stage of the service, as described below.

Data Fields Collected for Those Screened Positive at Triage:

- Name
- Telephone number
- email address (optional)
- Visual Acuity
- Language

Further Data Fields Collected for Onward Treatment:

- Eye Condition
- Prescription
- Diagnosis

Data Collection Tools:

Android Mobile Devices - Data will be collected by Peek's implementing partners using Android devices through the Peek Capture application. Peek Capture enforces security controls that include strong device passcodes and native Android encryption. Data stored is time limited, the device syncs via an encrypted connection with a Peek managed server, the data is then deleted to minimise the risk of data stored on the device.

Data Storage:

The data is stored on a Peek managed server hosted in a Virtual Private Cloud (VPC) utilising the Amazon Web Services (AWS) Cloud. Each Peek powered programme is hosted on it's own dedicated server and a VPC that will reside in the UK/EU ensuring all of the data privacy safeguards as governed under the GDPR. All data collected is securely stored in AWS data centers which are state of the art, utilising innovative architectural and engineering

approaches. More information, including a virtual tour, can be found by visiting the link below.

https://aws.amazon.com/compliance/data-center/

Software:

- Peek Capture - is an application that runs on Android devices that supports eye health screening and referral pathways to treatment
- Peek Admin - is a web based data platform application that is used to view the data collected by Peek Capture, it tracks the Programme progress, provides insights and helps ensure no one is left behind.
- STATA and R, and Excel will be used to analyse the data exported from Peek Admin

Hardware:

- Peek servers are hosted on Amazon Elastic Compute cloud-based virtual machines running Amazon Linux.
- Android devices, locally managed by Peek's implementing partners.

Data-related activities

Task	Description
Start gathering SES data	In month 1 we will start gathering sociodemographic data from: • a representative sample of all those presenting to be screened. • all those identified with an eye care need and referred on for treatment These data will be transferred from Android devices in the field to Peek Admin, hosted on AWS. Note that Peek programmes run continuously, and we intend to gather data from participants in every programme so that we can promote equitable service delivery.

Clean SES data	Routine manual data cleaning will be conducted periodically by Peek administrators. Internal software guardrails will pick up simple errors
Analyse SES data	Every month we will perform simple descriptive statistical analysis of presentation rates and treatment attendance rates by SES category. The output of this analysis will be anonymised and presented as mean attendance rates for each SES subgroup e.g. males x%, females z%.

Quality checks

- Errors are flagged at the point of data entry by software that only accepts pre-specified responses e.g. phone numbers must be comprised of a set string length of digits.
- The software has built-in logic steps
- We will institute training and supervision for all data collectors
- Application logging, audit trails and alerting direct administrators to given issues post-collection e.g. when SMS messages fail to be delivered
- Post-collection human data checking using the Peek Admin programme e.g. for ID disambiguation

5. How will you address ethical & legal issues within your research?

- What permissions are needed? E.g. to collect data in country, analyse data for specific purpose, share data
- From whom must approval be obtained? E.g. study participant, ethics committees, data provider
- How will permissions be provided? E.g. ask participants to sign a consent form, sign a Data Transfer Agreement

Permissions

Local permissions for Peek powered eye health programmes are already in place. This is in the form of data processing agreements with Peek and the local MoH and/or local implementing partner. This provides a legal agreement between the parties that the data can be collected and processed. The proposed research will be authorised by the same parties to ensure full

transparency and the data collection and processing will be managed under the same data processing agreement.

We will obtain written informed consent to collect, analyse, and publish anonymised aggregate participant data in peer-reviewed journals and online open-access data repositories. Individuals will not be identifiable.

In line with UK guidance on risk-adapted approaches to obtaining informed consent, participants will provide consent by ticking a box underneath the following statement:

"I understand that my anonymous data may be shared with other researchers or online. I understand that I will not be identifiable from this information. I understand that my decision will not affect the care that I receive, and I am free to change my mind anytime I like."

Consent will be obtained when participants initially present for screening.

For screening programmes that include children (<18 years), we will seek consent from their parents/legal guardians using the following statement, sent home on a paper form along with the generic participant information leaflets:

"I understand that my child's anonymous data may be shared with other researchers or online. I understand that my child will not be identifiable from this information. I understand that my decision will not affect the care that my child receives, and I am free to change my mind anytime I like."

Approval will be sought from research ethics committees at LSHTM and each of the countries where screening takes place.

Documentation

Standard operating procedures and an overall study protocol will be developed in line with LSHTM research guidance to cover all aspects of the research project.

Standardised online training modules have been delivered for programme implementing partners tasked with data collection in the field.

Training will be delivered to all project staff to ensure that they understand the requirements and are able to follow the SOPs.

We have a data compendium which describes the custom sociodemographic variables that we will collect in each country, available here.

STORAGE AND SECURITY

Pre research data collection and storage in Peek powered eye health programmes

The data will be collected in Peek powered Eye Health School and Community Programmes using Peek's Capture application. Data will be collected by Peek's implementing partners using Android devices through the Peek Capture application. Peek Capture enforces security controls that include strong device passcodes and native Android encryption. Data stored is time limited, the device syncs via an encrypted connection with a Peek managed server, the data is then deleted to minimise the risk of data stored on the device.

The data is stored on a Peek managed server hosted in a Virtual Private Cloud (VPC) utilising the Amazon Web Services (AWS) Cloud. Throughout the eye health programme life cycle only approved implementation partners and Peek team members have access to programme data. Access is strictly controlled through the Peek Admin web based data platform application. This is used to view the data collected by Peek Capture, it tracks the Programme progress, provides insights and helps ensure no one is left behind.

Peek Capture security:

- Peek Capture is installed on implementing partners managed Android devices
- Peek Capture enforces security controls that include strong device passcodes and native Android encryption.
- Data stored is time limited, the device syncs via an encrypted connection with a Peek managed server, the data is then deleted to minimise the risk of data stored on the device.

Peek Admin security:

- Strong passwords, minimum of 12 characters, password strength meter where only 'strong' is accepted, blacklist passwords are enforced to ensure easily guessed and passwords found in data breaches cannot be used.
- 2-Factor Authentication to protect user account security.
- User access permissions are controlled through account privileges, this controls scope of programme so access is restricted and limited to only what a user requires for their

work, admin privileges are restricted to only those that require the access, account management and patient level reporting.
- Accounts disable automatically after 60 days of inactivity.
- User access reviews available for implementing partners to ensure leavers and inactive accounts are removed.

Peek Platform Data Security Assurance:

Peek is an International Standardisation Organisation (ISO) 27001 certified organisation. ISO 27001 certification requires an annual audit by an accredited external auditing body who verify compliance with the industry best practice information security controls.

Peek servers hosted in a Virtual Private Cloud (VPC) utilising the Amazon Web Services (AWS) Cloud. Each Peek powered programme is hosted on it's own dedicated server and a VPC that will reside in the UK/EU ensuring all of the data privacy safeguards as governed under the GDPR. All data collected is securely stored in AWS data centers which are state of the art, utilising innovative architectural and engineering approaches.

More information, including a virtual tour, can be found by visiting the link below:

https://aws.amazon.com/compliance/data-center/.

Annual penetration tests conducted by a 3rd party specialist security testing company. The purpose of the test is to verify whether robust security mechanisms are in place to prevent unauthorised users from accessing data and infrastructure. This penetration test includes:

- Identification of potential vulnerabilities occurring in the application and defining possible attack scenarios conducted with techniques typical for attacks on web applications;
- Simulated attacks from the perspective of an anonymous and standard user;
- Testing API endpoints from the perspective of an anonymous and standard user, including mechanisms such as user authentication, access control, and data validation;
- Security assessment of our infrastructure against the latest industry standard AWS CIS Foundations Benchmark.

The AWS Compliance Program provides further assurance and understanding of the robust controls in place to maintain security and compliance in the cloud. AWS regularly achieves third-party validation for thousands of global compliance requirements that are continuously monitored to meet security and compliance standards for the most sensitive data and privacy

requirements. AWS supports more security standards and compliance certifications than any other offering, including PCI-DSS, HIPAA/HITECH, FedRAMP, GDPR, FIPS 140-2, and NIST 800-171, helping satisfy compliance requirements for virtually every regulatory agency around the globe. More information can be found by visiting https://aws.amazon.com/compliance/programs/.

Peek Platform Data Security Controls:

Peek Servers:

Peek servers hosted in a Virtual Private Cloud (VPC) utilising the Amazon Web Services (AWS) Cloud. Each Peek powered programme is hosted on it's own dedicated server and a VPC that will reside in the UK/EU ensuring all of the data privacy safeguards as governed under the GDPR.

Server OS is Amazon Linux ustlising AWS AMIS to provide base images for our system drives and enhances security by focusing on two main security goals, limiting access and reducing software vulnerabilities. Security updates are applied automatically to test once a week and then rolled out a week later automatically to other environments

Docker:

Peek server software runs in Docker containers. Docker shields application software from variations in platform and co-hosted software. It ensures that development, test and production environments run the same context as one another to ensure consistent, predictable behaviour. Peek servers also use docker swarm mode to achieve failsafe reliability and replication of Mongo databases.

Databases:

Server data is stored in Mongo databases, a fast, scalable, json document database. Peek infrastructure uses a Mongo replica set across two hosts. There are two replicas each holding a full copy of the data and one arbiter. The arbiter is only used for the election of a new master if one of the nodes was to become unavailable. The Mongo database and journal are held on AWS Secure EBS volumes. This provides 256-bit AES encrypted using a key managed under the Amazon Key Management Service.

Amazon Key Management Service, allows us to create and manage cryptographic keys and securely control their use across a wide range of AWS services and within our applications. AWS KMS is a secure and resilient service that uses hardware security modules that have been validated under FIPS 140-2 to protect the encryption keys. AWS KMS also integrates with AWS CloudTrail providing us with secure logs of all key usage. Backups on S3 are also encrypted using keys managed by AWS Key Management Service.

Logging and Monitoring:

Peek Server and Mongo Server logs and uploaded to AWS Cloudwatch for storage and monitoring. AWS Cloudwatch collects monitoring and operational data in the form of logs, metrics, and events and alerts us immediately of problems in any environment, both application and infrastructure.

Network Security:

AWS Security groups are used to provide firewall-like network access control and allow inbound traffic on HTTP and HTTPS ports. Outbound traffic is permitted on any port. The SSH traffic is restricted to subnets associated with devops engineers and the deployment servers. TLS 1.2 is used to secure traffic between device or browser and server.

Operational access to the AWS console is protected with AWS IAM MFA which uses 2-Factor Authentication and ensures that access to AWS is restricted to users with knowledge of password and possession of a specific approved mobile device. Automated access to the AWS API uses AWS Roles with restricted privileges needed for housekeeping, logging and alarm maintenance. No user use is made of Access Keys to eliminate the vulnerabilities of file-system-based credentials.

Threat Detection:

AWS Guard Duty is enabled, this provides a threat detection service that continuously monitors for malicious activity and unauthorised behaviour to protect access, workloads and data. The service utilises up-to-date threat intelligence feeds from AWS, CrowdStrike, and Proofpoint and continuously evolves through machine learning.

Backups:

An Image is maintained of the Server Host using AWS AMI to ensure continuous availability.

A snapshot of the encrypted data volume, containing database and journal, is taken four times daily. Snapshots are retained for two weeks. Access to the snapshots is strictly controlled. Old backups are automatically deleted after 90 days. Backups are stored on AWS S3 storage, also encrypted providing 256-bit AES encryption. The backups are stored across AWS multiple availability zones, this ensures that the data resides in multiple data centres separated geographically and stored in AWS secure data centres.

Additionally, a further backup is made off AWS. Off-AWS backups are replicated to Google Cloud daily via Google Transfer service to identically named buckets and files with a retention policy of 90 days.

Data Centres:

All data collected is securely stored in AWS data centers which are state of the art, utilising innovative architectural and engineering approaches.

Disaster Recovery:

A full disaster recovery test is performed at least annually to ensure servers, applications and databases can be fully recovered within 24 hours.

Export/data sharing for analysis

At the analysis stage pseudo-anonymised data will be exported in an encrypted zip file CSV file to LSHTM researchers to perform statistical testing. The zip file will be saved on the protected LSHTM server and only named project staff will be given access. Passwords will be sent separately. We will only ever export the minimum data required for the analyses.

Labelling conventions

1. Keep file names short, meaningful and easily understandable to others.
2. Order the elements in a file name in the most appropriate way to retrieve the record.
3. Avoid unnecessary repetition and redundancy in file names and paths
4. Avoid obscure abbreviations and acronyms. Use agreed University abbreviations and codes where relevant.
5. Avoid vague, unhelpful terms such as “miscellaneous” or “general” or “my files”

6. Use capital letters to delimit words, as the preferred option, although underscores (_) or hyphens (-) may add clarity, they make the file name longer.

7. For numbers 0-9, always use a minimum of two digit numbers to ensure correct numerical order (e.g. 01, 02, 03 etc.)

8. Dates should always follow same format: YYYY-MM-DD e.g. 2017-04-25

9. When including a personal name give the family name first followed by initials, with no comma in between e.g. SmithAB

10. Avoid using common words such as 'draft' or 'letter' at the start of file names unless doing so will make it easier to retrieve the record.

11. Use alphanumeric characters i.e. letters (A-Z) and numbers (0-9). Avoid using invalid characters in file names such as *? \ / : # % ~ { }

12. The file names of records relating to recurring events should include the date and a description of the event, except where the inclusion of these elements would be incompatible with rule 3.

13. The version number of a record should be indicated in its file name by the inclusion of 'V' followed by the version number (e.g. V01, V03 etc.). However versioning is enabled automatically in systems such as Office 365 and One Drive for Business, making it unnecessary to duplicate this information in the file name itself.

e.g. 2021-11-19_Topic_Filename-variable01

How will we keep data safe and secure?

Only anonymised data will be used - personal, sensitive, or otherwise confidential data is not needed for the research		Store personal details in a separate secure location & link it via an identifier	Not required	Delete personal & confidential details at earliest opportunity (specify when below)	X
Use digital storage that require a username/password or other security feature	X	Physical security (such as locked cabinet or room)	X	Protect portable devices using security features, e.g. biometric	

Encrypt storage devices	X	Encrypt during transfer	X	Avoid cloud services located outside EU	X
Take 'Information Security Awareness training'	X	Ensure backups are also held securely	X		
Notes:	The aggregated Peek data that is shared with LSHTM project staff will not contain any names, however the data being shared may still permit the identification of individuals depending on the domains being shared and may therefore constitute pseudo-anonymised data. We also note that there is not adequate shared secure storage space at LSHTM. We will have to use our personal H drives which is suboptimal for joint working and version control.				
Identify additional steps you will take to avoid, reduce, or eliminate risks that may affect your resources.					

ARCHIVING & SHARING

All data will be stored for 10 years.

- Files intended for sharing may be hosted in the LSHTM data repository (http://datacompass.lshtm.ac.uk) or a 3rd party repository, such as UK Data Service, ArrayExpress, Zenodo, etc.
- Internal and confidential files can be held on the LSHTM Secure Server
- Internal confidential files will be retained on Peek's secure servers.
- LSHTM analyses will be saved on encrypted and password-protected files on LSHTM SharePoint, with access restricted to the project team. Once the project is complete these files will be moved to a secure server.
- Data presented in publications (anonymised aggregate mean attendance rates for each SES subgroup) will be published on GitHub.

When will the resources be made available?

During the research life		At the same time as findings are published	x	A set time after research end, e.g.	

		in an academic journal		12 months. Specify below	
Resources already available (provide details below)		On completion of my thesis		Other (provide details below)	
Further information / Other					

How will we make other researchers aware that the resources exist?

Publish a metadata record describing the resources in a repository or other catalogue		Obtain a Digital Object Identifier (DOI) or other permanent ID	
Cite resources in future research papers, e.g. in the data access statement or reference list	x	Cite resources in project reports	x
Publish a description for the project website		Write and publish a Data Paper	
Add resources to a list of your academic outputs	x		
Other measures / Further details			

What steps will we take to ensure resources are easy to analyse and use in future research?

Prepare a codebook or other documentation that provides an accurate description of content		Store resources in open file formats such as CSV, Rich Text, etc. See https://www.ukdataservice.ac.uk/manage-data/format/recommended-formats	x
Write a user guide that provides a high-level overview of research		Apply a standard licence that allows a broad range of uses (e.g. Creative Commons, Open Data Commons)	

Designate a corresponding author / data custodian who will handle data-related questions	x	Use domain-specific standards that make it easy to import and analyse data	
Other / Further information			

Conditions on access/use

Requirement:	To be addressed by:
In line with the UK concordat on open research data (2016), anonymised data from this trial will be made available to bona fide research groups (evidenced via CVs and the involvement of a qualified statistician), and in line with the trial's publicly available data sharing policy, following review and approval from the trial's data monitoring committee. No reasonable request will be turned down, and the appropriate data will be made available within 1-month of receiving the request. There may be multiple levels of permission required in-country before data can be shared, including national ministry of health approval and local implementation partner approval	The PI will forward requests for data to the in-country leads in order to seek the relevant permissions. We will respond to any boa fide request within 28 days.

RESOURCING

With respect to costs of resources, we have adequate funding within the Wellcome project grant. The data is collected through active live Peek powered programmes where funding and resources is already provided for data collection and data security.