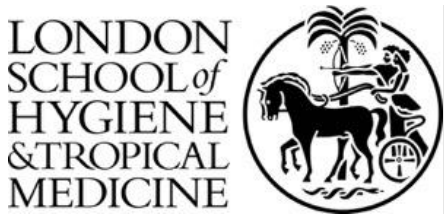
Improving equitable access to community-based health services: Developing and testing a new model in Kenya's national eye screening programme

- Dr Luke Allen -



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Department of Clinical Research
Faculty of Infectious and Tropical Diseases
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Declaration

I, Dr Luke Allen, conform that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Luke Allen

1st May 2024

Abstract

Background

Approximately one third of the global population cannot access essential health services. Access is strongly determined by sociodemographic group membership, with marginalised groups often experiencing the highest health needs but the worst access to care. I aimed to develop a continuous improvement approach to identify and address inequitable barriers to care, and then test this approach in the context of a community-based eye screening programme in Kenya, where half of all people do not receive the eye care they need.

Methods

I conducted evidence reviews to inform the development of an overall approach (dubbed 'IM-SEEN'), and then implemented the three stages in Meru county, Kenya: 1) a cross-sectional sociodemographic analysis of access to community-based eye care clinics, 2) interviews, a survey, and a multistakeholder workshop to identify barriers and potential service modifications to improve equitable access to care, 3) setting up an embedded randomised controlled trial (RCT) to test the most promising service modification within the ongoing screening programme.

Findings

After analysing data from 4,240 people referred to local eye clinics, I found that only 46% reached care. Younger age, male gender, and sales/services/manual occupation were the strongest predictors of non-attendance ($p<0.001$). During interviews with 67 people aged 18-44 who had not received care, 21 different barriers and 25 potential solutions were suggested. I asked a further 401 members of the same group to rank the solutions and took the results to a multistakeholder workshop. Lay representatives, programme partners, and public health experts identified *enhanced information provision* as the most promising solution. I set up an embedded, pragmatic, adaptive platform trial. In the near future this will be used to test whether enhanced information provision – and other interventions that arise from further iterations of the IM-SEEN cycle - improve access to care.

Conclusions

The IM-SEEN approach grounds continuous service improvement in engagement with groups who face the greatest barriers to care. The approach can be used to rapidly generate and test service modifications intended to improve equitable access to care.

“The loss of sight is a tragedy, but when it happens despite being preventable, that is an outrage.”

Tedros Adhanom Ghebreyesus

“The main challenge to making progress towards Universal Health Coverage comes from persistent barriers to accessing health services.”

WHO Thirteenth General Programme of Work

‘Leave no one behind’ is the central, transformative promise of the 2030 Agenda for Sustainable Development.

Signatories to the Agenda for Sustainable Development

“Every system is perfectly designed to get the results it gets.”

Paul Batalden

Table of Contents

List of Appendices

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Peek Vision

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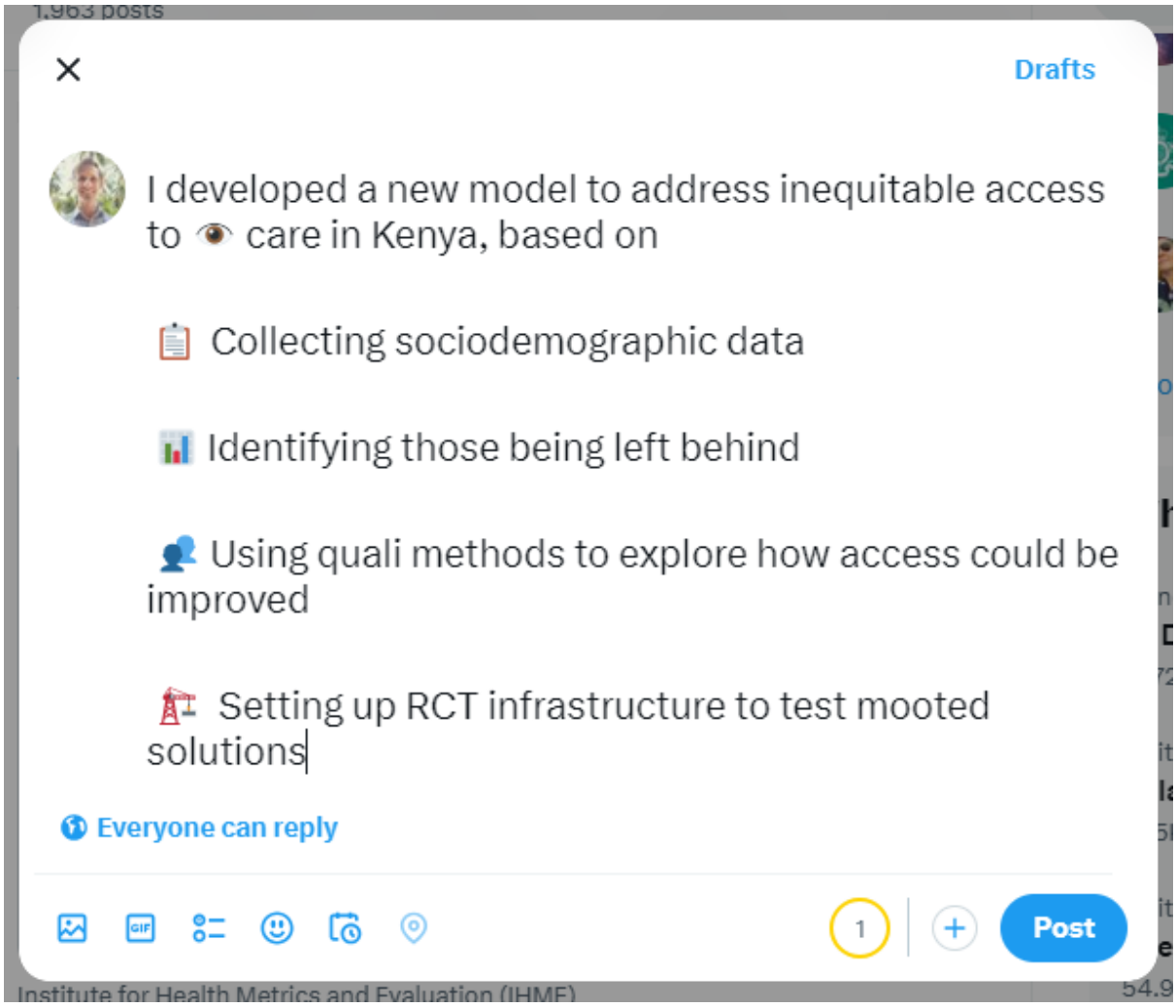
Thesis in a sentence

We should be continuously identifying and engaging with people who face the greatest obstacles to accessing health care.

Thesis in a tweet



Infographic summary

Who faces the greatest obstacles to eye care?

INTERNATIONAL CENTRE FOR EYE HEALTH

peek vision

THE CHALLENGE

Globally, only around **half of people** who are screened for an eye problem manage to reach treatment for their condition, even if it's for free.

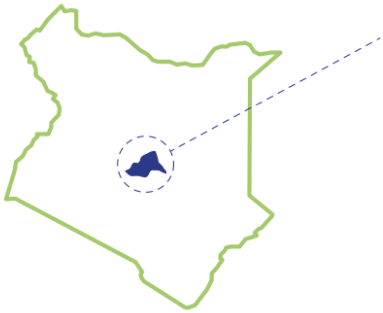
THE APPROACH

This PhD project aimed to develop a system to:

Identify the groups with the lowest attendance rate

Identify the barriers facing them

Test interventions suggested by these groups



MERU COUNTY

An ongoing eye screening programme in Kenya's Meru county was studied. Of 4,240 people referred to clinics, only **46% arrived for treatment**. People under 44-years-old were the least likely to access care.

THE ENGAGEMENT

We interviewed younger adults who couldn't access care and asked them what was stopping them. We collected suggestions on how to improve attendance from 67 people, then asked 400 more to rank the ideas.

THE INTERVENTION

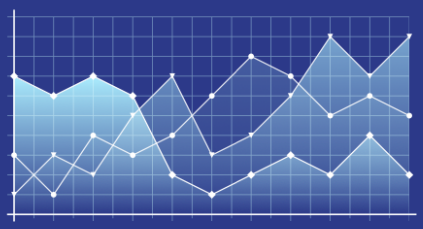
What we found was many younger adults experienced poor counselling at screening. They wanted more information about when and where to go for treatment, what would happen at the clinic, and if there would be any costs.

THE TRIAL

We have created a platform trial that will test service modifications suggested by left-behind groups. It will administer interventions to half of people referred to clinics, before seeing whether this group is more likely to attend treatment than those receiving standard care.

NEXT STEPS

We will use the platform trial to test whether enhanced counselling improves access in late 2024. We will then continue to use the approach in Kenya and other countries to identify and tackle low and inequitable access to care. In regular screening programmes, only 25% of referred people reach treatment. Whilst programmes powered by Peek Vision can lift this figure to 50%, we aim to connect much higher numbers of people with the care they need, focusing on left-behind groups.



Lay summary

Low and unequal access to health services is a big problem around the world. Often it's the poorest and most marginalised groups of people that face the greatest obstacles to getting the care they need. In 2015, world leaders came together at the United Nations to pledge to deliver 'universal health coverage', which means ensuring that all people have access to all the health care they need, without suffering financial hardship. The same world leaders promised to 'leave no one behind' and 'reach the furthest behind first'.

I've been working with eye screening programmes in Botswana, Kenya, India and Nepal, alongside researchers and screening programme managers in each of these countries, plus Peek Vision - the organisation who provide all of the programme design, screening software and programme reporting, and my fellow researchers at the London School of Hygiene & Tropical Medicine. Analysts from Peek Vision suggest that in most of the screening programmes they support, only around half of all people found to have an eye problem manage to access the care they need at treatment outreach clinics, even if it's provided for free. Sadly, the proportion of people connected to care is even lower across traditional eye screening programmes, with only around 1 in 5 tending to receive the care they need. This is a common story across many health services, and across many different countries. As a result, programme managers are trying to improve access to their services. This task is difficult because they don't know which groups are being left behind, they don't know how to modify their services to make it easier for these people to access, and even if they did, they don't have scientifically robust ways of testing whether changes to their services actually improve attendance.

For my PhD, I led the development of a new approach that could be used to identify which groups are facing the biggest barriers to accessing care in Kenya's Meru County eye screening programme. To do that, I introduced a set of questions that were asked of every person who was found to have an eye problem and referred to their local treatment clinic. These questions were about each person's age, gender, marital status, religion, income, education, occupation, disabilities, health insurance, vehicle ownership and type of flooring. The eye screeners gathered these data from 4,240 people who were referred, and then we performed a statistical analysis to see which characteristics – if any – were associated with not being checked-in at the treatment clinic. Younger age, male gender, and sales/services & manual occupations were all strongly associated with poor access. Those aged under 44 years old were the least likely to access care. Overall, we found that only 46% of all those referred were able to access these clinics.

Next, I developed an approach to rapidly interview young people who didn't manage to access care. We asked these people about the unique barriers they faced, and for their ideas on how we could improve the programme to improve access. Normal 'qualitative' interviews can take months to perform and analyse, which is too long (and expensive) for most health programmes to support. I performed a systematic internet search to find examples of previous studies that had found faster ways to get the same results. I then created a bespoke approach and we used it to explore 67 younger adults' ideas about how to improve the programme (in 1 week). I wanted to check these ideas with a much bigger number of young people who had not been able to access care, so I trained data collectors to call 400 people and ask them to rank each of the suggestions. I then held a meeting with the programme funder, the programme implementers, and lay representatives where we reviewed the top-rated suggestions and picked one to try. We settled on providing people with more information about the treatment outreach clinics, as many younger people told us they did not attend because they didn't know why it was important, what happened there, and if there would be any costs. For context, when people are referred, they are told when and where to go, but not this extra information.

For the final part of my PhD project, I set up a special way of testing potential solutions called a 'platform randomised controlled trial'. This enables local researchers to robustly test any number of service modifications. The first trial will start later this year, testing whether provision of the extra information makes a difference to attendance rates. In these trials a random number generator will decide who gets the service modification (e.g. an enhances SMS reminder). Working with some very clever statisticians, I helped to set up the algorithm that lives inside the Peek Vision screening software. It will keep track of who has been referred, whether they were randomly assigned to receive the modification (e.g. the enhanced reminder or the standard information), and how many people from each group reach care. The algorithm has been programmed to compare the check-in rate every week and tell the programme managers when it is confident that either there is a meaningful difference between the groups, or that it is confident there is no meaningful difference at all.

I set up the trial in such a way that it can be used to test lots of different things over time, but always looking to compare some new service modification against standard care, in terms of which is associated with better access. It is really important to use robust tools to test whether ideas work. In science 'negative' results are just as important as 'positive' results, as they help us focus our resources and effort on things that actually work. The platform trial took a long time to set up, but will make it much faster to run a long series of trials to test lots of different service modifications. The idea is that the programme managers are now equipped to rapidly find out what works and what doesn't.

In the coming years, the approach could be used to test a wide range of potential service improvements in eye screening programmes across the world. For instance, platform trials could be used to test ideas like subsiding the cost of spectacles, providing free transport to outreach clinics, or phoning people up to re-book them in for assessment if they do not attend on their appointed day (all of which were suggested by left behind groups in Uttar Pradesh when I visited two weeks ago).

Looking further ahead, the approach that I've helped to develop could also be used in a very wide range of non-eye settings; in fact anywhere where health services are not equally accessible to all groups. For instance, my own GP practice in Oxford has relatively low levels of cervical cancer screening uptake, and I have a hunch that women from non-European ethnic groups may be facing systematic obstacles. The simple approach I have developed in this PhD could be used to analyse data that we already hold (but very rarely use) to work out if access rates differ for different sociodemographic groups. Our reception team could call a sample of women from the group with the lowest access rates to explore any unique barriers and discuss potential solutions. Then we could use randomisation as we implement these suggested changes to work out whether they truly work. On a larger scale, the approach can be used across major programmes, as well as for primary care-based services that manage multiple conditions. I'm currently preparing follow-on work to use our approach to improve access to diabetes, blood pressure, and nutrition services in Kenya, working with the national government.

In summary, I led the development of a new approach to 1) Identify the group with the worst to access to care, 2) rapidly engage with this group to understand their ideas for how to make things better, and 3) test these ideas using a robust approach that is embedded into the screening programme software.

Along the way, I performed a number of additional pieces of research:

- I wondered whether it would be cheaper and faster to use phone calls, web surveys, or automated phone calls to ask the questions about income, occupation, education etc, so I performed a systematic search of previous studies that had compared these approaches. Analysis of 11 studies from seven countries suggested that response rates, acceptability, and data quality were very similar across the different modalities.
- I wondered whether it would be cheaper and faster to use phone calls to interview people, rather that driving out to meet them all face-to-face, however I was worried that the answers from phone calls would be less rich. So we did both and then compared the costs, time requirements, and the richness of the data from both approaches. We found that phone calls were indeed quicker and less expensive. They generated shorter quotes and less data overall, but an equivalent number of themes i.e. unique barriers and solutions.

- I coordinated some pilot work to plug the testing algorithm into the Peek Vision screening software in Botswana. We found that the algorithm worked well, but the trial was stopped before it could properly end because the government suspended the treatment clinics due to issues hiring enough optometrists.
- I also published an article reviewing the philosophical concepts undergirding 'universal health coverage', and a paper that summarises the new approach, dubbed '**Im**provement **s**tudies for **e**quitable and **e**vidence-based i**n**novation', or 'IM SEEN' for short. That includes the image below, outlining the three main stages: Gather, Engage, and Test (Figure 1).

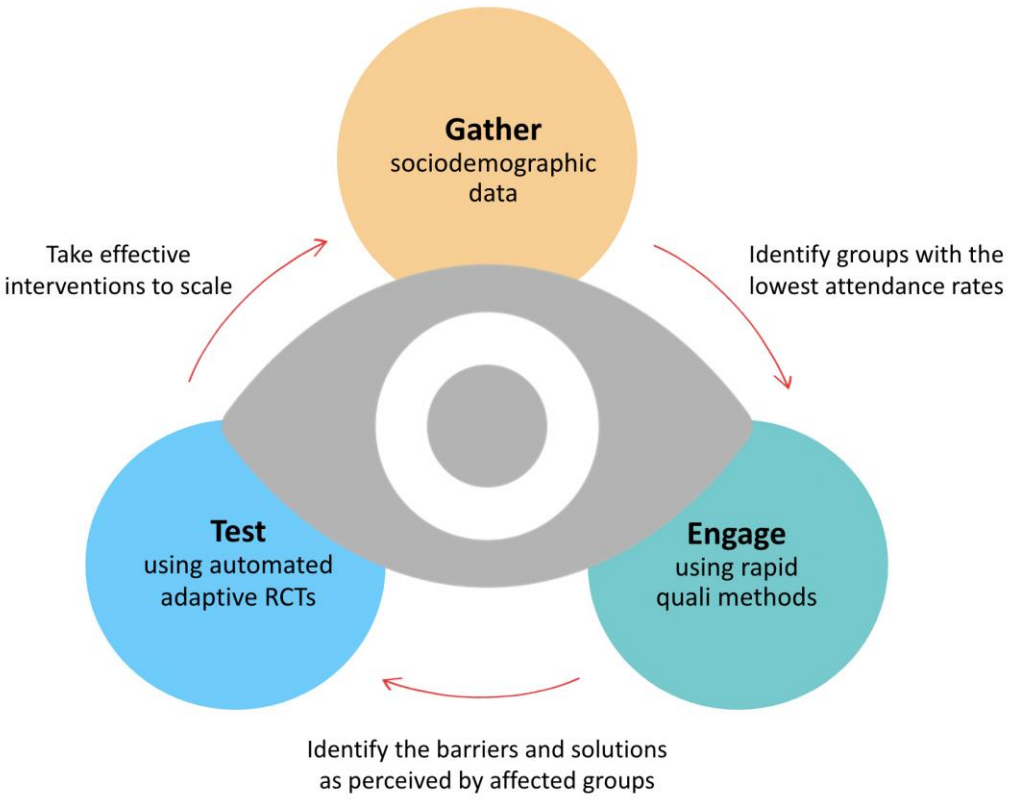


Figure 1: The three stages of the 'IM-SEEN' approach

Extended scientific abstract

Background

In the face of ubiquitous socioeconomic inequalities and poor access to high quality care, world leaders have pledged to deliver universal health coverage and 'leave no one behind'. However, without routine data collection, health programme managers have no way of knowing which groups are being left behind. They also lack rapid tools to identify the pertinent barriers faced by marginalised groups, or their ideas around solutions. Programme managers also lack the skills, time, and resources to robustly evaluate whether service modifications equitably improve attendance.

The field of eye care provides an instructive example. Avoidable visual impairment is a major cause of global disability that severely limits social and economic participation, despite the availability of highly effective and low-cost interventions like spectacles and cataract surgery. Research suggests that members of disadvantaged social groups are the least likely to receive basic eye care. Programme managers want to improve equitable access but have limited resources available to do so.

Aim

I aimed to develop a continuous improvement approach that can be used to identify and equitably address barriers to access. I aimed to test the approach in a community-based eye screening programme: identifying which group was the least likely to access eye care; exploring their perceptions of barriers and potential solutions using rapid methods; and then setting up an adaptive platform trial that could be used to test the most promising of these solutions using an embedded, automated, design.

Methods

This thesis comprises: 1) a literature review of the philosophical underpinnings of universal health coverage and *health for all;* 2) collaborative work to develop the initial continuous improvement approach; 3) a systematic review to compare the costs and performance of different modalities of sociodemographic data collection; 4) a smartphone-based survey to pilot this approach; 5) an equity analysis to identify which groups face the greatest barriers to accessing treatment clinics in Meru County, Kenya; 6) a scoping review of rapid methods to engage with left behind groups to explore their perceptions of barriers and potential solutions; 7) a rapid exploratory-sequential mixed-methods study to explore the perceptions of the left behind group in Meru County, and then identify a service modification to test; 8) an embedded study to compare the time requirements, costs, and data richness of face-to-face vs telephone-based interviews; 9) an adaptive platform trial master protocol that can

be used to test multiple interventions over time; 10) the protocol for an embedded, pragmatic, automated, individual-level, two arm, superiority randomised controlled trial to test the intervention suggested by the left behind group, under the adaptive platform trial master protocol.

Findings

My literature review concluded that approaches to delivering universal health coverage and health for all are increasingly grounded in 'proportionate universalism' i.e. resourcing and delivering services at a scale and intensity that match each given group's level of need. However, this approach has proven difficult to operationalise. The 'IM-SEEN' approach that I led the development of seeks to identify the group with the worst access to care and focus service improvements around the experiences, ideas, and perceptions of this group. My systematic review found that response rates exceeded 80% for in-person and voice calls, and high levels of equivalence and acceptability were reported across all modalities, however no cost data were reported. My smartphone-based pilot survey found that fewer than 10% of people provided their sociodemographic data using this modality. My equity analysis of data from 4,240 people found that age, gender, and occupation were the strongest predictors of non-attendance. Of these, younger age (<44 years) was the most strongly associated characteristic ($p<0.001$). My scoping review found a number of novel techniques that can be used to conduct qualitative interviews quickly without necessarily compromising quality. My exploratory sequential mixed-methods study involved telephone interviews with 67 people aged 18-44, and 400 surveys with members of the same group. 21 barriers and 25 potential solutions were suggested. After a multistakeholder meeting it was decided to implement and test enhanced information provision via SMS reminders and at the point of referral counselling. My embedded study found that telephone interviews were 40% faster and 45% less-expensive than in-person interviews, but generated less rich data. However, both approaches produced an equivalent number of unique barriers and potential solutions. The adaptive platform trial master protocol uses an automated approach whereby randomisation, allocation, outcome assessment, and statistical testing (using stopping rules) are all embedded into the screening programme software. Finally, I have written the protocol for the first randomised controlled trial to take place in Kenya, testing whether enhanced SMS and counselling improves attendance in comparison with usual care.

Conclusions

The IM-SEEN approach grounds continuous service improvement in engagement with groups who face the greatest barriers to care. The approach can rapidly generate and test service modifications intended to improve equitable access to care.

Abbreviations

APT	Adaptive platform trial
CBM	Christian Blind Mission
cRCT	Cluster randomised controlled trial
GDP	Gross domestic product
HDI	Human development index
ICEH	International Centre for Eye Health
ISRCTN	International Standard Randomised Controlled Trial Number
KEMRI	Kenya Medical Research Institute
LMIC	Low- and middle-income countries (World Bank analytic classification)
LSHTM	London School of Hygiene & Tropical Medicine
MoH	Ministry of Health
MRC	Medical Research Council
NCD	Non-communicable disease
PAHO	Pan American Health Organization
RCT	Randomised controlled trial
RMNCH	Reproductive, maternal, newborn and child health
SES	Socioeconomic status
VIP	Vision Impact Project
WHO	World Health Organization

Acknowledgements

This thesis had a lot of moving parts, embedded within a fast-moving programme, run with an amazing team, distributed across many time zones. This project was - and continues to be - a team effort and I'm indebted to everyone who made this thesis possible. Firstly, thanks to Andrew Bastawrous, my friend and primary supervisor who originally talked me into the role as we walked around Streatley meadow. Your visionary leadership, humility, trusting delegation, and passionate commitment to health and social justice are inspiring. Thank you to Matthew Burton, my secondary supervisor for your carefully considered advice, concern for my holistic development, and conscientious review of the many, many pages this work has generated – extending well beyond the papers included in this thesis.

Thank you to Dave Macleod – longsuffering statistician – for your patience with me, your responsiveness, and your competence. Thanks also to Jacqui Ramke, my other PhD advisory panel member, for ensuring that equity remained at the heart of everything we worked on. Your co-author comments always bring sharp focus to the most marginalised.

Thanks to Min Kim who has been working hard to develop and test the underlying adaptive Bayesian algorithm that powers our RCTs. In Kenya, it's been my great pleasure to work with Michael Gichangi, Cosmas Bunywera, Hilary Rono, Lorna Mutwiri, and Lorna Kajuju. Thanks to our data collectors Dickson Gachobi, Purity Kathure, Emmaculate Muturi, Elizabeth Mutile Muasa, Faith Kagwiria, and Benjamin Ntabathia, and to the screeners and eye clinic staff who run the VIP programme. Thanks also to the local and national Ministries of Health, and KEMRI for your welcome and continued support. Christian Blind Mission and African Inland Church teams are also essential to the continued operation of the VIP programme in Meru and other counties. Thanks to Josiah Onyango for reuniting me with my mobile phone in Nairobi, and the wider team at COESCA for your warm support. Thanks to Oruko Samuel for your dry sense of humour and safely driving me (and my family) many hundreds of miles over the course of the project. This work would not have been possible without Sarah Karanja, a brilliant and unflappable KEMRI social scientist who has become a valued collaborator and good friend.

In Botswana I'm grateful to Bakgaki 'BK' Ratshaa, Oathokwa Nkomazana, Ari Ho-Foster, Keneilwe Motlhatlhedi, Kgotlaetsile Sewawa, and the wider team at the University of Botswana, and the Ministries of Health and Education.

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Up in Glasgow, I'm grateful to Shona Mackinnon and David Blaine for your help with the JAMA Network Open systematic review; you both made it more enjoyable than it had any right to be. Similarly, Hagar Azab and Ronald Jonga did a great job assisting with the BJGP Open scoping review, thank you.

I'd like to acknowledge the thousands of people in Kenya, Botswana, India and Nepal who participated in this research, granting permission for their data to be used without any direct benefit to themselves. I'm profoundly grateful for your trust and generosity. Me and the team are working hard to translate our findings into real-world changes to make eye care available to all.

I want to thank my family for their love, tolerance, and support, particularly around the travel and endless zoom calls at funny times of day. Jo, Theo, Ori, and Atti – I love you all dearly and I'm immensely proud to call you my own. Thanks to my parents for your consistent loving support, and especially to Dad for proof reading much of this thesis.

Finally, I'm grateful to my examiners for committing your time and mental energy to read and appraise my work.

Figure 1: Eating nyama choma in Meru with Jo, Sarah, and Lorna

Person	Position	Contribution
Hagar Azab	Research assistant, LSHTM	Systematic review second reviewer
Andrew Bastawrous	Professor, LSHTM	Supervisor. Guidance with project design, fieldwork, analysis, and thesis writing
David Blane	Senior clinical lecturer, University of Glasgow	Support with the design of the systematic review
Matthew Burton	Professor, LSHTM	Supervisor. Guidance with project design, fieldwork, analysis, and thesis writing
Nigel Bolster	Head of Engineering, Peek Vision	Software lead. Assisted with study design and implementing the RCT algorithm
Cosmas Bunywera	Programme management lead, Peek Vision	Managed Peek's side of the screening progamme in Meru
James Carpenter	Professor, LSHTM & MRC clinical trials unit	Design support for the adaptive platform trial

Jenny Evans	Assoc professor, LSHTM	Guidance with scoping review study design
Dickson Gachobi	Research assistant, KEMRI	Performed interviews and surveys in Meru
Michael Gichangi	Head of Ophthalmic Services, Kenyan Ministry of Health	Guidance with project design and facilitation of all work in Kenya
Stephen Gichuhi	Associate professor, University of Nairobi	Reviewed and revised the first draft of the systematic review writeup
Iris Gordon	Information specialist, LSHTM	Co-design and conduct of searches for the systematic and scoping reviews
Ari Ho-Foster	Assistant programme director, research & grad studies, University of Botswana	Guidance with study design for the overall approach, helped to navigate local regulatory processes in Botswana
Mohd Javed	Programme manager Shroffs Charity Eye Hospital	Review of the rapid qualitative protocol

Ronald Jonga	Research assistant, LSHTM	Screening and data extraction for the scoping review
Faith Kagwira	Research assistant, KEMRI	Performed interviews and surveys in Meru
Lorna Kajuju	Research assistant, Meru County Department of Health	Facilitated in-person interviews in Meru
Sarah Karanja	Senior research scientist, KEMRI	Research design support for the qualitative elements, logistics, supervision of research assistants, support with analysis, interpretation, and contextualisation of the data
Min Kim	Statistician & fellow PhD candidate LSHTM	Development of the Bayesian algorithm, simulation testing, and guidance with the platform trial design
Purity Kathure	Research assistant, KEMRI	Performed interviews and surveys in Meru
Shona Mackinnon	Academic GP NHS Scotland	Second reviewer for the systematic review, assisted with parts of the analysis and revision process

David Macleod	Associate prof, statistician, LSHTM	PhD advisor and lead statistician for the underlying research programme. Advice and support on all statistical aspects of the thesis
Ana Patricia Marques	Assistant prof, health economist, LSHTM	Advice on health economics elements of the thesis
Sailesh Mishra	Executive Director Nepal Netra Jyoti Sangh	Guidance with project design and facilitation of all work in Nepal
Kenilwe Motlhatlhedi	Lecturer, University of Botswana	Guidance with project design and facilitation of all work in Botswana
Elizabeth Mutile Muasa	Research assistant, KEMRI	Performed interviews and surveys in Meru
Emmaculate Muturi	Research assistant, KEMRI	Performed interviews and surveys in Meru
Lorna Mutwiri	Research assistant, Meru County Department of Health	Facilitated in-person interviews in Meru

Alice Mwangi	Country director, Operation Eyesight	Reviewed and revised the first draft of the systematic review writeup
Oathokwa Nkomazana	Professor, University of Botswana	Guidance with project design and facilitation of all work in Botswana
Benjamin Ntabathia	Research assistant, KEMRI	Performed interviews and surveys in Meru
Bakgaki Ratshaa	Researcher, University of Botswana	Contributed to research design, Managed logistics and local academic processes in Botswana
Jacqueline Ramke	Associate professor, LSHTM	PhD advisor and health equity sounding board, advised on methods and helped to refine analyses and writeups
Hilary Rono	Kenya country lead, Peek Vision	Oversaw all screening programme activities in Kenya and provided valuable input on methods and approach
Abhishek Roshan	Project manager, NNJS	Guidance with project design and facilitation of all work in Nepal

Shalinder Sabherwal	Director of public health & projects Shroff's Charity Eye Hospital	Guidance with project design and facilitation of all work in Nepal
Oruko 'Sammy' Samuel	Self-employed	Driving many hundreds of miles
Nam Thaker	Head of continuous improvement, Peek Vision	Methods input and advice on how to maximise the real-world utility of the IM-SEEN cycle
Malebogo Tlhajoane	Research Fellow LSHTM	Programmatic support, methods input, formatting of articles for submission, and assistance with managing ethics processes

Figure 2: Screening team after a day of village outreach

PhD structure

Part 1: Background

Chapter 1: Health for all, Universal Health Coverage, and essential eye services

Chapter 1 introduces the central ideas of 'health for all' and Universal Health Coverage (UHC), and then examines the global evidence on health inequalities. There is clear evidence that marginalised groups often face the greatest barriers to accessing care, despite having the greatest need. Later sections in the chapter zoom in to consider inequalities in access to eye care around the world, before introducing the geographic and programmatic context for this PhD.

Chapter 2: The philosophical foundations of health for all and UHC

Chapter 2 lays the philosophical groundwork of the thesis; critically reviewing the theoretical underpinnings of 'health for all' and UHC, with an emphasis on the trade-offs involved in seeking to deliver health outcomes that target groups with the greatest needs. This paper documents the need for real-world approaches to identify and address inequalities within health programmes.

- Allen LN. The philosophical foundations of 'health for all' and Universal Health Coverage. Int J Equity in Health. 2022 Dec;21(1):1-7.

Chapter 3: Improvement Studies for Equitable and Evidence-based Innovation: An overview of the 'IM-SEEN' approach

Chapter 3 sets out the approach for quantifying and addressing inequalities in access to eye care. The 'IM-SEEN' model is based on three stages: 1) gathering and analysing sociodemographic data, 2) engaging with the group that is found to have the worst access to care in order to elicit their ideas for service improvements, and 3) testing these ideas through the use of embedded pragmatic RCTs.

- Allen LN et al. Improvement Studies for Equitable and Evidence-based Innovation: an overview of the 'IM-SEEN' model. Int J Equity in Health. 2023 Dec. 22(1), pp.1-8.

Part 2: Gathering sociodemographic data

Chapter 4: Comparing modalities for sociodemographic data collection

Chapter 4 is a systematic review that explores the resource requirements and performance of three different modalities of sociodemographic data collection; in-person, voice call, and automated telephone calls. We found that response rates exceeded 80% for in-person and voice calls, and high levels of equivalence and acceptability were reported across all modalities, however no cost data were reported.

- Allen LN et al. Performance and Resource Requirements of In-Person, Voice Call, and Automated Telephone-Based Socioeconomic Data Collection Modalities for Community-Based Health Programs: A Systematic Review. JAMA network open. 2022 Nov 1;5(11):e2243883.

Chapter 5: Equity analysis of access to community eye clinics in Meru, Kenya

Chapter 5 presents the results from the first 'Gather' stage of the IM-SEEN approach. Following the protocol set out in chapter 6, screeners gathered sociodemographic data from 4,240 consenting people who screened positive. We found that age, gender, and occupation were the strongest predictors of non-attendance. Of these, younger age was the most strongly associated characteristic ($p<0.001$).

- Allen LN, et al. Access to community-based eye services in Meru, Kenya: a cross-sectional equity analysis. Under review at the International Journal of Equity in Health.

Part 3: Engaging with left behind groups

Chapter 6: Scoping review of methods for identifying barriers and solutions to improve access to community health services

Having identified younger people as the group least likely to access care, chapter 6 presents a scoping review of the different methods that have been used to rapidly identify barriers and potential solutions. I specifically set out to identify design characteristics of approaches that are grounded in the experiences and perspectives of intended service users, and that can deliver timely and usable findings.

- Allen LN et al. Rapid methods for identifying barriers and solutions to improve access to community health services: a scoping review. BJGP Open. 2023 Dec 1;7(4).

Chapter 7: Developing bespoke methods to rapidly identify barriers and solutions for the IM-SEEN approach

Chapter 7 takes the findings of the scoping review and sets out a bespoke exploratory sequential mixed-methods approach for engaging with those from the left behind group who do not manage to access care. A core aim of this chapter is striking a balance between rigor and scalability (i.e. affordability and feasibility). I describe how qualitative telephone interviews and deductive framework analysis will be used to derive a long list of potential interventions, followed by a quantitative telephone-based ranking survey conducted with a representative sample of people from the same group. The top-rated interventions will be taken to a multi-stakeholder meeting comprising lay representatives, screeners, and programme managers. This group will select the most promising intervention to implement and test based on likely impact, risk, cost, and feasibility

- Allen LN et al. Identifying barriers and potential solutions to improve equitable access to community eye services in Botswana, India, Kenya, and Nepal: a rapid exploratory sequential mixed-methods study protocol. Under review at BMJ Open.

Chapter 8: Results of a rapid exploratory sequential mixed-methods study to identify barriers and potential solutions to unequitable access to care

Chapter 8 presents the results of the mixed-methods study conducted in line with the protocol presented in chapter 7. Interviews were conducted with 67 people aged 18-44 who had not been able to access care in Meru. I identified 21 unique barriers and 25 potential solutions. When we asked 401 other non-attenders to rank these interventions, the top three choices were adding more staff, adding more clinic locations, and ensuring that clinics were fully stocked and able to manage all possible eye conditions. Participants at the multi-stakeholder meeting reviewed all of the ranked solutions and decided that enhanced counselling and SMS reminder messages offered the best balance of cost, risk, impact, and feasibility.

- Allen LN et al. Identifying barriers and potential solutions to improve equitable access to community eye services in Meru, Kenya: a rapid exploratory sequential mixed-methods study. Under review at Lancet Global Health.

Part 4: Testing solutions

Chapter 9: Setting up an automated, pragmatic, embedded, Bayesian adaptive platform trial

Chapter 9 introduces adaptive platform trials and describes how they allow multiple interventions to be tested over time using the same population, primary outcome, and statistical approach. I present the submitted manuscript of the master protocol that will be used to run individual RCTs in Kenya and other sites.

- Allen LN et al. Protocol for an adaptive platform trial of intended service user-derived interventions to equitably reduce non-attendance in eye screening programmes in Botswana, India, Kenya & Nepal. Under review at BMJ Open.

Chapter 10: Enhanced patient counselling and enhanced SMS reminder messages to improve access to community-based eye care services in Meru, Kenya: protocol for an individual-level, two arm, superiority RCT within an adaptive platform trial

Chapter 10 presents the protocol for an RCT to test the enhanced counselling intervention under the adaptive platform trial. This trial represents the next phase of work after completion of my PhD.

- Allen LN. Enhanced patient counselling and enhanced SMS reminder messages to improve access to community-based eye care services in Meru: an individual-level, two arm, superiority RCT within an adaptive platform trial. Under review at BMC Trials.

Part 5: Discussion

Chapter 11: Discussion

Chapter 11 summarises the overall findings, lessons learned, limitations, and next steps – including application to other areas of public health.

Part 1: Background

Chapter 1

Health for all, Universal Health Coverage, and essential eye services

Map in a rural Kenyan primary care facility showing the local catchment population

Source: Author

Key messages

- Health systems and leaders have committed to extending health coverage, focusing on sociodemographic groups who have been 'left behind'.
- In the field of vision impairment, the social enterprise Peek Vision has been helping to double the proportion of people accessing care, but half of people still don't get the care they need.
- My aim was to develop a continuous improvement approach that can be used to identify and equitably address barriers to eye care in Kenya's Meru county.

Health for all and Universal Health Coverage

The principles and architecture that define contemporary global health are deeply rooted in early efforts to prevent global conflict. In April 1945, amidst the ashes of World War II, representatives of 50 countries gathered in San Francisco for a 'United Nations Conference on International Organization'. Over a period of two months, these international representatives drafted the original charter for the United Nations (UN). Birthed in blood, this international organisation was explicitly set up to prevent a third world war (Figure 1), establishing rules for friendly international relations grounded in respect for equal rights, international law, and the principles of freedom and justice (Box 1).[1]

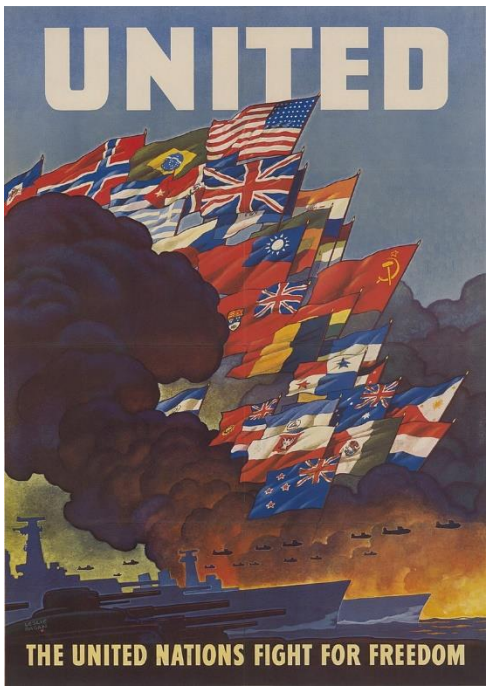

Figure 1: The wartime propaganda origins of the term 'united nations'

Source: 'Fight for Freedom'. US Office of War Information. 1943

Box 1: Article 1 of the 1945 Charter of the United Nations

The Purposes of the United Nations are:

1. To maintain international peace and security, and to that end: to take effective collective measures for the prevention and removal of threats to the peace, and for the suppression of acts of aggression or other breaches of the peace, and to bring about by peaceful means, and in conformity with the principles of justice and international law, adjustment or settlement of international disputes or situations which might lead to a breach of the peace;
2. To develop friendly relations among nations based on respect for the principle of equal rights and self-determination of peoples, and to take other appropriate measures to strengthen universal peace;
3. To achieve international co-operation in solving international problems of an economic, social, cultural, or humanitarian character, and in promoting and encouraging respect for human rights and for fundamental freedoms for all without distinction as to race, sex, language, or religion; and
4. To be a centre for harmonizing the actions of nations in the attainment of these common ends.

Source: UN Charter, 1945. Available at: https://www.un.org/en/about-us/un-charter/chapter-1

During the conference, representatives from Brazil and China recommended the establishment of an international health organisation, and over the next few months the constitution for the World Health Organization (WHO) was drafted, and later approved in New York in July 1946. The constitution came into force on 7th April 1948 (now celebrated as 'world health day') with the stated objective of attaining the highest possible level of health for all peoples.[2,3] The WHO's founding principles frame health as fundamental to sustaining world peace.

The assertion that enjoying the highest attainable standard of health is a right to be enjoyed by all people, 'without distinction of race, religion, political belief, economic or social condition' codified a powerful rebuff to the horrors of the holocaust. Yet in the late 1940s, this aspirational call for equality belied the systematic racism and discriminatory practices that characterised most health systems.[4,5] Then, as now, a person's ability to live a long and healthy life was primarily determined by the community and conditions into which they were born, grew up, lived, worked, and aged.[6,7] To this day, skin colour, religion, belief, and socioeconomic status continue to shape and constrain access to healthy environments, good education, decent job opportunities, safe housing, and effective medical care.[8,9]

In the UK, the pioneering architect of the NHS was particularly concerned with the impact of poverty on access to care. Aneurin Bevan argued that "no society can legitimately call itself civilized if a sick person is denied medical aid because of lack of means."[10] The founding principle of the NHS was that good health care should be available to all, with services delivered free at the point of delivery based on clinical need.[11,12] These important themes will be examined in greater detail in the next chapter.

Despite – or perhaps because of - the continued horrors of the 20th century, world leaders reaffirmed their commitment to the equal right of all peoples to health in 1978, at the International Conference on Primary Health Care in Alma-Ata, Kazakhstan (Figure 2).[13] Responding to emerging evidence that medical care only contributed modestly to improvements in living standards,[14–16] the seminal Declaration of Alma-Ata argued for a holistic 'whole-of-society' approach to health that emphasised action on social, economic, and political determinants alongside universal access to high-quality healthcare, with the wider health system centred around strong primary care.[13] A product of its time, the wording of the Declaration also reflected growing international push-back against biomedicalism, paternalism, hospital-centrism, American economic hegemony, and the market-based distribution of medical care.

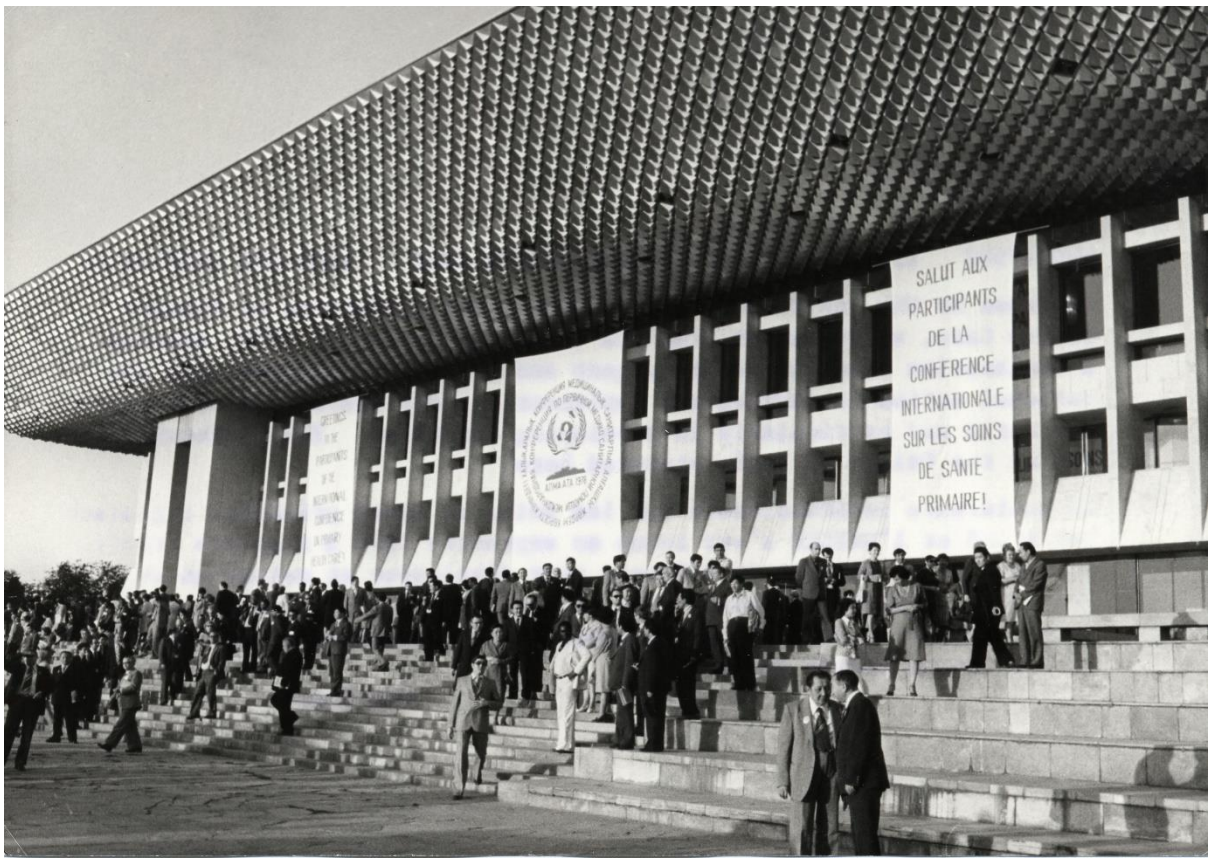

Figure 2: Representatives gather outside the meeting hall in Alma-Ata

Source: PAHO. Image available at: https://www3.paho.org/english/dd/pin/alma_photos.htm. Public domain.

The Alma-Ata Declaration was midwifed by the inspirational three-term WHO Director General Halfdan Mahler (Figure 3), the son of a Danish parish priest who advanced WHO's hugely ambitious '*health for all'* agenda, explicitly leaning into the moral and political imperatives for extending universal access to high-quality care and healthy environments for all people. Mahler argued vociferously for greater investment in community-based primary care systems, emphasising the importance of engaging with local communities as co-creators.[17,18] Moral and rights-based arguments - grounded in a range of ethical theories – continue to dominate the framing of WHO's work to expand access to health services.[19–21]

Figure 3: Halfdan Mahler (R) sat with Edward Kennedy at the Alma-Ata conference in 1978

Source: PAHO. Image available at: https://www3.paho.org/english/dd/pin/alma_photos.htm. Public domain.

Similarly, Mahler's reconceptualisation of WHO and primary care aimed squarely at progressively advancing 'health for all without discrimination of any kind' endures to this day. For instance, 'health for all' was used as the official tagline for world health day on WHO's 75th anniversary.[22] The principles of extending access to care for all people underlies the contemporary concept of Universal Health Coverage (UHC), commonly defined as 'ensuring that all people can access quality health services without facing financial hardship'.[19] The current WHO Director General Tedros Adhanom Ghebreyesus

has described UHC as the 'centrepiece' of the health-related Sustainable Development Goals – the UN's current 'blueprint' to achieve a peace and prosperity for people and the planet.[20,23,24]

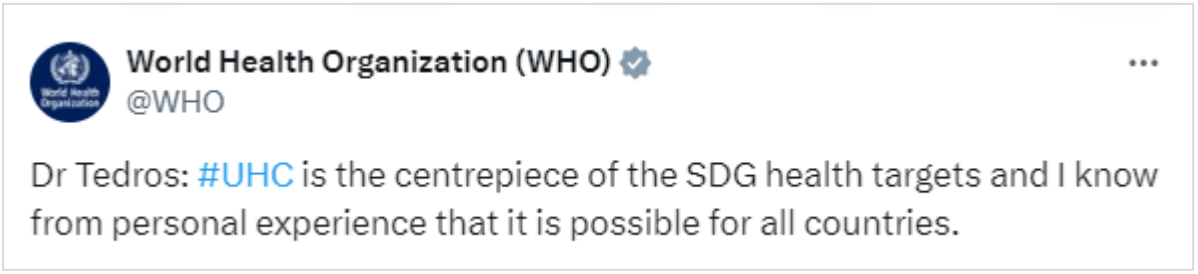

Figure 5: Tweet posted July 17th 2017
Source: X (formerly Twitter)

Extending equitable access to primary care services has become a leading global health priority, representing the technical manifestation of advancing health for all and achieving UHC.[25,26] This aim of connecting all people and groups with essential services also resonates with the broader 'central, transformative promise' of the SDGs which is to 'leave no one behind' and 'reach the furthest behind first'.[24]

UN member states are monitoring their progress towards UHC using 14 tracer indicators, reported on a scale from 0 to 100 for reproductive, maternal, newborn and child health services (RMNCH); infectious disease services; non-communicable disease services (NCDs); and service capacity and access indicators.[27] Two thirds of the indicators pertain to services that are delivered in the community setting by primary care teams. Unfortunately, progress towards UHC has stalled since 2018, with the global UHC service coverage index static at 68/100. This indicates that in the average country, approximately one third of the population will lack access to essential health services.[27,28] Furthermore, wide inequalities in access to care persist within each country.[6] It is estimated that eliminating wealth-related inequalities in under-five mortality would save 1.8 million lives each year in low- and middle-income countries (LMICs).[29]

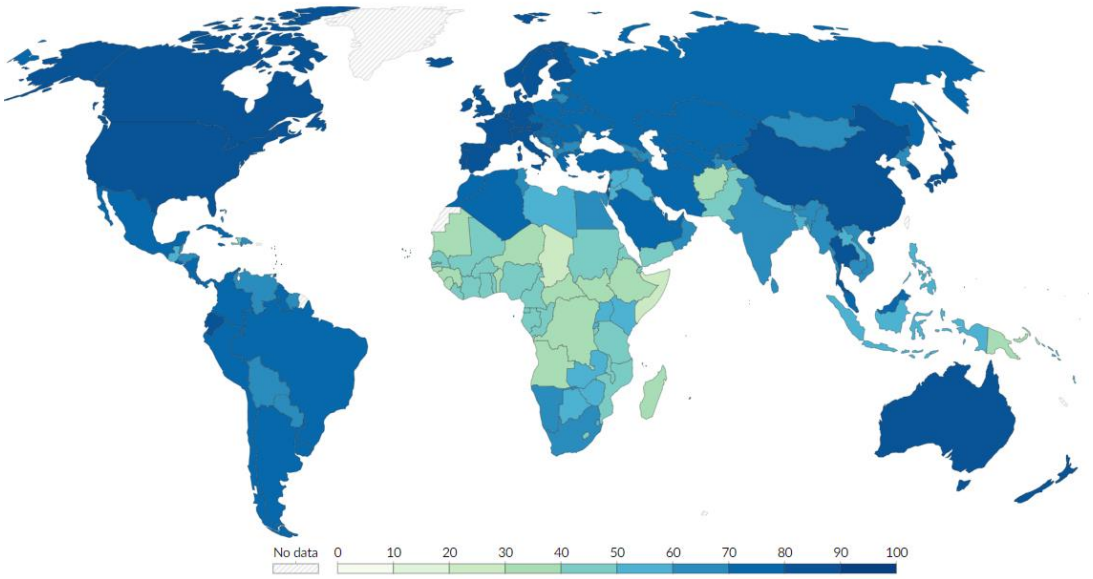

Figure 6: UHC service coverage index

Source: OurWorldInData.org. Data from WHO Global Health Observatory (2022). CC BY license

It's not entirely clear why global progress towards UHC has stalled. Whilst COVID-19 had a major impact on the continuity of existing health services,[30] the global slowdown was well underway before 2019.[31] Incremental gains around infectious diseases have been offset by negligible action or even reversals in coverage for maternal and child care and non-communicable diseases (NCDs).[31] At the macro level, the Director General's UHC report to the WHO Executive Board in December 2023 identifies a number of potential contributing factors, including lower levels of external funding, workforce and infrastructure constraints, and insufficient political will.[32] Within countries and individual health programmes, complex supply and demand factors govern access to individual services.[33] Multiple frameworks have been developed to conceptualise access. Table 1 provides a brief summary of some of the most prominent models.

Table 1: Access to care frameworks

Author/framework name	Conceptualisation of access
Andersen–Aday Conceptual Model[34]	Access is determined by predisposing factors, enabling factors, and illness variables
Mooney[35]	Access is a function of supply- and demand-side factors

Andersens' Behavioural Model of Health Services Use[36]	Access is a function of health services use predisposition, healthcare need, enabling and impeding factors to utilisation
Penchansky and Thomas'[37]	Access is the 'fit' between the needs of patients and the capacity of healthcare system
Frenk[38]	Access is determined by the population's ability to seek then obtain care, based on the availability of resources, 'utilization power', resistance, and health system performance
Levesque[33]	Access is determined by approachability, acceptability, availability & accommodation, affordability, and appropriateness; and five corresponding abilities to perceive, seek, reach, pay for, and engage

All of these frameworks adopt multidimensional views of the patient and provider factors that influence whether people receive the care they need, and highlight the importance of context.[39] They can be applied to different health sector domains, including access to eye services. Different groups tend to face different barriers to accessing care and the central commitments of UHC and the Sustainable Development Goals revolve around understanding and dismantling these barriers for every population group so that access can improve and inequalities can decrease.

Inequality in access becomes 'inequity' when differences between groups are "unavoidable, unnecessary, and unfair" – for instance denying services to a person because of the colour of their skin or their marital status.[40] Health service leaders have historically used forms of 'positive selectivism' to target the provision of services to people belonging to social, economic and demographic groups that face barriers to care. However UHC tends to harness the more sophisticated ethical concept of 'proportionate universalism', arguing that health coverage should improve for all, with the greatest gains experienced by those with the greatest baseline needs.[41] Chapter 2 will dig further into the ethical and philosophical foundations of global efforts to advance *health for all*.

Eye care

I set out to work on a big, ubiquitous problem: that a large proportion of the world's population does not have access to essential health services, and marginalised and disadvantaged groups are the least likely to receive the care that they need. My PhD focuses on one small slice of this issue – the microcosm of low and inequitable access to eye care.

As with the UHC tracer interventions, one third of the global population lacks access to basic eye care.[42] Approximately 43 million people are blind a further 1 billion people are currently living with unaddressed vision impairment.[42,43] Over 90% of these people live in low- and middle-income countries, and four fifths of all visual impairment is avoidable or treatable with extremely cost-effective interventions like spectacles (starting at £1 a pair) and cataract surgery (a 15-minute procedure[44]). Recent years has seen a pivot towards 'primary eye care' in recognition of the fact that the vast majority of eye health determinants manifest at the community level and require local, integrated action, led by community-based teams.[45]

Poor vision leads to social exclusion, poor education outcomes, reduced economic prosperity and reduced quality of life.[43] Damningly, recent research suggests that marginalised groups – i.e. those already facing social exclusion and economic hardship – experience the lowest rates of access to eye care – further compounding their socioeconomic disadvantage.[43,46] These studies found that older female widows living in rural areas had access rates 2-3 times lower than more advantaged groups such as urban married men.

Given the ubiquity of the issue, access to eye care services is a powerful proxy for UHC. Accordingly, there have been ongoing efforts to include eye care indicators in the updated 2025 UHC service coverage index.[47] Governments are also paying increasing attention to the impact of avoidable poor vision in their populations. Global funding for eye care has more than doubled since the launch of the multisectoral 'VISION 2020: Right to sight' initiative in 1999,[48,49] and as mobile technologies have lowered the financial and practical barriers to community-based eye screening, a growing number of LMICs are conducting large-scale screening programmes.[50–53]

Peek Vision – a London School of Hygiene & Tropical Medicine non-profit spin-out - is the leading provider of smartphone-based software that is currently being used to run 69 screening programmes across 12 LMICs, reaching over 400,000 people each month.[53] These programmes equip non-healthcare personnel such as teachers and community health workers with a validated app-based visual acuity test that can be delivered by with the same accuracy as clinically approved tests operated by health professionals.[54–56] During screening, each participant is presented with a series of letter 'E's in different sizes and orientations from a distance of 3m. Participants are asked to point in the direction that the E is pointing in (i.e. upwards in Figure 7) and the screener swipes the screen in the direction indicated by the participant. An algorithm calculates visual acuity based on the smallest E that is consistently identified correctly. This approach can be used with literate and illiterate people from ages 5-years and up.

Peek Vision also provides patient flow management software that enables programme managers to track the proportion of people identified with an eye issue; the proportion of people referred to receive treatment at the local primary care facility; and – importantly – the proportion of people who actually receive the care that they need. These data are presented on an online dashboard that programme managers can interrogate in real-time as their screening programmes progresses (Figure 7).

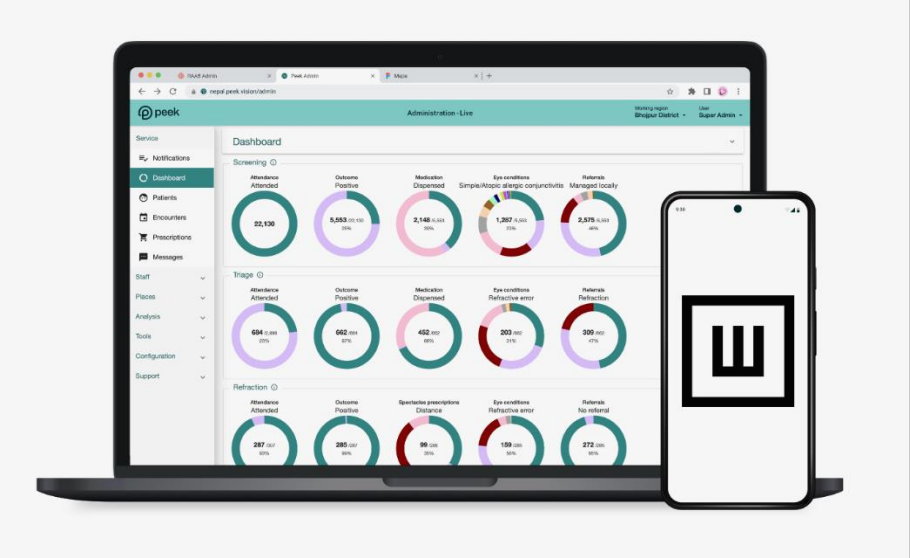

Figure 7: An example Peek-powered programme dashboard and an upward-pointing E on the smartphone-based visual acuity testing app

Source: Peek Vision. Permission granted for reproduction

According to internal Peek data, approximately 20-30% of all those screened are found to have an unmet eye need in LMICs. Published research from Kenya has shown that only 22% of people identified with an unmet eye need are connected to care in standard screening programmes. That means that approximately 80% of people are not able to access services. These figures align with international survey data which suggest that 80-85% of people with refractive error and cataracts are not able to access effective care in lower middle-income countries.[57,58] The use of Peek software to perform screening and manage patient flow has been shown to more than double the proportion of people who are connected to care, from 22% to 54%.[59] Figure 8 illustrates the rough proportion of the general population in an average LMIC who have an eye need (commonly defined as distance visual acuity <6/12, or near vision impairment) and are connected to care by standard screening programmes and those that use Peek Vision software.

Even with Peek, roughly half of all people identified with a need do not manage to access care. Peek is increasingly investing in continuous improvement approaches to try and incrementally raise the proportion of people connected to care, however this work is yet to be systematised, and only more recently has been based on engagement with the groups who are being left behind. Furthermore, the Peek programmes are currently set up to only basic sociodemographic data that would enable the identification of which sociodemographic groups are the least likely to receive care.

Figure 8: Proportion of the total population who need and access care in an average lower middle-income country

In terms of eye care-specific frameworks, the dominant access model - which is taught on the LSHTM Masters Course - stresses the importance of seven broad factors in determining access to services (Box 2).[60]

Box 2: Factors influencing access to eye care services

Awareness - including the clinician

Bad services i.e. poor quality

Costs

Distances

Escorts/chaperones

Fear e.g. myths around eye surgery

Gender

This framework does not include important sociodemographic characteristics like ethnicity, age, language, marital status, urban/rural location, education, or occupation. This is significant because we know that structural societal barriers make it much harder for certain groups to access care.[6] Previous work has shown that access to eye services in Kenya, Nigeria and Sri Lanka is strongly associated with age, gender, marital status, and urban/rural location - and intersectionality is also strongly at play[46,61] (where overlapping identities and experiences compound disadvantage).[62] This is an important gap and further work is needed to introduce routine sociodemographic data collection and intersectional disaggregation in eye service provision to identify those being left behind.[63]

Context of this thesis

My PhD sits within a collaborative project, jointly funded by the NIHR and Wellcome Trust, that aims to improve equitable access to eye care, focusing on four countries that are currently using Peek-powered programmes to screen their populations in Botswana, Kenya, India, and Nepal. The research collaborative includes the LSHTM-based International Centre for Eye Health, Peek Vision, the Kenyan Ministry of Health, the University of Botswana, Nepal Netra Jyoti Sangh, Dr Shroffs Charity Eye Hospital, and the College of Ophthalmology for Eastern, Central and Southern Africa. I was appointed as the international research lead in early 2020.

Leveraging the opportunities afforded by Peek's real-time, end-to-end patient flow monitoring capabilities, the original value proposition of the project centred around the opportunity of harnessing data-driven continuous improvement techniques from technology sector to reduce the number of people being left behind (discussed in further detail in Chapter 3). My particular focus has been on introducing new elements of data capture and analysis to identify the socioeconomic groups that are least likely to receive care; and then working with these groups to generate hypotheses around how equitable access could be improved; and finally testing these hypotheses within ongoing screening programmes, using embedded RCTs. The idea was to develop and test a scalable approach for equity-focused continuous improvement that could be applied across all Peek programmes.

This thesis reports my journey leading the development of the overarching methodological approach that can be used to continuously improve equitable access to care, and its application in Kenya, with reflections on its potential for wider use in other systems and settings beyond the test case of eye care.

Setting

Kenya is a large and relatively stable Sub-Saharan lower middle-income anglophone democracy with a population of 55 million (Figure 9).[64] Its economy is the seventh largest in Africa, with a gross domestic product (GDP) of USD 113 billion, however it ranks 21st out of all 54 African nations for GDP per capita.[65] Mean life expectancy at birth is 66.1 years, an improvement of 12.2 years since the turn of the millennium.[66] It has a 'medium' human development index value of 0.58, ranking 152nd out of all 191 countries and territories.[67] Over three quarters of all births are registered but only 39% of deaths were registered in 2018 – the most recent year for which data are available.[66] Kenya's current health expenditure is 5% of GDP[66] and its UHC service coverage index score was 53 in 2021: above the Sub-Saharan mean of 43, but below the lower-middle income country mean of 58.[68]

Figure 9: Kenya
Source: Inkscape, CC BY license

An estimated 7.5 million people are currently living with untreated vision impairment in Kenya, but less than a quarter are able to access services.[69] The Vision Impact Programme (VIP) is a major Peek-powered screening programme that has been set up to address this issue, operating in ten of Kenya's 47 counties. The programme is funded by Christian Blind Mission (CBM), implemented by a range of local partners, and conducted in close collaboration with county health offices under the auspices of the national ministry of health. The national director of eye services, Dr Michael Gichangi, is part of our research collaboration and is a co-author on many of the papers included in this thesis. Since the start of the VIP programme in October 2021, over two million people have been screened (Figure 10), of whom approximately 600,000 have been identified with an eye care need. Of these people referred to local clinics, only 350,000 have managed to access care. That means that 42% of those identified with an eye problem have not been able receive care – a quarter of a million people so far.

Figure 10: VIP screeners in action

Source: Author. Consent granted by all those in the image.

The decision to focus my PhD on Kenya was driven primarily by practicality. At the start of my PhD Nepal's programme was only screening 30 people per week, and India's programme had not yet begun. After a strong start, Botswana's nationwide programme stalled due to a shortage of optometrists. Kenya's VIP programme was running relatively smoothly, and the start of my fieldwork aligned perfectly with the commencement of screening in Meru County.

Meru County (Figure 11) is approximately 200 miles north of Nairobi; a five-hour drive. It sits on the Eastern slopes of Mount Kenya and includes the expansive Meru national park (Figure 10). To the nearest ten thousand, the 2019 census recorded a population of 990,000 comprised of 250,000 households.[70] The local government currently reports a population of 1.35 million.[71] Just under 10% of its population live in Meru town, which is the sixth largest urban conurbation in the country.[71] Alongside tourism, agriculture is the main source of employment, with wooden goods, tea and khat being the major cash crops. Employment stands at 56.4%; around 20% higher than the national average.

Figure 11: Meru County

Source: Karte: NordNordWest, CC BY license

Education levels, access to water and sanitation, fertility rates, and infant mortality rates in Meru are very similar to the national mean.[72] The county's burden of disease also closely reflects the national average (Figure 12).[73] According to the County Government consolidated work plan, Meru has 144 community health units, 419 primary care facilities, and 25 hospitals.[74] There are 16 consultants, 33 medical officers, 81 public health officers, 672 nurses, 76 clinical officers, and 278 community health promoters working in or with government facilities, approximating half of the estimated requirement for health personnell.[74] There are no routinely reported eye personnel data.

In Meru's screening programme, small teams of screeners have been trained to go house-to-house screening every resident aged over 5-years-old. Those who fail the visual acuity test, report a subjective problem with their eyes, or are found to have an obvious eye problem on simple visual inspection (e.g. red eye) are given an appointment to attend a local outreach clinic 1-2 weeks later. These clinics are commonly held at the local primary care facility, as well as in churches, halls, and other meeting spaces. Early data from Meru's programme suggested that around one third of all those screened are found to have an eye issue, but only half of these people receive care at their local clinic. Figure 13 shows the dashboard display data after a third of the county (approximately 350,000 people) had been screened.

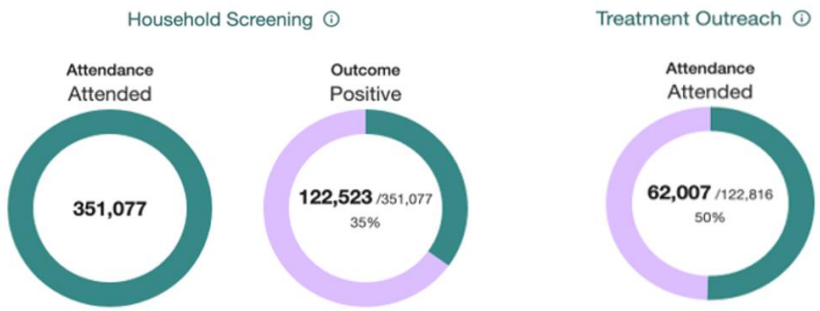

Figure 13: Screenshots from the Peek dashboard for the Meru screening programme

Source: Peek Vision. Permission granted for reproduction.

Thesis rationale

In summary, the big problem is that 4.5 billion people lack access to essential health services. Progress in expanding coverage seems to be stuck, despite major international commitments to provide health for all. Access to care is strongly patterned by sociodemographic contours, with the wealthy and powerful often enjoying much better access than those in disadvantaged and marginalised groups. Major international commitments to 'leave no one behind' and 'reach the furthest behind first' are not translating into meaningful improvements. In part, this is because there are not routine mechanisms for identifying left behind groups, engaging with them to understand the unique barriers they face, and testing solutions designed to tackle these issues.

The field of eye care offers a near-perfect microcosm, with over a billion people currently living with unaddressed visual impairment and marked inter- and intra-national inequalities in access to care. Encouragingly, a number of LMICs are launching major screening programmes, and these often carry the aim of reaching all groups and closing inequalities. However, these programmes do not routinely assess whether they are reaching all groups or include mechanisms to identify and tackle unequal barriers to care.

There is a critical need for new service delivery approaches that centre around improving equitable access to care. These should be rooted in the concepts of justice, equity, and proportional universalism. The processes involved in identifying and tackling poor and unequal access to care need to be simple enough that they can be adopted by a wide range of service leaders. However, feasibility and scalability need to be balanced against accuracy and reliability: tools are needed that can robustly identify which sociodemographic groups are being left behind; what unique barriers these people face; and what can be done about them. Improving equitable access to care is a long-term project, requiring ongoing work to continually improve.

Aim

The overall aim of my thesis was to develop a continuous improvement approach that can be used to identify and equitably address barriers to care.

I aimed to test the approach in Meru's community-based eye screening programme: identifying which group was the least likely to access eye care; exploring their perceptions of barriers and potential solutions using rapid methods; and then setting up an adaptive platform trial that can be used in the future to test promising solutions using embedded, automated, randomised controlled trials (RCTs).

Whilst my thesis focuses on Meru's screening programme, I was also able to draw on other work taking place in Botswana, India, Nepal, and Kwale County in South-East Kenya.

Objectives

Background

1. Conduct a literature review on the philosophical underpinnings of UHC and 'health for all' – two foundational concepts for my PhD.
2. Develop the framework for an approach to equitably improve access to care, working with local collaborators.

Gather sociodemographic data

3. Conduct a scoping review to compare different modalities for sociodemographic data collection in terms of costs, time requirements, and data quality.
4. Develop an equity analysis approach for gathering and analysing sociodemographic data and apply it in Meru county's eye screening programme in order to identify which groups are being left behind in this part of Kenya.

Engage with left behind groups

5. Conduct a scoping review of rapid approaches that are being used to explore barriers and solutions to improve access to community-based services, focusing on methods and techniques that can expedite the research process without sacrificing scientific rigor.
6. Based on the findings of this review, develop a rapid, non-tokenistic, mixed-methods approach to engage with groups found to have poor access to care, in order to explore their ideas for how to improve services.
7. Apply this mixed-methods approach in Meru, focusing on the group found to experience the worst access to care in my equity analysis (objective 4).

Test solutions

8. Develop an adaptive platform trial master protocol to test service modifications that arise from mixed-methods engagement work.
9. Set up an RCT under this platform trial in Meru, to test one or more solution that arises from the mixed-methods study (objective 7). My post-doctoral work will focus on conducting this trial and taking the approach to scale in other settings and with other conditions.

This thesis presents a series of nine published/submitted papers in the subsequent nine chapters, followed by a closing discussion chapter. Chapter 3 sets out the overall approach. More detailed methods for each stage are unpacked in the relevant chapters. Where relevant, undergirding protocols and supporting methods papers are referenced in the preamble for each chapter and reproduced in the Appendices.

Chapter 2

The philosophical foundations of ‘health for all’ and Universal Health Coverage

Central Kenya from the air, August 2023
Source: Author

Key messages

- There are a range of ethical approaches for tackling unjust health inequalities.
- The concepts of 'Health for All' and Universal Health Coverage are grounded in highly aspirational 'sufficientist' arguments. A range of thinkers have argued that prioritarian considerations should guide action towards these goals i.e. focusing on the worst off.
- Proportionate universalism has been promulgated as a vehicle for reconciling universalism with prioritarian values; seeking to provide services to all, but with the greatest gains experienced by groups that are the furthest behind.
- It is not possible to equitably extend coverage without first collecting sociodemographic data to identify which groups are being left behind.

This chapter reviews the core concepts that undergird efforts to improve equitable access to care. This literature review was published in the International Journal of Equity in Health.

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Student ID Number	2004040	**Title**	Dr
First Name(s)	Luke		
Surname/Family Name	Allen		
Thesis Title	Improving equitable access to community-based health services: Developing and testing a new model in Kenya's national eye screening programme		
Primary Supervisor	Andrew Bastawrous		

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COMMENT

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The philosophical foundations of 'health for all' and Universal Health Coverage

Luke N. Allen*

Abstract

The WHO constitution calls for 'health for all' and Universal Health Coverage has been called "the ultimate expression of fairness", however it is not always clear how health systems can move towards equity. Should we prioritise the needs of the worst off? And if so, should we direct resources to these marginalised groups or marginalised individuals? This article provides an overview of the philosophical underpinnings of health equity and proportionate universalism, highlighting the trade-offs involved in operationalising a core tenant of global health practice.

Keywords: Equity, Inequalities, Ethics, Social justice, Proportionate Universalism

A lofty aspiration

Health inequalities are ubiquitous [1–3]. Some arise from natural human variation and physiological differences, for instance people with white skin are more likely to develop skin cancer than people with black skin [4]. However, many other inequalities stem from avoidable and unfair social structures—such as the differences in all-cause mortality according to skin colour [5]. The inverse care law states that the supply of medical care is inversely proportionate to need [6], and the most disadvantaged groups in society almost universally experience the worst health outcomes [7]. WHO state that "many of the populations that have the worst health statuses face systemic discrimination based on race, ethnicity, gender, sexual orientation, socioeconomic status, location, religion, educational status and disability [8].

Addressing unjust inequalities is a fundamental tenet of global public health: the 1948 WHO constitution is built around the aspiration of 'health for all' [9] and the Alma-Ata and Astana Declarations on Primary Health Care espouse the principles of social justice and the 'fundamental right to health without distinction of any kind' [10, 11]. These principles were driving themes under the visionary leadership of Halfdan Mahler, who served three terms as WHO Director General from 1973 – 1988. During his tenure Mahler oversaw a major shift in focus from single diseases viewed through 'medically tainted glasses' to holistic primary health care and engagement with the wider social, political, and economic determinants of health [12]. He was instrumental in developing and leading the WHO's defining 'Health For All by 2000' programme of work, seeking "a level of health that will permit all the people of the world to lead socially and economically satisfying and productive lives…based on the fundamental values of social justice and equity." [13].

Universal Health Coverage (UHC) is the contemporary manifestation of health for all, and all WHO member states have committed to "achieve UHC, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all" in Sustainable Development Goal target 3.8 [14].

But what do we actually mean by advancing health *for all*, and how might we get there – or at least begin moving in the right direction? This short review summarises the most important ethical theories that have undergirded attempts to operationalise this audacious concept in the form of Universal Health Coverage.

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Should we tackle inequalities?

Some economists and philosophers have argued that efforts to reduce inequalities are illiberal [15], unmeritocratic [16], and – in the view of Friedrich Nietzsche – reflective of moral failure [17]. Whilst these views are extreme, most philosophers and economists agree that a degree of inequality is socially desirable because it provides incentives for people to take personal responsibility for their actions [18]. The precondition for this inequality is a form of effort-based meritocracy where gains, success, and outcomes are related to skill and hard work – rather than parentage, private education, or social class. In other words, everyone should be able to achieve the same gains with the same effort. As Aristotle put it; "equals should be treated equally" [19].

Of course, in real life the playing field is not fair, and authors like Daniel Markovits has argued that meritocracy is a "pretence, constructed to rationalize an unjust distribution of advantage" [20]. Public anger at differential access to education, resources, and opportunities has manifest regularly throughout human history – including in contemporary demonstrations against the 'one-percent' moneyed elite [21].

Assuming that at least some health inequalities are unjust and should be tackled, there is a surprisingly broad spectrum of philosophical positions that can support the common goal of reducing inequalities. The three main schools of thought that have been developed to consider the distribution of social resources are *egalitarianism, sufficientism*, and *prioritarianism*. We will consider each in turn.

Egalitarian approaches concerned with equality. The primarily aim is to *close gaps* so that all people experience the same outcomes. In mathematical terms, the focus is on the range rather than the mean i.e. it doesn't matter what the absolute outcome is, as long as everyone has the same. This can apply to inputs, outputs, or outcomes, leading to radically different policy goals e.g. 'everyone has equal access to the same services' vs 'everyone achieves the same life expectancy'. Ideally, those with the worst baseline health outcomes would see their health improved to match the best-off, however proponents of egalitarianism can also implicitly or explicitly achieve their ends by 'levelling down' i.e. taking resources away from advantaged members of society. Most would agree that taking resources away from people so that everyone has nothing is perfectly equal, but probably undesirable. Efforts to reduce inequalities should ideally consider the absolute level of the given outcome, as well as the relative distribution.

In contrast to egalitarians, proponents of sufficientism take the view that inequalities can largely be ignored as long as everyone *has enough* [22]. The threshold for 'enough' can be couched in absolute terms, such as the US$1.90 international poverty line [23], or it might be a relative threshold, for instance Adam Smith famously argued that everyone should have enough to be able "to appear in public without shame" [24]. Similarly, the women's suffrage demand for 'bread and roses' was an assertion that basic necessities extend beyond food and shelter to include education, art and beauty [25]. However it is defined, the definition of *enough* is commonly tied to evolving social standards. For instance, mobile phone ownership and an internet connection are basic necessities for participation in everyday life today but were opulent curiosities in the 1990s. Whilst sufficientism guarantees that everyone obtains a certain level, the focus is on the floor rather than the upper limits and aspirations of what a society can achieve.

The third main approach to addressing inequalities is prioritarianism [26]. Its proponents place primacy on the conditions of the worst-off members of society and judge the moral value of any action by the extent to which it improves their lot. Like sufficientists, prioritarians are not actually concerned with inequality in itself: they are only concerned with the inequitable distribution of resources and outcomes insofar as redistributing them would improve the status of the most disadvantaged. This can lead to acceptance of inequalities when there are no further actions that would change the status quo.

Application to health inequalities

These three theories apply to inequalities in access to all forms of resources. For health inequalities it is important to make the distinction between inequalities stemming from immutable factors (e.g. skin colour), unjust social structures (e.g. institutional sexism) and outcomes over which people exercise a degree of personal agency, such as diet. It is important to recognise that there is a spectrum here, as 'choices' are heavily shaped and constrained by our environment [27].

Whitehead and Dahlgren have argued that inequalities become inequities when they are "unavoidable, unnecessary, and unfair" [28]. Michael Marmot goes on to say that "putting them right is a matter of social justice." [1]. This position is ascendant within global health and aligns with elements of John Rawls' theory of justice [29]. Rawls deftly combined the optimum level of inequality with a prioritarian approach using his 'difference principle'; that inequalities are permitted insofar as they benefit the least advantaged in society, and his 'maximin rule'; that interventions should be weighed by the extent to which they maximise the utility of the worst off. Together these principles only permit inequalities that would make the most disadvantaged even worse off if they were addressed [29].

Rawls's theory of justice was confined to sovereign states and dealt with the distribution of services rather than health itself: he was not concerned with the pattern of health outcomes as long as the basic structure of society is just [29, 30]. However, Normal Daniels has argued that by demanding fair equality of opportunity, Rawls's theory of justice requires a robust flattening of the socioeconomic health gradient [31, 32]. Both philosophers have been criticised for focusing on means and resources whilst implicitly disregarding human diversity and differing capabilities to use resources that leads to differences in outcomes [33].

Building on Aristotelian ethics [34] and Sen's capability approach [27, 35], Ruger has argued that the concept of global health equity should focus on realising each individual's capability to be healthy and function as a flourishing member of society [36, 37]. Her approach treats health as an instrumental and intrinsic good. Rather than pursuing the achievement of equal health outcomes, Ruger's conceptualisation of 'health for all' centres on providing the social conditions required for people to have the capability to experience good health. She outlines four key domains: the quality of services and resources; personal capacity to enable healthy functioning; social support for health agency to allow individuals to make use of resources; and prevailing health norms [38].

Operationalising 'health for all' with Universal Health Coverage

When we come back to consider WHO's foundational aim of achieving the highest standard of health for all – without distinction, we can see that; 1) a highly aspirational, absolute threshold is being advanced; and 2) there is a concern for understanding and addressing differential attainment of that goal. The advent of Universal Health Coverage (UHC) – dubbed "the ultimate expression of fairness" by former Director General Margaret Chan [39]—helped to translate the lofty vision into the concrete aims of extending health services and financial risk protection. Whereas Mahler's tenure highlighted the plight of the poor [40], the conceptualisation of UHC that was advanced under Chan's leadership was built on a philosophical foundation of sufficientism: each country should select a minimum basket of services and a maximum financial exposure threshold that should be applied to every citizen [41].

Given that access is not universal for most services, UHC forces policymakers to consider which groups to include first as new services are rolled out. From the point of view of a health programme manager faced with suboptimal service coverage, their main concern may be to boost coverage rates as cost-effectively as possible with little regard for which group receives extended access first.

There is nothing intrinsically prioritarian in the definition of UHC, and concerns have been raised that "people who are poor could well gain little until the final stages of the transition from advocacy to achievement" [42]. In response to this perceived risk, WHO convened the *Commission on Making Fair Choices on the Path to UHC*. The commissioners' final report argued that "it is unacceptable to expand coverage for well-off groups before doing so for worse-off groups when the costs and benefits are not vastly different" [43]. In an accompanying editorial, Chan explained that "To include more people fairly, countries should first expand coverage for low-income groups, rural populations, and other groups disadvantaged in terms of service coverage, health, or both" [39]. This view echoes an open Lancet letter signed by 267 economists who argued stated that policymakers should focus on extending services to the "poorest and most marginalised populations." [44].

Interestingly, whilst Rawls argued that the focus on the worst-off should be absolute, the WHO position tacitly implies that there is a threshold at which the additional costs of prioritising disadvantaged groups become unjustifiable. Another important but undefined issue is how to select which groups to target. The WHO equity consultive group has suggested nine core domains, based on earlier work by the *Commission on Social Determinants of Health*. These are income, wealth, education, occupation, ethnicity/race/indigeneity, gender, area of living (urban/rural), refugee/immigrant status, religious and political beliefs, and sexual orientation [43]. However, WHO does not seem to have adopted these domains in any further normative guidance.

Universalism, selectivism, and the distribution of care

The idea of prioritising certain sociodemographic groups represents a marked departure from Beveridgean 'general universalism' – an impartial approach to welfare that does not take need into account when distributing social benefits. In Beveridge's original – pointedly egalitarian—vision for the British NHS, everyone would be eligible and everyone would receive the same service, irrespective of sociodemographic characteristics, means, or need [45–47].

Systems based on the related principle of 'specific universalism' also seek to be impartial in the distribution of benefits, but they recognise that some social groups face barriers. In response, benefits are distributed within a framework of extending social rights, such as the right to

health, as a way of ensuring that that services are genuinely available to all [48].

Carey, Crammond and De Leeuw have noted that both forms of universalism tend to conflate equality with equity, commonly leading to situations where those on the margins of society do not actually have their needs met [47]. As such, many governments have introduced elements of 'selectivism' to target the provision of services according to need across the social gradient.

The WHO report discussed above advocates for what is known as 'positive selectivism' – using membership of a social group to determine access, irrespective of the unique needs of individuals within those groups [43]. An alternative approach is 'negative selectivism' which uses means-testing to target individuals, irrespective of their sociodemographic characteristics [49]. Perhaps counterintuitively, negative selectivism has been repeatedly associated with poor outcomes, summarised by Francis-Oliveiero as "stigmatisation, increased social distance between recipients and non-recipients, administrative cost for means-testing, and also misclassifications, under-coverages and leakages" [50].

Proportionate universalism

Aiming to find a balance between universalism and selectivism, Théda Skocpol proposed 'targeted universalism' in the early 1990s [51]. Her approach resonates with the 'weighted priority' form of prioritarianism that emerged in the late 1990s, and shifted from exclusively focusing on the worst-off towards distributing benefits to all, in accordance with baseline wellbeing [52, 53]. These ideas were adopted and adapted for public health by Michael Marmot who advocated for 'proportionate universalism' in his 2010 report *Fair Society, Healthy Lives* [1]. Proportionate universalism combines positive selectivism with universalist principles of equality and fairness; seeking to provide services to all, with additional resources provided to members of specific groups in order to offset the structural challenges that they face: "actions should be universal, but with an intensity and a scale that is proportionate to the level of disadvantage." [1].

Francis-Oliviero and colleagues note that this definition leaves scope for broad interpretation, citing examples of single interventions with graded intensities; single interventions designed to disproportionately impact disadvantages groups; and the provision of different intervention for different groups [50]. Similarly, Benach and colleagues have argued that the essence of proportionate universalism is that "benefit increases through the gradient and the gap between socio-economic groups is reduced" [54]. However this definition and Marmot's both leave room for inequalities to persist indefinitely, as long as they are continually narrowing. In contrast, 'health for all' seems to demand a closure of inequalities, manifest in the full realisation of health for every person.

Application today

All UN member states have committed to achieving UHC by 2030 – guaranteeing access to quality essential health-care services for all [55]. This takes a Rawlsian input-based approach – guaranteeing that individuals receive comprehensive services but making no promises about the resultant distribution of health outcomes. No country has- or is likely to fully deliver UHC [56, 57] and gaping inequalities in life expectancy and other health outcomes remain within and between all countries [58–60]. As additional health services and financial protection schemes are rolled out, priority should be given to closing these unjust gaps. Proportionate universalism encourages health system leaders to deliver the greatest benefit for worst-off groups, whilst aiming to improve outcomes for all groups.

Any progress in this sphere is predicated on the collection and analysis of sociodemographic data so that managers can identify groups at the highest risk of being left behind. In their recent review, Francis-Oliviero et al. found very few examples or operational models that have successfully achieved proportionate universalism in service delivery [50]. More work is needed to develop and test routine approaches within healthcare.

Alongside this work, it is important to note that UHC focuses on service delivery rather than capabilities or seeking to influence unjust social norms and structures. We know that the social determinants of health are much more important in determining health outcomes than healthcare services, however the kind of whole-of-society 'health in all policies' approaches that grapple with underlying unjust social structures – central to the *Health For All by 2000* programme and the Alma-Ata and Astana Declarations—remain a fringe interest rather than a core priority for most people working in the field of health [61, 62]. Those of us who work on health inequalities should be seeking to influence the macro-level social structures that compound and perpetuate disadvantage, rather than simply tinkering with the health manifestations at the fringes.

The challenge of advancing UHC should be viewed primarily through a political lens, as it deals with power, influence, and the distribution of finite resources. In *Nicomachean Ethics* Aristotle argued that we should seek to participate in the political sphere and that politics is the higher form of ethics. This sentiment has been echoed by Ghilardi and colleagues who called for health workers and researchers become more politically and socially engaged as a core element of their work [63]. Virchow famously asserted that "medicine is a

social science" whose practitioners are obligated to work with politicians in order to address the core drivers of ill health [64]. Many see political activism as lying beyond the purview of medicine [65]. Mahler acknowledged that the real work of advancing health for all is not a neat biomedical and managerial exercise, but a "complex, often messy process involving the interplay of physical, social, economic, and political variables" [13].

Conclusion

WHO's mandate of delivering health for all rests primarily on philosophical foundations; in an egalitarian belief that all humans have equal value, and that advancing care is a matter of justice. Whilst Mahler was alive to the prioritarian moral imperative driving the organisation's work, seeking "a more equitable distribution of resources for health…in keeping with the principles of paying greater attention to the underprivileged" [40], the rationale underlying much of the WHO's current work is framed in sufficientist, economic and technocratic terms. These appeals to nation enlightened self-interest reflect the prevailing nationalistic geopolitical zeitgeist, however WHO may gain additional traction in exploiting the philosophical foundations of its work, akin to the very successful rights-based calls for action on HIV [66].

Mahler used WHO's mandate and voice to "focus world attention on health inequities" [67]. Framing UHC as a robust form of redistributive justice and putting more emphasis on the ethics of inaction may put additional pressure on politicians. WHO cannot escape the normative role that it plays, and should consider leaning into this space with the establishment of a ethics standing committee. There is precedent: an in-house ethicists was appointed in 1999 [68], and various task-and-finish consultive groups have been convened, including the aforementioned group for equity and UHC [43].

Approaches to delivering UHC are increasingly grounded in proportionate universalism, recognising that greater effort is required to optimise the health of marginalised groups. Whilst proportionate universalism is conceptually powerful, it has proven difficult to operationalise. There is a need for real-life models that provide graded levels of provision according to need. This will also translate into financing and provider payment systems that account for the effort involved in overcoming barriers to deliver care for marginalised groups.

An important first step is ensuring that our health systems adequately monitor and quantify the characteristics that are associated with poor outcomes. There are examples of nascent health service delivery approaches that aim to use such data to deliver proportionate universalism, but research is required to understand whether they achieve the stated aims of closing gaps whilst improving health outcomes for all. Finally, whilst it is vital that we develop health systems that account for and address inequalities, we must not fall into the trap of focusing wholly on downstream 'cure'. We must seek to remedy unjust social structures through political engagement alongside targeted practical support.

Abbreviations

UHC: Universal Health Coverage; WHO: World Health Organisation.

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Publisher's Note

Chapter 3

Improvement Studies for Equitable and Evidence-based Innovation: An overview of the 'IM-SEEN' approach

The IM-SEEN collaborators meeting in Nairobi
Source: Andrew Bastawrous

Key messages

- Whilst health system leaders and programme managers have committed to extend coverage with a focus on left behind groups, this work is rarely systematised.
- Seemingly few health services/programmes routinely gather and analyse sociodemographic data to identify which groups are facing the greatest barriers to accessing care.
- Seemingly few health services/programmes routinely engage with those who are being left behind to direct efforts to improve equitable access.
- Seemingly few health services/programmes routinely use robust scientific approaches to test whether service modifications are causally associated with improved outcomes.
- The IM-SEEN approach uses routinely collected data and rapid methods to address these gaps.

This chapter sets out the IM-SEEN approach. Ahead of our first all-partner in-person meeting in Nairobi in 2022, I prepared the initial draft of the framework and background materials summarising the main problems with the status quo. I knew that we needed to introduce elements to routinely gather sociodemographic data; analyse these data to identify the groups experiencing the worst access to care; some form of engagement with these groups to understand what the issues were and how they might be addressed; a testing element that used a gold-standard approach; and then a mechanism to take effective interventions to scale. Figure 1 shows a screenshot from one of the slides that I presented at the in-person partner meeting, summarising what I felt to be the main questions.

During the meeting we discussed the name for the research programme, settling on 'Improvement studies for equitable and evidence-based innovation' (IM-SEEN). This acronym aims to convey our focus on finding and listening to those who are being left behind.

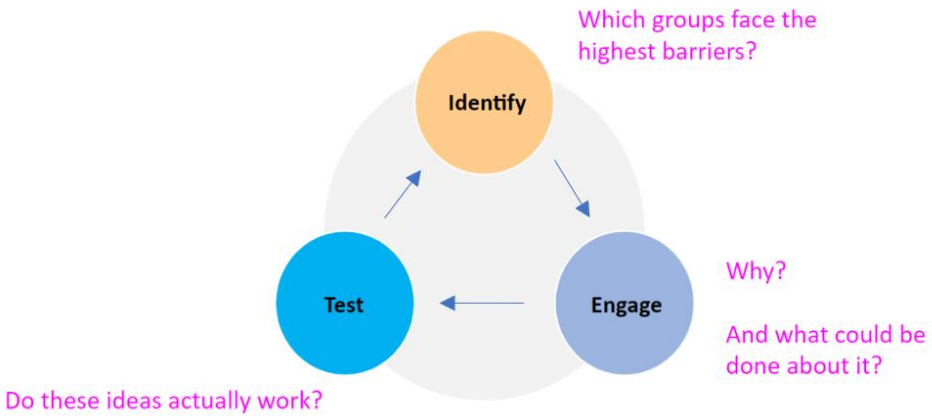

Figure 1: Slide from the partner meeting that identifies critical gaps in our knowledge

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RESEARCH PAPER COVER SHEET

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SECTION A – Student Details

Student ID Number	2004040	**Title**	Dr
First Name(s)	Luke		
Surname/Family Name	Allen		
Thesis Title	Improving equitable access to community-based health services: Developing and testing a new model in Kenya's national eye screening programme		
Primary Supervisor	Andrew Bastawrous		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

SECTION B – Paper already published

Where was the work published?	International Journal of Equity in Health		
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SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I sketched out the original IM-SEEN model and presented the first draft of the elements and cycle to the wider collaborator group for their feedback and comments. Early stages of development were strongly informed by ongoing discussions with Andrew Bastawrous. Following presentation of my first draft to the wider collaborative group. I led the iterative refinement of the model. I wrote the first draft of the summary manuscript and led the process of revision, submission, response to peer-reviewers, and finalisation of the proofs.

SECTION E

Student Signature	Luke Allen
Date	26th April 2024

Supervisor Signature	REDACTED
Date	30-04-2024

International Journal for Equity in Health

COMMENT

Open Access

Improvement studies for equitable and evidence-based innovation: an overview of the 'IM-SEEN' model

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Abstract

Background Health inequalities are ubiquitous, and as countries seek to expand service coverage, they are at risk of exacerbating existing inequalities unless they adopt equity-focused approaches to service delivery.

Main text Our team has developed an equity-focused continuous improvement model that reconciles prioritisation of disadvantaged groups with the expansion of service coverage. Our new approach is based on the foundations of routinely collecting sociodemographic data; identifying left-behind groups; engaging with these service users to elicit barriers and potential solutions; and then rigorously testing these solutions with pragmatic, embedded trials. This paper presents the rationale for the model, a holistic overview of how the different elements fit together, and potential applications. Future work will present findings as the model is operationalised in eye-health programmes in Botswana, India, Kenya, and Nepal.

Conclusion There is a real paucity of approaches for operationalising equity. By bringing a series of steps together that force programme managers to focus on groups that are being left behind, we present a model that can be used in any service delivery setting to build equity into routine practice.

Keywords Equity, Continuous improvement, Universal Health Coverage

Background: pervasive health inequalities

Health outcomes are inequitably distributed across and between populations [1–3]. The inverse care law states that the availability of medical care is inversely proportional to need [4]. The most disadvantaged groups in society often experience the worst health outcomes [5].

As signatories to the Sustainable Development Goals seek to advance Universal Health Coverage (UHC), governments and health system leaders face complex decisions about how to extend access to services whilst balancing equity considerations against cost-effectiveness: for example, it is often expensive to reach disadvantaged and remote communities.

In the 2010 review 'Fair society, Healthy Lives', Michael Marmot introduced the concept of 'proportionate universalism' (Table 1), arguing that health services should benefit all, but with the greatest gains experienced by those with the greatest needs [1]. Following on from

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Table 1 Proportionate universalism [1, 8, 9]

Proportionate universalism combines targeting with universalist principles of equality and fairness; seeking to provide services to all, with additional resources provided to members of specific groups who face structural disadvantage [1]. This builds on prioritarian [8] principles outlined in the Alma-Ata Declaration that calls for "the progressive improvement of comprehensive health care for all… Giving priority to those most in need"[9].

this, in 2014, WHO published 'Making fair choices on the path to UHC' which urged system leaders to focus on extending coverage of a core basket of priority services to all citizens; paying particular attention to ensuring that disadvantaged groups are not left behind [6]. In the same year, WHO and the World Bank issued a joint call for services to routinely gather data on core sociodemographic indicators, arguing that data collection is the essential first step in moving towards redressing health inequalities [7].

Unfortunately, whilst sociodemographic data collection has become more widespread, ubiquitous inequalities persist, [3] suggesting that our health systems are not translating new intelligence into meaningful action. An added problem is that interventions and service modifications designed to address inequalities are rarely evaluated using robust scientific techniques such as randomised controlled trials (RCTs) [10].

Our team – a collaboration between the International Centre for Eye Health (ICEH) at the London School of Hygiene & Tropical Medicine (LSHTM), the University of Botswana, the Kenyan Ministry of Health, Nepal Netra Jyoti Sangh, the College of Ophthalmology for Eastern, Central and Southern Africa, and Peek Vision – has been funded by the NIHR and The Wellcome Trust to develop and field-test an equity-focused continuous improvement model that addresses these challenges (Table 2). Whilst other publications from our group provide detailed methods for each of the elements and will present emerging findings, this paper seeks to provide a holistic overview of how the model fits together, the issues it seeks to address, and potential application to other fields.

The IM-SEEN model

The model that we have developed is based around three elements: routinely gathering sociodemographic data from service users and regularly interrogating these data to identify which groups are experiencing the worst outcomes; engaging with representatives from these groups to elicit their perspective on the main issues and solutions; and then using rigorous randomisation-based testing of these potential solutions in order to equitably improve outcomes (Fig. 1). Each element requires scientifically-grounded work; gathering and analysing data; conducting interviews; and running pragmatic embedded trials.

We have dubbed the overall approach 'IM-SEEN': Improvement Studies for Equitable and Evidence-based Innovation. The acronym highlights our focus on engaging with members of underserved groups and basing the improvement cycle around their concerns and ideas, rather than making assumptions or acting on the behalf of these communities.

The IM-SEEN model was iteratively developed by a team of public health specialists, statisticians, qualitative researchers, economists, programme implementers, ethicists and government policymakers. AB, ON, MG, SM, MB and NB scoped the initial need for an approach to continually improving health service outcomes with a focus on those 'left behind' to close socioeconomic gaps.

Table 2 Applying the model in the field of eye care

Whilst the model has been designed so that it can be applied in any setting, our focus is improving equitable use of primary care services in line with the broader aims of Universal Health Coverage. Our group is in the process of field-testing the model in large community-based eye screening programmes operating in Botswana, India, Kenya and Nepal

Eye health is a major global public health issue and 90% of the 1.1 billion people with correctable vision impairment live in low and middle income countries [11]. It is thought that only around half of those identified with a need at screening actually attend clinic to receive treatment – which is close to the African regional mean for non-attendance across all service types [12]. Evidence is limited, but suggests that women, widows, and those from rural areas are the least likely to receive the care they need [11, 13]

The advent of smartphone-based eye assessment and the digitisation of vision screening programmes has made it much more affordable to rapidly screen and treat large populations. The most widely used digital platform is currently supplied by Peek; a social enterprise non-profit spin-out from LSHTM whose app-based programme has been rigorously evaluated [14–20]. Peek has agreements in place with international non-governmental organisations (NGOs), local NGOs and governments in twelve LMICs to support eye screening programmes that should reach tens of millions of people over the next decade [21]. Our group has been working with Peek to embed the IM-SEEN model into their processes and software. We anticipate that this method will allow local eye health system leaders to conduct rapid randomised controlled trials (RCTs) within their programmes to test incremental modifications aimed at reducing socioeconomic gaps in service provision, with the greatest gains seen in disadvantaged groups

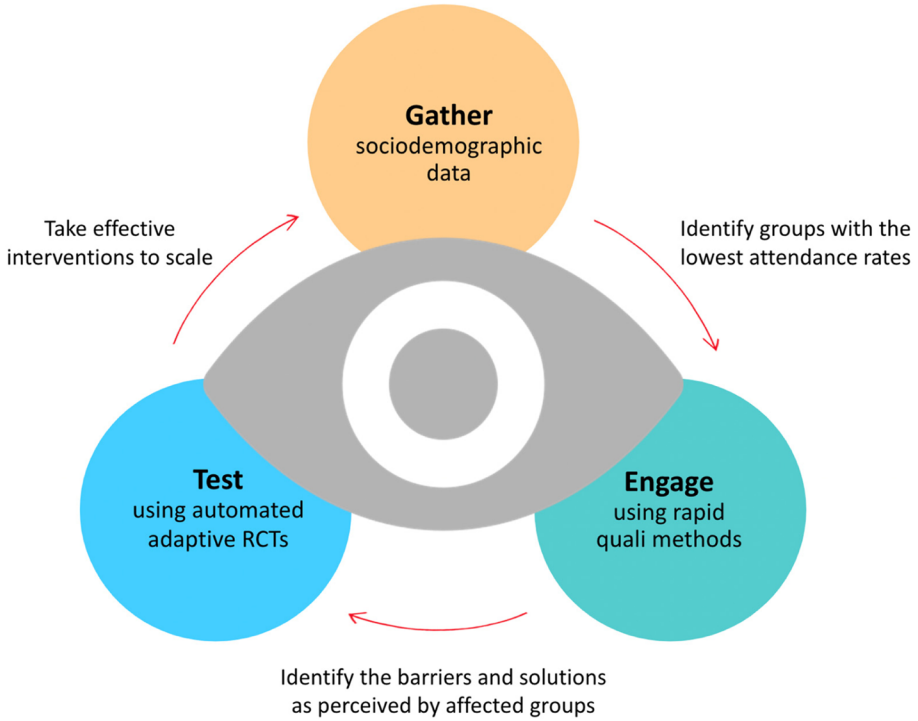

Fig. 1 The IM-SEEN approach to continually improving equitable outcomes

LA led a series of reviews and the drafting of early models which were iteratively refined between 2021–2023 during a series of online and in-person workshops funded by the NIHR and Wellcome Trust. The core team are co-authors of this paper.

The IM-SEEN process for continuous equitable improvement

Gathering sociodemographic data to identifying underserved groups

The first step in model involves quantifying baseline inequalities and identifying the sociodemographic group(s) with the worst outcomes. This process should be built into routine data collection, with analysis and reporting automated as much as possible.

In our eye programmes, screeners are digitally documenting the sociodemographic characteristics (including age, sex, ethnicity/language, religion, education, health status, assets, and income) of every individual who is found to have an eye need and referred on to receive further care. Quarterly meetings are used to review these data with the programme leads. We use multivariable logistic regression to identify which characteristics are most strongly associated with non-attendance. Detailed methods are available in a separate publication [22].

Understanding why certain groups do not attend – and what could be done about it

Once the characteristics most strongly associated with non-attendance have been identified, the next step is to engage with representatives from these underserved group(s) to understand the barriers they face, and then collaboratively identify service modifications that might improve outcomes. These engagement and co-creation processes should seek to obtain meaningful and actionable data with minimum time and resource requirements.

Our team has conducted a scoping review of rapid qualitative methods that can be used to elicit barriers and potential solutions [23]. Based on this work we have developed a bespoke rapid qualitative elicitation approach: research assistants will perform telephone interviews with non-attenders in each setting and use an a priori deductive framework to code responses. The sample size will be determined by thematic saturation. The long list of barriers and potential solutions derived from these interviews will not necessarily be generalisable to all non-attenders from the same underserved group. To identify the potential solutions that are felt to offer the most value by a statistically representative sample, we will send SMS messages to approximately 400 other non-attenders from the same underserved group, asking them to rank the mooted solutions. The top-ranked interventions will be reviewed by the national leadership team to

assess risk, cost, feasibility, and likely impact. Safe and feasible interventions that have a scientifically plausible mechanism of action will be implemented and rigorously evaluated. A detailed protocol for this elicitation process has been published online [24].

Testing promising interventions

Once a set of interventions have been derived from engaging with non-attenders, the next step is to implement them and evaluate whether they improve outcomes and reduce sociodemographic gaps. The IM-SEEN model uses a platform randomised controlled trial (RCT) design to assess whether a service modification is causally associated with improvement. This means that the intervention is randomly allocated to individuals or sites. This is only ethical when there is clinical equipoise i.e., it is unclear whether the intervention is better or worse than the status quo. Each intervention will be reviewed by an independent in-country ethics committee.

Allocation, outcome assessment, statistical testing, and reporting should be automated as much as possible to reduce costs to the health programme. Changes within the most underserved groups are the primary outcomes. Mean changes for the entire population is a secondary outcome.

In Botswana's eye screening programme, we have embedded an automated platform trial that routinely collects and analyses all referral and attendance data. A simple Bayesian algorithm coded in R allocates referred individuals to the intervention or control arm, automatically reviews attendance data, and performs interim statistical testing according to predetermined stopping rules. The algorithm continually adjusts the allocation ratio to favour the best-performing arm(s), minimising the number of people who are assigned to less/ineffective arms. Our trial is not yet complete, but the detailed protocol has been published elsewhere [25].

We are in the process of seeking ethical approval to establish platform RCTs in each country. These use a master protocol that specifies the population (people identified with an eye care need) and primary outcome (attendance), but allow multiple interventions to be tested over time. Every time a new intervention is suggested, ethics committees only have to review the risks of that intervention, having already approved the overall trial architecture. This makes it much more efficient than running serial individual RCTs for each new intervention that is suggested. We are in the process of publishing a detailed protocol for the overall platform trial design.

Taking effective service improvements to scale

Once interventions have been rigorously assessed, the final step is to take effective interventions to scale across the entire national programme and then repeat the cycle. We envisage that the process will lead to incremental improvements, with approximately 1–2 cycles per year, depending on local leadership and resourcing.

Why is this model needed?

From data collection to action

Many services now acknowledge and quantify inequalities but do not or cannot translate this intelligence into meaningful action. Where it does happen, the disaggregation of data to assess inequalities and intersectionality [26] often occurs only at the completion of a programme, when there is low potential for the findings to result in change. We feel that there is a need for a practical tool to guide managers through the process of systematically analysing routinely collected sociodemographic data in real-time, and then turning that insight into robust action to improve outcomes for all service beneficiaries, with the greatest effort focused on those with the greatest need.

Engaging and co-creating

Whilst people affected by a given problem tend to have sensible ideas about how to fix it, initiatives to target underserved groups (e.g. those living in remote areas) are rarely developed with meaningful input from service users themselves [27, 28]. Instead, managers sit down to discuss potential issues and solutions on behalf of the underserved groups, and then implement service modifications without further consultation. This is partly because it can be time-consuming and expensive to seek non-tokenistic input from others – especially from those at the margins of society [27]. However, this needs to change. Community engagement and empowerment is one of the core tenets of Primary Health Care [29] and all governments have committed to deliver health systems that place greater decision-making power in the hands of the people [9, 29].

A model for continuous equity-driven service improvement should meaningfully engage with representatives of the groups found to be facing the highest barriers. Ultimately it is these service users who have the best understanding of why they cannot access care or achieve good outcomes, and they are likely to have practical ideas for how the service could be modified to better serve their population.

We note that service leaders need scientifically robust yet rapid and affordable methods for eliciting barriers and co-designing solutions, however current engagement exercises tend to cluster between two opposing

poles: expensive, bespoke, in-depth qualitative research that takes many months to plan and execute on one hand, and zero/tokenistic engagement on the other. The first approach provides robust findings at a very high cost for service providers, the second is affordable but does not produce usable intelligence. Somewhere between the two lies a minimum viable product; the cheapest and fastest possible approach that delivers meaningful data based on genuine engagement.

Industry tends to use focus groups and telephone surveys for rapid market research, but we are not aware of any rapid pragmatic research methods being routinely used in health service improvement; for instance, the recent King's Fund workshop on 'improving services by listening to patient voices' did not showcase any qualitative methods that could be conducted in fewer than six months [30]. This is a strategic barrier to co-production [31]. Our work to develop rapid yet robust methods represents a step forward, but our approach is still in the process of being tested. The IM-SEEN model stipulates that ideas for service improvements should come from engagement with affected communities, but does not dictate the exact methods as different contexts require different approaches.

Checking whether 'service improvements' actually improve services

Once potential solutions have been identified it is vital that they are rigorously evaluated. This should entail checking whether any changes made to the service lead to changes in outcomes – positive or negative – as well as understanding the effect size and distribution among different groups. Specifically, it is important to check that access and outcomes improve for all groups, ideally with the greatest gains observed among groups with the greatest need.

Despite widespread lip service to 'continuous improvement', in our experience, service modifications designed to boost equity are often conducted as one-off initiatives. Furthermore, efforts to reduce inequalities tend to be poorly evaluated [10]. This is surprising given the rise and rise of *Plan Do Study Act* cycles [32–34]. Whilst the core 'PDSA' model is based on the scientific approach of formulating a hypothesis, collecting data to test the hypothesis, analysing and interpreting results, and making inferences to iterate the hypothesis, [35] most quality improvement initiatives fail to quantify change appropriately and it is rare to find truly iterative examples where services have progressed through more than one or two revolutions of the cycle [36, 37].

Even when a service *does* routinely gather high quality data and test hypothesis-driven innovations, the process tends to be limited by an overdependence on crude before-after testing or interviews with a handful of service users (which can offer valuable information about how/why and intervention works but tells us nothing about the mean effect size). We need to be sure that any observed changes in outcomes are driven by service modifications. More than that, we need to ask if it is ethical to modify services without recourse to robust means of evaluating impact – especially where unintended consequences could lead to harm or a deterioration in service quality or equity.

The most robust means of evaluating whether service innovations, reconfigurations, amendments, adaptations, and other 'improvements' actually confer benefit is by conducting randomised controlled trials [38]. However, RCTs are generally expensive, require specialist statistical support, and can take years to run, rendering them unfeasible for most settings [39]. When resources are available, the expensive price tag exerts a strong pressure to reserve this tool for service amendments that have a high 'pre-test' probability of success. This means that the least robust service modifications are systematically subjected to the weakest levels of methodological scrutiny, potentially squandering resources, incurring opportunity costs, and even exposing users to harm.

The rising use of RCTs in industry – often referred to as 'A/B testing'—has spawned a wave of low-cost, real-time, automated approaches to running real-time pragmatic trials in order to optimise services with high-quality empirical data. The 'test everything with controlled experiments' approach was born of the observation that tiny service changes sometimes had large impacts on important outcomes, and that most large, expensive reforms based on promising ideas fail to deliver the intended change [40]. Allied work from non-health areas of continuous improvement has demonstrated that multiple small improvements can lead to large overall gains – strengthening the case for multiple rapid tests of multiple service modifications [41, 42]. This mature and powerful 'test everything' approach is being used to optimise search engines, improve web page click-throughs, and drive profit margins [43–45] but has not yet made the transition to health service improvement.

As health programmes increasingly digitise patient flow, opportunities are emerging to embed prospective randomisation and statistical testing into administrative software [46]. The adoption of 'built-in' testing would reduce the barriers for routine RCT testing. By making it easier to perform RCTs to test service modifications, we would vastly improve safety by helping managers to reliably differentiate between effective and ineffective amendments. The automation of randomization, allocation, and statistical analysis works best when algorithms

can be directly embedded into clinical software, as this eliminates the delays associated with human factors.

Even automated RCTs still take time and specialist expertise to set up, and these costs mean that programmes will have fewer resources to deploy for service delivery. The time taken to design the trial and obtain ethical approval can also delay the implementation of potential service improvements. These ethical issues must be weighed against the fact that introducing interventions without robust evaluation can lead to the unknowing delivery of ineffective or harmful interventions. Nevertheless, given the work, time and costs involved in setting up a platform trial, this approach will deliver the greatest cost-benefits if used to continually assess a large number of interventions over a long period of time.

Changes and interventions that are found to be effective at improving outcomes and reducing the inequalities should be taken to scale across entire services. In summary, there is a need to develop embedded RCT testing code that can run resource-light trials in order to provide robust evidence on whether well-intentioned service modifications are helping or harming.

Discussion

In this paper we have presented an overview of the IM-SEEN model and a description of how we are applying it in the field of eye health in four different country programmes. A key strength and limitation of the model is that is describes essential elements but does not prescribe the exact methods. Whilst we are using a specific set of sociodemographic indicators and multivariable logistic regression to identify groups with the lowest attendance rates in Botswana, Kenya, India and Nepal, this specific approach will not be appropriate for all scenarios. To take a hypothetical example, a regional cervical screening service associated with urban/rural disparities may want to use chi-square testing, followed by Rapid Anthropological Assessment [47] as these specific methods are best suited to the programme's needs. Similarly, our model is based on the use of automated adaptive RCTs as these minimise the number of people exposed to ineffective or harmful interventions and should facilitate rigorous and efficient continuous identification of service modifications that improve equitable outcomes. However, there are virtually infinite potential configurations for these RCTs and it would not be appropriate for our team to mandate one specific approach.

Whilst the model is been designed for use in any field, its initial deployment and empirical testing is underway in community-based eye health services. Our model directly supports the recommendations of the 2019 World Report on Vision through promoting high quality implementation and health systems research, empowering people and communities, and creating an enabling environment to implement integrated people centred eye care [48]. These themes resonate with the core pillars of the Astana Declaration on Primary Health Care: empowering people and communities, and advancing equitable care that is responsive to local needs [29].

One major advantage of testing the model in smartphone-based eye screening programmes is that exposure and outcome data are routinely digitally collected and stored in a unified database where an automated testing system can operate with minimal need for human intervention. We are keen to apply the model to address other areas such as the inequitable uptake of cancer screening, inequitable diagnosis and provision of treatment for diabetes and hypertension, and the distribution of vaccines. The model demands that sociodemographic data are obtained from intended service beneficiaries and that the primary outcome is recorded – be that attendance, treatment, cure, or anything else. Ideally, the primary outcome will be recorded routinely and digitally for every patient. Where this is not the case, additional costs will be incurred. Taking eye care as an example, the ultimate outcome is corrected vision but service attendance is often used as a proxy.

There has been a proliferation of theoretical models of proportionate universalism and pro-equity service delivery, but as Francis-Oliviero and colleagues note in their review of the field, interventions and real-world examples are rare [10]. As far as we are aware, the IM-SEEN model is the first operational model that has been developed to drive continuous evidence-based and equitable improvement in real-world programmes. As results from the model's application in the field of eye care services emerge, we will continue to refine the approach and apply it to other areas. We encourage other researchers, programme managers and policymakers to adopt the principles – if not the model itself in future work to extend health service coverage to all groups, with a focus on those with the greatest need.

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None.

Authors' contributions
LNA wrote the draft manuscript. All authors reviewed, revised, and approved the final manuscript.

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AB and NB both work for Peek Vision.

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Publisher's Note

Part 2: Gathering sociodemographic data

Chapter 4

Comparing modalities for sociodemographic data collection

Cacti in Nairobi (because who wants to see a photo of a systematic review being performed?)
Source: Author

Key messages

- Gathering sociodemographic data is the essential first step in identifying and addressing inequitable access to care.
- There are a number of different modalities that can be used to gather these data.
- I led a systematic review to compare the performance and resource requirements of in-person data collection vs. phone calls and automated phone-based data collection.
- Acceptability and data equivalence were comparable across all approaches. There were insufficient data on costs to make any firm conclusions.
- Given that mode effects appear to be minor, I concluded that modality choice should be guided by the programme needs and available resources.

The first stage of the IM-SEEN approach is embedding the collection and analysis of socioeconomic data into a given programme's routine operation. In Kenya's VIP programme the budget had already been set for the year, and any additional costs for data collection would lead to a reduction in the total number of people who could be screened. Similarly, additional time spent gathering data was time that could otherwise be spent screening. Given these pressures on time and resources, I developed a protocol for a systematic review to compare different modalities of data collection in terms of costs, time taken, and methodological performance.

The decision to use the term 'sociodemographic' rather than 'socioeconomic' was based on the observation that the latter is often used in the context of proxies for social position that combine multiple social, economic, and demographic factors e.g. race, education and income.[75,76] Our use of 'sociodemographic' was intended to convey that our focus was on collecting a wide range of core characteristics without the intention of combining them to assess social position.

The choice of modalities to include in the review was based on a series of discussions with Peek and programme implementing partners. I included all potentially feasible options: in-person data collection (i.e. by screeners at the point of referral), telephone calls (which could be conducted by a team from a central call centre), automated phone calls (i.e. where a bot gathers data by asking participants to dial/say a number in answer to a series of multiple-choice questions). Given that I anticipated asking people about more than one-or-two sociodemographic domains, and each domain (e.g. education) has multiple potential response options, no-one thought it would be feasible to gather these data via SMS surveys, as each message is limited to 160 characters. However, I did include web-based self-completed surveys on the basis that hyperlinks can be sent via SMS.

Our protocol was published in BMJ Open[77] (Appendix 1). The final paper was published in JAMA Network Open.[78] I used the process to teach an academic GP registrar with an interest in global health how to conduct systematic reviews: Dr Shona Mackinnon did as great job as co-reviewer, and I'm also grateful to Dr David Blaine, also based in Glasgow, for his input.

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Student ID Number	2004040	**Title**	Dr
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Surname/Family Name	Allen		
Thesis Title	Improving equitable access to community-based health services: Developing and testing a new model in Kenya's national eye screening programme		
Primary Supervisor	Andrew Bastawrous		

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Where was the work published?	JAMA Network Open		
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SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I was the lead author for this systematic review. I worked with an information specialist (Iris Gordon) to design the search, and I led on all other aspects of the research; from developing the protocol and setting the inclusion and exclusion criteria, to leading data extraction, analysis, and presentation. I recruited and trained Shona Mackinnon as the second reviewer. I wrote the first draft of the manuscript and led the process of iterative revision and submission. I led the revision process, supported by Shona. David Blane supported with guidance around selecting outcomes. The remaining co-authors provided valuable input at the review and revision stages.

SECTION E

Student Signature	Luke Allen
Date	26th April 2024

Supervisor Signature	REDACTED
Date	30-04-2024

JAMA Network Open

Original Investigation | Global Health

Performance and Resource Requirements of In-Person, Voice Call, and Automated Telephone-Based Socioeconomic Data Collection Modalities for Community-Based Health Programs

A Systematic Review

Luke N. Allen, MPH, MBChB; Shona Mackinnon, MSc; Iris Gordon, PhD; David Blane, PhD; Ana Patricia Marques, PhD; Stephen Gichuhi, PhD; Alice Mwangi, MSc; Matthew J. Burton, PhD; Nigel Bolster, PhD; David Macleod, PhD; Min Kim, MSc; Jacqueline Ramke, PhD; Andrew Bastawrous, PhD

Abstract

IMPORTANCE Gathering data on socioeconomic status (SES) is a prerequisite for health programs that aim to improve equity. There is a lack of evidence on which approaches offer the best combination of reliability, cost, and acceptability.

OBJECTIVE To compare the performance of different approaches to gathering data on SES in community health programs.

DATA SOURCES A search of the Cochrane Library, MEDLINE, Embase, Global Health, ClinicalTrials.gov, the World Health Organization International Clinical Trials Registry Platform, and OpenGrey from 1999 to June 29, 2021, was conducted, with no language limits. Google Scholar was also searched and the reference lists of included articles were checked to identify further studies. The search was performed on June 29, 2021.

STUDY SELECTION Any empirical study design was eligible if it compared 2 or more modalities to elicit SES data from the following 3 categories: in-person, voice call, or automated telephone-based systems.

DATA EXTRACTION AND SYNTHESIS Two reviewers independently screened titles, abstracts, and full-text articles and extracted data. They also assessed the risk of bias using Cochrane tools and assessed the certainty of the evidence using the Grading of Recommendations, Assessment, Development and Evaluation approach. Findings were synthesized thematically without meta-analysis.

MAIN OUTCOMES AND MEASURES Response rate, equivalence, time, costs, and acceptability to patients and health care professionals.

RESULTS The searches returned 3943 records. The 11 included studies reported data on 14 036 individuals from 7 countries, collecting data on 11 socioeconomic domains using 2 or more of the following modes: in-person surveys, computer-assisted telephone interviews (CATIs), and 2 types of automated data collection: interactive voice response calls (IVRs) and web surveys. Response rates were greater than 80% for all modes except IVRs. Equivalence was high across all modes (Cohen $\kappa > 0.5$). There were insufficient data to make robust time and cost comparisons. Patients reported high levels of acceptability providing data via IVRs, web surveys, and CATIs.

(continued)

Key Points

Question What are the relative strengths and weaknesses of different socioeconomic data collection modes?

Findings In this systematic review of 11 studies with 14 036 individuals, high levels of equivalence and acceptability were found across in-person surveys, computer-assisted telephone interviews, and 2 types of automated data collection: interactive voice response calls and web surveys; cost and time comparisons were rarely performed. Response rates were greater than 80% for all modes except interactive voice response.

Meaning This systematic review identified no substantial evidence that remote and automated data collection modes are any worse than in-person approaches, and there was no compelling evidence that these approaches are faster or cost less.

+ Supplemental content

Author affiliations and article information are listed at the end of this article.

Abstract (continued)

CONCLUSIONS AND RELEVANCE Selecting an appropriate and cost-effective modality to elicit SES data is an important first step toward advancing equitable effective service coverage. This systematic review did not identify evidence that remote and automated data collection modes differed from human-led and in-person approaches in terms of reliability, cost, or acceptability.

JAMA Network Open. 2022;5(11):e2243883. doi:10.1001/jamanetworkopen.2022.43883

Introduction

Rationale

Inequalities in health are pervasive and persistent. Women and girls, individuals living in rural areas, and persons with lower levels of income, education, and social status all tend to experience higher barriers to accessing care than other groups.[1-4] To understand and redress socioeconomic inequalities, international development partners are increasingly calling for socioeconomic status (SES) data to be routinely collected and analyzed by all health systems and programs.[5,6]

Previous work has reported that SES data can be collected using a variety of modalities in the community setting, including in-person interviews, telephone calls, and automated telephone-based systems.[7] There is growing interest in using mobile phones to collect data for global health programs on the basis that this modality is lower cost, faster, and more flexible than in-person approaches.[8,9]

Croke et al[10] have argued that telephone-based data collection is acceptable in settings where mobile phone ownership rates exceed 80%. While this percentage is an arbitrary threshold, we note that the share of the population that has access to a telephone exceeds the proportion of those who own a telephone. Mobile phone ownership has increased sharply in the past decade such that there are now approximately 100 mobile phone subscriptions for every 100 people in low- and middle-income countries (LMICs).[11,12] Across Sub-Saharan Africa, where telephone ownership is lowest, telephones have been used for a wide range of applications including surveillance, surveys, behavior change interventions, monitoring and evaluation, and training.[12-17]

It is well known that the mode of data collection (eg, in-person, telephone interview, or short message service [SMS]) can influence survey response rates and other performance characteristics, especially when the questions are of a sensitive nature.[18,19] Previous research suggests that telephone-based data collection approaches may reduce social desirability bias—where responders provide what they perceive to be socially acceptable answers even if they are not accurate—compared with in-person approaches.[20] However, telephone-based approaches also tend to have lower response rates and have historically presented under-coverage biases due to lower penetration among less-educated and low-income groups.[21]

Pariyo and colleagues[22] have noted the dearth of research comparing different modalities of SES data collection in LMICs. Given the increasing feasibility and potential efficiency gains of using telephones for SES data collection, we aimed to systematically review the findings of empirical studies that have compared in-person vs voice call vs telephone-based modalities for gathering SES data for community-based health programs in terms of their performance characteristics, resource requirements, and acceptability to participants and service professionals.

Methods

This registered review followed a published protocol.[23] It also followed the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) reporting guideline and Cochrane guidelines.[24,25]

Eligibility Criteria

Population

In this systematic review, the population was composed of studies rather than people, namely, those that sought to compare 2 or more modalities for SES data collection from individuals enrolled in community-based health programs. Studies that reported on only 1 mode of data collection were excluded.

For the purpose of this review, *health programs* were defined as organized activities to improve 1 or more health outcomes in a defined population. *Community-based* encompasses all settings except hospitals. Some researchers exclude primary care facilities from definitions of community-based care[26]; however, these facilities were included in this review, along with outreach and mobile clinics, community centers, schools, workplaces, and people's own homes.

Socioeconomic status is a critically important but nebulous concept that pertains to social and economic standing within society.[27] It determines exposure to the social determinants of health; "the conditions in which people are born, grow, live, work, and age"[2]; and relates to issues of privilege, power, and control.[28] Almost all health outcomes are patterned according to SES, with the most disadvantaged populations experiencing the worst health outcomes.[2,28,29] Socioeconomic status is commonly measured using income, educational level, occupation, and other metrics, such as wealth, caste, and place of residence. We included all of these domains, as well as any other proxies that are identified by researchers as capturing SES.

Interventions

The interventions being studied are 3 different groups of modalities for collecting SES data (**Box**). The focus is on the modality of data collection (eg, in-person vs voice call vs automated) rather than the content of the wording that is used to elicit information.

We excluded approaches that used a blend of modes to elicit SES data. We excluded studies in which the SES questions and wording were not kept constant across modes. Studies that gather SES

Box. Definitions of the 3 Data Collection Approaches Used in This Review

In-person data collection included any form of exchange between a program implementer and a participant or their responsible guardian where the program implementer asks predefined questions to ascertain the participants' socioeconomic status and a synchronous response is received, ie, both parties occupy the same time and space, and the response is recorded by the implementer before the encounter is terminated. Any recording modality used by the program implementer will be included, such as pen and paper or completion of an electronic form. For this review we will also include self-administered questionnaires as a subtype of in-person data collection, provided that the data collection instrument was provided when the participant presented to a program implementer in person, the participant was asked to complete the data entry form, and the participant submitted their responses before departing. Any nonhospital location was accepted.

Voice call data collection includes real-time, telephone-based verbal exchanges between program implementers and participants whereby SES data are elicited and recorded by the program implementer using predefined questions. This category included computer-assisted telephone interviews—where the interviewer follows prompts on a computer screen, usually in a call center—as well as non–computer-assisted telephone interviews. Videocalls were included as another subtype of voice calls.

Automated telephone-based data collection included any mobile telephone–based asynchronous exchange of information whereby participants are sent a standardized text message (also known as a short message service [SMS]), multimedia message (MMS), or automated phone call (sometimes called interactive voice response or IVR) and asked to provide SES data. Interactive voice response calls use prerecorded messages that prompt respondents to provide answers using speech, eg, state your age in years or by entering numbers on the keypad eg, press 1 for yes and 2 for no. We allowed responses to be provided using the same modality or any other digital form, eg, entering details on a webpage/web survey. Interventions that required participants to engage with human program implementers (eg, human-led SMS exchanges) were excluded from this modality. All forms of phrasing of the requests and responses were included. Reasoning that all smartphones come with a preloaded browser, we included web surveys that can be accessed by a hyperlink, as long as the link was sent via SMS or MMS. We excluded data collection approaches that required the download of third-party software, including email.

data at the household or community level were only included if these data were used to make assumptions about the SES of identifiable individual participants enrolled or due to be enrolled in the service delivery program of interest.

Comparator

Studies that examined any 2 or more modalities were eligible. We excluded studies that only reported outcomes for 1 modality, that is, in which comparisons were not possible between modes. There was no index or gold standard data collection modality. Interventions that bundled requests for SES data with requests for other data (eg, broader demographic data) were included, as long as separate results were reported for the SES data collection element.

Outcomes

Our 2 primary outcomes were performance characteristics and resource requirements. We reported these outcomes at the level of the following individual SES items.

Performance Characteristics

- Response rate: number of completed SES items divided by the total number of elicitation attempts. This outcome was calculated at the level of each SES item.
- Equivalence: agreement between the responses obtained from 2 or more different modalities. Recognizing that equivalence can vary by question, we report equivalence for each SES item. We report equivalence figures that aggregated multiple SES questions in a secondary analysis; however, we do not report aggregate equivalence figures that mixed SES items with non-SES items. Following Marcano Belisario et al[30] and Gwaltney et al,[31] we used comparisons of mean scores between modalities and/or correlations and/or measures of agreement, including intraclass correlation coefficients, Pearson product-moment correlations, Spearman ρ, and weighted κ coefficients.

Resource Requirements

- Time: the time taken to gather SES data using each approach (range and mean).
- Costs: any financial data on the costs of operating the data collection approach. These approaches include fixed costs (equipment, software, insurance, and personnel required to set up a given data elicitation modality) and ongoing support costs. We aimed to calculate the fixed and per-person costs to purchasers per completed survey.

Our secondary outcome was acceptability to participants and service professionals, based on survey or interview results reporting on how program implementers and participants perceived the collection modality in terms of intrusiveness, ease of use, time requirement, and general acceptability, as well as perceived advantages, barriers, disadvantages, and additional costs presented by the beneficiaries, data collectors, or study authors.

Measures of Effect

For each outcome we present raw values and risks ratios. We used the most commonly studied modality (computer-assisted telephone interview [CATI]) as the reference group.

Study Types to Be Included

All empirical study designs that compared 2 or more data collection modalities were included. Studies were only included if they compared modalities that had been used to gather data from participants. Studies that used simulated data or data obtained from populations other than the intended beneficiaries were excluded. Both quantitative and qualitative study designs were included as long as they reported 1 or more of the outcomes of interest. Review articles were excluded, but the primary studies they discussed were screened for potential inclusion.

Information Sources

We searched the following information resources: the Cochrane Library, MEDLINE, Embase, Global Health, ClinicalTrials.gov, and the World Health Organization International Clinical Trials Registry Platform for current and ongoing trials. We searched OpenGrey for gray literature and the first 20 pages of Google Scholar. We checked the reference lists of included studies and relevant systematic reviews to identify any additional potentially relevant reports of studies. We contacted key authors to uncover additional or upcoming studies.

Search Strategy

The search strategy was built around 3 blocks: data collection modalities, SES concepts, and study design and setting terms (eMethods in the Supplement provides the full strategy). The search was limited to human studies published since 1999 (the year that it first became possible to send cross-network SMS messages). We searched for full-text studies published in any language. We did not include reports of studies published as conference abstracts. The search was performed on June 29, 2021.

Study Selection

Two of us (L.N.A. and S.M.) independently screened all titles and abstracts and full texts using online software (Covidence). Studies that did not meet the inclusion criteria were excluded. Disagreements were resolved through consensus-based discussion and discussion with a third reviewer (D.B.) when necessary. We recorded reasons for exclusion at the full-text screening stage.

Data Extraction and Management

Two of us (L.N.A. and S.M.) independently extracted study characteristics and data from the included studies using a custom data extraction form that was based on the Cochrane template.[25] We emailed study authors to request additional information and primary data if any aspect of their article precluded the assessment of eligibility or inclusion in the data synthesis.

Data Items

We extracted the following items from each study:

- Article details
- Study design, population, and setting
- Questions used to assess SES (SES domains and individual response options)
- Number of times SES data were collected from each participant (eg, cross-sectional or serial)
- Modalities used to collect SES data:
  - Modality name and definition
  - Who gathered the SES data
  - When data were gathered in the patient journey/program
  - Equipment used
  - Who provided the data
  - Synchronous or asynchronous data collection
- Types of comparison and outcome measures
- Outcomes: response rate, completeness, equivalence, time, costs, and all qualitative text provided on acceptability

Risk of Bias Assessment for Included Studies

Two of us (L.N.A. and S.M.) independently assessed risk of bias using the Cochrane RoB2 tool for randomized studies[32] and ROBINS-I[33] for nonrandomized studies. Disagreements were resolved by consensus and discussion with a third reviewer (D.B.) if necessary. The risk of bias for each outcome across individual studies was summarized by risk of bias tables. We also produced a review-level narrative summary of the risk of bias.

Principal Summary Measures

We used ratios to present principal differences between modalities as we considered the relative level of agreement, cost, or acceptability between each approach for a given SES item to be more important than the absolute level.

Strategy for Data Synthesis

Had data been available, we planned to pool effect estimates using a random-effects model.[34] Given the heterogeneity in study design, interventions, and outcomes of the included studies, we used a narrative synthesis without a meta-analysis approach, following reporting guidelines from Campbell and colleagues.[35] We stratified the synthesis by modality, SES domain, and outcome. We assessed heterogeneity by considering study design, interventions, and outcomes. To assess the risk of bias across studies we assessed selective outcome reporting by comparing protocols (when available) with published reports.

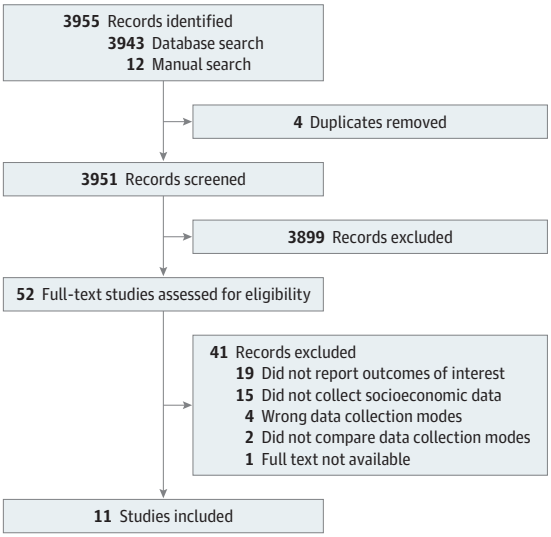
Additional Analyses

We planned to exclude studies at high risk of bias from the synthesis and primary analysis. We planned to perform a secondary analysis that included all studies irrespective of their risk of bias. We also planned to perform a secondary analysis assessing whether findings differed between high-income and LMICs.

Assessment of Certainty of Evidence

We used the Grading of Recommendations, Assessment, Development and Evaluations criteria to assess the certainty of the primary outcomes.[36,37] One of us (L.N.A.) collated the evidence for each primary outcome and suggested initial ratings that were discussed with another of us (S.M.) and agreed on by joint decision. For randomized clinical trials, evidence was assumed to be of high certainty and then downgraded due to risk of bias, inconsistency of results, indirectness of evidence, imprecision, or publication bias. For observational studies, evidence started at low certainty but was upgraded for a large effect size, dose-response, gradient, or plausible confounding that decreases the magnitude of effect.

Figure 1. Study Flow Diagram



Results

Search Results

Our search returned 3943 records and additional searches returned a further 11 studies (**Figure 1**). We contacted 24 study authors for full texts or missing data. Only 1 study[38] was excluded because we could not obtain the full text.

Study Characteristics

The 11 included studies reported data on 14 036 individuals from 7 countries: 5 from the US,[39-43] 2 from Australia,[44,45] and 1 each from Bangladesh and Tanzania,[22] Burkina Faso,[46] Kenya,[47] and the Netherlands[48] (**Figure 2**). As such, 3 studies (27.3%) reported data from 4 LMICs. All studies were published in English. **Table 1** summarizes the included studies' designs, modes used, SES domains, and outcomes.

Study Designs

One study used a randomized crossover survey design.[22] Parallel 2-arm[39,40,48] and 4-arm[44] surveys were more prevalent, with participants randomly allocated to different survey instruments and comparisons made between the instruments. Gagliardi et al[41] used a nonrandomized parallel 2-arm approach. Greenleaf et al[46] randomized participants to CATIs or interactive voice response calls (IVRs) and compared response rates between arms, but also compared both arms with findings from an in-person survey completed 11 months previously to calculate equivalence. The 4 remaining studies used test-retest approaches.[42,43,45,47] The vast majority of studies collected SES data as part of broader surveys. Only Chittleborough et al[45] had the primary aim of comparing different modalities for collecting SES data.

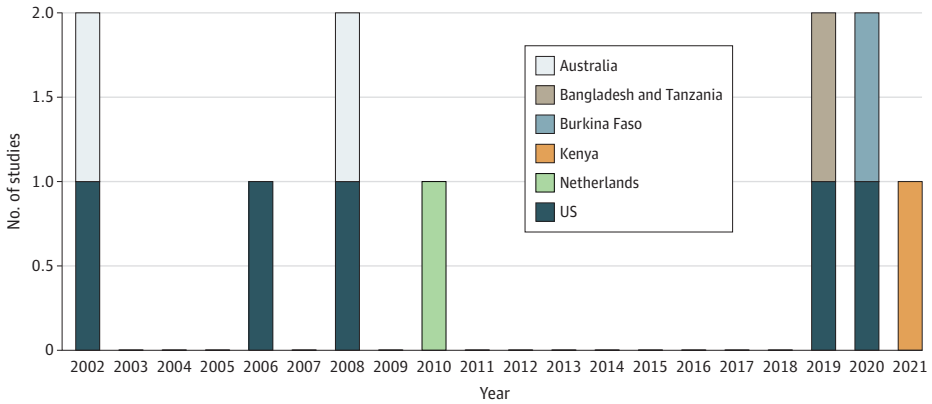
Risk of Bias

eFigure 1 and eFigure 2 in the Supplement summarize the risk of bias for each study. Overall, 7 studies were found to be at low risk of bias; we had some concerns regarding 4 studies, and none were found to be at high risk of bias. The risk of bias across studies (including selective outcome reporting) was low to moderate.

Data Collection Modalities

None of the included studies used SMS, multimedia message (MMS), or non-CATI approaches. CATIs were used in all 11 studies: this approach entails conducting real-time telephone calls and leading participants though a series of questions read from a computer screen, with responses usually entered using the same program. Three studies used data collected as part of an existing national

Figure 2. Publication Year and Study Population Location of Included Studies



survey,[44,45,48] 1 study used data collected by primary care administrative staff as part of an implementation and comparative effectiveness study,[41] and the remaining 7 studies used members of the research team to collect the data; in 3 of these studies data were collected as part of a larger parent study.[42,43,47]

In-person data collection,[40,45-47] web surveys,[39,42,43,48] and IVRs[22,41,44,46] were each assessed by 4 studies. Two studies[44,46] included hybrid IVR arms when a researcher called the participant at the beginning or end of the IVR data collection activity. We included these studies because all SES data were collected during the IVR phase; however, we have singled these studies out in the ensuing analyses because we might expect this approach to achieve a higher response rate than IVR approaches with no associated human interaction. All of the studies directly compared CATIs against one other approach except for Greenleaf et al,[46] who compared CATIs against IVRs for response rate, time, and costs, and they compared CATI and IVR approaches against in-person survey for equivalence. eFigure 3 in the Supplement illustrates the comparisons made between each modality.

Socioeconomic Domains

Eleven different SES domains were reported across the 11 included studies (eTable 1 in the Supplement). More than one-third of the studies collected data on educational level, marital status, household income, and employment; however, multiple different response options were used, and

Table 1. Study Characteristics of Included Studies Reporting the Performance Characteristic of 2 or More SES Data Collection Modes

Source	Design	Population	Study focus	Modes used to collect SES data	SES domains	Outcome domains
Corkrey and Parkinson,[44] 2002, Australia	Parallel, randomized, 4-arm survey	2880 Adults with fixed telephone connections, nationally representative sample	Drugs and alcohol use survey	CATI, IVR, hybrid CATI/IVR	Educational level, marital status, country of birth, employment	Costs, acceptability
Ellen et al,[39] 2002, US	Randomized, parallel 2-arm survey	223 African American adolescents living in San Francisco	Teen sexual behavior data collection	CATI, web survey	Household structure, school enrollment	Costs, acceptability
Graham et al,[43] 2006, US	Test-retest: CATI followed by web survey 2 d later	213 Internet users who searched for stop smoking and navigated to the intervention site	Smoking habits survey, nested within a RCT testing a smoking cessation intervention	CATI, web survey	Household income	Equivalence (Cohen κ)
Graham and Papandonatos,[42] 2008, US	Test-retest: CATI then web 2 d later	422 Internet users who searched for stop smoking and navigated to the intervention site	Smoking habits survey, nested within an RCT testing a smoking cessation intervention	CATI, web survey	Household income	Equivalence (Cohen κ)
Chittleborough et al,[45] 2008 Australia	Test-retest: in-person then CATI 6 mo later	2206 South Australian adults living in metropolitan areas and listed in the electronic white pages	SES data collection	CATI, in-person	Parental educational level, occupation, employment status, household income, educational level, urban/rural, country of birth, marital status	Response rate
Nagelhout et al,[48] 2010, the Netherlands	Randomized, parallel, 2-arm survey	2072 Adult smokers registered with an online survey database	Tobacco use data collection	CATI, web survey	Educational level, marital status	Response rate, time, costs
English et al,[40] 2019, US	Parallel, randomized, 2-arm survey	900 Adults from rural American Indian communities in New Mexico	General public health survey	CATI, in-person	Educational level; household income, employment status	Response rate, time, costs
Pariyo et al,[22] 2019, Bangladesh and Tanzania	Randomized crossover survey	2196 Adults with mobile phone access in Bangladesh and Tanzania	Noncommunicable diseases data collection	CATI, IVR	Education, urban/rural	Equivalence (Cohen κ)
Gagliardi et al,[41] 2020, US	Parallel, nonrandomized, 2-arm study	1008 Women overdue for cancer screening in a US health system	Primary care cancer screening outreach	CATI, IVR	Primary care registration	Costs
Greenleaf et al,[46] 2020, Burkina Faso	Randomized, parallel 2-arm survey	1766 Women aged 15-49 y who own a mobile phone	Family planning data collection	CATI, IVR[a]	Educational level, marital status, urban/rural	Response rate, equivalence (Cohen κ), costs, time
Ashigbie et al,[47] 2021, Kenya	Test-retest CATI then in person <24 h later for a 10% subsample	130 Adults registered with Kenyan health facilities	Access to medicines survey	CATI, in person	Educational level, wealth	Time, costs

Abbreviations: CATI, computer-assisted telephone interview; IVR, interactive voice response; RCT, randomized clinical trial; SES, socioeconomic status.

[a] Greenleaf et al[46] used hybrid-IVR: participants were first called by a researcher to set up the process and take consent, and the participant was then transferred to an IVR system for data collection.

no 2 studies used exactly the same wording or response options. eTable 2 in the Supplement provides the survey items and response options used for each SES domain within each study.

Response Rate

Four studies presented data on the response rates for individual questions, defined as the number of completed SES responses divided by the total number of elicitation attempts (**Table 2**). Not every study provided sufficient data to permit the calculation of 95% CIs.

Socioeconomic status data collection using CATIs was found to have either superior or equivalent response rates compared with IVRs. The response rates were found to be similarly high in each domain by Gagliardi et al[41] and 100% in all the SES domains collected by Greenleaf et al,[9] whereas response rates using IVRs ranged from 68% to 73%. Nagelhout et al[48] found response rates using CATIs and web-based data collection to be similarly high.

Chittleborough et al,[45] the only study to report response rates for individual SES domain-level questions, compared CATIs and in-person data collection and found similar response rates between the 2 methods, although English et al[40] reported an overall survey completion rate of 35.7% using CATIs compared with 68.9% in-person—a ratio of 0.52. English et al[40] also reported that this lower rate was noted despite the fact that the CATI was significantly shorter (25 vs 45 minutes). A potential confounding factor was that a nominal incentive was offered to individuals who completed the in-person survey, but this was not logistically possible to offer those completing CATIs, although the English et al[40] highlighted that the interviewers were trained not to mention the incentive until after the survey had been completed to reduce the risk of bias.

Equivalence

Six studies assessed the level of agreement between the SES responses obtained from 2 or more different modalities. All used weighted κ coefficients. eTable 3 in the Supplement presents findings by SES domain. In a crossover design, Pariyo et al[22] presented 2 sets of coefficients for each indicator depending on which modality was used first. The authors provided no interpretation for the very low agreement between IVRs and CATIs for education in Tanzania. They noted that the higher levels of agreement observed with performing IVRs first for other domains (which extend beyond the 2 SES domains presented herein) may be due to a form of selection bias where less-educated people may drop out of IVRs.[22] Apart from this domain, all other κ values were greater than 0.51, which Cohen[49] suggested interpreting as moderate agreement, with many exceeding 0.8: almost perfect agreement.

Table 2. Response Rates

Source	Domains[a]	CATI response rate, %	Response rate, comparator, %	Ratio CATI/comparator
Chittleborough et al,[45] 2008	Highest level of education	100	100 In person	1.00
	Occupation (6 categories)	100	100 In person	1.00
	Employment status (7 categories)	99	98.1 In person	1.01
	Household income (4 categories)	89.2	88.4 In person	1.01
	Area of residence (metropolitan/country)	100	100 In person	1.00
	Marital status	100	100 In person	1.00
	Country of birth	100	100 In person	1.00
Pariyo et al,[22] 2019	Residential area	100	68 IVR	1.47
	Ever attended school	100	71 IVR	1.41
	Marital status	100	73 IVR	1.37
Nagelhout et al,[48] 2010	Educational level	96.8	99.2 Web survey	0.98
	Marital status	99.5	99.7 Web survey	1.00
Gagliardi et al,[41] 2020	Insurance	99.3	99.5 IVR	1.00

Abbreviations: CATI, computer-assisted telephone interview; IVR, interactive voice response.

[a] The denominator for each domain is the entire population for each study listed in Table 1.

Time

Three studies quantified the time taken to gather SES data using different approaches (eTable 4 in the Supplement). None presented ranges and Nagelhout et al[48] and English et al[40] did not present times for both of the approaches that they used. All 3 studies presented the time taken to complete the entire survey—not just the SES instruments. Ellen et al[39] and Nagelhout et al[48] used the same number and wording of questions irrespective of modality. Ashigbie et al[47] found that CATIs were 1.48 times slower than in-person surveying, but crucially, this did not include the time taken to travel to each household.

Costs

Seven studies presented cost data[39-41,44,46-48]; however, there was little consistency in the cost items included in the estimations for each modality and, in some cases, specific details of costs included were not provided. All studies that reported cost data compared CATIs with another mode of data collation, and there was notable variability in the cost-effectiveness, measured as cost per completed interview, of the different modalities between the studies related to response rates, interviewer costs, and participant reimbursement. We present the ratio of CATIs to other modes in eTable 5 in the Supplement.

Two studies compared CATIs with in-person interviewing: English et al[40] found that both methods incurred high costs, but in-person interviewing was more cost-effective than telephone per completed survey due to the low response rate of telephone administration among American Indian or Alaska Native rural populations. Conversely, Ashigbie et al[47] found telephone interviewing to be less expensive than in-person interviewing in semiurban and rural communities in Kenya. Although the interviews took longer, the process was less time-consuming because data collectors did not have to travel, often via poor road networks, to houses that may not be close to each other, incurring further cost. Nagelhout et al[48] found web surveys to be more cost-effective than CATIs due to lower fieldwork costs and slightly lower participant reimbursements required, while Ellen et al[39] found web surveys to be more expensive when combining actual costs for interviewers, mailing, telephones, travel, incentives, and supplies.

One study found IVRs to be more cost-effective than CATIs owing to reduced personnel costs,[41] but 2 studies[44,46] found IVRs to be less cost-effective due to the costs associated with recording the automated survey in multiple languages, additional airtime costs to complete the survey, and lower completion rates.

Acceptability

None of the studies explored acceptability to providers. Two studies presented data on acceptability to participants: Ellen et al[39] found no statistically significant differences ($P > .05$) in perceived comfort, honesty, and accuracy in answering full surveys delivered by CATIs vs web survey. We note that Ellen et al[39] did not single out acceptability of the SES-specific questions. Corkrey and Parkinson[44] assessed participants' perception of ease, enjoyment, stress, and likability using IVRs and CATIs. Both methods scored equally highly for all 4 domains. eTable 6 in the Supplement presents the GRADE level of certainty for each of the key findings from the review's primary outcomes.

Secondary Analyses

None of the studies had high risk of bias, so none were excluded from the primary analyses. When we repeated the analyses comparing studies conducted in high-income vs LMIC settings we found that there were insufficient data to compare equivalence or time requirements for different modes. Greenleaf et al[46] found a lower response rate with IVRs in Burkina Faso (72%) than Nagelhout et al[48] found with the same modality in the Netherlands (99%); however, participants in the latter study were financially reimbursed, so this example is not a fair comparison. Ashigbie et al[47] and Greenleaf

et al[46] both obtained very high CATI response rates (>95%) in LMICs; however, response rates were similarly high for the same items asked in high-income settings.

The cost per completed CATIs ranged from AU $6 to US $211 (approximately AU $7 and US $240 in 2022) depending on accounting practices. Heterogeneity in the application of each method and accounting practices precludes any firm conclusions, but data collection modes used in LMICs do not appear to be systematically more or less expensive than those used in high-income countries.

Discussion

Summary of Main Findings

Our systematic review included 11 studies that collected data on 11 different SES domains using 4 different modalities under the 3 overarching categories of in-person, voice call, and automated approaches. All studies used CATIs, 4 used web surveys, 4 used in-person approaches, and 3 studies used IVR methods. None of the included studies used SMS data collection, and all of the in-person approaches involved home visits. Despite an overall low risk of bias across the studies, comparisons were limited by marked heterogeneity in the SES items used.

There is not enough evidence to say whether automated approaches are less costly than nonautomated data collection modalities. This lack of evidence is mainly due to differences in costing approaches used, as well as heterogeneity in how each modality was used. Only Ashigbie et al[47] compared the time taken to complete surveys, finding that CATI was 1.48 times slower than in-person elicitation; however, their figure did not include the travel time involved for home visits so the level of certainty for this finding is very low. Two studies compared the acceptability of CATIs vs IVR[44] and CATIs vs web survey,[39] finding no statistically significant differences in reported comfort, honesty, accuracy, ease, enjoyment, stress, or likability, which were assessed at the level of the whole survey rather than isolating the SES questions.

We can be moderately certain that response rate is equally high for SES questions asked via CATI, web survey, and in-person interview. Response rates may be slightly lower for IVR than for other modes, which may be largely related to incomplete responses. Greenleaf et al[46] found high rates of break-off, where 19.7% of individuals (n = 174) consented but answered less than 50% of the relevant questions using this method. We postulate that human-led interactions exert a stronger social pressure not to terminate the call partway through the interview.

Equivalence between answers elicited using automated vs nonautomated approaches was moderate to substantial for all comparisons made. Responses provided by CATIs seem to be equivalent to those provided by web survey and in-person interviews.

Equivalence was also generally moderate to high between CATI and IVR, with the marked exception of eliciting educational attainment in Tanzania ($\kappa = 0.03$), where there appeared to be systematic underreporting at initial IVR compared with CATI follow-up. This finding suggests that there may have been a systematic issue in understanding this prerecorded question. The authors also noted that if a respondent accidentally entered an incorrect option on IVR, there was no facility to change their answer.[22]

In sum, CATI, web surveys, and in-person approaches can all attain very high response rates and appear to collect equivalent data. Our review found a slightly lower response rate with IVRs than the other modes, although this finding is based on 2 studies. We did not find sufficient evidence to suggest that time requirements, costs, or acceptability vary meaningfully between modes. Automated approaches (ie, web surveys and IVRs) have comparable response rates and similarly high perceived levels of acceptability compared with surveys conducted in person or with the telephone, although there are very few studies contributing evidence.

The time and costs for each mode seem to depend on the baseline telephone response rate for the population of interest and the distances involved in home visits: sometimes it may be more cost-effective to visit households than to repeatedly call. The length of telephone calls can also be a material factor when airtime is expensive, and there is low-quality evidence to suggest that IVRs may

take longer than human-led calls. However, we note that IVRs do not involve personnel costs beyond setting up and managing the software.

Comparisons With the Wider Literature

The World Health Organization recommends that health programs and researchers should routinely gather socioeconomic data on a wide range of domains.[5,6] We note that none of our included studies collected data on religion, sexuality, or disability.

We found that respondents using IVRs and CATIs felt they were honest with their answers, even when answering sensitive questions. The wider evidence suggests that automated approaches, such as IVRs and web surveys, may obtain more honest answers than CATIs or in-person interviews[15,50-52] due to reduced social distance and desirability bias.[22] Automated approaches may also reduce bias that can arise from the social dynamics of interacting with a human, such as acquiescence[18,53] and nonuniform questions, because a computer presents the same question in the same way every time, whereas a person does not.[54] Social dynamics involved in providing answers to a real person may reduce the risk of satisficing (ie, providing the first/easiest option to complete the survey quickly).[55] We did not find evidence to support or refute this hypothesis. Self-administered approaches, such as web surveys, may place a higher cognitive burden on respondents that can lead to disengagement[53] and satisficing.[55] Coupled with our findings that web surveys tended to achieve low response rates and were not much less costly than other options, we recommend that researchers consider using alternative options. One final important source of difference between automated and nonautomated modes is the measurement error that can stem from the fact that respondents can ask for clarifications and amend their answers, whereas these options are often not available for IVR and some web survey modes.[22]

We did not find enough data to make robust comparisons between the use of different modes in LMICs vs high-income countries. Reviews conducted by Gibson et al[12] and Greenleaf et al[9] suggest that more research is required to understand the reliability and accuracy of different modes in low-income settings.

In 2015, Ballivian and colleagues[8] argued that telephone-based data collection approaches can introduce selection bias. This argument is less of a problem now that telephone ownership is so high around the world; however, low-income groups may be the least likely to own mobile phones and this is a material consideration for work seeking to obtain representative SES data for a given population. Remote and rural communities may also have unreliable network coverage. A further issue raised by Ballivian and colleagues[8] is the lower response rates from telephone-based approaches vs face-to-face data collection modes; however, we did not find this factor to be an issue in the included studies.

None of our included studies examined SMS/MMS or clinic-based data collection. A 2008 study from a California ambulatory care service found that collecting race and ethnicity and language data using a paper questionnaire at the front desk yielded an 88% response rate at a cost of $0.21 per completed survey.[56] West and colleagues[57] found that CATIs were faster and less costly than manual SMS data collection for a 15-item survey of Nepalese adults. These studies were excluded from our review because they did not use comparators.

Strengths and Limitations

Our study had a number of strengths: our search was designed by a Cochrane information specialist (I.G.), and we included a wide range of databases and other sources. We used independent dual screening, data extraction, and quality scoring, and followed best practice guidelines throughout the study. We included a wide range of outcomes to maximize the utility of the review for program managers faced with difficult decisions about which modality to use.

This study has limitations. The performance of individual SES items in a given questionnaire is likely to be influenced by the preceding items, the focus of the overall survey, and broader contextual factors. To minimize bias, we calculated and reported intermodal comparison rates rather than reporting absolute levels. Although this approach is methodologically robust, decision-makers are

unlikely to select a mode on the basis of how it performs for individual survey items. We did not search for or extract data on sample frame errors and nonresponse errors.[58] We excluded articles that were published before 1999, which may have excluded useful studies. We note that not all telephones can be used to access web surveys.

Conclusions

Our review reinforces the message that the choice of survey mode should be guided by the type of questions being asked, the population, and the resources available.[8,10] We found that CATIs, IVRs, web surveys, and in-person interviews have all been used to attain high response rates with comparable answers in a range of settings. Marked heterogeneity in their deployment makes it very difficult to reach conclusions about their relative costs and benefits, and future work should aim to align accounting practices with those used by major reviews. Given the absence of evidence that automated and telephone-based systems deliver inferior data, we recommend that decision-makers try approaches that are likely to offer cost savings; however, it is important to review response rates early on and consider the extent to which selection bias is influencing the findings.

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SUPPLEMENT.

eMethods. Search Strategy
eFigure 1. RoB-2 Risk of Bias Table for Randomized Studies
eFigure 2. ROBINS-I Risk of Bias Table for Nonrandomized Studies
eFigure 3. Comparisons Between Data Collection Modes
eTable 1. Socioeconomic Domains Used in the Included Studies
eTable 2. Response Options Within Each SES Domain
eTable 3. Equivalence Between Modalities of 6 Studies Reporting Equivalence Between Data Collection Modes

Post-script: in-person vs phone-based data collection

Having found no good evidence that response rate and data equivalence vary meaningfully across the different modes, I explored options for setting up interactive voice response and web-based surveys. As the Meru programme had not yet started, I conducted this pilot work in Botswana - an upper middle-income Sub-Saharan democracy with a national Peek-powered school eye health screening programme and similar mobile phone ownership rates to Kenya.[79,80] After a series of meetings with Peek and all of the major telecoms operators it became clear that myriad regulatory hurdles rendered interactive voice response calls unfeasible in the near-to-medium term.

I set up a study to explore the response rate to a web-based survey, sent to potential participants as a hyperlink in an SMS. I worked with Play Verto to design the survey - an innovative online survey developer with experience developing UN web-surveys (sent via SMS hyperlinks) with response rates of >80%.[81] Looking ahead to the next phase of the research, I designed the survey to collect data on barriers to accessing care rather than each participant's sociodemographic characteristics. Local research leads in Botswana, Kenya, and Nepal all strongly felt that the response rate was likely to be low, and that participants would be particularly unlikely to disclose personal data. I planned to review the response rate for this survey that asked less personal questions in Botswana, with a view to moving on to pilot test a separate sociodemographic SMS survey in Kenya if the response rate was anywhere near 80%.

This pilot study – which is currently being written up - found that the overall response rate to the survey was 8%. This finding confirmed our local researchers' suspicions that web-surveys are not a viable option for our purposes.

After discussions with Peek and the wider collaborative, we agreed to proceed with in-person data collection. We reasoned that the time taken to collect data would be the same or shorter than the time taken for phone-based data collection – given that people may not always answer the phone first time, if at all. Furthermore, by training screeners to gather data at the point of referral we could eliminate potential bias associated with only being able to gather data from people who had access to a working phone at the time of the call.

Chapter five presents further detail on the final 'Gather' approach that I developed to collect and analyse data across all Peek-powered programmes, and reports findings from its application in Meru in 2023.

Chapter 5

Equity analysis of access to community eye clinics in Meru

A VIP screener asking sociodemographic questions as part of the new referral process
Source: Author. Consent has been granted by both of the people in the photo

Key messages

- I performed a literature review which identified 11 sociodemographic domains that are commonly used by international development organisations and other researchers.
- Starting with these domains, I led an iterative review processes with multistakeholder groups in Botswana, Kenya, India, and Nepal to develop country-specific sociodemographic questionnaires to be embedded in local screening programmes.
- In Meru county's programme, we gathered data from just over 4,000 people at the point of referral to local eye services.
- Analysis of attendance data enabled us to identify which groups were the least likely to receive care: younger adults, males, and those working in sales/services and manual jobs.
- Younger age (18-44-years) was the characteristic that was most strongly associated with poor access.

Having decided to proceed with in-person data collection, I led the development of an operational approach to embed the routine collection and analysis of sociodemographic data within Peek-powered programmes operating in Kenya, Botswana, India and Nepal. The first stage was identifying the most appropriate domains and questions to ask in each setting. I performed a literature review and a secondary analysis of the data collected during my systematic review from Chapter 4, examining which domains each of the included studies had used. This process identified 11 broad domains that were then tailored for each country. I wrote up the process as well as the overall approach for collecting and analysing data in the 'Gather' master protocol, which was published in Wellcome Open Research and is presented in Appendix 2.

I then led the application of the approach in Meru, with data collection taking place from April – July 2023. This chapter presents the pre-print of this study, which has been submitted to the International Journal of Equity in Health.

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RESEARCH PAPER COVER SHEET

Please note that a cover sheet must be completed for each research paper included within a thesis.

SECTION A – Student Details

Student ID Number	2004040	**Title**	Dr
First Name(s)	Luke		
Surname/Family Name	Allen		
Thesis Title	Improving equitable access to community-based health services: Developing and testing a new model in Kenya's national eye screening programme		
Primary Supervisor	Andrew Bastawrous		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

SECTION B – Paper already published

Where was the work published?	N/A		
When was the work published?	N/A		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	N/A		
Have you retained the copyright for the work?*	Choose an item.	Was the work subject to academic peer review?	Choose an item.

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SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	International Journal of Equity in Health
Please list the paper's authors in the intended authorship order:	Luke Allen, Sarah Karanja, Michael Gichangi, Cosmas Bunywera, Hilary Rono, David Macleod, Min Kim, Malebogo Tlhajoane, Matthew Burton, Jacqueline Ramke, Nigel Bolster, Andrew Bastawrous

Stage of publication	**Submitted**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I performed the underlying literature review of sociodemographic domains and led the multistakeholder process of identifying an appropriate question list for Kenya. I coordinated efforts to integrate these questions into the Peek screening software. Cosmas Bunwera led this process from the Peek side, working with Sarah Karanja and Hilary Rono to organise training of the screeners. I worked closely with David Macleod to design the statistical approach, with ultimate decisions coming down to me e.g. decisions around sample sizes and what constitutes a 'meaningful difference'. I wrote the r code to download the data and stitich it together. David performed the regression. I led the workshop where we presented the findings to local stakeholders, who then selected which 'left-behind' group to focus on. I wrote the paper, sought co-author input, and integrated all of these comments to produce the final draft.

SECTION E

Student Signature	Luke Allen
Date	26th April 2024

Supervisor Signature	REDACTED
Date	30-04-2024

Access to community-based eye services in Meru, Kenya:

a cross-sectional equity analysis

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Abstract

Background: Over 80% of blindness in Kenya is due to curable or preventable causes, with an estimated 7.5 million Kenyans in need of quality eye care services. Embedding sociodemographic data collection into the national eye screening programme could help identify the groups facing systematic barriers to care. We aimed to determine the sociodemographic characteristics that are associated with access among patients diagnosed with an eye problem and referred for treatment in the national eye screening programme.

Method: We used an embedded, pragmatic, cross-sectional study design. A list of sociodemographic questions was developed with input from researchers, community members, policymakers, and programme implementers. After five rounds of iteration, the final sociodemographic question set included the following domains: age, gender, religion, marital status, disability, education, occupation, income, housing, assets, and health insurance. These were integrated into an app that is used to screen, refer, and check-in (register) participants within a major eye screening programme. We gathered data from 4,240 people who screened positive during community screening and were referred to a local outreach treatment clinic in Meru County. We used logistic regression to identify groups for whom services were inaccessible.

Findings: Only 46% of those who were referred to local treatment outreach clinics were able to access care. In our fully adjusted model, at the 0.05 level there were no statistically significant differences in the odds of attendance within the domains of disability, health insurance, housing, income, or religion. Strong evidence ($p<0.001$) was found of an association between access and age, gender, and occupation, with males, younger adults, and those working in sales, services and manual jobs being the least likely to access care.

Conclusions: Less than half of those identified with an eye need and referred to free local clinics were able to access care in Meru. Younger people are being left behind, with less than a third of those aged 18-44 receiving care. Future work should explore the barriers and potential solutions to equitably improve access to care for this group.

Keywords

Equity; socioeconomic inequalities; access; primary care; eye care

Introduction

More than one billion people currently live with preventable or untreated visual impairment, and over 90% of these cases are easily treatable with highly cost-effective interventions like spectacles and cataract surgery.[7] The vast majority of people with untreated eye conditions live in low- or middle-income countries, and within these countries marginalised groups are often disproportionately affected.[7–9] Extending access to eye services is a global health priority that aligns with both the principles of proportionate universalism[1] and Primary Health Care: an approach to health that prioritises the worst-off and seeks to advance equity and *health for all*.[2]

An estimated 7.5 million people require eye health services in Kenya, but less than a quarter are able to access services.[3] In 2022 the government launched the 'Vision Impact Programme' (VIP) in which community-based teams use smartphones to administer 'tumbling E' visual acuity assessments, using an app developed by the social enterprise Peek Vision (Figure 1).[4] Those who screen positive - i.e. their visual acuity is found to fall below a predetermined threshold (<6/12 in either eye) are referred to a local outreach treatment clinic, commonly held in a primary care facility, where they receive free further assessment and care, including spectacles, eye drops, or onward referral for cataract surgery at a local hospital as required. Screeners also refer people who have a red eye or another issue upon basic visual inspection, and anyone who feels they have an eye problem, even if there are no clinical signs and their visual acuity is >6/12.

Figure 1: A woman having the visual acuity of her right eye screened with a 'tumbling E' assessment on the Peek Vision app

Caption: Eyes are tested one at a time. The screener stands 3m away from the participant. The Peek app displays a series of letter E symbols in different sizes and orientations. The participant is asked to point in the direction that they think the E is facing (upwards in the figure). The screener swipes the screen in the direction indicated by the participant. A simple algorithm calculates visual acuity based on the number of correct/incorrect swipes for each letter size. Those whose vision falls below this threshold are referred to the local outreach treatment clinic on a given date. Photography consent was granted by all those in the picture.

In the VIP programme's first year, over a million people were screened and more than 150,0000 were managed at free treatment outreach clinics.[5] Whilst this is a remarkable achievement, internal Peek data suggest that there are important issues with clinic accessibility, as less than half of those who were identified with an eye problem during community-based screening received care at their local clinic.

Access is determined by both patient and provider factors,[6] and evidence from other countries suggests that certain groups such as females, widows, and those in rural areas - may face unique structural barriers to accessing eye care services.[7] Currently, no sociodemographic data

beyond age, gender, and language are being collected in the VIP screening programme, and these data are not currently being used to perform equity analyses. As such, any sociodemographic inequities are invisible.

Acknowledging the risk that "poorer, less advantaged segments of the population could be left behind" as countries expand access to health services in pursuit of UHC, joint WHO and World Bank guidance recommends that health programmes routinely gather data on gender, wealth, and place of residence (urban/rural) to monitor equity in effective service coverage.[8] The recent UN Resolution on Vision, the Lancet Commission on Global Eye Health, and the Declaration of Astana all call on global health partners to analyse the equity impact of their programs across different sociodemographic populations.[9–11] This aligns with the 'central transformative promise' of the Sustainable Development Goals which is to 'leave no one behind' and the commitment to 'reach the furthest behind first'.[12]

Working with the Ministry of Health, a local community advisory board, the VIP programme implementing partner, and Peek Vision, we aimed to integrate a set of sociodemographic questions into the community-based screening process in Meru county and perform the first assessment of whether all sociodemographic groups are experiencing similar levels of access to primary eye care.

Methods

Population

The VIP programme has been designed to screen all residents aged over 18 years in ten of Kenya's 47 counties.[13] Working with the national director of eye services, we identified Meru county as the best place to conduct our study, based on the fact that it contains a mix of urban and rural areas, has a leadership engaged with equity-focused quality improvement, and had a screening schedule that aligned with our research timeline. Meru is a central high-altitude county on the slopes of Mount Kenya with a population of 1.55 million, most of whom live in Meru town, the seventh largest urban centre in the country. Agriculture is the main source of employment, with khat and tea being the most prevalent cash crops.

Sociodemographic domains

We started by performing a literature review and a secondary analysis of data from a systematic review to identify the sociodemographic domains that are being used by other programmes, agencies, and researchers around the world. Full details and results are available in our published protocol.[14] Briefly, we identified 11 broad domains that had been used or recommended in the peer-reviewed literature and UN agency reports: age, gender, residence (urban/rural), language, ethnicity/tribe/race/caste, refugee/immigrant status, marital status, religion, occupation, income, and wealth.[8–10,15–19] We drafted response options for each domain that aligned with those used in the widely-used USAID Demographic and Health Survey (DHS) that has been used to complete more than 400 surveys in 90 countries[20,21] and the Rapid Assessment of Avoidable Blindness (RAAB) instrument that has been used for over 300 surveys in 80 countries.[22] This was to ensure that all ensuing data complied with international norms and were maximally useful for domestic policymakers.

Next, we set up a multi-stakeholder workshop that included representatives from Peek Vision, the implementing partner organisation (Christian Blind Mission), the Ministry of Health, and local academics with experience and expertise in sociodemographic data collection. This group adapted each of the draft domains to the Kenyan context, and adding in a housing question as an indicator of wealth.

Over the course of four hybrid workshops, we iteratively refined the list of domains and questions stems, seeking to align them with pre-existing locally collected data and ensuring that the wording accorded with cultural norms. We removed the question on tribe/ethnicity as this was considered to be potentially inflammatory. Supplementary tables 1-4 present further detail on the decisions made at each stage.

All decisions were made by consensus, and after five rounds of iteration the final list included 11 domains with between 2-8 individual response options (Table 1). Every domain also included 'don't know' and 'do not want to answer'. The draft survey instrument was translated into Kiswahili and back-translated into English to check that meaning had not been lost. The survey was piloted with laypeople using a 'think aloud' approach,[23] and then in the actual screening programme with approximately 100 service users. No changes were indicated during piloting.

Table 1: Sociodemographic domains and response options

Domain	Question stem	Response options
Gender	What is your gender?	Female
		Male
		Other
Age	What is your age?	18-24
		25-34
		35-44
		45-54
		55-64
		65+
Language	What is your preferred language?	Kiswahili
		English
Marital status	What is your marital status?	Single
		Married
		Divorced/separated
		Widowed
Assets	Does your household own a bicycle, motorbike, scooter, car, or truck?	None
		Bike or Moto or Scooter

		Car or Tuck
Disability	Do you have any difficulty with hearing, walking, climbing steps or communicating?	No
		Yes (one or more)
Education	What is your highest level of education?	None
		Primary
		Secondary
		Post-secondary
Health insurance	Do you have health insurance?	No
		Yes, active
		Yes, not active
Housing	Do you have Electricity, Solar, or a Generator at home?	No
		Yes
Income	In the last month, what was your approximate income?	KES <24,000
		KES 24,000-32,333
		KES >32,333
Occupation	What is your occupation?	Not employed
		Farming
		Domestic service
		Professional*
		Sales & services
		Skilled manual
		Unskilled manual
		Student/pupil
Religion	What is your religion?	Christian
		Islam
		Hindu
		Other

*Note: Includes professional or manager or technician or clerical

Screening approach

In the VIP programme, community health workers go house-to-house and assess the vision of all residents. For each participant, they enter the following demographic details into the Peek app:[24] name, contact phone number, age, and gender. Next, they perform a 'tumbling E' visual acuity assessment using a smartphone. As stated above, if the participant's vision falls below a pre-specified acuity threshold, or if they have a visible or reported subjective eye complaint

(e.g. a red or painful eye), then the participant is referred to the local clinic for further assessment and treatment. At this point their preferred language is recorded. The participant is given an appointment date and is sent a follow-up reminder text message. On the day of assessment, participants are checked-in (registered) by staff using the same Peek app at the clinic. This means that Peek hold a record of all those referred and can generate a complete list of all those who have and have not been checked-in on their appointed date.

We added the extended list of sociodemographic questions to the Peek app. These questions were asked of every person who was found to have an eye problem and referred to their local treatment outreach clinic. Informed written consent to gather these additional sociodemographic data was obtained by the community health workers who performed the screening, using paper consent forms.

Sample size

Our aim was to compare the odds of attendance between different sociodemographic subgroups (e.g. males vs females). Our community advisory group suggested that we would want to detect differences in attendance of 5-10% or more between subgroups. With a 95% confidence level and a maximally conservative proportion of 50% attendance, we calculated that we would need to have at least 1,566 people in each subgroup to have 80% power to detect a 5% difference between subgroups, or 385 people in each subgroup to detect a difference of 10%. We decided to set our sample size at 3,850 which would provide 80% power to detect differences of 10% between groups that contain at least 10% of the overall population, while still providing power to detect a difference of 5% in subgroups that make up 40% of the population. We deemed that this would enable robust comparisons between most subgroups, and accepted that we would only be able to identify large differences between subgroups that contained very few people e.g. those in the highest income category or those reporting a religion other than Christianity or Islam.

We reviewed the number of people who had been recruited on a weekly basis and stopped data collection on the day that the sample exceeded 3,850.

Statistical analysis

We used logistic regression to calculate the adjusted odds of non-attendance for each sociodemographic subgroup. Our statistical approach is outlined below:

1. Perform simple logistic regression with attendance as the outcome. Separately add each sociodemographic domain as an exposure. (Unadjusted model)
2. Adjust each model for age and gender. (Minimally adjusted model)
3. Adjust each model for all other sociodemographic variables. (Fully adjusted model)
4. Test an interaction between each sociodemographic variable and age category (Effect modification by age)
5. Test an interaction between each sociodemographic variable and gender (Effect modification by gender)

Post-hoc sensitivity analyses

To quantify the impact of intersectionality,[25,26] we estimated the probability of attendance for people with different combinations of sociodemographic characteristics that were found to be the strongest predictors for poor access.

After completing our analysis, our Kenyan Ministry of Health collaborators sensibly hypothesized that severity of eye condition could explain differences in attendance by age and other sociodemographic domains, reasoning that those with painful or severe conditions would be more likely to seek care than those with mild or painless conditions. Data on eye conditions had already been collected during screening. We categorised these diagnostic codes into five categories that grouped conditions based on their likely acuity and impact (below). Then we re-ran the regression models with and without this new eye condition data.

- Normal vision
- Loss of vision (visual acuity <6/12 vision in either eye)
- Chronic problem: Growth on eyeball, Lump on lids, White pupil, Strabismus
- Acute problem: Conjunctivitis, Redness, Redness with discharge, Red and watery itchy eye
- Urgent problem: Eye injury, Pain, Whole eyeball swollen

Bias

To reduce the risk of selection bias the sociodemographic questions were asked of every consecutive person who was referred until we had collected data from at least 3,850 people. We developed a robust set of questions to minimise the risk of recall bias, grounded in the literature and tailored to the local context by a group of experts and community representatives. We delivered standardised training to the data collectors in order to minimise the risk of measurement bias. We also performed unannounced observations of screeners to check that the questions were being asked as intended. We found no issues.

Ethics

This study was approved by LSHTM and KEMRI ethics committee and the National Commission for Science, Technology & Innovation. Written informed consent was obtained from every participant.

Findings

Between April and July 2023, 136,912 people aged >18 years old were screened in Meru county and 32,835 people were found to have an eye problem that required referral to a local treatment outreach clinic (24.0%). We gathered and analysed data from the first 4,240 of these referred people who consented to provide their sociodemographic information. As several hundred people were screened every week, our final sample exceeded 3,850.

Of these 4,240 people, just under half were able to access their appointment (46.0%). In our fully adjusted model, we found very strong evidence ($p<0.001$) of an association between three variables and access: gender, with men found to be less likely to access care than women; age, with younger people less likely to access care than older people; and occupation, where those in skilled/unskilled manual labour and sales & services occupations had the lowest access. Younger people had the worst access overall, with only 32% of those aged 18-44 years being checked-in at clinics compared to 54% of those aged ≥45 years old.

Three other variables showed some weaker evidence of an association with the outcome; education ($p=0.03$), marital status ($p=0.03$), and vehicle ownership ($p=0.03$). (Table 2)

Table 2: Attendance by sociodemographic group

		N	N Attended	% Attended	Unadjusted OR	p-value	Adjusted for age and gender	p-value	Adjusted for everything	p-value
Gender	Female	2700	1317	49%	Ref	<0.001	Ref	<0.001	Ref	<0.001
	Male	1540	634	41%	0.73 (0.65-0.83)		0.67 (0.59-0.76)		0.72 (0.63-0.83)	
Age	18-24	271	78	29%	0.42 (0.32-0.57)	<0.001	0.41 (0.31-0.55)	<0.001	0.49 (0.35-0.69)	<0.001
	25-34	615	189	31%	0.46 (0.38-0.57)		0.45 (0.36-0.55)		0.51 (0.41-0.63)	
	35-44	730	256	35%	0.57 (0.47-0.69)		0.55 (0.46-0.67)		0.59 (0.48-0.72)	
	45-54	1048	512	49%	Ref		Ref		Ref	
	55-64	786	429	55%	1.26 (1.05-1.51)		1.27 (1.05-1.53)		1.21 (1.00-1.46)	
	65+	790	487	62%	1.68 (1.39-2.03)		1.71 (1.42-2.07)		1.61 (1.31-1.99)	
Transport assets	None	3644	1726	47%	Ref	0.0001	Ref	0.002	Ref	0.03
	Bike/Moto/scooter	328	125	38%	0.68 (0.54-0.86)		0.86 (0.68-1.10)		0.87 (0.68-1.12)	
	Car	268	100	37%	0.66 (0.51-0.85)		0.64 (0.49-0.83)		0.69 (0.52-0.92)	
Disability	No	3637	1629	45%	Ref	<0.001	Ref	0.87	Ref	0.99
	Yes	603	322d	53%	1.41 (1.19-1.68)		0.98 (0.82-1.18)		1.00 (0.83-1.20)	
Education	None	284	149	52%	Ref	<0.001	Ref	0.002	Ref	0.03
	Primary	1787	906	51%	0.93 (0.73-1.20)		1.43 (1.09-1.87)		1.42 (1.07-1.87)	
	Secondary	1538	666	43%	0.69 (0.54-0.89)		1.28 (0.97-1.69)		1.30 (0.97-1.73)	
	Post-secondary	631	230	36%	0.52 (0.39-0.69)		1.03 (0.76-1.40)		1.12 (0.81-1.56)	
Health insurance	No	2530	1154	46%	Ref	0.35	Ref	0.77	Ref	0.12
	Yes, active	909	437	48%	1.10 (0.95-1.28)		1.02 (0.87-1.19)		1.20 (1.01-1.43)	
	Yes, not active	801	360	45%	0.97 (0.83-1.14)		0.95 (0.80-1.12)		1.04 (0.88-1.24)	
Cement floor	No	703	353	50%	Ref	0.015	Ref	0.21	Ref	0.48
	Yes	3537	1598	45%	0.82 (0.69-0.96)		0.90 (0.76-1.06)		0.94 (0.79-1.12)	
Income	No response	1984	935	47%	Ref	<0.001	Ref	0.007	Ref	0.11
	<24,000	2050	939	46%	0.94 (0.84-1.07)		0.92 (0.81-1.04)		0.91 (0.80-1.04)	
	24,000-32,333	132	56	42%	0.83 (0.58-1.18)		0.84 (0.59-1.22)		0.98 (0.67-1.45)	

	>32,333	74	21	28%	0.44 (0.27-0.74)		0.41 (0.24-0.69)		0.54 (0.30-0.95)		
Marital status	Single	904	320	35%	Ref		Ref		Ref		
	Married	2977	1435	48%	1.96 (1.64-2.33)		1.37 (1.12-1.66)		1.29 (1.05-1.59)		
	Divorced/separated	200	93	47%	1.83 (1.33-2.51)	<0.001	1.12 (0.79-1.57)	0.005	1.10 (0.77-1.55)	0.03	
	Widowed	333	185	56%	2.63 (2.01-3.41)		1.05 (0.77-1.42)		1.03 (0.76-1.42)		
	Other	26	11	42%	1.54 (0.70-3.41)		0.87 (0.38-1.97)		0.89 (0.38-2.00)		
Occupation	Not employed	801	367	46%	Ref		Ref		Ref		
	Farming	1593	892	56%	1.50 (1.27-1.78)		1.29 (1.08-1.54)		1.24 (1.03-1.49)		
	Domestic service	297	162	55%	1.42 (1.09-1.85)		1.45 (1.10-1.91)		1.44 (1.09-1.90)		
	Professional	202	79	39%	0.76 (0.55-1.04)	<0.001	0.86 (0.62-1.19)	<0.001	1.05 (0.73-1.52)	<0.001	
	Sales & services	449	151	34%	0.60 (0.47-0.76)		0.73 (0.56-0.93)		0.76 (0.58-0.98)		
	Skilled manual	400	138	35%	0.62 (0.49-0.80)		0.78 (0.60-1.01)		0.79 (0.60-1.04)		
	Unskilled manual	417	140	34%	0.60 (0.47-0.76)		0.72 (0.56-0.93)		0.72 (0.55-0.93)		
	Student/pupil	81	22	27%	0.44 (0.27-0.73)		0.86 (0.49-1.51)		1.00 (0.56-1.77)		
Religion	Christian	4129	1907	46%	Ref		Ref		Ref		
	Islam	81	36	44%	0.93 (0.60-1.45)	0.09	0.95 (0.60-1.50)	0.15	1.07 (0.67-1.69)	0.24	
	Other	30	8	27%	0.42 (0.19-0.95)		0.44 (0.19-1.00)		0.49 (0.21-1.14)		

Figures 1 and 2 plot the adjusted odds ratios of attendance for the demographic and economic factors.

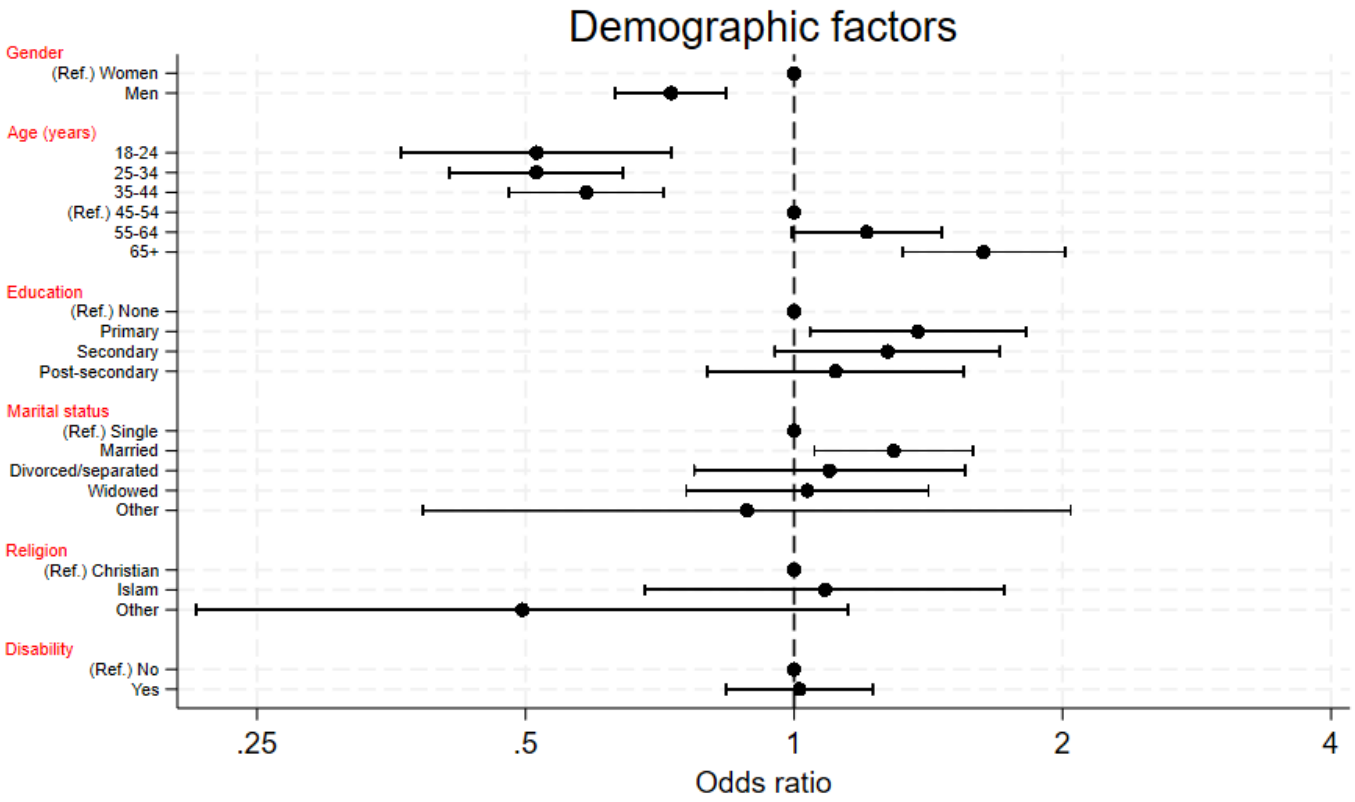

Figure 1: Plot of fully adjusted odds ratios of attendance according to demographic factors

Ref. = Reference group, disability = yes means the participant responded that they had difficulty with at least one of hearing, walking, climbing steps or communicating

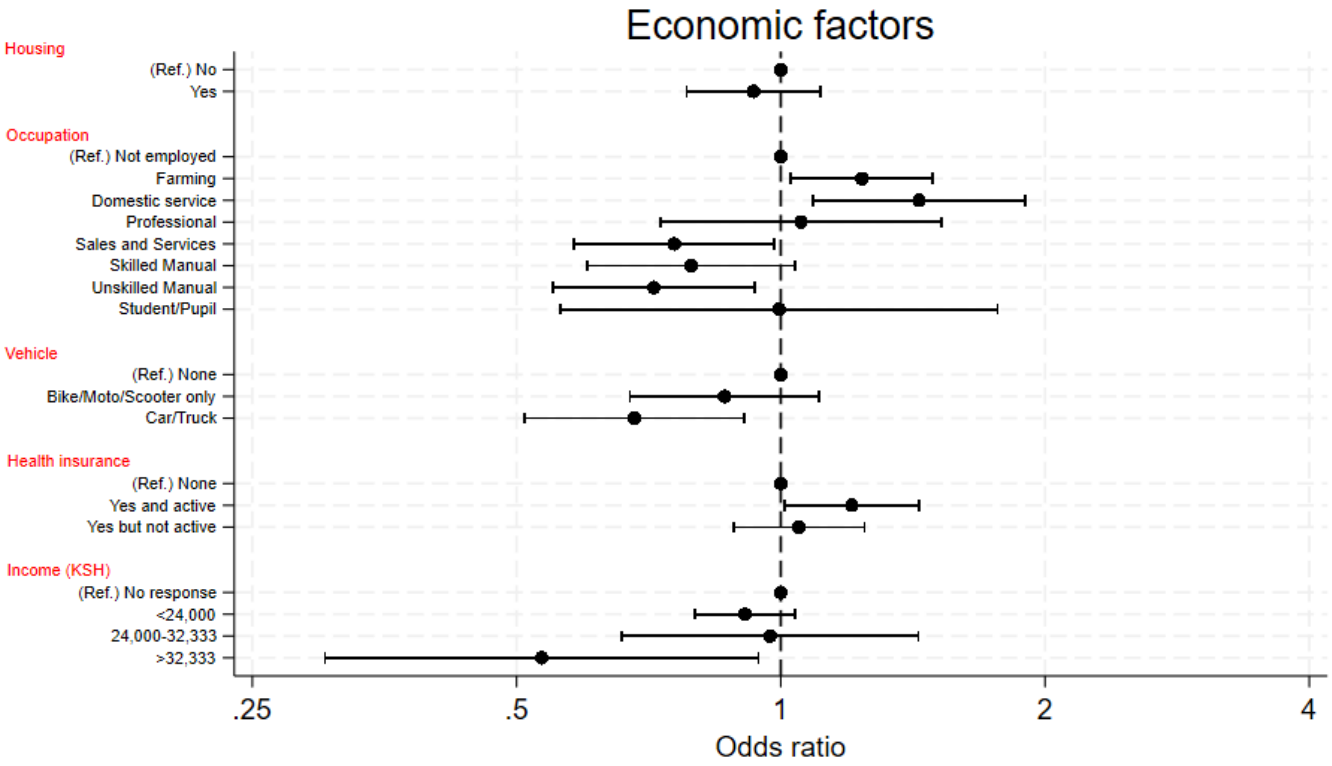

Figure 2: Plot of fully adjusted odds ratios of attendance according to economic factors

Ref. = Reference group

We tested for effect modification and identified some weak evidence (p=0.05) of an interaction between age and gender, suggesting that the difference in attendance between men and women is greater at younger ages than in older (Figure 3 and Supplementary Table 5).

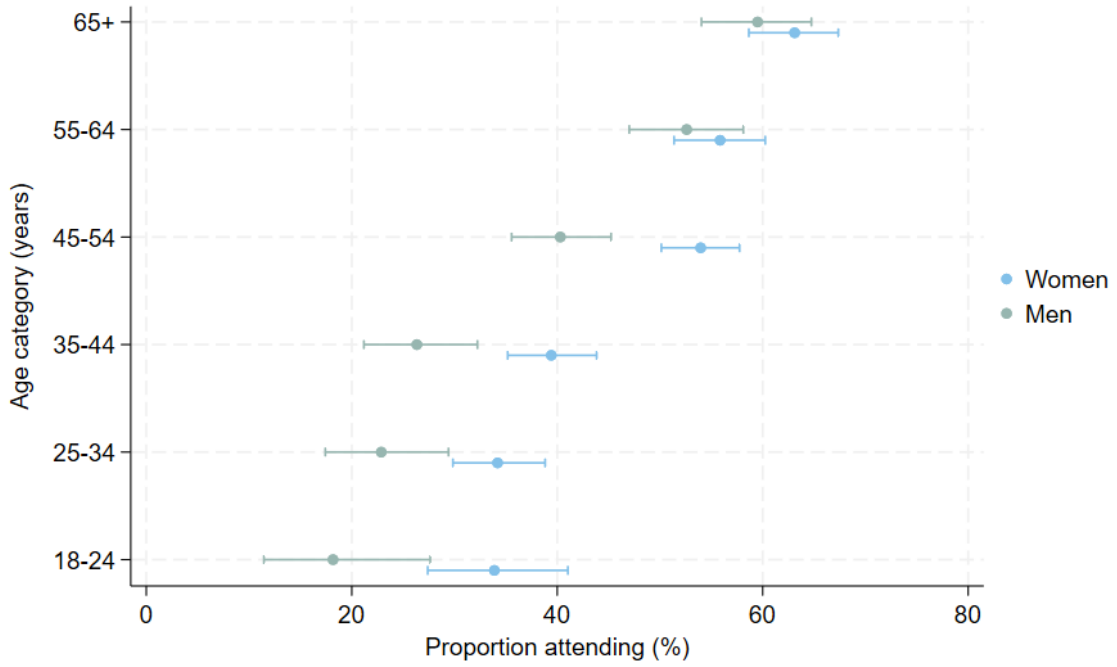

Figure 3: Clinic attendance within each age and gender group

Sensitivity analyses

To quantify the impact of intersectionality, we estimated the probability of attendance for people with different combinations of age, gender (including the interaction between age and gender), and occupation – the three strongest predictors of access. Age and gender were already categorical variables. For simplicity, we dichotomised occupation into a binary variable, grouping together the three categories of occupation that had the lowest attendance (skilled/unskilled manual and sales & services).

We found that the expected lowest attending group is 18-24-year-old males who work in sales/service/manual jobs, where we estimate that only 14% of people with these three characteristics would be able to access care (95% CI: 8-22%). The highest estimated access rate was 64%, found among females aged 65+ not working in those occupations (95% CI: 59-68%).

In our second sensitivity analysis we adjusted for severity of eye condition. We found that eye condition did not affect the effect estimates, suggesting that this variable was not driving greater attendance in older people. Supplementary table 6 presents the full results.

Discussion

The growing emphasis on extending Universal Health Coverage and 'leaving no-one behind' means that programme managers around the world are increasingly being expected to identify populations that face unique barriers to care. Aligning with findings from previous research in Kenya,[27] we found that less than half of all people who screened positive in Meru's VIP project were able to access care. This resonates with a 2018 systematic review that found that 43% of all African outpatient appointments are not attended, with younger adults and those from lower socioeconomic groups being the least likely to attend.[28]

We found that younger men working in sales, services, or manual jobs were the least likely to attend. This stands in stark contrast to existing research on access to eye services which has shown older age, female gender, and widowhood to be the strongest predictors of poor access.[7,10] However, these studies focused on cataract care which affects people later on in life, whereas the VIP programme manages all eye conditions in all ages.

Given that Kenya ranks 110th out of 144 countries in the UN's gender equality ranking,[29] we were surprised that men were 30% less likely to attend than women in the fully adjusted model. However, this is not an unusual finding: despite having greater power, privileges, and opportunities than women in virtually all societies, men almost universally experience higher rates of poor health, lower rates of health care access, and lower overall life expectancy.[30,31] Differences in healthcare-seeking behaviour are thought to drive much of the gender gap in access rates, related to differences in perception of risk and pervasive social ideals of masculinity.[32] Whilst younger men were the least likely to attend in Meru, younger women were less likely to attend than older women, suggesting that youth is an independent predictor. Overall, age was by far the strongest predictor, with the youngest cohort (18-24y) three times less likely to have been checked-in than the oldest (65+), even after adjusting for occupation and severity of eye condition.

We hypothesise that younger adults may be more likely to be 'hustling' than older people – i.e. working in informal jobs with no fixed salary or paid sick leave, and therefore facing higher financial opportunity costs when taking time out to attend a clinic. The fact that people working in (often informal) sales, services, and manual labour were also less likely to attend than those working in other areas seems to corroborate this hypothesis.

To a lesser extent, car/truck ownership and high level of income were also associated with poor access. We hypothesise that this is because richer people who are told they have an eye problem at screening may be seeking private care rather than attending the VIP clinics. We plan to conduct a further set of interviews with people from this group to explore this issue further.

Our study had a number of limitations. We did not include questions on religion, tribe/ethnicity, or sexuality due to concerns about cultural sensitivities, but these are all important markers of potential access challenges.[17,18] With a larger sample we would have been able to detect smaller differences between groups, however it would have taken longer to conduct the study and the embedded nature of this research comes with pressure to deliver rapid and timely findings. Finally, we have not yet validated our sociodemographic questions. This work is currently underway, however the process of selecting the items and response options was based on extensive literature review and wide stakeholder engagement to ensure that we were using previously-validated questions with strong external validity.

Conclusion

Less than half of those referred to local eye clinics received treatment. We found evidence of large sociodemographic inequalities, with younger people, males, and those working in sales, services, and manual jobs facing the highest barriers. Overall, age was the strongest predictor. Future work should focus on exploring the specific barriers faced by younger adults and their ideas for how services could be modified to improve access to essential eye care.

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Appendix

Supplementary Tables 1-4: Sociodemographic variable section process

Supplementary Table 1: Sociodemographic variables from the first multi-stakeholder workshop

Domain (Data type)	Adult response options	Notes
Age (years) (Discrete)	Any integer >18	Already routinely collected in all Peek programmes
Gender (Categorical)	• Female • Male • Other	Already routinely collected in all Peek programmes The DHS and RAAB7 surveys only include female/male. We have added 'other'
Phone ownership (Ordinal)	Do you need someone else to receive your text message reminders? • Yes, my mother or father • Yes, my spouse • Yes, my daughter or son • Yes, other • No (= phone ownership)	Already routinely collected in all Peek programmes
Place of residence (Categorical)	N/A	Urban/rural location automatically inferred from screening location
Distance from screening location to clinic (km) (Discrete)	N/A	Distance between screening location and clinic location has been found to be a predictor of outcomes This is automatically calculated by the Peek software.
Language (Categorical)	• [list languages]	Country-specific lists will be derived from the latest Demographic and Health Survey
Relationships (Categorical)	• Married or living together • Divorced/separated	Options may need tailoring depending on the context.

	• Widowed • Never married or lived together	
Ethnicity (Categorical)	• [List ethnic groups] • Other	Country-specific lists will be derived from the latest Demographic and Health Survey
Migrant/refugee (binary)	Are you a migrant or refugee? • Yes • No	May be inflammatory depending on the setting
Religion (Categorical)	• [List main religions] • Other not listed • None	Country-specific lists will be derived from the latest Demographic and Health Survey
Education (Ordinal)	• None/pre-school only • Non-formal (included Quranic) • Some primary • Completed primary • Some secondary • Completed secondary • University	Options taken from the RAAB7 survey as it offers more detail than the DHS model questionnaire (early childhood education programme/Primary/Secondary/Higher) Non-formal/Quranic options may not be appropriate in settings where the prevalence of these forms is negligible
Occupation (Ordinal)	• Unemployed • Unskilled manual • Skilled manual • Professional • Homemaker	For children, programme implementers will ask what their parent's do for work and then code the highest occupational category on their behalf
Income (proxy) (Ordinal)	When you think about the food in your household would you say you have: • Less than adequate food for the needs of the household • Just adequate • More than adequate	This question is being used in the RAAB7 eye health survey as a proxy for income The survey is designed for >50y olds, so the response options may not be appropriate for children
Income adequacy (Ordinal)	When you think about the income in your household would you say it is: • Not enough to cover our needs, we must borrow, • Not enough to cover our needs, we use savings,	This question is being used in the RAAB7 eye health survey as a proxy for income The survey is designed for >50y olds, so the response options may not be appropriate for children

	• Just enough to cover our needs, • Enough to cover our needs, we are able to save a little • Enough to cover our needs, we are building savings	
Wealth (Binary)	Is your house's floor made out of cement? • Yes • No	The specific indicator used here will depend on the location
Assets (Binary)	Does your household own: • [List assets from DHS]	Shortest possible list of assets to be selected by country working groups

Note: Every question will have the additional options: 'Do not want to answer' and 'Don't know'.

Supplementary Table 2: Sociodemographic variables from the second multi-stakeholder workshop

Domain	Adult response options	Notes
Age	Any integer >18	Already routinely gathered
Gender	•Female •Male •Other	Already routinely gathered
Phone ownership	Do you need someone else to receive your text? message reminders? • Mother or father • Spouse • Daughter or son • Other • No (=phone ownership)	Already routinely gathered
Place of residence	N/A	Urban/rural automatically inferred
Distance to clinic	N/A	Automatically calculated by Peek
Language	What language do you speak most often at home? •English •Swahili •Borana •Embu •Kalenjin •Kamba •Kikuyu •Kisii •Luhya •Maragoli •Luo	Workshop participants felt that it would be inflammatory to ask about tribe/ethnicity. Language will be used as a Proxy

	•Maasai •Meru •Mijikenda •Pokot •Somali •Turkana •Other	
Relationships	•Never married •Married •Living together •Single •Divorced/separated •Widowed	
Migrant status	Were you born in Kenya? •Yes •No •Don't want to answer	This question may be redundant. Kenya is currently home to 500,000 refugees, however, they mainly live in camps and this information will already be collected under 'Place of residence'. Outside of Nairobi, the migrant population that does not live in camps is negligible.

Religion	What is your religion? •Roman Catholic •Protestant/other Christian •Islam •Other •No religion	Responses taken from the 2014 DHS
Education	What is you highest level of completed schooling? •No education •Some primary •Primary complete •Some secondary •Secondary complete •More than secondary	Adult responses aligned with the 2014 DHS
Occupation	What is your occupation? •Unemployed •Agriculture •Unskilled manual •Skilled manual •Sales and services •Clerical •Professional/technical/managerial •Homemaker	Interviewer to categorise and code the highest

Food adequacy	When you think about the food in your household would you say you have: • Less than adequate food for the needs of the household •Just adequate •More than adequate	Question taken from RAAB7 – may remove due to poor face validity
Income adequacy	When you think about the income in your household would you say it is: • Not enough to cover our needs, we must borrow, • Not enough to cover our needs, we use savings, • Just enough to cover our needs, • Enough to cover our needs, we are able to save a little • Enough to cover our needs, we are building savings	From RAAB7, but poor face validity.
Housing	Is your house's floor made of earth, sand, or dung? •Yes •No Do you have water piped into your own house or yard? •Yes •No Does your household have electricity? •Yes •No What kind of toilet does your household you use? •Own toilet/latrine •Shared toilet/latrine •None (bush/field)	All options taken from the 2014 DHS

Assets	Do you own a smartphone? •Yes •No Does your household own a: •Bicycle •Motorcycle/scooter •Car or truck Do you own your dwelling? •Yes •No	

Supplementary Table 3: Sociodemographic variables from the third multi-stakeholder workshop

Domain	Adult response options	Child response options	Notes
Age	Any integer >18	Any integer 5 - 17	Already routinely gathered
Gender	•Female •Male •Other	•Female •Male •Other	Already routinely gathered
Phone ownership	Do you need someone else to receive your text? message reminders? • Mother or father • Spouse • Daughter or son • Other • No (=phone ownership)	Provided contact number: • Mother or father • Guardian • Teacher • Other	Already routinely gathered
Place of residence	N/A	N/A	Urban/rural automatically inferred
Distance to clinic	N/A	N/A	Automatically calculated by Peek
Language	What language do you speak most often at home? •English •Swahili •Borana •Embu •Kalenjin •Kamba •Kikuyu •Kisii •Luhya •Maragoli •Luo	What language do you speak most often at home? •English •Swahili •Borana •Embu •Kalenjin •Kamba •Kikuyu •Kisii •Luhya •Maragoli	Used instead of ethnicity

	•Maasai •Meru •Mijikenda •Pokot •Somali •Turkana •Other	•Luo •Maasai •Meru •Mijikenda •Pokot •Somali •Turkana •Other	
Relationships	•Never married •Married •Living together •Single •Divorced/separated •Widowed	*Do you live with:* • Both parents • Just one parent • Another relative • Guardian (non-relative) • Orphanage	
Religion	What is your religion? •Roman Catholic •Protestant/other Christian •Islam •Other •No religion	What is your religion? •Roman Catholic •Protestant/other Christian •Islam •Other •No religion	Responses taken from the 2014 DHS

Education	What is you highest level of completed schooling? •No education •Some primary •Primary complete •Some secondary •Secondary complete •More than secondary	N/A	Adult responses aligned with the 2014 DHS
Occupation	What is your occupation? •Unemployed •Agriculture •Unskilled manual •Skilled manual •Sales and services •Clerical •Professional/technical/managerial •Homemaker	What are your parents' jobs? •No parents •Unemployed •Agriculture •Unskilled manual •Skilled manual •Sales and services •Clerical •Professional/technical/managerial •Homemaker	Interviewer to categorise and code the highest
Income adequacy	When you think about the income in your household would you say it is: • Not enough to cover our needs, we must borrow, • Not enough to cover our needs, we use savings, • Just enough to cover our needs, • Enough to cover our needs, we are able to save a little • Enough to cover our needs, we are building savings	N/A	From RAAB7, but poor face validity.

Housing	Is your house's floor made of earth, sand, or dung? •Yes •No Do you have water piped into your own house or yard? •Yes •No Does your household have electricity? •Yes •No What kind of toilet does your household you use? •Own toilet/latrine •Shared toilet/latrine •None (bush/field)	Is your house's floor made of earth, sand, or dung? •Yes •No Do you have water piped into your own house or yard? •Yes •No Does your household have electricity? •Yes •No What kind of toilet does your household you use? •Own toilet/latrine •Shared toilet/latrine •None (bush/field)	All options taken from the 2014 DHS
Assets	Do you own a smartphone? •Yes •No Does your household own a: •Bicycle •Motorcycle/scooter •Car or truck Do you own your dwelling? •Yes •No	Does your household own a smartphone? •Yes •No Does your household own a: •Bicycle •Motorcycle/scooter •Car or truck	

Supplementary Table 4: Sociodemographic variables from the fourth multi-stakeholder workshop

Domain	Adult response options (>18y)	Child response options	Notes
Age	How old are you?	How old are you	Already routinely gathered
Gender	•Female •Male •Other	•Female •Male •Other	Already routinely gathered
Phone ownership	Do you need someone else to receive your text message reminders? •Mother or father •Spouse •Daughter or son •Other • No (= phone ownership)	Provided contact number: •Mother or father •Guardian •Teacher •Other	Already routinely gathered
Place of residence	N/A	N/A	Urban/rural automatically inferred
Distance to clinic	N/A	N/A	Automatically calculated by Peek
Language	What is your mother tongue? •English •Swahili •Borana •Embu •Kalenjin •Kamba •Kikuyu •Kisii •Luhya •Maragoli •Luo •Maasai	What is your mother tongue? •English •Swahili •Borana •Embu •Kalenjin •Kamba •Kikuyu •Kisii •Luhya •Maragoli •Luo •Maasai	

	•Meru •Mijikenda •Pokot •Somali •Turkana •Other	•Meru •Mijikenda •Pokot •Somali •Turkana •Other	
Relationships	•Married •Single •Divorced/separated •Widowed •Other	*Do you live with:* •Both parents •Just one parent •Another relative •Guardian (non-relative) •Orphanage	We removed 'never married' because this is the same as single We removed 'living together' because this question is loaded with social stigma Ideally, we would ask children if one or more parent had died, but we don't want to cause distress. In the future we could consider asking teachers for this information
Religion	What is your religion? •Christian •Islam •Hindu •Other	What is your religion? •Christian •Islam •Hindu •Other	We removed 'no religion' as this group is negligible Christian denominations were aggregated, and we added 'Hindu'

Education	What is you highest completed level of schooling? •No education •Primary •Secondary •Post-secondary	N/A	We reworded the question and removed 'completed' and 'some' options to simplify the list
Disability	Do you have difficulty **hearing**, even if using a hearing aid(s)? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all • Don't know Do you have difficulty **walking or climbing steps**? • No difficulty • Some difficulty •A lot of difficulty •Cannot do at all •Don't know Do you have difficulty **remembering or concentrating?** • No difficulty • Some difficulty •A lot of difficulty •Cannot do at all •Don't know	Do you have difficulty **hearing**, even if using a hearing aid(s)? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all • Don't know Do you have difficulty **walking or climbing steps**? • No difficulty • Some difficulty •A lot of difficulty •Cannot do at all •Don't know Do you have difficulty **remembering or concentrating?** • No difficulty • Some difficulty •A lot of difficulty •Cannot do at all •Don't know	New question added at the request of implementing partners Response options taken from the Washington Group Short Set on Functioning: https://www.washingtongroup-disability.com/question-sets/wg-short-set-on-functioning-wg-ss/ The same options will be used for adults and children. UNICEF does have a child-specific question set, but it is more than double the length.

	Do you have difficulty with **self-care**, such as washing all over or dressing? • No difficulty • Some difficulty •A lot of difficulty •Cannot do at all •Don't know Using your language, do you have difficulty **communicating,** for example understanding or being understood? • No difficulty • Some difficulty •A lot of difficulty •Cannot do at all •Don't know	Do you have difficulty with **self-care**, such as washing all over or dressing? • No difficulty • Some difficulty •A lot of difficulty •Cannot do at all •Don't know Using your language, do you have difficulty **communicating,** for example understanding or being understood? • No difficulty • Some difficulty •A lot of difficulty •Cannot do at all •Don't know	
Occupation	What is your occupation? •Not employed •Agriculture •Domestic service •Unskilled manual •Skilled manual •Sales and services •Clerical •Professional/technical/managerial	What are your parents' jobs? [staff to categorise & code only the highest] •No parents •Not employed •Agriculture •Domestic services •Unskilled manual •Skilled manual •Sales and services •Clerical •Professional/technical/managerial	We aligned the occupation categories with the 2014 DHS, adding domestic services

Income	What income band are you in? •Less than 24,000 KSh/month (288,000/yr, 10% Tax band) •Between 24,000 - 32,333 KSh/ month (288,000 - 100,000/yr, 25% Tax band) •More than 32,333 KSh/month (388,000/yr, 30% Tax band)	N/A	We removed the question on food adequacy as we felt it was not likely to render robust information. We also dropped the subjective question on income adequacy due to concerns about face validity. We replaced these income questions with a more direct item on income categories, based on the Kenya Revenue Authority tax bands
Housing	What is your floor made of in your house? •Cement •Other Do you have a source of water within your compound? • Yes • No Does your household have electricity, solar, or a generator? •Yes •No What type of toilet facility do members of your households usually use? • Own toilet/latrine •Communal toilet/latrine •None (bush/field)	What is your floor made of in your house? •Cement •Other Do you have a source of water within your compound? • Yes • No Does your household have electricity, solar, or a generator? •Yes •No What type of toilet facility do members of your households usually use? • Own toilet/latrine •Communal toilet/latrine •None (bush/field)	We switched from 'earth, sand or dung' to 'cement'. This is the reciprocal question and is faster to ask. We switched from 'do you have water piped into your own house or yard?' to 'do you have a source of water within your compound' because some rich people use boreholes We revised the wording of the toilet question changed to add greater clarity All options are aligned with the 2014 DHS

Assets	Do you own a smartphone? •Yes •No Does your household own a: •Bicycle •Motorcycle/scooter •Car or truck •None •Other	Does your household own a smart phone (with a touch screen)? •Yes •No Does your household own a: •Bicycle •Motorcycle/scooter •Car or truck •None •Other	We noted that smartphone ownership is so prevalent that it is only a sensible proxy for wealth in rural areas

Supplementary Table 5: stratum specific effect estimates of association between attendance and age and gender

Strata	Category	Unadjusted OR	p-value
18-24 years	Female	Ref	
	Male	0.43 (0.23-0.81)	0.008
25-34 years	Female	Ref	
	Male	0.57 (0.38-0.85)	0.005
35-44 years	Female	Ref	
	Male	0.55 (0.39-0.77)	0.001
45-54 years	Female	Ref	
	Male	0.58 (0.45-0.74)	<0.001
55-64 years	Female	Ref	
	Male	0.88 (0.66-1.17)	0.37
65+ years	Female	Ref	
	Male	0.86 (0.64-1.15)	0.305
Women	18-24y	0.44 (0.31-0.62)	
	25-34y	0.44 (0.34-0.57)	
	35-44y	0.56 (0.44-0.70)	
	45-54y	Ref	
	55-64y	1.08 (0.85-1.37)	
	65+y	1.46 (1.15-1.86)	<0.001
Men	18-24y	0.33 (0.18-0.59)	
	25-34y	0.44 (0.30-0.65)	
	35-44y	0.53 (0.37-0.75)	
	45-54y	Ref	
	55-64y	1.64 (1.22-2.22)	
	65+y	2.17 (1.61-2.94)	<0.001

Note: The p-value for the interaction term was 0.048

Supplementary Table 6: Regression with additional adjustment for eye condition

		N	N Attended	% Attended	Unadjusted	p	Adjusted for age & sex	p	Adjusted for everything	p	Additionally adjusted for eye condition	p
Gender	F	2700	1317	49%	Ref	<0.001	Ref	<0.001			Ref	<0.001
	M	1540	634	41%	0.73 (0.65-0.83)		0.67 (0.59-0.76)		0.72 (0.63-0.83)	<0.001	0.71 (0.62-0.83)	
Age cat	18-24	271	78	29%	0.42 (0.32-0.57)		0.41 (0.31-0.55)		0.49 (0.35-0.69)		0.54 (0.38-0.77)	<0.001
	25-34	615	189	31%	0.46 (0.38-0.57)		0.45 (0.36-0.55)		0.51 (0.41-0.63)		0.55 (0.43-0.69)	
	35-44	730	256	35%	0.57 (0.47-0.69)		0.55 (0.46-0.67)		0.59 (0.48-0.72)		0.61 (0.49-0.74)	
	45-54	1048	512	49%	Ref	<0.001	Ref	<0.001	Ref	<0.001	Ref	
	55-64	786	429	55%	1.26 (1.05-1.51)		1.27 (1.05-1.53)		1.21 (1.00-1.46)		1.20 (0.99-1.45)	
	65+	790	487	62%	1.68 (1.39-2.03)		1.71 (1.42-2.07)		1.61 (1.31-1.99)		1.65 (1.33-2.04)	
Asset	None	3644	1726	47%	Ref	0.0001	Ref	0.002	Ref	0.03	Ref	0.02
	Bike/Moto/scooter	328	125	38%	0.68 (0.54-0.86)		0.86 (0.68-1.10)		0.87 (0.68-1.12)		0.86 (0.67-1.10)	
	Car	268	100	37%	0.66 (0.51-0.85)		0.64 (0.49-0.83)		0.69 (0.52-0.92)		0.68 (0.51-0.91)	
Disability	No	3637	1629	45%	Ref		Ref		Ref	0.99	Ref	0.86
	Yes	603	322	53%	1.41 (1.19-1.68)	<0.001	0.98 (0.82-1.18)	0.87	1.00 (0.83-1.20)		1.02 (0.84-1.23)	
Education	None	284	149	52%	Ref	<0.001	Ref	0.002	Ref	0.03	Ref	0.05
	Primary	1787	906	51%	0.93 (0.73-1.20)		1.43 (1.09-1.87)		1.42 (1.07-1.87)		1.37 (1.04-1.82)	
	Secondary	1538	666	43%	0.69 (0.54-0.89)		1.28 (0.97-1.69)		1.30 (0.97-1.73)		1.27 (0.95-1.70)	
	Post-secondary	631	230	36%	0.52 (0.39-0.69)		1.03 (0.76-1.40)		1.12 (0.81-1.56)		1.10 (0.79-1.53)	
Health insurance	No	2530	1154	46%	Ref	0.35	Ref	0.77	Ref	0.12	Ref	0.13
	Yes active	909	437	48%	1.10 (0.95-1.28)		1.02 (0.87-1.19)		1.20 (1.01-1.43)		1.20 (1.01-1.43)	
	Yes not active	801	360	45%	0.97 (0.83-1.14)		0.95 (0.80-1.12)		1.04 (0.88-1.24)		1.04 (0.88-1.23)	
Housing	No	703	353	50%	Ref	0.015	Ref	0.21	Ref	0.48	Ref	0.43
	Yes	3537	1598	45%	0.82 (0.69-0.96)		0.90 (0.76-1.06)		0.94 (0.79-1.12)		0.93 (0.78-1.11)	
Income	No response	1984	935	47%	Ref	<0.001	Ref	0.007	Ref	0.11	Ref	0.11
	<24,000	2050	939	46%	0.94 (0.84-1.07)		0.92 (0.81-1.04)		0.91 (0.80-1.04)		0.91 (0.80-1.04)	
	24,000-32,333	132	56	42%	0.83 (0.58-1.18)		0.84 (0.59-1.22)		0.98 (0.67-1.45)		1.00 (0.67-1.47)	
	>32,333	74	21	28%	0.44 (0.27-0.74)		0.41 (0.24-0.69)		0.54 (0.30-0.95)		0.53 (0.30-0.94)	
Marital	Single	904	320	35%	Ref	<0.001	Ref	0.005	Ref	0.03	Ref	0.05
	Married	2977	1435	48%	1.96 (1.64-2.33)		1.37 (1.12-1.66)		1.29 (1.05-1.59)		1.30 (1.06-1.59)	
	Divorced/separate	200	93	47%	1.83 (1.33-2.51)		1.12 (0.79-1.57)		1.10 (0.77-1.55)		1.11 (0.78-1.58)	
	Widowed	333	185	56%	2.63 (2.01-3.41)		1.05 (0.77-1.42)		1.03 (0.76-1.42)		1.04 (0.76-1.43)	
	Other	26	11	42%	1.54 (0.70-3.41)		0.87 (0.38-1.97)		0.89 (0.38-2.00)		0.88 (0.38-2.03)	
Occupation	Not employed	801	367	46%	Ref	<0.001	Ref	<0.001	Ref	<0.001	Ref	<0.001
	Farming	1593	892	56%	1.50 (1.27-1.78)		1.29 (1.08-1.54)		1.24 (1.03-1.49)		1.25 (1.04-1.51)	
	Domestic service	297	162	55%	1.42 (1.09-1.85)		1.45 (1.10-1.91)		1.44 (1.09-1.90)		1.41 (1.06-1.86)	
	Prof/tech/man/Cle	202	79	39%	0.76 (0.55-1.04)		0.86 (0.62-1.19)		1.05 (0.73-1.52)		1.07 (0.74-1.54)	
	Sales & services	449	151	34%	0.60 (0.47-0.76)		0.73 (0.56-0.93)		0.76 (0.58-0.98)		0.76 (0.58-0.98)	
	Skilled manual	400	138	35%	0.62 (0.49-0.80)		0.78 (0.60-1.01)		0.79 (0.60-1.04)		0.79 (0.60-1.04)	
	Unskilled manual	417	140	34%	0.60 (0.47-0.76)		0.72 (0.56-0.93)		0.72 (0.55-0.93)		0.72 (0.55-0.94)	
	Student/pupil	81	22	27%	0.44 (0.27-0.73)		0.86 (0.49-1.51)		1.00 (0.56-1.77)		0.99 (0.55-1.75)	
Religion	Christian	4129	1907	46%	Ref	0.09	Ref	0.15	Ref	0.24	Ref	0.22
	Islam	81	36	44%	0.93 (0.60-1.45)		0.95 (0.60-1.50)		1.07 (0.67-1.69)		1.06 (0.67-1.69)	
	Other	30	8	27%	0.42 (0.19-0.95)		0.44 (0.19-1.00)		0.49 (0.21-1.14)		0.48 (0.20-1.11)	

		N	N Attended	% Attended	Unadjusted	p-value	Adjusted for age & sex	p	Adjusted for everything	p
Eye condition	Normal	209	86	41%	0.68 (0.51-0.91)	<0.001	0.64 (0.47-0.86)	0.012	0.66 (0.49-0.89)	0.008
	Loss of vision	1878	954	51%	Ref		Ref		Ref	
	Chronic	336	158	47%	0.86 (0.68-1.08)		0.85 (0.67-1.08)		0.84 (0.66-1.07)	
	Acute	1368	563	41%	0.68 (0.59-0.78)		0.83 (0.71-0.96)		0.80 (0.68-0.93)	
	Urgent	449	190	42%	0.71 (0.58-0.87)		0.93 (0.75-1.16)		0.88 (0.71-1.11)	

Part 3: Engaging with left behind groups

Chapter 6

Scoping review of rapid methods for identifying barriers and solutions to improve access to community health services

Rapid qualitative research methods being used in rural Uttar Pradesh
Source: Author. Consent has been provided from both individuals in the photo

Key messages

- Previous work found that younger adults were the least likely to receive care in Meru county's eye programme.
- We wanted to engage with this group to understand what specific barriers they faced and what could be done about them, and wanted to use rapid and scalable methods.
- I led a scoping review to explore the approaches used by other researchers for rapid identification of barriers and solutions.
- I identified a wide range of methods and techniques that speed up the research process without sacrificing rigor or data quality, including active recruitment strategies, data collection at the point of recruitment, the use of data collection teams working with local community members, the use of direct-from-audio transcription of quotes, and the use of deductive framework approaches for rapid analysis.

Having identified the groups that were least able to access care in Part 2 of my thesis, I set about developing the methods for engaging with representatives of this group to explore their perceptions and experiences of barriers, and their ideas for how the service could be improved. The approach had to be non-tokenistic and scientifically robust in order to deliver reliable findings, yet feasible and rapid enough to deliver those findings in a timely manner to make them operationally useful for the programme managers.

I started with a scoping review to explore how other research teams had struck this balance, paying particular attention to the methodological techniques they had employed to expedite data collection and analysis without sacrificing quality or rigor. Our protocol was published in BMJ Open[82] and is available in Appendix 3.

I hired and trained two research assistants to help with screening and data extraction. I am particularly grateful for their help, thanks Hagar and Ronald. The final review was published in BJGP Open.

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RESEARCH PAPER COVER SHEET

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SECTION A – Student Details

Student ID Number	2004040	**Title**	Dr
First Name(s)	Luke		
Surname/Family Name	Allen		
Thesis Title	Improving equitable access to community-based health services: Developing and testing a new model in Kenya's national eye screening programme		
Primary Supervisor	Andrew Bastawrous		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

SECTION B – Paper already published

Where was the work published?	BJGP Open		
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SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I was the lead author for this scoping review. I worked with an information specialist (Iris Gordon) to design the search, and led on all other aspects of the research; from developing the protocol and setting the inclusion and exclusion criteria, to leading data extraction, analysis, and presentation. I recruited and trained Hagar Azab and Ronald Jonga as the second and third reviewers. I wrote the first draft of the manuscript and led the process of iterative revision and submission. I led the revision process, supported by Hagar who re-drafted two sections in the findings. My remaining co-authors provided support with helpful comments on the original draft and the revision.

SECTION E

Student Signature	Luke Allen
Date	26th April 2024

Supervisor Signature	REDACTED
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RESEARCH

Rapid methods for identifying barriers and solutions to improve access to community health services: a scoping review

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Abstract

Background: The advancement of universal health coverage (UHC) is largely based on identifying and addressing barriers to accessing community health services. Traditional qualitative research approaches provide excellent insights but have unfeasibly high resource requirements for most care providers.

Aim: To identify, categorise, and evaluate methods that have been used to identify barriers to and/or solutions for improving access to community-based health services, grounded in engagement with affected communities, excluding approaches that take >14 days.

Design & setting: This was a scoping review.

Method: Following Joanna Briggs Institute (JBI) guidelines, a search was undertaken using the Cochrane Library, Ovid MEDLINE, Ovid Embase, Ovid Global Health, and Google Scholar. An information specialist designed the search, and dual independent review and data charting were used.

Results: In total, 44 studies were included from 30 countries, reporting on 18 different clinical services. Thirty studies used self-described 'rapid' approaches; however, the majority of these did not justify what they meant by this term. Nearly half of the studies used mixed- or multi-methods and triangulation to verify early findings. All of the qualitative studies used interviews and/or focus groups, which were often supplemented with observations, document review, and mapping activities. The use of in situ snowball and convenience sampling; community members as data collectors and cultural guides; collaborative summarisation (review of findings with community members and end-users); and deductive framework analysis expedited the research processes. There were no data on costs.

Conclusion: There are a wide range of methods that can be used to deliver timely information about barriers to access. The methods employed in the articles reviewed tended to use traditional data collection approaches in innovative ways.

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How this fits in

There have been abundant calls to routinely engage communities as part of extending access to health services, but most organisations have very limited time and resources to dedicate to this work. This

study found that it is possible to rapidly obtain insights from those at the fringes. These assessments could play an important role in extending health service access to marginalised communities.

Introduction

Extending universal health coverage (UHC) has been described as central to achieving the Sustainable Development Goals.[1] As most health interactions take place in primary care, there is growing interest in understanding and tackling barriers to accessing these community-based services.[2–4]

Previous research has demonstrated the ubiquity, inequity, and impact of poor access to health care across numerous settings and service domains.[5–7] The ascendant principles of primary health care (PHC) have focused attention on equitable access to community-based health services, grounded in community engagement and empowerment.[3,8,9] As such, managers are facing increasing pressure to ensure that the services they run are accessible to all. Given that the factors influencing access are complex and unique in every setting,[10] health managers and policymakers require tools to rapidly and cost-effectively identify local barriers and elicit potential solutions as a core part of routine health service provision.[11]

Seminal conceptual models of access stress both supply and demand-side factors;[10,12–14] however, attempts to redress poor access seem to disproportionately focus on eliciting the views of those on the supply side.[15] The World Health Organization (WHO) noted that it is invariably *'experts who identify the problems and formulate interventions, while the problems and solutions as perceived by those at particular risk rarely constitute the base for action'*.[16] It is increasingly recognised that efforts to improve access and attendance should be grounded in engagement with affected communities.[3,16,17]

Traditional qualitative data collection approaches, including key informant interviews (KII), in-depth interviews (IDI), ethnographic observations, and focus group discussions (FGD), commonly take many months to plan, execute, analyse, and report.[11,18,19] High time, expertise, and resource requirements can be prohibitive for managers seeking rapid data to understand and address local issues with negligible time and resources to spend on research activity.[11,20–22] While some forms of surveys and other quantitative approaches can be deployed relatively quickly and inexpensively, these methods are not best suited for exploring perspectives on barriers and potential solutions.[23,24]

Ideally, health service managers would be able to deploy rapid, affordable, and methodologically robust tools to engage with affected communities to elicit barriers and solutions to improve access. Such tools would have very wide application across a broad range of settings; support the development of PHC-oriented systems that are built on community engagement; and equitably extend UHC.

Aim and objectives

This study aimed to identify, categorise, and evaluate rapid methods currently in use to identify barriers to and/or solutions for improving access to community-based health services, grounded in engagement with affected communities. For each method the study aimed to document the approach to sampling and recruitment; data collection, integration, and analysis; as well as time and resource requirements.

Method

Protocol and guidelines

A scoping review was chosen to be performed because this is the most appropriate method for mapping the *'extent, range, and nature of research activity in a particular field'*.[25–28] A published protocol[29] and the Joanna Briggs Institute methodology, based on the principles of Arksey and O'Malley and Levac *et al*, were followed.[30–32] The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist extension for scoping reviews was used (PRISMA-ScR) to report the findings.[33]

Eligibility

The core concept was the methods used for engaging intended service beneficiaries to elicit their perceptions of barriers to access, and/or generating ideas for service modifications that could improve access. Methods seeking to engage with those who were eligible for a given service but who had

not managed to attend were focused on. Methods were excluded that sampled exclusively from attendees. Methods were included where engagement activities targeted intended beneficiaries of any non-digital community-based health service in any country, serving any need. The review was not limited to any specific population, culture, or geography.

The study focused on rapid methods, starting with an essentially arbitrary threshold, *'methods that can be used to deliver a list of barriers and potential solutions within 14 days or less'*.[29] It was noted that non-health sectors routinely deliver qualitative findings within a matter of weeks[34] with timeliness, validity, and accuracy sufficient to justify $476 billion of market research spending in 2021.[35] There is evidence that policymakers and health programme managers want — and to some extent expect — answers to health service research questions within a matter of days, so that norms and expectations around the term 'rapid' differ depending on context.[11,20,21,36]

Given that few definitions of rapid research use concrete time thresholds[37] and that it is not standard practice for research articles to report the length of time taken between starting fieldwork and generating findings, studies were included that did not state how long they took, as long as they met all other inclusion criteria. Studies and approaches were divided into those that specifically used the term 'rapid' or a synonym to describe their approach versus studies and approaches that did not use these terms.

The focus was on access to existing community-based services. ***Table 1*** sets out the inclusion and exclusion criteria. Systematic reviews were excluded but their reference lists were searched and any underlying primary studies that met the inclusion criteria were included. The present study included articles published in any language since 1978; the year of the Alma-Ata Declaration on Primary Health Care.[8] While the focus was on qualitative methods, quantitative methods were not exluded.

Search strategy

The search strategy was designed by an information specialist (IG) and built around rapid community-based methods and access to health services.[26,27] The search focused on the following: themes of access and differential access; barriers and solutions; community setting; types of research; and exclusion criteria. The Cochrane Library, Ovid MEDLINE, Ovid Embase, Ovid Global Health, and the first 20 pages of Google Scholar were searched. The search strategy, including all identified keywords and index terms, was adapted for each included database and/or information source. ***Box 1*** presents the search strategy for MEDLINE and Supplementary Appendix S1 presents the tailored search strategies for all databases. The reference lists of included studies and relevant systematic reviews were checked to identify

Table 1 Summary of inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
• Methods that elicit barriers to access and/or solutions from intended service beneficiaries or their proxies (for example, parents and carers) • Established community-based services • Empirical research	• Methods that exclusively engage with service providers or policymakers • Methods that exclusively engage with people who have managed to attend a service or health facility (service users) • Methods that engage with a mix of intended service beneficiaries and service users/providers, but do not provide disaggregated findings for intended beneficiaries • Methods that explicitly state that they take >14 days between starting fieldwork and generating findings • Inpatient hospital services • Experimental or pilot services • Fully digital services • Services that do not require any interaction with a clinician • Enforced or compulsory services • Letters, reviews, conference abstracts, non-empirical research, and methodological texts • Published pre-1978

any additional potentially relevant reports of studies. Key authors were contacted to uncover additional or upcoming studies.

Evidence selection

All identified citations were collated and uploaded into Covidence (Veritas Health Innovation) and duplicates were removed. Abstracts and full texts were screened by two independent reviewers (HA and RJ) and studies that did not meet the inclusion criteria were excluded. Disagreements were resolved through consensus-based discussion and consultation with a third reviewer (LA) where necessary.

Data charting

Two reviewers independently extracted study characteristics and data from the included studies using a form developed for this scoping review (see Supplementary Appendix S2). The form was piloted and refined during the process of extracting data from the first five articles to align it with the types of evidence that were being presented, namely the participants, concept, context, study methods, and key findings relevant to the review question (***Box 2***).

All of the items identified in the original protocol were retained, but the ordering and wording of some items were reworked. The corresponding author of all articles were contacted to request

Box 1 Search terms used for MEDLINE

- Health Services Accessibility/
- Health Equity/
- Social Determinants of Health/
- (social adj2 determinant adj2 health$).tw.
- ((health$ or social$ or racial$ or ethnic$) adj5 (inequalit$ or inequit$ or disparit$ or equit$ or disadvantage$ or depriv$)).tw.
- (disadvant$ or marginali$ or underserved or under served or impoverish$ or minorit$ or racial$ or ethnic$).tw.
- barrier$.tw.
- (solution$ or improve$ or strateg$ or access$ or challeng$).ti.
- Community-Based Participatory Research/
- Community-Institutional Relations/
- (communit$ adj3 (engag$ or participat$)).tw.
- CBPR.tw.
- (participat$ adj2 health adj2 research).tw.
- (communit$ adj2 academic adj2 partnership$).tw.
- (collective adj2 empower$).tw.
- (equity adj2 mobili$ adj2 partnership$ adj2 communit$).tw.
- (ethnograph$ or communitarian$).tw.
- Interviews as Topic/
- Patient Health Questionnaire/
- Self Report/
- Q-Sort/
- Q-Sort.tw.
- Q-methodolog$.tw.
- (system adj2 dynamic adj2 model$).tw.
- (nominal adj2 group$ adj2 technique$).tw.
- or/1–25
- Problem Solving/
- ((rapid$ or agile) adj2 (appraisal$ or assessment$ or approach$ or evaluation$ or evaluate$ or technique$ or tool$ or method$ or research$)).tw.
- or/27–28
- 26 and 29
- in vitro.tw.
- (assay$ or microb$).tw.
- Critical Care/
- or/31–33
- 30 not 34
- limit 35 to humans
- limit 36 to (comment or editorial or letter)
- 36 not 37
- limit 38 to yr="1978 -Current"

Box 2 Extracted data

- Article characteristics and study type
- Type of approach (for example, focus group) and description
- Ethics and governance requirements
- Sampling and recruitment methods
- Data collection approach
- Main output, if anything other than a prioritised list of potential service modifications
- Resource requirements:
  - Number of personnel, and essential skills or level of training
  - Number of days for each person, full-time equivalent
  - Total number of days taken from conception to findings including planning, recruitment, engagement, and analysis stages
  - Equipment
  - Total financial cost
- Framework used to structure interaction and elicit barriers and solutions
- Level of community participation
- Power relations, prevailing knowledge, and beliefs and cultural barriers, as described by the authors

missing or additional data. The lead author was also contacted if no response was received from the corresponding author within 10 days.

The level of community participation for each study was assessed using definitions set out in the WHO Europe toolkit on social participation (***Box 3***).[16] These four approaches are based on those codified by the International Association for Public Participation: 'inform', 'consult', 'involve', 'collaborate', and 'empower', noting that inform and consult are combined by WHO under the 'community-based' approach.[38,39] Each form of community engagement has legitimacy in its own right, and the most appropriate level for a given project depends on the aims and available resources.[39] Given that the focus is on methods for identifying problems and potential solutions (that is, stopping short of implementation), the authors expected that most included studies would be community-oriented.

The following were also extracted: any mention of power imbalances between researchers and community-intended service beneficiaries; acknowledgements of prevailing local knowledge; and beliefs and cultural barriers to collaboration between the community members and research team. This was based on the recommendations of Turk *et al*[17] and a large systematic review on community participation in health systems research, which found these important issues to be chronically overlooked.[15]

Data analysis and presentation

A narrative descriptive synthesis without meta-analysis was conducted. The synthesis was stratified by methodological approach and presented a summary table of individual study characteristics. As mentioned above, approaches were separately analysed that used 'rapid' or other synonyms to describe themselves. In keeping with usual practice for scoping reviews, methodological quality assessment of included studies was not conducted.[32,40]

Results

Study characteristics

Box 3 The four levels of community participation[16]

- **Community-oriented**: the community is informed and mobilised to participate in addressing immediate short-term concerns with strong external support.
- **Community-based**: the community is consulted and involved to improve access to health services and programmes by locating interventions inside the community with some external support.
- **Community-managed**: there is collaboration with leaders of the community to enable priority settings and decisions from the people themselves with or without external support of partners.
- **Community-owned**: community assets are fully mobilised and the community is empowered to develop systems for self-governance, establish and set priorities, implement interventions, and develop sustainable mechanisms for health promotion with partners and external support groups as part of a network.

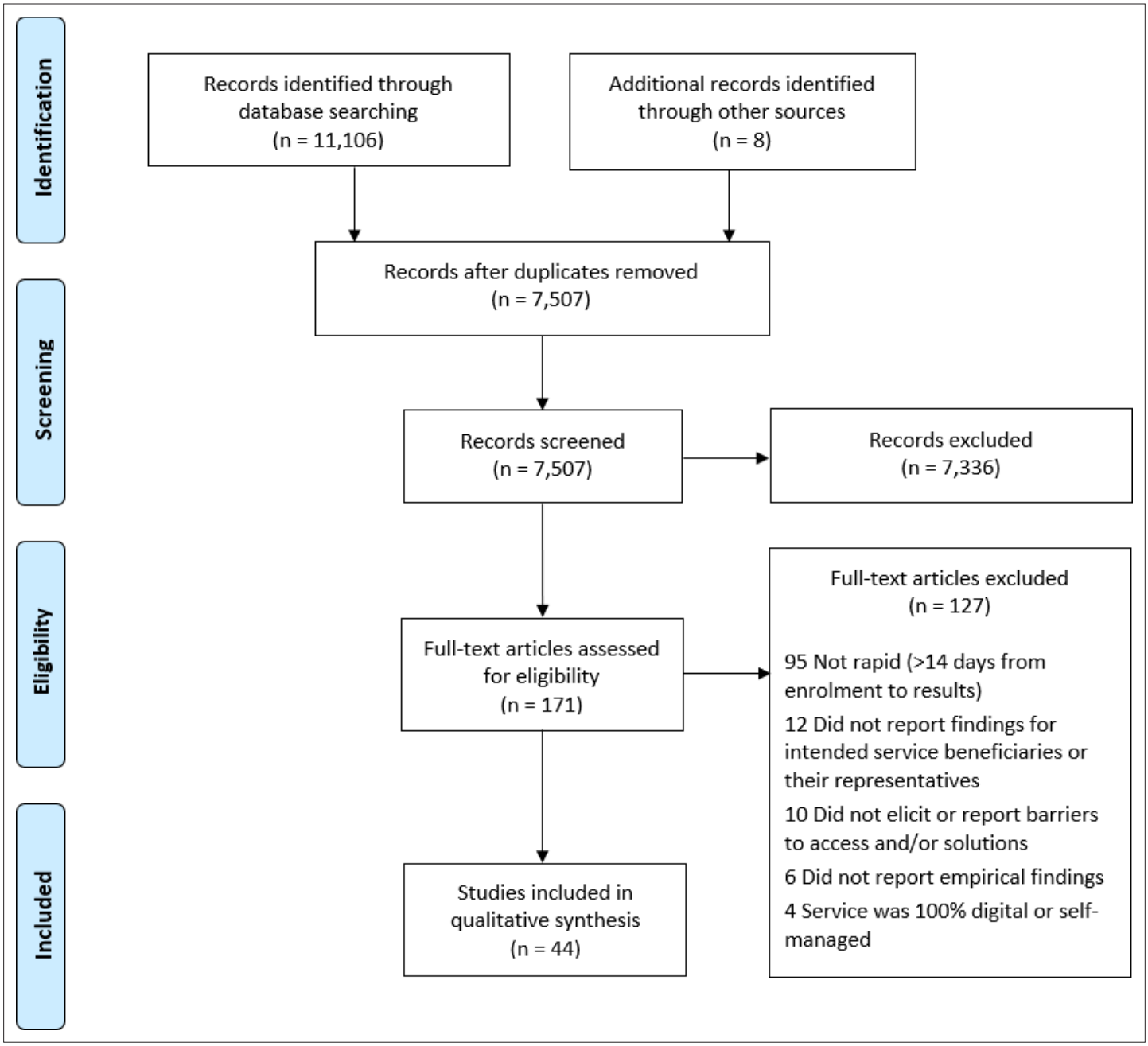

Figure 1 PRISMA diagram

The searches returned 7507 unique records. After excluding irrelevant articles based on title and abstracts, 171 full texts were screened with moderate agreement (Cohen's kappa 0.47). In total, 68 authors were emailed to establish how many days their research approach took as it was not clear from the full text; 15 replies were received. All studies were included where the time taken to conduct the study was ambiguous but all other inclusion criteria were met (43 studies). A single study[41] that stated it took a length of <14 days to complete was also included (totalling 44 studies; ***Figure 1***).

Across the 44 included studies,[41–84] 30 countries were represented, with 19 studies (43%) based in high-income countries[41,48,52,53,55,56,63,65–67,70,71,73,74,76,79,81,82,84] and the remaining 57% based in low- and middle-income countries (LMICs).[42–47,49–51,54,57–62,64,68,69,72,75,77,78,80,83] Overall, 12 studies came from the US;[41,48,52,56,65–67,73,74,76,81,82] four from India;[47,64,72,78] two each from Australia,[55,63] Bangladesh,[46,57] Colombia,[53,58] Indonesia,[50,69] Mozambique,[45,62] Nigeria,[42,79] the Philippines,[44,60] and Mali;[43,45] and one each from Bhutan,[59] Burkina Faso,[42] Canada,[75] Eritrea,[68] Ethiopia,[49] Georgia,[84] Ghana,[54] Kenya,[77]

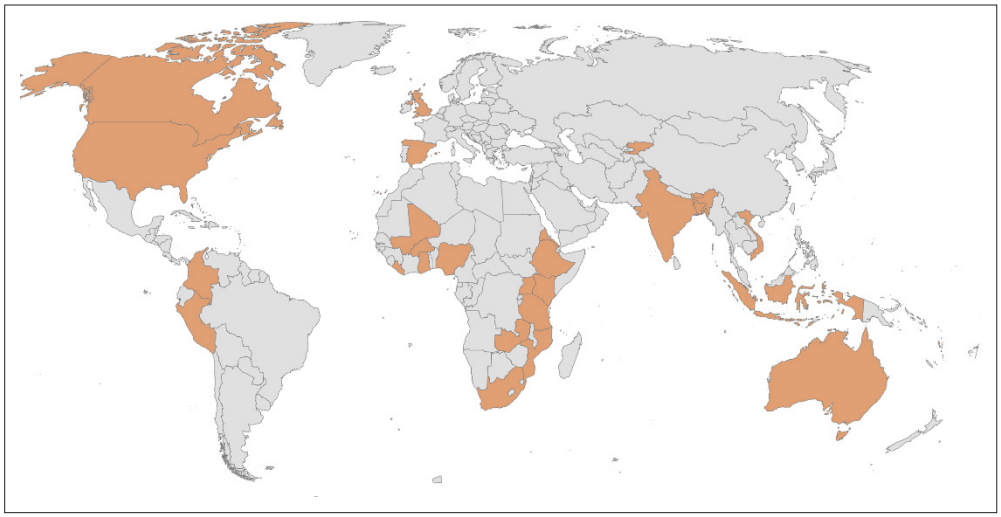

Figure 2 Countries represented in the scoping review

Kyrgyzstan,[43] Liberia,[80] Papua New Guinea,[51] Peru,[43] South Africa,[83] Spain,[71] Tanzania,[43] Uganda,[42] the UK,[70] Vanuatu,[61] Vietnam,[44] and Zambia (***Figure 2***).[45] Four studies were conducted in multiple countries[42–45] and the remainder focused on single countries.

Nearly three-quarters of studies (73%) had been published since 2010 (***Figure 3***).[41–44,46–53,56–65,67,68,71,73–78,80] All studies were published in English.

Supplementary Table S1 summarises the study characteristics of the individual studies, dividing them into the following two groups: the 30 studies that used methods described as 'rapid'; and the 14 studies that did not use this term. It is noted again that only one study[41] explicitly stated that it took <14 days and that a number of the studies from the second group may well have taken >14 days to complete, but this was not able to be ascertained definitively.

Ethical review

A large number of studies (59%) obtained ethical review from university ethics committees and, where required, national institutional review boards.[41–43,46–68] Bedford *et al* obtained ethical approval from local *'county health teams'*, with *'support'* from the UNICEF Country Office (2017), and 14 studies did not provide any information on ethical review.[44,45,55,69–80]

Shimkhada *et al*'s Twitter study was exempted by the University of California, Los Angeles university ethics board.[81] Othieno obtained written consent before conducting IDIs and FGDs with immigrants and refugees living with HIV, but stated that their organisation (the Minnesota HIV Planning Council) did not require external ethical review for this or any other needs assessments.[82] Cook *et al* stated that

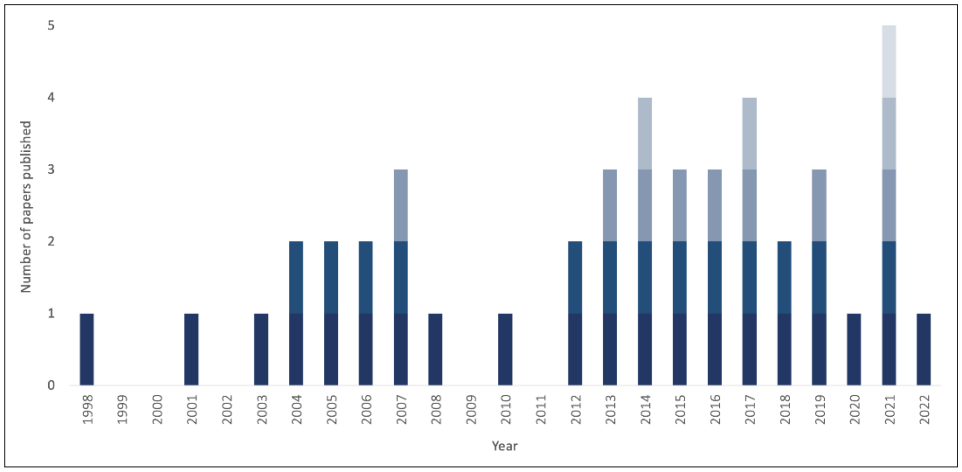

Figure 3 Year of publication for the included studies

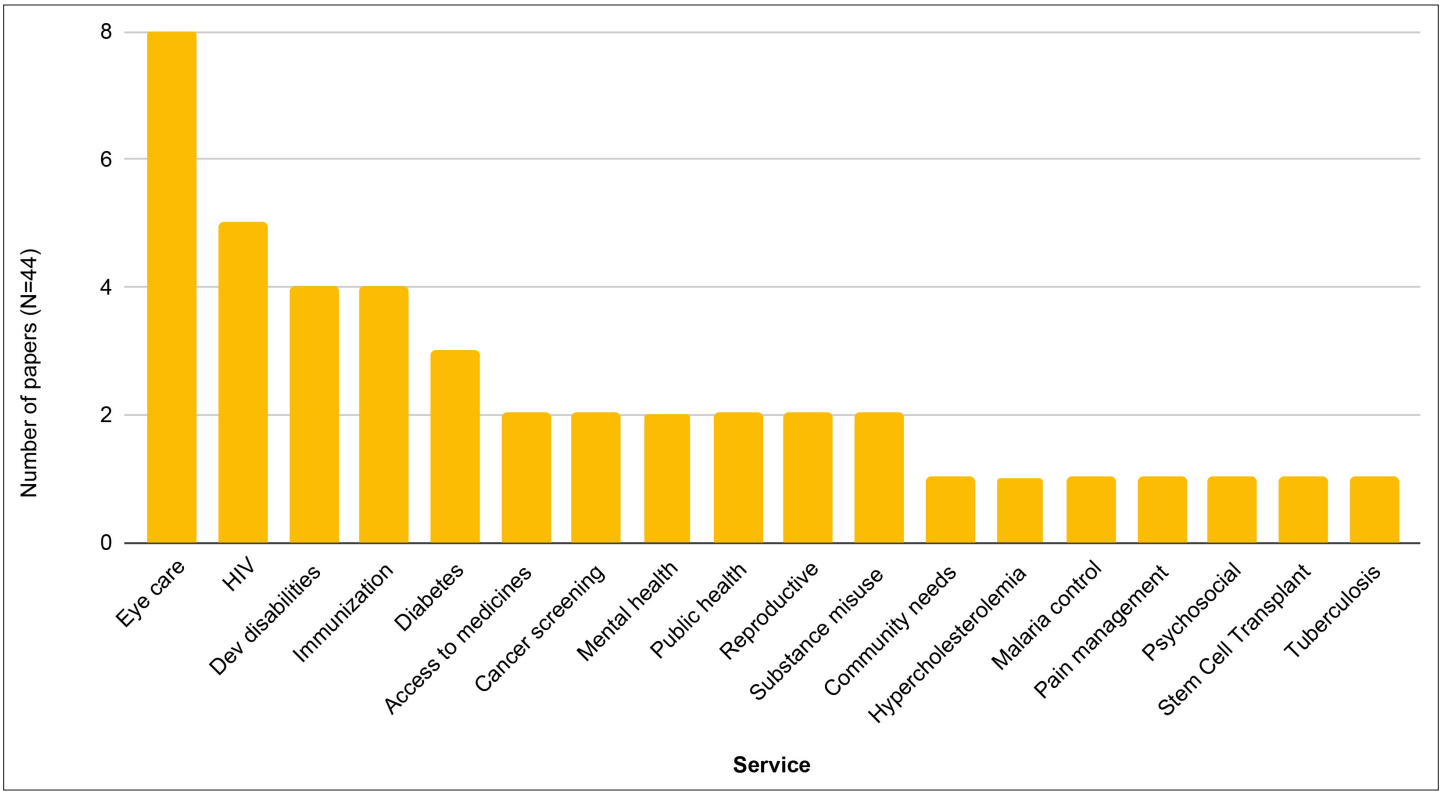

Figure 4 Number of studies assessing each type of service

ethics review was not required for their survey of barriers to cataract services because the activities *'were planned as a component of the ongoing Vision 2020 cataract case finding in the district'*.[83]

Services

The studies reported on 18 clinical services. The most commonly studied service was eyecare (18% of all studies); eight of these studies used the Rapid Assessment of Avoidable Blindness (RAAB) or aligned methods.[51,58,59,68,72,78,79,83] Many more RAAB surveys were screened but excluded because they did not report barriers or stated that they took >14 days to complete. The next most commonly assessed service was HIV (11% of all included studies),[49,63,73,77,82] followed by developmental disabilities (9%)[54–56,60]; immunisation (9%);[46,52,62,80] diabetes (9%);[43–45,84] access to medicines (5%);[45,47] cancer screening (5%);[41,81] substance misuse (5%);[71,74] mental health (5%);[53,66] public health intervention (5%); [54,69] reproduction (5%);[50,65] and single studies assessing community needs and barriers related to access in the areas of hypercholesterolemia care, stem cell transplant, malaria, pain management, psychosocial needs, and tuberculosis (***Figure 4***).[42,48,57,64,67,70,76]

Eliciting barriers to access and/or solutions was the sole focus of eight of the 44 included studies (18%).[46–50,64,81,82] The remaining 36 assessed these factors alongside other aims; for instance, Beran *et al*'s article assessed insulin availability[45] and Brown *et al*'s article assessed community assets.[70] All studies tended to use similar methods for eliciting barriers and solutions, irrespective of whether this was a primary or secondary aim.

Data collection methods

Thirteen studies (30%) used surveys to assess barriers, including all of the eyecare service studies.[41,48,51,58–60,64,70–72,78,79,83] IDIs and KIIs were the most commonly employed data collection approaches, used by all of the remaining 31 studies. Interviews were commonly combined with FGDs, cultural expert interviews, policy and administrative document review, surveys, observations, and mapping activities. Overall, 52% of the studies used a single method to elicit barriers and solutions, 41% used multiple qualitative methods, and 7% used mixed qualitative and quantitative methods (see Supplementary Table S1).

Box 4 Rapid approaches mentioned in the included studies

- PRA: Participatory Rapid Appraisal
- RA: Rapid Appraisal
- RAAB: Rapid Assessment of Avoidable Blindness
- RACSS: Rapid Assessment of Cataract Surgical Services
- RAnthroA: Rapid Anthropological Assessment
- RAP: Rapid Assessment Procedure
- RAPIA: Rapid Assessment Protocol for Insulin Access
- RARE: Rapid Assessment, Response, and Evaluation
- RAS: Rapid Assessment Survey
- RAD: Rapid Assessment of Disability
- RHA: Rapid Health Assessment
- RPA: Rapid Participatory Appraisal
- RQA: Rapid Qualitative Assessment

Thirty studies described their methods as 'rapid' (see Supplementary Table S1), and 26 of these used an established rapid-research approach (***Box 4***). The characteristics of these approaches are summarised in Supplementary Table S2. As has been discussed, despite using the term rapid, only one of these studies actually reported duration.[41] The vast majority of studies used ostensibly standard approaches for recruitment, data collection, and analysis without explaining what distinguished them from 'non-rapid' approaches or which design features enabled the studies to be conducted faster than usual.

Two studies stated that their rapid approach traded methodological rigour for speed. Brennan and Rimba stated that their team used *'established "quick and dirty" methods'* to gather mixed data *'in a timely manner'* for their post-tsunami assessment,[69] with 'quick and dirty' refering to the use of small (and therefore possibly non-representative) samples, trading 'precision' for 'timeliness'. Beran *et al* espoused the use of *'pragmatic'* methods that *'provide adequate information, without necessarily being "scientifically perfect"'*.[45] These authors argued that pragmatism is an important principle for rapid assessments, alongside speed, cost-effectiveness, and the use of multiple data sources, which can be used to establish the validity and reliability of findings through the process of triangulation. None of the other rapid studies conceded any speed-related limitations or methodological trade-offs.

Sampling and recruitment

Surveys tended to use multistage cluster random sampling, and this approach was largely driven by primary aims that were unrelated to eliciting barriers and solutions; for example, establishing generalisable prevalence rates. Studies that used other data collection approaches tended either not to report how they recruited participants or to recruit by approaching key informants within the local community and relevant health services to identify initial interviewees, and then used snowballing and in situ convenience sampling to recruit additional participants (see Supplementary Table S1). Six studies used additional methods to recruit participants: posters,[52] flyers,[65] social media,[63,65,81] local organisations,[63,75] clinics,[63] and postcards.[76] Very few studies provided information on who was responsible for recruitment (see Supplementary Table S2), and none provided information on the resources involved in terms of time.

Among the subset of self-described 'rapid' approaches, three studies recruited participants via adjacent services[47,52,53] and seven studies recruited convenience or snowball samples by directly approaching people within the community of interest.[41,46,57,69,73,74,82]

All of the studies that used qualitative methods employed purposive sampling to the extent that they aimed to recruit a range of different voices from the target population of intended service beneficiaries, often focusing on those who were deemed vulnerable or marginalised.[41,46,57,69,70,73,74,82]

Sample sizes

None of the included articles provided a justification for their sample sizes apart from Jones *et al*, who continued interviewing until achieving thematic saturation.[67] Several of the research teams conducted >100 interviews, often supplemented with observations and surveys to identify barriers that were deliberately generalisable to the entire population of intended service beneficiaries.[43–46,62,69,80] Elwy

et al, Cusack *et al*, Brown *et al*, and Hill *et al* used interviews and FGDs with smaller numbers of participants but retained the same focus on population-level generalisability of findings.[52,54,70,74] Other teams hewed to more traditional qualitative approaches, using IDIs, KIIs, and FGDs to gather rich data from small numbers of participants, trading broader transferability for thick description of the perceptions and experiences of these participants.[47,50,53,57,73,82]

Data integration and analysis

All studies that employed Participatory Rapid Appraisal (PRA),[57] Rapid Assessment Procedure (RAP),[50] Rapid Participatory Appraisal (RPA),[70] Rapid Appraisal, Rapid Assessment, Response and Evaluation (RARE),[73,74,82] or Rapid Assessment Protocol for Insulin Access (RAPIA)[44,45] used triangulation to check the reliability or validity of findings obtained from different approaches. Of the two different ways that triangulation is generally used in mixed-methods research,[85,86] it seemed that most of the studies described a process of corroborating findings, rather than using different methods to gain a more complete picture of a given phenomenon, although insufficient information was provided to be certain.

Three of the four mixed-methods studies did not specify how quantitative and qualitative data were integrated.[44,45,62,73] Cusack *et al* used a template analysis approach to integrate data around related themes within each domain.[74]

The single-method quantitative surveys both used simple descriptive statistics, while all but one of the 21 single-method qualitative studies used thematic analysis (see Supplementary Table S1).[53] Three 'rapid' studies used regular research team debrief sessions, which included lay data collectors and service providers to *'discuss and corroborate findings'*,[73] *'summarise key themes and observations'*,[46] and *'review and verify'* the research notes and emerging findings.[80]

Nicosia *et al* used an unnamed and unreferenced analytical approach *'developed for rapid health services and implementation research'*.[76] This involved pasting interview data into an *'analytic matrix template'* in Microsoft Excel that organised responses by interview theme. Several other rapid approaches used similar frameworks and deductive analytical tools, which are likely to expedite the analytical process in comparison with inductive coding approaches. Cusack *at al* used *'template analysis'* in their RARE assessment, but provided no reference or further information on what this entailed.[74] Acosta *et al* used the RAP approach of pasting relevant quotes into a unified matrix with one row per participant, and one column per domain.[53] Bam *et al* used a similar deductive approach to analysis, collating IDI and KII quotes with lists of barriers obtained from a mapping exercise in a single data matrix. The research team used colour-coded highlighting to apply *a priori* codes, although it is not clear how these codes were developed.[57]

Elwy *et al* analysed videocall IDI and FGD data using a *'rapid, deductive directed content analysis approach'* described by Hsieh and Shannon,[87] which involved populating an *a priori* coding framework (comprised of four domains and 40 subdomains), taken from an existing framework on barriers to accessing vaccination.[52] Jones *et al* developed an *a priori* codebook based on their study's undergirding framework, stakeholder summaries, and their interview guide domains.[67]

Costs and resources

None of the 44 articles reported any data on costs and none of the authorship teams provided these data via email. Only one study mentioned equipment requirements (audiorecorders[55]), and only five studies stated how many people were involved in data collection: Mathias *et al*[64] trained 11 locals to collect data from 2400 participants; Burks *et al*[73] employed five data collectors and a field coordinator for their study that involved 54 participants; Patrick-Ferife *et al* used five local research assistants to collect data from 684 people,[79] and studies led by Bedford[80] and Watanabe[61] both used three data collectors for studies involving 141 and 57 participants, respectively.

Level of participation and power relations

Three studies adopted a community-based approach with research teams collaborating with locals to work as facilitators and engage with study participants.[64,67,73] It was not possible to establish the level of participation for two of the included studies,[65,76] and the remaining 39 used a community-oriented participation approach. Typically, this meant that the local community was informed — either electronically, by phone, or via word of mouth — of the study and invited to participate as interviewees or FGD participants. Fourteen studies engaged local community members as part of

the research team. The rapid approaches used in each of these were as follows: Rapid Assessment of Disability, RARE, RAPIA, IDI and FGD, RAAB, PRA, RAP, RPA, Rapid Anthropological Assessment, and Rapid Qualitative Assessment. None of the included studies explicitly mentioned power relations or imbalances or acknowledged prevailing local knowledge or cultural barriers to participation; however, studies led by Bam, Brown, Mathias, and Burks (presented below) implicitly addressed a number of these themes through their use of rapid approaches designed to empower and partner with local community members.

Burks *et al*[73] employed participatory, mixed-methods action research, using four representative community members to gather data, 'guided' by the principle investigator. This study was based on a participatory action research paradigm. That is, there was collaboration between and within community participants at all levels of the study. A benefit of this type of research is that participants and locals of the community under study are empowered and have ownership of the study and its outcomes. The RARE methodology encourages continuous collaboration among community officials, representatives from indigenous communities, and public health workers.

Mathias *et al*[64] recruited data collectors who also identified with the study population. Data collectors recruited from the community of interest received a 4-day training programme that covered the interview procedures.

Studies led by Bam and Brown both used approaches with 'participatory' in the name. Bam *et al*[57] used PRA to map out perceptions of tuberculosis (TB)-related illnesses with the aid of diagrams and illustrations. Participants were also asked to identify accompanying barriers and facilitators for TB treatment. Similarly, Brown *et al*[70] used RPA to identify a community's perception of its own needs and build a relationship with service providers. RPA included data collection on *'community structure, needs, and role within existing service provision'*.[70]

Discussion

Summary

This scoping review identified 44 individual studies, including 30 studies that used one of 14 different self-described 'rapid' approaches for eliciting barriers and/or solutions to accessing community health services. Nearly half of the studies used mixed- or multi-methods, with interviews, FGD, and surveys being the most commonly employed data collection approaches, often supplemented with site visits. All of the included studies grounded their findings in the data provided by intended service beneficiaries, and a number of the rapid approaches involved local community members in data collection and analysis.

Despite many of the studies claiming to be rapid, the approaches to governance, sampling, recruitment, data collection, and analysis were orthodox for the majority of included studies. The use of team-based multi-method data collection and triangulation was used to offset truncated data collection periods, in some cases followed by same-day team-based analysis using a range of deductive tools and frameworks.

Nearly one-third of the included studies used surveys, which effectively asked participants to rank the importance of barriers that had been pre-selected by the research team. The remaining studies used qualitative methods, which are much better suited for eliciting people's perspectives on barriers and understanding what could be done.[19,88,89]

Strengths and limitations

This study followed international best practice guidance and a published protocol. A comprehensive search strategy was used, which was designed by an experienced information specialist, and dual independent screening and data extraction were used. However, the study has important limitations. It is very likely that a large body of experience on rapid assessments of barriers to access exists, but has not been written up and published in the peer-reviewed literature. Up to 43 out of the 44 included studies may have taken considerably longer than 2 weeks to conduct. Sixty-eight per cent of the included studies used self-described 'rapid' methods, but the vast majority didn't explain or justify the use of this term. As such, this review failed to find any data on the length of time that any one approach designates for sampling, recruitment, data collection, and analysis. Critically, nor did any study (or corresponding author) provide detail on the costs and resource requirements involved.

The study deliberately focused on methods that elicit barriers and solutions by engaging with intended service beneficiaries rather than service providers or policymakers. This choice was driven by a desire to ground future assessments in community engagement, recognising that the status quo often treats service users as a 'nice-to-have' afterthought. In reality, the factors that influence access are multilevel and multifactorial. Findings from community-based assessments must be integrated with findings from engagement with service providers, planners, and policymakers who bring unique and important perspectives on supply-side factors, and many of the included studies did in fact engage with a wide range of stakeholders. A limitation of the review is that it stopped short of assessing how findings were used to improve service delivery and benefit service users. Future research should examine the impact of this kind of work.

A final important limitation is that the study did not set out to answer the question of whether rapid methods produce valid and trustworthy findings. There is a potential risk that the conclusions reached about barriers and potential solutions are thrown together so quickly that they oversimplify the issues, with the further risk that action on the findings leads to unintended consequences that might exacerbate inequitable access. The study found an absence of evidence that well-conducted rapid research systematically produced biased or harmful results, and the overall impression is that these tools can provide useful targeted information as an adjunct to more traditional, longer research engagements. Work by Taylor *et al* suggested that rapid approaches conducted by less-experienced researchers can deliver comparable findings to more traditional, slower methods conducted by senior qualitative researchers;[90] however, more work is needed in this space to explore the internal and external validity of rapid methods.

Comparison with existing literature

In the run up to 2030 health officials are coming under increasing pressure to boost access to community health services, and a core element of this work is understanding and redressing barriers. Ideally, this work would be led by highly trained qualitative researchers embedded within every community health service; however, there are nowhere near enough researchers for this work globally, nor the time or money.[91,92] Given the scale of the need, identifying rapid and inexpensive approaches is vital.

The very concept of 'rapid and inexpensive' qualitative research with data collection conducted by non-specialists sounds oxymoronic to many, and is anathema to purists. However, Beebe[18] has argued that intensive, team-based qualitative approaches that use triangulation and iterative analysis and data collection can deliver important, valid insights from 'the insider's perspective' within a matter of days or weeks, rejecting the conflation of 'rapid' with 'rushed'. Similarly, Johnson and Vindrola-Padrosc have argued that quick approaches don't necessarily have to be 'dirty'.[36] While it does take time to build rapport, understand complexity, capture insider's perspectives, and triangulate findings,[93–96] rapid work can still achieve meaningful engagement, deep understanding, and decision-oriented data.[18,95] McNall and Foster-Fishman[97] and Trotter and Singer[98] have argued that rapidly conducted qualitative work can even offer advantages over longer research projects in terms of promoting community engagement (by necessity) and delivering findings that can inform real-time decision making.

The 2013–2016 Ebola epidemic expedited the uptake of rapid qualitative methods and marked the first time that WHO and UNICEF recruited dedicated teams of social scientists to support their emergency responses. However, the insights provided were often difficult for policymakers to understand, and were not ultimately used to inform real-time decision making.[36]

Several of the approaches included in this review reconciled this translation issue by linking intended service beneficiaries, service providers, and policymakers through the very process of data collection and analysis. For instance Jalloh *et al*[46] had WHO, Centers for Disease Control and Prevention, and UNICEF partners join for team-based analysis of the transcripts from focus groups and interviews, while the studies that used the RARE approach worked closely with community members to sense-check findings and ensure that they had strong external validity to the specific community critical to the phenomena studied.[73,74,82] Many of the studies recruited participants directly from the local community, and married IDI and FGD with observations and walks through the areas of interest.

When it comes to analysis, the deductive framework approaches used by many of the rapid models may be faster than inductive coding. However, the important work of selecting the most appropriate *a priori* framework effectively shifts some of the burden of analysis to pre-data collection rather than eliminating it completely. The real benefit may be that once the work of developing a methodologically

sound coding framework is complete, people with less qualitative expertise can potentially lead elements of data collection and analysis. This could see centralised teams of qualitative researchers developing coding frameworks for all services in a given context, and the supervising of the collection and analysis of data by non-experts.

In terms of identifying an appropriate *a priori* conceptual framework, a large number have been developed for health service access.[10,12–14,99–101] Many adopt multidimensional views of the patient and provider factors that influence whether people receive the care they need, and highlight the importance of context.[10,13,99,102–104] Levesque *et al*'s model is one of the most commonly used, and lists five domains and related abilities that could be used to develop codes for deductive analysis.[99] Obrist *et al*[104] have identified an aligned set of domains, along with five sets of livelihood assets that can be used to structure understanding of barriers to accessing health services in low-income settings.

Taylor *et al*[11] have previously suggested that the time a qualitative research project takes can be reduced by allowing less time between data collection episodes; for example, conducting all interviews on the same day, using multiple team members if necessary; reducing data management time by eschewing the transcription process and using notes, summaries, mind maps, and untranscribed audiorecordings instead; and speeding up the analysis phase by using one-page summaries to explore large datasets.

When surveys are used, it is important that the pre-defined options are based on empirical qualitative work that can be generalised to the population in question. There is a high risk that predefined lists offered to participants may not contain the most important barrier or solution for that context. Some surveys traverse the gap between quantitative and qualitative approaches by presenting 'white box' questions that allow responders to provide free-form perceptions of the barriers they face in their own words. However, without an interviewer, the opportunity to paraphrase questions, probe for more information, and observe body language is lost, limiting the value of the data.

Sampling in qualitative research does not aim to establish a representative sample for the sake of statistical inference, but rather to identify a specific group of information-rich people, which enables the theoretical generalisability of findings to other similar cases.[19] In qualitative research, participants are purposely selected and included in the research based on their ability to extensively explore a certain topic or phenomenon. The researcher is expected to select a wide range of responders with access to extensive knowledge that can yield in-depth understanding rather than empirical generalisations.[105,106] While many of the included studies interviewed >40 participants (and in some cases hundreds), this is unusual for qualitative research. Data and thematic saturation can be reached after interviewing 10–20 people,[107,108] although qualitative sample size adequacy is ultimately driven by the complexity of the research question and heterogeneity of the target population.[19,105]

In George *et al*'s[15] systematic review of 260 papers that described more than nominal community participation in health systems research, community members helped to implement interventions in 95% of the included studies, but only contributed to the identification or description of the underlying problem in 18% of the studies. The present study deliberately set out to identify approaches that specifically gather and analyse data from intended service users, and found that this work is being done across a wide range of settings and services. The vast majority of the included articles took a community-oriented approach, and three used a community-based approach, working alongside community members to collect and analyse data.

Oliver *et al*[109] have cautioned that coproduction brings costs as well as benefits, and these affect the research itself, the research process, and pose professional and personal risks for researchers and stakeholders, as well as *'risks to the wider cause of scholarship'*. The take-home message is to carefully reflect on the aims and requirements for each unique project and then design the approach appropriately.

For research projects, the process of seeking and obtaining ethical review and ultimate approval for data collection is essential to protect participants and data collectors from harm. However, it can take many months and is often difficult to navigate for the uninitiated, including the average community health service manager. Even mature and well-resourced systems, such as that operated by the UK NHS Health Research Authority (HRA) are complex and take up to 60 days to deliver an initial opinion after receiving all the required documentation.[110] Projects led by researchers affiliated with a university will often require approval from their university committee as well as the national committee.

Box 5 Recommendations

- Ask whether formal ethical review is needed. Service evaluation projects generally do not need review unless they seek to extrapolate local findings to a wider population.
- Recruit in situ, directly approaching participants rather than using passive approaches such as posters and adverts.
- Collect data at the point of recruitment, and aim to collect all data within the shortest possible amount of time.
- Use multiple forms of data collection to triangulate findings, such as direct observations, walks, site visits, interviews, and focus groups.
- Use teams of data collectors if possible, and consider working with community members who have expert local and social knowledge.
- Consider analysing data directly after collection, working from notes and audiorecordings, if appropriate.
- Analyse findings iteratively and collectively in real-time with local community members who can sense-check the findings and help identify further confirming or disconfirming cases.
- Aim to involve the ultimate users of the recommendations (that is, policymakers and service managers) in the process of analysis and the development of recommendations.
- Consider using *a priori* deductive framework approaches for data collection and analysis.
- Where appropriate, aim to compile all relevant findings on a single sheet to summarise large and complex datasets.

The HRA states that formal research ethics reviews are only required for data collection that seek to extrapolate findings to a wider population. In contrast, service evaluation projects (and service improvement or development projects) do not require formal research ethical review.[110,111] Among the included studies, 15 did not mention ethics at all[44,45,55,69–79,84] and two studies explicitly stated that review was not required because their data collection activities were part of routine health service delivery and evaluation processes; however, they did seek written informed consent from participants.[82,83] The take-home message is that rapid projects seeking to identify issues within a local service do not necessarily need to obtain external ethical review, although advice should be sought before proceeding.

McNall and Foster-Fishman[97] have argued *'the timeliness of information is no less critical than its accuracy'*, and the present review has identified a number of design features that can reduce the time taken between posing the original research question (in this case *'what barriers prevent intended service beneficiaries from accessing the services they require and what could be done about it?'*) and delivering findings (***Box 5***).

Implications for research and practice

This scoping review identified a large number of research design innovations that can speed up the process of exploring barriers and potential solutions to improve access to community health services. However, the paucity of data on costs and the exact number of days that each step takes limits the ability to identify a dominant approach from the 14 different self-described 'rapid' methods. A number of studies were found where 'rapid' was a misnomer, with the term being used to describe traditional research techniques with no explanation for how or why results were obtained any faster than normal. Among the remaining studies, a common set of design features have been identified that may reduce the time taken to recruit participants and collect and analyse data (***Box 5***). Future research should evaluate whether approaches that utilise these strategies produce timely and robust findings, ideally with resources and cost data. Finally, a wide range of studies were found that ground the work of understanding barriers to access in the experiences and perspectives of intended service beneficiaries themselves. It is hoped that future work in this area continues to engage affected communities in the planning, execution, interpretation, and application of rapid research intended to equitably extend health for all.

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Ethical approval

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Provenance

Freely submitted; externally peer reviewed.

Data

The underlying studies are all cited in the reference list. All of the study tools are available in the supplementary material.

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Chapter 7

Developing bespoke methods to rapidly identify barriers and solutions for the IM-SEEN approach

Data collectors hired to perform interviews and surveys in Meru
Source: Author. Consent has been provided from all individuals in the photo

Key messages

- Based on my scoping review findings, I developed a novel rapid approach for identifying barriers and solutions.
- This starts with a series of phenomenological interviews with people from the left behind group, exploring their perceptions of what prevented them from accessing care and how the service could be modified to improve access. A team of local data collectors perform the interviews and enter direct quotes into a deductive analytic matrix directly after the conclusion of the interview. Iterative data collection and analysis is overseen by the lead researchers at a daily debrief.
- Once thematic saturation is achieved, the long-list of all subjective solutions is presented to a second, representative sample of people from the left behind group. They are asked to rate each potential solution from 1-3 in terms of its likely impact.
- This ranked list of generalisable solutions is finally taken to a multistakeholder workshop where programme leads, public health experts, and community representatives select one or more intervention to implement, based on likely impact, cost, risks, and feasibility.

Having identified a range of rapid approaches and research techniques that could be used to deliver robust and timely findings, I developed a master protocol for the Engage stage of the IM-SEEN approach. I started with a literature review of how other research teams had sought to identify barriers to accessing eye care services, followed by a review of 'access to healthcare' conceptual frameworks. I then applied what I had learned from the scoping review to set out a robust mixed-methods approach to generating operationally useful insights that are grounded in the experience and perceptions of people who have been left behind. I developed an overarching master protocol to define the approach that will be used in all four IM-SEEN countries. The protocol is currently under peer-review at BMJ Open.

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Student ID Number	2004040	**Title**	Dr
First Name(s)	Luke		
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Thesis Title	Improving equitable access to community-based health services: Developing and testing a new model in Kenya's national eye screening programme		
Primary Supervisor	Andrew Bastawrous		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

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Stage of publication	**Submitted**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I designed the approach and drafted the first draft of the manuscript. Sarah Karanja provided additional qualitative methods support. My other co-authors provided valuable input with comments on the first and second drafts.

SECTION E

Student Signature	Luke Allen
Date	26th April 2024

Supervisor Signature	REDACTED
Date	30-04-2024

Identifying barriers and potential solutions to improve equitable access to community eye services in Botswana, India, Kenya, and Nepal: a rapid exploratory sequential mixed methods study protocol

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Abstract

Introduction Evidence suggests that certain groups face substantial barriers to accessing eye care services. This study seeks to explore barriers and potential solutions as perceived by members of the population groups who are least able to access care in the context of four national eye screening programmes. We aim to use rapid yet robust mixed methods that allow us to identify generalisable findings and testable service modifications to improve equitable access to care.

Methods and analysis This is a multi-phased exploratory sequential mixed methods study. First, we will conduct interviews with people purposively selected from the sociodemographic subgroups with the lowest odds of accessing care within each screening programme. Taking a phenomenological approach, we will explore their perceptions of barriers and potential service modifications that could boost attendance at eye clinics among people from these 'left behind' groups. We will use a deductive analytic matrix to facilitate the rapid analysis of qualitative data. Space will be made for the inductive identification of themes that are not necessarily captured in the framework. Sample size will be determined by thematic saturation. Next we will conduct a survey with a representative sample of non-attenders from the same left behind groups, asking them to rank each suggested service modification by likely impact. Finally, we will convene a multistakeholder workshop to asses each service modification based on ranking, likely impact, feasibility, cost, and potential risks. The most promising service modifications will be implemented and evaluated in a follow-on randomised controlled trial, the methods for which will be reported elsewhere.

Ethics and dissemination This project has been approved by independent research ethics committees in Botswana, Kenya, India, Nepal and the UK. We will disseminate our findings through local community advisory boards, national eye screening meetings, in peer-reviewed journals, and at conferences.

Strengths and limitations of this study

- We have developed a bespoke rapid qualitative approach that is designed to deliver rich and robust data with speed and relatively low costs. Our approach is based on a prior scoping review of rapid methods.
- By using mixed methods we are able to move from rich data to statistically generalisable findings that can be implemented across four national programmes.
- Our project is embedded withing real-world programmes and will deliver actionable intelligence directly to policymakers, programme funders, and programme implementers.
- Our work places the experience and perspectives of 'left behind' groups at the very centre of programmatic quality improvement. This protocol has benefited from the active engagement of lay representatives in each of the four countries.

Background

Universal Health Coverage (UHC) has been described as the core of the health-related Sustainable Development Goals.[1,2] As such, boosting access to community-based services has become an important global health priority.[3,4] Our research team is studying access to eye services in screening programmes that use Peek Vision systems in Botswana, India, Kenya and Nepal (Box 1).[5] These large screening programmes are identifying hundreds of thousands of children and adults who need glasses, cataract surgery and other cost-effective, life-changing interventions. However, internal data show that only 30-50% of those identified with a need are able to access local treatment outreach clinics, even in programmes where treatment is free. These access figures align with those from other eye services in low- and middle-income countries (LMICs)[6–11] and with a 2018 review that found mean outpatient clinic attendance to be approximately 50% across a wide range of services and settings.[12] The 'central transformative pledge' of the Sustainable Development Goals is to 'leave no one behind', and UN Member States have pledged to identify 'left behind' groups and ensure that services 'reach the furthest behind first'.[13] We want to ensure that eye care programmes are identifying inequalities in access, engaging with 'left behind' groups to understand the specific barriers they face and exploring potential service modifications that would help to improve access.

Box 1: Peek-powered eye screening programmes

Peek is a social enterprise that spun out from The London School of Hygiene & Tropical Medicine (LSHTM). Peek have developed a rigorously validated eye screening app that is used in tens of low- and middle-income countries to enable non-specialist teams to perform large-scale community screening programmes.[14–18] These screening programmes follow two main formats. First, in mobile programmes, a small team works its way through an entire population by sequentially screening children in schools and/or communities in village meeting points or by going house-to-house. An example is Kenya's Vision Improvement Project that has already screened over a million people. The other type of programme is static, where primary care teams within a given geographic catchment are trained to use the app and then screen patients opportunistically as they present to the primary care facility with other health problems. An example would be the health posts trained to use Peek in Rajbiraj, Nepal. In both cases, screeners use the Peek app to deliver 'tumbling E' vision acuity assessments, identifying those whose vision falls below a pre-determined threshold. These positive cases are then referred to local triage and treatment outreach clinics where they are re-assessed by eye professionals and offered eye medication, spectacles, or onward 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, College of Ophthalmology of Eastern Central and Southern Africa, Nepal Netra Jyoti Sangh, Shroff Eye Centre, Dr Shroff's Charity Eye Hospital, and the University of Botswana to improve attendance rates and improve equity in screening programme outcomes.

Literature review: methods to assess barriers to access and potential solutions

Whose perspective do we want to hear?

Across all health service research, efforts to understand and redress barriers to access have disproportionately focused on eliciting the opinions and perspectives of 'experts' and service providers at the expense of affected people and communities.[19] Grounding elicitation work in the experiences and perceptions of service users and non-attenders is important both for ethical reasons[19,20] and because their perceptions often differ to those of service providers.[21,22] Whilst elicitation studies from the field of eye care have largely been alive to this fact, there are still major issues: the approaches used

to explore peoples' perceptions have been disproportionately based on the use of closed-questions and surveys, or use under-theorised and poorly described qualitative methods.[7,9,21–25]

Quantitative vs qualitative approaches for exploring barriers and solutions

The literature on barriers to accessing eye care is dominated by findings from in-person surveys that have been bolted on to population-based screening studies. These commonly take the form of a single survey item where participants are asked to choose or rank reasons for non-attendance from a pre-selected list of options.[8,9,23,24,24,26–30] This is also the approach used in *Rapid Assessment of Avoidable Blindness* (RAAB) surveys – of which over 300 have been conducted in more than 80 countries.[31] In our review of the literature, we only found two studies that provided a rationale for the list of barriers that they present to participants: Marmamula et al. asked participants in South India to rank 15 barriers that had been generated by previous focus group work.[32] However, none of the focus group participants were intended service beneficiaries or people with lived experience of trying to access eye care (all were service providers, public health experts, and researchers).[33] Furthermore, whilst the people responding to the final survey all had some form of vision impairment, they had not necessarily ever been referred to a service, which may explain why 'lack of felt need' and 'lack of awareness' were the most frequently selected barriers. Sengo et al performed a literature review and interviewed 25 people in Mozambique with vision impairment to identify which barriers should be used in a wider survey.[34] However, the exercise was inadequately described and the authors do not provide any detail on how the qualitative data were analysed.

Almost all surveys use a familiar list of barriers that commonly recur in qualitative studies, including costs, distance, lack of trust, communication challenges, fear, scheduling issues, lack of awareness, lack of a chaperone, and low priority accorded to the issue (Box 2).[7,9,21–23,25–28,32,34,35,35,36] The main limitation in using surveys with these preselected items is that other important factors may be at play in a given population, but it is impossible to ascertain what they are without using open questions.[37] Methods to elicit these barriers do not have to be particularly sophisticated: even though Sengo et al. appear to have used fairly crude qualitative methods, their study still uncovered important issues including overcrowding in the local hospital, self-medication, and the use of spectacles bought on the street.[34] Similarly, while the method outlined by Marmamula et al. to interview 199 elderly non-attenders provided no reference to theory, no underlying framework, and no detail on the analytical approach, the work proved vital, with two thirds of respondents citing novel barriers including lack of family consent and the adverse impact of other health conditions.[38] These factors would not have been elicited from participants through a standard survey.

Box 2: Commonly cited barriers to accessing eye care

- High costs
- Distance or transport issues
- Low trust in service providers
- Low perceived service quality
- Poor service communication
- Fear
- Scheduling conflicts or other obligations
- Low awareness of available services
- Lack of a chaperone
- The perception that vision impairment is not a significant impediment to function

When are *any data* better than *no data*? Poorly designed qualitative studies can lead researchers to the wrong- and sometimes harmful conclusions, just as 'flying blind' without any understanding of the issues faced by service users can lead managers to introduce well-meaning 'improvements' that carry negative unintended consequences. We would argue that using appropriate, theory-driven qualitative methods with a sensible sample and well-described methods is actually a very low threshold to clear and can add real value at low cost in settings where the alternative is not using any open questions at all.

Previous qualitative studies that have examined access to eye care

In reviewing the eye care literature, we have found six examples of relatively well-conducted and well-reported studies that have methods designed to explore perceptions of barriers and potential solutions. Ahmad et al. used an open-ended survey question and content analysis to identify barriers to accessing eye care among the general population in Karachi, Pakistan. Unsurprisingly, given the population included, low perceived need was a major reason for not seeking care, however issues around health beliefs and cultural attitudes were surfaced that represent important issues for local health teams to engage with.[39] Zabeck et al. used structured telephone interviews to explore barriers to access among 28 Americans who had become blind. Using a constant comparative approach they found that social support structures and personal readiness to change were important factors for some people, alongside familiar themes of geographic access and low trust in providers.[40] Elam and Lee conducted content analysis on data from four focus groups with American community members at risk of not attending eye services. Issues around health insurance, racism, unfriendly service at the clinic, and procrastination supplemented familiar themes of cost, trust, and fear.[35] Kulkarni and colleagues conducted in-person interviews with transgender people and sex workers with vision impairment in Pune, India, followed by focus group discussions with service providers. Their interview topic guide used

deductive (i.e. pre-identified) themes to structure the questions, but also made space "to identify previously unexplored domains". It appears that the provider focus groups were conducted in parallel in order to triangulate findings from the interviews. This approach was also used in studies led by Owsley and Okoye; both triangulated interview data from the target population with the perspectives of service providers, and Okoye et al also engaged with policymakers.[21,22]

Which population should be sampled?

Whilst most eye care studies that assess access have sampled participants from either the general population or the population of intended service beneficiaries, three studies have specifically engaged 'non-attenders' (we note that this term is not perfect as it implicitly places responsibility for access onto users rather than services). It is likely that those who have been diagnosed with an eye condition; referred; and not managed to access those services will have greater insight on the barriers to access and potential solutions than members of the general population who do not have this lived experience. Chou et al used a survey with pre-selected items to elicit reasons for non-attendance,[25] but Gower and colleagues used semi-structured telephone interviews which enabled participants to cite barriers that the researchers might not have considered *a priori*.[7] Similarly, Marmamula used in-person semi-structured interviews to elicit reasons for low eye clinic access among elderly care home residents.[38]

Theory

Very few of the qualitative studies that we found grounded their analyses in theory or a conceptual framework. Whilst there are many different conceptual frameworks on generic barriers to accessing services,[41–43] we are not aware of any that have been developed for eye care beyond the Australia-focused tripartite division of 'predisposing', 'enabling', and 'need' characteristics described by Keefe et al in 2002.[44] Despite the breadth of eye service utilisation studies that have been conducted in the past two decades, it seems that it is rare for quantitative or qualitative eye care studies to use theory to inform the design of data collection activities or guide interpretation of findings. Positively, unlike healthcare access research from other fields, approaches that are grounded in eliciting the views of people and communities (as opposed to 'experts') are the norm, but these disproportionately sample form the general target population, rather than those with lived experience of being unable to access care.

Aim & objectives

In this study we aim to develop a rapid, theory-based, scientifically robust approach that can be used to elicit barriers to accessing eye care services and potential solutions through engagement with 'non-attenders' from sociodemographic groups that experience the lowest overall access rates when

referred from screening programmes. We intend to use this approach in eye screening programmes in Botswana, India, Kenya, and Nepal and then apply the findings within the same services with the ultimate aim of improving equitable access to care. Findings from one programme will not be applied to the others, although learning will be shared across sites. All four national screening programmes run on software provided by Peek Vision.

Objectives

1. In each country, conduct interviews with people from left behind groups who have not been able to access clinics to explore barriers and potential solutions.
2. In each country, conduct phone interviews with a representative sample of people from left behind groups, asking them to rank each of the mooted solutions.
3. In each country, convene the programme funder, programme implementing team, community representatives, and national eye care policymakers at a workshop to review the ranked solutions and select one or more for implementation and evaluation.

Programme-specific requirements

The nature of the screening programmes imposes a methodologically challenging set of requirements. Given that some Peek-powered programmes screen entire regions in a matter of months, the approach that we use must be able to deliver service modifications rapidly enough to benefit a reasonable proportion of the remaining intended beneficiaries; ideally within weeks-to-months. Next, rather than presenting participants with a pre-selected list of barriers and service modifications and then asking them which are most important, we want to use open questions that allow participants to use their own words to identify issues and approaches that the research team may not have necessarily considered. We recognise that coding and interpreting these responses requires time – however speed is a key objective to ensure feasibility when running at large scale on tight resources. Peek is keen for its programme partners to use any resultant methods that can improve referral uptake, but the cost of these research activities will ultimately be borne by programme funders and will likely be offset by a reduction in the total number of people screened. As such, there is considerable pressure to keep the overall costs as low as possible. A related constraint is that the elicitation approach will only have access to a small number of staff with basic research training. We note that the availability of experienced qualitative and mixed-methods health system researcher staff is low in almost all of the LMICs where Peek-powered programmes operate.[45,46] Next, as stated above, we want to base decisions on the experiences and perspective of those directly affected; people who have been identified with an eye need and referred, but who have not been able to access services. Furthermore, we aim to focus on the needs of the sociodemographic group with the worst access to care (‘reaching the furthest behind

first') so that any improvements disproportionately benefit these groups, thereby improving equity (in line with the idea of proportional universalism). Finally, despite being rapid, inexpensive, non-prescriptive, equitable, and primarily conducted by non-experts, we are committed to using robust methods to deliver valid, non-tokenistic findings. This is vital in order to inform programmatic changes that stand a chance of improving access rates (Box 3).

Box 3: Our improbable wish-list

We want to develop a rapid elicitation tool that:

- Can deliver a set of barriers and potential solutions within weeks-months
- Uses open questions rather than a pre-defined list of response options
- Provides barriers and potential solutions that are generalisable
- Gathers data from non-attenders from sociodemographic groups with the lowest attendance rates within each programme
- Can be largely conducted by non-experts, albeit with expert supervision
- Is inexpensive
- And is methodologically robust

Approach

Philosophical paradigm

Our aim requires methods that span the space between constructivist and positivist philosophical paradigms.[47] Whilst the task of seeking to understand perceptions of barriers and solutions is primarily phenomenological, we intend to generalise the findings (i.e. make statistical inferences) and develop service modifications that will be applied across entire programmes within each country. To traverse this philosophical rift we will use a pragmatist paradigm, originally advanced by Charles Sanders Peirce.[48,49] Pragmatism holds that 'truth' is determined by practical application and consequences, and it is agnostic on the type of research techniques used as long as they answer the research question.[48,50]

Undergirding theory

There are a large number of conceptual frameworks on access to health services.[41,43,51–55] As our ultimate aim is to elicit ideas for ways of improving services to boost equitable access, we have elected

to use the popular model developed by Levesque and colleagues (Figure 1)[43] that divides factors into those pertaining to services and those relating to potential service users. We want to focus our analysis on areas that we are most able to change i.e. the structure, staffing, organisation, and communications of eye services, in contrast to user characteristics like social support networks, assets, and health literacy which are important but much harder for us to influence.

The Levesque framework is based on the findings of a systematic review that identified five determinants; approachability; acceptability; availability & accommodation; affordability; and appropriateness, along with corresponding abilities to perceive, seek, reach, pay for, and engage with services. These factors feed into a process of seeking care that resonates with the Tanahashi framework[56] and the concept of effective coverage[57] i.e. access is predicated on a series of steps that include perceiving an initial need, desiring care, seeking out potential providers, traveling to the location at a time that it is open and staffed, and having sufficient resources to be seen. Access only occurs when the requisite supply and demand side elements are in place.

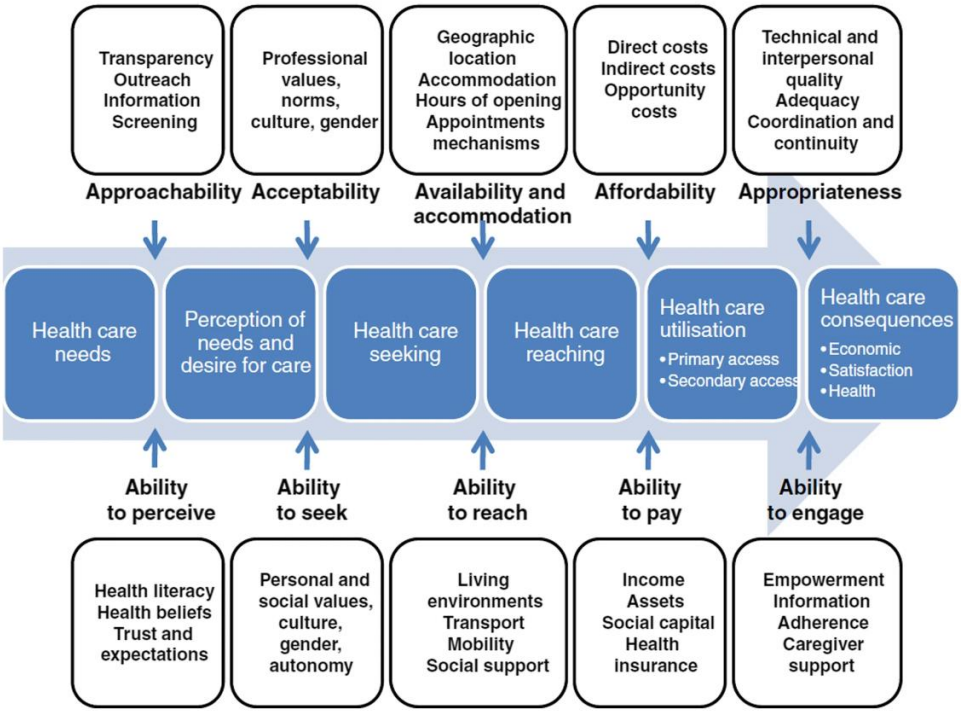

Figure 1: The Levesque framework

Obrist and colleagues have developed an aligned model with a specific emphasis on 'analysis for action' and application in low-income settings.[41] Their five dimensions; availability, geographic/logistical

accessibility, affordability, adequacy, and acceptability (Table 1) overlap with those presented by Levesque, and are supplemented by five types of livelihood assets that determine ability to recognise need and seek out health services: human capital (local knowledge, education, skills); social capital (social networks and affiliations); natural capital (land, water, and livestock); physical capital (infrastructure, equipment, means of transport); and financial capital (cash and credit). The authors note that many of these assets are influenced by macroeconomic and political conditions, climate change, and many other forces over which people have very little control, and are also difficult for service managers to influence directly.[41]

Table 1: Obrist's five dimension of access

Dimension	Questions
Availability: The existing health services and goods meet clients' needs.	What types of services exist? Which organizations offer these services? Is there enough skilled personnel? Do the offered products and services correspond with the needs of poor people? Do the supplies suffice to cover the demand?
Accessibility: The location of supply is in line with the location of clients.	What is the geographical distance between the services and the homes of the intended users? By what means of transport can they be reached? How much time does it take?
Affordability: The prices of services fit the clients' income and ability to pay.	What are the direct costs of the services and the products delivered through the services? What are the indirect costs in terms of transportation, lost time and income, bribes, and other "unofficial" charges?
Adequacy: The organization of health care meets the clients' expectations.	How are the services organized? Does the organizational set up meet the patients' expectations? Do the opening hours match with schedules of the clients, for instance the daily work schedule of small-scale farmers? Are the facilities clean and well kept?
Acceptability: The characteristics of providers match with those of the clients.	Does the information, explanation, and treatment provided take local illness concepts and social values into account? Do the patients feel welcome and cared for? Do the patients trust in the competence and personality of the health care providers?

Methodology

We require mixed methods that draw on the strengths of both qualitative and quantitative approaches to answer a multi-layered question: what are the main barriers to accessing eye services in each location and what can be done about them?

Qualitive methods deliver rich, descriptive data based on interviews, discussions, and/or observations with a select number of participants who are often purposively chosen because of their specific characteristics. As such, the findings can be transferred to similar cases and contexts, but they are not intended to be generalisable. In contrast, quantitative methods deliver numerical data and - with representative sampling - are able to provide evidence for causality, generalisability and magnitude of effect.[58,59]

We will use a mixed methods approach; starting with qualitative methods to explore non-attenders' perceptions of the barriers and potential solutions in each setting. We will use the identified themes to

develop a unique, user-derived list of potential service modifications within each screening programme. We will then use quantitative methods – a survey - to establish which of these are perceived to be the most impactful through engagement with a representative sample of non-attenders, effectively validating or 'sense-checking' the qualitative findings with a larger, representative group. The ranked suggestions for service improvements will then be taken to a multistakeholder workshop where the top-ranked solutions will be considered for implementation based on their likely impact, feasibility, cost, and potential risks.

Context

This project constitutes the 'Engage' element of the broader 'IM-SEEN' continuous improvement approach.[60] It is preceded by activity to gather sociodemographic data from those being screened in each setting and the identification of which groups experience the lowest access rates (Figure 2). The purpose of the current 'Engage' project is to gather and prioritise a list of barriers and potential solutions, grounded in the perceptions of left behind groups. A follow-on project will use an RCT to test whether the most promising solution(s) actually equitably improve access to services.

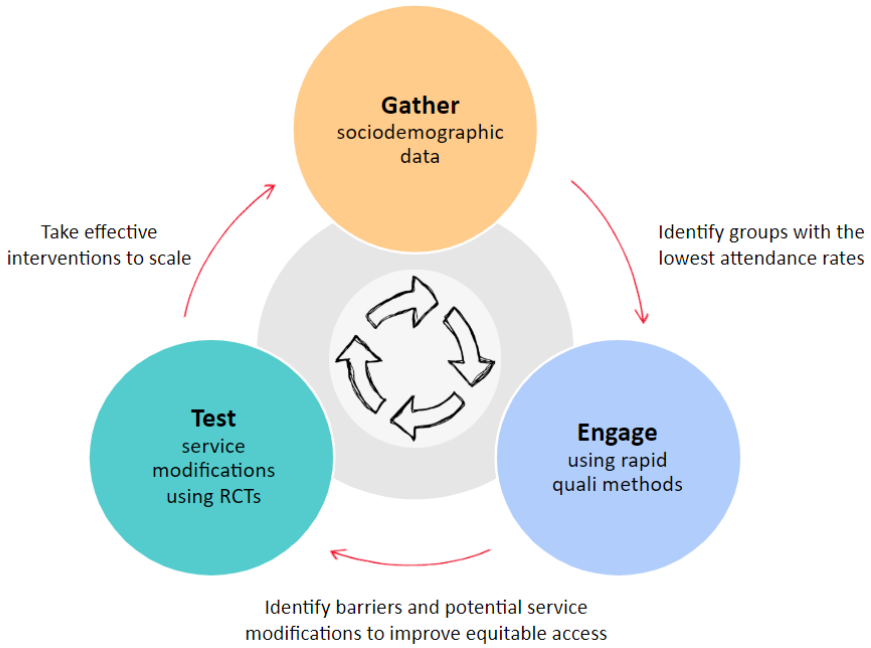

Figure 2: This current project represents the 'Engage' component in the wider 'IM-SEEN' continuous improvement project

Methods

Summary

We will use a four-stage rapid exploratory sequential mixed methods study design (Figure 3). First, we will conduct telephone interviews with non-attenders purposively selected from the sociodemographic subgroup that has the lowest overall access rate within each screening programme. We will explore their perceptions of barriers potential solutions and compile a long list of all suggested solutions/service modifications. We will discuss the long list with the programme funder and implementer to rule out any suggestions that are felt to be completely unfeasible e.g. providing helicopter transport for everyone who is referred. Next, we will conduct a telephone survey, asking a representative sample of non-attenders from the same left behind group to rank the remaining suggestions by likely impact. Finally, this list of prioritised service modifications will be put to a group of programme funders, programme implementers, community representatives, and eye care policymakers. Participants will review the top-ranked service modifications and select one or more to test based on likely impact, feasibility, cost, and potential risks. The intervention that is perceived to offer the best value according to these criteria will be implemented and evaluated within the context of an embedded pragmatic randomised controlled trial, the methods for which will be reported elsewhere. This approach will be conducted independently in each country. Figure 3 provides an overview of the study elements.

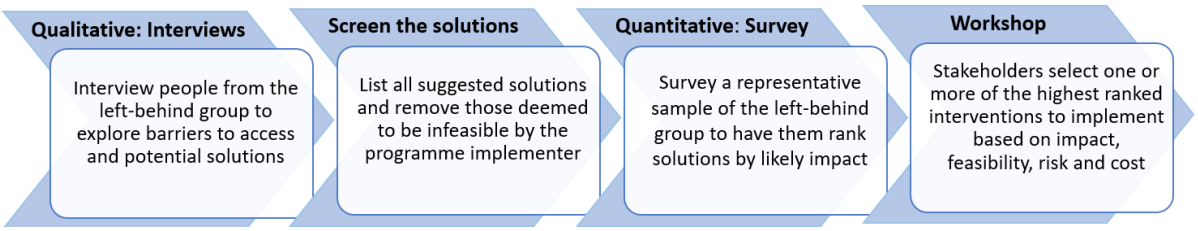

Figure 3: Overview of the sequential mixed-methods approach

Developing a rapid qualitative approach

Our study is not the first that seeks to use rapid and low-cost qualitative methods that can be led by less-experienced researchers (early-career researchers and those with basic- rather than postgraduate training) to answer an open question. Rapid methods have been in use for over 30 years, as described by Beebe,[61–63] Handwerker,[64] Pearson,[65] Bentley,[66] Scrimshaw et al.,[67] and Johnson and Vindrola-

Padros.[68,69] There are also examples of rapid qualitative studies that have intentionally used teams of less experienced researchers.[70]

Rapid qualitative methods are often used to reduce time and costs, and to improve efficiency, accuracy, and 'obtain a closer approximation to the narrated realities of research participants'.[69] These studies generally take between a few days to a few months, depending on the design, with most taking a couple of weeks to complete.[68,71] A large number of dedicated approaches have been developed, including 'Rapid Ethnographic Assessment',[72] 'Participatory Rural Appraisal',[73] 'Rapid Rural Appraisal',[74] 'Rapid Appraisal' (a form of 'Rapid Qualitative Enquiry'),[61] 'Rapid Assessment Procedures',[61,67] and 'Rapid Assessment Response and Evaluation'.[75,76]

In their review of rapid qualitative methods, McNall and Foster-Fishman identify the following key features: these studies commonly use mixed and multi methods to triangulate data; they tend to be participatory – with representatives of the target population involved in planning and implementation; they are team-based with all members working collaboratively on all aspects of the research process; and they are iterative - with data being analysed as they are collected and early findings being used to guide additional data collection until theoretical saturation is reached.[77] The authors also note that the central trade-off is between speed and trustworthiness. Vindrola-Padros and Vindrola-Padros identified seven key challenges that apply to all rapid qualitative approaches, summarised in Table 2.[71]

Table 2: Risks of rapid research, as described by Vindrola-Padros and Vindrola-Padros[71]

Design feature	Potential risks
Sample size and representativeness	'Dependency on most accessible informants and loss of multiplicity of voices.'
Community participation	'Local research assistants are not always available, have the required skills or willingness to take part. Training takes time. Research undertaken by researchers without an anthropological background might limit the quality of the study'
Team-based approach to design, data collection and analysis	'Recruitment might be an issue and clear roles in the field need to be outlined'
Brief engagement time	'Inability to capture changes over time, understand all relevant social and cultural factors at stake, or conflict and contradictions… New researchers might get more attention, but lack familiarity with the study area.

	Prolonged engagement often increases credibility and internal validity. Prolonged engagement might also lead to stronger relationships between research participants and the field researchers. The rapid study timeframes might not allow researchers to critically analyse the position they play in the field site and their role in the collection and analysis of data.'
Governance	'Time pressures should not deter researchers from undergoing the required governance and informed consent processes.'

Many of these risks can be met head-on e.g., by obtaining ethical approval and informed consent, thinking carefully about team roles, and purposively sampling from the most marginalised groups. The extent to which community members can or should be engaged is dependent on the study aims and local contextual factors. The greatest challenges are around developing robust findings based on a brief engagement period. Triangulation can help (i.e. using multiple methods or data sources to develop a comprehensive understanding of phenomena (p247[78]) but this limitation renders rapid methods unsuitable for qualitative research projects that require a deep, emic understanding of complex phenomena and issues.

Building on established rapid qualitative analysis, our team has conducted a scoping review to identify rapid approaches that have been specifically used to assess barriers and solutions to improve access to community health services.[79] We identified a number of innovative methodological techniques that can be used to minimise the length of time between data collection and implementation of the final set of findings. Many of these design features are best suited for deductive framework analyses where participants' experiences are sought in relation to a clearly defined a priori research question, in our case; 'what stopped you attending and what could be done about it?'

In line with findings from a broader review of rapid methods,[69] we found that many approaches focused on eliminating or expediting the transcription phase, either by performing simultaneous data collection and analysis, or by coding data directly from audio. This is a common design feature of studies that use 'RAP' sheets (*Rapid Assessment Procedure* data templates): data collectors enter quotes and/or open codes into analytic matrices during the interview or afterward, working directly from the audio recording.[70] Clearly this limits the depth and richness of the analysis and makes the approach inappropriate for complex and nuanced qualitative research questions, however many applied research teams have used contemporaneous analysis to elicit meaningful and non-tokenistic findings in contexts where there is a narrow and clearly articulated aim. The few methods studies that have compared these

direct coding approaches against coding based on transcripts of the same interviews/focus group discussions found that both approaches generated similar themes with acceptable reliability.[80,81]

In our scoping review, we found that the most commonly used application of direct coding was in entering data into a deductive template during the interview and/or directly afterwards, working from handwritten notes and/or the audio recording rather than a transcript. The loss to analytical power from obviating a written record can be partly offset by having data collectors co-located, which has been shown to lead to informal discussion and analysis through natural debriefing conversations.[70] Some researchers have formalised this process, holding group meetings directly after data collection to collaboratively summarise, analyse, and interpret findings, such as in the work led by Jalloh.[82]

Many rapid studies seeking to understand barriers to healthcare access make use of deductive templates or matrices to chart data or use 'one sheet of paper' techniques to aid rapid analysis and presentation of findings.[82–86] Miles and Huberman have argued that data reduction, display, and the drawing of conclusions happens simultaneously in qualitative analysis (p10),[87] and that the use of matrices can drive credibility and trustworthiness.[88] Whilst the use of a priori codes and/or themes to populate a framework template may save time at the analysis stage and potentially reduce the skill requirement, the burden of work is shifted to an earlier stage of the project rather than eliminated.

A further issue is that deductive approaches are misaligned with the general aim of moving away from pre-selected checklists of potential barriers and making space for affected people to describe the issues in their own words, ideally surprising researchers by describing barriers and potential solutions that had not previously been considered, and by 'making the familiar strange'.[89] However, Pope and Mays argue that virtually all qualitative analytic approaches involve a combination of inductive and deductive reasoning, and the use of a deductive framework does not necessarily preclude inductive coding.[47] They make a strong case for 'abductive' reasoning that benefits from the efficiencies of the deductive framework approach whilst "leaving space for more inductive identification of themes and issues not predicted at the outset" (p19).

Based on the lessons learned from reviewing the literature, we aim to adopt several rapid techniques to increase the speed and affordability of our qualitative research element, detailed below.

Interviews with non-attenders or their proxies

Recruitment and sampling

Participants in Peek-powered screening programmes operating in Botswana, Inda, Kenya, and Nepal provide their name, a contact number and - if they consent - data on approximately ten

sociodemographic domains including age, sex, education, income, assets, and health status (the unique lists for each national programme and selection processes have been detailed in a previous IM-SEEN publication[90]). Peek has consent procedures and agreements that enable these data to be shared with our embedded research team. In each country we will conduct quantitative equity analyses to identify which sociodemographic characteristics are most strongly associated with non-attendance in each programme. This work has already been completed in Meru, Kenya, where we found that younger people, males, and those working in sales, services, and manual jobs were the least able to access care. In our intersectional analysis we found that only 14% of young men who worked in sales, services, and manual jobs accessed clinics in comparison to 50% across the entire referred population.

In line with the global health principles of equity and health for all, in each setting we will purposively engage with the sociodemographic groups that are found to experience the lowest access rates. We will purposively recruit people who have been referred but not accessed care within two weeks of their appointed date from the left behind subpopulation.

We will have the phone numbers for every person who did not access care from the left behind subpopulation. We will generate a spreadsheet that contains each person's name, unique study ID number, phone number, and screening date. We will order the names randomly, using a random number generation function in R or Excel, and then work down from the top of the list.

Our sample size will be determined by the point at which we reach thematic saturation. Empirical evidence suggests that the majority of all themes and concepts emerges within the first 5-6 interviews[91,92] and that saturation is usually reached within 9-17 interviews when conducted among a relatively homogeneous population.[93,94] We will use Guest and colleagues' approach to assessing saturation, using a prespecified base size (i.e. a minimum number) of 12 interviews, followed by runs of two interviews and a 0% new information threshold. In other words, we will stop conducting new interviews once no new themes emerge after two interviews in a row, with a minimum sample size of 14 ('12+2'). We will budget conservatively for 20 interviews in each location.

Data collection

Small teams of data collectors will conduct interviews in each country. All data collectors will have at least basic training in qualitative methods but will not necessarily be full-time qualitative researchers. Where possible we will recruit, and train lay members from the target population to assist with data collection. All data collectors will be fluent in the language(s) spoken by the target population.

We will use semi-structured telephone interviews, directly exploring participants' views of the issues that prevented them from attending clinic and the potential service modifications that they feel would

have enabled them to attend. We will call potential participants and explain the study, and then seek recorded audio consent. All interviews will be conducted in the participant's own language.

Whilst face-to-face interviews probably offer richer data in comparison with telephone interviews, we have opted for the latter on the basis of feasibility. Peek do not collect people's home addresses, and even if we did have this information, the national screening programmes cover extremely large areas, meaning that it might take weeks of travel to conduct the interviews. In contrast, multiple phone interviews can be conducted each day, with much lower costs, whilst avoiding the personal safety risks to data collectors that come with extensive travel. A number of methods papers have argued that qualitative findings do not vary significantly between telephone and in-person modalities.[95,96]

We will try to contact each interviewee three times, calling at different times of the day. If we are unable to reach them, we will move down the randomly sorted list and try the next non-attender. Interviews will be audio recorded. The recording will include the participants' unique identifier, the consent process, and – if given – confirmation of consent to participate. The following interview items will be used:

Barrier elicitation questions

- In your own words, can you talk me through why we didn't see you/your child at that clinic?

Probing questions

- Are there any other factors that prevented you/him/her from attending?
- Is there anything else you'd like to share?

Solution elicitation questions

The last part of the interview is exploring whether there is anything we could do to address these barriers and make it more likely that other people like you/children like [child's name] will attend in the future.

- So, to start, what would make the biggest difference?

Probing questions

- What else would help?
- What other changes could we make to the programme that would make it easier for you/children like [child's name] or people like you/children like [child's name] to attend?

- Are there any other specific changes that we could make to the way that the programme or eye clinics run?

Qualitative Analysis

During the interview, data collectors will note the major barriers and solutions, and the time that they were mentioned. Immediately after the interview has concluded, the data collectors will listen back to the interview recording and navigate to the noted times. They will then type out the full quotes for each barrier or proposed solution verbatim into an analytic matrix, working from the audio recording, with one interviewee per column, and one theme per row.

We have chosen to use this direct data entry approach because it is faster than generating and then working from transcripts, and because the nature of our (relatively simple) research question is more descriptive than explanatory. We have developed a bespoke deductive matrix that is grounded in the access models of Levesque et al.[43] and Obrist[41] et al.

Development of the analytic matrix

We first mapped the Obrist dimensions to the service domains identified by Levesque (Table 3).

Table 3: Mapping Obrist's service dimensions to those described by Levesque et al.

Levesque dimensions	Levesque descriptors	Aligned Obrist dimensions and descriptors
Approachability	Transparency, outreach, information, screening	N/A
Acceptibility	Professional values, norms, culture, gender	'Acceptibility' – Provider norms and values align with users**,** ~~trust, patients feel welcomed and cared for~~
Availability	Geographic location, accomodation, opening hours, appointment mechanisms	'Accessibility' –Geographic location, transport options, and time to travel 'Adequacy' – the service organiation and opening times meets clients' expectations. Facilities are clean and well kept
Affordability	Direct-, indirect-, and opportunity costs	'Affordability' - Direct-, indirect- (including bribes and unofficial charges), and opportunity costs
Appropriateness	Technical and interpersonal quality, adequacy, **coordination and continuity**	'Availabilty' - The service meets clients' needs: enough skilled personnel, products and services correspond with needs and **cover demand** 'Acceptibility' – ~~Provider norms and values align with users,~~ trust, patients feel welcomed and cared for

Notes

Text in bold is not captured by the other framework

Struck-through text highlights which elements of Levesque's 'Acceptability' dimension align with Obrist's descriptors of 'Acceptability' and 'Approproiateness'

Next, unencumbered by the requirement to begin all descriptors with the letter 'A', we selected domain descriptors that we felt captured the essence of each unique element from across the two frameworks (Table 4). We felt that Levesque's 'availability' domain straddled two different concepts; those relating to distance/transport and facilities.

Table 4: Drawing out unique service domain terms

Service domains	Levesque	Obrist	Unified service descriptor
Awareness of the service	'Approachability' - Transparency, outreach, information, screening	N/A	The service provides clear information about what is available to potential beneficiaries in the catchment population
Cultural values and health beliefs	'Acceptibility' - Professional values, norms, culture, gender	'Acceptibility' – Provider norms and values align with users	The service norms and values align with those of intended users e.g. around gender interactions or health beliefs
Distance and transport	'Availability' - Geographic location, ~~accomodation, opening hours, appointment mechanisms~~	'Accessibility' – Geographic location, transport options, and time to travel	The service is nearby and served by good infrastructure and transport options
Facilities	'Availability' - ~~Geographic location,~~ accomodation, opening hours, appointment mechanisms	'Adequacy' – the service organiation and opening times meets clients' expectations. Facilities are clean and well kept	The facilities are clean, well kept, well organised, and open at predictable and convenient times
Costs	'Affordability' - Direct-, indirect-, and opportunity costs	'Affordability' - Direct-, indirect- (including bribes and unofficial charges), and opportunity costs	The direct costs of care, associated costs, and opportunity costs are all affordable for intended beneficiaries
Service quality	'Appropriateness' - Technical and interpersonal quality, adequacy, coordination and continuity	'Availabilty' - The service meets clients' needs: enough skilled personnel, products and services correspond with needs and cover demand 'Acceptibility' –Clients trust the providers and feel welcomed and cared for	Services are well stocked and staffed by competent staff who are able to meet the needs of intended beneficiaries with warmth and care

Note: Text in the descriptors that is not relevant for the domain in question has been struck through.

Next we added in the domains that pertain to users, mapping them to the service domains and providing a unified descriptor (Table 5). The Levesque framework identified three areas that do not naturally correspond with service characteristics: themes around the desire to seek care, the capacity to participate in care (e.g. though shared decision making with a clinician or medication concordance), and empowerment and social support.

Table 5: Adding in corresponding service user domains

Service domains	User domains - Levesque	User domains – Obrist	Unified user descriptor
Awareness of the service	Ability to percieve – Health literacy, ~~health beliefs,~~ ~~trust and expectations~~	Human capital (local knowledge, education, skills)	Local knowledge, education and skills, and health literacy
Cultural values and health beliefs	Ability to seek – personal and social values, culture, gender, autonomy	N/A	Personal and social values and norms
Distance and transport	Ability to reach – living environments, transport, mobility, social support	Physical capital (infrastructure, equipment, and means of transport) and social capital (social networks and affiliations)	Location, transport options, mobility, and social support
Facilities	N/A	N/A	N/A
Costs	Ability to pay – Income, assets, social capital, health insurance	'Financial capital' (cash and credit) which is largely rooted in 'natural capital' (land, water, and livestock) and social capital (social networks and affiliations)	Assets, cash, credit, insurance and social capital
Service quality	Ability to percieve – ~~Health literacy,~~ health beliefs, trust and expectations	N/A	Personal criteria for jusding the effectiveness and quality of services, based on health beliefs, expectations, and trust
Other	'Service utilisation' – this pertains to the desire and ability to engage with care, requiring information, motivation, capacity, empowermet, adherence, and caregiver support	N/A	Desire to seek care Personal capacity to participate in care Empowerment and social support

Next we mapped the common barriers that were indentified in our literature review of the existing eye care literature (Box 2) to the unified descriptors of service and user domains (Table 6).

Table 6: Mapping service and service user domains to common barriers from existing eye care research

Domain	Service factors	User factors	Barriers from Box 2
Awareness of the service	The service provides clear information about what is available to potential beneficiaries in the catchment population	Local knowledge, education and skills, and health literacy	• Poor service communication • Low awareness of available services
Cultural values and health beliefs	The service norms and values align with those of intended users e.g. around gender interactions or health beliefs	Personal and social values and norms	•
Distance and transport	The service is nearby and served by good infrastructure and transport options	Location, transport options, mobility, and social support	• Distance or transport issues • Lack of a chaperone
Facilities	The facilities are clean, well kept, well organised, and open at predictable and convenient times	N/A	• Scheduling conflicts
Costs	The direct costs of care, associated costs, and opportunity costs are all affordable for intended beneficiaries	Assets, cash, credit, insurance and social capital	• High costs
Service quality	Services are well stocked and staffed by competent staff who are able to meet the needs of intended beneficiaries with warmth and care	Personal criteria for jusding the effectiveness and quality of services, based on health beliefs, expectations, and trust	• Low percieved service quality • Low trust in service providers
	N/A	Desire to seek care	• Not percieved as important, or other obligations percieved as more important
	N/A	Empowerment, personal capacity and social support participate in care	• N/A
	N/A	N/A	• Fear

Finally, we reconfigured this table to create a deductive template that can be used to enter quotes during and directely after each interview. The whole point of using interviews rather than a (much cheaper and faster) survey is to be able to uncover barriers and potential solutions that the research team had not previously considered. As such, the template, interview prompts, and data collector training all emphasise the 'other' column.

Themes	Barriers	Interviewee													Solutions	Interviewee												
		1	2	3	4	5	6	7	8	9	10	11	12	13	14+		1	2	3	4	5	6	7	8	9	10	11	12	13	14+
Costs	Sub-theme 1															Sub-theme 1													
	Sub-theme 2															Sub-theme 2													
	Sub-theme 3															Sub-theme 3													
Distance /transport	Sub-theme 1															Sub-theme 1													
	Sub-theme 2															Sub-theme 2													
	Sub-theme 3															Sub-theme 3													
Desire/priority to seek care	Sub-theme 1															Sub-theme 1													
	Sub-theme 2															Sub-theme 2													
	Sub-theme 3															Sub-theme 3													
Clinical service quality	Sub-theme 1															Sub-theme 1													
	Sub-theme 2															Sub-theme 2													
	Sub-theme 3															Sub-theme 3													
Facilities	Sub-theme 1															Sub-theme 1													
	Sub-theme 2															Sub-theme 2													
	Sub-theme 3															Sub-theme 3													
Awareness & communication	Sub-theme 1															Sub-theme 1													
	Sub-theme 2															Sub-theme 2													
	Sub-theme 3															Sub-theme 3													
Fear	Sub-theme 1															Sub-theme 1													
	Sub-theme 2															Sub-theme 2													
	Sub-theme 3															Sub-theme 3													
Norms, values, & health beliefs	Sub-theme 1															Sub-theme 1													
	Sub-theme 2															Sub-theme 2													
	Sub-theme 3															Sub-theme 3													
Empowerment, support & capacity	Sub-theme 1															Sub-theme 1													
	Sub-theme 2															Sub-theme 2													
	Sub-theme 3															Sub-theme 3													
Other	Sub-theme 1															Sub-theme 1													
	Sub-theme 2															Sub-theme 2													
	Sub-theme 3															Sub-theme 3													
	Sub-theme 4															Sub-theme 4													
	Sub-theme 5															Sub-theme 5													

Figure 4: Our analytic matrix

Process for completing the matrix

During the interview, data collectors will expand the column width for the relevant interviewee number. They will type notes on each barrier into the relevant row, using the participant's own words. Data collectors will repeat the process when asking for potential interventions that would have made it possible to attend, adding ideas to the matrix, supported by direct quotes. They will probe for further forms of service modification (which we are able to change) that would make a tangible difference.

Directly after the interview they will listen back to the audio recording to correct and expand upon quotes that they noted during the interview. All quotes will be directly translated into English. Data collectors will replace the 'Sub-theme n' text in the 'Barriers' and 'Solutions' columns with add their own (inductive) codes, for instance; 'long queue at clinic', 'cost of spectacles', or 'rumours of rude staff'. The number of sub-themes is not limited; new rows can be added as required. As stated above, after a minimum of 14, interviews will continue until no new sub-themes emerge from two successive interviews. Data collectors will debrief with national research leads each day. The national research leads and the international research manager will collaboratively check quality and consistency of data entry, review all quotes and sub-themes, and assess when thematic saturation has been reached. Once qualitative data analysis is complete, all audio recordings will be deleted.

Use of findings

Once saturation is reached, the wider research team will use the full matrix to generate a list of all the individual barriers and solutions that arose from the interviews. These may include things like sending SMS reminders, reducing the distance that people have to travel, or altering the way that people are counselled before being referred.

The long list of solutions will be reviewed by the programme funder and programme implementer to rule-out any service modifications that are completely unfeasible – such as paying people $100 to attend, or providing free individual transport for every participant. The short list of potential service modifications will form the basis of a survey that will be sent to a wider sample of non-attenders in order to identify the most promising actions at a generalisable level.

Survey

As stated above, we will have a complete list of every non-attender belonging to the sociodemographic group with the lowest overall attendance rate. We will administer a telephone survey to a representative sample of non-attenders from this group, excluding all of those who have already been interviewed. We will use a 95% confidence interval, a 5% margin of error, and a conservative assumption that the total population size is 1 million people (with the same characteristics as the most marginalised group). This renders a sample size of 384.

We will use computer generated numbers to obtain a random sample of non-attenders to call. Data collectors will seek verbal audio recorded consent before reading through the full list of potential service modifications that arose from the interview stage. Respondents will be asked to rank each suggestion from 1-3 on a simple Likert scale:

1. It would make a big difference - i.e. if we introduced this change then you or people like you would definitely attend
2. It would make a moderate difference - i.e. it would greatly increase the chances, but it would not be enough by itself to guarantee attendance by itself
3. It would make a small difference - i.e. it might help a few people, but the impact is likely to be minimal

We will calculate the average score for each service modification and generate a ranked list. Workshop participants will review the ranked list and select the most promising service modification to implement and evaluate.

Workshops

Our team already has formal agreements and pre-existing working relationships with Peek programme leads, programme funders, programme implementers, eye care policymakers, and community advisory boards in each location. In each country we will invite these stakeholders to a 60–90-minute workshop to review the study findings and select one or more service modifications to implement. Workshop discussion will be led in English (the working language of the project in each country) by a facilitator from our research team. The researcher will present a brief overview of the barriers and potential solutions suggested by non-attenders and their proxies, and then facilitate discussion to explore the groups' perceptions of which barriers they can realistically address, and which solutions offer the best balance of impact (based on survey respondent scores), cost, risk, and feasibility. The aim is to identify promising service modifications that can be deployed and tested using RCTs to equitably improve access to care.

The process of decision-maker group discussion aligns with rapid methods that use group discussion with the ultimate research users as a key part of data analysis, interpretation, and application. The workshop will close with the identification of the most promising service modification to test and discussion of next steps.

Output

The primary output of this mixed-methods study will be the selection of one or more feasible service modification(s) that has been identified by intended service users and agreed by service managers. This process will conclude during the workshops held in each country. The selected service modification(s) will be

tested across the relevant programmes using an adaptive randomised trial design, as part of the broader 'IM-SEEN' approach.

Ethical Considerations

We will seek ethical approval from the LSHTM ethics committee and all relevant ethics committees in Botswana, India, Kenya, and Nepal.

Consent to be contacted for recruitment

In the screening stage that takes place before this project's elicitation activities, written tick-box consent will be sought to use personal and contact data to recruit non-attenders for this current study. Our team is fully embedded in the screening programmes in each country, and there are memoranda of understanding in place that govern the sharing of data between parties.

> *Consent wording used at screening, using Botswana as an example:*
>
> *I understand that my / my child's anonymised data may be shared with other researchers or online in a public repository for research. I understand that I may be contacted by Ministry of Health partner organisations inviting me to participate in future studies to improve access to eye care services. I understand that I can call [phone number] for free to ask any questions; that my decision will not affect the care that I / I or my child receives; and that I can change my mind at any time.*

Consent for telephone interviews

For the qualitative interviews, we will call potential participants and provide information about the purpose and risks of the telephone interview using an appropriate version of the Botswana script shown below. Potential participants will have the opportunity to discuss the study and ask questions.

> *Hello, my name is_____. I am a researcher from the University of Botswana, working with the Ministries of Health and Basic Education on the Pono Yame eye screening programme.*
>
> *Your child recently had their eyes screened at school and was found to need further assessment. Our records indicate that, like many other children, they were unable to attend that appointment.*
>
> *You are being contacted because you have previously provided consent to be contacted by Ministry of Health partner organisations regarding research being conducted for eye care services. I am calling to invite you to participate in a 30-minute interview. Your participation is completely voluntary. This means that you do not have to do it unless you want to.*

We want to understand the barriers that prevented your child from attending. We are also asking about how we could change the Pono Yame programme to make it easier for children to attend appointments.

Before agreeing, here is the background information that you need to know:

We have invited you because, like many other referred children, your child did not attend. We want to hear about the issues that you personally faced that prevented your child from attending, and your ideas on how to make things easier. In total we are aiming to interview about 20 people.

Who are we? I work with a group of researchers from the University of Botswana and the London School of Hygiene and Tropical Medicine. We are working to improve the national Pono Yame eye screening programme that will visit every school in the country. The leaders of the research are Prof Keneilwe Motlhatlhedi and Dr Luke Allen.

We will take the responses from all of the interviews and discuss the ideas for improvement with the leaders of the national programme. We hope to use your suggestions to make the programme work better.

We are also conducting a set of face-to-face interviews and online surveys with other parents and guardians. We want to compare the responses we get from these different approaches.

In this 30-minute interview there are no risks to you or your child. If you agree to take part, we will send you a 100-pula airtime voucher to compensate you for your time. It is important to note that agreeing or declining to take part does not have any impact on your child, their schooling, or the services they receive.

You can stop the interview at any time.

I will record the interview. Our team will anonymise your data and keep it safe and secure on a password-protected computer in London. When the study is completed, we will write-up our findings and publish them online so that other researchers can use the information to help people in other places.

The University of Botswana and London School of Hygiene and Tropical Medicine ethics committees have both approved this study.

You can ask me any questions you like now. I can also give you the email address and phone number of the lead researchers if you'd like to contact them directly [provide the contact details for BK, Keneilwe or Luke as required]. If you have any other concerns I can also give you the contact details for the London School of Hygiene and Tropical Medicine Research Governance and Integrity Office.

Do you have any questions?

Are you happy to begin the interview?

Consent for the telephone survey

For the telephone survey, we will call potential participants and provide information about the purpose and risks of the telephone interview using an appropriate version of the Kenyan script shown below. Potential participants will have the opportunity to discuss the study and ask questions.

Good morning/afternoon

My name is .... and I'm calling from the Vision Impact Project eye screening programme. We saw you a few weeks ago and referred you to the local clinic, but we did not see you on your appointed day.

In fact, half of all people who were referred did not attend. We have sought feedback on ways we could improve our service, and I wanted to ask you which of the ideas we have stand the best chance of helping people like you to access care. It should take approximately 15 minutes of your time.

If you are happy to proceed, I need to tell you a bit more about the survey. I will then double-check that you are still happy to proceed.

I will ask you about a set of potential changes that we are thinking about making. I will ask you to rate each one in terms of how likely you think it is to make a difference at helping people access our clinics.

Your responses will help us to shape and improve our services for others, but there are no direct benefits to you for taking part. Thinking about the issues that prevented you from getting care may be distressing to you. If you face any discomfort because of the questions asked, you can skip any question or ask to end the call whenever you choose.

If you don't want to take part, that's ok. You can drop out of the survey at any point. Your decision will not affect your health care or your future relations with the Vision Impact Project in any way.

Your anonymised answers will be combined with those from other people and kept safe and secure on password-protected computers in Nairobi and London. None of the data will be used for commercial use. We will publish our findings in a research journal and in a public repository so that other researchers can learn from what we find. Your personal information will not be included in our findings and there is no way that you can be identified from any of the reports that we will produce.

If you have any questions, you can ask me now, or I can put you in contact with the study coordinator - Sarah Karanja from Kenya Medical Research Centre. If you have any questions about your rights as a research participant, I can connect you with the Kenya Medical Research Centre Ethics team who approved this survey.

Does that all make sense? Do you have any questions for me?

Are you happy for me to start?

Consent for participation in the workshop

All participants will be participating in the workshop as a routine part of their duties in connection with the respective eye programme. As such, consent is not required. The only output from this workshop will be the intervention(s) that will be implemented and evaluated using RCTs.

Risks and strategies to mitigate

The risks to participants from the interviews, survey, and focus group discussion are low and there are no physical risks. Dwelling on the issues that prevented attendance may cause psychological distress. Data collectors will be trained to supportively manage mild levels of distress and will signpost participants to other sources of support if participants become moderately or severely distressed.

Any issues, complaints or concerns will be reported to the principal investigators. Participants will be provided with their email addresses and office phone numbers. Participants will also be given the number of the local field coordinator for operational queries, and the LSHTM RGIO contact details for any other concerns about the conduct of the study.

We will compensate telephone interviewees for their time with an airtime voucher worth 100 BWP / 500 KES / 800 NPR (approximately £5). The voucher will be sent via SMS to telephone interviewees. Given the lower time and cognitive burden, survey responders will not be offered reimbursement, neither will workshop participants as quality improvement is a core part of their role.

All data collected will be encrypted and stored on secure servers protected with strong authentication controls including two-factor authentication. All data will be processed and safeguarded in compliance with the EU and UK's General Data Protection Regulation (GDPR). Data will be anonymised and kept confidential. After 7 years all study data will be destroyed. We have developed a robust Data Management Plan (Appendix 1).

Discussion

The series of elicitation elements in this study will produce a list of barriers to accessing eye health services, as perceived by patients or their proxies, as well as insight into what service modifications may be most useful for overcoming these barriers. The survey and workshop will refine this list, identifying those service modifications that are deemed to be most impactful by a representative sample of non-attenders, as well as offering the optimal balance of impact, cost, and risk by programme managers.

Whilst our analytic framework is grounded in the literature, the obviation of transcription and dual coding by highly trained qualitative researchers clearly limits the reliability of the interview findings. We have deliberately sought to develop a method that can be deployed in low-resource settings where there are not necessarily qualitative researchers available and time is at a premium. Previous work has shown that rapid qualitative methods led by less-experienced research assistants are able to generate valid findings when the subject matter is not overly complex. Seeking a list of potential barriers and solutions meets these criteria.

The highest-ranked potential service modifications will be presented to local and regional policymakers and stakeholders to garner their views on which should be prioritised for implementation, based on their likely impact, feasibility, cost, and potential risks. Stakeholders include community advisory board representatives in each setting. By having community members assist with analysis and interpretation of study findings, this design provides a participatory approach to the selection of interventions and health service modifications that will be tested in subsequent work. Those responsible for funding and implementing the modifications will also play a role in reviewing data and selecting the most appropriate interventions to test.

Improvements in access to health services and health equity are the key component of this study as we seek to focus on the needs of the most marginalised groups of non-attenders. We aim to refine and apply these methods to address other areas blighted by inequitable and low access.

Limitations

Despite the fact that phone penetration is high in the countries we are working in, not everyone has their own phone and it is also likely that members of the most disadvantaged groups will be the least likely to respond to our telephone interviews and surveys, as well as being the least likely to attend services. It is possible that those with access to phones have different opinions on barriers and interventions and this could bias the results. In terms of alternatives, postal surveys are problematic for a range of other reasons including the lack of addresses, poor reliability of the postal service, and issues with loss of data. In-person surveys would be the most robust way of ensuring that every voice is heard, but we do not have the time or resources given the national scale of the programmes.

Dissemination

Our findings will be shared with lay representatives, community advisory board members, local and national programme funders and implementing partners, Peek Vision, and national eye care policymakers. No participant names or identifiable information will be used. The study findings will also be disseminated during quarterly review meetings with implementing partners, community workers and representatives from the

county health management committee, and bi-annual partner meetings. We will also present our findings at national, regional and/or international conferences.

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Study status

At the time of manuscript submission we have piloted the approach in Kenya and obtained ethical approval for every country. We have not started recruitment or data collection in Botswana, India, or Nepal.

Declaration of interest

None of the authors have any interests to declare.

Study coordination centre:

London School of Hygiene & Tropical Medicine. This trial will adhere to the principles outlined in the International Conference on Harmonisation Good Clinical Practice (ICH GCP) guidelines, protocol, and all applicable local regulations.

Patient and public involvement

Lay representatives from our community advisory boards in Botswana, India, Kenya, and Nepal reviewed the original draft, provided feedback on the proposed methods, and reviewed the final version of this protocol, as well as contributing to earlier related studies as part of the broader IM-SEEN project.

Acknowledgements

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Appendix: Data Management Plan

1. DATA SOURCES AND DATA COLLECTION PROCESSES

The research objectives require the collection of quantitative survey data, as well as qualitative data in the form of audio recordings and quotes from study participants. Table 1 below outlines the data fields to be collected throughout the various stages of the data collection process. All data will be treated as personal data for the purpose of data capturing and processing, as collectively, it can be combined in a way that could make it identifiable.

Data from the initial screening process will be collected in Peek powered Eye Health School and Community Programmes using Peek's Capture application. During the initial screening process only basic and non-personal identifying data is collected, with the exception of telephone number. Following initial screening, all those identified as requiring referral will 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 outlined in table 1 below. 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.

Following triage of individuals who had screened positive, a four-stage rapid exploratory sequential mixed-methods study design will be used to evaluate barriers to health access among non-attenders who had been flagged for onward treatment. Telephone interviews will be conducted among 60 non-attenders, purposively selected from socio-demographic groups with the lowest overall attendance rates. The aim of the telephone interviews is to explore and evaluate their perceived barriers to clinic attendance, and develop a list of potential solutions.

Once interventions and service modifications have been identified, these will be tested through a series of pragmatic, embedded, adaptive parallel, multi-arm randomized control trials (APT). The intention of the APT is to continuously improve attendance rates, particularly amongst those groups with the lowest engagement rates overall. Table 1 outlines each of the data collection phases, the data fields to be collected, and the study populations of each of the stages discussed.

Table 1: Data collection phases, data fields and study populations for broader I'M SEEN project

	Phase	Data Fields Collected		Eligible Population
1.	**Initial Screening Process**	• Age • Gender • Language • Awareness (optional) • Diabetes status (optional)	• Spectacle status • Visual Acuity • Eye Condition • Telephone Number	All included in PEEK screening programme
2.	**Collection of sociodemographic data**	• Health insurance status • Language • Marital Status • Religion • Migrant/refugee status • Housing	• Ethnicity • Disability • Occupation • Education • Food adequacy • Asset ownership • Family members	All those identified as requiring referral
3.	**Elicitation questions (via telephone interview)**	*Barrier elicitation questions:* • In your own words, can you talk me through why we didn't see you/your child at that clinic? *Probing questions:* • Are there any other factors that prevented you/him/her from attending? • Is there anything else you'd like to share? • Of the issues you mentioned, which is the most important?		Non-attenders of onward treatment appointments purposively selected by sociodemographic group.

Solution elicitation questions:

The last part of the interview is exploring whether there is anything we could do to address these barriers and make it more likely that other people like you/children like [child's name] will attend in the future.

- So, to start, what would make the biggest difference?

Probing questions:

- What else would help?
- What other changes could we make to the programme that would make it easier for children like [child's name] to attend?
- Are there any other specific changes that we could make to the way that the programme or eye clinics run?
- Who do you feel should implement this/these changes?"
- You mentioned [list their proposed solutions]. Some of these may be beyond our control, but if we managed to [list their proposed programme-related changes], do you think that would be enough to allow children like your son/daughter to attend?"

4.	**Online Survey (hyperlink sent via SMS)**	Ranking of proposed service modifications proposed during telephone interview using mobile phone numbers gathered during initial screening process.	Representative sample of non-attenders
5.	**Programme Leader/Stakeholder Workshop**	Audio recording of workshop conversation during which the list of prioritised service modifications derived from the online survey will be discussed and evaluated for testing	Service managers, programme implementers, national and regional eye care policymakers, as well as any other relevant stakeholders.
6.	**Adaptive Platform Trial**	Examples of possible interventions delivered at the individual and cluster levels include: *Individual* *Population (cluster)* • SMS messages	Children over 5 years, and adults who participate in PEEK-powered eye screening programmes. Those who do not meet local clinical service eligibility criteria will be excluded.

• Voice messages • Visual acuity thresholds • eVouchers • Physical vouchers • Chaperones • Individualised transport assistance	• Change to language of messages sent to participants • Radio broadcasts • Training for implementers • New clinic times or locations • New bus services

2. DATA COLLECTION TOOLS

Various data collection tools will be used to populate the data fields outlined in table 1.

Quantitative Data:

- Android Mobile Devices – Survey data, and data derived from the APT (phases 1,2, 4 and 6) 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 APT will be embedded within Peek software used in parallel with a Bayesian algorithm that will be used to autonomously run response adaptive trials.

Qualitative Data:

- Play Verto – The online survey will be administered through Play Verto, a play-based online survey group who have worked with the United Nations and others to develop engaging short surveys that have impressively high response rates in low- and middle-income countries. The survey will be sent as a hyperlink in an SMS. PlayVerto will gather, store and process. After, they will transfer (anonymised data) it to LSHTM who will perform further processing and storage. LSHTM will share aggregate anonymised findings with partners and in public domain.

- Data Abstraction Matrix: During the telephone interviews, data collectors will directly enter notes, quotes, open codes, and abstractions into a matrix. Data gathered, processed and stored by local partner organization. Then shared with LSHTM (fully-anonymised responses to be shared).

- Audio Recordings – Telephone interviews will involve verbal communication and discussion, and thus will be collected and stored using digital audio-recording methods.

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.
- Play Verto – is a play-based online survey group who have worked with the United Nations and others to develop engaging short surveys that have impressively high response rates in low- and middle-income countries.
- 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.

3. 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 needs 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%.
Conduct telephone interviews, online surveys and stakeholder workshop	In order to better understand barriers to accessing eye services a series of activities will be conducted through a four-stage sequential mixed-methods approach. These include: 1. Telephone Interviews – Telephone interviews will be conducted with non-attenders, purposively selected from subgroups with the lowest attendance rates. 2. Following telephone interviews, a single list of suggested solutions will be compiled 3. Online survey – An online survey will be conducted among a representative sample of non-attenders to rank mooted interventions/service modifications. 4. Stakeholder workshop – Programme leaders and key stakeholders will then select one or more of the highest ranked interventions to test, based on impact, feasibility, risk and cost. Following completion of this process, data will be analysed to elicit barriers to care and recommended interventions/service modifications to improve attendance rates.
Testing of service modifications through APT	An automated adaptive platform trial (APT) will iteratively test a series of interventions selected with intended service beneficiaries to increases attendance rates among marginalised groups. This will be done through a Bayesian, embedded, pragmatic, superiority, adaptive platform trial platform that will use response adaptive randomisation.

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

4. 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, and 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 before screeners visit the school:

> *"I understand that my child's anonymous data may be shared with other researchers. 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.

5. 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,

6. DATA STORAGE AND SECURITY

Data collection, management and storage for this study will be managed by seven entities described below:

A. Peek Vision Capture Application
B. Play Verto
C. The London School of Hygiene and Tropical Medicine
D. Botswana: The University of Botswana
E. India: Dr Shroff Charity Eye Hospital
F. Kenya: Kenya Medical Research Institute?
G. Nepal: Nepal Netra Jyoti Sangh

Peek Capture Application

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. h

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 here.

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.

Play Verto

Play Verto Data capture tool

Data collection via our web-based application is all stored on a AWS RDS dedicated server, located in Ireland. This database utilises AWSs own encryption, AES-256 at rest, for maximum security. 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 here.

Only approved team members have access to the data. Access is strictly controlled through the Play Verto's Admin and AWS Admin. Where Password protection is required and the use of 2-factor authentication where applicable.

Play Verto Capture security:

- Play Verto is a web-based application therefore can only be accessed via a public URL.
- Play Verto enforces security controls that include strong device passcodes and 2-factor authentication where applicable…
- Data stored is encrypted via AES-256 encryption

Play Verto Admin security:

- We have a strong password policy in place for all our accounts, requiring a minimum length of 8 characters.
- 2-Factor Authentication to protect user account security.
- User access permissions are controlled through account privileges. So access is restricted and limited to only what a user requires for their work.

Play Verto Platform Data Security Assurance:

Play Verto complies with CyberEssentials Certification and IASME Governance Standard. Data collection via our web-based application is all stored on a AWS RDS dedicated server, located in Ireland. This database utilises AWSs own encryption, AES-256 at rest.

Monthly automated penetration tests conducted by Detectify The purpose of the test is to verify whether robust security mechanisms are in place to prevent unauthorised users from accessing data and infrastructure. We have maintain Threat score of 0 and 10/10, OSWASP SCORE *(The worldwide non-profit organization Open Web Application Security Project (OWASP)'s list of the ten most common vulnerabilities, known as OWASP Top 10, is often used as a security standard. Detectify covers OWASP Top 10 and provides an easy way for you to see which categories you pass or fail.)*

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/.

Play Verto Platform Data Security Controls:

Play Verto Servers:

Data collection via our web-based application is all stored on a AWS RDS dedicated server, located in Ireland. This database utilises AWSs own encryption, AES-256 at rest, for maximum security. Ensuring all of the data privacy safeguards as governed under the GDPR.

Databases:

Server data is stored in Mongo databases, a fast, scalable, json document database. Play Verto 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:
Play Verto 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.

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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 centres 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?

- Delete personal & confidential details at the earliest opportunity (specify when)
- Use digital storage that require a username/password or other security feature
- Physical security (such as locked cabinet or room)
- Encrypt storage devices
- Encrypt data during transfer
- Avoid cloud services located outside EU
- Take 'Information Security Awareness training'
- Ensure backups are also held securely

The aggregated data that is shared among project staff and partners 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.

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.

Resources will be made available at the same time as findings are published in an academic journal. Once available, we will make other researchers aware that the resources exist by:

- Citing resources in future research papers, e.g. in the data access statement or reference list
- Citing resources in project reports
- Adding resources to a list of our academic outputs

The following steps will be taken to ensure that resources are easy to analyse and use in future research:

- Store resources in open file formats such as CSV, Rich Text, etc. See https://www.ukdataservice.ac.uk/manage-data/format/recommended-formats

- Designate a corresponding author / data custodian who will handle data-related questions

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.

Chapter 8

A rapid, exploratory sequential, mixed-methods study to identify barriers and potential solutions in Meru

Data collectors performing telephone interviews to explore barriers and potential solutions in Meru
Source: Author. Consent has been provided from all individuals in the photo

Key findings

- Interviews revealed a set of barriers that centred around the meta-themes of long queues, conflicting work commitments, opportunity costs, and inadequate provision of information.
- All of the suggested solutions were rated as moderately-highly likely to improve access to care by a representative sample of people from the left behind group.
- Workshop participants – including community representatives – identified a bundle of interventions that they felt represented the best balance of impact, feasibility, cost, and risks. These were around improving provision of information during verbal counselling and in SMS reminder messages.
- Budgetary limitations meant that other highly rated interventions could not be tested.

Having set out the overall IM-SEEN Engage approach, I then implemented it in Meru, working closely with Sarah Karanja - a social scientist based at KEMRI. Sarah and I delivered two days of training to a group of six locally-recruited data collectors in August 2023. Interviews, surveys and the multistakeholder workshop were all completed within six weeks in September-October 2023. The writeup was posted on medRxiv and is currently undergoing peer review at Lancet Global Health.

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RESEARCH PAPER COVER SHEET

Please note that a cover sheet must be completed for each research paper included within a thesis.

SECTION A – Student Details

Student ID Number	2004040	**Title**	Dr
First Name(s)	Luke		
Surname/Family Name	Allen		
Thesis Title	Improving equitable access to community-based health services: Developing and testing a new model in Kenya's national eye screening programme		
Primary Supervisor	Andrew Bastawrous		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

SECTION B – Paper already published

Where was the work published?	N/A		
When was the work published?	N/A		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	N/A		
Have you retained the copyright for the work?*	Choose an item.	Was the work subject to academic peer review?	Choose an item.

*If yes, please attach evidence of retention. If no, or if the work is being included in its published format, please attach evidence of permission from the copyright holder (publisher or other author) to include this work.

SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	Lancet Global Health
Please list the paper's authors in the intended authorship order:	Luke Allen, Sarah Karanja, Michal Gichangi, Cosmas Bunywera, Emmacukate Muturi, Dickson Gachobi, Purity Kathure, Elizabeth Mutile Muasa, Lorna Mutwiri, Lorna Kajuju, Faith Kagwira, Benjamin Ntabathia, Hilary Rono,

	David Macleod, Min Kim, Malebogo Tlhajoane, Matthew Burton, Jacqueline Ramke, Nigel Bolster, Andrew Bastawrous
Stage of publication	**Submitted**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I trained and supervised the data collectors with Sarah Karanja. I led the analysis with additional support from Sarah. I wrote the first draft of the manuscript, sought input from my co-authors, and completed the final version of the manuscript. Lorna Mutwiri and Lorna Kajuju supported with interview logistics. Hilary Rono and Cosmas Bunwera helped me think through how the approach would integrate with the Peek quality improvement process. All other authors provided comments on the draft.

SECTION E

Student Signature	Luke Allen
Date	26th April 2024

Supervisor Signature	REDACTED
Date	30-04-2024

Identifying barriers and potential solutions to improve equitable access to community eye services in central Kenya: a rapid exploratory sequential mixed methods study

Authors

Name	Title	Institution	Qualification
Luke Allen	Principle Investigator	London School of Hygiene and Tropical Medicine (LSHTM)	MBChB Medicine, MPH Global Health, BSc International Health, PGD Health Research, PGCE Clinical Education,
Sarah Karanja	Co-Investigator	Kenya Medical Research Institute, Centre for Public Health Research	MA Medical Sociology, MSc. Global Bioethics
Michael Gichangi	Co-Principle Investigator	Ministry of Health, Ophthalmic Services Unit	MSc. Public Health for Eye Care, PGD Public Health for eye, M. Med (Ophthalmology), MBchB
Cosmas Bunywera	Co-investigator	Peek Vision	MSc Project Management
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Summary

Background: Recent research has found that less than half of people identified with an eye problem in Meru county's screening programme were able to access care, with younger adults being the least likely to receive the care they needed. We aimed to interview and survey members of this 'left behind' group to explore barriers and identify potential solutions using a rapid mixed-methods approach.

Methods: First, we conducted interviews to explore perceptions of barriers and potential solutions. Next, we asked a representative sample to rank the suggested solutions by likely impact. Finally, we held a multistakeholder meeting to identify which of the top-ranked interventions offered the best balance of impact, feasibility, cost, and potential risks. We used a deductive matrix and thematic analysis to rapidly analyse the interview data.

Results: We conducted 67 interviews. Barriers to access included long queues, conflicting work engagements, and lack of clear information. Proposed solutions focused on reducing queue lengths, providing better counselling and clinic information, holding mop-up clinics, and maintaining adequate stocks & supplies. We conducted ranking surveys with 401 additional people from the left behind group. All proposed solutions were ranked at moderately-to-highly likely to improve equitable access. Fifteen people attended the multistakeholder meeting, including community representatives. Workshop participants unanimously selected enhanced counselling and SMS reminders as the interventions that offered the best balance of impact, risk, cost, and feasibility. The other proposed solutions were deemed impractical or unaffordable.

Conclusion: Rapid mixed-methods and multistakeholder collaboration were used to identify a range of potential service modifications that will be implemented within the ongoing programme. Our approach was centred on the experiences and perceptions of those who face the highest barriers to care.

Research in Context

Evidence before this study

Previous research in Kenyan community screening programmes has shown that at least half of those found to have an eye health need will not be able to access care at their local treatment clinic, even if the care is provided free. Work in Meru County has shown that younger adults less are likely than any other sociodemographic group to check-in at their local clinic, but it's not clear what the specific barriers are for this group. Across the African continent, approximately half of all ambulatory appointments are missed across all specialities, and sociodemographic inequalities are ubiquitous. In pursuit of Universal Health Coverage (UHC) and the Primary Health Care principles of equity and justice, health system managers are increasingly focused on identifying, trying to understand, and then address unequal access to care, however the traditional approach to identifying barriers and solutions has tended to centre around expert opinion rather than engagement with affected groups.

Added value of this study

This study builds on previous efforts to introduce routine sociodemographic data collection into the county-wide eye screening programme operating in Meru, Kenya, as well as additional sites in Meru County, Botswana, Nepal, and Uttar Pradesh. Having already identified younger adults as the least likely to receive care in Meru County, this study introduces a novel mixed-methods approach for engaging with members of this left behind group to rapidly identify barriers and scalable solutions. We used innovative methods to complete interviews and qualitative analysis in under two weeks, followed by a rapid survey to rank the potential solutions that emerged from this work with a representative sample of younger adults who had not been able to access care. Finally, a multistakeholder workshop with strong local and lay representation identified the top-ranked solutions that would be feasible to introduce and test within the ongoing screening programme. In addition to local evidence for action, this study presents an approach that any community-based programme could use to generate robust, non-tokenistic insights from affected communities within a matter of weeks, minimising the research time requirement and number of senior researchers required whilst maintaining rigorous scientific standards.

Implications of all the available evidence

Equitably advancing UHC is predicated on identifying and overcoming unique barriers to care, however existing efforts rarely involve consultation or co-creation with affected communities. Building on existing rapid qualitative and mixed-methods methods, we have developed a cutting-edge approach to

identify barriers, prioritise solutions, and identify service modifications that are feasible to introduce. We have applied this approach in Meru County, where younger adults – who were the least likely to access care – suggested a bundle of interventions centring on improving the provision of information and SMS reminders. Our research group will use an embedded RCT to implement and test this bundle, in the context of an equity-focused continuous improvement model that we are also implementing in Botswana, India and Nepal to incrementally improve access for all, with a focus on left behind groups.

Introduction

Improving equitable access to community health services lies at the heart of Universal Health Coverage (UHC) and 'leaving no one behind' is the 'central, transformative promise' of the Sustainable Development Goals.[1–4] WHO's *Thirteenth General Programme of Work* states that 'the main challenge to making progress towards UHC comes from persistent barriers to accessing health services'.

Our research collaborative is developing and testing a novel approach to identify and address inequitable access to care using the 'IM-SEEN' approach ('Improvement studies for evidence-based and equitable innovation'). This involves identifying which groups are being left behind in a given programme; engaging with these groups to understand the unique barriers they face and their ideas for service improvements; and then testing these potential solutions with embedded randomised controlled trials (RCTs).[5]

We are applying this model in the context of community-based eye screening programmes in Botswana, India, Kenya, and Nepal. Uncorrected visual impairment affects over a billion people worldwide, levying major social and economic costs, despite the availability of highly cost-effective treatments like spectacles and cataract surgery.[6] Our first set of findings from a cross-sectional equity analysis of over 4,000 people in Kenya's Meru county found that only 46% of those found to have an eye need were able to access their free local treatment outreach clinic.[7] We found that younger adults, males, and those working in sales, services, or manual jobs were the least likely to receive the care they need. Age was the strongest predictor of poor access, with less than a third of people aged 18-44 years receiving care compared to two thirds of those aged >45 years, even after controlling for severity of eye condition and a wide range of other factors.

Traditionally, ideas for how to improve programmes come from 'experts', service providers, or surveys of service users - rather than affected people themselves.[8,9] In the context of renewed interest in Primary Health Care[10–12] and the insidious persistence of colonialism and epistemic injustice in global health,[13–15] increasing attention is being paid to person- and community-centredness. Simply put, advancing equitable access to health services must be done *with*, rather than *to,* or *on behalf of* left behind groups.[9]

In this study we aimed to engage with younger adults who had not been able to access eye care in Meru in order to explore their perceptions of how the local services could be modified to improve access. Working within a live programme, we aimed to deliver robust, non-tokenistic, and generalisable

findings within a matter of weeks, with a view to testing suggested service modifications with a subsequent embedded RCT.

Methods

Setting

Meru is a county with a population of 1.5 million in central Kenya, 110 miles north of Nairobi. It includes Mount Kenya and Meru National Park. The capital, Meru town, is home to a quarter of a million people. Agriculture is the main source of employment, with khat and tea representing important cash crops. Kenya's Vision Impact Programme ('VIP') has been operating in Meru since July 2022, and has reached over 350,000 people to date, according to internal data. Teams of screeners go house-to-house testing all adults' vision using a simple smartphone-based app developed by Peek Vision.[16] Screeners refer people whose visual acuity falls below 6/12; those who have a red eye or another issue upon basic visual inspection; and anyone who feels they have an eye problem, even if there are no clinical signs and their visual acuity is >6/12. Our research team has been working with screeners to gather sociodemographic data from every person who screened positive and was referred to an outreach clinic for further assessment and treatment between April – July 2023. As stated above, we had previously found that younger adults are the least likely to be checked-in at treatment clinics but we did not know what the main barriers were or what could be done about them.

Research paradigm, theory, and methodology

We used a pragmatist philosophical paradigm[17,18] and a phenomenological approach[19,20] to explore these young adults' lived experiences and perceptions of barriers to accessing eye clinics, and potential solutions. We grounded our work in the complementary frameworks developed by Levesque et al and Obrist et al.[21,22] Both conceptualise access to care in terms of service and service-user characteristics. This distinction is helpful as our ultimate aim was to identify service modifications that improve accessibility for younger adults. We required mixed methods to answer a multi-layered question: what are the main barriers to accessing eye services in each location and what could be done about them?

Methods overview

This study was conducted in three stages. In Stage 1, we used interviews to generate a long-list of perceived barriers and potential solutions. Then, in Stage 2, to move from subjective experiences to generalisable service modifications, we conducted a telephone survey where a representative sample

of younger adults who did not receive care ranked each of the suggested solutions by likely impact. Finally, in Stage 3, these ranked solutions were reviewed by a multistakeholder group who identified a package of interventions to test based on likely impact, feasibility, cost, and risks.

Team composition and reflexivity

This project was part of the broader 'IM-SEEN' programme of work that seeks to develop a new, rapid, robust, and responsive approach to continuously improving access to care, starting in the field of community-based eye screening programmes in Botswana, India, Kenya, Nepal. LSHTM-based researchers (LA, AB, MB, JR, DM & MK) working with Kenya's Ministry of Health eye lead MG, AB and NB from Peek Vision - the screening programme software provider, and SK - the local research lead SK based at KEMRI, had already conducted a collaborative equity assessment of Meru's VIP programme. LA – a mid-career British clinician, policy advisor, and mixed-methods public health researcher - led the development of the methodological approach to be used in all countries to engage with members of the left behind groups. LA worked closely with SK – a mid-career female Kenyan public health social scientist – to tailor the approach for Meru County, supported by the wider team. LA and SK recruited and trained six local, early-career data collectors (DG, EMM, EM, PK, BN and FG) to conduct the interviews and surveys. We were interested in understanding the barriers and solutions as perceived and described by affected people in their own words. SK and LA facilitated the multistakeholder workshop where findings were interpreted by lay representatives, other members of the left behind group, and local programme managers. This local multistakeholder group collectively made the final decisions on which suggested service modifications to take forward for implementation.

Stage 1: interviews

Recruitment and sample size

Peek Vision – the programme software provider - provided us with a list of every person aged 18-44 years who had not been able to access their clinic appointment in Meru. In random order, we phoned people from this list to invite them to participate in the interviews, and sought recorded verbal informed consent. We tried each person three times before moving on to the next.

We planned to use Guest and colleagues' approach to determine our sample size based on thematic saturation, using a 'base' of 12 interviews followed by runs of two interviews with a 0% new information threshold.[23] In other words, we aimed to continue recruiting interviewees until no new themes emerged after two interviews in a row, with a minimum sample size of 14 ('12+2' approach).

Interview modality

We wanted to use telephone interviews, based on empirical evidence that they can be completed faster at lower cost than in-person interviews, and with equivalent data richness.[24–28] However, we were not entirely convinced that the data would be equivalent. As such, we decided to recruit two separate samples and use both modalities, conducting an embedded mode-comparison study[29] that will be reported elsewhere.

Data collection

Three pairs of Kenyan data collectors with at least basic qualitative training and fluency in English, Kiswahili, and the local dialect conducted semi-structured interviews using the topic guide summarised in Box 1 (see Appendix 1 for the full script). For the telephone interviews, calls were made on speakerphone in a private space and recorded using the phone's inbuilt call recording app. As one data collector conducted the interview, the other noted down the times at which each unique barrier and potential solution was mentioned. After the call, the interview recording was immediately replayed and the data collectors entered verbatim quotes directly from the audio into our analytic matrix. The same process was used for in-person interviews, but with an audio recorder instead of a mobile phone. Our decision to use direct-from-audio transcription was based on findings from a background systematic review that we conducted on rapid qualitative approaches.[30] Interviewees did not review their transcribed quotes in the matrix. In-person interviews were conducted in private rooms in four different health facilities where interviewees' responses could not be overheard. Only the data collectors and the interviewee were present for each interview.

Box 1: Topic guide

Barriers

- In your own words, can you talk me through why we didn't see you at that clinic?

Probing questions

  - Are there any other factors that prevented you from attending?
  - Is there anything else you'd like to share?

Solutions

- What would make the biggest difference in addressing these barriers?

Probing questions

- What else would help?
- What other changes could we make to the programme that would make it easier for you to attend?
- Are there any other specific changes that we could make to the way that the programme or eye clinics run?
- You mentioned [list their proposed solutions]. Some of these may be beyond our control, but if we managed to [list their proposed programme-related changes], do you think that would be enough?

That's the end of my questions. Is there anything else you would like to add?

Data analysis

We utilised an abductive analytic approach,[19] whereby data collectors initially entered verbatim quotes relating to barriers and solutions into a deductive framework matrix, nesting each quote under one of ten broad *a priori* themes that had emerged from a literature review that is described in our protocol:[31]

- Costs
- Distance and transport
- Desire/priority to seek care
- Clinical service quality
- Facilities
- Awareness & communication
- Fear
- Norms, values, health beliefs
- Empowerment, support & capacity
- Other (making room for surprising/unexpected themes)

At daily debrief sessions, SK and LA reviewed the matrix with the data collectors and used inductive coding to identify unique barriers and solutions. The decision to use an analytic matrix and collective interpretation was based on the findings of our previous systematic review, which had found these techniques to be rapid and robust.[30]

Our matrix had one participant per column and one sub-theme per row – with a new row created every time a sub-theme (a unique barrier or solution) was identified. Each sub-theme (e.g. 'loss of earnings') was nested under the relevant theme (e.g. 'costs') The process of data entry is demonstrated in this short online video (http://tinyurl.com/29asc6nm) and a blank matrix template is available here.

We generated one matrix for the telephone interviews and another for the in-person interviews. This was so that we could compare the themes that emerged from each modality in our embedded study. For our main analysis, presented here, we pooled all barriers and solutions identified using both modalities.

We trained the data collectors over two days and performed fourteen pilot telephone interviews before starting data collection. Videocall debriefing sessions were held at the end of each day.

Additional analysis

Our original equity analysis had also indicated that people with the highest incomes and those who owned a car or truck may have been less likely to attend that those reporting no vehicle ownership and lower incomes. We conducted an additional ten interviews with people who reported earnings in the highest income category to assess whether the barriers they reported differed from those reported by younger adults. We hypothesised that richer people did not access VIP services because they had sought private care after being identified with an eye need during eye screening.

Output and screening

We created a summary list of all of the unique solutions that had emerged from the interviews. Before taking these to a representative sample for ranking, we met with the implementing partner to identify any ideas that would be completely infeasible given the constraints of the programme e.g. providing helicopter transportation. Any interventions that were deemed to be completely infeasible were removed from the list. We asked the director of Peek Vision to independently review these decisions.

Stage 2: telephone survey

Survey instrument

We used the vetted list of solutions to generate a simple telephone-based survey (Appendix 2) where respondents were asked to rank each suggestions from 1-3 on a Likert scale:

4. It would make a big difference - i.e. if we introduced this change then you or people like you would definitely attend,
5. It would make a moderate difference - i.e. it would greatly increase the chances, but it would not be enough to guarantee attendance by itself,
6. It would make a small difference - i.e. it might help a few people, but the impact is likely to be minimal.

The telephone ranking survey was piloted with 26 people.

Sampling and recruitment

We used a 95% confidence interval, a 5% margin of error, and a conservative assumption that the total population size was 1 million people, rendering a minimum sample size of 384. We took the same list of 18–44-year-olds who had not been able to access care, and used random numbers to generate a call order, removing those who had already been included in the qualitative interviews. The same six data collectors tried calling each person three times before moving on to the next.

Data collection and Analysis

Data collectors obtained recorded informed verbal consent, and then read through the survey instrument using an online data entry form. Data collectors entered the respondents' score for each proposed solution. We calculated the simple mean for each solution, and then ranked solutions by mean score.

Stage 3: multistakeholder workshop

Once we had this ranked list of solutions, we convened an online workshop with representatives from the programme implementer, programme funder, the county and national health ministry teams, and our community advisory board. We facilitated a discussion where each stakeholder shared their perceptions of the likely impact, feasibility, costs, and risks associated with each solution. As external public health and research 'experts', LA and SK restricted their contributions to presenting the ranked solution scores, facilitating the discussion, and providing information on the general strength of the international research evidence for each of the proposed solutions. At the end of the workshop, we asked the participants to collectively agree on one or more solution to implement in the VIP programme. Figure 1 provides an overview of our entire approach.

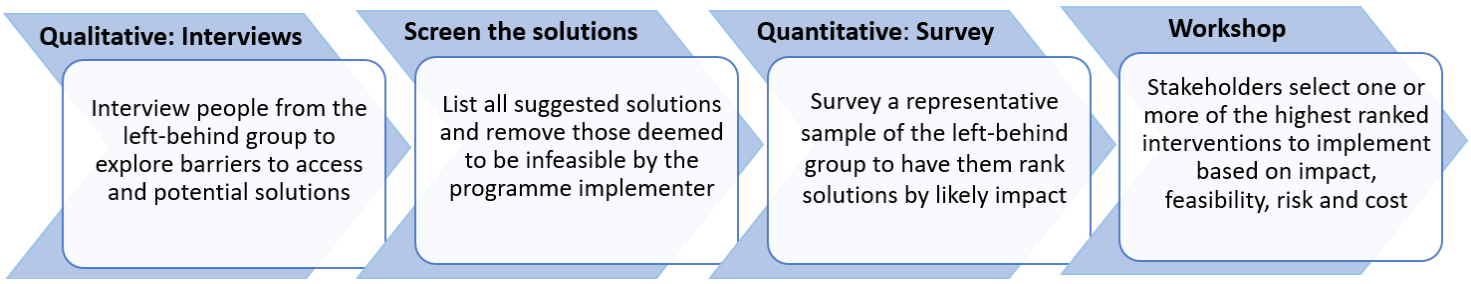

Figure 1: Overview of the sequential mixed-methods approach

This study was approved by KEMRI and LSHTM ethics committees. Those who attended in-person interviews were given a transport reimbursement of KES 500 (USD 3). We used the COREQ checklist to report our study (Appendix 3).

Findings

Interviews

We made 143 phone calls to invite people to participate in in-person and telephone interviews. Three people declined; 29 did not pick up after three calls; and 34 people agreed but either were not home (13 people) or did not arrive at the agreed interview location (21 people) on the day of their in-person interview; six were not eligible as they told us they had actually received care (i.e. they had not been checked-in properly); and four had moved to a different part of the country. In total we conducted 36 telephone interviews and 31 face-to-face interviews over the course of eight days in September 2023. All our participants were aged 18-44 years old and 53.2% were male.

We ended up performing more interviews than were needed to achieve thematic saturation with the 12+2 approach due to the efficiency of our data collectors. At the debrief on day two, they had already completed 24 telephone interviews. Our research leads had not assessed whether saturation had been reached by the time of the call, so – erring on the side of caution - they advised completing a further day of interviews. By the end of day three, 36 telephone interviews had been completed. A detailed retrospective saturation analysis, presented in Appendix 4, concluded that approximately 30 interviews were required to reach thematic saturation (Figure 1). We conducted 31 in-person interviews to enable fair comparison between telephone and in-person interviews for our embedded study.

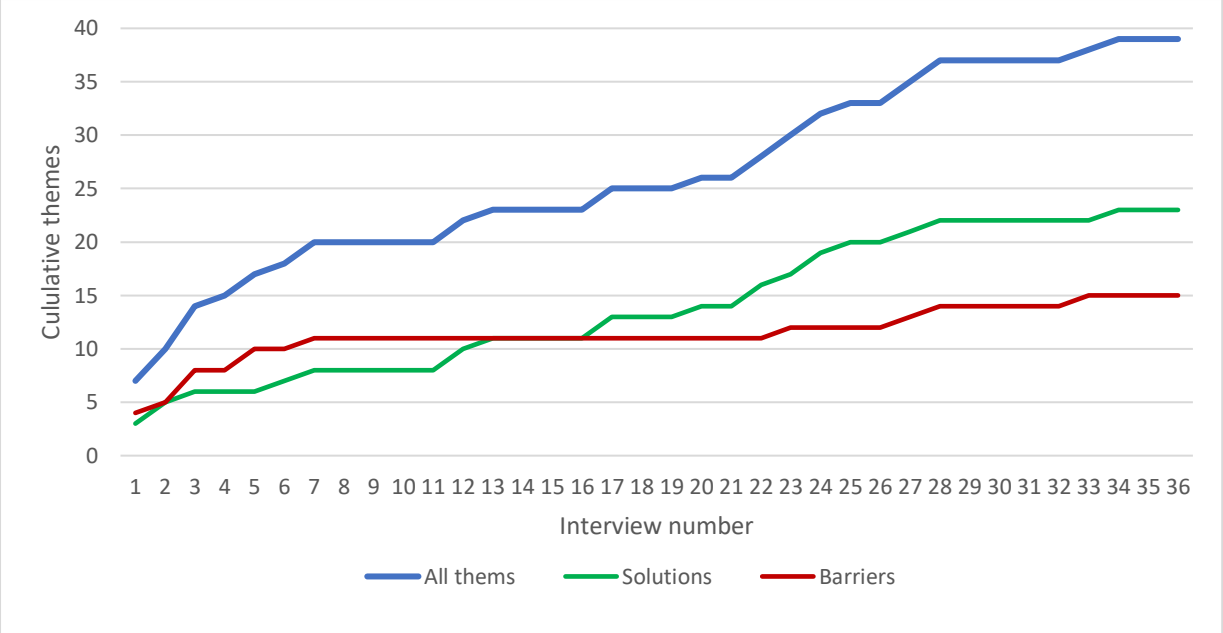

Figure 2: Accumulation of themes as the interviews progressed

Supplementary Table 1 (Appendix 5) presents the 21 unique barriers that were identified along with all the quotes from both sets of interviews. Direct, indirect, and opportunity costs; long queues; difficulty getting time off work; and insufficient information about opening times and dates emerged as important themes. We also identified several meta-themes; participants were generally able to access the clinic locations but left after seeing long queues of several hundred people. Many felt they could not 'waste time' waiting to be seen, given the associated loss of potential earnings.

> *"I choose to go to work to make money rather than spend my days' time not knowing whether I will get attended to… If I don't work, I don't get money. MFK008, in-person*

Another important cross-cutting theme was the perceived lack of information about the clinics: where they were, days of operation, opening and closing times, and what services were available. Assumptions around (non-existent) costs and early closures also prevented some people from attending.

> *"I also forgot the exact location where I was to go for the eye check-up and no one followed up to remind me of the place and date." MT33, telephone*

> *"They did not tell us if we need to come with money or not. Eye treatment, we are usually told to come with money. I assumed I'll go there and they will ask me for money and I did not have it." MFK204, in-person*

One interviewee also told us that the counselling he had received at the point of referral was inadequate. He wanted more information about what would happen at the clinic and on why attending was important, especially given that he did not even realise he had a problem:

> *"They just told me that I have problems with my eyes and I should visit [town name] dispensary so I did not know what I was going to do there, is it surgery, is it being given medication, is it being tested again? And for me I have always known that my eyes are okay, and on that day they told me that they are not okay. They were very brief and I didn't know what to expect, so that shock of being told that I have an eye problem which I have never had before is the reason why I did not go." MFI03, in-person*

In terms of novel barriers, one person told us that they left the queue because they were "an introvert" and didn't like the crowd (MT772, telephone); another felt their eye problem needed emergency treatment and sought care elsewhere (MFK02, in-person). One interviewee specifically named male health seeking behaviour as the main reason he didn't attend:

> *"As a man it is very hard to prioritize my health as I am manly focused on my family's wellbeing and It is easy to forget my health needs" (MT250Z, telephone).*

Finally, one young man explained that being made to queue alongside women and children was shameful:

> *"There were women on the line. They could have different lines for youths and women for some us to be comfortable because it is shameful to be on the same line with women and children, with worries how they will perceive me as young man. It was a challenge for me to just stand there with women… I had to go back that day without being attended even though right now my eyes have a problem. MT040, telephone*

The 25 proposed solutions to improve access centred around reducing the clinic queue lengths so that people could be seen quickly and then get back to work. Ideas included adding more clinics, holding them closer to villages or workplaces, increasing staff punctuality and speed, scheduling fewer people to attend each day, and extending the opening days and hours. The other meta-theme related to the provision of more detailed information around clinic services and opening times. Table 1 presents a summary of all 25 suggested solutions along with illustrative quotes. A full list all solution-related quotes is presented in Appendix 6.

Reviewing feasibility

As planned, we presented the list of all 25 suggestions to senior representatives from the implementing partner. We asked them to identify any suggestions that would be completely infeasible to deliver, given that they are responsible for funding all aspects of the programme. They felt that the programme budget would not permit additional payments for transport reimbursement or attendance incentives. Given that the outreach clinics involve multiple members of staff and large volumes of equipment and supplies, they also felt that it simply wouldn't be feasible to deliver a door-to-door version of the outreach clinic. These suggestions were removed from the list. The director of Peek Vision agreed with each of these decisions. The remaining 21 suggestions were put to a representative sample of people from the left behind group in a ranking survey.

Table 1: Solutions and implementing partner feasibility assessment

Potential solutions, by theme	Illustrative quotes	Feasibility review
Costs		
Provide transport fare	If I can be provided with fare, I would definitely attend the clinic because the challenge is income. MT 09 – telephone	*Insufficient programme budget*
Subsidise treatment	You should consider needy people who cannot afford [spectacles]… At least organise yourselves and look for the needy to help them, If I get that money I can go and get the spectacles because no one is happy when their bodies have a problem. I cannot even read the bible or the numbers on the phone. MT 148 – telephone	*Treatment is already provided for free*
Pay people to attend	I'm asking if we can be compensated with the amount we could have been paid, because we leave our job, so at least you are sure - even if you're not going to work on that day - your children are not going to sleep hungry. Because some of us, we're the providers of our families. MFI 04 – in-person	*Insufficient programme budget*
Distance and transport		
Move clinics closer to where people live and work	The outreach should be situated in a place which is easily accessible to many people and where many people live... It should not be very far from where people live. MT 28 – telephone	*Potentially feasible*
Provide transport	If you give me transport and day to come, I will come. MT 10 – telephone	*Insufficient programme budget*

Provide door-to-door services	Consider door-to-door services, but I don't know if that's possible. MFI 03 – in-person	*Insufficient programme budget*
Clinical service quality		
Improve punctuality and efficiency	I think those that are providing the services should be punctual and fast. MT 07 – telephone	*Potentially feasible, new measures already in place to improve efficiency*
Ensure that all medicines and glasses can be provided on-site	After being screened you should receive all the services like medicine and everything, you get solution for everything, but not again looking for services from other places. MFNG05 – in-person	*Potentially feasible*
Add more staff at each clinic	The doctors attending people should be many. Because like… people were so many, and most of them went back without being attended to. So if there were many doctors it would have been easy. MFK 009 – in-person	*Potentially feasible*
Facilities		
Keep the clinics open for a greater number of days	Add more days for the clinic so that people who did not manage to attend the clinic on their appointment dates can still get a chance to be treated. Many people have eye problems but they are also busy looking for ways of surviving during these tough economic times. MT 174Z – telephone	*Potentially feasible*
Extend clinic opening hours	If it's possible, if the exercise could extend the working hours, let's say from 4pm to 6pm, that one too I could manage, because I would have come from work. MFK02 – in-person	*Potentially feasible to keep clinics open until 6pm*

Keep the clinics open on the weekend	Maybe if the exercise could be scheduled off working days - that's during the weekend, in Saturday or Sunday, because at that time am free without work, I could turn up. MFK02 – in-person	*Potentially feasible*
Add more clinic locations	Have more many work station where people can easily access the services to reduce the distance people need to travel to get treatment. MT 010Z – telephone	*Potentially feasible*
Hold mop-up clinics for those who didn't manage to attend	The outreach should be conducted another time so that the people who were left unattended could be attended. MT48 - telephone	*Potentially feasible*
Give each person a specific appointment slot	The attendance number in the outreach should be issued in line with the referral messages clients received. The message should also have the attendance number and the time allocation to help the clients organize themselves to attend. MT772 - telephone	*Potentially feasible*
Schedule fewer people to attend each day	I would also like it if you control the number of people you schedule for a particular day, because now you have experience of how many people you can attend for a day, schedule just that amount of people so that everyone may be attended to. That way everyone will be aware what time they will attend so that they may not waste the whole day. It wasn't fair of you to call that many people, they were already sick and they had to wait for hours under the scorching sun. MFK 01 – in-person	*Potentially feasible*
Awareness & Communications		
Send a reminder text on the appointment day and the day before	That same same [sic] day for the clinic I should receive a reminder message to remind me to attend. I have many things I can easily forget… A reminder message should be sent before and during that day to attend the clinic. MT656 – telephone	*Potentially feasible*

Send a text to individuals who missed the outreach clinic to invite them to attend on another day	If a person never made it to the outreach, he should be notified of the next eye clinic outreach even if it is in another location. Because one cannot be busy all the time. MT46 - telephone	*Potentially feasible*
Phone call reminder, especially for those who cannot read	Maybe you can remind us by calling us - as you have today. MFKI08 – in-person	*Potentially feasible*
Explain why attending clinic is important at the point of referral	Also during screening we should be given more information why this clinic is important. MT656 – telephone	*Potentially feasible*
Use churches and radio broadcasts to remind people to attend	Mobilize the clinical outreach, especially on churches and radios. MT48 – telephone	*Potentially feasible*
Specify clinic opening and closing time at the point of referral	Communicate well on the exact opening and closing times, so that people may not come and get stranded outside and eventually go home without getting treated. There were so many people outside the facility who got devastated because they thought that the exercise would go on at least up to close of business hours. I feel like if you communicated well on the closing hours, I would have programmed myself well and come in the morning, whereby I could get the treatment that I required. MFNG03 – in-person	*Potentially feasible*
Allow people to choose their appointment day	Next time they should ask me when I am available instead of putting a date for me because of my work. The biggest challenge for me was timing.	*Potentially feasible*
Clarify what services are available at the outreach clinic and specify if	Clarify information, because of the Worldcoin* thing, so during screening we should be given more information. Anything free - people think it's hidden things. MT100 – telephone	*Potentially feasible*

there are any costs linked to these services	People should also be announced that they will be helped, not only will they be screened; there will be other help. MFNG03 – in-person	
Other		
Sperate younger people, women & children, and elderly people	Address the line issue and have women on their [own] lines. But youth can just have their line where we can mingle and interact - for example on how hard the economy is - and by the time we realise the line is shortening. But with women on the same line we will not have anything to talk about. MT040 – telephone What I would want you to improve is that next time hire competent queue managers who control how people are coming in, and the elderly, pregnant mothers and mothers with small children to be put on their own queue so that there will be effective treatment. MFK01 – in-person	*Potentially feasible*

*For more on the Worldcoin controversy see: https://time.com/6300522/worldcoin-sam-altman/

Survey and selection workshop

It took two days to train the data collectors and pilot the survey, and five days to complete ranking exercise. In total, data collectors called 440 people, of whom 401 completed the survey (response rate = 91%).

All of the suggestions received a mean score between 2.4–2.9, indicating that all of the potential solutions were felt to offer at least a moderate chance of improving attendance. Table 2 presents the scores for individual-level solutions (that could be tested in an individually randomised RCT) and solutions that would be implemented at the clinic level (requiring testing with cluster RCTs).

Our online workshop included representatives from the community advisory board, the screening programme implementing partner organisation, the programme funder, the national eye screening programme office, Kenya Society for the Blind, and the county health department. After our team had presented the survey findings, we facilitated a discussion around each of the proposed solutions in turn.

The majority of the suggested clinic-level interventions required additional human resources or clinic locations. The programme funder and implementing partner recognised the issues around long queue times in some locations, but were very clear that inflation had already taken the programme over budget and there were no spare resources to introduce additional clinics or staff. The top-ranked suggestion related to frustration experienced by people who attended the treatment outreach clinic but were found to have a complex eye problem that required onward referral to the local hospital for specialist spectacles (where care is subsidised but not free). The workshop participants also recognised this problem, but agreed that it was not possible to have advanced ophthalmic care services present at each outreach clinic. The group suggested clarifying the process of tiered referrals during counselling. The workshop participants felt that organising separate queues for different ages and genders would be practically feasible, however imposing separation may cause problems for friends/family/colleagues who attend together. After reviewing all of the suggestions, the workshop participants unanimously agreed to implement and test the following bundle of interventions relating to counselling and the provision of enhanced information in SMS reminders:

- Send a reminder text on the appointment day and the day before
- Clarify what services are available at the outreach clinic and costs linked to these services
- Specify clinic opening and closing time at the point of referral
- Explain why attending clinic is important at the point of referral

Overall, the ethics review process took four months. The interviews took nine days to complete, and the survey took seven days, including training and piloting. We held the multistakeholder workshop one month after the survey had concluded, with the delay driven by scheduling challenges.

Table 2: Mean scores for each of the suggested solutions and workshop consensus

Service modifications	Score	Workshop consensus
Individual-level solutions that could be implemented and tested with individual-level RCTs		
Phone people who cannot read to remind them to attend	2.93	Operationally feasible but time-consuming, and therefore expensive. To be considered in the future if additional funds become available
Send a text to individuals who missed the outreach clinic to invite them to attend on another day	2.93	This is predicated on holding additional mop-up clinics, but there are no available additional funds for these
Clarify what services are available at the outreach clinic and specify if there are any costs linked to these services	2.88	Feasible. This information can be provided verbally and in a follow-on SMS reminder message
Send a reminder text on the appointment day and the day before	2.88	Messages are already sent the day before. We can add another message on the day of the appointment
Specify clinic opening and closing time at the point of referral	2.77	Feasible. This information can be provided verbally and in a follow-on SMS reminder message
Explain why attending clinic is important at the point of referral	2.76	Feasible. This information can be provided verbally and in a follow-on SMS reminder message
Give each person a specific appointment slot	2.56	This is not operationally feasible
Clinic-level interventions that could be implemented and tested with cluster RCTs		
Ensure that all medicines and glasses can be provided on-site (i.e. rather than having to refer specialist cases to the local hospital)	2.96	It is not possible to provide comprehensive specialist services at every clinic due to limited numbers of ophthalmologists. This is a communication issue here around which services/supplies are available at outreach clinics

Add more staff	2.95	This is not currently feasible with the current levels of programme resourcing
Add more clinic locations to reduce the distance people have to travel	2.94	This is not currently feasible with the current levels of programme resourcing
Hold mop-up clinics a week or so later for those who didn't manage to attend	2.93	This carries a cost implication but may be feasible in the future
Keep the clinics open for a greater number of weekdays	2.91	This is not currently feasible with the current levels of programme resourcing
Use churches and radio broadcasts to remind people to attend	2.85	There is a risk that people who have not been screened (and may have normal vision) will attend outreach clinics, overwhelming services
Increase the punctuality and speed at which our staff work	2.85	Work is already underway across all clinics to improve efficiency. There are no further specific ideas that we could test here
Refer fewer people for the same day to reduce queue numbers on each day	2.83	Not feasible due to associated costs of holding extra clinics on additional days
Have a separate line for older people	2.73	Feasible
Add additional clinic locations, including in public buildings	2.64	All available and appropriate spaces are currently being used, including public buildings
Have separate lines for women and children	2.60	Feasible
Keep the clinics open on the weekend	2.56	This is not currently feasible with the current levels of programme resourcing.
Have a separate line for younger people	2.55	Feasible
Keep the clinics open until 6pm	2.50	This is not currently feasible with the current levels of programme resourcing.
Allow people to choose their appointment day	2.43	This is not operationally feasible

Green = feasible, orange = potentially feasible, red = not feasible

The current verbal counselling script and SMS reminder messages that are used in the VIP programme are presented in Box 2. The SMS reminders are currently sent on the day of referral and the day before the clinic appointment. We drafted a new verbal counselling script and SMS reminder message that included the suggested new elements that were agreed in the workshop. We asked the workshop participants to review the new wording via email, as well as two representatives from the left behind group. Based on this feedback we made three minor changes. The original script and description of these changes is presented in Appendix 7. The enhanced counselling and SMS reminder will be tested in an individual-level RCT in a subsequent study.

Box 2: Original and new counselling and SMS reminder wording

Usual care counselling, delivered verbally at the point of referral

"I have examined your eyes, and you have a problem. I have referred you in the system and you will receive an SMS with where and when you are supposed to attend treatment. You will come for treatment on <<date>> at <<location>>. The examination will be free and you will be informed of anything else on the material day.

Current SMS reminder, sent on the day of referral and day before the appointment

Dear <<name>>, you were examined and found to have an eye problem. Kindly report on <<location>> on <<date>> for assessment. For more information contact Meru Referral Hospital.

Enhanced counselling script, based on interview, survey, and workshop feedback

"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 and provide any eye drops or medicines that you might need. If you need glasses, the specialists will tell you what kind you need, and what your prescription is. The assessment is completely free. Note that a small proportion of people will be found to have complex eye problems that require onward referral for hospital assessment and special lenses that cost more than standard glasses. However, the vast majority of people have their needs fully met at the outreach triage clinic and do not need hospital referral.

With treatment, you will be able to see more clearly. This will help with your work, seeing faces, and using your phone. It is important that you attend the clinic to protect your vision. The clinic will only be running from <<day>> to <<day>>, so if you don't manage to attend, you may not be able to get free care again in the future."

Enhanced SMS reminder, based on interview, survey, and workshop feedback, to be sent on the day of referral, the day before the appointment, and on the day of the appointment

We found that you had an eye problem. Please attend the outreach clinic at <<location>> on <<date>> between <<9am-2pm>>. The specialist assessment is free

If you are found to have a complex problem, you may be referred to a hospital for further care or specialist glasses, and this may include a fee

However, the vast majority of people who attend the outreach get their eye problem fixed without the need for any further referral

It's important that you attend to protect your vision, and you might not have a future opportunity to access free care. See you on <<date>>

Sensitivity analysis

We conducted ten additional interviews with high-income individuals aged 18-44 who had not managed to access care, based on previous evidence that this group were potentially facing unique barriers. We triangulated the themes with those from the other interviews. High-income interviewees did not mention loss of wages as a potential barrier, but the cost of treatment and transport were raised, along with conflicting engagements, long queues, and lack of clear information. No unique or discordant barriers were identified. Similarly, the solutions raised were closely aligned with those from the other interviews, including requests for financial subsidies and incentives – suggesting that this group were not necessarily very affluent i.e. our original 'high-income' threshold (USD 2,600/year, aligned with the national top income tax threshold) was set too low. The only unique solutions related to a request for more stylish spectacle frames; "Next time come with spectacles of good standard, not for the old people." (HIG3); the use of Community Health Promoters to remind people to attend; and asking for permission from employers to get time off. Full quotes and codes are presented in Appendix 8.

Discussion

We conducted 67 interviews and 401 solution ranking exercises with people from the sociodemographic group that had previously been found to face the greatest barriers to accessing eye care services in Meru – young adults aged 18-44 years. These people told us that lack of clear information, long queues, and the opportunity costs associated with long queues were the main barriers to receiving care. Whilst lack of clear information and inadequate counselling have emerged from multiple previous studies in diverse settings and populations,[32–36] the theme of long queues does

not commonly appear in the wider literature or appear as one of the drop-down barrier options that is used in *Rapid Assessment of Avoidable Blindness* (RAAB) surveys that have been deployed in over 80 countries.[37] We postulate that the ubiquity and fundamental intractability of this problem in resource-scarce settings leads to them being perceived as the status quo rather than a specific barrier. Research from several other African countries suggests that most patients generally wait 1-4 hours to receive ambulatory care,[38–43] and even in a well-resourced setting like the UK, 10% of patients are currently waiting more than 12 hours to receive emergency care.[44] Younger adults may be more sensitive to long wait times as they are more likely to be in active employment than older adults, and may be more likely to be 'hustling' with multiple informal jobs that do not provide protected sick leave, meaning that they experience the greatest potential opportunity costs from waiting in line for several hours.[45]

Rapidly surveying a representative sample of younger adults enabled us to move from subjective to generalisable themes. For instance, if we had stopped after completing the interviews, we would not know whether the issue of mixing men and women in the queues was a major structural barrier to access for this group, an unusual individual quirk, or something in-between. In the event, we found that scores accorded to all of the 21 potential solutions clustered between 2.5-3.0, indicating that members from the left behind group felt that all of the suggestions were moderately-to-highly likely to improve access to care. We cannot exclude the possibility that the universally high scores are at least partially driven by cultural norms and/or a form social desirability bias.[46,47] We took all of the ranked suggestions to a multistakeholder meeting that included representatives from the left behind group, the local community, the programme funder and implementer, and a national eye charity. This group weighed the rankings against considerations of the risks posed by each intervention, their collective estimation of likely impact, the associated costs, and the operational feasibility of implementing each solution. This group reached a consensus agreement to focus on a bundle of solutions aimed at providing timely and clear information about the outreach clinics.

The selected interventions focus on empowering individuals with the information they need. However, a different perspective is that the workshop participants dismissed more highly-ranked service-side solutions in lieu of minor interventions that place responsibility for access on intended service users, in line with the widely debunked 'information deficit model'.[48] Allen has previously argued that efforts to equitably advance UHC and 'health for all' should focus on unjust social structures and resist focussing wholly on 'downstream' technocratic solutions. In the context of this study, the paucity of good jobs, the absence of adequate social welfare systems and strong labour laws that guarantee paid sick leave are examples of major structural challenges for younger adults, however these were not raised by the interviewees.

The greatest strengths and limitations of our approach pertain to voice and epistemic justice.[13] We strove to centre our approach around the perspectives of those with lived experience of not being able to access care. The 'pose' and 'gaze' of the project[15] focus on the credibility and value of this group, as well as locally recruited data collectors' work in sensemaking through their initial interpretative work as they engaged with the analytic matrix. Findings from this process fed directly into the local programme, with their implications wholly determined by local stakeholders. Although Europeans and Kenyan public health experts were involved in leading the project, the primary interpretation was locally owned and the resulting solutions will be locally implemented for the benefit of local Meru residents.

The programme funder and implementing partner held veto rights as they were ultimately responsible for delivering service modifications and could not be 'made' to implement any of the suggested service modifications. However, community, charity, and public health stakeholders reached one accord with the programme leads on the infeasibility of introducing additional staff of clinics given their shared appreciation of how inflation had literally decimated the programme budget. Nevertheless, our approach involved (and necessitated) epistemic tension; even though all of the solutions came from the left behind group, the final decision on how to modify the programme required consensus between different stakeholder groups with imperfectly overlapping interests and unequal power in the final determination. We feel that including programme managers is a design strength rather than a flaw, as there is no value in presenting programmes with a *post-hoc* shortlist of unworkable suggestions. Furthermore, the process of bringing them into conversation with community members, eye care advocates, and representatives from the left behind group can create shared understanding and constructive dialogue. Our role as 'external' research leads primarily involved developing rapid and robust methods that would surface non-tokenistic and reliable suggestions, as well as convening actors and facilitating the overall process. We aim to work with local partners to embed this approach so that future iterations can be wholly led by local teams.

Finally, our unplanned sampling deviation led us to conduct more interviews than expected. The post-hoc sensitivity analysis presented in Appendix 3 suggests that if we had adherence to our original '12+2' approach, we would have missed four barriers and 12 additional solutions. We agree with Guest and colleagues that current approaches to assessing and reporting saturation in qualitative research are opaque, however our empirical analysis suggests that – for studies like ours – saturation is only reached after three interviews in a row reveal no new themes, after a minimum of 15 initial interviews have already been conducted (the '15+3' approach).[23]

Conclusions

Interviews and ranking surveys conducted with people who were not able to access eye care services identified 21 barriers and 25 potential solutions, centring around reducing the time it takes to be seen, and providing clearer information about the eye clinics. Multistakeholder workshop participants ended up selecting interventions that did not fundamentally alter how clinics are operated, instead opting for amendments to the way that information is provided. Even so, these service modifications came directly from those who were being left behind, and were rated likely moderately-to-highly likely to improve access. Including service funders and managers in interpretive and deliberative processes means that our findings will result in concrete, locally-led service modifications. Further work will evaluate the impact of these changes using an embedded, pragmatic RCT.

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Appendix 1: Call scripts

Telephone interview consent script and topic guide

Hello, my name is_____. I am a researcher from KEMRI, working with the Ministriy of Health and the VIP eye screening programme.

Your recently had your eyes screened and were found to need further assessment. Our records indicate that, like many other people, you were unable to attend that appointment.

You are being contacted because you have previously provided consent to be contacted regarding research being conducted for eye care services. I am calling to invite you to participate in a 15-minute interview. Your participation is completely voluntary. This means that you do not have to do it unless you want to.

We want to understand the barriers that prevented you from attending. We are also asking about how we could change the VIP programme to make it easier for people like you to attend appointments.

Before agreeing, here is the background information that you need to know:

We have invited you because, like many other people, you did not attend. We want to hear about the issues that you personally faced that prevented you from attending, and your ideas on how to make things easier. In total we are aiming to interview about 20 people.

Who are we? I work with a group of researchers from the KEMRI and the London School of Hygiene and Tropical Medicine. We are working to improve the VIP eye screening programme. The leaders of the research are Prof Michael Gichangi and Dr Luke Allen.

We will take the responses from all of the interviews and discuss the ideas for improvement with the leaders of the national programme. We hope to use your suggestions to make the programme work better.

We are also conducting a set of face-to-face interviews with other people who did not manage to access care. We want to compare the responses we get from these different approaches.

In this 15-minute interview there are no risks or benefits to you. It is important to note that agreeing or declining to take part does not have any impact on the services you receive.

You can stop the interview at any time.

I will record the interview. Our team will anonymise your data and keep it safe and secure on a password-protected computer in London. When the study is completed, we will write-up our findings

and publish them online so that other researchers can use the information to help people in other places.

The KEMRI and London School of Hygiene and Tropical Medicine ethics committees have both approved this study.

You can ask me any questions you like now. I can also give you the email address and phone number of the lead researchers if you'd like to contact them directly [provide the contact details for Sarah Karanja or Luke Allen as required]. If you have any other concerns I can also give you the contact details for the London School of Hygiene and Tropical Medicine Research Governance and Integrity Office.

Do you have any questions?

Are you happy to begin the interview?

[If yes, proceed; if no thank them for their time and end the call]

Opening questions

To start with, during the home visit by the vision impact project team, please describe your experience with the eye screening.

Probes:

- How long did the examination take?
- Was the test comfortable? If yes, why? If no, why not?

Barrier elicitation questions

You were assessed at home and found to have an eye problem that required further assessment. You were asked to attend the community eye clinic on [date] and reminders were sent to this mobile number.

- In your own words, can you talk me through why we didn't see you at that clinic?

Probing questions

- Are there any other factors that prevented you from attending?
- Is there anything else you'd like to share?
- Of the issues you mentioned, which is the most important?

Solution elicitation questions

The last part of the interview is exploring whether there is anything we could do to address these barriers and make it more likely that you will attend in the future.

- So to start, what would make the biggest difference?

Probing questions

- What else would help?
- What other changes could we make to the programme that would make it easier for you to attend?
- Are there any other specific changes that we could make to the way that the programme or eye clinics run?
- You mentioned [list their proposed solutions]. Some of these may be beyond our control, but if we managed to [list their proposed programme-related changes], do you think that would be enough?

That's the end of my questions. Is there anything else you would like to add?

Probing questions

- After missing the outreach clinic appointment, did you seek medical care from a different healthcare facility for your eye condition?
- If no, why not?
- If yes, where did you seek medical care?

Thank you so much for your time.

Call script to invite people to participate in an in-person interview.

Hello, my name is_____. I am a researcher from the Kenya Medical Research Institute (KEMRI), working with the Ministries of Health and Education on the Vision Impact Project eye screening programme.

You recently had your eyes screened at the community outreach programme and was found to need further assessment. Our records indicate that, like many other people, you were unable to attend that appointment.

You are being contacted because you have previously provided consent to be contacted by Ministry of Health partner organisations regarding research being conducted for eye care services. I am calling to invite you to participate in an in-person interview in the next few weeks. Your participation is completely voluntary. This means that you do not have to do it unless you want to.

If you agree, I will arrange to meet you in or near where you live to ask you some questions about the barriers that prevented your child from attending. I also want to ask about how we could change the Vision Impact Project to make it easier for people to attend appointments.

To compensate you for your time you will receive a [KES 500 equivalent] airtime voucher.

If you are interested, I can send you the full study information via WhatsApp or email or talk it through on the phone with you now.

[switch to phone PIL script here as required]

Appendix 2: Quantitative Ranking Survey

Interviewer name

Short-answer text

Participant ID
Short-answer text

Consent

Good morning/afternoon

My name is .... and I'm calling from the Vision Impact Project eye screening programme. We saw you a few weeks ago and referred you to the local clinic, but we did not see you on your appointed day.

In fact, half of all people who were referred did not attend. We have sought feedback on ways we could improve our service, and I wanted to ask you which of the ideas we have stand the best chance of helping people like you to access care. It should take approximately 15 minutes of your time.

If you are happy to proceed, I need to tell you a bit more about the survey. I will then double-check that you are still happy to proceed.

I will ask you about a set of potential changes that we are thinking about making. I will ask you to rate each one in terms of how likely you think it is to make a difference at helping people access our clinics.

Your responses will help us to shape and improve our services for others, but there are no direct benefits to you for taking part. Thinking about the issues that prevented you from getting care may be distressing to you. If you face any discomfort because of the questions asked, you can skip any question or ask to end the call whenever you choose.

If you don't want to take part, that's ok. You can drop out of the survey at any point. Your decision will not affect your health care or your future relations with the Vision Impact Project in any way.

Your anonymised answers will be combined with those from other people and kept safe and secure on password-protected computers in Nairobi and London. None of the data will be used for commercial use. We will publish our findings in a research journal and in a public repository so that other researchers can learn from what we find. You personal information will not be included in our findings and there is no way that you can be identified from any of the reports that we will produce.

If you have any questions, you can ask me now, or I can put you in contact with the study coordinator - Sarah Karanja from Kenya Medical Research Centre. If you have any questions about your rights as a research participant, I can connect you with the Kenya Medical Research Centre Ethics team who approved this survey.

Does that all make sense? Do you have any questions for me?

Are you happy for me to start?

The first two potential improvements are aimed at making it easier for people to get to a clinic.

There are three options to choose from:

1. It would make a small difference - i.e. it might help a few people, but the impact is likely to be minimal

2. It would make a moderate difference - i.e. it would greatly increase the chances, but it would not be enough by itself to guarantee attendance by itself

3. It would make a big difference - i.e. if we introduced this change then you or people like you would definitely attend

If we add more clinic locations to reduce the distance people have to travel, how likely is that to make a difference?

1 []
2 []
3 []

Expand the list of referral clinics to include additional public health facilities and private and faith-based hospitals

1 []
2 []
3 []

The next set of improvements are about reminding people about the clinic

Explain why attending clinic is important at the point of referral
1 []
2 []
3 []

Clarify what services are available at the outreach clinic and specify if there are any costs linked to these services

1 []
2 []
3 []

Send a reminder text on the appointment day and the day before

1 []
2 []
3 []

Send a text to individuals who missed the outreach clinic to invite them to attend on another day

1 []
2 []
3 []

Phone people who cannot read to remind them to attend

1 []
2 []
3 []

Use churches and radio broadcasts to remind people to attend

1 []
2 []
3 []

The next set of improvements are about extending clinic opening hours

Keep the clinics open for a greater number of weekdays
1 []
2 []
3 []

Specify clinic opening and closing time at the point of referral

1 []
2 []
3 []

Keep the clinics open until 6pm

1 []
2 []
3 []

Keep the clinics open on the weekend

1 []
2 []
3 []

Hold mop-up clinics a week or so later for those who didn't manage to attend

1 []
2 []
3 []

Allow people to choose their appointment day

1 []
2 []
3 []

The next set of improvements are about reducing waiting times

Add more staff to reduce the queue waiting time
1 []
2 []
3 []

Refer fewer people for the same day to reduce queue numbers on each day

1 []
2 []
3 []

Give each person a specific appointment slot

1 []
2 []
3 []

Increase the punctuality and speed at which our staff work

1 []
2 []
3 []

Have a separate line for younger people

1 []
2 []

3 []

Have separate lines for women and children

1 []
2 []
3 []

Have a separate line for older people

1 []
2 []
3 []

The final set of improvements are about stocks & supplies

Ensure that clinics are fully stocked so that all medicines and glasses can be provided on-site
1 []
2 []
3 []

Thank you so much for your time, we really appreciate your generosity, your responses will help us to improve the service

Is there anything else you would like to feed-back to us?
Long-answer text

Thank you again, goodbye

Appendix 3: COREQ checklist

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	9, 10
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	1, 2, 3
Occupation	3	What was their occupation at the time of the study?	1, 2, 3
Gender	4	Was the researcher male or female?	9, 10
Experience and training	5	What experience or training did the researcher have?	1-3, 9, 10, 11
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	9, 36, 38
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	36, 38, 39
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	9
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	8, 9, 11
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	8, 9
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	9
Sample size	12	How many participants were in the study?	14, 23
Non-participation	13	How many people refused to participate or dropped out? Reasons?	14, 23
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	10, 12, 13
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	10, 13
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	14
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	10-12, 22-23,
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	N/A
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	9, 10, 13
Field notes	20	Were field notes made during and/or after the inter view or focus group?	10, 11
Duration	21	What was the duration of the inter views or focus group?	36, 40
Data saturation	22	Was data saturation discussed?	9,14,29,47-54
Transcripts returned	23	Were transcripts returned to participants for comment and/or	10

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	10, 11
Description of the coding tree	25	Did authors provide a description of the coding tree?	11
Derivation of themes	26	Were themes identified in advance or derived from the data?	11
Software	27	What software, if applicable, was used to manage the data?	11
Participant checking	28	Did participants provide feedback on the findings?	12, 13, 17
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	10, 11, 55-83
Data and findings consistent	30	Was there consistency between the data presented and the findings?	14-17
Clarity of major themes	31	Were major themes clearly presented in the findings?	18-22
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	12, 27

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.

Appendix 4: Post-hoc saturation analysis

We originally set out to use Guest and colleague's simple formula for assessing whether thematic saturation had been achieved.[1] They describe saturation as "the point in data collection and analysis when new incoming data produces little or no new information to address the research question", and identify three components that can be used to establish when this point occurs:

- The base, i.e. the minimum number of interviews to be conducted before calculating whether saturation has been achieved. It is similar to the 'initial analysis sample' described by Francis et al.[2] Guest et al suggest base sizes of 4-6, based on a review of the literature.
- The run length, i.e. the number of interviews that we review to assess whether any new themes have emerged, with reference to those that have already emerged in the base. Guest et al suggest conducting runs of 2-3.
- The new information threshold, i.e. the number of new themes identified in each run as a proportion of the themes identified in the base interviews. Guest et al suggest that researchers may want to stipulate that saturation is only achieved when a run identifies no new themes (new information threshold = 0%), or that the new themes identified represent ≤5% of the themes identified in the base interviews.

We set out to use a conservatively large base size of 12 interviews, based on a literature review presented in our protocol,[ref] with runs of two, and a 0% new information threshold. We also decided that we would compare the new information (number of themes) identified in the runs against all previous interviews, rather than just those in the base.

As detailed in our findings section, we ended up conducting 36 interviews. By reviewing the number of themes that were identified in each interview, we are able to retrospectively assess the point at which saturation would have been reached using a range of different base, run, and new information threshold permutations.

For our initial analysis (Table 1), we used a base of 12 and compared new information obtained from each run of two interviews against the themes identified from the original base of 12 interviews. We performed individual analyses for barriers and solutions. We highlighted the points at which the new of 0% was met.

Table 1: Saturation for barriers and solutions with runs of two compared to a base of 12

Interview number	Barriers				Solutions			
	Barriers identified	Novel barriers	Cumulative barriers	New info: runs of 2	Solutions identified	Novel solutions	Cumulative solutions	New info: runs of 2
1	4	4	4	N/A	3	3	3	N/A
2	4	1	5	N/A	3	2	5	N/A
3	3	3	8	N/A	1	1	6	N/A
4	2	0	8	N/A	1	1	6	N/A
5	3	2	10	N/A	2	0	6	N/A
6	1	0	10	N/A	2	1	7	N/A
7	1	1	11	N/A	2	1	8	N/A
8	1	0	11	N/A	1	0	8	N/A
9	1	0	11	N/A	0	0	8	N/A
10	1	0	11	N/A	1	0	8	N/A
11	3	0	11	N/A	1	0	8	N/A
12	1	0	11	N/A	1	2	10	N/A
13	1	0	11	N/A	1	1	11	N/A
14	1	0	11	0.0%	1	0	11	10.0%
15	1	0	11	0.0%	2	0	11	0.0%
16	1	0	11	0.0%	0	0	11	0.0%
17	1	0	11	0.0%	2	2	13	20.0%
18	1	0	11	0.0%	1	0	13	20.0%
19	1	0	11	0.0%	1	0	13	0.0%
20	2	0	11	0.0%	2	1	14	10.0%
21	1	0	11	0.0%	1	0	14	10.0%
22	1	0	11	0.0%	4	2	16	20.0%
23	2	1	12	9.1%	2	1	17	30.0%
24	1	0	12	9.1%	3	2	19	30.0%
25	2	0	12	0.0%	3	1	20	30.0%
26	0	0	12	0.0%	1	0	20	10.0%
27	1	1	13	9.1%	2	1	21	10.0%
28	2	1	14	18.2%	1	1	22	20.0%
29	2	0	14	9.1%	2	0	22	10.0%
30	1	0	14	0.0%	1	0	22	0.0%
31	2	0	14	0.0%	2	0	22	0.0%
32	2	0	14	0.0%	2	0	22	0.0%
33	2	1	15	9.1%	1	0	22	0.0%
34	0	0	15	9.1%	1	1	23	10.0%
35	0	0	15	0.0%	1	0	23	10.0%
36	0	0	15	0.0%	1	0	23	0.0%

Table 1 shows that two interviews in a row were completed with no new barriers identified by interview number 14. By this point, 11 barriers had been identified. In the remaining 22 interviews a further four barriers were identified.

For the solutions, saturation was achieved by interview number 15. By this point 11 unique solutions had been identified. By the end of 36 interviews, a further 12 solutions had been identified.

In summary, had we used Guest and colleagues approach with a conservative base of 12, less conservative runs of two, and a very conservative new information threshold of 0%, we would have stopped after interview number 15, missing out on a third of the unique barriers that emerged across our 36 telephone interviews.

In our next analysis, we counted the total number of barriers *and* solutions (themes) that emerged from each interview. We ran six additional scenarios, using runs of two, three, and four against the base of all themes identified in the first 12 interviews. We also used runs of two, three, and four against all themes identified in all preceding interviews.

Table 2: Different run lengths and base sizes to assess saturation, using all themes in each interview

Interview number	Themes identified	Novel themes	Cumulative themes	Runs of 2		Runs of 3		Runs of 4	
				Base = 12	Base ≥12	Base = 12	Base ≥12	Base = 12	Base ≥12
1	7	7	7						
2	7	3	10						
3	4	4	14						
4	3	1	15						
5	5	2	17						
6	3	1	18						
7	3	2	20						
8	2	0	20						
9	1	0	20						
10	2	0	20						
11	4	0	20						
12	2	2	22						
13	2	1	23						
14	2	0	23	4.5%	4.5%				
15	3	0	23	0.0%	0.0%	4.5%	4.5%		
16	1	0	23	0.0%	0.0%	0.0%	0.0%	4.5%	4.5%
17	3	2	25	9.1%	8.7%	9.1%	8.7%	9.1%	8.7%
18	2	0	25	9.1%	8.7%	9.1%	8.7%	9.1%	8.7%
19	2	0	25	0.0%	0.0%	9.1%	8.7%	9.1%	8.7%
20	4	1	26	4.5%	4.0%	4.5%	4.0%	13.6%	13.0%
21	2	0	26	4.5%	4.0%	4.5%	4.0%	4.5%	4.0%
22	5	2	28	9.1%	7.7%	13.6%	12.0%	13.6%	12.0%
23	4	2	30	18.2%	15.4%	18.2%	15.4%	22.7%	20.0%
24	4	2	32	18.2%	14.3%	27.3%	23.1%	27.3%	23.1%
25	5	1	33	13.6%	10.0%	22.7%	17.9%	31.8%	26.9%
26	1	0	33	4.5%	3.1%	13.6%	10.0%	22.7%	17.9%
27	3	2	35	9.1%	6.1%	13.6%	9.4%	22.7%	16.7%
28	3	2	37	18.2%	12.1%	18.2%	12.1%	22.7%	15.6%
29	4	0	37	9.1%	5.7%	18.2%	12.1%	18.2%	12.1%
30	2	0	37	0.0%	0.0%	9.1%	5.7%	18.2%	12.1%
31	4	0	37	0.0%	0.0%	0.0%	0.0%	9.1%	5.7%
32	4	0	37	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
33	3	1	38	4.5%	2.7%	4.5%	2.7%	4.5%	2.7%
34	1	1	39	9.1%	5.4%	9.1%	5.4%	9.1%	5.4%
35	1	0	39	4.5%	2.6%	9.1%	5.4%	9.1%	5.4%
36	1	0	39	0.0%	0.0%	4.5%	2.6%	9.1%	5.4%

Table 2 shows that using a more conservative base that includes all interview conducted does not materially change the point at which saturation is deemed to have been achieved. However, increasing the run length from three to four was a associated with a much later saturation point; 32 interviews with a 0% new information threshold. Interestingly, the use of a higher new information threshold (<5%) would lead to very similar saturation points of between 14-16 interviews depending on run length.

Finally, we plotted the cumulative themes that emerged over the course of the 36 interviews. Figure 1 illustrates the fact that the majority of unique barriers were identified by interview number seven, followed by a long plateau. Shorter plateaus in the number of solutions arising from interviews 7-11 and 13-16 were followed by incremental gains until levelling off again around interview number 28. The paucity of new information arising from interviews 13-16 drive the saturation decisions in the analyses performed above.

Figure 1: Accumulation of themes as the interviews progressed

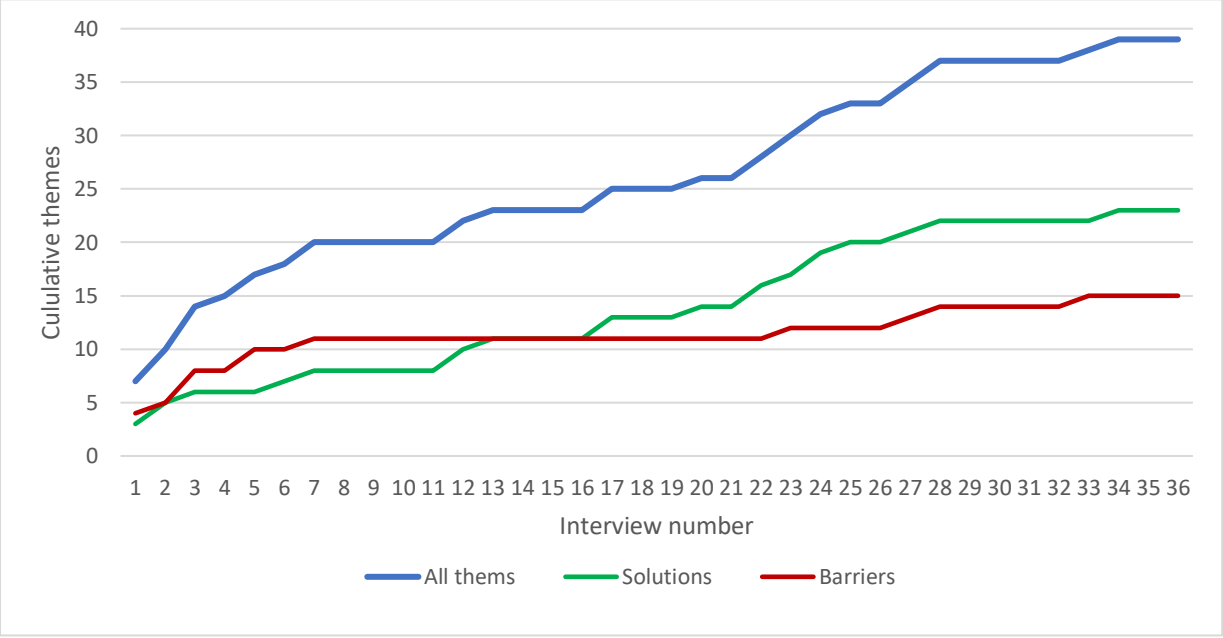


Figure 1 suggests that for this specific set of interviews, a base size of 15 and a run length of three might have yielded a more appropriate saturation point, given that new themes continued to accrue until around interview number 28. Table 3 shows that using a conservative base of ≥15 interviews and

a new information threshold of 0% leads to saturation by interview number 30, 31, and 32 with respective run lengths of two, three, and four.

Researchers like Coenen et al. have suggested that run lengths of two are adequate,[3] whilst others have recommended runs of three.[2,4] Based on our findings presented in table we decided that we would use a base of ≥15 and runs of three for future studies.

Table 3: Re-running the saturation analysis with a base of => 15 and runs of 2-4.

Interview number	New information with a base of ≥15		
	Runs of 2	*Runs of 3*	*Runs of 4*
15			
16			
17	8.7%		
18	8.7%	8.7%	
19	0.0%	8.7%	8.7%
20	4.0%	4.0%	13.0%
21	4.0%	4.0%	4.0%
22	7.7%	12.0%	12.0%
23	15.4%	15.4%	20.0%
24	14.3%	23.1%	23.1%
25	10.0%	17.9%	26.9%
26	3.1%	10.0%	17.9%
27	6.1%	9.4%	16.7%
28	12.1%	12.1%	15.6%
29	5.7%	12.1%	12.1%
30	0.0%	5.7%	12.1%
31	0.0%	0.0%	5.7%
32	0.0%	0.0%	0.0%
33	2.7%	2.7%	2.7%
34	5.4%	5.4%	5.4%
35	2.6%	5.4%	5.4%
36	0.0%	2.6%	5.4%

Application to second data set

As we had conducted a second set of 31 in-person interviews, we were able to test whether the ≥15+3 approach would have ended data collection at an appropriate point, i.e. without missing

additional themes that arose in further interviews, nor prolonging data collection long after all themes had been identified.

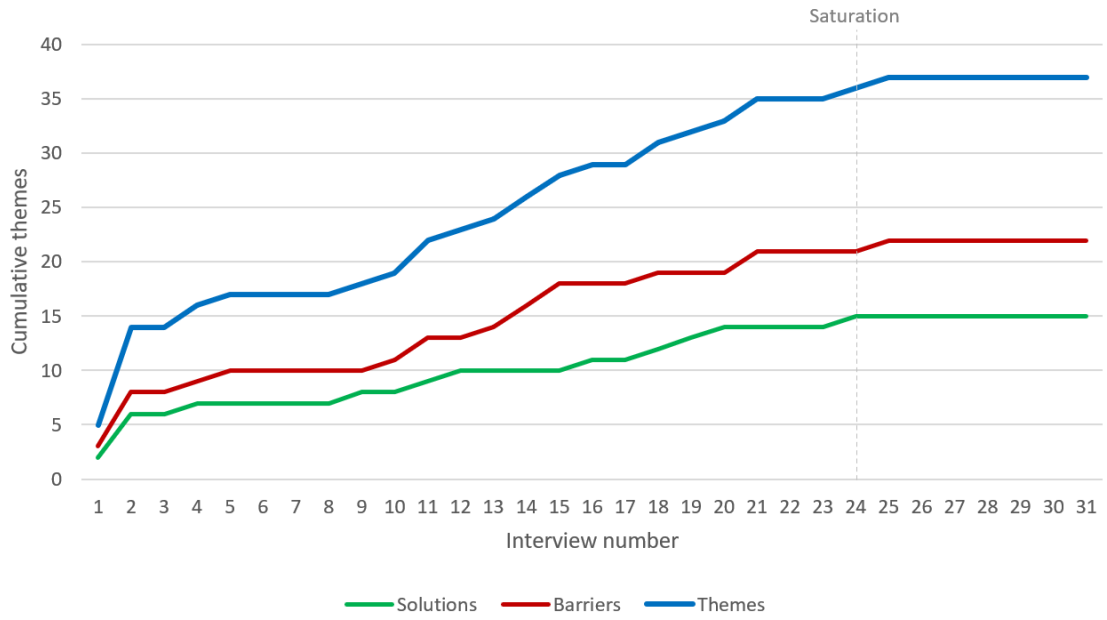
Table 4 shows that using this approach identifies interview number 24 as the point at which saturation is achieved.

Table 4: Saturation analysis of 31 in-person interviews using a base of ≥15 and a run length of three

Interview number	Solutions	Barriers	All themes	New information
15	10	18	28	
16	11	18	29	
17	11	18	29	
18	12	19	31	5.6%
19	13	19	32	5.6%
20	14	19	33	5.6%
21	14	21	35	10.5%
22	14	21	35	10.5%
23	14	21	35	10.5%
24	15	21	36	0.0%
25	15	22	37	4.8%
26	15	22	37	4.8%
27	15	22	37	4.8%
28	15	22	37	0.0%
29	15	22	37	0.0%
30	15	22	37	0.0%
31	15	22	37	0.0%

Using this cutoff would have led to the inclusion of all solutions, and all but one of the barriers identified across the 31 interviews. Figure 2 plots the saturation point on a line graph.

Figure 2: Accumulation of themes as the interviews progressed



Based on this retrospective analysis of our data, our group has decided to use the 15+3 approach to assess saturation in our future qualitative research projects.

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Appendix 5: Supplementary Table 1: Barrier quotes

Themes	Quotes
Costs	
Perceived cost of drops/spectacles	- At other service providers like Neema opticians the consultation only is about ksh.1000, so it becomes a challenge. And after checkup, spectacles are about KSH 3,000. (MT40) – tel - I am short sighted and I have problems with light as well. I went to seek for the services but it was too expensive for me. (MT100) – tel - If I could come it could have costed me: in case I was told to buy something like medicine or specs. You know now that could be an issue since there is no money. (MFNG 03) – f2f - When queuing I was told by others who had been attended that there were no medicine, then I decided to leave... After being checked I realized that people were told to go and buy medicine on their own. (MFI01) f2f
Loss of wage/income	- I am the breadwinner in my household and losing a day is very costly and a hard decision to make. The economy is hard and my family looking up to me. (MT250Z) – telephone - People find it discouraging to go to the outreaches and waste time on long lines. The economy is hard had they have families to feed. (MT010Z) - tel - I am a motorbike rider. I was screened in my village and asked to attend the eye clinic outreach but on reaching the dispensary I meet so many people and very long queues. I was given one of the last appointment numbers in the outreach. I choose to go to work to make money rather than spend my days' time not knowing whether I will get attended to… If I don't work, I don't get money. (MFK008) f2f
Transport costs	- Also the fare to come all the way to Meru [from the town I moved to] was a challenge so could not manage to travel on the date given for appointment. (MT09) – tel - I would also have a problem getting to the outreach clinic due to cost, I didn't have fare and that place is far, you have to use almost 150 shillings to and fro, so that is 300 shillings. (MFNG 03) – f2f

	- Transport was an issue. Travelling from Timau to here its far; around 230 shillings and 300 to go back. My biggest barrier was transport. (MFK2 06) in-person - Transport from Isiolo to Kinoru its a lot so I could not come back. (MFK2 05) – f2f - The main challenge that affected me its transport. I would use around 1500ksh for transport. That is what prevented me from coming. (MFK2 04) – f2f - The distance from [suburb] where I stay to Getembeni dispensary where I was to go for the eye check-up is very far, since I have to use transport of around 70 to 100 shillings to and fro, depending on the day. That was also another challenge why I did not make to go there; because sometimes that might be too expensive for me. (MFI 03) in-person - I did not have fare that day my fare is like 140 ksh. So since I did not have fare I was unable to come. (MFG 06) in-person - "Transport is also a challenge. But you see for me, I did attend to that place, but it did cost me. You see from here home at [location] to Moteteria is 100 bob, so to and fro it's 200 sometimes. It's expensive for some; like for me I used 400 that day on fare, but I overheard another old woman who said that she didn't go because she didn't have transport money. (MFG01) – f2f
Distance and transport	
Distance to the referral site	- I work in Thimagiri market Centre and the clinical outreach was held in Meru town, which is quite a long distance. Even if I had sneaked to attend the outreach, I could not have managed. But If the outreach was held near my market centre I would surely have attended the outreach (MT250Z) – telephone - My home area is Nkobo and on the day of screening I just happened to be a passer-by in that place which I don't know how it's even called. After screening, I was given an appointment for my eye check- up. The place is very far from where I live... So because the place was very far, and I did not know where the check-up clinic was exactly located, I didn't turn up for my first eye check-up. (MT33) -tel - I recently moved to a far located place that was the reason I never attended my appointment (MT28) – telephone - I was screened in Meru but I relocated to [town] after I found a job. (MT984) – tel - I met with the VIP team when I was still staying in Meru town then but later on I relocated to [town] and the distance from there to Gitoru where I was referred for further screening is far. (MT09) – tel

	- I relocated to home which is [town name] and the distance from there to Gitoru where I was referred for further screening is far - MT09 – tel - There was no station close to me. It was quite far from where I stay (MT 823z) – tel - I would also have a problem getting to the outreach clinic due to cost, I didn't have fare and that place is far... (MFG03) – f2f - Also the distance from Ingoki where I stay to Getembeni dispensary where I was to go for the eye check-up is very far... (MFI03) – f2f
Desire and priority to seek care	
Conflicting work engagement	- I got there around 8 or 9am and found the line was quite long... I could not wait since I was to go to work that day... I could not come back later to the clinic because I work out of town, and I normally come back late at around 8pm (MT40) -tel - I could not manage to attend the clinic outreach since that day I was working. (MT28) – tel - If I was not on duty I would attend (MT028) – tel - On that day I had a meeting... and I thought I wouldn't take a lot of time but I was late to attend the clinic. (MT07) – tel - I went and found that there were a lot of people and it was my work day. I work at a workshop company so I went back. (MT100) - tel - My boss never granted me a sick off to attend the eye clinic outreach because there was no one to cover off my duties. I work in an hotel and there was a big conference that day. I reported to work at 7am and left work at 8pm at night. (MT010Z) - telephone - I did not attend the outreach clinic because I went to Kitale to do farm work, I was instructed by my boss to do the farmwork. I had told him that I had an appointment but he did not give me a chance to attend the clinic (MT174ZZ) - telephone - The day they had sent me for check-up I went for a job I was called to do, then I did not have the chance to go for check-up due to this job. I was sent for clinic at Kinoru and the constructor sent me for work in Isiolo. (MT10) – tel

	- It was either on Thursday or Friday when I met with VIP people on my way to town when I was checked and referred to Kinoru the next week on Monday, but unfortunately you know I am a hustler, I am a house technician, so I was called same day for some work at Isiolo County… So I had to take the job offered, (MT15) – tel - I was referred on a Monday, which is usually a busy day at work, I got held up at work on the clinic day and I could not be given permission…. If I was not at work that day I would have attended the clinic. (MT17) – tel - I was not around, I had gone for a job in Isiolo (MT44) - tel - I stay in Meru but on the clinic appointment day I had sent my boys to a certain job but they were underperforming and I feared that I might lose the job so I went to Isiolo to handle business. I had thought that the work could have taken around two to three hours but it went on for two days. (MT46) – tel - I did not attend the outreach clinic because I went to Kitale to do farm work, I was instructed by my boss to do the farmwork. I had told him that I had an appointment but he did not give me a chance to attend the clinic… I had to travel to Kitale because that's where I make my daily bread. (MT174ZZ) - tel - It was on a Friday and the screener told me to go to Igoji dispensary the following Tuesday to get checked up, but that was a very busy day at work I was not given permission from job by my boss. If I got permission I would go to the clinic for the check-up. I tried to ask my boss for permission to go to the clinic and he refused. (MT496) – tel - Yes if I was not on duty I would attend (MT028) - tel - It's work-related issues - especially on Monday as Monday usually has a lot of work. (MT656) – tel - I was in a far-away place so I was not able to attend the clinic. I had a short and urgent trip'. (MT183z) – tel - I did not get time to go that day, I was at work. (MT504z) – tel - "They had come to my home, since they were going door to door examining people, and they told me that I had problem with my eyes, so they asked me to report to the dispensary by 8am. On that day, I arrived as early as 7:40 am since I wanted to be served first so that I could go back to work. They arrived at around 8am and found that already we were there, though they took time to set their working stations

	which took time to start, and I think they started at around 9am and I couldn't wait that long 'cos that was going to mess my job, so I decided to go to work and told myself "if they will come next time and the time was convenient for me, I'd attend". (MFG 02) – in-person - I was screened in Gathumbee. They were holding a smartphone and asking you to read some letters. My main issue was reading under sunlight and my eyes were itchy. I missed the clinic outreach because I was working in a far place… I was willing to come but held back due to my job (MFNG 01) – in-person - I was at Maua that time, I work for [large corporation] and they can call me in for duties any time in different towns e.g. Mandera and Marsabit. I was planning to come for the eye clinic that day; I do not joke around with my eyes because I know how serious it is. I have been having eye problems ever since I was a small child. Unfortunately during that day I was called to be on duty at 5:00 am at Maua and I had to go. (MFKIA 012) – in-person - I came to the outreach clinic stayed from 9am to 1pm and left, I was called to go for work to mombasa [3:10]. There were many people in the queue, I am a driver, I work in different places, that day I was called and informed that the parcel was ready so I had to go. (MFNG05) – f2f - During the clinic day, the boss said I could not come to the clinic because there was no one at work that day, and it could not be left unattended so I missed the clinic that day. (MFKIA 08) – f2f - I did not come to the clinic that day because I was occupied all day at work that day… I work at a cyber cafe. We open from 8;00 Am to 6;30 Pm but it depends on how the days work is. (MFKIA 06) – f2f - The exercise was also scheduled for the following week but I never managed to turn up because of work. I work at [educational establishment] and since it was not on my off day, I couldn't just fail to turn up for work so that I could come to be checked. (MFK 02) – f2f - That day of the check-up I was at work, and was my work day and if you don't turn up for work you won't be paid for that day (04:19) and even if you ask for a day off, you won't be paid for that day. (MF1 04) – f2f - "I had to go back to my business because I had some clients who were waiting for me, and after doing my work for that day, I did go back to the center again but it was already 5 pm in the evening and there was no one there. (MFG 01) – f2f

	- In building and construction. You know you can't just leave work you must wait till the time work is complete… The work is the one made me not to come: I prioritised work. (MFG07) – f2f - [After attending an all-day school meeting] I was to go close the job. (MFK05) – f2f - I mostly drive at night. By the time I get to my destination my eyes are paining, So when the program said, I promised to seek for help. I found a very long line that morning; it's like people slept there and the clinic had not opened yet. They opened around 8am. There was a queue but you know with many people you can get played. We were given numbers and wait for your number to be called, I did not wait for my number to be called out: I was around number 80. I did not wait. I had a certain job waiting for me, that is why I came early so I can be attended and go back. I asked one of the staff if there is another slot and he told me there was, so I left. I later came back at 2pm and found more people than I left them. (MFK 04) – f2f - When I arrived, I found so many people and I realized ill not be able to get help. I came with my daughter at around 9am. We found very many people. When I arrived at the gate I was told am number 421 and I was hopeful that after clinic I'll go to work. We stayed till 12pm. I left and went to work. The clinic had about 700 people. (MFI 02) f2f - I came where I was referred at Gakoromone dispensary but there were a lot of people and very long queues. I decided to go back and come back later that day in the evening. I came but still there were a lot of people at 4pm that day. I got other work to do. There were about 100 people. I did not even go past the gate: I came saw the big numbers of people then I decided to go back. I work as a boda boda person. (MFG05) f2f - On that day I was far from home tending to my shamba [plantation]. (MFNG03) f2f
Other conflicting engagement	- I was given an appointment but that day I travelled urgently (MTO1) - tel - I was referred at an outreach clinic. That day I was at a school meeting, so I ran late. I did not make it to the clinic on time... I prioritised going to the school meeting since I could be fined if I get late to the school meeting… On the clinic day I decided that I will go again when you guys come back comes back. (MT39) – tel - On that check-up day, I did not manage to attend to that dispensary because I had gone somewhere else. I had gone to a school meeting of my child, and when I came from there it was late. Even though I went to the school meeting, I had in mind that I should go to the eye check-up but I had to attend to the child's school meeting first, and when I came back I did not go to the check-up point. (MT546z) - tel

	- I was at my neighbour's event. I thought I could leave by 2pm but my friends were there, and it was an important gathering. I thought I would come back for the outreach but I ended up staying there for two days. I know I made a mistake by not attending the outreach but I have said to myself that if the outreach will be conducted again then I will attend. (MT47) – telephone - I was told to come for the clinic but I didn't make it, I had a meeting in school that same day so i decided to go for the meeting then attend the outreach later. We stayed there all the day. I was hoping I would get time to pass by the outreach but I didn't make it [2:30].I was willing to attend the outreach but by the time I was coming back, it was already late at 6pm. (MFNG03) – f2f - I went back home two days before clinic day... I did not have to come back from [hometown] since it was far and I did not have any other work engagements in Meru. I prioritised taking care of home chores since no one else was at home. (MFK2 05) -f2f - The day I was referred to come here at Kinoru dispensary happened to be the burial date for my husband's grandmother. (MFK 03) in-person - My mother was sick, she had a problem with her blood pressure, and normally she stays alone at home and someone had to look after her until she was better... Without that emergency, I was very willing to turn up, because even after coming back, I took my own initiative to seek the service somewhere else - at Meru General . I was checked and I was found to have a problem and I needed to purchase specs costing around 7,000 which I did not manage to purchase because that's too expensive for me. (MFK 01) – f2f - During the clinic day, my leg was so painful I could not come, I was shot by police I later went to hospital and stayed for two weeks (MFKIA 07) – in-person - The clinic day happened to be my child's schools meeting so I did not make. (MFK 05) – f2f - The screening exercise was much okay, after that I was given an appointment date, which was on a Wednesday, but unfortunately early that day I was called from my daughter's school that she was sick so I had to go and pick her from school and take her to hospital , from hospital, I did come with her to the appointment centre but the queue was long around 30 people already in the queue, it was at around 10 to 11 am, and since I was with a sick child I could not be that patient to wait for my turn to be served. (MFK 02) in-person
Forgot	- I also forgot the exact location where I was to go for the eye check-up and no one followed up to remind me of the place and date. (MT 33) – telephone

	- The message yes came to my phone on Friday but over the weekend I forgot. Its basically forgetting and work priority. (MT656) – telephone - What happened, I lost my phone and was not able to remember the exact date when I was told to show the clinic. (MT36) - tel
Clinical service quality	
Long queue	- I got there around 8 or 9am and found the line was quite long. I could not wait since I was to go to work that day. (MT040) - tel - I went and found that there were a lot of people and it was my work day. I work at a workshop company so I went back. (MT100) – tel - People find it discouraging to go to the outreaches and waste time on long lines. The economy is hard had they have families to feed. (MT010Z) – tel - I went where I was referred at the chiefs camp clinic and found out that there were a lot of people... Then I was puzzled how I will be attended… Then I decided I'll go some other date. (MT34) – tel - There were very many people in the outreach clinic. Most of the people in the queues were not attended and the place was so congested, there was only one dispensary but people were so many. I had someplace to go by 10am so I left because I could not wait any longer (MT48) - telephone - I went in the morning at the dispensary which I was referred to but there were way too many people. I had other personal errands to run. I did not want to waste time there because the line was moving very slowly. [I came back at] 5pm and the people were still crowded at the facility… I figured the poor service was because the clinic was free. (MT147) – tel - It got to 6pm and I went back home… I had not be attended since morning: I went from morning until evening and I had an eye problem but I had to endure. I completely left that process (MT533) - telephone - When I arrived at the outreach clinic, the turnout was very huge with long queues. I was very uncomfortable. I dislike long ques because I am an introvert. I arrived at 9am and stayed up to 1pm then I left. I felt like I was wasting my time. If I waited I would be attended to at the evening. (MT772) - telephone - People were too many. I was number seven-hundred-and-something. There were around more than 1,000 people. I came next week Monday but I was not attended as the people were very many (MT 952Z) – tel

	- I overheard that day that the line was long that day. You know someone can get tired of the line, maybe you have work to do later… I went later only to find the long line: I thought I could go and get attended quickly [but] I had to go back to work (MT504z) – tel - I came to the outreach clinic stayed from 9am to 1pm and left. I was called to go for work to Mombasa [3:10]. There were many people in the queue, I am a driver, I work in different places, that day I was called and informed that the parcel was ready so I immediately left. (MFNG05) – f2f - I attended the clinical appointment at Kianjuri but I met a lot of people and the queue was so long. I stayed for around four hours, till 1pm, I lost hope of being attended to and I went home… I also met a lot of elderly people who were more in need of the eye services than me so I thought It was better for me to give them a chance to get treatment and I could come another day or time. (MFKIA011) – f2f - I had the option to go to the appointment on either Monday or Friday. I selected Friday because I'm busy working on Mondays. However, when I arrived at the outreach on Friday, there was a large crowd, and large crowds, and I didn't receive an appointment number. When I inquired, I was informed that all appointment numbers for the day had already been given. I was not given an appointment number and I was not attended to. People prefer to go to private hospitals rather than wasting a lot of time in the queues. (MFK009) - f2f - I am a motorbike rider. I was screened in my village and asked to attend the eye clinic outreach but on reaching the dispensary I meet so many people and very long queues. I was given one of the last appointment numbers in the outreach. I choose to go to work to make money rather than spend my days' time not knowing whether I will get attended to. (MFK008) – f2f - I also asked around and was told there was a very long queue. (MFK05) – f2f - I mostly drive at night. By the time I get to my destination my eyes are paining, So when the program said, I promised to seek for help. I found a very long line that morning; it's like people slept there and the clinic had not opened yet. They opened around 8am. There was a queue but you know with many people you can get played. We were given numbers and wait for your number to be called, I did not wait for my number to be called out: I was around number 80. I did not wait. I had a certain job waiting for me, that is why I came early so I can be attended and go back. I asked one of the staff if there is another slot and he told me there was, so I left. I later came back at 2pm and found more people than I left them. (MFK 04) – f2f - When I came I found a very long queue. The line being long made me to leave… There were about 600 people. There were also some people who did not follow the order of the queue using the provided numbers, some people. (MFK01) f2f

	- I realized I'll get late for work, so I went back. Then at around 10am I came back and met a very long queue. (MFI 01) f2f - When I arrived I found so many people and I realized ill not be able to get help. I came with my daughter at around 9am. We found very many people. When I arrived at the gate I was told am number 421 and I was hopeful that after clinic I'll go to work. We stayed till 12pm. I left and went to work. The clinic had about 700 people. (MFI 02) f2f - On that day, I did not have much time on my side, but I did come, but it was already late at around 11 in the morning, and other people had already come and there was a long queue, and there was no way I could have maybe been excused to receive the services then go back to my work. (MFG01) f2f - I came where I was referred at Gakoromone dispensary but there were a lot o people and very long queues. I decided to go back and come back later that day in the evening. I came but still there were a lot of people at 4pm that day. There were about 100 people. I did not even go past the gate: I came saw the big numbers of people then I decided to go back. I work as a boda boda person. (MFG05) f2f
Insufficient numbers of staff	- The line was moving very slowly because there were not enough eye doctors attending that day(min 5:30)I have tried looking for help in several facilities like the general hospital but the medicine does not help usually so i was looking for something different that day, only to be delayed the whole day. I figured the poor service was because the clinic was free(min8) (MT147) – telephone - I came next week Monday. I was not attended as well people were very many. There were very few doctors attending the large crowd: there were about three doctors. (MT952z) – tel - I felt like the doctors were rushing with the treatment so that they may cover many people. (MFK 04) – in-person - The clinic had about 700 people. Doctors were 3-4, and using one room. (MFI02) f2f
Facilities	
Clinic not open at stated times	- On 21st I arrived at around at around 3:30pm but I found that they had already closed their work for the day. We met with the doctors at the door and they told me that they were not taking any more patients at the time. There were still many people who did not get attended that day (MFNG 03) – in-person

	- The day I was referred I came at 8:00 am and met the gate was closed. There were no people and because I was at work I realized I'll get late for work so I went back. (MFI 01) – f2f - Doctors also came a bit late; around 10am. (MFI02) – f2f - They asked me to report to the dispensary by 8 am. On that day, I arrived as early as 7:40 am since I wanted to be served first so that I could go back to work. They arrived at around 8am and found that already we were there, though they took time to set their working stations which took time to start, and I think they started at around 9am. And I couldn't wait that long coz that was going to mess my job, so I decided to go to work and told myself if they will come next time and the time was convenient for me, I'd attend. (MFG 02) f2f
Awareness & communication	
Lack of clear information on services available	- They did not tell us if we need to come with money or not. Eye treatment, we are usually told to come with money. I assumed I'll go there and they will ask me for money and I did not have it. MFK2 04 – in-person - The most important barrier is when I realized that even if I come ill not receive help. She told me even if you go you will not receive help you will be sent to general hospital so you will waste the whole day and there will be no help. (MFG 06) – in-person
Lack of clear information on appointment days	- The following day, I did not go to the centre because I knew that those who have specialized with eyes wouldn't be there, something I heard from my neighbours. (MT546z) - tel - We were not told how many days the clinics would go for, I was only given a single day. I did not know if it was running for other days. If I knew the days I would come, you know here I don't have to use fare, it's just a walking distance (MFK 03) -in-person
Lack of clear information on appointment times	- I was not sure when they open and close. (MFKIA 06) – f2f - I did not know about the opening and closing times. I thought it's like the normal working hours; form 8am to 4pm (MFK O5) – in-person
Insufficient counselling	- They just told me that I have problems with my eyes and I should visit Ingoki dispensary so I did not know what I was going to do there, is it surgery, is it being given medication, is it being tested again? And for me I have always known that my eyes are okay, and on that day they told me that they are not okay. They were very brief and I didn't know what to expect, so that shock of being told that I have an eye problem which I have never had before is the reason why I did not go. (MFI 03) – in-person
Did not receive reminder message	- … and no one followed up to remind me of the place and date of the check-up since I never received a message to remind me of the scheduled appointment. (MT 33) – telephone

	- You know the date came and they had told us the would call and they never called… I did not get any [SMS] message. (MT823z) - tel
Fear	
Fear	- "Another thing that hindered me from reaching that place of check-up was because of fear, you see this place is not home, and I don't know people here you can tell someone to take you to some place and they might end up raping you or taking your property so you so you will probably be filled with fear. Another reason of fear, it's because it involves the eyes many people are fearing since that incident of Worldcoin so it's not easy to trust anyone. And you get in a group, you're the only one who agreed to be screened so the others will discourage you from going, telling you that you'll be killed or something bad will happen to you, because of the recent activities of so many online scamming, it's not easy to go to receive help even when you have a problem because you can't trust anyone. (MF1 04) in-person - Then I was scared because of the Worldcoin thing so I developed some fear. This also made me not to come for clinic that day. (MFK2 05) – in-person - My eyes have been having problems since I was young but I have never sought for treatment, despite foreign actors always coming to give us free service. My mother used to tell me that you do not joke with eyes, you don't give everyone access to your eyes because some may be bad people who may put bad substances on your eyes because her brother once did that and his eyes got worse with time. That's why I feared to seek treatment. (MFK 03) in-person
Norms, values, health beliefs	
Discomfort with mixed genders in the queue	- There were women on the line. They could have different lines for youths and women for some us to be comfortable because it is shameful to be on the same line with women and children, with worries how they will perceive me as young man. It was a challenge for me to just stand there with women… I had to go back that day without being attended even though right now my eyes have a problem. (MT040) - telephone
Male health seeking behaviour	- As a man it is very hard to prioritize my health as I am manly focused on my family's wellbeing and It is easy to forget my health needs (MT250Z) - tel
Assumption that eye problem wouldn't be addressed	- I am short sighted and I have problems with light as well... I was told that they were only treating eyes defects like short sited and long sited people and they were not giving glasses for protecting light. (MT100) - tel
Other	

Dislike crowded places	- When I arrived at the outreach clinic, the turnout was very huge with long queues. I was very uncomfortable. I dislike long ques because I am an introvert. I arrived at 9am and stayed up to 1pm then I left. (MT772) - telephone
Sought services elsewhere	- After the screening I was told to go for the referral clinic at Meru Prisons. That day my eyes were red and had discharge. They gave me a later clinic date. The condition of my eyes was worsening daily and I could not wait for the clinic. Light exposure made my eyes red and they would start tearing so I had to look for an alternative. I went to Meru general hospital, I was given medication and my eyes are now so okay. (MFK 02) - in-person

Appendix 6: Supplementary Table 2: Solution quotes

Theme	Quotes
BARRIERS	
Costs	
Provide transport fare	If I can be provided with fare, I would definitely attend the clinic because the challenge is income and moving to Gitoru requires money - MT 09 – telephone According to how the economy is, if we can be given fare, at least you can borrow some money for transport to attend the outreach, then refund later. You can also help people after screening at least give some assistance, you can tell us to look for some money and then you top up so that we can manage to buy medicine and specs since if its only coming to be checked, even if I keep coming again and again it will not be of much help. MFNG 03 – I also feel like, at least we should be provided with fare - MFG 01 –
Subsidise treatment	You should consider needy people who cannot afford [spectacles]… At least organise yourselves and look for the needy to help them, If I get that money I can go and get the spectacles because no one is happy when their bodies have a problem. I cannot even read the bible or the numbers on the phone - MT 148 – tel According to how the economy is, if we can be given fare, at least you can borrow some money for transport to attend the outreach, then refund later. You can also help people after screening at least give some assistance, you can tell us to look for some

	money and then you top up so that we can manage to buy medicine and specs since if its only coming to be checked, even if I keep coming again and again it will not be of much help. MFNG 03 –
Pay people to attend	You should also give people some little money if they attend the appointment - MT 46 - tel I'm asking if we can be compensated with the amount we could have been paid because we leave our job so at least you are sure - even if you're not going to work on that day - your children are not going to sleep hungry. Because some of us, we're the providers of our families. MFI 04 –
Distance and transport	
Move clinics closer to where people live and work	The outreach should be situated in a place which is easily accessible to many people and where many people live... It should not be very far from where people live - MT 28 – tel Because I was just a passerby, it will be better if the eye screening was brought to where I live in Nkobo – MT33 – tel Have the stations close to the people where we can all reach. MT 823z – tel I can go to the outreach clinic if its situated near me where i will get help but not going all the way to Meru MT682 - tel If the outreach was held near my market centre I would surely have attended the outreach – MT 250Z – tel You should bring the services closer to the people… Because you have the people's contacts and where they live, you can conduct an outreach in a place which near to where they live. MT 183z - tel

	They should bring the clinics near the people to cut cost on transport - MFK2 04 – Services should also be near - some facilities are at a long distance so it becomes difficult to go there. - MFK 009 – in-person For distance, I think you should organize and bring the services to someplace that's near to us for example chief's camp - MFI 03 – in-person Clinics should be set in various places in every county. So that the clinics would be near people. MFK2 05 – in-person I am suggesting if they could take the services to every dispensary and for my case, a near dispensary like for me, [name] dispensary. - MFG 01- in-person Also, it would be easier if they could bring the services to nearer facilities for instance for people from my area, to [name] dispensary - MFG 02 – in-person
Provide transport	If you give me transport and day to come, I will come. MT 10 – telephone For the elderly you can look for means of transport, many of them will come. You can organise with people like chiefs so that they can know how to take people to the places where the services are offered. - MFK 009 – in-person if they would be able to provide transport that would be OK. MFG O7 – in-person

Door-to-door services	Is it possible to have a doctor visiting them [elderly people] door to door? It would be better for those who aren't able to go there - MT 15 – tel If possible, you can take the services to people's homes considering there are those very old who cannot make it to the appointment centres - MFK 01 – in-person Consider door to door services but I don't know if that's possible. MFI 03 –
Clinical service quality	
Improve punctuality and speed of staff	I think those that are providing the services should be punctual and fast - MT 07 – tel Increase [the number of] doctors from four to ten, and then those doctors to arrive early at around 8am– MFI 02 - in-person The solution is still time, though 8am is still okay, but I think if maybe they could work on their organization so that much time is not wasted on preparing the working stations - MFG 02 – in-person
Ensure that all medicines and glasses can be provided on-site	Equip more drugs in the dispensary - MT 48 – tel When you see someone, make sure they get medication or give them spectacles; not writing prescriptions and referring them to chemists. I think this does not help. You should have all the medication for all allergies and spectacles, not referring people to places - MT 533 – tel

	After being screened you should receive all the services like medicine and everything, you get solution for everything but not again looking for services from other places. MFNG05 – in-person Also, the program should improve on their equipment and machines used for examination, so that the services will be satisfactory. MFG 01 – in-person Next time let the doctors be many and let them come with medicines. MFI01 – in-person For the issue of specs , maybe you can add more resources that are enough for everyone next time. MFG03 – in-person
Add more staff at each clinic	Add more eye doctors that day so that they may help each other in covering more people on the clinic days - MT 147 – tel Have many check-up doctors, not bringing two or three of them. That day they were only five or six, you see them attending all those people - is impossible - MT 533 – tel Increase the number of doctors so that the clients can be served more efficiently and on time - MT 772 – tel Add more doctors so that everybody will be served - MT 952Z - tel Maybe you should add more doctors to attend to more people so the lines can move faster - MT 504 Z – tel Those people doing screening should be many because staying for two three hours with this economy is a loss. MFNG05 – in-person

	There is a high number of people requiring eye services thus the number of doctors should increase - MFKIA 011 – in-person Increase the staff because there were very many people increase the doctors from four to ten - MFK2 04 – in-person Increase doctors from four to ten. MFI 02 – in-person Increase no of doctors so that I will not take long waiting because I have other duties to do. Next time let the doctors be many and let them come with medicine… Add doctors from three to six: that would be OK. – MFI 01 – in-person The doctors attending people should be many. Because like… people were so many, and most of them went back without being attended to. So if there were many doctors it would have been easy. MFK 009 – in-person I think next time you should increase the number of doctors attending so that every individual may get good quality service - MFK 05 – in-person Maybe next time you can add more manpower because for the long queues and stuff… I have a feeling that there are those who never got attended to at all because of lack of enough time, due to inadequate staff - MFG 03 – in-person …and set more stations, and also doctors to be added in those stations. MFG 05 – in-person

Schedule fewer people to attend each day	When you register, register few people… Having 1000 people wastes a lot of time and you cannot handle such a crowd. If you target 100 people, you will attend all of them. Having many people will have them trolling around all day. You see, I had an eye problem but I swore never to come back again, I would rather go to the hospital than come waste time around just because it is free - MT 533 – tel The outreach should limit the number of clients they are attending to. It make no sense to refer 600 people and they cannot fully attend to in a day. They should choose a much smaller number comprised of people they had referred. MT 772 – tel You should take time to examine every patient as it should without minding the workload ahead, that's why I think you should schedule less people. MFK04 – in-person I would also like it if you control the number of people you schedule for a particular day, because now you have experience of how many people you can attend for a day. Schedule just that amount of people so that everyone may be attended to… It wasn't fair of you to call that many people, they were already sick and they had to wait for hours under the scorching sun. MFK01 – in-person
Facilities	
Keep the clinics open for a greater number of days	The screening exercise should not be done just once, it should be repeated maybe even for three days during weekdays before an appointment for the first check-up is made - MT 33 – tel Maybe you can add more days so that you can schedule few people on one day - MT 147 – tel You should extended the number outreach days to attend to more people - MT 001 – tel

	If there were more days I could have attended the clinic. I suggest that you add more clinic days - MT 39 - tel Come at least two days consecutively; let it not be one day. If I miss one day, I will be able to go the following day - MT 34 – tel Add more days for the clinic so that people who did not manage to attend the clinic on their appointment dates can still get a chance to be treated. Many people have eye problems but they are also busy looking for ways of surviving during these tough economic times - MT 174Z – tel You should extended the number outreach days to attend to more people - MT 01 – tel Also you should add the number of outreach days to attend to more people. MT47 - tel Add more clinic days around 3-4 days - MT 952Z – tel For me I'd suggest that next time you have a similar exercise, at least add more days because this time you had only specified for one day, this will assist those who hadn't managed to reach that day to have another chance. MT 546z - tel Add more days. You see I was referred for one day if there was a next day I would purpose to come - MT 504 Z – tel

	Having a single day for clinics gets people congested… I think that Monday, Wednesday, or even the whole week of clinic will be easier for most people to access the clinic as it is easier to ask for permission from work and be sure you will be attended. With the whole week one can get a day to go and if they do not get attended that day, they can still choose the next day and will be sure to be attended. MT040 – tel You should also do those outreach clinics for more days at least two or three days in a month. That time they were doing the outreach for just one day. MFNG05 – in-person The outreach should not be in one day. It should be at least two days in a week. If you allow everyone to the outreach there will be long queues and many of them will not be attended. MFKIA 012 – in-person You can also add days, if I miss today, I can come the next day. If you add the days, and make sure you remind us, it is okay. MFKIA 08 – in-person If you add the clinic days I feel it is okay. MFKIA 07 – in-person You can just extend the clinic days to have more of them, like four to five days. MFKIA 06 – in-person More appointment days maybe for like 2 weeks. MFK 01 – in-person

	If possible you can also add some days like then you were checking people on Monday and Friday because many people were interested but did not get help. MFK 009 – in-person If it is possible, have the clinics for at least two days: if you miss today, you can purpose to come the following day because even those people were too many. MFK 05 – in-person You know if you give the clinic like three days, you can even travel for a safari, come back the next day and still attend the clinic. So I would suggest you schedule more days for the clinics. MFK 03 – in-person Look for a day like Friday because work load is few. MFK04 – in-person
Extend clinic opening hours	If they would extend services to the evening at 5pm that would be okey since most people are out of work. MT100 – tel I would say that you guys had a great job in our community according to many testimonies from the people who made it to the clinic and I regret not going, I feel devastated. However I would suggest that you add some more opening and closing hours so that people who are committed during the day can access the clinic. MT39 – tel Open the clinics early and have the two days and people coming early. MFK 05 – in-person Also have the clinics start as early, like if we come around 6:30am the clinics can open at 7am. I feel like that days clinic started late they started at 8am, I was there at 6:30am. MFK04 – in-person

	Also if it's on weekdays, if it's possible if the exercise could extend the working hours, let's say from 4 pm to 6 pm, that one too I could manage, because I would have come from work. MFK02 – in-person
Keep the clinics open on the weekend	The biggest challenge for me was timing. If timing was ok I would have attended; like weekends I'm not usually very busy. MT100 tel You should have clinics on Saturdays because that is when most people are not held up at work. Having the clinics on Monday is hectic as people are held up at work and getting permission is quite difficult... Sometimes bosses do not grant day offs on busy days, especially week days. If you could make the clinics to be on a weekend many people will attend, I will also attend if you make the clinic day to be on a weekend. When you make it on a Saturday many people will attend because even if they are busy they get off from work quite early at around 1pm. MT17 – tel I am always free on Saturday and Sunday… I think that Monday, Wednesday, or even the whole week of clinic will be easier for most people to access the clinic as it is easier to ask for permission from work and be sure you will be attended. With the whole week one can get a day to go and if they do not get attended that day they can still chose the next day and will be sure to be attended. MK040 – tel Maybe if the exercise could be scheduled off working days - that's during the weekend, in Saturday or Sunday, because at that time am free without work I could turn up. MFK02 – in-person
Add more clinic locations	Have more many work station where people can easily access the services to reduce the distance people need to travel to get treatment. Even the elder people can reach the outreaches also it give them option on where they can get treatment because on line on a particular station but be short where as the other might be long. MT 010Z – tel

	Some people should be referred to other hospitals like MTRH. MT48 – tel Have eye medics even in Nyeri. MT984 – tel Next time there such a project, its best if you people divided the community people according to their villages or maybe sub-location 9:10 so that people don't overcrowd in the same place like that day because I think that day the whole location was referred to Kambiti which made the area overcrowded and we could not receive the services because the people were many. MT38 – tel Set more clinic centers so that people will not need to travel from far. MFK2 06 – in-person You should have many stations and also the doctors attending people should be many. Some other places can be used like churches and it will be easier for people to go to access the place. MFK009 – in-person You know so many people have eye problems like all those that were that day. Next time have many centers, like three, not one like that day. MFK04 – in-person Let there be more facilities for the clinics, like five stations. That would be OK. MFG07 – in-person

	If there will be more stations for check-up that would ease the long queues. Even the clinics should be set up even in schools nearby, then people would not be as many that day. At least five stations would be good in this area of Gakoromone. Come with machines even to the nearby schools and set more stations, and also doctors to be added in those stations. MFG05 – in-person For the long queues, am suggesting if there will be more screening centers to avoid overcrowding at one center and the long queues. MFG03 – in-person
Mop- up clinics	The outreach should be conducted another time so that the people who were left unattended could be attended. MT48 - tel If the outreach is done once more I could go. You should come back because there more people who were not attended to - MT47 – tel Just tell us when you are coming back to the community for other clinics. Even this week you can tell us you are coming and we shall attend… Plan for when you are coming next, three days this time will be better so that if someone misses one they can still have a chance. MT496 – tel Let's say, those people who never managed to attend on that particular appointment day, they should be followed up immediately maybe later that day or the following day so that their appointment can be rescheduled. For me, I would have wished that the exercise would be repeated for more days following up on those who missed the opportunity. MFK01 – in-person
Give each person a specific appointment slot	The attendance number in the outreach should be issued in line with the referral messages clients received. The message should also have the attendance number and the time allocation to help the clients organize themselves to attend. MT772 - tel

Schedule fewer people to attend each day	I think you should schedule less people. MFK04 – in-person I would also like it if you control the number of people you schedule for a particular day, because now you have experience of how many people you can attend for a day, schedule just that amount of people so that everyone may be attended to. That way everyone will be aware what time they will attend so that they may not waste the whole day. It wasn't fair of you to call that many people, they were already sick and they had to wait for hours under the scorching sun. MFK 01 – in-person
Awareness & Communications	
SMS reminders, including on the day of the clinic	Sending them SMS message and remining them to attend their clinic appointment or calling them. MFK008 – in-person That same same day for the clinic I should receive a reminder message to remind me to attend. I have many things I can easily forget… A reminder message should be sent before and during that day to attend the clinic. MT656 – tel They should make announcements early; not a day before the clinic.. They can make announcements three days before so that you can be prepared. Even sending messages four days before, its OK. MFK2 05 – in-person Next you send me a message to remind of the clinic and a phone call will be okay to remind me of the appointment. MT36 - tel
Send a text to individuals who missed the outreach clinic to invite them to attend on another day	If a person never made it to the outreach, he should be notified of the next eye clinic outreach even if it is in another location. Because one cannot be busy all the time. MT46 - tel

Phone call reminder, especially for those who cannot read	Next you send me a message to remind of the clinic and a phone call will be okay to remind me of the appointment. MT36 – tel Sending them SMS message and remining them to attend their clinic appointment or calling them. MFK008 – in-person If someone didn't make to attend the outreach, you can call the to remind them. MFNG03 – in-person Maybe you can remind us by calling us as you have today. MFKI08 – in-person In order to create the trust and be sure that this exercise is medical, at least you should call on the day of the check-up so that you can explain the exercise in detail - so that we can get to trust the exercise because sending just a message as a reminder is not convincing enough or satisfactory. MFI 04 – in-person
Explain why attending clinic is important at the point of referral	Also during screening we should be given more information why this clinic is important. MT656 – tel They should also be informed the importance because some people may end up blind. MFNG03 – in-person
Use churches and radio broadcasts to remind people to attend	Mobilize the clinical outreach especially on churches and radios. MT48 – tel Also, the activity should be announced and advertised to people in public, for example in TV or radio shows. At least even if I don't know you, someone else might have seen you, so people will be able to come more freely without the fear of being scammed or conned. MFI 04 – in-person

	It should be announced in public so that everybody will get there because the message can come when the phone is off. Let it be publicly announced that certain day will be clinic day, we meet at a specific place. MFG 07 – in-person
Specify clinic dates and times	I would propose that if you have a project like that one you communicate well on the exact opening and closing times, so that people may not come and get stranded outside and eventually go home without getting treated. There were so many people outside the facility who got devastated because they thought that the exercise would go on at least up to close of business hours. I feel like if you communicated well on the closing hours I would have programmed myself well and come in the morning whereby I could get the treatment that I required. MFNG03 – in-person You should communicate on the time because I did not know that the clinic was opening early, and tell the people to come early enough so that they may be attended effectively. MFK04 – in-person Communicate well on how many days you will be available, when I know the duration which you are staying I will avail myself. MFK03 – in-person
Allow people to choose their appointment day	Next time they should ask me when I am available instead of putting a date for me because of my work. The biggest challenge for me was timing. MT100 – tel Communicate with client if they will be available for the outreach. If not allocate them another day and time. MT894 – tel
Clarify what services are available at the outreach clinic and specify if there are	Clarify information because of the Worldcoin thing, so during screening we should be given more information. Anything free people think its hidden things. MFK2 06 – in-person

any costs linked to these services	People should also be announced that they will be helped, not only will they be screened, there will be other help. MFNG03 – in-person They should tell me that the services are free so that ill not assume that there are charges... they should tell us the clinics are free. MFK2 04 – in-person
Norms, values & health beliefs	
Sperate younger people, women & children, and elderly people	Address the line issue and have women on their [own] lines. But youth can just have their line where we can mingle and interact - for example on how hard the economy is - and by the time we realise the line is shortening. But with women on the same line we will not have anything to talk about. MT040 – tel One day of the outreach should be reserved for the elderly and the other day for the other people since you should give priority to elderly people. If you allow everyone to the outreach there will be long queues and many of them will not be attended. MFKIA 012 – in-person What I would want you to improve is that next time hire competent queue managers who control how people are coming in, and the elderly, pregnant mothers and mothers with small children to be put on their own queue so that there will be effective treatment. MFK01 – in-person

Appendix 7: Original drafts: Intervention counselling script and SMS reminder

Original enhanced 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 and provide medicines and spectacles as required, all free of charge. 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. This may incur a cost. However, the vast majority of people have their needs fully met for free at the outreach triage clinic and do not require any further referral.

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 clinic will only be running from [day] to [day], so if you don't manage to attend, you may not be able to get free care again in the future."

Original intervention SMS script

We found that you had an eye problem. Please attend the outreach clinic at <<location>> on <<date>> between 9am-5pm to receive free medicines/spectacles

If you are found to have a complex eye problem, you may be referred to a hospital for further care or specialist glasses, and this may include a fee

However, the vast majority of people who attend the outreach get their eye problem fixed, for free, without the need for any further referral

It's important that you attend, as your eye problem may get worse, and you might not have a future opportunity to access free care. See you on <<day>

Changes

We made three changes based on feedback:

1. One of the young men from the left behind group wanted us to change the sentence *"It is important that you attend the clinic or your eye problem may get worse"*, to make it 'less scary'. We had included this original sentence based on interview feedback that we needed to better explain the importance of attending. For instance: "They should also be informed the importance because some people may end up blind". We changed the wording to read; "It's important that you attend to protect your vision."
2. Due to inflation-imposed budget constraints, the clinics are no longer able to provide all glasses and medications for free. At this point in time it is not clear how subsidised the costs will be. We removed wording stating that the treatments will be free. We kept wording stating that the assessment will be free as this still represents a major advantage over attending a high-street provider or hospital clinic.
3. Representatives from Peek vision advised that "see you on <<day>>" might be misleading, as the day of the appointment might be more than a week away (e.g. next Friday rather than this Friday). We changed this auto-populated section to "see you on <<date>>".

Appendix 8: Barrier and solution quotes from the interviews with high-income people

Themes	Quotes
BARRIERS	
Costs	
Perceived cost of drops/spectacles/services	- There is a friend of mine who was also referred to general hospital to buy specs which were costing 3500 shillings [7.37]. (HIG7) - I just know if I come for the clinic, I will be told I have a problem and I will be required to pay for the services but if I know I will get free services I will be motivated. (HIG4)
Loss of wage/income	- N/A
Transport cost.	- The day of appointment I got a job transfer from Meru to Maua (2:50). It's the transport from Maua to Meru the fare is too high (HIG3)
Distance and transport	
Distance to the referral site	- N//A
Desire and priority to seek care	
Conflicting work engagement	- I was given a date to be checked but that day I went to work in Nairobi, we had other programmes in Nairobi that day on insurance that's why I did not make it [2.35], I work with insurance and I often go to Nairobi for work, I don't have specific time or date to go to Nairobi but mostly I usually go on Thursdays and Mondays [4.30]. (HIG1)

	- I didn't attend the clinic since I travelled to Isiolo and that day I was working in Isiolo, [3.10]. It was a working day, and I was on duty, I didn't get some time to attend the outreach clinic. (HIG2) - The day I was supposed to go for clinic i went back at work in Nyeri. The day of clinic appointment was the same day i went back for work. (02:42) (HIG5) - There is a place I went that day, I went to work in Naivasha, I don't work specifically in Meru, the work I do is usually anywhere like now I am in Maua [1.05], I do fitting, I fix things like gypsum and wardrobes. I can come another day especially from next week because now I am free [2.25]. (HIG6)
Other conflicting engagement	- I was screened and told that my left eye had a problem, was referred to Kinoru dispensary but I was sick that day. That whole period I was unwell and that specific day I was weaker (HIG4) - I was told to first buy a certain drug and then go to general hospital in case I don't improve [1.15], after using that drug the problem cleared so I dint go to the general hospital. I had told them I wouldn't get time to go to the hospital they told me to buy that drug I use before I organise myself [4.00]. I used that drug for just one month but the problem cleared totally (HIG7
Forgot	- I was screened and told that my left eye had a problem, was referred to Kinoru dispensary but I was sick that day and I also forgot about the clinic [1.43]. (HIG4)
Clinical service quality	
Long queue	- I went and found that the queues were very long at Kinoru dispensary (2:23) I went around 10am.i stayed for about an hour. And I work at Makutano, so I went back. (HIG3)

	- The queue was too long, people were so many, so I just went back to job [0.52], where they were offering the service was different from where we see patients, we were not sharing the clinics we had given them a separate place but within the same compound [1.35]. (HIG8) - Reason why I did not go is that I used my card and I decided to go another hospital and use my card instead of Meru general hospital, where I was referred. I went to life care hospital. Even if I go to general ill find long queues (11:30) (HIG10) - I went around 3 pm and the queues were very long around 2000 people many people did not go to see doctor due to long queues still at 3pm there were a lot of people (4:34) then i decided to go back home (HIG11) - I was worried about going to the hospital because there is usually so much queue (HIG7)
Insufficient numbers of staff	- N/A
Facilities	
Clinic not open at stated times	N/A
Awareness & communication	
Lack of clear information on services available	- N/A
Lack of clear information on appointment days	- We were not told the specific day to go to the hospital, maybe we can be told to go a specific day and be given a note so that one can know that a certain day he/she will be going to the hospital. (HIG7)
Lack of clear information on appointment times	- N/A

Insufficient counselling	- N/A
Did not receive reminder message	- N/A
Fear	
Fear	- N/A
Norms, values, health beliefs	
Discomfort with mixed genders in the queue	- N/A
Male health seeking behaviour	- N/A
Assumption that eye problem wouldn't be addressed	- N/A
Dislike crowded places	- N/A
Sought services elsewhere	- N/A

SOLUTIONS	
Costs	
Provide transport fare	- Provide us with transport, if provided with fare I can come, 730 shillings will be okay for me [15.12], I can request for permission to go to the clinic for few minutes because people get permission even to go to hospital when they fall sick, [15.39] (HIG2)

Subsidise treatment	- If you could have convinced me and promise me that I would get spectacles for free, I could get motivated [8.15]. I just know if I come for the clinic, I will be told I have a problem and I will be required to pay for the services but if I know I will get free services I will be motivated. (HIG4) - I wouldn't even forget to attend the clinic [8.24], for example if you offer things like operation for free or even lower the cost of the services then people would be so motivated (HIG4) - That drug was so costly, I bought it at 1050 at [location] chemist [4.17], many people would not afford to buy drugs so in future you can have variety of drugs and even different spectacles even if we can pay for some amount, you get served once [7.50]. There is a friend of mine who was also referred to general hospital to buy specs which were costing 3500 shillings [7.37]. (HIG7)
Pay people to attend	- N/A
Distance and transport	
Move clinics closer to where people live and work	- Since you people are concerned and are following up on us, you can even come to the remote areas for those who can't access the clinics in town since there are so many people with eye problems, like the way CHVs works, you can even take people like me to go round to remote areas since there are mothers who can't reach the clinics in towns. you can also get to other places like Samburu rather than proving services only to Meru County, it was even in media that a place like Samburu people have eye problems so you can visit such places as you observe what people are going through, [9.12] (HIG2) - If I can do my appointment where I am e.g. Nyeri or Kirinyaga, if the service could be brought near my working area (04:44) (HIG5) - Bring services closer to people especially in rural places (4:48) in a school or a public ground (HIG9)

Provide transport	- N/A
Avoid setting up clinics in areas with difficult terrain	- You should also avoid rural areas where roads are not accessible e.g. that time it was raining and therefore most of the people wouldn't make it to the clinic, [7.40]. (HIG1)
Door-to-door services	- N/A
Clinical service quality	
Improve punctuality and speed of staff	- N/A
Ensure that all medicines and glasses can be provided on-site	- N/A
Provide high quality spectacles/frames	- Next time come with spectacles of good standard, not for the old people. Come with glasses with good standard (6:39) (HIG3) - ...and next time come with spectacles of different types and medication (HIG10)
Add more staff at each clinic	- Adding the number of medical staffs so that people can be attended fast, if I had gone to the clinic and found a long queue I would just go back since I can't keep waiting in the queue, If someone come from far and the services are given fast, he/she can't feel like they are wasting time. (HIG1)
Schedule fewer people to attend each day	- if they do it again, they say a particular area should be attended at a particular day this will avoid overcrowding and long queues... (HIG10)
Facilities	
Keep the clinics open for a greater number of days	- Adding the number of days to be twice a week or if its monthly once a week (HIG8)
Extend clinic opening hours	- N/A
Keep the clinics open on the weekend	- If it was on weekend Saturday I would attend (03:21) (HIG5) - you should do the clinics during weekends especially Saturdays [4.34], a day like Wednesday is very tricky, most people work the whole week then get paid on Saturdays so they can make it to attend the clinic [5.24]. (HIG6)

Additional workstations	- many stations to see people and to have many doctors (5;15) (HIG11)
Add more clinic locations	- You can set up other places for the outreach clinic like Nairobi and other places for those travelling during that day [5.40] give many places where people can be checked for example the way I didn't make to attend the clinic in Meru I could have found some few hours to be checked somewhere else, [5.40]. (HIG1)
Mop- up clinics	- Schedule another clinic and I will come, inform me like one week before so that I will be prepared [3.01]. (HIG6)
Give each person a specific appointment slot	- Give people different appointment dates to avoid overcrowding (7:57) a particular number of appointment for a specific day of appointment (8:08) and come with a message to show u are supposed to be here today (8:17)dont give all people one day for appointment. (HIG3)
Schedule fewer people to attend each day	- N/A
Awareness & Communications	
SMS reminders, including on the day of the clinic	- You should also send text messages like the way you sent me a message last time [10.03] (HIG2) - Remind people about the clinic before the clinic day by sending text messages…Even though I was sick, if I could be reminded, I would try my best to come. (HIG5) - Send people text messages twice in the phone like one day before the clinic [10.38]. (HIG6)
Send a text to individuals who missed the outreach clinic to invite them to attend on another day	- N/A
Phone call reminder, especially for those who cannot read	- N/A
Use CHPs to remind people to attend	- The CHVs can be going home to home telling people 'This is the day you should come to see the doctor' [4.26]. (HIG8)

Explain why attending clinic is important at the point of referral	- …also educate people about its importance as you convince them, also extra services like spectacles [6.09]. (HIG5)
Use media, posters, churches and radio broadcasts to remind people to attend	- Advertise using posters and media so that people can get the information, during the screening not everyone was aware and not all were screened, other people were not around so if you advertise everyone gets the information, [10.02]. (HIG1) - Advertise more like using stickers where there is movement of people like Makutano [9.35] some people didn't know about the screening and others also forgot [10.04] (HIG6)
Specify clinic dates and times	- N/A
Allow people to choose their appointment day	- N/A
Clarify what services are available at the outreach clinic and specify if there are any costs linked to these services	- N/A
Norms, values & health beliefs	
Separate younger people, women & children, and elderly people	- N/A
Other	- I can request for permission to go to the clinic for few minutes because people get permission even to go to hospital when they fall sick, [15.39]. (HIG2)

Post-script: mode effects

As described in the manuscript, I was not convinced that telephone interviews would render the same data quality as face-to-face interviews. As such, I designed an embedded mode comparison study, recruiting two separate samples of interviewees. The protocol has been accepted for publication in the International Journal of Qualitative Methods and the study findings have been posted on medRxiv[83] and submitted to the same journal.

Appendix 4 presents the full study. In brief, in-person interviews generated more data but the same number of potential solutions compared to telephone interviews. As expected, in-person interviews took longer to complete and were more expensive than telephone interviews (Table 1). Based on these findings, I recommended that we continue with telephone interviews for future iterations of the IM-SEEN cycle.

Table 1: Summary findings from the embedded in-person vs telephone interview mode effect study

Domain	Metric	Modality		p	Ratio
		In-person	Telephone		
Richness	Mean interview duration in minutes and seconds (range)	10.20 (4.19 - 15.20)	8.30 (3.10 - 30.10)	0.005	1.11
	Analytic matrix wordcount – barriers	4,453	2,674	N/A	1.67
	Analytic matrix wordcount – solutions	2,638	2,094	N/A	1.26
	Total number of barriers identified	15	14	N/A	1.07
	Total number of solutions identified	22	22	N/A	1.00
	Mean number of barriers mentioned by each participant (range)	1.94 (0-4)	1.58 (0-3)	0.142	1.23
	Mean number of solutions mentioned by each participant (range)	2.23 (0-5)	1.61 (0-4)	0.029	1.39
	Interviewer global rating of richness (1-3)	3.0	2.0	0.014	1.5
	Interviewer global rating of ease of building rapport (1-3)	3.0	2.0	0.014	1.5
Time	Time taken to organise and complete all interviews	5 days	3 days	N/A	1.67
Costs	Cost to complete all interviews	USD 668.29	USD 375.71	N/A	1.78

Part 4: Testing solutions

Chapter 9

Setting up an automated, pragmatic, embedded, Bayesian, adaptive platform trial

One of the primary care facilities that will participate in the platform trial RCTs

Source: Author

Key messages

- Randomised controlled trials (RCTs) are the most robust way of quantifying whether an intervention or service modification is causally associated with a change in outcome, such as access to care.
- Platform trials enable serial RCTs to test multiple different interventions in the same population with the same outcome. They are well suited for continuous improvement approaches.
- I set up an international platform trial to test interventions in Botswana, Kenya, India and Nepal's screening programmes.
- The platform uses an automated Bayesian algorithm to autonomously perform statistical testing on routinely collected digital outcome data. The platform also uses an adaptive design, with recruitment and interim statistical testing continuing until pre-defined stopping rules are met.
- This overarching platform trial architecture was then used to test the counselling and SMS reminder interventions in Kenya, as presented in chapter 10.

Chapter three argued that health programmes constantly modify the way that they deliver services but rarely implement these service 'improvements' in the context of a robust trial. The only way of knowing whether a service modification is causally associated with an improvement (and the only way of robustly quantifying the effect size) is by using randomisation so that all known and unknown confounders are equally distributed between the arms. Unfortunately, randomised controlled trials are time-consuming, expensive, and complicated to run.[84]

Given their large resource requirements, RCTs are generally reserved for testing interventions that already have a relatively high pre-test probability of success. Perversely, this means that service modifications with the lowest chances of conferring benefit are the least likely to be subjected to rigorous testing. It also makes it less likely that modest service modifications suggested by intended service beneficiaries will be implemented and robustly evaluated. Failure to use RCTs can lead programmes to miss surprisingly effective minor tweaks, as well as mistakenly pushing ahead with expensive but useless (or even harmful) major service changes.

We wanted to develop a testing approach that makes it as affordable and feasible as possible to conduct serial RCTs to evaluate service modifications identified by left behind groups. Platform trials are perfect for the task of testing multiple interventions with the same broad population (left behind groups) and outcome (access). Compared to traditional trials that are set up to test one specific interventions,

platform trials are open-ended, meaning that they can be used to test different interventions over time. The population, statistical approach, operating characteristics, and outcome are specified at the beginning, but new interventions can be added at any time, or dropped according to pre-specified stopping rules.[85,86] This flexible approach has been described as the 'future of medical research'.[87] Platform trials have been around for decades, but their use has proliferated since the start of the Covid-19 pandemic where multiple interventions were tested in the same disease with the same set of outcomes. High-profile examples include the PRINCIPLE,[88] RECOVERY,[89] and PANORAMIC[90] trials.

A further way of lowering the resource requirements for routine, continuous RCT testing is by embedding platform trials within health programme management software and aligning outcomes with routinely collected data. This obviates the need for researchers to independently gather outcome data, saving time and costs. To further reduce resource requirements, I wanted to automate as much of the trial as possible. There is no reason why a series of algorithms within the Peek app could not perform randomisation, allocation, and statistical testing. For a digital intervention like a new SMS message, the software should also be able to deliver the intervention autonomously.

I worked with Nigel Bolster – Peek's Head of Product – to hone these specifications, and an impressive group of Peek production coders who built these new capabilities into the software. I also worked with a PhD stats student, Min Kim (under the supervision of David Macleod), to develop the specifications for a Bayesian algorithm that could perform automated testing within Peek. Min then wrote the code and tested the algorithm using multiple Monte Carlo simulations. The algorithm works by reviewing the accruing attendance data from n arms, and then assessing whether one or more stopping rule has been met, e.g. there is a >x% probability that one arm is superior. We embedded the algorithm into the Peek app and piloted it in Botswana's national eye screening programme where it has been performing as expected. The study will not conclude until screening resumes in Botswana, following a long suspension. The protocol has been published in BMC Trials (Appendix 5).[91]

I developed an adaptive platform trial master protocol that synthesised all of these design features to run embedded, pragmatic, automated, Bayesian trials of interventions within any Peek screening programme, with an initial focus on the four partner countries. This chapter presents the master protocol which has been submitted to BMJ Open.

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RESEARCH PAPER COVER SHEET

Please note that a cover sheet must be completed for each research paper included within a thesis.

SECTION A – Student Details

Student ID Number	2004040	**Title**	Dr
First Name(s)	Luke		
Surname/Family Name	Allen		
Thesis Title	Improving equitable access to community-based health services: Developing and testing a new model in Kenya's national eye screening programme		
Primary Supervisor	Andrew Bastawrous		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

SECTION B – Paper already published

Where was the work published?	N/A		
When was the work published?	N/A		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	N/A		
Have you retained the copyright for the work?*	Choose an item.	Was the work subject to academic peer review?	Choose an item.

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SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	BMJ Open
Please list the paper's authors in the intended authorship order:	Luke Allen, Min Kim, Malebogo Tlhajoane, David Macleod, Oathokwa Nknomazana, Michael Gichangi, Sailesh Mishra, James Carpenter, Sarah Karanja, Ari Ho-Foster, Bagkaki Ratshaa, Nigel Bolster, Jacqueline Ramke, Matthew Burton,

	Andrew Bastawrous.
Stage of publication	**Submitted**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I performed the initial literature searches and groundwork that identified an adaptive platform trial as the most promising vehicle for what we wanted to achieve. I drafted the initial protocol and brought in the external expert James Carpenter to support with ensuring that the design was watertight. Aandrew Bastawrous, David Macleod, and Matthew Burton contributed to designing the platform, and Min Kim developed the Bayesian algorithm. I worked with Malebogo Tlhajoane, Min, David and Sarah to set the secondary outcomes and work through how the algorithm would use accuring data. I was responsible for taking the final decisions on how the trial would run. I worked closely with LSHTMs ethics committee leaders and the research office to establish new protocols for how the trial would be reviewed. I sought comments and suggestions from the remaining co-authors and integrated them into the final draft, with proof-reading and formatting support from Malebogo.

SECTION E

Student Signature	Luke Allen
Date	26th April 2024

Supervisor Signature	REDACTED
Date	30-04-2024

Protocol for an adaptive platform trial of intended service user-derived interventions to equitably reduce non-attendance in eye screening programmes in Botswana, India, Kenya & Nepal

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- Prof Andrew Bastawrous, Chief Investigator, LSHTM

Abstract

Background

Only 30-50% of people referred to clinics during community-based eye screening are able to access care in Botswana, India, Kenya, and Nepal. The access rate is even lower for certain population groups. This platform trial aims to test multiple, iterative, low-risk public health interventions and simple service modifications with a series of individual randomised controlled trials (RCT) conducted in each country, with the aim of increasing the proportion of people attending.

Methods and Analysis

We will set up a platform trial in each country to govern the running of a series of pragmatic, adaptive, embedded, parallel, multi-arm, superiority RCTs to test a series of service modifications suggested by intended service users. The aim is to identify serial marginal gains that cumulatively result in large improvements to equity and access. The primary outcome will be the probability of accessing treatment among the population group with the worst access at baseline. We will calculate Bayesian posterior probabilities of clinic attendance in each arm every 72 hours. Each RCT will continually recruit participants until the following default stopping rules have been met: >95% probability that one arm is best; >95% probability that the difference between the best arm and the arms remaining in the trial is <1%; or 10,000 people have been recruited. Lower thresholds may be used for RCTs testing interventions with very low risks and costs. The specific design of cluster RCTs will be determined by our research team once the intervention is known, but the population and outcome will be the same across all trials.

Discussion

This APT will be used to identify effective service modifications, driving continuous improvements in access.

Ethics and Dissemination

This trial will be reviewed by UK and local ethics committees. Results will be shared via local workshops, social media, and peer-reviewed publications.

Registration: ISRCTN53970958

Keywords: Health services research, platform trial, embedded trial, global health, mHealth, equity

Strengths and Limitations

- Randomised control trials are resource intensive and often require lengthy set up periods. The adaptive platform design allows for the evaluation of multiple interventions with a single outcome, governed by a predefined set of criteria
- The study defaults are designed to test multiple low-risk, incremental service modifications in series, and quickly identify those that are just as good as, or superior to the status quo.
- Our high default tolerance for type I error means that we will often incorrectly identify arms as superior when really there is no difference. This is acceptable when arms confer similar costs and negligible risks.
- Our default very low type II error rate means that we will very rarely mistakenly identify an inferior arm as being superior.
- Our trial is embedded within screening programmes and uses automated randomisation, allocation, data collection, and statistical testing to minimise resource requirements.

Introduction

This protocol sets out the approach for running platform trials in four countries that will test interventions suggested by local intended service beneficiaries with the intention of improving equitable access to community-based eye services. Box 1 sets out the definitions of common terms used in the protocol.

Many health programmes experience large mismatches between those identified with a clinical need and those who access services. A recent international systematic review of 'no-show' appointments across all medical specialities in primary and secondary care estimated that 23% of clinic appointments are not attended, with the highest rate observed on the African continent (43%).[1] Complex supply and demand factors govern access to health services,[2] and systematically marginalised populations are often the least likely to receive care.[3,4] Improving access to care lies at the heart of Universal Health Coverage (UHC) and is a core element in the Sustainable Development Agenda.[5]

Eye services offer an instructive case study. Approximately 1.1 billion people (over 10% of the global population) live with vision impairment that could be corrected.[6] Two very cost-effective interventions - spectacles and cataract surgery – could eliminate over 90% of all vision impairment worldwide. Although provision of these services has risen in recent decades, effective coverage rates exhibit marked socioeconomic gradients at the international and intra-national levels, for example, the global effective refractive coverage is reported at 36%, with high-income countries reporting 90% and low-income only 6%.[6]

In major eye screening programmes, once people have been identified with an eye need and referred, typically only around 30-50% of these people receive care. Often there are marked socioeconomic inequalities in terms of which groups face the highest barriers to eye care.[6–8]

Box 1: Terms used in this protocol

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, but note that this term can carry the implication that intended service beneficiaries are to blame when in reality, it is often features of the service that present unsurmountable obstacles to access, especially for left behind groups. We also note that both access and attendance are 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 services. This includes near or distance vision impairment and non-visually impairing eye conditions, included but not limited to: uncorrected and under-corrected refractive errors, cataract, eye redness, 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.[9] Multiple population subgroups and domains can be used for disaggregation including as age, sex, ethnicity, occupation, income, socioeconomic status etc.

Platform trial

Platform trials use shared infrastructure and a master protocol to run multiple individual trials that test different interventions against a constant outcome (attendance) in the same target population (people identified with an eye need at screening and referred for further care).

Individual trial

A randomised controlled trial of a single intervention (e.g. a voucher or SMS reminder message) that is performed under the platform trial protocol.

Intervention/service modification

We use the term '**intervention'** when a new element is added to programmes (such as vouchers), and '**service modification'** when an existing element is tweaked, such as amending opening hours, or the wording used in communication materials.

Arms

Variants or 'doses' of the intervention/service modification. These are tested against each other and a control arm. For instance, an individual trial might test vouchers (the intervention) with three different arms; $1, $5, and $10 against a control arm (no voucher).

Embedded

The trial takes place within a real-world clinical programme, using routinely collected data.

Pragmatic

The interventions will be delivered to typical patients by programme staff (rather than research staff).

Adaptive

The algorithm will use of stopping rules to run regular interim analyses. Recruitment will continue until one or more of the stopping rules is met, meaning that sample size will be optimised.

Bayesian

The testing algorithm will use a Bayesian rather than a frequentist statistical approach; incorporating prior beliefs into the analysis and then using accruing data to continuously update the probability of events, as probability distributions.

Our research collaborative (LSHTM, Peek Vision, COESCA, Kenyan MoH, University of Botswana, NNJS, Dr Shroff's Charity Eye Hospital) is working with four major eye screening programmes to identify the population groups least able to access care in each setting (Table 1).

Table 1. Eye screening programmes

Country	Programme description	Dates	Population
Botswana	The 'Pono Yame' national school-based programme. Screeners travel to every school in the country and refer positive cases to local triage and treatment camps	2022-2024	One national programme: 500,000 children aged 5-18y
India	House-to-house community-based screening in three sites in central Uttar Pradesh.	2023-2025	Three sites: each with 50,000 to 70,000 adults and children.
Kenya	Community-based screening programmes in Meru and Kwale with school-based and primary care facility-based screening.	2022-2025	Two sites with: each with approximately 1 million adults and children
Nepal	Regional primary care-based passive screening programme in Rajbiraj, Eastern Nepal.	2022-2023	One regional site with approximately 70,000 adults and children

Through interviewing representatives from the sociodemographic groups that face the highest barriers to care, we aim to identify potential service modifications that could equitably improve access. Testing whether these intended service user-derived service modifications are causally associated with positive change requires the use of randomisation.

Randomised control trials (RCTs) provide the most robust means of appraising whether an intervention is causally associated with a change in a given outcome. Unfortunately, the resources and technical expertise required to run an RCT generally preclude their use by day-to-day health services. To overcome this barrier, we are proposing use of an automated RCT platform embedded within app-based patient workflow screening and referral systems to perform elements of randomisation, allocation, outcome assessment, and statistical testing. Global health programmes constantly adapt in order to better meet the needs of their beneficiaries, however the impact of these adaptations is rarely assessed. By reducing the barriers for rigorously testing service modifications, we hope to equip programme managers with the ability to run resource-light, real-time, embedded RCTs to continuously improve their programmes and address socioeconomic inequalities in attendance and outcomes.

Rather than running serial RCTs – each requiring lengthy set-up periods and very similar protocols, we intend to set up a platform trial. This design uses a master protocol to evaluate multiple interventions in the context of a single outcome in a perpetual manner. Platform trials are a form of multi-intervention, multi-stage design.[10] Figure 1 illustrates how multiple different interventions can be tested in individual trials under a single overarching platform trial protocol.

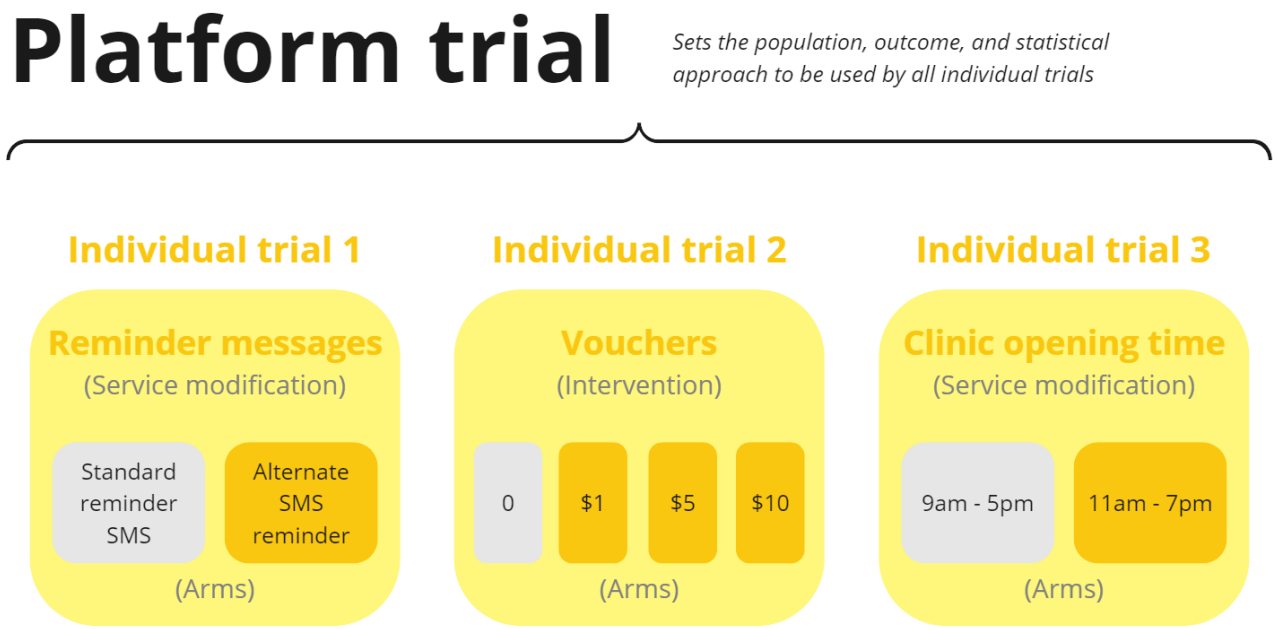

Figure 1: Three example individual trials that test new interventions against the status quo (grey boxes) as part of an overall platform trial

Addressing inequitable service outcomes is likely to require multiple different modifications in the context of continuous improvement. Early data from Botswana suggests that approximately 1/10 schoolchildren have an unmet eye health need but less than a third are able to access community eye clinics to receive care. Data from Kenya suggests that only a third of younger adults identified with an eye need are able to access care.

In each setting where Peek eye screening programmes run, we intend to engage with representatives from groups that are facing the highest barriers to accessing care to explore their perceptions of the types of interventions and service modifications that could improve access. Our platform trial will be used to test the interventions suggested by these left behind groups.

Objectives

This platform trial will iteratively test a series of interventions selected with intended service beneficiaries to increase attendance rates in community-based eye screening programmes in Botswana, India, Kenya and Nepal. Each of these programmes use the mature and validated app-based screening system developed by Peek Vision.[11–15] Programme managers in each country are interested in identifying incremental gains from multiple service modifications to deliver iterative improvements in equitable access.

Trial design

This Bayesian, embedded, pragmatic, superiority, platform trial protocol will be used to evaluate multiple interventions against a control group, using a constant outcome. The same platform approach will be used in each setting, but the interventions will all be locally-derived and tested. In each setting, the platform trial will be embedded into the local eye screening programme, using referral and attendance data directly derived from the patient management and flow software in each setting.

Study setting

Platform trials will be established in regional and national community-based eye screening programmes in Botswana (national), Nepal (one regional site), Kenya (two regional sites), and India (three regional sites). All seven sites operate using integrated screening and patient management software developed by Peek Vision. In each site our platform trial will use data routinely gathered using Peek software.

Peek Vision is a leading provider of eye screening software worldwide. The 'Peek Capture' app is used to screen participants for vision impairment, to capture observations by screeners and health practitioners, and to gather demographic data, as well as linking 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). Our trial will use these routinely collected data to test whether a series of interventions are able to reduce the proportion of people from marginalised groups with an eye care need who do not attend triage clinic once referred (Figure 2).

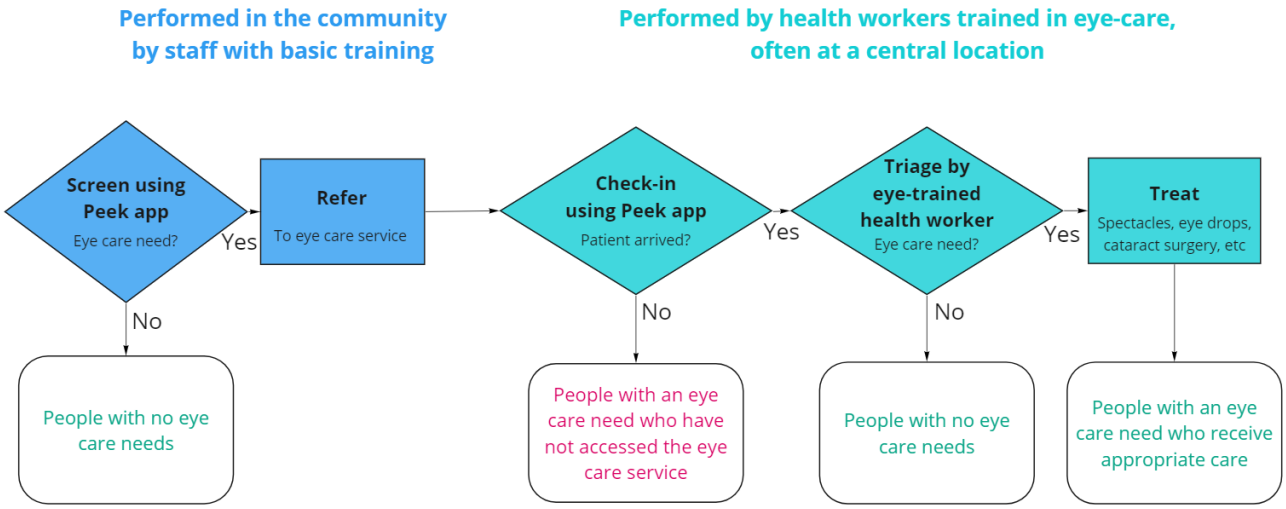

Figure 2: Schematic of patient flow through a Peek programme

Eligibility criteria

As a pragmatic trial, the eligibility criteria are determined by local programmes. We will include children aged over 5 years and adults who participate in Peek-powered eye screening programmes as outlined in Table 2. We will exclude those who do not meet local clinical service eligibility criteria, such as age (most programmes exclude children younger than 5 years).

Interventions

Interventions and administration

This platform trial is being set up to test service modifications suggested by representatives of groups that face the highest barriers to receiving care. The intention is to continuously improve attendance rates with the greatest gains focused on left behind groups.

This platform trial forms the testing element of a broader continuous improvement model called 'IM-SEEN' (IMprovement Studies for Equitable and Evidence-based iNnovation). The model has already been integrated into Peek programmes (orange boxes shown in Figure 3). In this continuous improvement approach, data collectors gather contact details and sociodemographic data from those found to have an eye problem prior to referring them. This means that programme managers using Peek have a complete record of who has not attended clinic on the appointed day, and they are able to identify the population group with the lowest attendance. Next, the programme leadership team can engage with representatives of left behind groups to elicit barriers and identify potential service improvements that would reduce non-attendance – such as changing the clinic location or amending the wording of the SMS reminder messaging. The final step is to use embedded RCTs to test these proposed improvements with new referrals. Effective interventions will be adopted across the programme. Further information on the broader IM-SEEN approach has been published elsewhere.[8]

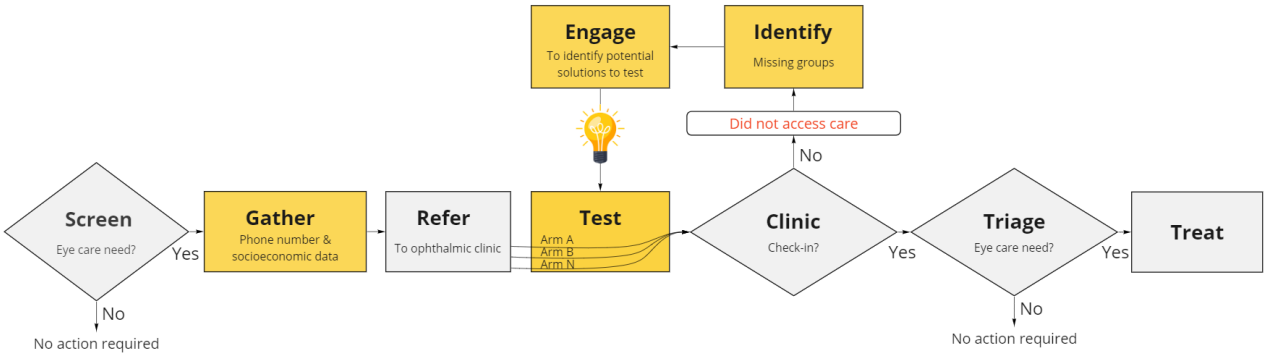

Figure 3: Elements in the IM-SEEN continuous improvement model

Screeners collect data on age, sex, location, language, ethnicity, health status, education, occupation, and income/assets, with minor local variations and enter these data into the Peek app directly after screening. Some of these categories are binary whereas other have multiple response options e.g. language. In all, the survey data can be used to divide screening populations into approximately 60 different groups, each defined by a single characteristic e.g. 'female' or 'primary school education'. We perform multivariable logistic regression to identify which population subgroups have the lowest attendance in each site.

We then conduct interviews with members of the group with the lowest attendance to identify potential service modifications to improve attendance. Rather than designing de-novo interventions, or selecting complex interventions, the focus of this process is on identifying very simple service modifications such as changing the time, day, or location of clinics, changing the language or wording of reminder SMS messages, or providing simple incentives like vouchers. There is scope to identify other 'off-the-shelf' interventions that have previously been shown to work in other contexts, but the focus is firmly on translation and implementation research rather than discover or knowledge generation i.e., the platform trial will be used to run 'T3/T4' implementation studies in each site.[16]

Once the elicitation studies have generated a list of potential service modifications, a local management group comprised of community representatives, programme managers, public health experts and programme managers (Box 2) will select a shortlist of service modification that can be tested, based on the following criteria:

- Impact: is the intervention likely to improve attendance? i.e., has this intervention been tested in other contexts and demonstrated a meaningful effect?
- Risk: what level of risk does the intervention pose to service users?
- Feasibility: how easily can we implement the intervention?
- Cost: is the intervention affordable for the programme given existing budgetary constraints?

All interventions felt to present any more than minimal risk to participants will be excluded. An explicit trade-off discussion will be held around the maximum financial resources that can be released to fund the testing of one or more intervention (which carries an opportunity cost in terms of the number of people who can be screened) and the minimum 'meaningful' improvement that would be required to justify this expenditure. For instance, the local management group may be willing to screen 1% fewer

people if attendance rates in the worst-off group improved by >5%. This decision directly informs the next step: agreeing the stopping rule thresholds for the trial ('x', 'y', and 'n' in the three rules below):

1. There is a >**x**% probability that one arm is best.
2. There is a >**y**% probability that the difference between the arms remaining in the trial is <1%.
3. [Optional] A maximum of **n** people have been recruited.

The first two rules will be used for every trial, but the values of x and y will vary depending on the intervention. Some individual trials may introduce a third rule to close trials with indeterminate results after a maximum number of people have been recruited or after a maximum length of time.

The management group will select the thresholds that are most appropriate for the given individual trial, guided by a statistician. The group may accept lower thresholds (and therefore higher risks of type I & II error) for trials of interventions with very low costs, risks, and implementation requirements. For instance, in testing two different versions of a SMS reminder message that are exactly the same cost, the group may use a 51% probability that one arm is best. In contrast, there is a greater imperative to minimise type I and II errors for costly or more risky interventions. The chosen thresholds and the intervention will be reviewed by an independent ethics committee for each individual trial.

We aim to test multiple intervention/service modifications over time in each site e.g. trialling different wording of SMS reminders, or different clinic opening hours, or vouchers of different values – and then take the most effective version to scale across the local programme before repeating the cycle to identify the next intervention/service modifications to test. Individual trials will end once the stopping rules are met. The overall platform trial will close once attendance exceeds 80% for all groups in that particular site.

Box 2: Programme management team

The platform trial infrastructure is being set up by the IM-SEEN collaborators, comprised of LSHTM, Peek Vision, COESCA, Kenyan MoH, University of Botswana, NNJS and Dr Shroff's Charity Eye Hospital using Wellcome Trust and NIHR funds, and in collaboration with national eye care administrators. Decisions around which interventions to test will be made by a multistakeholder group that includes the screening programme funders, implementing partners, and community representatives, with support from LSHTM statisticians. Once the first few interventions have been tested, it is anticipated that the local programme management teams will assume total responsibility for the platform trial process in each country, led by the relevant national decision-makers with responsibility for funding and administering the screening programme in collaboration with local lay representatives and programme implementers. Our ultimate aim is that the broader IM-SEEN process of gathering sociodemographic data, engaging with left behind groups, identifying interventions, and testing them can be taken to scale across many different sites and services, and that as the approach matures, an increasing number of decisions can be delegated from senior managers to local programme implementers.

Types of interventions

This platform trial will be used in each country to test multiple interventions in series i.e. one after the other. It is likely that interventions will be identified that can be administered either at the individual or cluster level. Cluster randomisation will be performed by the teams' statisticians with pairs of clusters matched by social, geographic, economic and demographic factors. Examples of cluster interventions may include local broadcasts to sensitise populations, new transport services to a given clinic, or changes to the opening times, languages, or locations of clinics.

Examples of individual-level interventions might include vouchers, changes to communication content, wording, timing, and modality (e.g. text message reminder messages), the use of differing visual acuity thresholds, or individual assistance with transport.

We envisage that every consenting person who is referred will be enrolled into the trial that is running at the time they are screened. Our hope is that interventions will lead to a rise in overall attendance in addition to a (larger) rise in attendance among the left behind population group. This outcome would support the broader goals of proportionate universalism whereby outcomes improve for all, with the greatest gains seen in those with the greatest baseline need.[17]

In some cases, the intervention recommended by the left behind group and selected for testing may be 100% specific for that group – for instance providing SMS reminders in a new language. In this circumstance, we would not administer the intervention to every person who is referred. Rather, we will restrict that individual trial to the left behind population group.

Some of these individual-level interventions are digital and could be administered by the Peek software directly after randomisation– for instance by sending different variants of an SMS reminder message, or an electronic voucher via SMS. Other individual-level interventions will require human involvement, such as giving out paper vouchers, or organising transport. Table 2 provides a matrix of example interventions.

Table 2: Examples of digital and non-digital interventions delivered at the individual and cluster levels

Type of intervention	Individual	Cluster
Digital	No human input required for intervention delivery. Peek software performs random allocation and delivers the intervention e.g. · SMS messages · Pre-recorded voice messages · Visual acuity thresholds · *eVouchers*	Humans select the clusters and the Peek software delivers interventions e.g. · SMS messages sent to a headteacher · Messages sent to a village chief · Pre-recorded voice messages sent to a primary care facility manager

Non-digital	Peek software performs random allocation then informs the human team. They deliver the interventions e.g. · Physical vouchers · Chaperones · Individualised transport assistance	Peek software can randomise the clusters, but humans need to deliver the interventions e.g. · Radio broadcasts · Training for implementers · New clinic times or locations · New bus services

Note that this trial will not test any pharmaceutical or medical interventions: the focus is on low-risk service modifications and public health interventions.

This platform trial offers the flexibility of being able to test a number of different interventions under the same master protocol i.e. always using the same population and primary outcomes. Each individual trial that takes place within the overall platform trial will have one or more arms (i.e. different variants/doses of individual interventions) tested against each other and a control. The investigators will not make any efforts to standardise interventions or their delivery as this is a pragmatic trial testing real-world delivery.

The local management group and programme funders will be responsible for obtaining the funding required for each intervention using the resources available to their services. They will be facilitated to apply for external grant funding to cover the costs of interventions where appropriate. We note that many potential interventions such as changing the wording of SMS reminder messages will only incur small marginal costs.

Discontinuing or modifying interventions

Arms will be discontinued (or modified to remove the risk) if there is evidence that they are harming exposed individuals. We note that only low/negligible-risk service modifications will be tested. Risk will be assessed at the intervention selection stage by a group of researchers, programme managers and lay representatives. Interventions that are deemed to be appropriate will also be independently reviewed by independent ethics committees in each setting before they are implemented in the platform trial.

There are no *a priori* strategies to improve adherence as we are not pre-specifying the interventions.

As our trials will be embedded within routine service delivery, we cannot exclude the possibility that other initiatives will be introduced by local teams before, during, or after individual trials. We will report all programmatic changes that take place during individual trials that could bias our findings.

Outcomes

This platform trial focuses on testing interventions that improve equitable access to eye services among those identified with a need during screening. We will use attendance as a proxy for access. Our analysis focuses on the population groups found to have the lowest attendance at baseline.

Primary outcome: The proportion of people attending triage clinic on their appointed date from the left behind group, measured using attendance data collected by staff when people check-in.

The left behind group will be identified at baseline as part of the 'identify' stage of the IM-SEEN process. This group will be constituted of the group(s) with the lowest baseline attendance rates that collectively constitute at least 10% of the total population. A focus on left behind groups is important to programme managers who are trying to close gaps, extend health service coverage, and ensure that their services do not exacerbate existing inequalities.

When referred participants check-in at ophthalmic clinics, their attendance status is recorded by administrative staff using the Peek app, which automatically updates a central database that holds records of each participant's eye care need, sociodemographic characteristics, arm allocation, and attendance status at the ophthalmic clinic on the appointed date. Our Bayesian algorithm will review the attendance data for every referred participant every 72 hours and calculate the probability of attendance within each arm. In our modelling we have estimated that 100 people will be referred every 72 hours. This aligns with what we have observed in India and Kenya where approximately 1,000 people are screened per day, of whom approximately 1/3 are referred. We have stipulated that the left behind group will include at least 10% of the total population (i.e. 100 people every 72 hours). In programmes where fewer people are referred every 72 hours, the interim analysis window will be extended as appropriate.

Secondary outcome: The proportion of people attending triage clinic on their appointed date across the entire population, measured using attendance data collected by staff when people check-in.

If an intervention is found to increase attendance among the left behind group, we also want to check whether there has been an impact on the overall mean attendance rate. This is to hedge against adopting an intervention that improves access for the left behind group but leads to a large 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.

Participant timeline

This platform trial is embedded within routine screening programmes. From the individual participant perspective, they will flow through the screening programmes as normal; participants will present and have their eyes checked by a first-line screener either in their own home, at a school, local clinic, or community meeting place, depending on the setting. 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 triage centre where their eyes will be re-checked by a more highly skilled practitioner and treatment will be delivered. Those requiring more advanced care will be referred on to the appropriate service provider.

Some programmes use a roaming team of screeners who visit communities sequentially. Others train screeners who remain in one location. Table 3 summarises the two approaches.

Table 3: Different screening programme approaches

	Outreach screening model	Primary care screening model
1. Community-based screening	Outreach screeners trained to use the Peek app attend schools/local venues and screen those who are present before moving to the next location	Primary care staff are trained to use the Peek app to opportunistically screen and refer those who present to primary care
2. Referral to triage	Those who screen negative (i.e. with no eye health need) are discharged. Those who screen positive provide their contact details and answer a series of socioeconomic questions. They are then referred to triage.	
3. Triage, basic treatment, & further referral	An ophthalmic nurse checks-in attenders using the Peek app and then performs an eye examination. Simple treatments are provided for basic issues (e.g. eye drops for conjunctivitis). Other cases are referred for refraction and/or further care. Referral status is recorded in the Peek app.	
4. Specialist treatment	A receptionist checks-in those who present to receive refraction or further ophthalmic treatment using the Peek app at the secondary or tertiary clinic.	

In some settings, triage will be co-located with screening. In others it will be co-located with the provision of refractive services, and in others it will be co-located with refraction and all other specialist treatment providers i.e. in a hospital. Figure 4 shows the three different configurations of screening, triage, and treatment.

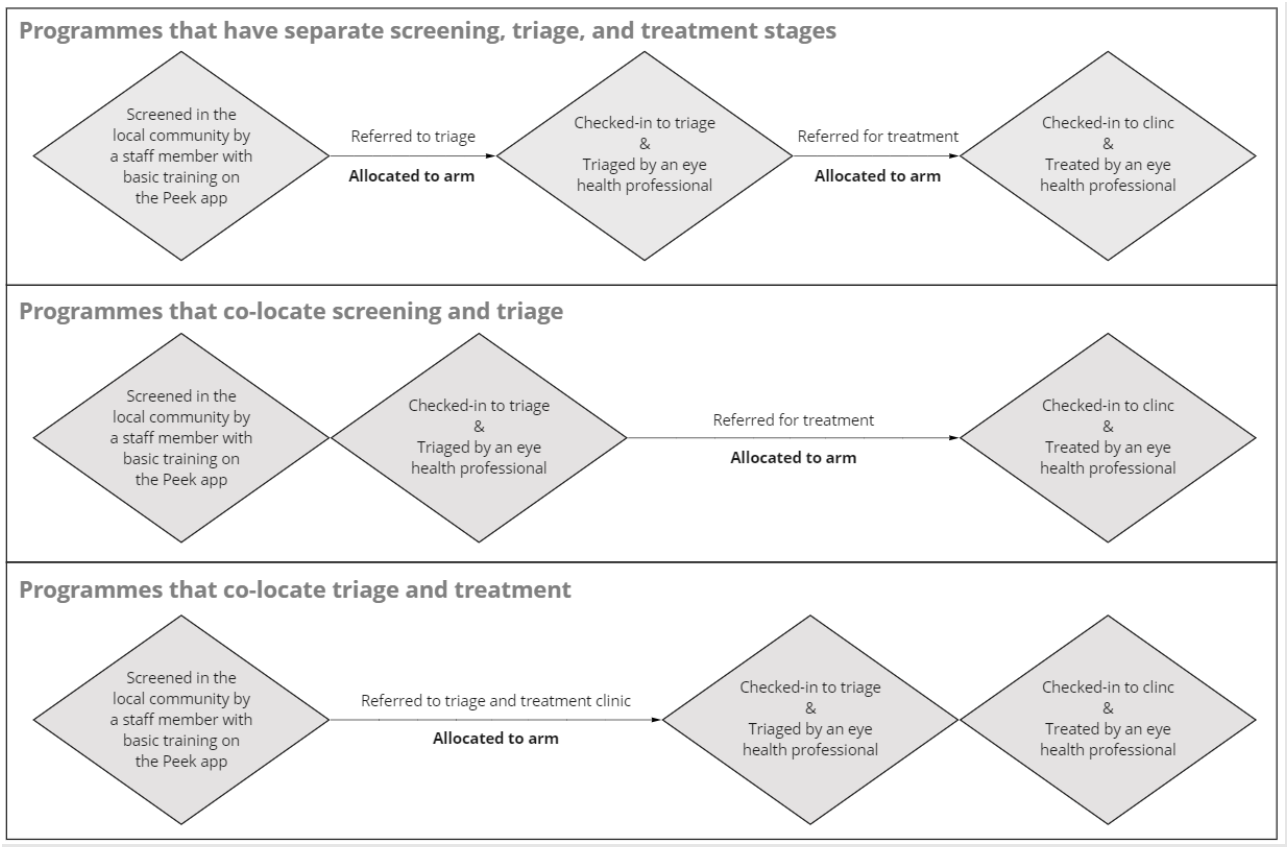

Figure 4: Flow through a generic screening programme for those requiring treatment

Most programmes aim to progress to a model of co-locating triage with screening or treatment in order to reduce the appointment burden on participants and minimise loss-to-follow-up. In the former case, participants testing positive at screening are 'referred' to a room next door for triage. In the latter case, they are given an appointment to attend a central triage & treatment clinic, commonly 1-2 weeks after screening. In most programmes SMS reminders are sent on the date of referral and the day before the appointment. Interventions will be allocated by the algorithm at the point of referral.

Sample size

As we are using stopping rules, will not pre-specify a minimum sample size or estimate effect sizes for the intervention arms. Instead, participants will be continually recruited until we reach a pre-determined maximum sample size or sufficient data accrue to trigger one or more of the other stopping rules. Triallists have argued that this approach is more "efficient, informative and ethical" than traditional fixed-design trials as this approach optimises the use of resources and can minimise the number of participants allocated to ineffective or less effective arms.[18] Every 72 hours the algorithm will review the attendance data and calculate the probability of attendance within each arm.

Operating characteristics for individual trials of interventions administered to individual participants

Based on extensive scenario modelling, we have decided to use the following stopping rules for individual trials that test interventions administered to individuals (rather than clusters):

1. There is a >x% probability that one arm is best i.e. there is a >0% difference between the arms. (Default x = 95%)
2. There is a >y% probability that the difference between the best arm and the arms remaining in the trial is <1%. (Default y = 95%)

Individual trials may include a third 'ceiling' stopping rule around a maximum length of time that the trial will run for, or a maximum sample size, depending on the context. For instance, there may only be funding to run a particular service modification for 12 months, or there may only be capacity to trial a new intervention for the first 10,000 people. The default ceiling will be 10,000 participants.

Each individual trial will end once one or more of the stopping rules has been met. At that point the superior arm will become the new standard care in the programmes(s) where it was tested. The overall platform trial will be stopped once attendance reaches or exceeds 80% for every sociodemographic group in a given site. Figure 5 provides a visual representation of how the trial will run, including the point at which new interventions can be added.

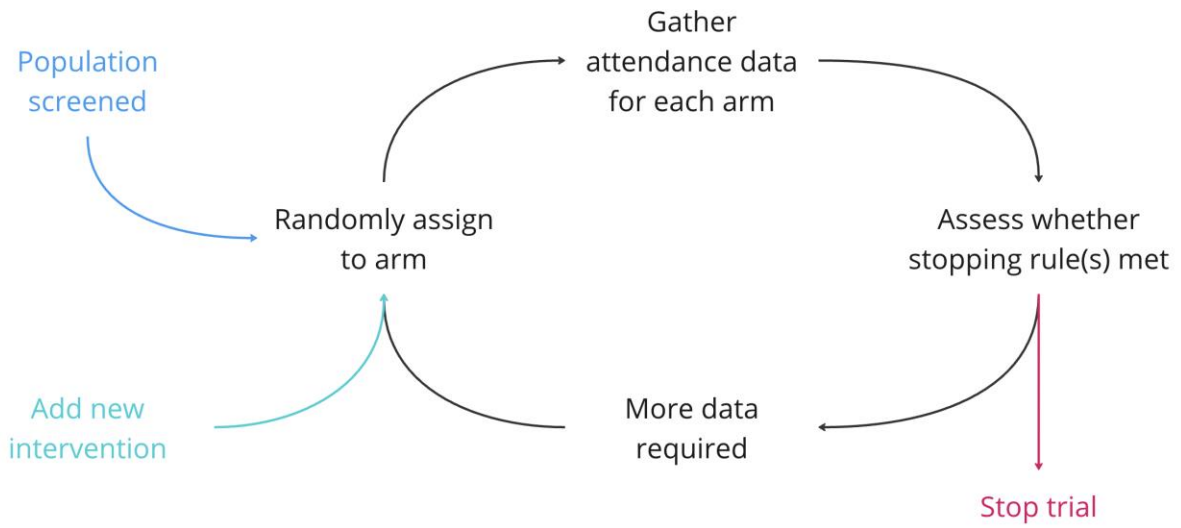

Figure 5: Platform trial schematic

We conducted simulations to estimate the impact of the early stopping rules on error rates and sample sizes. For both rules, 95% threshold values were used as default. We assumed a fixed 1:1 ratio for two-arm trials where the control arm had 50% outcome rate and the intervention arm has an effect difference of d, ranging from 0% to 5%. A total of 1,000 simulations were conducted for each value of d, and we assumed that interim analysis would take place for every 100 outcomes observed.

In this trial, we prioritize high statistical power (1- β). Minimizing β will protect against the risk of incorrectly identifying an inferior arm as a winning arm. Simulation results show that the expected power in our trial will be at least 98% when an intervention arm is more effective than the control arm by a difference of 3% or greater. When the winning arm is only marginally more effective by a difference of 1%, our trial will still ensure a statistical power of 92%, which is greater than the power of 80% used in most conventional trials. It is noted that the high statistical power in our trial comes at the cost of increased chance of committing type I error. Furthermore, it will take longer to run the trial to find smaller differences. When there is no difference between arms, we expect 32% chance of making false positive conclusions (Table 4). But we will treat the risk of committing type I error as not a major concern because we expect no or minimal harm in selecting either of the two arms with equal effectiveness.

Table 4. Expected error rates and sample size, by true effect difference between arms (d)

True effect difference between arms (d)	Type I error (α)	Type II error (β)	Median sample size [IQR]
0%	32.1%		19,950 [3075,43525]
1%		8.4%	8,150 [2500,22650]
2%		3.1%	3,800 [1500,8100]
3%		1.8%	2,100 [1000,4100]
4%		0.4%	1,600 [900,2700]
5%		0.6%	1,200 [700,2000]

10%		0%	500 [400,800]
15%		0%	300 [300,400]
20%		0%	200 [200,300]
25%		0%	200 [200,200]

The values of posterior probabilities specified in rules 1 and 2 will be determined by our research team at the start of each individual trial. The default values will be 95% as above, however it might be appropriate to use lower thresholds for interventions where the costs and risks are negligible, and higher thresholds when the costs and/or risks are high. For example, to decrease the chance of committing type I errors, the probability threshold in rule 1 will be increased from 95% to a higher value (Figure 6).

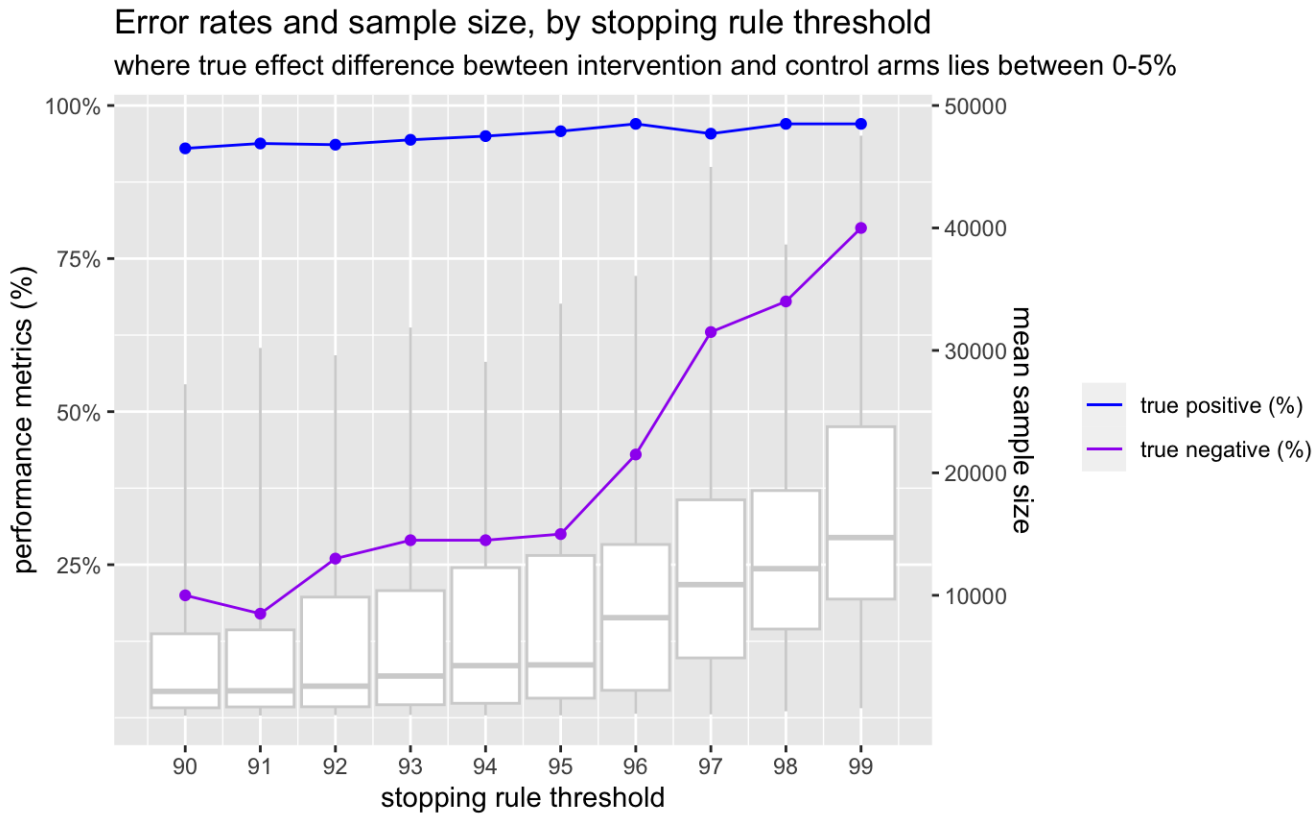

Figure 6. Expected error rates and sample size, by changing stopping rule threshold

Interventions administered to clusters

Where the chosen intervention can only be implemented in clusters rather than randomising individuals to receive the intervention, the local management team will be convened to develop a design tailored to the intervention. An important factor to account for in any design will be determining

how much the outcome varies by cluster and how large each cluster is. For cluster-level interventions it is likely we will carry out a more traditional approach with a fixed number of clusters randomised before declaring one arm the winner. The number of clusters randomised will be based on the intra-cluster correlation, the current attendance rate, the size of the clusters and the effect size for which we want to be powered to detect.

Recruitment

As the trial is pragmatic, the responsibility for recruiting screening participants lies exclusively with local programme managers. Programme implementers will enrol participants by seeking consent from all those who require referral for further assessment and care.

Allocation

Sequence generation

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. Where appropriate blocking will be used with blocks between 4-12. Stratification will be used where appropriate.

Allocation concealment mechanism

For interventions delivered to individuals, the allocation sequence will be generated within the Peek system in real-time, as participants are referred. As human trial managers are not involved in allocation there is no need for concealment.

For cluster trials these will be done randomly. Restricted randomisation will likely be used in this scenario to achieve balance between arms.

Implementation

The algorithm will be set up so that it can implement digital interventions such as SMS messages without human investigators being exposed to the allocation status of individual participants. For interventions that require human intervention – such as providing transport, chaperones, or physical vouchers, implementers will be informed of individual participants' assignment status via the Peek app at the stage that intervention needs to be delivered.

External independent review of interventions prior to implementation

As and when new interventions are selected for testing, they will need to be externally reviewed by an independent national ethics committee to ensure that the intervention(s) do not pose undue risk. The platform trial is designed to test low/negligible risk service modifications. Coupled with the fact that the master protocol will already have receive ethical approval, this should enable rapid/expedited ethical review of new interventions rather than full committee review. Table 5 summarises example interventions and risk thresholds.

Table 5: Risk thresholds and example interventions

Level of risk	Descriptor	Example interventions
High	Risk markedly higher than standard care: high probability of physical, psychological, social, or economic harm	N/A
Moderate	Risk somewhat higher than standard care	N/A
Low	Comparable to the risk of standard care	• Vouchers/discounts/subsidies • Changes to which professional perform the screening/triage • Use of different screening technologies e.g new equipment • Use of different medications e.g. eye drops • Free chaperones or transport
Negligible	Small modifications to existing routine programme where the process of obtaining consent would introduce burdens to the patient that are greater than the intervention itself	• Frequency, days, or time of day that reminder SMS messages are sent • Wording of SMS communications • Community sensitisation (e.g. radio commercials/plays/training) • Clinic days, times, and locations • Option to code additional eye conditions (beyond low acuity)Patient flow • Information presented to programme managers e.g. access to a dashboard • Types of reminders e.g. SMS or picture message or voice message or leaflet

Once the master adaptive platform trial has received ethics approval, individual interventions will be submitted as amendments to the master APT in the form of new appendices. Individual trials will not commence until ethics approval has been received from LSHTM and the relevant local ethics committee(s).

Masking

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 will not be masked to assignment. For interventions that require human delivery (e.g. handing out a paper voucher), implementers will be able to view allocation status out of necessity. Outcome assessment will be performed by a different group - those responsible for checking-in participants at triage clinic. No steps will be taken to mask these staff to participant allocation status. Ongoing interim data analysis will be performed by the Bayesian algorithm every 72 hours.

Unmasking

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

The Data Safety and Monitoring Committee (DSMB) will have access to all data at any point and for any reason, including to unmask assignment if required. The trial steering committee members will only be able to access these data as per the adverse event protocol outlined below.

Data Collection

Data collection methods

As stated above, outcome assessment (attendance at clinic) will be recorded when participants check-in at clinic on their appointed date. Each participant's attendance status will be recorded on their central record.

Retention

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

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.

Statistical methods

All analysis will be conducted using R. 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.

During this adaptive trial, clinic attendance in each arm will be assessed using Bayesian methods. At each prespecified interim analysis point, a binomial distribution of outcome will be described for each arm using the total number of participants allocated to the arm and the number that attended at clinic. The binomial distribution will be combined with a prior distribution to update the posterior distribution of each arm. A regularizing prior of beta(100,100) will be applied to reduce overfitting until a reliable amount of data is accrued. A Monte-Carlo simulation will be used to update posterior distributions at each interim analysis point. Posterior probabilities will be calculated and compared to the stopping rules as to whether the trial should continue into the next day or end early. If there is sufficient evidence to meet one of the stopping rules, the trial will terminate and proceed to the final analysis stage.

Upon completion of the trial, a complete case analysis will be performed on all eligible participants in the trial on an intention-to-treat basis. The primary endpoint of the trial is clinic attendance the left behind subgroups after randomization. Within a selected subgroup, the primary analysis will use beta-binomial models to estimate the posterior distribution of attendance in each arm. Posterior probabilities will be calculated to compare the proportion of attendance between arms and to identify an arm that results in the highest likelihood of attendance. For the secondary endpoint, beta-binomial models will also be used but expanded to all participants in the trial. A more detailed description of the statistical methods will be reported as open access as a separate statistical analysis plan.

Equity analyses

The primary aim of the platform trial is improving equity. We focus on attendance rates in the left behind group, and also look at how attendance rates in this group compare to those among the entire population.

Non-adherence and missing data

Missing data is not a problem because the outcome is attendance. Non-adherence will depend on the intervention. We will use intention-to-treat analysis.

An independent Data and Safety Monitoring Board (DSMB) will be appointed in each country with the primary aim of assuring safety of participants in the trial(s). The DSMBs will advise the steering committee and sponsor on continuation or stopping of the trial(s) based on safety and efficacy considerations. Each DSMB will have three members, all independent of the running of the trial, and all with relevant clinical and epidemiological experience. Each DSMB will operate independently of the study sponsor and the steering committee. Each DSMB will confirm their own specific meeting arrangements and draw up their own charter, working from the template produced by the Damocles Study Group.[19] It is proposed that each DSMB would meet prior to the beginning of each individual trial conducted under the platform protocol, one third of the way through, and at the end of each individual trial, to assess the safety of the trial procedures. Each DSMB will agree the way it will monitor the data, what it requires from the investigators in this respect and will communicate this to the PIs. All data can be interrogated remotely in real-time. The DSMB may visit the study coordination centre to assess data management, record keeping and other important activities. Each DSMB will determine the manner in which it will monitor the data, what it requires from the investigators in this respect and will communicate this to the PIs.

Botswana DSMB

- Billy Tsima
- Lemphi Moremi
- Mantate Manyothwane

Kenya DSMB

- Nyawira Mwangi
- D Stephen Gichuhi
- Moses Mwangi

Nepal

- Sabina Shrestha
- Sanjib Mishra
- Rajiv Ranjan Karn

India

- Shalinder Sabherwal
- Javed Nayab
- Atanu Majmudar

Consent

Written informed consent will be sought by screeners during screening - at the point that participants are identified as having an eye care need and referred on for further care. Consent will be recorded either on paper forms or by using an electronic tick box (as appropriate for low-risk trials). Whichever format is used, consent status will be recorded on the Peek app.

Participants will be given the contact details of the research managers and will be free to leave the trial at any time. There will be no remuneration for participants.

Patient and public involvement

Lay people and community advisory committees have reviewed and contributed to the development of this protocol. The interventions that the platform trial will test will be derived from engagement with affected groups. Lay representatives will assist with interpretation and publication of the trial findings.

Adverse event reporting and harms

An adverse event (AE) is defined as any untoward medical occurrence in a patient or study participant. 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 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 on a secure, password-protected file on a LSHTM 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 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.

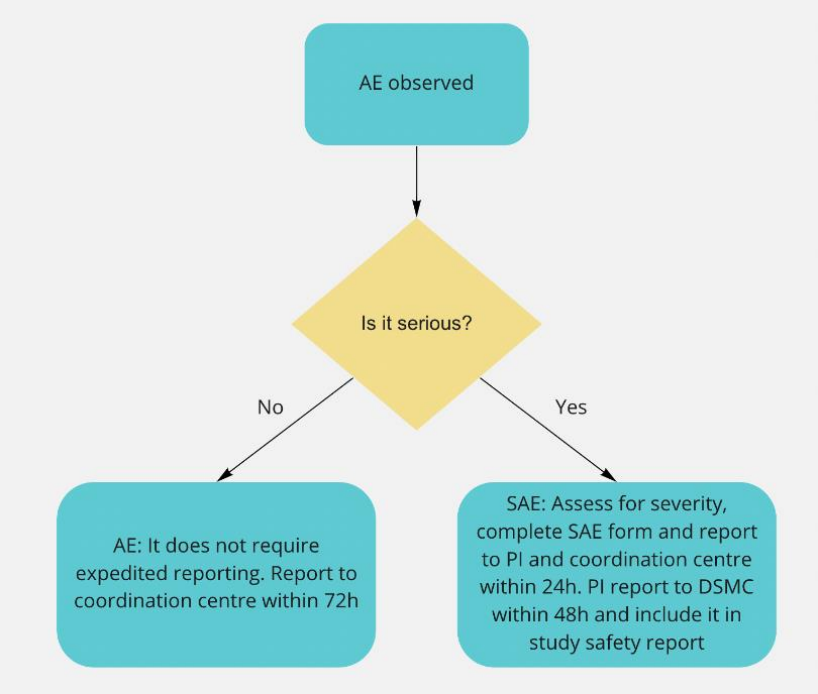

Figure 5: Approach for managing adverse events

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 mean attendance but is associated with a decline among left behind groups. However, 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.

Our estimate of the probability/proportion will be biased because, on average, the stopping rules will be triggered at a 'local peak'. As such, we will be able to identify that, say, A is better than B, but the estimate of the attendance rate in A will be an overestimate.

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 in our individual study writeups. 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

Each individual trial will have its own protocol that will be published online. The results of each trial will be immediately fed back to the relevant programme managers. Findings will also be shared with wider stakeholders, including eye care professionals, policymakers, and community representatives at dedicated dissemination meetings. We will write-up all individual trials for publication in the peer-reviewed literature and share lay-friendly summaries via social media.

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Competing Interests

The Peek Vision Foundation is a registered charity in England and Wales, with a wholly owned trading subsidiary, Peek Vision Ltd (09937174). MJB is a trustee of the Peek Vision Foundation and AB is Chief Executive Officer of the Peek Vision Foundation and Peek Vision Ltd. All other authors have no competing interests

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Appendix: CONSORT checklists

Section	Item	Standard 2010 CONSORT Item	Equity extension	Pragmatic extension	Adaptive extension	Page
Title						
Title	1a	Identification as a randomised trial in the title	If health equity is a major focus, consider using the term "health equity" in the title.			1
Abstract						
Structured Summary	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	State research question(s) related to health equity			2
	1c		Present results of all planned health equity analyses			2
	1d		Describe extent and limits of applicability to populations of interest across PROGRESS-Plus characteristics			2

Introduction						
Background	2a	Scientific background and explanation of rationale	Describe rationale for focus on health equity	Describe the health or health service problem that the intervention is intended to address and other interventions that may commonly be aimed at this problem		3,5,6
Objective	2b	Specific objectives or hypotheses	State the objective being addressed with reference to health equity			7
Methods						
Trial Design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Describe aspects of trial design that were chosen to answer equity questions			7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons			Type of adaptive design used, with details of the pre-planned trial adaptations and the	12-13

					statistical information informing the adaptations Important changes to the design or methods after trial commencement (such as eligibility criteria) outside the scope of the pre-planned adaptive design features, with reasons	
Participants	4a	Eligibility criteria for participants	Report population eligibility criteria across relevant PROGRESS-Plus characteristics.	Eligibility criteria should be explicitly framed to show the degree to which they include typical participants and/or, where applicable, typical providers (eg, nurses), institutions (eg, hospitals), communities (or localities eg, towns) and settings of care (eg, different healthcare financing systems)		8-9, 14

	4b	Settings and locations where the data were collected	Report context and relationship to health inequity			7
	4c		Report details of partnerships with populations and communities, where applicable.			5,7,23
Intervention	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Report whether comparator intervention is the standard of care, and whether it has equity implications.	Describe extra resources added to (or resources removed from) usual settings in order to implement intervention. Indicate if efforts were made to standardise the intervention or if the intervention and its delivery were allowed to vary between participants, practitioners, or study sites		8,11-12

				Describe the comparator in similar detail to the intervention		
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Report whether outcomes were identified as relevant and important to population(s) across PROGRESS-Plus characteristics and how this was done	Explain why the chosen outcomes and, when relevant, the length of follow-up are considered important to those who will use the results of the trial	Any other outcome measures used to inform pre-planned adaptations should be described with the rationale	13
	6b	Any changes to trial outcomes after the trial commenced, with reasons				N/A
Sample Size	7a	How sample size was determined	Report whether analyses focused on health equity objectives are powered to detect differences.	If calculated using the smallest difference considered important by the target decision maker audience (the minimally important difference) then report where this difference was obtained	How sample size and operating characteristics were determined	15-16

	7b	When applicable, explanation of any interim analyses and stopping guidelines			Pre-planned interim decision-making criteria to guide the trial adaptation process; whether decision-making criteria were binding or non-binding; pre-planned and actual timing and frequency of interim data looks to inform trial adaptations	15-18
Randomisation Sequence Generation	8a	Method used to generate the random allocation sequence				19
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Report whether randomisation was stratified on PROGRESS-Plus characteristic(s)		Type of randomisation; details of any restriction (such as blocking and block size); any changes to the allocation rule after trial adaptation decisions; any pre-planned allocation rule or algorithm to update	19

					randomisation with timing and frequency of updates	
Allocation Concealment Mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned				19
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions				19
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		If blinding was not done, or was not possible, explain why		20
	11b	If relevant, description of the similarity of interventions				11-12, 19-20
	11c	[only applies for ACE]			Measures to safeguard the confidentiality of interim information and minimise	20-22

					potential operational bias during the trial	
Statistical Methods	12a	Statistical methods used to compare groups for primary and secondary outcomes			Statistical methods used to compare groups for primary and secondary outcomes, and any other outcomes used to make pre-planned adaptations	15-18, 21
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Report details of additional analyses focused on health equity, including whether analyses to estimate heterogeneity of effects between population subgroups were done on an additive or multiplicative scale, and whether pre-specified.			16, 21
	12c	[ACE only]			For the implemented adaptive design features, statistical methods used to	21

					estimate treatment effects for key endpoints and to make inferences	
Ethical Concerns	a	[equity only]	Report details of ethical clearance and informed consent			19,23
Results						
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome	Describe for each group, numbers of participants who were assigned, received and who were analyzed across relevant PROGRESS-Plus characteristics	The number of participants or units approached to take part in the trial, the number which were eligible, and reasons for non-participation should be reported	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome and any other outcomes used to inform pre-planned adaptations, if applicable	8,9,15,16
	13b	For each group, losses and exclusions after randomisation, together with reasons	Describe for each group, losses and exclusions after randomisation across relevant			8

			PROGRESS-Plus characteristics, with reasons.			
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Report whether methods of recruitment were designed to reach populations across relevant PROGRESS-Plus characteristics.		Dates defining the periods of recruitment and follow-up, for each group	5
	14b	Why the trial ended or was stopped				10
	14c	[ACE only]			Specify what trial adaptation decisions were made in light of the pre-planned decision-making criteria and observed accrued data	
Baseline Data	15	A table showing baseline demographic and clinical characteristics for each group	Present the baseline characteristics also across relevant PROGRESS-Plus characteristics.			N/A
	15b	[ACE only]			Summary of data to enable the assessment of similarity	N/A

					in the trial population between interim stages	
Numbers Analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups				N/A
Outcomes and Estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)				N/A
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended				N/A
	17c	[ACE only]			Report interim results used to inform interim decision-making	N/A
Ancillary Analysis	18a	Results of any other analyses performed, including subgroup analyses and adjusted	Give the results of additional analytic approaches related to			N/A

		analyses, distinguishing pre-specified from exploratory	equity objectives distinguishing pre-specified from exploratory.			
	18b		Details of implementation (coverage, intensity) in each trial arm across relevant PROGRESS-Plus characteristics			N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Report whether intervention generated inequities (e.g. unintended effects) were assessed			N/A
Discussion						
Limitation	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Report any limitations related to assessing effects on health equity.			24
Generalizability	21	Generalisability (external validity, applicability) of the trial findings	In addition, report applicability related to population of interest across PROGRESS-Plus characteristics.	Describe key aspects of the setting which determined the trial results. Discuss possible differences in other settings where clinical		5,24-25

				traditions, health service organisation, staffing, or resources may vary from those of the trial		
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence				N/A
Other Information						
Registration	23	Registration number and name of trial registry				2
Protocol	24	Where the full trial protocol can be accessed, if available				2
	24b	[ACE only]			Where the full statistical analysis plan and other relevant trial documents can be accessed	TBD

Funding	25	Sources of funding and other support (such as supply of drugs), role of funders				25

ACE, Adaptive designs CONSORT Extension

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Appendix: Data management plan

1. DATA SOURCES AND DATA COLLECTION PROCESSES

The research objectives require the collection of quantitative survey data, as well as qualitative data in the form of audio recordings and quotes from study participants. Table 1 below outlines the data fields to be collected throughout the various stages of the data collection process. All data will be treated as personal data for the purpose of data capturing and processing, as collectively, it can be combined in a way that could make it identifiable.

Data from the initial screening process will be collected in Peek powered Eye Health School and Community Programmes using Peek's Capture application. During the initial screening process only basic and non-personal identifying data is collected, with the exception of telephone number. Following initial screening, all those identified as requiring referral will 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 outlined in table 1 below. 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.

Following triage of individuals who had screened positive, a four-stage rapid exploratory sequential mixed-methods study design will be used to evaluate barriers to health access among non-attenders who had been flagged for onward treatment. Telephone interviews will be conducted among 60 non-attenders, purposively selected from socio-demographic groups with the lowest overall attendance rates. The aim of the telephone interviews is to explore and evaluate their perceived barriers to clinic attendance, and develop a list of potential solutions.

Once interventions and service modifications have been identified, these will be tested through a series of pragmatic, embedded, adaptive parallel, multi-arm randomized control trials (APT). The intention of the APT is to continuously improve attendance rates, particularly amongst those groups with the lowest engagement rates overall. Table 1 outlines each of the data collection phases, the data fields to be collected, and the study populations of each of the stages discussed.

Table 1: Data collection phases, data fields and study populations for broader I'M SEEN project

	Phase	Data Fields Collected		Eligible Population
1.	Initial Screening Process	• Age • Gender • Language • Awareness (optional) • Diabetes status (optional)	• Spectacle status • Visual Acuity • Eye Condition • Telephone Number	All included in PEEK screening programme
2.	Collection of sociodemographic data	• Health insurance status • Language • Marital Status • Religion • Migrant/refugee status • Housing	• Ethnicity • Disability • Occupation • Education • Food adequacy • Asset ownership • Family members	All those identified as requiring referral
3.	Elicitation questions (via telephone interview)	*Barrier elicitation questions:* • In your own words, can you talk me through why we didn't see you/your child at that clinic? *Probing questions:* • Are there any other factors that prevented you/him/her from attending? • Is there anything else you'd like to share? • Of the issues you mentioned, which is the most important?		Non-attenders of onward treatment appointments purposively selected by sociodemographic group.

Solution elicitation questions:

The last part of the interview is exploring whether there is anything we could do to address these barriers and make it more likely that other people like you/children like [child's name] will attend in the future.

- So, to start, what would make the biggest difference?

Probing questions:

- What else would help?
- What other changes could we make to the programme that would make it easier for children like [child's name] to attend?
- Are there any other specific changes that we could make to the way that the programme or eye clinics run?
- Who do you feel should implement this/these changes?"
- You mentioned [list their proposed solutions]. Some of these may be beyond our control, but if we managed to [list their proposed programme-related changes], do you think that would be enough to allow children like your son/daughter to attend?"

4.	Online Survey (hyperlink sent via SMS)	Ranking of proposed service modifications proposed during telephone interview using mobile phone numbers gathered during initial screening process.	Representative sample of non-attenders
5.	Programme Leader/Stakeholder Workshop	Audio recording of workshop conversation during which the list of prioritised service modifications derived from the online survey will be discussed and evaluated for testing	Service managers, programme implementers, national and regional eye care policymakers, as well as any other relevant stakeholders.

6. Adaptive Platform Trial	Examples of possible interventions delivered at the individual and cluster levels include: *Individual* • SMS messages • Voice messages • Visual acuity thresholds • eVouchers • Physical vouchers • Chaperones • Individualised transport assistance	*Population (cluster)* • Change to language of messages sent to participants • Radio broadcasts • Training for implementers • New clinic times or locations • New bus services	Children over 5 years, and adults who participate in PEEK-powered eye screening programmes. Those who do not meet local clinical service eligibility criteria will be excluded.

2. DATA COLLECTION TOOLS

Various data collection tools will be used to populate the data fields outlined in table 1.

Quantitative Data:

- Android Mobile Devices – Survey data, and data derived from the APT (phases 1,2, 4 and 6) 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 APT will be embedded within Peek software used in parallel with a Bayesian algorithm that will be used to autonomously run response adaptive trials.

Qualitative Data:

- Play Verto – The online survey will be administered through Play Verto, a play-based online survey group who have worked with the United Nations and others to develop engaging short surveys that have impressively high response rates in low- and middle-income countries. The survey will be sent as a hyperlink in an SMS. PlayVerto will gather, store and process. After, they will transfer (anonymised data) it to LSHTM who will perform further processing and storage. LSHTM will share aggregate anonymised findings with partners and in public domain.
- Data Abstraction Matrix: During the telephone interviews, data collectors will directly enter notes, quotes, open codes, and abstractions into a matrix. Data gathered, processed and stored by local partner organization. Then shared with LSHTM (fully-anonymised responses to be shared).
- Audio Recordings – Telephone interviews will involve verbal communication and discussion, and thus will be collected and stored using digital audio-recording methods.

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.
- Play Verto – is a play-based online survey group who have worked with the United Nations and others to develop engaging short surveys that have impressively high response rates in low- and middle-income countries.
- 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.

3. 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 needs 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%.
Conduct telephone interviews, online surveys and stakeholder workshop	In order to better understand barriers to accessing eye services a series of activities will be conducted through a four-stage sequential mixed-methods approach. These include: 1. Telephone Interviews – Telephone interviews will be conducted with non-attenders, purposively selected from subgroups with the lowest attendance rates. 2. Following telephone interviews, a single list of suggested solutions will be compiled 3. Online survey – An online survey will be conducted among a representative sample of non-attenders to rank mooted interventions/service modifications. 4. Stakeholder workshop – Programme leaders and key stakeholders will then select one or more of the highest ranked interventions to test, based on impact, feasibility, risk and cost. Following completion of this process, data will be analysed to elicit barriers to care and recommended interventions/service modifications to improve attendance rates.

Testing of service modifications through APT	An automated adaptive platform trial (APT) will iteratively test a series of interventions selected with intended service beneficiaries to increases attendance rates among marginalised groups. This will be done through a Bayesian, embedded, pragmatic, superiority, adaptive platform trial platform that will use response adaptive randomisation.

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

6. 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

4. 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, and 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 before screeners visit the school:

"I understand that my child's anonymous data may be shared with other researchers. 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.

5. 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,

6. DATA STORAGE AND SECURITY

Data collection, management and storage for this study will be managed by seven entities described below:

A. Peek Vision Capture Application
B. Play Verto
C. The London School of Hygiene and Tropical Medicine
D. Botswana: The University of Botswana
E. India: Dr Shroff Charity Eye Hospital
F. Kenya: Kenya Medical Research Institute?
G. Nepal: Nepal Netra Jyoti Sangh

Peek Capture Application

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. h

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 here. 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?

- Delete personal & confidential details at the earliest opportunity (specify when)
- Use digital storage that require a username/password or other security feature
- Physical security (such as locked cabinet or room)
- Encrypt storage devices
- Encrypt data during transfer
- Avoid cloud services located outside EU
- Take 'Information Security Awareness training'
- Ensure backups are also held securely

The aggregated data that is shared among project staff and partners 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.

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.

Resources will be made available at the same time as findings are published in an academic journal. Once available, we will make other researchers aware that the resources exist by:

- Citing resources in future research papers, e.g. in the data access statement or reference list
- Citing resources in project reports
- Adding resources to a list of our academic outputs

The following steps will be taken to ensure that resources are easy to analyse and use in future research:

- Store resources in open file formats such as CSV, Rich Text, etc. See https://www.ukdataservice.ac.uk/manage-data/format/recommended-formats
- Designate a corresponding author / data custodian who will handle data-related questions

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.

Post-script: The process of obtaining ethical review

The process of obtaining ethical approval was somewhat challenging given that this was LSHTM's first platform trial. I worked closely with the research governance and integrity office and the ethics committee secretariat to develop the school's ethics and governance architecture for assessing and managing platform trials, using the IM-SEEN APT protocol as a test case. As part of this work, I reached out to the University of Toronto's primary care team who had recently run a global conference for the leaders of platform trials in order to discuss the issues of governance and data management. Most of the research teams I corresponded with shared that they had no standalone pathways for ethical review, undermining one of the core potential strengths of platform trials – the speed associated with ethics committees only having to review the intervention, having already approved the rest of the trial architecture.

After several months of discussion, LSHTM settled on an approach whereby the overall trial protocol is submitted, reviewed, and approved, with subsequent individual trials submitted as amendments to the master protocol. Overarching trial protocols will receive full committee review, but subsequent individual amendments (i.e. individual trials that will run according to the APT master protocol) will be sent for chair's review. If the chair sees no issues, then approval can be granted within two weeks. If the chair has any concerns about the proposed intervention to be tested, then it will be sent for full committee review. I'm proud of the role I played in helping to develop this proportional approach, as I feel it offers a good balance between rigor and speed, and saves the full committee from having to re-review elements that they have already seen and approved. It took five months from initial submission to approval for the APT master protocol, including three rounds of clarifications and multiple meetings. In contrast, review and approval for the protocol of the first RCT intervention to be tested (presented in the next chapter) took four days.

In retrospect, it would have been easier to submit the first intervention alongside the master protocol as some of the committee members found it confusing to review a trial with no intervention. Many of the Canadian ethics board require that the first full committee review of an APT also includes at least one intervention. This experience informed the way that we approached ethics in Kenya, given that the KEMRI ethics committee had never reviewed a platform trial before either, and their overall system for approvals requires many additional stages. I was also cognisant that the ethics committee had not previously reviewed a trial that used Bayes, stopping rules, automated allocation, automated data collection, or automated statistical testing. As such, I waited until we knew what the first intervention would be (enhanced counselling) and then submitted the trial as a RCT that included a number of novel design features. Once this initial trial was approved as a standalone study, I planned to submit the master APT. The plan is to submit future interventions under this APT.

Chapter 10

Protocol for an embedded, pragmatic, automated, individual-level, two arm superiority RCT within an adaptive platform trial

My colleague Sarah training local screeners on how to seek and document consent
Source: Author. Consent has been granted from all those in the photo

Key messages

- Using the overarching adaptive platform trial architecture, I led the development of a protocol to test the counselling and SMS reminder interventions with an RCT in Meru.
- This initial trial will form the first part of my post-doctoral work.
- Under this protocol, the Peek app will randomise people to be read either the standard care counselling script or the intervention script at the point of referral.
- The Bayesian algorithm will analyse clinic check-in data every seven days, comparing the probability of attendance in each arm.

The final part of my thesis involved designing the trial that will test the enhanced counselling intervention under the master adaptive platform trial protocol. In discussion with the local team and our group statisticians I made one amendment to the operating characteristics of the master APT protocol; changing the interim statistical testing period from three days to seven days, based on a review of the number of people likely to be screened each day. This calculation is explained in the paper.

The trial has been registered with ISRCTN (https://doi.org/10.1186/ISRCTN11329596) and approved by LSHTM and KEMRI ethics committees. Given the fact that we are using stopping rules rather than a fixed sample size, the trial could potentially run for over a year before stopping. I intend to lead this trial with my Kenyan collaborators as my first post-doctoral project. The trial protocol has been submitted to BMC Trials. Note that the journal's formatting standards require that each section of the protocol should be numbered in curly brackets to align with the CONSORT check-list items.

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RESEARCH PAPER COVER SHEET

Please note that a cover sheet must be completed for each research paper included within a thesis.

SECTION A – Student Details

Student ID Number	2004040	**Title**	Dr
First Name(s)	Luke		
Surname/Family Name	Allen		
Thesis Title	Improving equitable access to community-based health services: Developing and testing a new model in Kenya's national eye screening programme		
Primary Supervisor	Andrew Bastawrous		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

SECTION B – Paper already published

Where was the work published?	N/A		
When was the work published?	N/A		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	N/A		
Have you retained the copyright for the work?*	Choose an item.	Was the work subject to academic peer review?	Choose an item.

*If yes, please attach evidence of retention. If no, or if the work is being included in its published format, please attach evidence of permission from the copyright holder (publisher or other author) to include this work.

SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	BMC Trials
Please list the paper's authors in the intended authorship order:	Luke Allen, Min Kim, Michael Gichangi, David Macleod, James Carpenter, Malebogo Tlhajoane, Sarah Karanja, Nigel Bolster, Matthew Burton, Andrew Bastawrous

Stage of publication	**Submitted**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I wrote the first draft and sought input from my co-authors. Min Kim, David Macleod, Andrew Bastawrous, Matthew Burton, James Carpenter, and Malebogo Tlhajoane helped me refine the testing approach. Nigel Bolster led on tweaking the algorithm to work as set out in the paper. Sarah Karanja and Malebogo supported me with the developemnt of patient information and consenting documentation. I led the process of obtaining ethical review at LSHTM and drafted the application for Kenya. Sarah then led the rest of the Kenyan ethics process as the lead local researcher.

SECTION E

Student Signature	Luke Allen
Date	26th April 2024

Supervisor Signature	REDACTED
Date	30-04-2024

Protocol for an individual-level, two arm, superiority RCT within an adaptive platform trial: Enhanced patient counselling and SMS reminder messages to improve access to community-based eye care services in Meru, Kenya:

Luke Allen[1], Min Kim[1], Michael Gichangi[1,2], David Macleod[1], James Carpenter[1,3], Malebogo Tlhajoane[1], Sarah Karanja[4], Nigel Bolster[1], Matthew Burton[1], Andrew Bastawrous[1]

1. London School of Hygiene and Tropical Medicine, London, UK
2. Ministry of Health, Nairobi, Kenya
3. University College London, London, UK
4. Kenya Medical Research Institute, Nairobi, Kenya.
5. Peek Vision, London UK

Abstract

Background: 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 Meru 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, and only 30% of young adults (18-44 years old) were able 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.

Methods: Younger adults told us that better counselling at the point of referral would be likely to improve attendance rates. Based on their feedback, we have developed a script that will be read to participants in the intervention arm at the point of referral, and then sent as a reminder SMS the following day. We will assess whether attendance rates are higher among those randomised to receive this enhanced counselling compared to those who receive standard care. The primary outcome will be the proportion of people from the left behind group who attend triage clinic. Our secondary analysis will examine overall mean attendance across all groups. We will calculate Bayesian posterior probabilities of attendance in each arm every seven days and continually recruit participants until one of two stopping rules have been met: there is a >95% probability that one arm is best or there is a >95% probability that the difference between the arms is <1%.

Discussion: This Bayesian RCT will be embedded into the clinical workflow software that is used to manage referrals and clinic attendance. It will test whether a simple, low-cost, service user-derived intervention is able to improve access to services among a population group that is currently being left behind.

Trial Registration: ISRCTN 11329596, Registered on 02 February 2024

Keywords

Health services research, Bayesian trial, embedded trial, pragmatic trial, equity, access

Administrative Information

Title {1}	Enhanced patient counselling and enhanced SMS reminder messages to improve access to community-based eye care services in Meru, Kenya: An individual-level, two arm, superiority RCT within an adaptive platform trial
Trial registration {2a and 2b}.	ISRCTN 11329596, Registered on 02 February 2024
Protocol version {3}	Version 1, 15 February 2024
Funding {4}	This work was supported by the National Institute for Health Research (NIHR) (using the UK's Official Development Assistance (ODA) Funding) and Wellcome [215633/Z/19/Z] under the NIHR-Wellcome Partnership for Global Health Research. The views expressed are those of the authors and not necessarily those of Wellcome, the NIHR or the Department of Health and Social Care.
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Name and contact information for the trial sponsor {5b}	London School of Hygiene & Tropical Medicine. For further information regarding the sponsorship conditions, please contact the Research Governance and Integrity Office: London School of Hygiene & Tropical Medicine Keppel Street London WC1E 7HT Tel: +44 207 927 2626 Email: RGIO@lshtm.ac.uk
Role of sponsor {5c}	The study sponsor and funders will not have any role in- or ultimate authority over the study design; collection, management, analysis, and interpretation of data; writing of the report; or the decision to submit the report for publication.

Introduction

Background and rationale {6a}

Approximately 1.1 billion people (over 10% of the global population) live with vision impairment that could be easily corrected.[1] Two very cost-effective interventions - spectacles and cataract surgery – could eliminate over 90% of all vision impairment worldwide. Although provision of these services has risen in recent decades, effective coverage rates exhibit marked socioeconomic gradients at the international and intra-national levels, for example, the global effective refractive coverage is reported at 36%, with high-income countries reporting 90% and low-income only 6%.[1]

In major eye screening programmes, once people have been identified with an eye need and referred on, only around 30-50% of these people access care, and research from Nigeria and Sri Lanka suggests that unmarried (primarily widowed) women and people living in rural areas are the least likely to access care.[2]

This protocol outlines an intervention to be implemented in Kenya's Vision Impact Project in Meru County. Previous studies conducted by our team found that only 50% of people found to have an eye care need during screening were able to access local treatment outreach clinics, once referred. An equity analysis found that age was associated with access: only 30% of younger adults (aged 18-44 years) accessed care once referred.

In interviews with younger adults who were not able to access care we identified a number of barriers and potential solutions to improve access to care for this group. We then conducted a survey with 401 additional young adults who were not able to access care and asked them to rank the potential solutions/service modifications by likely impact. One of the top-rated ideas was to provide additional information about treatment outreach clinics at the point of referral and in follow-on SMS reminder messages. Specifically, younger adults who were not able to access care told us that enhanced counselling should include information on;

- The outreach treatment clinic opening times,
- the services that are available at these clinics (vs those that require onward referral to hospital-based services),
- any costs involved at the outreach clinic,
- and the importance of attending

This trial is intended to test whether provision of this additional information is associated in a higher probability of accessing care. The trial is being conducted under an overarching adaptive platform trial protocol that is being used to test multiple low-risk service modifications to improve access to care, with a focus on 'left behind' groups.

Objectives {7}

To test whether provision of additional information around clinic opening times, services, costs, and the important of attending via in-person counselling at the point of referral and via reminder SMS messages increases the probability of accessing treatment outreach clinics compared to standard care.

Trial Design {8}

This is a Bayesian, pragmatic, superiority, two-arm, individual-level, randomised controlled trial, embedded within the Vision Impact Project screening programme in Meru, Kenya. We will use routinely collected referral and attendance outcome data derived from the patient management and flow software.

Methods

Study setting {9}

This trial will be embedded within the Vision Impact Project (VIP) that is operating in Meru, Kenya. The programme has screened over one million people in the past year using a simple smartphone-based visual acuity screening app. Hundreds of thousands of people have been identified with an eye need and referred for free further assessment at local treatment outreach clinics. However, only half of those referred have been able to access this free care.

Our trial will be integrated into the screening and patient management software developed by Peek Vision. Peek Vision is a leading provider of eye screening software worldwide. The 'Peek Capture' app is used to screen participants for vision impairment, to capture observations by screeners and health practitioners, and to gather demographic data, as well as linking 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). Our trial will use these routinely collected data to test whether a series of interventions are able to reduce the proportion of people from marginalised groups with an eye care need who do not attend triage clinic once referred.

Eligibility criteria {10}

As a pragmatic trial, the eligibility criteria are determined by the local VIP programme. We will include all adults (>18 years) who participate. We will exclude those who do not meet local clinical service eligibility criteria.

Consent {26a, 26b}

Informed consent will be sought by screeners during screening - at the point that participants are identified as having an eye care need and referred on 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. Consent will be recorded digitally using an electronic tick box (as appropriate for low-risk trials). 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. Participants will be given the contact details of the research managers and will be free to leave the trial at any time. There will be no remuneration for participants.

Interventions

Interventions and administration {6b, 11a}

The intervention is a script and reminder SMS message that have been developed in line with suggestions from intended service beneficiaries from the left behind group. During interviews with 67 non-attenders from the left behind group, 25 different potential service modifications were suggested. We then asked 401 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, the programme funder, the programme implementing partner, the county health management team, and the community advisory board. This group unanimously agreed that it would be feasible to implement and test a counselling intervention that bundled together four suggestions: that those referred be informed of the treatment outreach clinic opening times, the services that are available at these clinics (vs those that require onward referral to hospital-based services), any costs involved at the outreach clinic, and the importance of attending. A draft script that included these elements was reviewed and revised by all of the above stakeholders and a lay representative/intended service beneficiary from the left behind group. The text was translated into Swahili and back-translated into English to check that meaning had not been lost.

Control arm: usual care referral counselling

"I have examined your eyes, and you have a problem, I have referred you in the system and you will receive an SMS with where and when you are supposed to attend treatment. Then you will come for treatment on <<Date>> at << clinic >>, the examination will be free, however if the doctors find that you require spectacles, you will be referred to a place where you can purchase them. Any further information will be provided on the day of your appointment.

Intervention arm: enhanced 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 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 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."

The relevant script will be read out to the participant by the screener at the point of referral. The wording of the usual care counselling script is based on the screening programme training materials and observations of what screeners currently tell participants. No elements have been removed i.e. this script accurately reflects usual care. Screeners do not usually read this information out to participants; however, we are introducing standardised wording to reduce the risk of contamination i.e. screeners delivering the same enhanced counselling elements to participants in both the intervention and control arms.

All people who are referred are sent automated SMS reminder messages on the day of referral, the day before the appointment, and on the appointment day. These messages are generated and sent by the Peek Vision app. The content of the intervention SMS was developed by the research team in collaboration with a lay representative from the left behind group. The messages are sent in either English or Kiswahili, depending on the participant's chosen language.

Control SMS Script

Dear <<name>>, you were examined and found to have an eye problem. Kindly report on <<location>> on <<date>> for assessment. For more information contact Meru Referral Hospital.

Intervention SMS script

We found that you had an eye problem. Please attend the outreach clinic at <<location>> on <<date>> between 8am-5pm to receive eye care services.

If you are found to have a complex eye problem, you may be referred to a hospital for further care or specialist glasses, and this may include a fee.

It's important that you attend, as your eye problem may get worse. See you on <<day>>

Figure 1 shows the point at which the interventions are delivered.

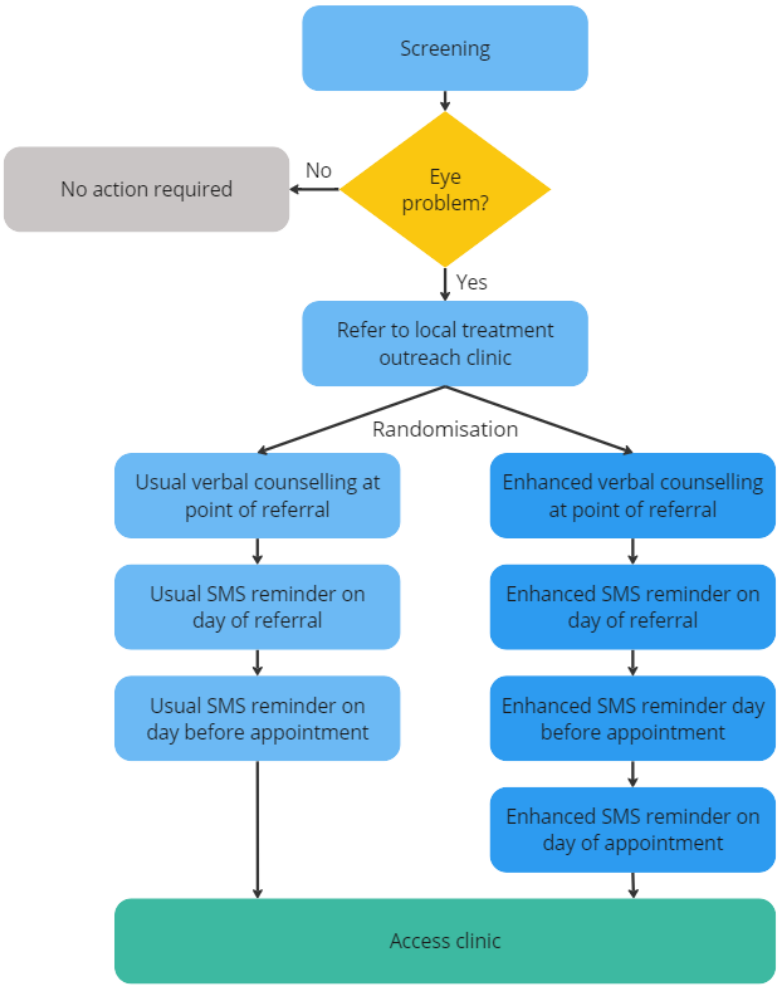

Figure 1: RCT schematic

The theory of change is based around a classical information deficit model of behaviour change. The intervention is needed because many people are not accessing services, and these people tell us that an important barrier is the lack of clear information about opening times, services offered, costs, and the importance of attending. We will provide this information verbally at the point of referral and send a summary via SMS to those in the intervention arm. We will test whether those who receive this enhanced counselling information are more likely to attend than those who do not.

Whilst the information deficit model has received justifiable criticism for oversimplifying behaviour change - often in the context of paternalistic uninvited information provision[3] - this intervention was suggested by people who told us that they genuinely could not access services for want of basic information. The wider literature suggests that SMS reminders can play a small but important role in improving access to care,[4–6] however there is much less research on the provision of verbal information at the point of referral.[7]

Discontinuing or modifying interventions {11b}

Arms will be discontinued (or modified to remove the risk) if there is evidence that they are harming exposed individuals.

Adherence {11c}

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

Concomitant interventions {11d}

As our trials will be embedded within routine service delivery, we cannot exclude the possibility that other initiatives will be introduced by local teams before, during, or after individual trials. We will report all programmatic changes that take place during individual trials that could bias our findings.

Provisions for post-trial care {30}

As this is a negligible risk trial, no provisions will be made for post-trial care.

Outcomes {12}

Primary outcome: The proportion of people attending triage clinic up to 14 days after their appointed date, from the left behind group (adults aged 18-44 years old), measured using attendance data collected by staff when people check-in.

Our left behind group comprises of younger adults (aged 18-44 years) as this group was found to be the least likely to receive care in a previous study in Meru's VIP programme.[8] A focus on left behind groups is important to programme managers who are trying to close gaps, extend health service coverage, and ensure that their services do not exacerbate existing inequalities.

When referred participants check-in at treatment outreach clinics, attendance status is recorded by administrative staff using the Peek app, which automatically updates a central database that holds records of each participant's eye care need, sociodemographic characteristics, arm allocation, and attendance status at the ophthalmic clinic on the appointed date. We care less about whether a given participant attends on their appointed data and more about whether they receive care at all, even if that that means attending the clinic at later date. Internal data suggest that over 80% of people who access clinics do so on their appointed date, a further 15% access within a week of their appointed date, and virtually all do so within 14 days.

Our Bayesian algorithm will review the attendance data for every referred participant every 7 days and calculate the probability of attendance within each arm, reviewing whether each participant has been checked-in at all in the time between the day of referral and 14 days after their clinic appointment date. In our modelling we have estimated that 300 people aged 18-44 years old will be referred every 7 days. This aligns with what we have observed in the VIP programme so far, where approximately 1,000 people are screened per day, of whom approximately 1/3 are referred.

Secondary outcome: The proportion of people attending triage clinic on their appointed date across the entire population, measured using attendance data collected by staff when people check-in.

If an intervention is found to increase attendance among the left behind group, we also want to check whether there has been an impact on the overall mean attendance rate. This is to hedge against adopting an intervention that improves access for the left behind group but leads to a large 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.

Sample size {13, 14}

As we are using stopping rules, will not pre-specify a minimum sample size or estimate effect sizes for the intervention arms. Instead, participants will be continually recruited until sufficient data accrue to trigger one or more of the other stopping rules. Triallists have argued that this approach is more "efficient, informative and ethical" than traditional fixed-design trials as this approach optimises the use of resources and can minimise the number of participants allocated to ineffective or less effective arms.[9] Every 7 days the algorithm will review the attendance data and calculate the probability of attendance within each arm.

Based on extensive scenario modelling, we have decided to use the following stopping rules for this trial:

1. There is a >95% probability that one arm is best, i.e. the difference between the two arms is >0%.
2. There is a >95% probability that the difference between the best arm and the arms remaining in the trial is <1%.

Recruitment {15}

As the trial is pragmatic, the responsibility for recruiting screening participants lies exclusively with local programme managers. Programme implementers will enrol participants by seeking consent from all those who require referral for further assessment and care.

Allocation

Sequence generation {16a}

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. Where appropriate blocking will be used with blocks between 4-12.

Allocation concealment mechanism {16b}

For interventions delivered to individuals, the allocation sequence will be generated within the Peek system in real-time, as participants are referred. As human trial managers are not involved in allocation there is no need for concealment.

Implementation {16c}

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 read script A or B in the patient's preferred language. The screener will then read the corresponding counselling script from a piece of card (A will be the usual care script, B will be the intervention script). The app will also autogenerate and send the enhanced reminder SMS on the same day, the day before the appointment and on the appointment day to all those assigned to the intervention arm. The control arm will receive the usual SMS reminder on the same day and the day before the appointment.

Masking

Who and how {17a}

Once assigned by the algorithm, each participant's online record will automatically update to display which arm they have been allocated to. Participants 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 those responsible for checking-in participants at triage clinic. No steps will be taken to mask these staff to participant allocation status. Ongoing interim data analysis will be performed by the Bayesian algorithm every 7 days.

Unmasking {17b}

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

Data Collection

Data collection methods {18a}

Attendance at clinic will be recorded when participants check-in at clinic on their appointed date. Each participant's attendance status will be recorded on their central record.

Retention {18b}

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

Data management {19, 27}

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 (Additional file 1).

Statistical methods {20a, 21b, 20b}

All analysis will be conducted using R. 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.

During this trial, clinic attendance in each arm will be assessed using Bayesian methods. At each interim analysis point, a binomial distribution of outcome will be described for each arm using the total number of participants allocated to the arm and the number that attended at clinic. The binomial distribution will be combined with a prior distribution to update the posterior distribution of each arm. A regularizing prior of beta(100,100) will be applied to reduce overfitting until a reliable amount of data is accrued. A Monte-Carlo simulation will be used to update posterior distributions at each interim analysis point. Posterior probabilities will be calculated and compared to the stopping rules as to whether the trial should continue into the next day or end early. If there is sufficient evidence to meet one of the stopping rules, the trial will terminate and proceed to the final analysis stage.

Upon completion of the trial, a complete case analysis will be performed on all eligible participants in the trial on an intention-to-treat basis. The primary endpoint of the trial is clinic attendance among the left behind subgroups after randomization. Within a selected subgroup, the primary analysis will use Monte Carlo simulations to estimate the posterior distribution of attendance between arms. Posterior probabilities will be calculated to compare the proportion of attendance between arms and to identify an arm that results in the highest likelihood of attendance. For the secondary endpoint, analysis will be expanded to all participants in the trial. A more detailed description of the statistical methods will be reported as open access as a separate statistical analysis plan.

Data Monitoring {5d, 21a}

From UK, Dr Luke Allen, Dr David Macleod (data analyst), Min Kim 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. Data analysis will be conducted by David and Min Kim and shared with all investigators.

An independent Data and Safety Monitoring Board (DSMB) has been appointed with the primary aim of assuring safety of participants in the trial. The DSMBs will advise the steering committee and sponsor on continuation or stopping of the trial based on safety and efficacy considerations. The DSMB has three members, all independent of the running of the trial, and all with relevant clinical and epidemiological experience. The DSMB will operate independently of the study sponsor and the steering committee. The DSMB will confirm its own specific meeting arrangements and draw up their own charter, working from the template produced by the Damocles Study Group.[10] It is proposed that the DSMB will meet prior to the beginning of the trial, one third of the way through, and at the end of the trial, to assess the safety of the trial procedures. The DSMB will agree the way it will monitor the data, what it requires from the investigators in this respect and will communicate this to the PIs. All data can be interrogated remotely in real-time. The DSMB may visit the study coordination centre to assess data management, record keeping and other important activities. The DSMB will determine the manner in which it will monitor the data, what it requires from the investigators in this respect and will communicate this to the PIs.

The board comprises a clinical trial specialist who does research in Diabetic Retinopathy, Ophthalmology, Public Health and Health Systems (Dr. Nyawira Mwangi), an ophthalmologist (Dr. Stephen Gichuchi), and a biostatistician (Mr. Moses Mwangi). DSMB will periodically review safety and efficacy data.

Patient and public involvement

Lay people and a community advisory board has reviewed and contributed to the development of this protocol and all preceding work around identifying the left behind group and identifying potential service improvements. Lay representatives will assist with interpretation and dissemination of the trial findings.

Adverse event reporting and harms {22}

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 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 on a secure, password-protected file on a LSHTM 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 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.

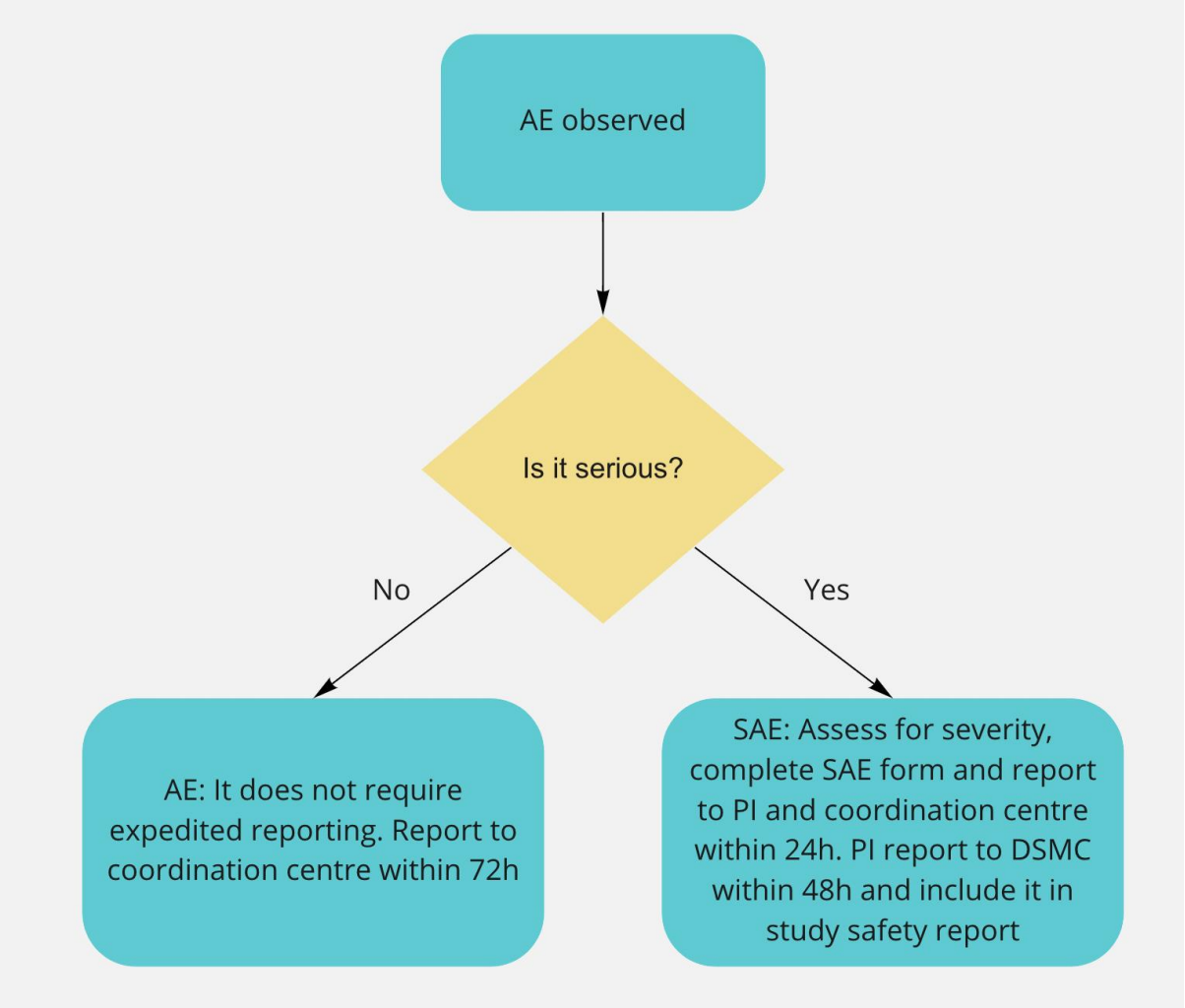

Figure 5: Approach for managing adverse events

Contact details for reporting SAEs

SAE forms will be sent to: gichangi58@yahoo.com and luke.allen@lshtm.ac.uk and the relevant in-country co-PI using the title 'Urgent - SAE'

Responsible Personnel

Chief Investigator (CI)

- The CI has overall responsibility for the conduct of the study and the ongoing safety and evaluation of any IMPs 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.

Principal Investigators (PI)

- The PIs have responsibility for the research performed at the local site, handling and management of investigational medical products, 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 study may be subject audit by the London School of Hygiene & Tropical Medicine under their remit as sponsor, the Study Coordination Centre and other regulatory bodies to ensure adherence to Good Clinical Practice.

Discussion

Limitations

It is unlikely that the addition of four items of information will have a large effect size. Nevertheless, the provision of this information was rated as 'highly likely' to improve access to clinics by a large majority of those who were surveyed in Meru. This particular intervention is one of many that will be tested in separate trials under the overarching platform trial. Text message reminders have obvious limitations in the context of services for those with poor vision, and many people in Meru do not have their own phone. Every screening participant provides a contact number, and it may be that they can have the message read out to them. Inability to receive or read an SMS message will affect those in the intervention and control arms equally, so this should not introduce bias. With the in-person counselling there is a risk of contamination if screeners end up providing the enhanced counselling information to all participants, irrespective of their allocation. The local trial management team will conduct observations to get a sense of whether this is happening. Contamination would lead to an underestimate of the intervention effect size.

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.

Our estimate of the probability/proportion will be biased. Because we choose to stop on average at a "local peak". So for example we're confident A is better than B, but the estimate of the attendance rate in A will be on average an overestimate.

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 review meetings with implementing partners, community health extension workers and representatives from the county health management committee, and bi-annual partner meetings. We will also publish our findings in peer-reviewed journals, and present abstracts at national, regional and/or international conferences.

Trial Status

Recruitment has not yet commenced.

List of Abbreviations

AE	Adverse Events
CI	Chief Investigator
DSMB	Data Safety Monitoring Board
LSHTM	London School of Hygiene and Tropical Medicine
PI	Principal Investigator
RGIO	Research Governance and Integrity Office
SAE	Serious Adverse Event
SMS	Short Message Service
VIP	Vision Impact Project

Ethics approval and consent to participate {24}

The study was granted ethical approval by the Kenya Medical Research Institute (KEMRI) scientific and ethics review unit, and the London School of Hygiene & Tropical Medicine research ethics committee on 6th February 2024.

Availability of data and materials {29}

Patient-level data will be pseudo-anonymised removing names and any other key identifiers before it is shared. Only the least amount of data will be shared, and where possible it will be fully anonymised and aggregated. All published findings will be at anonymous aggregate subpopulation level. 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 Management Plan (Additional file 1: Appendix 1), following review and approval from the trial's data monitoring committee.

Competing Interests {28}

The authors declare that they have no competing interests.

Funding {4}

This work was supported by the National Institute for Health Research (NIHR) (using the UK's Official Development Assistance (ODA) Funding) and Wellcome [215633/Z/19/Z] under the NIHR-Wellcome Partnership for Global Health Research. The views expressed are those of the authors and not necessarily those of Wellcome, the NIHR or the Department of Health and Social Care.

Trial Sponsor and Contact Information {5b}

London School of Hygiene & Tropical Medicine For further information regarding the sponsorship conditions, please contact the Research Governance and Integrity Office: London School of Hygiene & Tropical Medicine Keppel Street London WC1E 7HT Tel: +44 207 927 2626 Email: RGIO@lshtm.ac.uk

Role of Sponsor and Funders {5c}

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

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Part 5: Discussion

Chapter 11

Discussion

The Ministry of Health are keen to pilot our new approach in primary care
Source: Author

Key messages

- The IM-SEEN approach can be used to identify groups that are being left behind, and their perceptions of the main barriers and potential solutions. Future work will establish whether individual solutions improve access to care and the overall costs and impacts of completing multiple iterations of the cycle.
- Whilst every effort has been made to minimise time and resource requirements, the approach needs to be led by someone with mixed-methods research skills, impeding scalability.
- The approach aligns with concepts of population segmenting and lead generation commonly used in business. Despite having diametrically opposed goals, there is likely to be value in exploring these concepts in greater depth.
- The approach has broad applicability, and future work will focus on improving equitable access to hypertension, diabetes, and nutrition services in rural Kenya.

Original aim

The aim of this thesis was to develop a continuous improvement approach that could be used to identify and equitably address barriers to care. I aimed to test the approach in Meru's community-based eye screening programme, identifying which group was the least likely to access eye care, exploring their perceptions of barriers and potential solutions using rapid methods, and then setting up an embedded, automated, platform trial design that can be used to test the most promising solutions.

I started with a literature review of the philosophical underpinnings of universal health coverage and *health for all*. This informed initial collaborative work to develop the continuous improvement approach, dubbed 'IM-SEEN' (Improvement studies for equitable and evidence-based innovation). I then tested each of the three elements of approach in a community eye screening programme taking place in Kenya's Meru county, with additional pilot work conducted in rural Botswana.

Principal findings

Prioritarianism is more tractable than proportionate universalism in advancing UHC & health for all

My original literature review grounded my thesis project in the core philosophical arguments that shape public health efforts to identify and address unequal access to care. Inequalities become inequities when they are 'unavoidable, unnecessary, and unfair', and 'putting them right is a matter of social justice'.[8,40] 'Health for all' and UHC build on a combination of egalitarian, sufficientist, and prioritarian

principles, generally reconciled using ethical positions that lean heavily on the work of John Rawls.[92] Early Beveridgean efforts to distribute social benefits according to egalitarian principles of general universalism have largely been superseded by those that use 'positive selectivism' and 'targeted universalism' - focusing provision on groups that face the greatest barriers.[93,94] Building on the work of Théda Skocpol, Michael Marmot introduced the concept of 'proportionate universalism' in 2010, arguing that "actions should be universal, but with an intensity and a scale that is proportionate to the level of disadvantage."[8,41,95] In other words, services should be provided to all, but with additional resources provided to members of specific groups in order to offset the structural challenges that they face.

Whilst proportionate universalism is ascendent within global health, a recent review (that included Marmot as a co-author) concluded that very few organisations were actually operationalising this principle due to sizeable challenges in designing, delivering, and evaluating programmes that grade the provision of services according to the needs of all groups across the full spectrum of intended beneficiaries.[41] A simplified (and more explicitly prioritarian) version of this approach is represented by the sustainable development agenda promise to 'reach the furthest behind first',[24] which effectively swaps graded universal provision for universal provision with a special focus on the least privileged. This is the direction that we adopted.

The IM-SEEN approach can be used to identify groups that are being left behind

The next element in my thesis combined elements of proportionate universalism and prioritarianism. I set out a model that uses universal sociodemographic data collection to provide a complete picture of the (graded) unmet need faced by every sociodemographic group served by a given programme. This is married with a service improvement approach that specifically focuses on the group(s) with the lowest access. The IM-SEEN model was iteratively developed with input from the entire research collaborative and presented in the International Journal of Equity in Health.[96]

Socioeconomic data can be reliably collected in-person or via phone-based surveys

The first stage in the model is gathering sociodemographic data from every person found to have a need. I wanted the approach to be scalable; minimising time and costs without sacrificing data quality. I conducted a scoping review of the different modalities that can be used to gather sociodemographic data. I found that response rates, acceptability, and data quality were very similar across phone calls, in-person surveys, web surveys, and automated phone calls. There was little data on costs or time requirements. I followed a protocol published in BMJ Open[77] and published my findings in JAMA Network Open.[78]

I agreed with my research collaborators that the most efficient and unbiased means of collecting universal sociodemographic data would be to have screening personnel ask a list of questions at the end of screening, at the point of referral. The use of a separate web-based survey to gather these data appealed on the basis that it required very little time once the initial survey had been devised, and so could scale very cheaply in comparison with the fixed incremental costs associated with in-person data collection. However, our pilot work in Botswana found a very low response rate across all groups, rendering this approach unsuitable.

The Kenyan programme should use 11 sociodemographic domains

To identify the most appropriate sociodemographic questions to ask in Kenya I conducted another literature review of domains used by other researchers and development agencies. I then led a series of multistakeholder workshops to refine the list to be used in Kenya. We ended up with 11 domains; age, gender, language, marital status, transport assets, disability, education, health insurance, housing, income, occupation, and religion. This process, along with detailed methods for how to analyse the resulting sociodemographic data, was published in a protocol on Wellcome Open Research.[97]

Younger adults, males, and those in sales, services and manual jobs were being left behind in Meru

Working with screeners and Kenya's local research manager, we gathered data from 4,240 consecutive consenting people who screened positive and were referred for further care in Meru. Only 46% of these people were able to access their local treatment outreach clinic. In the fully adjusted regression analysis, three groups stood out; younger adults, males, and those working in sales/services/manual occupations. Overall, younger age was associated with the worst access to care, with only 32% of those aged 18-44-years receiving the care they needed. These findings were submitted to an open-access peer reviewed journal, with the pre-print published on medRxiv.[98]

Long queues, work conflicts, and inadequate counselling need to be addressed

Telephone and in-person interviews with people from this left behind group revealed a number of barriers ranging from insufficient provision of information to competing priorities and long queues. Interviewees proposed over 20 different potential solutions and service modifications, all of which were rated as being moderately-to-highly likely to improve access by a second, representative sample. Whilst increases in the number of clinics and personnel would help to reduce the waiting times, it was clear that the screening programme could not resource these changes given current budget constraints. A multistakeholder group that included lay representatives and programme managers agreed to take forward a bundle of interventions that focused on improving the information provided at the point of referral and conveyed in reminder SMS messages. This entire process followed a detailed protocol that

was submitted to BMJ open and published on medRxiv.[99] The findings have also been submitted to the Lancet Global Health, with the pre-print published on medRxiv.[100]

Multiple solutions can be tested under a new adaptive platform trial

Finally, I set up an overarching adaptive platform trial, registered with ISRCTN and submitted to BMJ Open. I then designed the first RCT to run within the platform trial's architecture, set up to test the enhanced counselling intervention against standard care in Meru with a primary focus on younger adults. The same platform trial infrastructure can be used to test further solutions that arise from future iterations of the IM-SEEN cycle. The protocol has been submitted to BMC Trials and is published on medRxiv.[101]

Reflections on findings

Which groups should the approach focus on?

Starting with my reflections on specific elements of the individual studies and their relative strengths and weaknesses, one of the major unanswered questions that stood out from the philosophical review was whether it would be possible to create a model that genuinely delivered proportionate universalism. Under Margaret Chan's leadership, WHO dubbed UHC the 'ultimate expression of fairness'[93] and advanced a sufficientist approach that focused on extending access to a basket of essential health services to all people. Service providers were encouraged to ensure that data were being used to identify left behind groups, but there was no real guidance on how to gather these data, what analyses to perform, or how to prioritise delivery across the spectrum of need.[102] Devising an approach that introduced routine sociodemographic data collection into Meru's eye screening programme was relatively easy, once the most appropriate domains and response options had been identified. Theoretically, this approach could also be applied to any health programme that screens or registers patients. I found it much harder to design the approach for data analysis i.e. identifying the group(s) that faced the lowest access to care. I was keen to ensure that the approach provided both crude and adjusted estimates for each subgroup (e.g. men, women, urban, rural low income, middle income, higher income etc) as well as intersectional data that combined multiple subgroup (e.g. rural low-income women). The main issue was sample size: with data from 4,000 people we might expect to have large and roughly equal numbers of men and women, however some of the subgroups only included very small proportions of the overall sample e.g. those in Meru reporting a religion other than Christianity of Islam (<1% of the total population). Small numbers in the subgroups leads to wide confidence intervals when making comparisons. This problem is compounded when we try to examine the effect of intersectionality. For instance in Meru we found that male gender, younger age, and

sales/services/manual occupations were the factors most strongly associated with poor access (only 14% of people with all three characteristics were able to access services), however this group represented less than 1% of the total population. There are also a very large number of different combinations of characteristics that can be calculated across 12 domains with more than 40 subdomains. This makes it hard to prescribe which combinations should be assessed and reported *a priori*, especially without prior knowledge of the prevalence of individual characteristics across the target population. I want the approach to be as simple as possible, and there is a trade-off here between the time and statistical skill requirement to perform the analysis, and the level of granularity that can be achieved.

I made the decision to focus the analytical process around presenting crude and adjusted access rates for each individual subgroup to facilitate easy identification of the characteristics that are associated with the worst overall access. Focusing the analysis on the bottom of the distribution represents a prioritarian departure from proportional universalism (which would focus on the graded spectrum of need). My rationale stemmed from wanting to keep things simple and scalable. There are two main considerations here: firstly, I did not think that it would be possible to grade the provision of many of the potential interventions (e.g. enhanced counselling) across multiple different groups. Secondly, the simpler approach of focusing on the group with the worst overall access to care is easier to explain to programme managers than talking about graded interventions across a spectrum of need, and it aligns with the prioritarian language of the SDGs ('reaching the furthest behind first'). The final version of the model blends universalism with prioritarianism by producing service modifications that are delivered to all, but are likely to have the greatest impact on the left behind group because the ideas come from this group.

To hedge against a situation where the bottom group represented a very small proportion of the overall population, we stipulated that the approach left behind group should constitute at least 10% of the overall population (i.e. >400 people for programmes that gather data from >4,000 people in each IM-SEEN cycle). This was partly to maximise the impact of service improvement efforts, and partly to ensure that the left behind group included a large enough sample of people for interviews (requiring at least 18 consenting people) and a representative survey (requiring at least 385 additional consenting people). An important limitation of this 10% threshold is that the left behind group might end up combining two or more discordant characteristics e.g. younger age and widowed marital status, or unskilled manual occupation and high income. In such a scenario, it would be unlikely that members of these groups would face common barriers. It is likely that a large number of interviews would be required to reach thematic saturation, and it might make sense to conduct separate ranking surveys and multistakeholder workshops to identify group-specific interventions. For example, in Meru we

unexpectedly found that car owners and those from the highest income group were less likely to access care than those who had no vehicle or belonged to the lowest income group (although the 95% confidence intervals overlapped). We decided to conduct a separate series of interviews with people from this group. Whilst that embedded study is not reported in my thesis, we found broad agreement in terms of the barriers and potential solutions that emerged, along with feedback that our threshold for 'high-income' was set too low (at USD 2,600/year). I am leading further work to establish new income thresholds, working with lay representatives and health economists in Kenya.

Moving forward, I would continue advising that the left behind group should include at least 10% of the total population to ensure that service modifications apply to a decent proportion of the population. I would encourage programme leads to conduct multiple sets of surveys and workshops if the interviews indicate a heterogenous set of barriers and potential solutions.

Our mixed-methods study was designed to place the voices and lived experiences of left behind people at the very centre of quality improvement. Too often our efforts to extend coverage to marginalised groups are delivered without any input at all from those we are trying to reach, running in the face of calls for 'nothing about us without us'.[103,104] Part of the problem has been that, by definition, groups traditionally described as 'hard to reach' are 'hardly reached' and 'seldom heard' (or heard but ignored) because they lack access to education, power, and resources.[105,106] I'm proud that the approach we have developed is entirely built around engaging with those who are currently being left behind.

Using mixed-methods to engage

A great strength of the 'engage' element is that is draws on both qualitative and quantitative methods. My literature review of other studies that have sought to identify barriers and solutions to improve access to community-based services found that almost all pre-existing work has used *either* surveys or interviews in isolation. Whereas surveys present respondents with a pre-specified list of 'drop-down' options that may or may not capture the 'real' issues, interviews allow respondents to describe the issues in their own words. However, the barriers and solutions that arise from interviews are not necessarily representative and therefore cannot be routinely generalised across the entire population. By linking qualitative interviews with a quantitative survey I was able to explore people's perceptions of what prevented them from receiving care - including surprising reasons that our research team wouldn't have necessarily thought of (like mixed ages in the queue, or even the inadequacy of the current counselling approach). The ranking survey then took these themes and allowed a representative sample of people from the left behind group to prioritise the issues.

Whilst I really like this approach, I ran into an unexpected issue in that all of the 25 solutions were rated as >2.4/3 (moderately-highly likely to improve access to care) and it was unclear whether these high and clustered scores reflected genuinely high appraisals or forms of acquiescence and/or social desirability bias, where the respondents may have felt social pressure to respond positively.[107,108] However, the wording of our survey script was specifically designed to reduce acquiescence, and telephone surveys have found to be superior to in-person surveys in terms of reducing social desirability bias.[109,110] Furthermore, my Kenyan research counterparts were as surprised as I was by the results, suggesting that a cultural proclivity was not at play. As such, I had no choice but to take the high scores are face value. Perhaps the simplest way to investigate the underlying cause of the universal high scores in the future would be to include several dummy suggestions alongside the genuine solutions in the next iteration e.g. reducing the number of clinics; charging $100 to be seen; or suggesting that we remove all forms of SMS reminder.

To be scalable, it was vital that the engage work package was rapid and affordable. Although identifying and tackling inequitable access to care is a global health and development priority, community-based programmes are unlikely to have significant resources available for this work. I worked hard to identify all of the possible ways of reducing time to completion and resource requirements without sacrificing methodological rigor. The use of a deductive analytic matrix and transcription of quotes direct from audio enabled us to train the data collectors, complete all 67 interviews, and conclude the analysis in less than a week, at a cost of approximately US$1,000. This activity was preceded by my work developing the *a priori* deductive themes and setting up the matrix, however now that this has been done once, I estimate that the marginal set-up time requirement for future iterations will be around half a day. Indeed, that's what I'm currently doing for Kwale county, as well as the Indian, Nepalese, and Botswanan programmes. Ultimately, I think the engage process can be overseen by one mid-level researcher who has experience conducting qualitative analyses.

We want to hear your views… as long as you own a mobile phone…

One of the biggest limitations of the engage work package is that it uses phone-based interviews and surveys to generate the prioritised list of potential solutions. This is clearly problematic for an approach that aims to engage with left behind groups i.e. those we might expect to have the lowest rates of mobile phone ownership in a given population. Participation in a Peek-based screening programme is predicated on providing a mobile number for any contact person (but does not require personal ownership), and internal data suggest that many people from elderly and poorer groups provide a contact number for a friend, relative, or village chief, rather than the number of a phone that they own

themselves. In Meru I noticed that a number of people on low-incomes owned a SIM card but not a handset: they borrow one when needed to check their messages and make or receive calls.

In the eventuality that the 'gather' analysis identifies a group that is unlikely to have a high mobile phone ownership rate – say, low-income elderly people - then the 'engage' stage cannot proceed unless there are approximately 400 people from that group who are contactable by phone. The chances of success rise as the size of this target population increases, and it may be that a larger overall sample will need to be recruited in order to expand the pool of potential participants from the left behind group. Assuming that it is possible to engage with a sufficient number of people from the left behind group, an additional concern is that these people are likely to be systematically different from others in the left behind group, for instance we might expect that richer and more highly educated elderly people in rural areas are the most easily contactable by phone. Does it matter that we are likely to be missing the most disadvantaged within the left behind group? Our statistician has convinced me that our design largely bypasses this issue. The regression analysis identifies characteristics associated with poor access to care. If low income, education, or asset ownership are found to be important predictors, then we will speak to people in these groups. Our data do not tell us anything about the differential rates of access within each of these groups, so we have to treat every member's views as equally valid. At the end of the day, if concerns about selection bias or intractable issues with generating an adequate sample size persist, we always have the option of reverting to in-person data collection. The only thing tying us to telephone-based data collection is the ethical imperative to optimise the use of programme resources, which would point us away from this modality in situations where phone calls are unable to generate reliable information for any reason.

The problem of low mobile phone access is rapidly diminishing around the world and – ironically - seems to follow the principles of proportionate universalism, with the fastest gains being seen in countries that are starting from the lowest base. At the turn of the millennium, only 1% of Africans owned a mobile phone.[111] That rose to 54% in 2012, and that figure is expected to reach around 90% by 2030.[112,113] Handsets now sell for as little as $20 across the continent, and in many countries more people have better access to phones than they do to clean water or electricity.[111] Recognising the importance of mobile phone ownership to development, Kenya has removed the 16% sales tax on handsets and across the country smartphone-based payments have become ubiquitous.[111] Still, there will always be groups with low access to mobile phones, as well as other aspects of digital poverty.[114] As such, considering the most appropriate mode of engagement will remain an important step in the IM-SEEN approach as we move to scale. Of note, our Indian collaborators have decided to conduct all interviews and surveys face-to-face in Mohammadi, Uttar Pradesh. They are working in a densely populated area where short travel times make in-person data collection relatively rapid.

Who really chooses the interventions?

As described in chapter 8, a major limitation of the mixed-methods approach is that intended service beneficiaries may well generate a long list of insightful and impactful service modifications but the responsibility for funding and implementing change lies with a different stakeholder group. Future iterations of the IM-SEEN approach could use research grants to fund intervention delivery, however our research team wanted to work alongside programme funders to sustainably embed this approach into routine programme delivery. A number of grant-makers do not fund intervention costs, and there is the added issue of not knowing what the intervention will be until the 'engage' element is completed.

Whilst we ended up with a remarkable degree of agreement between the multiple stakeholders around which solutions to test, I was frankly disappointed that the group landed on such a 'downstream' bundle of interventions that place responsibility on referred people rather than the structure and configuration of the screening programme itself. The literature around access to care is littered with terms like 'missed appointment', 'did not attend', and 'no show' that frame the issue primarily as one of misaligned patient priorities.[115] All the way through my thesis I have tried to stress the fact that supply and demand factors both influence whether a person receives the care they need. I tried to avoid using the wording of 'non-attendance' as the main outcome for all three trials, despite push-back from peer-reviewers and other researchers. Our interview prompts stressed supply-side issues, as did the analytic matrix. I also split the ranked solutions into those that relate to services vs individuals. In future work I will add a training module for data collectors that stresses the focus on service-side factors.

My hope is that 'negative' results from trials that test small, patient-facing interventions will prompt investment and action on the larger service-facing issues. Indeed, by demonstrating that the IM-SEEN approach can rapidly identify widely perceived barriers and highly rated solutions, my hope is that funders like CBM will allocate new line items to this process which can be used to fund larger project reconfigurations. Given that 50% of spending on eye programmes is effectively wasted on identifying people with eye needs that don't get treated, there is a strong argument to be made for screening fewer people in the context of a programme that is resourced to ensure that a higher overall proportion are connected to care. I will touch on this issue further in the next section.

Automating trials only makes them more efficient with repeated iterations

The final element of my thesis sought to reduce the resource requirements for testing service modifications with RCTs. Standard trials are expensive, complex, and time-consuming.[116] By leaning on the agile approaches used by Google and Microsoft, we successfully set up an adaptive platform trial that radically reduces the ongoing resource requirements needed to robustly test interventions. By

working with an impressive team of statisticians and software engineers at LSHTM and Peek Vision, we have established an embedded and automated testing system that can perform randomisation, allocation, implementation of digital interventions, outcome data collection and statistical testing. As with the qualitative approach, lots of the work has been front-loaded in setting up the stopping rules, parameters, and master protocol. However, once this has been done, the ongoing marginal requirements are much more achievable, and the ratio of effort-to-reward improves with every additional trial that is run. In future work I would like to quantify the exact costs and time requirements involved in this initial setup vs the ongoing costs. Even with reduced resource requirements, the real question is whether the automated approach is actually feasible to implement in an 'average' programme. It may well be more feasible to provide third-party statistical support, as is currently done with population health management services provided by groups like Johns Hopkins ACG and Optum.[117,118]

Reflections on the overall approach

Feasibility and scale

Feasibility and scalability is my first concern. Even though I have taken pains to minimise the skill and resource requirements, running an IM-SEEN cycle still represents a major investment for programmes – especially for those that currently aren't doing anything in this sphere. There is also no getting away from the need for at least one mid-level mixed-methods researcher who can deliver training, supervise data collection and analysis, set up multistakeholder meetings, and navigate the initial RCT design considerations and the local ethics process, ideally supported by a statistician as I have been. As such, the pathway to scale will have to start with organisations that are already committed to investing in processes to improve equitable outcomes.

To make this approach work in practice, an organisation would also need to have a commitment to equity, somewhere in the region of several thousand dollars to spend, and a system that digitally captures the outcome of interest (e.g. access to care). Having applied the approach in Kenya, India, Botswana, and Nepal, the key ingredient is a competent local project manager. I would suggest that this person feeds back to the wider team during quarterly review meetings in order to sustain the engagement of the wider team.

The sociodemographic analysis and interviews only took five days to complete in India, including a full day to train the local data collectors and a research supervisor. The survey is expected to take one further week. The local programme manager recommends that the costs associated with hiring and training the local research team should be bundled into the start of every new Peek programme, rather

than introduced separately once the programme is already established. Having a dedicated IM-SEEN support worker within Peek (such as their continuous improvement lead) could help to prompt regular reviews and source skills and experience from other programmes as needed to tackle any issues that emerge.

Applications

The WHO *Thirteenth General Programme of Work* states that "equity of access is central to UHC" and that "the main challenge to making progress towards UHC comes from persistent barriers to accessing health services."[119] The IM-SEEN approach enables programme managers to find out what left behind groups perceive the main barriers to be, and the potential solutions. I piloted the approach in the context of a community-based eye screening programme, but IM-SEEN could be used for any programme that has an initial contact point with the population where need is ascertained, followed by a separate contact point where care is delivered. Non-eye (e.g. cancer) screening programmes are an obvious example, but there are myriad other potential applications, for instance data could be collected from the population of women coded as requiring contraception by their primary care provider, with the outcome being ongoing prescription of the pill at 12 months. I'm currently in discussions with the Kenya's national head of primary care, the national community health strategy lead, and the national health IT lead around applying the IM-SEEN approach in two additional counties with the aim of using the IM-SEEN approach to improve access to diabetes, hypertension, and nutrition services, integrating Peek into pre-existing community-based screening activities performed by community health promoters. Whilst the beauty of the approach is that data collection and analysis are built around routine clinical processes, the model is dependent on the use of electronic record systems at the point of identifying/referring positive cases and – critically – the point where participants do or do not receive care. IM-SEEN requires digitisation of the check-in process at the clinic, and linkage of this dataset with the referral dataset.

Kenya's current model is based on community health promoters using android tablets (100,000 of these 'gadgets' were recently distributed[120]) to screen for common conditions and refer people to the local primary care facility. However, the vast majority of primary care clinics are still using paper records. Virtually all health systems are moving towards better digitisation of their health systems, and World Health Assembly resolutions, reports, and global surveys consistently reinforce that "UHC cannot be achieved without eHealth"[121] as digitisation facilitates health surveillance and "equitable access to health services."[122,123] As countries digitise their screening and referral processes, it will become progressively more feasible to implementing the IM-SEEN approach across a range of conditions and settings.

Does it work?

I don't have a straightforward answer to this question. The gather work package enabled us to identify a list of sensible socioeconomic questions, embed them with in routine data collection process, and then identify the groups with the lowest odds of being connected to care. The same approach has been successfully deployed in Nepal, India, and Botswana. The 'engage' work package led to the rapid identification of barriers and potential solutions in Kenya and India. Notably, the identification of left behind groups, training of local data collectors, and completion of the rapid interviews was all completed within less than a week in India. We have successfully set up the testing apparatus in Kenya that can be used to evaluate the effectiveness of multiple service modifications. Whilst each of these elements have been successful in their own right, access hasn't actually improved yet in any location, and won't do so until an effective intervention is introduced, found to be effective, and taken to scale.

Given the fact that it will be a number of months until the first RCT is ready to launch, and may take a year to complete, my post-doctoral work will be focused around quantifying the degree to which the model works as a whole. I hope to address unanswered questions around how effective the approach is compared to the status quo, and what the exact costs and time requirements are for each element. Success and effectiveness can be framed in a number of ways, and I need to be careful to select metrics that are aligned with those used by programme managers and funders.

Realigning funding incentives

The current funding mindset for community-based eye screening programmes is focused on the total number of people who are screened by a given programme. The team at Peek Vision have been working for several years to move that focus towards the total number of people 'connected to care', with an emphasis on the relative proportions of those from different sociodemographic groups receiving the care they need.[124] It's hard to see how a programme that screens a million people but doesn't connect any of them to effective care could be conceived as successful, but that's how the current incentives are aligned.

To lean on concepts from industry, the IM-SEEN approach is designed to help funders with market segmentation[125] and lead generation.[126] For-profit companies like Microsoft, Mars, and Mercedes use these tools to separate potential consumers into subgroups with similar needs and preferences, and then convert them into paying customers. Public health organisations are often in the reciprocal business of giving away free or subsidised services with a focus on those who cannot pay, but the same principles and approaches apply: we need to be able to understand the unique needs and preferences of the different subpopulations we aim to serve, and then develop tailored strategies that connect them with our services. Whereas a company might use segmentation to focus marketing efforts away from

marginalised and low-income groups (with low ability to pay), public health programme managers can use the same tools to do the reverse.

The gather element of the IM-SEEN approach helps to segment the target population according to which sociodemographic groups are the least likely to access care. The engage element is about co-developing lead generation strategies to convert people with a need into 'customers' for eye clinics. There is a wealth of experience in the business world that could strengthen these elements in the future, for instance, drawing on the way that companies use segmentation to tailor their communication, branding, and pricing strategies, and exploring whether focusing on easy wins rather than larger groups that are harder to influence aligns with a given programme's goals.[127]

An important next step for my post-doctoral work will be developing a pitch for funders that sells the IM-SEEN approach as a worthwhile investment. Given a fixed programme budget, investing resources in sociodemographic data collection, interviews & surveys, and RCT testing currently means that fewer people will be screened overall. However, if the proportion of people connected to care increases, the overall programme impact stands to improve, as does the equity impact if gains are concentrated on left behind groups. I can't currently claim that the overall approach extends coverage, but from my work in Kenya I can show that it identifies underserved groups and generates prioritised lists of barriers and actionable solutions, and these outcomes have value in themselves. I also have a strong case to make that programmes should be seeking to robustly evaluate their service modifications, and automated, adaptive platform trials provide a promising vehicle to this end. Success should be about identifying and addressing barriers to care in the context of an ongoing commitment to improve equitable access.

The randomisation paradox

Looking back at my work, a central underlying tension emerges between the ethical imperative to 'do no harm' and the competing ethical imperative to 'fail fast' i.e. maximise the speed at which ineffective (and effective) service modifications are identified. Out in the wild, health programmes and organisations like my own GP practice are constantly tinkering with the way they configure and deliver services. However, their before-after evaluations lack the ability to identify causal relationships. As such, the status quo involves blindly administering well-meaning 'service improvements' on patient populations without ever finding out if they actually improve outcomes. Service improvement/development projects are not classed as 'research' – and therefore do not require consent or ethical review - unless the findings are generalised beyond the organisation.[128]

The use of randomisation automatically turns an improvement/development project into a research project, bringing with it the need for consenting and ethical review.[128] The requirement introduces a perverse incentive to subject service modifications to less rigorous methods of evaluation. Similarly, the implicit messaging from research authorities is that randomisation carries intrinsic risks, when it is the only way of minimising the number of people allocated to receive an ineffective intervention. I don't think we should reduce the ethical review requirements for using randomisation, but I did find myself getting frustrated by the fact that health service leaders motivated by a desire to minimise harm and maximise good are faced with a much higher regulatory burden than those who are happy to introduce changes without properly checking that they are safe.

Similarly, whilst RCTs should ideally be used to test all service modifications, their associated administrative burden and hefty resource requirements mean that they are generally reserved for testing interventions that already have a reasonably high chance of success. Whilst that makes a lot of sense intuitively, it also means that the interventions judged to have the lowest pre-test probability of effectiveness are the least likely to be robustly evaluated. This matters because we aren't necessarily very good at predicting what will and won't work. A good example comes from the tech industry: Bing invested millions of dollars in a string of major projects designed to boost revenue, many of which failed to increase revenue at all. Their most impactful changes came from a tiny tweak to the way that adverts were presented, suggested by a lowly engineer. The idea was ignored for months until a software developer decided to implement the change – given that it was very simple to code – and run an A/B test (industry parlance for an RCT). This negligible change turned out to be Bing's most profitable idea to date.[129,130]

The tech industry's main players now routinely use RCTs to test every new suggestion, seeking empirical, causal data before taking promising-sounding interventions to scale. Given that their intervention costs (lines of code) are relatively low in reference to public health intervention costs, it is also easy to apply this powerful approach to test a whole range of minor tweaks and changes that don't sound particularly promising on face value. This maximises the chances of finding 'surprisingly good' interventions i.e. modest tweaks that deliver a large impact. The 'test everything with RCTs' approach also contributes to a continuous marginal gains approach, where modest improvements are compounded over time, leading to meaningful improvements in outcomes in the longer term.[131,132] The classical example comes from the British cycling team, whose Olympic success in 2008 and 2012 is widely attributed to Sir Dave Brailsford's focus on achieving 1% performance improvements across a wide range of areas.[133]

By introducing an adaptive platform trial structure in Kenya, and establishing a pathway for suggestions from left behind groups to reach programme managers, my work has set up a system for continuously generating hypotheses that can be tested using RCTs. Even if the enhanced counselling intervention provides zero benefit, there is real value in knowing that it isn't worthwhile pursuing. And if it delivers a modest improvement then great – let's move on to the next.

An important feature of the platform trial is that it can be used to test multiple interventions at once. Whilst ethical approval is still needed for each new RCT, only the intervention needs review, as the population, approach, outcome measures, and analytical approach have already been approved. Peek are committed to promoting a culture of continuously testing potential solutions, looking to rapidly establish what does and doesn't improve equitable access. I'm keen to find other systems that are similarly open to establishing 'RCT by default' approaches to ground their continuous improvement efforts on the highest ethical and most epistemologically robust standard.

Access vs effective coverage

A major limitation of the current version of the IM-SEEN approach is that we use arrival at a clinic as the primary outcome. This outcome is sometimes referred to as 'contact coverage'.[134] Whilst it does matter that we are able to identify and address inequitable access to treatment, arguably a more important primary outcome would be health gains derived from effective treatment (sometimes called 'effective coverage'[134]). The emphasis of the current IM-SEEN approach infers that everyone who checks in at a clinic receives effective care, however we know this is not the case in any health programme.[135–138] WHO and the World Bank define effective service coverage as "the proportion of people in need of services who receive services of sufficient quality to obtain potential health gains."[138] Our decision to use access rather than effective coverage was a concession to the fact that access/attendance data are routinely collected in virtually all health programmes, whereas universal clinical outcome data are not. 'Effective coverage' requires additional data collection activity, often after a time lag e.g. to assess visual acuity six months after provision of spectacles or cataract surgery.[43] Whilst using routinely collected data eliminates the need for additional work, there is a risk that the groups found to have the worst access to clinics will not necessarily be those who experience the worst health outcomes. For example, men were less likely to access care than women in Meru, but it is possible that women receive sub-standard care and end up with worse overall outcomes.

I'm very keen to explore opportunities to use effective coverage data in the future. Peek Vision have mooted introducing routine follow-up calls to assess longer term vision outcomes and have demonstrated the value of doing so in previous trials,[139] however this work is still at the conceptual stage for routine adoption and would require funder buy-in before being taken to scale. Primary care-

based non-communicable disease management programmes are ripe for this more holistic approach, as facilities hold longitudinal records of blood pressure, body mass index, blood sugar readings, and many other repeated measures that are updated on a regular basis to guide ongoing management. For instance, a future iteration of IM-SEEN could examine which groups found to be hypertensive during community-based screening are the least likely to have a recorded blood pressure at the local health facility, and engagement could focus on identifying ways to improve access to effective treatment. Similarly, RCTs could test interventions designed to improve both access and outcomes. For example, the RCT outcome could be 'probability of having a blood pressure recorded in the target range in the next six months.

Repackaging the approach to make it easier to digest

Having presented IM-SEEN to a number of different non-eye audiences over the past year, including teams at the World Bank, WHO, and the Agency Fund, I've concluded that a more memorable acronym might help people to retain the core elements of the approach. As such, I'm going to use 'FAIR access' as I take the approach forward, standing for **F**ind, **A**nalyse, **I**nterview & survey, and **R**andomise (Figure 1).

Figure 1: A first attempt at repackaging the IM-SEEN model as 'FAIR access' to aid dissemination

I think this acronym works better than IM-SEEN in terms of conveying the central aim (improving equitable access to care), and I wanted to split the 'gather' into two elements to better reflect the process, as the implementation of data collection is often followed by a long gap before sufficient numbers have accrued in order to perform the equity analysis. I intend to use the term 'socioeconomic' rather than 'sociodemographic' based on my personal observation that this term is more familiar to my intended general audience, meaning there is one fewer thing to have to explain. Ideally, the 'Interview' element in the figure would mention the prioritisation process, and the 'Randomise' element would mention embedded platform trials, but I wanted to keep things as simple as possible.

What's novel about this approach?

However it's badged, the idea of looking for inequalities and then addressing them is not new. Part-way through my thesis I came across the WHO 'Innov8 approach for reviewing national health programmes to leave no one behind'. This eight-step process includes; 'identify who is being left out of the programme', 'identify the barriers and facilitating factors that subpopulations experience', and 'produce a redesign proposal to act on the review findings'. Like me, the instigators hoped to operationalise the UN concept of 'leaving no one behind'.[140,141] Whilst a 200-page workbook was produced in 2016, it does not seem to have been used by anyone other than the lead authors in the past eight years, and the 'more information' WHO webpage has been taken down (https://www.who.int/life-course/partners/innov8/en/). Supported by WHO, the Indonesian health ministry has used the Innov8 approach to perform a health system assessment between 2014-2017, leading to a number of broad recommendations that do not seem to have been tested.[141] At first blush, this lack of traction doesn't bode particularly well for me, however IM-SEEN and Innov8 tackle the same issue in very different ways. Innov8 is aimed at national ministries of health and outlines processes required to perform wide-ranging assessments of the health system, rather than rapid appraisals of a specific service. The Innov8 manual describes the stepwise activities that need to happen e.g. 'identify the barriers', but does not provide methodological guidance on how to actually perform these tasks. IM-SEEN/'FAIR access' is designed to be used by service/programme managers and deliver findings as quickly as possible, using the least onerous methods, embedded within routine data collection processes.

Summary of strengths and limitations

My unique contribution has been to develop detailed methods that turn a high-level equity-focused continuous improvement cycle into a tangible, field-tested approach that can be deployed across a

range of settings – aligned with the central promise of the SDGs. The protocols I have created offer detailed guidance on how to perform each step, as well as the underlying scientific rationale for each decision that needs to be made. In Kenya this approach has been used to identify a group with low odds of receiving care, and to generate a list of actionable solutions to test. The overall approach places the voices of those who are being left behind at the centre of a rapid and scientifically robust cycle, designed to equitably improve access to care. The use of automation and *a priori* rapid techniques minimises the resource requirements without sacrificing quality. I have set up an adaptive platform trial that can be used to test multiple interventions over time, and I designed an initial RCT that can test the first set of solutions. In Botswana, India, Kenya, and Nepal, programme managers expected that female rural widows would be the least likely to access care, based on the single equity analysis that had been published in this field. My work has demonstrated that the groups with the lowest rates of access vary by location, often defying the expectations of local eye programme leaders. These findings underline the importance of gathering and analysing sociodemographic data, and caution against depending on expert opinion when it comes to identifying and addressing inequalities.

I have already discussed many limitations in the sections above, but several bear underlining: my initial philosophical review ended with a rejoinder that public health teams should seek to address macro-level drivers of inequalities, yet the first iteration of the IM-SEEN approach has led to the selection of downstream information provision. The engage element is predicated on high levels of mobile phone ownership amongst the left behind group, which may not be scalable in least-developed countries. This requirement also prevents us from selecting and engaging with target groups that have fewer than ~400 mobile phone owners. Access and attendance are proximal outcomes in that they do not automatically lead to the receipt of good quality care and improved health outcomes. And whilst all solutions come from left behind groups, they can be vetoed by programme funders. The biggest limitation of this approach is feasibility and scalability. The approach needs a dedicated member of staff with mixed-methods research skills, ideally working in a programme that uses digital records. Adaptive platform trials only speed things up if more than one intervention is to be tested, given that the initial setup takes just as long as a standard RCT. Finally, whilst the approach fosters engagement and generates a prioritised list of potential solutions, it's not yet clear whether these service modifications are effective or, crucially, cost-effective.

Next steps

My thesis project ends at the point of having obtained a commitment from the programme implementers and funders to test a package of interventions suggested by the left behind group in Kenya. I have set up an adaptive platform trial and developed the protocol for the initial RCT. My post-

doctoral work will focus on obtaining the final approvals for this trial from NACOSTI and then overseeing its delivery, working in close partnership with our Kenyan collaborators. I will continue working on my pitch to funders, arguing that they focus on who actually receives care, rather than how many people are identified with a need. I have identified seven further research projects to support the ongoing integration of the approach into the Peek system:

1. Automating the regression analysis
    a. Whilst statistical expertise will always be required, it should be possible to automate a number of the stages involved in running the early regression analyses. I have already written some r code to 'stitch together' the various output files from the Peek Vision database. I would also like to work with Peek to introduce a visualisation element in the Peek dashboard that enables programme managers to see which groups are the most and least likely to attend.

2. Using call centres for the interviews and surveys

    I was frankly surprised that telephone-based interviews performed so well in comparison with in-person interviews. I am dubious that surveys and interviews run from a central call centre would lead to equivalent results, but this approach would further reduce time and cost requirements. As such, I would like to run a second mode-effect study comparing in-person vs call-centre vs calls performed by locally recruited staff in at least two different countries.

3. Validating the sociodemographic questions
    a. The questions have been rolled out in the Kenyan Peek screening programme but have not yet been validated. I am currently supervising a Masters student who is leading a study to assess the inter-rater, test-retest, face validity, and content validity of the sociodemographic questions. This involves having two different screeners ask a group of participants the same set of questions to check for inter-rater consistency; having one screener call back a group of participants and re-ask the questions after a period of two weeks to check that the same answers are provided at different points in time; holding a focus group with lay representatives to check that the wording of each question makes sense given the underlying concept; and leading a workshop with health economists and content experts to check that the best response options are being used for each question. The latter elements (assessing face- and content validity)

will specifically set out to identify better income thresholds to distinguish between rich and poor. The analysis should be complete by August 2024.

4. Integrating response-adaptive-randomisation into the Peek testing algorithm
    a. I would like to work with Peek software engineers to apply the 'R-A-R' approach from the Botswanan pilot RCT to the next RCT that takes place in Kenya, allowing dynamic allocation redistributions as the trial progresses. This approach minimises the number of people allocated to less/ineffective arms, however it makes secondary outcome analyses difficult. I'd like to work through the trade-offs involved.

5. Quantifying the impact of the overall approach on access and equity
    a. Whilst I'm interested to see whether the upcoming RCT of enhanced counselling & SMS reminders finds any effect, I'm even more interested in whether repeated iterations of the cycle lead to compounded gains over time. I have drafted an MRC grant application for a cluster RCT comparing 18 v 18 Kenyan regions that will use the IM-SEEN approach vs usual care. The primary outcome is change in attendance over time.

6. Economic analysis of the approach
    a. For subsequent iterations of the cycle in Kenya I would like to work with our team's health economist to quantify the costs involved in conducting each of the elements. A better understanding of the costs will help funders in their decisions around how much they would need to invest. As stated above, I am also developing a pitch for funders that I will test with the Peek team.

7. Tools to scale
    a. I will develop a guidebook for programme managers that leads them through the process of embedding IM-SEEN into their programmes. This will include a series of short illustrative videos. I have already made a start on this.

8. Scaling into other fields
    a. As mentioned above, I am already in talks with the Kenyan government about deploying the IM-SEEN approach with community health promotors to tackle inequitable access to hypertension, diabetes and nutrition services. I'm also in discussion with a team at Harvard Medical School who have been using a similar

approach to address inequitable access to hepatitis care in the Philippines. Whether or not it's the IM-SEEN/FAIR approach that gets used, I'm committed to helping health systems identify and tackle inequalities wherever I can.

Conclusions

In this thesis I worked closely with an international team to develop a simple stepwise approach that health programmes can use to identify which sociodemographic groups are being left behind by their services, as well as a set of rapid and robust tools that can be used to identify the major barriers and ideas for how to overcome them. In Kenya's Meru county, we found that younger adults were the least likely to access care, and people from this group told us that long queues, conflicting engagements, and inadequate information provision were the main barriers. A wider multistakeholder group agreed to implement a bundle of interventions based around improving information provision. I have set up an adaptive platform trial that can be used to test this – and future service modifications. I will continue to work on refining the overall approach to minimise the time and resource requirements as far as possible without sacrificing methodological rigor. I'm excited by the opportunity to take this approach into other areas of healthcare, specifically NCD management in primary care.

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Entering a referred gentleman's phone number so that he can receive an SMS reminder

Source: Author. Consent granted by both of the people in the photo

Appendix 1: Systematic review protocol

Reference

Allen, L.N., Mackinnon, S., Gordon, I., Blane, D., Marques, A.P., Gichuhi, S., Mwangi, A., Burton, M.J., Bolster, N., Macleod, D. and Kim, M. Protocol: Performance and resource requirements of in-person versus voice call versus automated telephone-based socioeconomic data collection modalities for community-based health programmes: a systematic review protocol. BMJ Open, 12(4). 2022.

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Performance and resource requirements of in-person versus voice call versus automated telephone-based socioeconomic data collection modalities for community-based health programmes: a systematic review protocol

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ABSTRACT

Introduction Gathering data on socioeconomic status (SES) is a prerequisite for any health programme that aims to assess and improve the equitable distribution of its outcomes. Many different modalities can be used to collect SES data, ranging from (1) face-to-face elicitation, to (2) telephone-administered questionnaires, to (3) automated text message-based systems. The relative costs and perceived benefits to patients and providers of these different data collection approaches is unknown. This protocol is for a systematic review that aims to compare the resource requirements, performance characteristics, and acceptability to participants and service providers of these three approaches to collect SES data from those enrolled in health programmes.

Methods and analysis An information specialist will conduct searches on the Cochrane Library, MEDLINE, Embase, Global Health, ClinicalTrials.gov, the WHO ICTRP and OpenGrey. All databases will be searched from 1999 to present with no language limits used. We will also search Google Scholar and check the reference lists of relevant articles for further potentially eligible studies. Any empirical study design will be eligible if it compares two or more modalities to elicit SES data from the following three; in-person, voice call, or automated phone-based systems. Two reviewers will independently screen titles, abstracts and full-text articles; and complete data extraction. For each study, we will extract data on the modality characteristics, primary outcomes (response rate and equivalence) and secondary outcomes (time, costs and acceptability to patients and providers). We will synthesise findings thematically without meta-analysis.

Ethics and dissemination Ethical approval is not required, as our review will include published and publicly accessible data. This review is part of a project to improve equitable access to eye care services in low-ioncome and middle-income countries. However, the findings will be useful to policy-makers and programme managers in a range of health settings and non-health settings. We will publish our findings in a peer-reviewed journal and develop an accessible summary of results for website posting and stakeholder meetings.

PROSPERO registration number CRD42021251959.

Strengths and limitations of this study

- As far as we are aware, this review will be the first to directly compare three commonly used data collection modalities for the collection of socioeconomic status data.
- The review will be comprehensive, covering published and grey literature in any language.
- This review will be robust, using independent dual review at every stage, and following best-practice guidelines.
- There may only be a small number of articles in the literature that compare the different modalities head to head and provide data on the outcomes of interest.

INTRODUCTION

Rationale

Inequalities in health are pervasive and stubbornly persistent. Individuals with lower levels of income, education and social status tend to experience the worst health outcomes irrespective of where they are in the world.[1] Tudor Hart observed that the availability of good medical care tends to vary inversely with the need for it in the population served.[2] This

inverse care law manifests in the majority of global health and development programmes where individuals with the lowest socioeconomic status (SES) tend to face the highest barriers in accessing care and are the least likely to attain good outcomes.

Recognising marked international and intranational disparities in health outcomes, the WHO was constituted in 1948 with the mandate of advancing 'health for all'.[3] The contemporary manifestation of this mission is encapsulated in the concept of Universal Health Coverage (and Sustainable Development Goal target 3.8,[4] which seeks to extend coverage to disenfranchised groups. Emerging emphases on attaining effective coverage,[5] and equitable coverage[6 7] seek to shift the success criteria from supply-side provision of services to demand-side receipt of effective services according to need. These trends are underpinned by the principle of 'proportionate universalism': seeking to improve the health of all, with the greatest gains experienced by those with the greatest needs.[8] There is also an increasing interest in understanding the distribution of programme benefits across sociodemographic groups—for instance women, those living in rural locations and those living in conditions of poverty.[9]

All attempts to boost equity in service provision are predicated on adequate collection and analysis of sociodemographic data. Previous work has demonstrated that sociodemographic data can be collected using a variety of modalities in the community setting including in-person, telephone voice calls and using automated telephone-based systems[10] (box 1). However, as far as we are aware, the relative costs and benefits of the different modalities have not been studied, including the skills, equipment, time and financial resources required and acceptability to data collectors and service beneficiaries.

This review aims to answer the research question 'how do three common SES data collection modalities compare in terms of performance characteristics, resource requirements and acceptability to participants and service providers?' Selecting an appropriate and cost-effective modality is an important first step towards advancing equitable effective service coverage.

The findings of this review will directly inform the development of school and community-based eye health screening programmes that operates in several low-income and middle-income countries (LMICs) including Botswana, Ethiopia, Kenya, Nepal, Pakistan, Tanzania, Uganda and Zimbabwe.[11] However, the collection of SES data is relevant for a much wider range of global health programmes, as well as non-health programmes aimed at improving educational, agricultural, gender equity and economic outcomes, among others.

Descriptions of the interventions

Three different modalities for SES data collection constitute the interventions of interest for this review: in-person; voice call; and automated telephone data collection. Box 1 provides the definition for each.

Box 1 Definitions of the three data collection approaches used in this review

In-person data collection includes any form of exchange between a programme implementer and a participant or their responsible guardian, whereby the programme implementer asks predefined questions to ascertain the participants' socioeconomic status (SES) and a synchronous response is received i.e, both parties occupy the same time and space, and the response is recorded by the implementer before the encounter is terminated. Any recording modality used by the programme implementer will be included, such as pen and paper or completion of an electronic form. For this review, we will also include self-administered questionnaires as a subtype of in-person data collection, provided that; the data collection instrument is provided when the participant presents to a programme implementer in-person; the participant is asked to complete the data entry form; and the participant submits their responses before departing. Any non-hospital location will be accepted.

Voice call data collection includes real-time, telephone-based verbal exchanges between programme implementers and participants whereby SES data are elicited and recorded by the programme implementer using predefined questions. This category includes computer-assisted telephone interviews (CATI)—where the interviewer follows prompts on a computer screen—as well as non-CATI. Videocalls will be included as a subtype of voice-calls.

Automated telephone-based data collection includes any mobile-telephone-based asynchronous exchange of information whereby participants are sent a standardised text message, multimedia message or automated phone call (sometimes called interactive voice response or 'IVR') and asked to provide SES data. Responses can be provided using the same modality or any other digital form for example, entering details on a webpage. Interventions that require participants to engage with human programme implementers will be excluded. All forms of phrasing of the requests and responses will be included. We will exclude data collection approaches that require the download of third-party software, including email. For this review we will include web-surveys that can be accessed by a hyperlink, reasoning that all smartphones come with a preloaded browser.

Other terminology used in this review

Community-based health programmes

For the purpose of this review, health programmes are defined as organised activities to improve one or more health outcome(s) in a defined population. Community-based care encompasses all settings except hospitals. Other definitions of community-based care exclude primary care facilities,[12] but these will be included in this review, along with outreach/mobile clinics, community centres, schools, workplaces and people's own homes.

Programme implementers

Anyone with a formal responsibility to collect data on behalf of the health programme will be dubbed a 'programme implementer' for the purpose of this review. This term will cover voluntary and paid staff, and all cadre types.

Participants

Any health programme beneficiary/recipient/client/patient that is asked to provide their SES data will be dubbed a 'participant' for the purpose of this review.

Socioeconomic status

SES is a critically important but nebulous concept that pertains to social and economic standing within society.[13] It determines exposure to the social determinants of health; 'the conditions in which people are born, grow, live, work and age',[14] and relates to issues of privilege, power and control.[15] Almost all health outcomes are patterned according to SES, with the most disadvantaged populations experiencing the worst health outcomes.[13 16 17] SES is commonly measured using income, education, occupation and other metrics such as wealth, caste and place of residence. We will include all of these domains, as well as any other proxies that are identified by researchers as capturing SES.

Low-income and middle-income countries

Just as health inequalities exist within countries—driven by differential access to resources, power, privilege and control—the same set of factors drive international health inequalities. Preston found that national life expectancy was tightly correlated with gross domestic product (GDP) by purchasing power parity, following a logarithmic path whereby small rises in GDP are initially associated with large gains in life expectancy, followed by increasingly diminishing returns.[18 19] In 1978, the World Bank first divided countries into 'low-income' and 'middle-income' groupings, based on gross national income (GNI) per capita. Whereas GDP captures the total value produced in a nation, GNI also includes net income received from overseas. Despite the fact that national finances are a fairly crude proxy,[20 21] many development agencies have come to use the World Bank categorisations to define eligibility for support. This review will use the World Bank analytic classifications for fiscal year 2021; defining LMICs as countries with GNI per capita ≤ US$12 535[22] using the Atlas method.[23]

Objectives

We aim to systematically review the findings of empirical studies that have compared at least two different modalities for gathering SES data for community-based health programmes in terms of their resource requirements, performance characteristics, and acceptability to participants and service providers. Our findings should help programme managers make evidence-informed decisions when selecting the most appropriate modality for SES data collection.

METHODS AND ANALYSES

This protocol is reported according to the relevant sections of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Protocols guidelines.[24]

Population

For this methodological paper, the 'population' is composed of studies rather than people, namely those that seek to compare two or more modalities for socioeconomic data collection from individuals enrolled in health programmes. Studies that only report on only one mode of data collection will be excluded. Studies conducted in hospital-based ambulatory care facilities will be excluded.

Interventions

The interventions being studied are three different modalities for collecting socioeconomic data. The focus is on the modality of data collection (eg, in-person vs voice call vs automated) rather than the content of the wording that is used to elicit information.

Three different modalities for SES data collection constitute the interventions of interests for this review: in-person, voice-call and automated telephone systems, as defined in box 1. We will exclude approaches that use a blend of modes to elicit SES data. We will also exclude studies where the SES questions and wording are not kept constant across modes, for example, if a study asks about education via phone and face to face, the question must be worded in the same way for both approaches. This ensures that differences in response rates and other outcomes are only due to differences in mode of elicitation.

Studies that gather SES data at the household or community level will only be included if these data are used to make assumptions about the SES of identifiable individual participants enrolled (or due to be enrolled) in the service delivery programme of interest. Any two or more modalities can be studied. There is no index/gold-standard data collection modality. Interventions that bundle requests for SES data with requests for other data (eg, broader demographic data) will be included, as long as separate results are reported for the SES data collection element. Interventions that use a blend of two or more modalities to request or receive data will be excluded. Studies that use email for data collection will be excluded.

Comparator

In-person, voice call and automated telephone-based system attributes will be compared against each other. We will not include studies that only report outcomes for one modality i.e. where comparisons are not possible. For each mode, we will code the subtype of data collection, for example, distinguishing between computer-assisted telephone interviews (CATI) and non-CATI. There is a risk that response rates will be influenced by other items in the survey, setting and population. As such, our analysis will focus on outcome ratios between modes that pose the same questions in the same populations—rather than absolute levels as these may not be generalisable. We will report the wider context for each included study, and flag studies where SES questions are embedded within broader surveys that focus on taboo areas, for example, sexual behaviours or drug and alcohol use.

We will present outcomes for individual SES questions. We will only present data on identical questions

asked using different modes that is, if the wording is non-identical we will exclude the comparison from our analysis.

Primary outcomes

There are two groups of primary outcomes; performance characteristics and resource requirements. We will report these at the level of individual SES items.

Performance characteristics

- Response rate: number of completed SES items divided by the total number of elicitation attempts. This will be calculated at the level of each individual SES item.
- Equivalence: agreement between the responses obtained from two or more different modalities. Recognising that equivalence can vary by question, we will report equivalence for each individual SES item. We will report equivalence figures if they aggregate multiple SES questions in a secondary analysis, however, we will not report aggregate equivalence figures that mix SES items with non-SES items.
- Following Belisario and colleagues' Cochrane review,[25] we will use comparisons of mean scores between modalities and/or correlations and/or measures of agreement—which include intraclass correlation (ICC) coefficients, Pearson product–moment correlations, Spearman's r and weighted kappa coefficients.

Resource requirements

- Time: the time taken to gather SES data using each approach (range and mean).
- Costs: any financial data on the costs of operating the data collection approach will be included. Fixed costs include the costs of equipment, software, insurance and personnel required to set up a given data elicitation modality. We will also include any ongoing support costs. We will aim to calculate the fixed and per-person costs to purchasers.

Secondary outcome

Acceptability to participants and service providers

Survey or interview results reporting on how programme implementers and participants feel about the data collection modality in terms of intrusiveness, ease of use, time requirement and general acceptability, as well as perceived advantages, barriers, disadvantages and additional costs presented by the beneficiaries, data collectors or study authors. This includes an assessment of socioeconomic barriers to accessing the modalities.

Study types to be included

All empirical study designs that compare two or more data collection modalities will be included, for instance, in-person versus SMS approaches (SMS stands for 'short message service'). Studies must compare modalities that have been used to gather data from participants. Studies that use simulated data, or data obtained from populations other than the intended beneficiaries will be excluded. Both quantitative and qualitative study designs will be included as long as they report on one or more of the outcomes of interest. Review articles will not be included, but their primary studies will be screened for potential inclusion.

Search methods for identification of studies

Search strategy

The search strategy will be built around three blocks: the three data collection modalities, SES concepts and study design or study setting terms. The search will be limited to human studies published since 1999: the year that it first became possible to send cross-network SMS messages. We will search for full-text studies published in any language. We will not include reports of studies published as conference abstracts. The full search strategies used for each database are presented in the online supplemental appendix. The search will be performed on 29 June 2021. We plan to complete the review by October 2022.

Electronic databases

We will search the following information resources: the Cochrane Library, MEDLINE, Embase and Global Health. We will search ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform (ICTRP) for current and ongoing trials. OpenGrey will be searched for grey literature. The first 20 pages of Google Scholar will also be screened. We will check the reference lists of included studies and relevant systematic reviews to identify any additional potentially relevant reports of studies. Key authors will be contacted to uncover additional or upcoming studies.

Measures of effect

We will calculate mean differences for methodological performance between the modalities, as well as for time and cost differences. For equivalence, we will follow Belisario *et al*[25] and Gwaltney *et al*,[26] using comparisons of mean scores between modalities and/or correlations and/or measures of agreement—which include ICC coefficients, Pearson product–moment correlations, Spearman's r and weighted kappa coefficients.

Data collection and analysis

Selection of studies

Initial screening of studies will be based on the information contained in their titles and abstracts, using online software (Covidence systematic review software, Veritas Health Innovation, Melbourne, Australia. Available at www.covidence.org). Studies that clearly do not meet the inclusion criteria will be excluded. The first 10% of papers will be screened by two reviewers collaboratively to align interpretation of the inclusion criteria and clarify the wording as appropriate. Any changes or amendments will be recorded. All remaining records will be screened independently by two reviewers. They will meet after every 10% batch of papers has been screened to discuss any issues. Any disagreements will be resolved through

consensus-based discussion, or if necessary, discussion with a third reviewer.

We will obtain full texts for the potentially relevant papers. Two review authors will independently assess the papers against the inclusion criteria to determine their eligibility for inclusion. Non-English language papers will be translated into English. The review authors will resolve disagreements through consensus-based discussion, or if necessary, discussion with a third reviewer. The reviewers will record reasons for exclusion at the full-text screening stage. A PRISMA flow diagram will be completed to summarise the study selection process.[27]

Data extraction and management

Two review authors will independently extract study characteristics and data from the included studies using a custom Google Sheets data extraction form based on the Cochrane template for Randomised Controlled Trials (RCTs) and non RCTs.[28] The data extraction form will be piloted on 30 studies by two review authors and required amendments will be made by consensus. We anticipate a broad scope of included studies, so data charting will be an iterative process throughout the review, with agreement calculated and discussed at regular intervals (after each 10% batch of studies) and the data extraction form will be amended as required. Any discrepancies will be resolved by discussion, and a third reviewer will be consulted if necessary.

The following data will be extracted:

- Article title.
- Journal title.
- Authors.
- Country.
- Language.
- Publication year.
- Type of study.
- Focus of the service delivery programme.
- Sociodemographic characteristics for the population served: age, sex, urban/rural, ethnicity, marital status.
- Number of participants.
- Questions used to assess SES.
- Number of times SES data are collected from each participant.
- Types of intervention, including:
  - Modality.
  - Who gathers the SES data.
  - When in the patient journey/programme.
  - Equipment used.
  - Who provides the data.
  - Whether data collection is synchronous or asynchronous.
- Whether continuous improvement methods are used to refine the data collection approach, based on performance data.
- Types of comparison.
- Types of outcome measures.
- Outcomes: response rate, completeness, equivalence, time and costs—as described above.
- We will also extract all qualitative text provided on acceptability.

Risk of bias assessment for included studies

We will use the Cochrane 'RoB2' tool for randomised studies[29 30] and 'RoB-I' for non-randomised studies.[31] Two reviewers will independently assess risk of bias. The review authors will resolve disagreements through a consensus-based decision, or if necessary, discussion with a third reviewer.

The risk of bias for each outcome across individual studies will be summarised as a narrative statement and supported by a risk of bias table. A review-level narrative summary of the risk of bias will also be provided.

Contacting study authors

We will contact study authors to request additional information and primary data where any aspect precludes the assessment of eligibility or inclusion in the data synthesis.

Strategy for data synthesis

If data are available, we will pool effect estimates using a random-effects model.[32] However, we anticipate heterogeneity in study design, interventions and outcomes and therefore plan to use a narrative 'synthesis without meta-analysis' approach, following the 'SWiM' reporting guidelines from Campbell *et al*.[33] We will stratify the synthesis by intervention type and outcome. Studies found to be at high risk of bias will be excluded from the synthesis.

Assessment of heterogeneity

We will assess heterogeneity by considering study design, interventions and outcomes.

Analysis of subgroups or subsets

We will assess whether response rates for each modality vary according to age, sex, urban/rural, ethnicity and marital status where baseline data on the distribution of these characteristics within the general population are available.

We will perform secondary analyses to examine whether findings differ between high-income and LMICs, and including all studies found to be at high risk of bias.

Meta-biases

It is unlikely that we will be able to assess publication bias because it would require meta-analyses of 10 or more studies, but if we do have such an analysis we will create a funnel plot.[34] Selective outcome reporting will be assessed by comparing protocols (where available) with published reports.

Assessment of certainty of evidence

Where possible, the GRADE criteria will be used to assess the certainty of the primary outcomes.[35 36] One review author will collate the evidence for each primary outcome and suggest initial ratings. These will be deliberated by a team of review authors who will reach a joint decision for each outcome. For RCTs, evidence will be assumed to be

high certainty and then will be downgraded due to risk of bias, inconsistency of results, indirectness of evidence, imprecision, publication bias. For observational studies, evidence starts at low-certainty but can be upgraded if there is a large effect, dose-response, gradient or plausible confounding that decreases the magnitude of effect.

Patient and public involvement

No patient involved.

Ethics and dissemination

Ethical approval is not required, as our review will only include published and publicly accessible data.

We will publish our findings in an open-access, peer-reviewed journal and develop an accessible summary of the results for website posting and stakeholder meetings. Data generated from this review will be made available on reasonable request.

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Contributors LNA conceptualised and planned the study with SM, IG, DB, APM, MJB, DM, MK, JR and AB. IG and LNA designed the search terms. IG conducted the search. LNA and SM conducted screening, extraction and quality scoring. DB, APM, SG, APM, MJB, NB, DM, MK, JR and AB helped to analyse and interpret the initial findings. LNA wrote the first draft with SM. IG, DB, APM, SG, AM, MJB, NB, DM, MK, JR and AB critically revised iterations of the manuscript. All authors read and approved the final protocol.

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Appendix 2: ‘Gather’ protocol

Reference

Allen LN, Nkomazana O, Mishra SK, Ratshaa B, Ho-Foster A, Rono H, et al. Sociodemographic characteristics of community eye screening participants: protocol for cross-sectional equity analyses in Botswana, Kenya, and Nepal. Wellcome Open Research. 2022.

STUDY PROTOCOL

REVISED Sociodemographic characteristics of community eye screening participants: protocol for cross-sectional equity analyses in Botswana, India, Kenya, and Nepal [version 2; peer review: 3 approved]

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Abstract

Background

Attendance rates for eye clinics are low across low- and middle-income countries (LMICs) and exhibit marked sociodemographic inequalities. We aimed to quantify the association between a range of sociodemographic domains and attendance rates from vision screening in programmes launching in Botswana, India, Kenya and Nepal.

Methods

We performed a literature review of international guidance on sociodemographic data collection. Once we had identified 13 core candidate domains (age, gender, place of residence, language,

Open Peer Review

Approval Status ✓ ✓ ✓

	1	2	3
version 2 (revision) 16 Nov 2023		✓ view	✓ view
version 1 04 May 2022	✓ view	? view	✓ view

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ethnicity/tribe/caste, religion, marital status, parent/guardian status, place of birth, education, occupation, income, wealth) we held workshops with researchers, academics, programme implementers, and programme designers in each country to tailor the domains and response options to the national context, basing our survey development on the USAID Demographic and Health Survey model questionnaire and the RAAB7 eye health survey methodology. The draft surveys were reviewed by health economists and piloted with laypeople before being finalised, translated, and back-translated for use in Botswana, Kenya, India, and Nepal. These surveys will be used to assess the distribution of eye disease among different sociodemographic groups, and to track attendance rates between groups in four major eye screening programmes. We gather data from 3,850 people in each country and use logistic regression to identify the groups that experience the worst access to community-based eye care services in each setting. We will use a secure, password protected android-based app to gather sociodemographic information. These data will be stored using state-of-the art security measures, complying with each country's data management legislation and UK law.

Discussion

This low-risk, embedded, pragmatic, observational data collection will enable eye screening programme managers to accurately identify which sociodemographic groups are facing the highest systematic barriers to accessing care at any point in time. This information will be used to inform the development of service improvements to improve equity.

Keywords
sociodemographic, socioeconomic status, socioeconomic position, data collection, pragmatic research, embedded research, equity, global health, epidemiology, eye health, screening

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Any reports and responses or comments on the article can be found at the end of the article.

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REVISED **Amendments from Version 1**

In line with the reviewer comments and suggestions we have provided further information about the structure and flow of the screening programmes in each country. We now clarify that the same methods will be used to perform four separate studies: one in each location. we have removed an outdated figure, provided more of the rationale behind our decisions, and amended a number of sentences that required clarification.

Any further responses from the reviewers can be found at the end of the article

Introduction

Inequalities in eye health

Universal Health Coverage[1] and the principle of proportionate universalism[2] are responses to the fact that health outcomes are inequitably distributed across and between populations[2–4]. The inverse care law states that the supply of medical care is inversely proportional to need[5], and the most disadvantaged groups in society are often the least likely to attain good health outcomes[6].

Over one billion people currently live with visual impairment, levying major economic, social, and human costs[7]. Eye conditions exhibit marker inter- and intra-national inequalities in disease rates, access to care, and outcomes, with poorer, rural women often facing the highest barriers to accessing care[7–9].

In recognition of the enormous costs of preventable visual impairment, governments, health organisations and funding agencies are increasingly investing in national eye screening programmes[10]. Embedding sociodemographic data collection into these programmes could help to illuminate the distribution of risks, disease burden, access, and service utilisation. These data can be used to identify the groups facing systematic barriers to care, and to inform targeted work to redress inequalities.

A large number of countries and implementing partners use screening programmes designed by the social enterprise Peek Vision. These programmes run on a suite of Peek apps that are used for data entry, screening, referral, and clinic check-in; albeit with local modifications to the organisational flow and structure of the screening programmes depending on population and context. Peek-based screening programmes are currently running in eleven low-and middle-income countries (LMICs), and four new programmes setting up in Botswana, India, Kenya and Nepal will screen hundreds of thousands of people this year (Table 1). These four countries were chosen for the current project because they all have active Peek programmes led by institutions with active research interest and existing relationships with LSHTM.

All participants currently provide their age, sex, language, and location, but no data on religion, ethnicity, income, education, or occupation. At the point of screening in the community, the screening software automatically captures data on their visual acuity, any diagnoses made, referral, and attendance status for treatment.

Although programmes are tailored to each context, there are a core set of stages: the participants' first interaction with programme providers is when they are screened by a trained health or lay worker equipped with a hand-held android smartphone or tablet using the Peek Capture application. Participants have their vision assessed using the digitised and validated 'tumbling Es' approach[11]. Those whose vision does not meet a pre-set threshold 'screen positive' and are referred to triage (which may be co-located with the screening operation, or may be performed at another time/place). For example, in some school-based programmes, triage happens in a room next door

Table 1. Summary of Peek-powered programmes starting in 2022.

Country	Programme(s)	Eligibility criteria*	Population	Time period
Botswana	National School Programme: 'Pono Yame School Eye Health programme'	Every school child. Ages 5–18 years	500k	Feb 2022 – Feb 2025
Kenya	Ten counties with school and/or community eye health programmes	School children and/or community members	~10m	Jan 2022 – Jan 2025
Nepal	Community-based programme run by NNJS	Community members in the catchment area	~10k	July 2022 – July 2025
India	Regional programme in northern states of India. Study to be conducted within two screening programmes in Uttar Pradesh	Community members in the catchment area	~500k	2022 – July 2025

NNJS: Nepal Netra Jyoti Sangh

*note: eligibility criteria are set locally for each screening programme

immediately after visual acuity screening. Whereas in some door-to-door community-based programmes, those who screen positive are referred on to attend the local primary care facility a week or so later. The most common service design involves referral to a triage clinic at a later time and in a different location.

At triage, all those who have screened positive are formally assessed by a more highly skilled cadre within the programme. Participants are either deemed to have normal vision (i.e. false positive screening), or they are diagnosed with an eye condition ('triaged positive'). All of these true positive cases are treated with eye drops, other basic medications or provided with spectacles, as appropriate, at the community-based triage facility, or they are referred on for further specialist ophthalmic care (e.g. cataract surgery) if this cannot be provided on-site. This specialist care is often delivered at local hospitals. According to unpublished internal Peek data, up to half of those who screen positive and are referred on to triage actually attend their appointment. Even when triage is co-located with screening and happens on the same day, not everyone who screens positive attends. Furthermore, typically less than half of those referred on from triage for further ophthalmic assessment and treatment (e.g. spectacles or cataract surgery) attend. As part of a research grant to develop new approaches for continuous, equity-focused improvement, eye health programmes in Botswana, India, Kenya, and Nepal intend to start collecting, analysing, and reporting data on a wider range of sociodemographic variables, starting with new programmes launching in 2022. The same approach will be implemented for the further programmes that are planned in other countries. The intention is to identify the sociodemographic groups that are least likely to attend clinic, and then engage with representatives of these groups to explore potential service adaptations that could remove barriers and boost attendance rates, promoting proportionate universalism.

This work is being supported by academics, ministry of health officials, and health systems leaders in Botswana, India, Kenya, Nepal, and the UK.

Objective
Our primary objective is to quantify the association between each sociodemographic domain and clinic attendance in order to establish which characteristics are most strongly associated with non-attendance.

Research question
Of those diagnosed with an eye problem and referred on for treatment, which sociodemographic characteristics are most strongly associated with clinic non-attendance?

Hypothesis
Non-attendance will be highest among marginalised groups; including unmarried or widowed women and girls, and those with the lowest levels of education, the fewest material assets, and no formal employment.

Methods
Study design
We will use an embedded, pragmatic cross-sectional design. Working with national Ministries of Health and implementing partner organisations, we will develop a list of sociodemographic questions that will be embedded within the screening process in each country and asked of every person identified with an eye problem and referred on for further ophthalmic assessment and/or care.

Setting
The same cross-sectional design will be used to analyse routinely collected data from Peek-powered eye health programmes operating in Botswana, India, Kenya and Nepal. Peek runs a combination of community- and school-based programmes. Data collection will commence in 2022–2023.

Participants
This is an embedded, pragmatic study - as such data will be collected from the first 3,850 consecutive consenting adults and/or their children who present to Peek powered screening programmes in each study setting. Eligibility criteria are determined by national governments and local implementing partners. There are no exclusion criteria, however the youngest invitees are five years old. Parents/guardians will consent on behalf of their children.

Data collection
When participants present to eye screening programmes they will be checked-in by programme implementers using the Peek Capture app running on android smartphones. Age, sex, phone ownership, and location data will be obtained for every participant at the point at which they enter the screening programmes.

The sociodemographic questions will be asked of all those who are identified with an eye problem at screening and referred to triage clinics. These data will form the basis of the analysis: exploring the proportion of those with each characteristic who do or do not attend their triage appointment in each country.

At both stages, programme implementers will enter responses using pre-set drop-down options. All those involved in data collection will receive standardised training from Peek Vision, including training on maintaining confidentiality and supporting respondents if they become distressed. The questions will be administered in a confidential setting.

These sociodemographic questions will be routinely used in all future Peek Vision-based screening programmes, however we will only publish data from consenting participants.

Loss to follow up
Data of patients who are lost to follow-up will be kept and will be included in analysis as appropriate. Any study participant

who wishes to withdraw from the trial will be initially counselled. If they still wish to withdraw from the study, consent will be requested to include the previously collected data in the analysis. If this is not given all data relating to that participant will be removed from the analysis and will be reported to the trial Data Safety and Monitoring Committee (DSMC).

Closure

Recruitment into the study analysis will stop after 3,850 people have been enrolled, or 365 days after commencement in each country – whichever comes later. The one-year time period aligns with planned programme review meetings. As this study is a secondary analysis of (what will become) routinely collected data, there will be no changes to the way the screening programmes and their data collection approaches operate once the study ends.

Participants who entered the screening programme within three weeks of the end of the programme will be excluded from analysis of attendance rates. Those who were referred for treatment over three weeks before the close of the programme and had not attended by the close will be deemed non-attenders even if they subsequently attend after the closure of the study. This three-week cut-off is based on previous work from Kenya evincing a marked inflection point in attendance at this point.

Variables

Variable selection process

1. Literature review: We started with a literature review to identify which variables are recommended by global health organisations. Many different sociodemographic indicators can and have been used to stratify population outcomes, and it seems that there is no international consensus around which are the most important to include. The WHO *World Report on Vision* and the recent *Lancet Global Health Commission on Global Eye Health* both call for international eye health data (including disease prevalence and care coverage) to be stratified by equity dimensions but do not specify which domains should be employed[7,12].

Acknowledging the risk that "poorer, less advantaged segments of the population could be left behind" as countries expand access to health services, joint WHO and World Bank guidance recommends that managers gather data on gender, place of residence (urban/rural) and household income, expenditure, or wealth to allow comparisons between the rich and poor[13]. The 2021 UN Resolution 'Vision for Everyone' highlights women and those living in poverty[14], and WHO's *Making fair choices on the path to Universal Health Coverage* singles out "low-income groups and rural populations"[15]. Finally, the WHO *Commission on Social Determinants of Health* identified: income, wealth, education, occupation, ethnicity/race/indigeneity, gender, area of living, refugee/immigrant status, sexual orientation, and religious and political beliefs[6]. Galobardes and colleagues have previously developed a glossary of socioeconomic position indicators that provides the theoretical basis, measurement considerations, and strengths and limitations for many of these indicators[16,17].

In total, our review identified the following 16 sociodemographic variables:

- Age
- Disability and other health conditions
- Education
- Ethnicity/race/colour/culture/indigenous group membership
- Gender
- Income/expenditure
- Location (urban/rural)
- Migrant/refugee/internally displaced status
- National origin
- Occupation
- Political beliefs
- Religion
- Sexual orientation
- Social capital
- Socioeconomic status
- Wealth/assets

Howe and colleagues have argued that sociodemographic metrics used in global development should be simple, reliable, reproducible, and linked to a well-understood social stratification process[18]. Questions on age, gender, residence, ethnicity, marital status, education, and occupation all meet these criteria and have relatively non-contentious response options. However, it can be much more difficult to devise simple metrics to capture income, expenditure and wealth. We note the ubiquitous trade-off between comprehensiveness, fidelity, and feasibility here.

For this project we are primarily interested in the associations between attendance and individual sociodemographic characteristics rather than attendance and socioeconomic status. Socioeconomic status is a multidimensional construct that aims to capture access to resources and social position, often by combining income, education, and occupation[16].

2. Secondary analysis of systematic review data: Having established the variables recommended by the UN, WHO, World Bank, and Lancet Commission, next we assessed which

domains are actually used in practice. We performed a secondary analysis of data from a concurrent systematic review that examines phone-based sociodemographic data collection in community-based health programmes. The full methods have been published elsewhere[19]. This review included 11 studies that had tested different approaches to socioeconomic data collection using digital software. Data were collected from populations in eight countries (Australia, Bangladesh, Brazil, Burkina Faso, Kenya, the Netherlands, Tanzania and the USA). We assessed which variables were most commonly reported by these studies, taking an expansive view of sociodemographic variables that was grounded in work on the wider social determinants of health[6,20,21].

In total, 16 different variables were reported (Table 2). At least a third of studies collected data on education, marital status, household income and employment status. None of the studies collected data on sexual orientation, religious or political beliefs, ethnicity or indigeneity. We postulate that this may be because of the stigma and social sensitivity surrounding these issues, however no information was provided on why these variables were omitted. We also note that whilst income and assets (housing type) were collected, none of the studies collected data on expenditure.

Table 2. Sociodemographic variables used in the included studies.

Domain	Number of studies
Education	9 (75%)
Marital status	5 (42%)
Employment status	4 (33%)
Household income	4 (33%)
Residence (urban/rural)	3 (25%)
Country of birth (immigrant status)	2 (17%)
Occupation	2 (17%)
Housing type	1 (8%)
Drug and alcohol use	1 (8%)
Household structure	1 (8%)
Local built infrastructure	1 (8%)
Parent's education	1 (8%)
Primary care registration	1 (8%)
Race	1 (8%)
School enrolment	1 (8%)
Wealth	1 (8%)

3. Developing a master list of variables and indicators: Based on our literature review and analysis of the systematic review data, we identified 11 broad domains that could feasibly be introduced into routine data collection processes in Peek powered programmes:

- Age
- Gender
- Residence (urban/rural)
- Language
- Ethnicity/tribe/race/caste
- Refugee/immigrant status
- Household structure: marital status for adults and parent/guardian status for children
- Religion
- Occupation
- Income
- Wealth

We drafted the initial response options to align with the USAID Demographic and Health Survey (DHS) model questionnaire[22] that has been used for over 400 surveys in 90 countries[23]. and the Rapid Assessment of Avoidable Blindness (RAAB) instrument that has been used for more than 300 vision surveys in 79 countries[24]. This was to ensure that all data will comply with international norms and can be maximally useful for domestic policymakers. We devised separate response options for adults and children (<18 years).

In large-scale screening programmes time is at a premium, as every additional question asked has a cumulative impact on the total number of people who can be screened each day. Furthermore, the Peek Vision screening app imposed a technical limitation in that only ten additional questions could be added to the existing screening flow. As previously noted, whilst there are rapid ways to ascertain age, gender, residence, language, refugee/immigrant status, relationships, religion, and occupation, it can be much more difficult to devise simple metrics to capture robust information on income and wealth. The DHS model survey includes over 100 questions on wealth and income, including long lists of assets, modes of transport, cooking fuels etc. The Equity Tool group[25] have used *principle component analysis* to identify smaller question sets that can be used to identify the poorest households in over 60 countries. However, these compressed question sets still involve asking more than ten questions, some of which have multiple choice answers. During an initial online workshop our team agreed that we would aim to ask 3–5 short and simple additional sociodemographic questions that would help us to distinguish between richer and poorer households in each

country. The first draft of our master survey is presented in Table 3 below.

4: Tailoring surveys for individual countries: Next we set up multistakeholder workshops in Botswana, India, Kenya and Nepal – the four countries where data collection will be embedded first – to review the internal and external validity of the domains for each sociocultural setting; tailor the response options; and identify the most appropriate assets to use in order to distinguish richer from poorer households. For each workshop we invited a LSHTM public health researcher, a representative from Peek Vision who lives/works in the country, a representative from at least one implementing partner (the organisations that conduct the data collection and screening in the field), and local academics with experience and expertise in sociodemographic data collection. The participants discussed each domain with reference to previous domestic data collection exercises, cultural attitudes, and the most recent national DHS[26–28]. The updated survey items were then reviewed with a health economists trained in socioeconomic assessment, sent for wider team input via email, and revised based on this feedback. The first draft socioeconomic surveys are presented in in Table 4–Table 7.

5. Whole-team in-person workshop
In February 2022, the research collaborators from Kenya, Botswana and Nepal met in Nairobi to review the survey questions with academics, three health economists, and in-country implementing partners. A series of interactive sessions were held to review the underlying literature, revisit the intended outcomes, and examine recent survey approaches used in each country. Individual country teams then honed the domain list and question response items with support from the wider research collaborators. The final sociodemographic surveys for each country are presented below in Table 8–Table 10. The India screening programme team did not come to Nairobi. They will refine their survey items using a series of online workshops.

Summary of major changes from the in-person workshop: Migrant status was dropped from the Kenyan and Nepalese surveys. Household composition was added in Botswana. Disability was included in all settings. Nepal added a question on whether adults had health insurance. The income questions changed in all settings, and the food adequacy question was dropped for all settings. Workshops to refine the question list are still to take place in India.

6. Translation and piloting: The finalised survey instruments will be translated into the most commonly spoken language in each setting, back-translated into English to check that meaning has not been lost, and then piloted with laypeople by a domestic research assistant using a 'think aloud' approach[29]. Further refinements to optimise the response options and wording based on this feedback will be incorporated and re-translated

7. Post-pilot review: After the first six months we will review the questions with the data collectors and ask:

- Do any of the questions require clarifications? How could they be re-worded?
- Were any questions problematic, inappropriate, or particularly sensitive? How could they be reworded?
- Where there any questions where the interviewer felt the participants were not answering accurately?
- Do any questions need to be dropped? Or added?
- Do the questions perform adequately for all age groups?
- Is the time taken to ask the additional questions appropriate?

We will analyse the sociodemographic data that have been collected by programme implementers using the Peek Acuity app to calculate the mean number of seconds spent on each question, along with the interquartile range. We will discuss potential ways to reduce the time spent on the longest questions with the broader team. We will also assess the data entry information to assess which questions are most likely to be skipped, and whether the responses for any particular questions display characteristics that signal gaming or misinterpretation e.g., the first response option being ticked disproportionately often. Given that our questions draw heavily on the DHS model survey that is designed for >15 year olds, we will also perform stratified analyses that examine response rates and rates of missing items by age band. We will assess the validity and reliability of the questionnaire.

Outcome measures

Our primary outcome is attendance at triage clinic within 21 days (including weekends) of referral. We will compare this outcome between categories of sociodemographic characteristic. This cut-off has been selected because most appointments are made for one week after triage, and very few people attend more than two-weeks after their appointed date. Attendance is routinely recorded in the Peek Capture app when participants check-in to the clinic. Participants who entered the screening programme within three weeks of the end of the programme will be excluded from analysis of attendance rates. Those who were referred over three weeks before the close of the programme and had not attended by the close will be deemed non-attenders (even if they subsequently attend after the closure of the study).

Secondary analyses

We within 21 days of being referred from the triage clinic will report the prevalence of vision impairment among those presenting to triage, by sociodemographic group.

Table 3. Master survey - first draft – based on an online workshop discussion.

Domain (Data type)	Adult response options	Child response options	Notes
Age (years) (Discrete)	Any integer >18	Any integer 5 - 17	Already routinely collected in all Peek programmes
Gender (Categorical)	• Female • Male • Other	• Female • Male • Other	Already routinely collected in all Peek programmes The DHS and RAAB7 surveys only include female/male. We have added 'other'
Phone ownership (Ordinal)	Do you need someone else to receive your text message reminders? • Yes, my Mother or father • Yes, my Spouse • Yes, my Daughter or son • Yes, Other • No (= phone ownership)	Provided contact number: • My mother or father • My guardian • My teacher • Yes, other	Already routinely collected in all Peek programmes
Place of residence (Categorical)	N/A	N/A	Urban/rural location automatically inferred from screening location
Distance from screening location to triage clinic (km) (Discrete)	N/A	N/A	Referred participants are given an appointment at a specific clinic Distance between screening location and triage clinic location has been found to be a predictor of outcomes This is automatically calculated by the Peek software.
Language (Categorical)	• [list languages]	• [list languages]	Country-specific lists will be derived from the latest Demographic and Health Survey
Relationships (Categorical)	• Married or living together • Divorced/separated • Widowed • Never married or lived together	Do you live with: • Both parents • Just one parent • Another relative or carer	Options may need tailoring depending on the context.
Ethnicity (Categorical)	• [List ethnic groups] • Other	• [List ethnic groups] • Other	Country-specific lists will be derived from the latest Demographic and Health Survey
Migrant/refugee (binary)	Are you a migrant or refugee? • Yes • No	Were your parents born in this country? • Yes • No	May be inflammatory depending on the setting
Religion (Categorical)	• [List main religions] • Other not listed • None	• [List main religions] • Other not listed • None	Country-specific lists will be derived from the latest Demographic and Health Survey
Education (Ordinal)	• None/pre-school only • Non-formal (included Quranic) • Some primary • Completed primary • Some secondary • Completed secondary • University	N/A – all participants will be in school	Options taken from the RAAB7 survey as it offers more detail than the DHS model questionnaire (early childhood education programme/Primary/Secondary/Higher) Non-formal/Quranic options may not be appropriate in settings where the prevalence of these forms is negligible. All national child eye screening programmes in our study sites are implemented as school-based programmes
Occupation (Ordinal)	• Unemployed • Unskilled manual • Skilled manual • Professional • Homemaker	What are your parents' jobs? • No parents • Unemployed • Unskilled work • Skilled work	For children, programme implementers will ask what their parent's do for work and then code the highest occupational category on their behalf

Domain (Data type)	Adult response options	Child response options	Notes
Income (proxy) (Ordinal)	When you think about the food in your household would you say you have: • Less than adequate food for the needs of the household • Just adequate • More than adequate	When you think about the food in your household would you say you have: • Less than adequate food for the needs of the household • Just adequate • More than adequate	This question is being used in the RAAB7 eye health survey as a proxy for income The survey is designed for >50y olds, so the response options may not be appropriate for children
Income adequacy (Ordinal)	When you think about the income in your household would you say it is: • Not enough to cover our needs, we must borrow, • Not enough to cover our needs, we use savings, • Just enough to cover our needs, • Enough to cover our needs, we are able to save a little • Enough to cover our needs, we are building savings	When you think about the income in your household would you say it is: • Not enough to cover our needs, we must borrow • Just enough to cover our needs • Enough to cover our needs • More than enough, we are able to save	This question is being used in the RAAB7 eye health survey as a proxy for income The survey is designed for >50y olds, so the response options may not be appropriate for children
Wealth (Binary)	Is your house's floor made out of cement? • Yes • No	Is your house's floor made out of cement? • Yes • No	The specific indicator used here will depend on the location
Assets (Binary)	Does your household own: • [List assets from DHS]	Does your household own: • [List assets from DHS]	Shortest possible list of assets to be selected by country working groups

Note: Every question will have the additional options: 'Do not want to answer' and 'Don't know'

Table 4. Botswana sociodemographic questions following the multistakeholder workshop.

Domain	Adult response options	Child response options	Notes
Age	Any integer >18	Any integer 5 - 17	Already routinely gathered
Gender	• Female • Male • Other	• Female • Male • Other	Already routinely gathered
Phone ownership	Do you need someone else to receive your text message reminders? • Mother or father • Spouse • Daughter or son • Other • No (= phone ownership)	Provided contact number: • Mother or father • Guardian • Teacher • Other	Already routinely gathered
Place of residence	N/A	N/A	Urban/rural automatically inferred
Distance to clinic	N/A	N/A	Automatically calculated by Peek

Domain	Adult response options	Child response options	Notes
Language	What language do you speak most often at home? • Setswana • English • Kalanga • Shekgalagari • Herero • Sebirwa • Mbukushu • Sesarwa • Shona • Ndebele • Setswapong • Afrikaans • Subiya • Shiyeyi • Other (specify)	What language do you speak most often at home? • Setswana • English • Kalanga • Shekgalagari • Herero • Sebirwa • Mbukushu • Sesarwa • Shona • Ndebele • Setswapong • Afrikaans • Subiya • Shiyeyi • Other (specify)	Categories taken from the Botswana 2017 DHS
Tribe	Which tribe do you originate from? • Tswana (or Setswana) • Kalanga • Basarwa • Kgalagadi • European • Other • Not sure	Do you know which tribe you originate from? • Tswana (or Setswana) • Kalanga • Basarwa • Kgalagadi • European • Other • Not sure	Workshop participants felt that it might be difficult to appropriately word a question about tribe/ethnicity and that this question. We note that the 2017 DHS does not ask about ethnicity or tribe.
Relationships	• Married • Never Married • Living Together • Separated • Divorced • Widowed	Do you live with: • Both parents • Just one parent • Another relative or carer	Workshop participants felt that we should separate married and living together into different options. Ideally, we would ask children if one or more parent had died, but we don't want to cause distress. In the future we could consider asking teachers for this information
Migrant status	Are you a Botswana citizen? • Yes • No • Don't want to answer	Were your parents born in this country? • Yes • No • Not sure	This is a sensitive question that adults may not want to answer [4% of the population is non-Batswana]
Religion	What is your religion? • Christian • Islam • Bahai • Hinduism • Badimo • Other	What is your religion? • Christian • Islam • Bahai • Hinduism • Badimo • Other	Options taken from the 2017 DHS
Education	What is you highest level of completed schooling? • Pre-school • Primary • Secondary • Tertiary • Non-formal education	N/A	All children will be in school Adult responses aligned with the Botswana 2017 DHS

Domain	Adult response options	Child response options	Notes
Occupation	What is your occupation? • Unemployed • Unskilled manual • Skilled manual • Professional • Homemaker	What are your parents' jobs? • [No parents] • Unemployed • Unskilled manual • Skilled manual • Professional • Homemaker	Interviewer to categorise and code the highest
Income (proxy)	When you think about the food in your household would you say you have: • Less than adequate food for the needs of the household • Just adequate • More than adequate	Did you eat yesterday before you sleep? • Yes • No Or How many times did you go to bed hungry last week (because there was no food)?	Question taken from RAAB7 – may remove due to poor face validity
Income adequacy	When you think about the income in your household would you say it is: • Not enough to cover our needs, we must borrow, • Not enough to cover our needs, we use savings, • Just enough to cover our needs, • Enough to cover our needs, we are able to save a little • Enough to cover our needs, we are building savings	Does your family receive food baskets or free school uniforms from social services? • Yes • No • Not sure	May want to re-phrase 'social services'
Housing	Is your house's floor made of cement or tiles? • Yes • No Where do you get water? • Piped indoors • Tap in the yard • Communal tap • Other What do you use for lighting? • Electricity • Paraffin • Candle • Solar • Wood What kind of toilet do you use at home? • Own flush toilet • Own latrine • Shared toilet/latrine • None	Is your house's floor made of cement or tiles? • Yes • No Where do you get water? • Piped indoors • Tap in the yard • Communal tap • Other What do you use for lighting? • Electricity • Paraffin • Candle • Solar • Wood What kind of toilet do you use at home? • Own flush toilet • Own latrine • Shared toilet/latrine • None	8% of floors were made of mud and/or dung in 2017 Botswana is committed to ensuring availability and access to clean and safe water to its people (SDG6) All options taken from the 2017 DHS

Domain	Adult response options	Child response options	Notes
Assets	Do you own a smartphone? • Yes • No Does your household own: • Bicycle • Motorcycle/scooter • Car or truck	Does your household own a smartphone like this? [hold up touchscreen phone] • Yes • No Does your household own: • Bicycle • Motorcycle/scooter • Car or truck	All options taken from the 2017 DHS

Table 5. **Kenya sociodemographic questions following the multistakeholder workshop.**

Domain	Adult response options	Child response options	Notes
Age	Any integer >18	Any integer 5 - 17	Already routinely gathered
Gender	• Female • Male • Other	• Female • Male • Other	Already routinely gathered
Phone ownership	Do you need someone else to receive your text message reminders? • Mother or father • Spouse • Daughter or son • Other • No (= phone ownership)	Provided contact number: • Mother or father • Guardian • Teacher • Other	Already routinely gathered
Place of residence	N/A	N/A	Urban/rural automatically inferred
Distance to clinic	N/A	N/A	Automatically calculated by Peek
Language	What language do you speak most often at home? • English • Swahili • Borana • Embu • Kalenjin • Kamba • Kikuyu • Kisii • Luhya • Maragoli • Luo • Maasai • Meru • Mijikenda • Pokot • Somali • Turkana • Other	What language do you speak most often at home? • English • Swahili • Borana • Embu • Kalenjin • Kamba • Kikuyu • Kisii • Luhya • Maragoli • Luo • Maasai • Meru • Mijikenda • Pokot • Somali • Turkana • Other	Workshop participants felt that it would be inflammatory to ask about tribe/ethnicity. Language will be used as a proxy

Domain	Adult response options	Child response options	Notes
Relationships	• Never married • Married • Living together • Single • Divorced/separated • Widowed	*Do you live with:* • Both parents • Just one parent • Another relative • Guardian (non-relative) • Orphanage	Ideally, we would ask children if one or more parent had died, but we don't want to cause distress. In the future we could consider asking teachers for this information
Migrant status	Were you born in Kenya? • Yes • No • Don't want to answer	Were your parents born in this country? • Yes • No • Not sure	This question may be redundant. Kenya is currently home to 500,000 refugees, however they mainly live in camps and this information will already be collected under 'place of residence'. Outside of Nairobi, the migrant population that does not live in camps is negligible.
Religion	What is your religion? • Roman Catholic • Protestant/other Christian • Islam • Other • No religion	What is your religion? • Roman Catholic • Protestant/other Christian • Islam • Other • No religion	Responses taken from the 2014 DHS
Education	What is you highest level of completed schooling? • No education • Some primary • Primary complete • Some secondary • Secondary complete • More than secondary	N/A	All children will be in school Adult responses aligned with the 2014 DHS
Occupation	What is your occupation? • Unemployed • Agriculture • Unskilled manual • Skilled manual • Sales and services • Clerical • Professional/technical/managerial • Homemaker	What are your parents' jobs? • No parents • Unemployed • Agriculture • Unskilled manual • Skilled manual • Sales and services • Clerical • Professional/technical/ managerial • Homemaker	Interviewer to categorise and code the highest
Income	When you think about the food in your household would you say you have: • Less than adequate food for the needs of the household • Just adequate • More than adequate	Did you go to bed hungry last night? • Yes • No Or How many times did you go to bed hungry last week (because there was no food)?	Question taken from RAAB7 – may remove due to poor face validity

Domain	Adult response options	Child response options	Notes
Income adequacy	When you think about the income in your household would you say it is: • Not enough to cover our needs, we must borrow, • Not enough to cover our needs, we use savings, • Just enough to cover our needs, • Enough to cover our needs, we are able to save a little • Enough to cover our needs, we are building savings	N/A	From RAAB7, but poor face validity.
Housing	Is your house's floor made of earth, sand, or dung? • Yes • No Do you have water piped into your own house or yard? • Yes • No Does your household have electricity? • Yes • No What kind of toilet does your household you use? • Own toilet/latrine • Shared toilet/latrine • None (bush/field)	Is your house's floor made of earth, sand, or dung? • Yes • No Do you have water piped into your own house or yard? • Yes • No Does your household have electricity? • Yes • No What kind of toilet does your household you use? • Own toilet/latrine • Shared toilet/latrine • None (bush/field)	All options taken from the 2014 DHS
Assets	Do you own a smartphone? • Yes • No Does your household own a: • Bicycle • Motorcycle/scooter • Car or truck Do you own your dwelling? • Yes • No	Does your household own a smartphone? • Yes • No Does your household own a: • Bicycle • Motorcycle/scooter • Car or truck	

Table 6. Nepal sociodemographic questions following the multistakeholder workshop.

Domain	Adult response options	Child response options	Notes
Age	Any integer >18	Any integer 5 - 17	Already routinely gathered
Gender	• Female • Male • Other	• Female • Male • Other	Already routinely gathered

Domain	Adult response options	Child response options	Notes
Phone ownership	Do you need someone else to receive your text message reminders? • Mother or father • Spouse • Daughter or son • Other • No (= phone ownership)	Provided contact number: • Mother or father • Guardian • Teacher • Other	Already routinely gathered
Place of residence	N/A	N/A	Urban/rural automatically inferred
Distance to clinic	N/A	N/A	Automatically calculated by Peek
Language	What language do you speak most often at home? • Nepali • Maithali • Bhojpuri • Tharu • Tamang • Newar • Bajjika • Magar • Doteli • Urdu • Avadhi • Limbu • Gurung • Baitadeli • Other	What language do you speak most often at home? • Nepali • Maithali • Bhojpuri • Tharu • Tamang • Newar • Bajjika • Magar • Doteli • Urdu • Avadhi • Limbu • Gurung • Baitadeli • Other	
Ethnicity	What is your ethnicity? • Hill Brahmin • Hill Chhetri • Terai Brahmin/Chhetri • Other Terai caste • Hill Dalit • Terai Dalit • Newar • Hill Janajati • Terai Janajati • Muslim • Migrant • Other	What is your ethnicity? • Hill Brahmin • Hill Chhetri • Terai Brahmin/Chhetri • Other Terai caste • Hill Dalit • Terai Dalit • Newar • Hill Janajati • Terai Janajati • Muslim • Migrant • Other	Responses taken from 2016 DHS
Relationships	*What is your current marital status?* • Never married • Married • Divorced/separated • Widowed Has your partner been living away for the past six months or more? • Yes • No	*Do you live with:* • Both parents • Just one parent • Another relative • Guardian (non-relative) • Orphanage	One third of married couples live apart Options taken from the 2016 DHS Ideally, we would ask children if one or more parent had died, but we don't want to cause distress. In the future we could consider asking teachers for this information The Nepal team wanted a specific question asking if children not living with their parents are orphans

Domain	Adult response options	Child response options	Notes
Migrant status	Were you born in Nepal? • Yes • No • Don't want to answer	Were your parents born in this country? • Yes • No • Not sure	
Religion	What is your religion? • Hindu • Buddhist • Muslim • Kirat • Christian • No religion • Other	What is your religion? • Hindu • Buddhist • Muslim • Kirat • Christian • No religion • Other	Responses taken from the 2016 DHS
Education	What is you highest level of completed schooling? • No education • Primary • Some secondary • SLC and above ('school leaving certificate')	N/A	All children will be in school Adult responses taken from the 2016 DHS
Occupation	What is your occupation? • Unemployed • Agriculture • Unskilled work • Government or private employee • Business owner / professional • Housewife	What is your father's job? • Unemployed / no father • Agriculture • Unskilled work • Government or private employee • Business owner / professional	Interviewer to categorise and code the highest
Income	When you think about the food in your household would you say you have: • Less than adequate food for the needs of the household • Just adequate • More than adequate	Did you go to bed hungry last night? • Yes • No Or How many times did you go to bed hungry last week (because there was no food)?	Question taken from RAAB7 The team feel this question has poor face validity – to be discussed further with another health economist
Income adequacy	When you think about the income in your household would you say it is: • Not enough to cover our needs, we must borrow, • Not enough to cover our needs, we use savings, • Just enough to cover our needs, • Enough to cover our needs, we are able to save a little • Enough to cover our needs, we are building savings	N/A	To be discussed with another health economist – the team are not convinced this is a good measure

Domain	Adult response options	Child response options	Notes
Housing	Is your house's floor made of cement? • Yes • No Do you have water piped into your own house or yard? • Yes • No Does your household have electricity? • Yes • No What kind of toilet does your household you use? • Own toilet/latrine – inside dwelling • Own toilet/latrine – in yard/plot • Shared toilet/latrine • None (bush/field)	Is your house's floor made of cement? • Yes • No Do you have water piped into your own house or yard? • Yes • No Does your household have electricity? • Yes • No What kind of toilet does your household you use? • Own toilet/latrine – inside dwelling • Own toilet/latrine – in yard/plot • Shared toilet/latrine • None (bush/field)	All options taken from the 2016 DHS
Assets	Do you own a smartphone? • Yes • No Does your household own a: • Bicycle or rickshaw • Motorcycle or scooter • Car or truck • Three-wheel tempo Do you own your dwelling? • Yes • No	Does your household own a smartphone? • Yes • No Does your household own a: • Bicycle or rickshaw • Motorcycle or scooter • Car or truck • Three-wheel tempo	

Table 7. India sociodemographic questions following the multistakeholder workshop.

Domain (Data type)	Adult response options	Child response options	Notes
Age (years) (Discrete)	Any integer >18	Any integer 5 - 17	Already routinely collected in all Peek programmes
Gender (Categorical)	• Female • Male • Other	• Female • Male • Other	Already routinely collected in all Peek programmes The DHS and RAAB7 surveys only include female/male. We have added 'other'
Phone ownership (Ordinal)	Do you need someone else to receive your text message reminders? • Yes, my mother or father • Yes, my spouse • Yes, my daughter or son • Yes, other • No (= phone ownership)	Provided contact number: • Yes, my mother or father • Yes, my guardian • Yes, my teacher • Yes, other	Already routinely collected in all Peek programmes

Domain (Data type)	Adult response options	Child response options	Notes
Place of residence (Categorical)	N/A	N/A	Urban/rural location automatically inferred from screening location
Distance from screening location to triage clinic (km) (Discrete)	N/A	N/A	Referred participants are given an appointment at a specific clinic Distance between screening location and triage clinic location has been found to be a predictor of outcomes This is automatically calculated by the Peek software.
Language (Categorical)	• [list languages]	• [list languages]	Mostly Hindi, but there are a few other dialects
Relationships (Categorical)	• Married or living together • Divorced/separated • Widowed • Never married or lived together	Do you live with: • Both parents • Just one parent • Another relative or carer	Options may need tailoring depending on the context.
Ethnicity (Categorical)	• [List ethnic groups] • Other	• [List ethnic groups] • Other	Country-specific lists will be derived from the latest Demographic and Health Survey
Migrant/refugee (binary)	Are you a migrant or refugee? • Yes • No	Were your parents born in this country? • Yes • No	May be inflammatory depending on the setting
Religion (Categorical)	• [List main religions] • Other not listed • None	• [List main religions] • Other not listed • None	Country-specific lists will be derived from the latest Demographic and Health Survey
Education (Ordinal)	• Professional degree • Graduate or postgraduate • Intermediate or post high school diploma • High school certificate • Middle school certificate • Primary school certificate • Illiterate	N/A – all participants will be in school	Options aligned with local authority options. All national child eye screening programmes in our study sites are implemented as school-based programmes
Occupation (Ordinal)	• Professional (white collar) • Semi-professional • Clerical/ shop-owner/ farm • Skilled worker • Semi-skilled worker • Unskilled worker • Unemployed	What are your parents' jobs? • No parents • Unemployed • Unskilled work • Skilled work	For children, programme implementers will ask what their parent's do for work and then code the highest occupational category on their behalf
Income (proxy) (Ordinal)	• less than 6k • 7k-10k • greater than 10k,	• N/A	Thresholds discussed with health economist
Wealth (Binary)	Is your house's floor made out of cement? • Yes • No	Is your house's floor made out of cement? • Yes • No	The specific indicator used here will depend on the location
Assets (Binary)	Does your household own: • [List assets from DHS]	Does your household own: • [List assets from DHS]	Shortest possible list of assets to be selected by country working groups

A secondary outcome is attendance at the ophthalmic clinic within 21 days.

Sample size and data collection

Set against the ubiquitous constraint of limited resources, the central principle that drives sample size calculations is clinical significance i.e. when does a difference in attendance between two groups become important? We may feel that 2% higher attendance among men compared to women is not particularly concerning but a 20% difference represents a major equity issue. The decision about where the threshold of importance lies ultimately comes down to values, and the process of settling on a meaningful maximum margin of error is a value judgement. We held online deliberative discussions in each country with input from lay representatives. In all sites we agreed that 5–10% differences between groups represent what we felt to be the lower bound of 'significant'. As such, we will use a 5% margin of error.

We are aiming to compare odds of attendance between sociodemographic subgroups. The number of people in each subgroup is the factor that will determine our ability to make statistically significant comparisons for a given level of α, as well as determining the probability of type II error (i.e. incorrectly rejecting the null hypothesis). With a 95% confidence level, a 5% margin of error, and a maximally conservative proportion of 0.5, we would need to have at least 385 people in each subgroup to make statistically significant comparisons between groups.

In each study site we will collect data from the first 3,850 consecutive consenting people who are referred. This will

Table 8. Botswana update from in-person February workshop. To be translated into Setswana.

Domain	Adult response options	Child response options	Notes
Age	Any integer >18	Any integer 5 - 17	Already routinely gathered
Gender	• Female • Male • Other	• Female • Male	Already routinely gathered 'Other' removed for children as it is controversial and does not align with national data collection practices
Phone ownership	Do you need someone else to receive your text message reminders? • Mother or father • Spouse • Daughter or son • Other • No (= phone ownership)	Provided contact number: • Mother or father • Guardian • Teacher • Other	Already routinely gathered
Place of residence	N/A	N/A	Urban/rural automatically inferred
Distance to clinic	N/A	N/A	Automatically calculated by Peek
Language	What language do you speak most often at home? • Setswana • English • Kalanga • Shekgalagari • Herero • Mbukushu • Sesarwa • Shona • Ndebele • Afrikaans • Subiya • Shiyeyi • Other (specify)	What language do you speak most often at home? • Setswana • English • Kalanga • Shekgalagari • Herero • Mbukushu • Sesarwa • Shona • Ndebele • Afrikaans • Subiya • Shiyeyi • Other (specify)	Setswapong and Sebirwa were removed from the original list as they are not different from Setswana

Domain	Adult response options	Child response options	Notes
Tribe	Which tribe do you originate from? • Setswana • Kalanga • Shekgalagari • Herero • Mbukushu • Sesarwa • Shona • Ndebele • Afrikaans • Subiya • Shiyeyi • Other (specify) • Not sure	Do you know which tribe you originate from? • Setswana • Kalanga • Shekgalagari • Herero • Mbukushu • Sesarwa • Shona • Ndebele • Afrikaans • Subiya • Shiyeyi • Other (specify) • Not sure	Tribes have been aligned with languages. 'English' has been removed.
Relationships	• Married • Never Married • Living Together • Separated • Divorced • Widowed	Do you live with: • Your father • Mother • Grandparent(s) • Aunt • Uncle • Siblings • Other	The options have been expanded to add a greater degree of specificity
Household	How many people live in your home? [number]	How many people live in your home? [number]	This question has been added because it may be an important predictor of attendance i.e. large families with low incomes may struggle to pay for transport costs
Migrant status	Are you a Botswana citizen? • Yes • No • Don't want to answer	Were your parents born in Botswana? • Yes • No • Not sure	Changed 'this country' to 'Botswana' to be more specific
Religion	What is your religion? • Christian • Islam • Bahai • Hinduism • Badimo • Other	What is your religion? • Christian • Islam • Bahai • Hinduism • Badimo • Other	No changes made Options taken from the 2017 DHS
Education	What is you highest level of completed schooling? • Pre-school • Primary • Secondary • Tertiary • Non-formal education	N/A	No changes made Options align with the 2017 DHS

Domain	Adult response options	Child response options	Notes
Disability	Do you have difficulty **hearing**, even if using a hearing aid(s)? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all • Don't know Do you have difficulty walking or climbing steps? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all • Don't know Do you have difficulty remembering or concentrating? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all • Don't know Do you have difficulty with **self-care**, such as washing all over or dressing? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all • Don't know Using your usual language, do you have difficulty **communicating**, for example understanding or being understood? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all • Don't know	Do you have difficulty **hearing**, even if using a hearing aid(s)? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all • Don't know Do you have difficulty walking or climbing steps? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all • Don't know Do you have difficulty remembering or concentrating? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all • Don't know Do you have difficulty with **self-care**, such as washing all over or dressing? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all • Don't know Using your usual language, do you have difficulty **communicating**, for example understanding or being understood? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all • Don't know	New question added at the request of implementing partners Response options taken from the Washington Group Short Set on Functioning: https://www.washingtongroup-disability.com/question-sets/wg-short-set-on-functioning-wg-ss/ The same options will be used for adults and children. UNICEF does have a child-specific question set, but it is more than double the length.
Occupation	What is your occupation? • Unemployed • Unskilled manual • Skilled manual • Professional • Homemaker	What are your parents'/guardian's jobs? • [No parents] • Unemployed • Unskilled manual • Skilled manual • Professional • Homemaker	We have added 'guardians' Interviewer to categorise and code the highest

Domain	Adult response options	Child response options	Notes
Income adequacy	When you think about the income in your household would you say it is: • Not enough to cover our needs, we must borrow, • Not enough to cover our needs, we use savings, • Just enough to cover our needs, • Enough to cover our needs, we are able to save a little • Enough to cover our needs, we are building savings	Does your family receive food baskets or free school uniforms from social workers? • Yes • No • Not sure	We removed the question on food sufficiency. We felt it was unlikely to render robust data Botswana is the only country that will retain the RAAB7 subjective question on income sufficiency We re-phrased 'social services' to 'social workers'
Housing	Is your house's floor made of cement or tiles? • Yes • No Where do you get water? • Piped indoors • Tap in the yard • Communal tap • Other What do you use for lighting? • Electricity • Paraffin • Candle • Solar • Wood What kind of toilet do you use at home? • Own flush toilet • Own latrine • Shared toilet/latrine • None	Is your house's floor made of cement or tiles? • Yes • No Where do you get water? • Piped indoors • Tap in the yard • Communal tap • Other What do you use for lighting? • Electricity • Paraffin lamp (lebone) • Candle • Solar • Wood What kind of toilet do you use at home? • Flush toilet • Pit latrine • Shared toilet/pit latrine • None	All options taken from the 2017 DHS 8% of floors were made of mud and/or dung in 2017 Botswana is committed to ensuring availability and access to clean and safe water to its people (SDG6) Added 'lamp (lebone)' for paraffin We removed 'own' for toilet as we felt this word is redundant We added 'pit' before latrine
Assets	Do you own a smartphone? • Yes • No Does your household own: • Bicycle • Motorcycle/scooter • Car or truck	Does your household own a smartphone like this? [hold up touchscreen phone] • Yes • No Does your household own: • Bicycle • Motorcycle/scooter • Car or truck	No changes made. All options taken from the 2017 DHS

enable us to make statistically significant comparisons between groups that contain at least 10% of the overall population. Data will be collected by screening staff/volunteers working in each setting as part of the routine screening process that is conducted using the Peek Vision app.

Statistical analysis

Statistical methods

We will use logistic regression to report odds ratios for the outcome (non-attendance) for each sociodemographic domain in each country. Complete case analyses will be performed initially, but if missing data are more than 5% for a given variable then we will perform a range of sensitivity analyses to check the robustness of our estimates. We will publish anonymised aggregate data online, along with all our statistical code.

Our primary aim is identifying the population subgroups with the lowest attendance so that we can ultimately engage with representatives of these groups to try and improve access in

Table 9. Kenya update from in-person February workshop. To be translated into Kiswahili.

Domain	Adult response options (>18y)	Child response options	Notes
Age	How old are you?	How old are you	Already routinely gathered
Gender	• Female • Male • Other	• Female • Male • Other	Already routinely gathered
Phone ownership	Do you need someone else to receive your text message reminders? • Mother or father • Spouse • Daughter or son • Other • No (= phone ownership)	Provided contact number: • Mother or father • Guardian • Teacher • Other	Already routinely gathered
Place of residence	N/A	N/A	Urban/rural automatically inferred
Distance to clinic	N/A	N/A	Automatically calculated by Peek
Language	What is your mother tongue? • English • Swahili • Borana • Embu • Kalenjin • Kamba • Kikuyu • Kisii • Luhya • Maragoli • Luo • Maasai • Meru • Mijikenda • Pokot • Somali • Turkana • Other	What is your mother tongue? • English • Swahili • Borana • Embu • Kalenjin • Kamba • Kikuyu • Kisii • Luhya • Maragoli • Luo • Maasai • Meru • Mijikenda • Pokot • Somali • Turkana • Other	'What language do you speak most often at home?' changed to 'What is your mother tongue?' as we felt this was more specific This will be used as a proxy for ethnicity
Relationships	• Married • Single • Divorced/separated • Widowed • Other	*Do you live with:* • Both parents • Just one parent • Another relative • Guardian (non-relative) • Orphanage	We removed 'never married' because this is the same as single We removed 'living together' because this question is loaded with social stigma Ideally, we would ask children if one or more parent had died, but we don't want to cause distress. In the future we could consider asking teachers for this information
Religion	What is your religion? • Christian • Islam • Hindu • Other	What is your religion? • Christian • Islam • Hindu • Other	We removed 'no religion' as this group is negligible Christian denominations were aggregated, and we added 'Hindu'

Domain	Adult response options (>18y)	Child response options	Notes
Education	What is you highest completed level of schooling? • No education • Primary • Secondary • Post-secondary	N/A	We reworded the question and removed 'completed' and 'some' options to simplify the list
Disability	Do you have difficulty **hearing**, even if using a hearing aid(s)? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all • Don't know Do you have difficulty walking or climbing steps? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all • Don't know Do you have difficulty remembering or concentrating? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all • Don't know Do you have difficulty with **self-care**, such as washing all over or dressing? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all • Don't know Using your usual language, do you have difficulty **communicating**, for example understanding or being understood? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all Don't know	Do you have difficulty **hearing**, even if using a hearing aid(s)? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all • Don't know Do you have difficulty walking or climbing steps? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all • Don't know Do you have difficulty remembering or concentrating? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all • Don't know Do you have difficulty with **self-care**, such as washing all over or dressing? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all • Don't know Using your usual language, do you have difficulty **communicating**, for example understanding or being understood? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all Don't know	New question added at the request of implementing partners Response options taken from the Washington Group Short Set on Functioning: https://www.washingtongroup-disability.com/question-sets/wg-short-set-on-functioning-wg-ss/ The same options will be used for adults and children. UNICEF does have a child-specific question set, but it is more than double the length.
Occupation	What is your occupation? • Not employed • Agriculture • Domestic service • Unskilled manual • Skilled manual • Sales and services • Clerical • Professional/technical/managerial	What are your parents' jobs? [staff to categorise & code only the highest] • No parents • Not employed • Agriculture • Donestic services • Unskilled manual • Skilled manual • Sales and services • Clerical • Professional/technical/managerial	We aligned the occupation categories with the 2014 DHS, adding domestic services

Domain	Adult response options (>18y)	Child response options	Notes
Income	What income band are you in? • Less than 24,000 KSh/month (288,000/yr, 10% Tax band) • Bewteen 24,000 - 32,333 KSh/month (288,000 - 100,000/yr, 25% Tax band) • More than 32,333 KSh/month (388,000/yr, 30% Tax band)	N/A	We removed the question on food adequacy as we felt it was not likely to render robust information We also dropped the subjective question on income adequacy due to concerns about face validity. We replaced these income questions with a more direct item on income categories, based on the Kenya Revenue Authority tax bands.
Housing	What is your floor made of in your house? • Cement • Other Do you have a source of water within your compound? • Yes • No Does your household have electricity, solar, or a generator? • Yes • No What type of toilet facility do members of your households usually use? • Own toilet/latrine • Communal toilet/latrine • None (bush/field)	What is your floor made of in your house? • Cement • Other Do you have a source of water within your compound? - Yes - No Does your household have electricity, solar, or a generator? • Yes • No What type of toilet facility do members of your households usually use? • Own toilet/latrine • Communal toilet/latrine • None (bush/field)	We switched from 'earth, sand or dung' to 'cement'. This is the reciprocal question and is faster to ask. We switched from 'do you have water piped into your own house or yard?' to 'do you have a source of water within your compound' because some rich people use boreholes We revised the wording of the toilet question changed to add greater clarity All options are aligned with the 2014 DHS
Assets	Do you own a smartphone? • Yes • No Does your household own a: • Bicycle • Motorcycle/scooter • Car or truck • None • Other	Does your household own a smart phone (with a touch screen)? • Yes • No Does your household own a: • Bicycle • Motorcycle/scooter • Car or truck • None • Other	We noted that smartphone ownership is so prevalent that it is only a sensible proxy for wealth in rural areas

Note – The question on **migrant status** was removed on the basis that the migration population is negligible, and screening conducted in refugee camps will be signalled by location.

Table 10. Nepal – update from in-person February workshop. To be translated into Nepali and Maithali.

Domain	Adult response options	Child response options	Notes
Age	Any integer >18	Any integer 5 - 17	Already routinely gathered
Gender	• Female • Male • Other	• Female • Male • Other	Already routinely gathered

Domain	Adult response options	Child response options	Notes
Phone ownership	Do you need someone else to receive your text message reminders? • Mother or father • Spouse • Daughter or son • Other • No (= phone ownership)	Provided contact number: • Mother or father • Guardian • Teacher • Other	Already routinely gathered
Place of residence	N/A	N/A	Urban/rural automatically inferred
Distance to clinic	N/A	N/A	Automatically calculated by Peek
Language	What language do you speak most often at home? • Nepali • Maithali • Bhojpuri • Tharu • Tamang • Newar • Bajjika • Magar • Doteli • Urdu • Avadhi • Limbu • Gurung • Baitadeli • Other	What language do you speak most often at home? • Nepali • Maithali • Bhojpuri • Tharu • Tamang • Newar • Bajjika • Magar • Doteli • Urdu • Avadhi • Limbu • Gurung • Baitadeli • Other	No changes
Ethnicity	What is your ethnicity? • Hill Brahmin • Hill Chhetri • Terai Brahmin/Chhetri • Other Terai caste • Hill Dalit • Terai Dalit • Newar • Hill Janajati • Terai Janajati • Muslim • Migrant • Other	What is your ethnicity? • Hill Brahmin • Hill Chhetri • Terai Brahmin/Chhetri • Other Terai caste • Hill Dalit • Terai Dalit • Newar • Hill Janajati • Terai Janajati • Muslim • Migrant • Other	No changes
Relationships	*What is your current marital status?* • Never married • Married • Divorced/separated • Widowed Has your partner been living away for the past six months or more? • Yes • No	*Do you live with:* • Both parents • Just one parent • Another relative • Guardian (non-relative) • Orphanage	No changes
Health insurance coverage	Do you have active medical health insurance today? - Yes - No	N/A	New question added for medical health tourists on the basis that many Indians cross the border to access care

Domain	Adult response options	Child response options	Notes
Religion	What is your religion? • Hindu • Buddhist • Muslim • Kirat • Christian • No religion • Other	What is your religion? • Hindu • Buddhist • Muslim • Kirat • Christian • No religion • Other	No changes
Education	What is you highest level of completed schooling? • No formal education • Primary • Lower secondary • SLC or higher secondary • University	N/A	Adult options refined: 'Some secondary' changed to 'Lower secondary' and 'SLC and above' changed to 'SLC or higher secondary' or 'university'
Disability	Do you have difficulty **hearing**, even if using a hearing aid(s)? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all • Don't know Do you have difficulty walking or climbing steps? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all • Don't know Do you have difficulty remembering or concentrating? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all • Don't know Do you have difficulty with **self-care**, such as washing all over or dressing? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all • Don't know Using your usual language, do you have difficulty **communicating**, for example understanding or being understood? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all Don't know	Do you have difficulty **hearing**, even if using a hearing aid(s)? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all • Don't know Do you have difficulty walking or climbing steps? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all • Don't know Do you have difficulty remembering or concentrating? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all • Don't know Do you have difficulty with **self-care**, such as washing all over or dressing? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all • Don't know Using your usual language, do you have difficulty **communicating**, for example understanding or being understood? • No difficulty • Some difficulty • A lot of difficulty • Cannot do at all Don't know	New question added at the request of implementing partners Response options taken from the Washington Group Short Set on Functioning: https://www.washingtongroup-disability.com/question-sets/wg-short-set-on-functioning-wg-ss/ The same options will be used for adults and children. UNICEF does have a child-specific question set, but it is more than double the length.

Domain	Adult response options	Child response options	Notes
Occupation	What is your occupation? • Unemployed • Agriculture • Unskilled work • Government or private employee • Business owner / professional • Housewife	What is your father's job? • Unemployed / no father • Agriculture • Unskilled work • Government or private employee • Business owner / professional	Father used on the basis that this is the best indicator of socioeconomic status. Women have more senior positions than their male partners in a negligible proportion of households Interviewer to categorise and code the highest
Income adequacy	When you think about the income in your household would you say it is: • Not enough to cover our needs, we must borrow, • Not enough to cover our needs, we use savings, • Just enough to cover our needs, • Enough to cover our needs, we are able to save a little • Enough to cover our needs, we are building savings	N/A	No changes
Housing	Is your house's floor made of cement? • Yes • No Do you have water piped into your own house or yard? • Yes • No Does your household have electricity? • Yes • No What kind of toilet does your household you use? • Own toilet/latrine – inside dwelling • Own toilet/latrine – in yard/plot • Shared toilet/latrine • None (bush/field)	Is your house's floor made of cement? • Yes • No Do you have water piped into your own house or yard? • Yes • No Does your household have electricity? • Yes • No What kind of toilet does your household you use? • Own toilet/latrine – inside dwelling • Own toilet/latrine – in yard/plot • Shared toilet/latrine • None (bush/field)	No changes
Assets	Do you own a smartphone? • Yes • No Does your household own a: • Bicycle or rickshaw • Motorcycle or scooter • Car or truck • Three-wheel tempo Do you own your dwelling? • Yes • No	Does your household own a smartphone? • Yes • No Does your household own a: • Bicycle or rickshaw • Motorcycle or scooter • Car or truck • Three-wheel tempo	No changes

Notes: The question on migrant status ('Were you born in Nepal') was removed as the team felt it will be too inflammatory. The Nepalese team were concerned that data collectors will not have capacity to ask all of the questions. If this turns out to be the case, the team feel that Income, Occupation, and Housing are the three most important indicators to focus on.

future work. We will use multivariable logistic regression to calculate the adjusted odds of attendance for each subgroup. The analysis will be conducted independently in each country.

Whilst it is possible to use regression to build a predictive model, our project hews to the principles of positive selectivism that underlie the WHO conceptualisation of 'health for all' and Universal Health Coverage. In contrast to negative selctivism (individual-focused means-testing) WHO, the World Bank, the Lancet Global Health Commission on Global Eye Health and others call for health services to be extended on the basis of sociodemographic group membership. As such, we are primarily interested in identifying which subgroups have the lowest adjusted odds of attendance, rather than the predicted probability of attendance for an individual based on their characteristics.

Whilst our analysis will involve multiple comparisons, we will not use Bonferroni or other adjustments because our primary aim is identifying the 2–3 sociodemographic subdomains associated with the lowest attendance rates. We note that false positives are not associated with clinical risk in this project.

Analytic plan

We will use the following steps to perform the statistical analysis:

1. Count the number of people in each subgroup (e.g. males, females).
2. Calculate the proportion of people who attended within each subgroup.
3. Use univariable logistic regression with to assess the simple association between each subdomain and attendance, one at a time.
    a. We will present the odds ratio for each association with its p value and a 95% confidence interval.
    b. Associations where $p<0.05$ will be used to fit a multivariable model.
4. We will compare crude and fully adjusted estimates to assess whether there is any likely confounding.
5. We will then consider whether any of the variables lie on the causal pathway between any others, aided by the development of a causal loop diagram.
6. We will use pairwise testing to check for effect modification, examining whether the effect of any variable differs by the category of another variable. This will help us examine intersectionality.
7. We will plot a correlation matrix and use the Variance Inflation Factor for each variable to assess collinearity.
8. Based on these findings, we will fit a final, fully adjusted model that includes all independent variables. We will use this model to estimate the adjusted odds of attendance for each subdomain along with p values and 95% confidence intervals.
9. These values will be presented in a summary table and used to generate a coefficient plot.

We will summarise the output using the template table below (Table 11).

Based on our output, it will be possible to rank all of the subgroups according to adjusted odds of attendance. As noted above, our overall aim is to identify the sociodemographic groups with the lowest overall attendance, so that we can then work with representatives from these groups to identify barriers and potential solutions. In the spirit of proportionate universalism, we are hoping that solutions suggested by these groups will improve the overall mean attendance rate whilst delivering the greatest benefit to groups with the greatest baseline need.

Process of selecting the lowest group(s)

We want to ensure that our selected 'left behind' subgroup represents at least 10% of the total study population. This is because our follow-on work will develop and test interventions to try and improve attendance and we need to have a large enough pool of non-attenders to work with and then test the interventions.

There is a good chance that one single sociodemographic subgroup that contains >10% of the total population will be found to have the lowest adjusted odds of attendance with a p value of <0.05. However, it is also possible that a tiny group (i.e. reflecting a rare characteristic) is found to have the lowest overall odds. If this is the case, we will include the group(s) with the next-lowest overall odds until the included groups collectively represent >10% of the total study population.

Bias

To reduce the risk of selection bias, the sociodemographic questions will be asked of all those referred to triage clinics. We have developed robust sets of sociodemographic questions that minimise the risk of recall bias, and we will deliver standardised training to reduce the risk of measurement bias.

Referred participants will be given an appointment date at a local clinic for a free follow-up provided by the local eye service. In the vast majority of the places where screening programmes operate there simply are not any alternative providers. In cases where there are other providers, they are unlikely to be free. Nevertheless, we cannot rule out instances where non-attenders have not faced barriers to accessing care, they have simply sought care from other qualified providers. If some groups are more likely than others to seek care elsewhere this will bias our findings. Subsequent phases of our research will involve interviewing non-attenders to explore why they were not able to access our clinics, and at this stage we will be able to assess the extent to which this is a problem. For our current study we will assume that all non-attenders have not managed to access adequate care.

Table 11. Template table for summarising the regression output.

Characteristic	Category	n (%)	Attended n (%)	Univariate			Multivariate		
				Odds ratio	p	95%CI	Odds ratio	p	95%CI
Gender	Female								
	Male								
Age	N/A								
Location	Urban								
	Rural								
Ethnicity	Dominant ethnicity (e.g. Batswana)								
	Ethnicity 2								
	Ethnicity 3								
	Ethnicity n...[list all on individual lines]								
Language	Dominant language (e.g. Setswana)								
	Language 2								
	Language n...[list all on individual lines]								
Religion	Dominant religion								
	Religion 2								
	Religion n [list all on individual lines]								
Health problems	Yes								
	No								
Household size	1								
	2								
	...n [list all up to 15+ on individual lines]								
Concrete floor	Yes								
	No								
Social welfare receipt	Yes								
	No								
Parents' job	Professional/office								
	Skilled manual								
	Unskilled manual								
	Domestic								
Parents' nationality	Batswana								
	Other								
Household members	Mother								
	Father								
	Grandmother								
	Grandfather								
	Aunt								
	Uncle								
	Siblings								
	Others								

Data management

Any participants' identifiable data collected by the Study Coordination Centre will be stored securely and their confidentiality protected in accordance with the Data Protection Act 1998 on Peek Vision servers.

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.

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.

The data will be stored on a Peek managed server hosted in a Virtual Private Cloud (VPC) utilising the Amazon Web Services (AWS) Cloud. Each Peek powered programme will be 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 will be securely stored in AWS data centers which are state of the art, utilising innovative architectural and engineering approaches.

Ethical considerations

Ethical review

We have already obtained ethical approval from the LSHTM ethics committee, and ethics committees in Botswana, India, Kenya and Nepal.

Risks and Benefits

There are no direct benefits to participants. The information gleaned from the study will help us to identify and engage with the groups that are least likely to attend in attempt to improve access to those groups.

There are two main risks. Firstly, some participants may experience psychological discomfort when asked about their life circumstances, particularly if they are very disadvantaged or ashamed of their social and/or material conditions. Members of persecuted or marginalised ethnic, religious, or social groups may be afraid to disclose this information. The second risk is inadvertent disclosure of sensitive and confidential personal information.

In terms of mitigating these risks, we have developed sociodemographic questions with in-country teams and lay review in order to minimise the risk of causing distress. We will pilot the questions and revise the wording further if any issues arise. Sociodemographic questions will be asked in a confidential setting where others will not be able to hear the responses. Programme implementers will be trained to protect privacy and confidentiality during data collection. Programme implementers will also receive training on how to support participants who become distressed. This includes giving them time and space, offering supportive comments, and providing contact details for local support groups.

We are using world-class data management and storage processes to provide the highest possible level of protection for patient data. See the data management section below.

Consent

No participants will be placed under any compulsion or coercion. Participants will not have to provide consent in order to participate in- and benefit from the screening programmes. Participants will be able to decline to answer as many questions as they wish. We will use tick boxes rather than signatures to obtain written consent among non-literate groups. We will read out the study information and consent form for non-literate participants and provide impartial witnesses who will also sign the consent form in these instances.

Adult consenting procedure (in-person)

All adult participants will be asked to provide informed written (digital tick box) consent for their anonymised data to be published at the point that they present to services. Their consent will be taken by data collectors, and their consent status will be recorded in the Peek Acuity app.

For this negligible-risk study, the patient information leaflet (PIL) will be read to each adult:

> "Now I will ask you a series of questions about your income, education, occupation, and personal characteristics.
>
> We will use this information to check that our programme is reaching people from every background; and to make improvements where we are missing certain groups.
>
> We will anonymise your data and keep it safe and secure on a virtual server within the European Union (EU).
>
> We will not sell your data.
>
> We will publish our findings in a research journal and a public repository, but your personal information will not be included.
>
> You do not have to let us analyse and share your data; participation is completely voluntary. You can change your mind at any time and your decision will not affect the care you receive
>
> We have a researcher available to answer any questions you may have [may be via phone]
>
> Please read this statement and tick to indicate whether you consent or not:"

Potential participants will have the option to read the information for themselves if they wish. Each person will be asked if they would like to ask any questions or discuss the study further. If not, they will be handed the android device displaying the following text and tick boxes:

> *"I understand that my anonymous data may be shared with other researchers or online in a public*

repository, and 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."

[ ] I consent

[ ] I do not consent

Implementers will be given training on taking consent and dealing with questions as part of their orientation training.

The use of a tick box rather than a signature aligns with the MHRA/HRA joint guidance for low-risk trials[30] and extends participation to those who may not be able to write their names.

The statement will be available in all the major local languages. The relevant domestic technical working group for each country will perform the translation. The translation will be checked by a lay representative.

A consent statement will be read out to those who cannot read - this includes people with marked visual impairment. These people will be given the opportunity to provide verbal consent and tick digital boxes on the Android device to signal their consent if they agree to participate. Independent witnesses will be available at each screening site to co-sign the consent form for all illiterate participants. These witnesses will be provided by primary care centre for community screening programmes. There will not be any house-to-house screening.

Digital form used to obtain consent from adults who cannot read.

Statement to be read out by programme implementer	Participant's tick	Impartial witness tick
"I have had the information explained to by study personnel in a language that I understand. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily."		
"I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected."		
"I understand that data about me may be shared via a public data repository or by sharing directly with other researchers, and that I will not be identifiable from this information."		
"I agree to take part in the above named study."		

Obtaining remote consent for children

As parents/guardians will not be present at school on the day that screening teams attend, we will send participant information and consent forms in the week before the screening teams arrive. Depending on the programme, this will either be by SMS or a paper form sent home with the children. The material will be written in the local dialect and will provide a free-phone number, email address, and postal address to discuss any questions with the study with the in-country research manager.

We have worked with ethics committees at LSHTM and in the respective study site countries to develop a consent process that is proportionate to the level of risk. All ethics committees have approved written opt-out consent, given the low-risk nature of the project. All parents will be sent an SMS or paper form from the school and asked to reply/return a signed form only if they do not want their child to participate. Illiteracy is an issue, however schools routinely send material home with children for their parents and in each instance, we have been reassured by school representatives that simple processes are in place to support illiterate parents/guardians, such as having a literate friend or family member read the material to them, or having the teacher personally relay the information.

SMS consenting messages:

1. Hi! When we check your child's vision next week, we will also ask them a series of questions about their home situation and personal characteristics
2. We will use this information to check that our programme is reaching people from every background; and to make improvements where we are missing certain groups
3. We will anonymise all data and keep it safe and secure on a virtual server within the European Union (EU) for 10 years // We will not sell your child's data
4. We will publish our findings in a research journal and a public repository, but your child's personal information will not be included
5. There are no direct benefits or risks to you or your child. // The [Name] ethics board has approved this project.
6. Participation is voluntary. You can change your mind at any time // You can find more information here [bit.ly hyperlink] // Or free-phone +xxxxxxxxxxxxxx
7. Please read the next two messages very carefully. They set out a consent statement. Once you have read them, please respond if you DO NOT agree
8. I understand that my child's anonymised data may be shared with other researchers or online in a public repository for research

9. I understand that I can call +xxxxxxxxxxxxxx to ask any questions; my decision will not affect the care my child receives; and I can change my mind at any time

10. If you DO NOT consent for us to use your child's data, please reply to this message with your full name // Your message will be free

In areas where teams are not able to use SMS data collection systems, we will use paper forms sent home with children for their parents to sign. The forms will contain the same information, along with a tick box to provide consent.

If the parents/guardians are illiterate, they will be provided with a phone number to speak with a research coordinator. If they are unable to use the provided phone number, parents/guardians will be asked by the teachers to attend with their child on the day of screening to provide verbal consent.

Child assent

Assent will be sought from children by programme implementers before asking the sociodemographic questions:

"Now I am going to ask you some questions about you and your home life. You can say 'I don't know' or skip any questions that you don't want to answer. Please tick this [digital] box to show that you understand what I've just said."

Procedures for following-up non-attenders

All participants who do not present for treatment within locally set timeframes (generally 3–4 weeks from the date of referral) will receive SMS reminders and the in-country programme team will have access through Peek Admin to contact non-attenders by SMS or telephoning all non-attending patients.

Dissemination

Our findings will be shared with programme managers who will use the information to target sociodemographic groups with the lowest attendance rates. Managers will engage with members of these left-behind groups to explore the specific barriers they are facing and develop potential service improvements that will be trialled. Our findings will also be shared with screening partners around the world who are not currently analysing outcomes by sociodemographic indicators. We will publish our findings in a peer-reviewed journal, present the findings at conferences, and develop policy briefs to share with governments in each country.

Protocol study status

This was true at the time of submission. Now we have approval from ethics boards in the UK, Botswana, India, Kenya and Nepal. Recruitment has started in all four countries.

Data availability

OSF: Data Management Plan

https://osf.io/dyj3f/ (DOI: 10.17605/OSF.IO/DYJ3F)[31]

This project contains the following underlying data:

- Appendix_DMP.docx

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Appendix 3: Scoping review protocol

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Allen LN, Azab H, Jonga R, Gordon I, Karanja S, Evans J, Thaker N, Ramke J, Bastawrous A. Rapid methods for identifying barriers and solutions to improve access to community health services: a scoping review protocol. BMJ Open. 2023 Mar 1;13(3):e066804.

BMJ Open

Rapid methods for identifying barriers and solutions to improve access to community health services: a scoping review protocol

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ABSTRACT

Objectives Low attendance rates for community health services reflect important barriers that prevent people from receiving the care they need. Services and health systems that seek to advance Universal Health Coverage need to understand and act on these factors. Formal qualitative research is the best way to elicit barriers and identify potential solutions, however traditional approaches take months to complete and can be very expensive. We aim to map the methods that have been used to rapidly elicit barriers to accessing community health services and identify potential solutions.

Methods and analysis We will search MEDLINE, Embase, the Cochrane Library and Global Health for empirical studies that use rapid methods (<14 days) to elicit barriers and potential solutions from intended service beneficiaries. We will exclude hospital-based and 100% remotely delivered services. We will include studies conducted in any country from 1978 to present. We will not limit by language. Two reviewers will independently perform screening and data extraction, with disagreements resolved by a third reviewer. We will tabulate the different approaches used and present data on time, skills and financial requirements for each approach, as well as the governance framework and any strengths and weaknesses presented by the study authors. We will follow Joanna Briggs Institute (JBI) scoping review guidance and report the review using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews.

Ethics and dissemination Ethical approval is not required. We will share our findings in the peer-reviewed literature, at conferences, and with WHO policymakers working in this space.

Registration Open Science Framework (https://osf.io/a6r2m).

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ As far as we are aware, this will be the first review to evaluate the rapid approaches used to elicit barriers to access community health services and identify potential solutions.
⇒ Improving access and grounding service improvements in community engagement are two major global health priorities.
⇒ Our review will follow best-practice guidelines, use a search strategy devised by an information specialist, and use independent dual review at every stage.
⇒ We will miss rapid approaches that have been used effectively but not written about, and those that take longer than 14 days to deliver findings.

INTRODUCTION

Rationale

Many health programmes experience large mismatches between people identified with a clinical need and those who attend services. A recent international systematic review of non-attendance across all medical specialities estimated that 23% of clinic appointments are missed, with the highest rate observed in Africa (43%).[1] Low attendance rates often reflect significant barriers faced by users.[2] Marginalised populations are often the least likely to receive care.[3 4] Improving access to ensure that all individuals and communities receive the care they need lies at the heart of Universal Health Coverage—a core element in the Sustainable Development Agenda.[5 6]

Complex supply and demand factors govern access to health services and multiple frameworks have been developed, typically defining access as the ability to perceive, seek, reach, pay for and engage with care.[2 7–11] Access is increasingly being extended through the use of digital services and remote consultations.[12 13] While these services are useful, they come with their own set of barriers and equity issues, and cannot fully replace the central role played by in-person clinical providers.[12 14] When it comes to identifying barriers to attending in-person clinical services and potential solutions, WHO has noted that 'it is the experts who identify the problems and formulate interventions, while the problems and solutions as perceived by those at particular risk rarely constitute

the base for action'.[15] Efforts to improve attendance rates should be grounded in an understanding of both supply-side and demand-side barriers, elicited through engagement with affected communities.[2 16 17] The WHO Primary Health Care (PHC) Operational Framework defines engagement as 'the process of involving people and communities in the design, planning and delivery of health services, thereby enabling them to make choices about care and treatment options or to participate in strategic decision-making on how health resources should be spent'. Turk and colleagues note that health service interventions 'must be done with, and not simply done to, the people affected'.[18]

Research evidence aligns with common sense in finding that involving communities in the development of services improves health outcomes and sustainability.[18] For-profit enterprises seem to understand the value of engaging with their customers: many companies use focus groups and market research to continually hone their products and services to meet the evolving needs of their customer base.[19] Our sense is that health programmes are less active in this space. Ideally—given the scale of the problem—health system managers would be able to deploy affordable, rapid and methodologically sound tools to engage with the groups that face the highest barriers to accessing care in order to elicit their ideas for service improvements. In reality, existing qualitative elicitation and coproduction techniques commonly take more than a year to plan, execute, analyse and report.[20] They require formal ethical review, formally trained qualitative researchers, the use of specialist software and qualitative expertise to interpret and apply the findings.[20 21] These resource requirements are prohibitive for most health system managers, and in many low-income settings there is not a ready supply of specialist expertise.[22] This can lead to well-conducted but one-off engagement activities where the findings are inappropriately generalised to other groups or at the other end of the spectrum are tokenistic and/or methodologically flawed efforts to gather and act on service user feedback, . We are interested in exploring whether it is possible to obtain meaningful and robust findings with rapid tools[23]; here defined as approaches that take 14 days or less 'from entering the field to through to delivery of findings'[24] that is, contacting and recruiting participants, eliciting barriers through the collection and analysis of data, and developing a list of potential interventions to improve the service. Such tools would have very wide application across a broad range of settings and would support the development of PHC-oriented systems that are built on community engagement.[25] While 14 days are essentially arbitrary, it reflects an ambitious target for delivering usable intelligence that aligns with the timescales offered by market research firms to political parties and companies.[26]

Aim and objectives

We will perform a scoping review[27] of the literature to identify, categorise and evaluate the methods that are being used to rapidly elicit barriers and potential solutions from service users in any community-based health service. We want to understand the strengths and weaknesses of the different methods that have been used, their resource requirements, and their governance frameworks as described by their users.

Responding to the need for rapid, affordable and scientifically robust approaches that can be used to continually improve health services, we ultimately aim to identify the minimum viable product in this space. We want to identify approaches that provide sound, non-tokenistic and actionable intelligence with minimal time, money, equipment, personnel, and skill requirements.

Review question

What rapid methods have been used to engage with community-based health service users to elicit barriers to access and potential solutions? For each method, what are the main outputs, methodological strengths and limitations and resource requirements in terms of time, personnel and other costs? For the purposes of this review, 'community-based care' will be defined as non-hospital care that involves interaction with a clinician, and a 'community' will be defined as a group who share geographies, interests or identities. This definition is based on that used in the WHO Operational Framework for PHC a.[28] We will use the WHO Operational Framework definition for 'community engagement' that is presented in the introduction.[28] We note that Primary Health Care is not the same as community-based care: the former is a whole-of-society approach to health (that includes hospitals even though it focuses on primary care).[25]

METHODS AND ANALYSIS

Guidelines

Our review will be conducted in accordance with the JBI methodology, based on the principles of Arksey and O'Malley and Levac and colleagues.[29–31] Our review will be reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist Extension for Scoping Reviews (PRISMA-ScR, online supplemental file).[32] Scoping reviews are the most appropriate method for mapping and characterising the available evidence in a given area, and follow five steps[33–35]:

1. Defining the research question/s
2. Identifying relevant studies
3. Study selection
4. Charting the data
5. Collating, summarising and reporting the results

An iterative approach will be taken towards searching the literature, refining the search strategy, reviewing articles for inclusion, and extracting relevant data.[32 36–38]

Participants

As we are concerned with barriers to access, we will focus on methods that seek to engage with those who are eligible for a given service but have not managed to attend. As such, we

deem the sample population 'intended service beneficiaries' rather than 'service users'. We will include methods where engagement activities target service users and intended beneficiaries of any community-based health service in any country, serving any need. We will exclude methods that sample exclusively from attendees as—by definition—they have successfully overcome barriers to access.

We will include methods where engagement activities target lay representatives of intended service users such as patient advocacy groups, parents or village elders, however these findings will be reported separately in the findings. We will exclude methods that exclusively engage service providers, managers or policymakers. We will include approaches that engage a mix of users and providers as long as it is possible to disaggregate the findings pertaining to service user engagement.

As we are focusing on groups that face barriers to access, we will exclude approaches that exclusively engage with people who are present at their services, that is, our focus is on methods for contacting and engaging with non-attenders or their proxies.

Concept

We are interested in methods used for engaging service users to elicit their perceptions of barriers to accessing care and generating ideas for service modifications that could improve access rates and outcomes among people with similar characteristics.

We are focusing on rapid methods, defined as those that can be used to deliver a list of barriers and potential solutions within 14 days or less. This is an arbitrary threshold but draws from our clinical experience in leading health services and represents what we feel to be an acceptable amount of time to generate data to inform real-time decision-making.

Given that it is not standard practice to report the length of time taken to conduct research we anticipate that our search will not identify many studies. To overcome this issue we will include studies that do not state how long they took as long as they meet all other inclusion criteria. We will analyse these studies separately.

We will include all forms of established or novel methods from any scientific field of enquiry. We expect to find examples of the following types of method:

- Interviews: face-to-face, telephone, video call.
- Focus groups
- Group system dynamic modelling
- Q methodology
- Nominal group technique.
- Surveys: in-person, web, telephone, text message
- Rapid ethnography

Context

We are not limiting the review to any specific population, culture or geography. We will include studies from all countries and any setting except hospital inpatients. Our focus is on in-person access to existing services so we will exclude evaluations of novel services or new interventions.

We primarily define 'access' in terms of whether people are able to physically reach (ie, attend) a clinical provider to get the care they need. This includes attending prebooked appointments as well as presenting to services that do not require appointments. We will include outreach services and home-based care, but exclude virtual/digital remote consults. We will also exclude compulsory care such as when patients are sectioned for mental healthcare, and services where no interaction with a clinician is required, such as automated services to obtain self-testing kits.

Types of sources

We will include all empirical study types that report on the use of a given method to elicit barriers or potential solutions with a maximum of 14 days between commencing fieldwork and generating the findings.

We will exclude methodological texts, reviews, letters and conference abstracts. We will also exclude systematic reviews, but we will search their reference lists and include any underlying primary studies that meet our inclusion criteria.

Patient and public involvement

No patient and public involvement.

Search strategy

The search strategy will be built around rapid community-based methods and access to health services[39 40] (box 1). The search will be limited to human studies published since 1978; the year of the Alma-Ata Declaration on Primary Health Care. The search will be conducted in English but we will include full-text studies published in any language. We plan to complete the review by mid-2023. The search strategy results will be presented in a PRISMA flowchart that will show how studies were eliminated until final search yield that will constitute the basis for synthesis.

We will search the following information resources: the Cochrane Library, MEDLINE Ovid, Embase Ovid and Global Health Ovid. The first 20 pages of Google Scholar will also be screened. The search strategy, including all identified keywords and index terms, will be adapted for each included database and/or information source. Box 1 presents the search strategy for Medline. The Supplementary file (online supplemental appendix) presents the tailored search strategies for all databases. We will check the reference lists of included studies and relevant systematic reviews to identify any additional potentially relevant reports of studies. Key authors will be contacted to uncover additional or upcoming studies.

Study/Source of evidence selection

Following the search, all identified citations will be collated and uploaded into Covidence (Veritas Health Innovation, Melbourne) and duplicates will be removed. Following a pilot test, titles and abstracts will then be screened by two independent reviewers (HA and RJ) for assessment against the inclusion criteria. Studies that clearly do

Box 1 Search terms used for Medline

1. Health Services Accessibility/
2. Health Equity/
3. Social Determinants of Health/
4. (social adj2 determinant adj2 health$).tw.
5. ((health$ or social$ or racial$ or ethnic$) adj5 (inequalit$ or inequit$ or disparit$ or equit$ or disadvantage$ or depriv$)).tw.
6. (disadvant$ or marginali$ or underserved or under served or impoverish$ or minorit$ or racial$ or ethnic$).tw.
7. barrier$.tw.
8. (solution$ or improve$ or strateg$ or access$ or challeng$).ti.
9. Community-Based Participatory Research/
10. Community-Institutional Relations/
11. (communit$ adj3 (engag$ or participat$)).tw.
12. CBPR.tw.
13. (participat$ adj2 health adj2 research).tw.
14. (communit$ adj2 academic adj2 partnership$).tw.
15. (collective adj2 empower$).tw.
16. (equity adj2 mobili$ adj2 partnership$ adj2 communit$).tw.
17. (ethnograph$ or communitarian$).tw.
18. Interviews as Topic/
19. Patient Health Questionnaire/
20. Self Report/
21. Q-Sort/
22. Q-Sort.tw.
23. Q-methodolog$.tw.
24. (system adj2 dynamic adj2 model$).tw.
25. (nominal adj2 group$ adj2 technique$).tw.
26. or/1–25
27. Problem Solving/
28. ((rapid$ or agile) adj2 (appraisal$ or assessment$ or approach$ or evaluation$ or evaluate$ or technique$ or tool$ or method$ or research$)).tw.
29. or/27–28
30. 26 and 29
31. in vitro.tw.
32. (assay$ or microb$).tw.
33. Critical Care/
34. or/31–33
35. 30 not 34
36. limit 35 to humans
37. limit 36 to (comment or editorial or letter)
38. 36 not 37
39. limit 38 to yr=’1978-Current’

not meet the inclusion criteria will be excluded. The reviewers will meet after every 10% batch of papers has been screened to discuss any issues. Any disagreements will be resolved through consensus-based discussion, or if necessary, discussion with a third reviewer (LNA).

We will obtain full texts for the potentially relevant papers. The same two review authors will independently assess the papers against the inclusion criteria to determine their eligibility for inclusion. Non-English language papers will be translated into English. The review authors will resolve disagreements through consensus-based discussion, or if necessary, discussion with the same third reviewer. The reviewers will record reasons for exclusion at the full-text screening stage.

The results of the search and the study inclusion process will be reported in full in the final scoping review and presented in a PRISMA flow diagram.[41]

Data extraction

Two review authors (HA and RJ) will independently extract study characteristics and data from the included studies using a data extraction form developed by the reviewers. The data extraction form will be piloted on three studies by the same two review authors and required amendments will be made by consensus.[42] We anticipate a broad scope of included studies, so data charting will be an iterative process throughout the review. The data extraction tool will be modified and revised as necessary during the process of extracting data from each included evidence source. Any discrepancies will be resolved by group discussion. Modifications will be detailed in the scoping review. Where required, authors of papers will be contacted to request missing or additional data.

The data extracted will include specific details about the participants, concept, context, study methods and key findings relevant to the review question:

- Article title.
- Journal title.
- Authors.
- Country.
- Language.
- Publication year.
- Study type.
- Type of approach (eg, focus group) and description:
  - Setting.
  - Participants.
  - Facilitators.
- Main output if anything other than a prioritised list of potential service modifications.
- Methodological strengths and limitations, as documented by the authors.
- Resource requirements:
  - Number of personnel, and essential skills/level of training.
  - Number of days for each person, full time equivalent.
  - Total number of days taken from conception to findings; including planning, recruitment, engagement and analysis stages.
  - Equipment.
  - Total financial cost.
- Framework used to structure interaction and elicit barriers and solutions.
- Method of recording (notes, audio, etc).
- Other practical requirements or qualitative considerations reported in-text.
- Ethics and governance requirements.
- Level, form, frequency and intensity of participation:
  - Level of participation will be assessed using the five categories used by WHO: inform, consult, involve, collaborate and empower.

  - Form will be assessed using the four categories used by WHO: community-oriented, community-based, community-managed and community-owned.
  - Frequency is defined as the number of discrete interactions between the project team and the service users.
  - Intensity represents the extent to which participants interact, exchange information and influence decision-making in participation processes.[43]
- Power relations, prevailing knowledge and beliefs and cultural barriers,[18] described by the authors.
- Any documented power relations, prevailing knowledge and beliefs and cultural barriers.

Data analysis and presentation

We plan to conduct a formal narrative descriptive synthesis without meta-analysis. We will stratify the synthesis by methodological approach. We will present a summary table of the different methods used, grouped by discipline. We will also tabulate the resource requirements, form of participation and methodological strengths and limitations. Quantitative resource requirement data will be presented in whole numbers, days and 2022 US dollar amounts as appropriate. Ratios will be used to compare costs between approaches. Qualitative outcomes will be presented narratively. Methods used to engage with service users and service user representatives will be presented separately.

We will not conduct methodological quality assessment of included studies, in keeping with usual practice for scoping reviews.[27 29]

Limitations

Our review focuses on methods that operate extremely rapidly, using a 14-day cut-off. This choice has driven by our collective experience working with health service and system managers. We are aware that effective community engagement can often take (much) longer than 14 days, and that expediency may come at the cost of the value and nuance of the findings that are delivered. Nevertheless, just because it is unlikely that there are many robust approaches that can deliver meaningful and non-tokenistic findings within a very short timeframe, we feel it is still worth examining the literature to understand this space. There is a risk that rapid approaches produce oversimplified findings that further compound issues for marginalised groups. We will be careful to assess these risks.

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Contributors LNA conceptualised and planned the study with SK, IG, JE, NT and AB. IG and LNA designed the search terms with input from RJ, HA, SK, JE, JR and NT. LNA wrote the first draft with JR. HA, IG, SK, JE, NT, JR and AB critically revised iterations of the manuscript. All authors read and approved the final protocol.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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Appendix 4: Interview mode effects study

Reference

Allen LN, Karanja S, Tlhakanelo J, McCleod D, Thlajoane M, Bastawrous A. Comparison of telephone and in-person interview modalities: duration, richness, and costs in the context of exploring determinants of equitable access to community health services in Meru, Kenya. Under review at the International Journal of Qualitative Methods.

Comparison of telephone and in-person interview modalities: duration, richness, and costs in the context of exploring determinants of equitable access to community health services in Meru, Kenya

Abstract

Background: Our research team is conducting phenomenological interviews in Kenya with people who have not been able to access community eye health services, aiming to explore the barriers and ideas for potential service modifications. We conducted an embedded study that compared in-person and telephone interview modalities in terms of time requirements, costs, and data richness.

Methods: A team of six interviewers conducted 31 in-person interviews and 31 telephone interviews using the same recruitment strategy, topic guide, and analytic matrix for each interview. We compared the mean duration; mean number of themes reported by each participant; total number of themes reported; interviewer rating of perceived richness; interviewer rating of perceived ease of building rapport; number of days taken by the team to complete all interviews; and all costs associated with conducting the interviews in each modality.

Findings: In-person interviews were 44% more expensive and took 60% longer to complete than our telephone interviews (requiring 5 days and 3 days respectively). The average in-person interview lasted 110 seconds longer than the average telephone interview (p=0.05) and generated more words and themes. However, the full set of interviews from both approaches identified similar numbers of barriers (p=0.14) and the same number of solutions (p=0.03). Interviewers universally felt that the in-person approach was associated with better rapport and higher quality data (p=0.01). Triangulation of themes revealed good agreement, with 88% of all solutions occurring in both sets, and no areas of thematic dissonance.

Discussion: The in-person approach required more time and financial resources, but generated more words and themes per person, and was perceived to afford richer data by interviewers. However, this additional richness did not translate into a greater number of themes that our team can act upon to improve services.

Keywords: qualitative research; in-person interviews; telephone interviews; mode comparison; methods research

Introduction

Background

Qualitative interviews – especially those grounded in the phenomenological approach - are designed to elicit rich data about participants' lived experiences and perceptions of a given phenomenon.[1] Our research team has been using interviews to explore barriers to health service access and potential solutions that might improve accessibility by engaging with people who were referred to local eye clinics but were not able to access care in Kenya.[2]

Our project is embedded within the 'Vision Impact Project' (VIP) eye screening programme that operates in ten counties across the country. Over a million people have been screened in the past year, and over 150,000 of these people have received care in free local outreach clinics [3]. However, internal data from the screening programme suggest that up to half of all those referred to local treatment clinics are not accessing care. Furthermore, early data from a related study suggests that certain sociodemographic groups have much lower odds of accessing care than others. In Meru County we have found that younger adults (aged 18-44 years) are the least likely to receive the care they need.[4] We wanted to explore these peoples' experiences and perceptions of specific barriers to accessing care, as well as their ideas around any changes we could make to the eye care services to make it easier to access care.

The VIP screening budget is limited, and programme implementers are keen that our interviews can be conducted quickly and as inexpensively as possible whilst still delivering robust findings. The incentive to deliver timely and affordable findings is further underlined by our desire to see embedded qualitative research adopted more widely across routine programmatic quality improvement initiatives, so that the voices of intended service beneficiaries can be included in decision making. Based on the findings of a recent scoping review on rapid qualitative research methods[5] we have developed a rapid 'abductive' interview approach that uses a deductive analytic matrix to facilitate rapid iterative analysis of data whilst "making space for inductive identification of themes and issues not predicted at the outset".[1] Our work employs a phenomenological approach, grounded in a pragmatist philosophical paradigm.[6]

The work in Kenya is part of a broader overall project to develop equity-driven and evidence-based approaches to improve access to community-based services across Kenya, Botswana, India and Nepal.[7] Hundreds of thousands of people are being screened and referred to local services each year, however only around half are able to access care. We wanted to develop an interview approach that could be taken to scale across these four countries – and potentially beyond – to deliver timely

insights into how these programmes can be made more accessible, especially for 'left behind' groups. Given the scale of the project, telephone interviews are likely to offer the most pragmatic means of obtaining timely insights on how to improve services, however it is not clear what – if anything - would be lost from using telephone interviews as opposed to in-person interviews which generally represent the 'gold standard' in qualitative research.[8]

In-person interviews are commonly perceived the 'best' way of obtaining rich phenomenological data due to the fact that the interviewer can observe visual cues and quickly build rapport.[9–11] However, telephone interviews offer unique advantages: the increased social distance can make it easier for participants to discuss sensitive topics; travel time and interviewer safety concerns are eliminated; power imbalances are partially concealed; and overall costs can be greatly reduced – depending on the specific study design and population.[9,12,13] For our projects, participants can be spread across vast distances, meaning that the risks, costs, and time-requirements for in-person interviews are likely to compare poorly with telephone interviewing. However, we were unable to accurately quantify the trade-off between data quality and resource requirements between the two approaches. As such, we decided to conduct this study to assess which modality offers the best balance of richness, duration, and costs in the context of our work to explore barriers to access and potential solutions in Meru County, Kenya.

Mode comparison

A number of previous studies have sought to compare telephone and in-person interview modalities.[10,12–17] In qualitative research, quality is conceptually linked to the 'richness' of the data obtained, described by Charmaz in terms of revealing participants' true feelings, intentions and actions, and accessing their "otherwise inaccessible thoughts".[18] Many different proxies have been used to approximate richness in mode comparison studies. A crude but relatively common approach is to measure the duration or wordcount of each interview, working from the assumption that longer interviews, with more words spoken, are more likely to provide deeper insights into people's lived experiences.[12,13,15,16] Interview duration is often used in the same way, based on the assumption that longer interviews generate richer data, with some studies also reporting 'interviewer dominance' i.e. the proportion of the talking that is done by the interviewer as opposed to the participant.[16] Surprisingly few qualitative mode effect studies compare the actual content of the interviews, despite the fact that this is a more nuanced way of assessing the amount of topic-related data that are generated.[16,17] This approach is also relatively straightforward, requiring the reporting of the total number or unique themes that arise from each set of interviews and/or the mean number of themes identified by each interview.

A further approach entails having researchers subjectively rate their experience of each interview in terms of the perceived richness of the data obtained, as done by Abrams et al using a three-point Likert scale.[19] Other reported measures include quantifying the word count of associated field notes for each interview and counting the amount of conversational turn-taking that occurs in each interview.[15,16]

In this study, we aimed to compare the data richness obtained from two sets of in-person and telephone interviews, electing to use a broad range of proxies: interview duration and wordcount; number of themes identified; and subjective interviewer rating of richness and rapport. We aimed to gather additional data on the time taken to complete each set of interviews, and the associated costs. We hypothesised that telephone interviews would be faster and less expensive to complete than in-person interviews, but offer less-rich data across all metrics of comparison.

Methods

Interviews

A previous equity analysis conducted by our team in Meru had found that younger adults (aged 18-44 years old) were the least likely to receive eye care in the county's community-based screening programme.[4] We obtained a list of all of the younger adults who did not receive care from Peek Vision, a partner organisation that provides the screening and patient flow management software for the programme.[3] Peek also record contact numbers for all participants. We used computer-generated random numbers to identify interviewees from this target population, and to determine interview modality.

We performed the telephone interviews first. We performed 36 interviews but a retrospective saturation analysis found that saturation was reached after approximately 30 interviews. Our protocol for this study[20] stipulated that we would compare an equal number of interviews from both modalities, with a minimum of 20 v 20. We decided to conduct 31 additional in-person interviews and compare these against the first 31 telephone interviews.

The same team of six data collectors conducted all interviews using the same semi-structured interview guide. The same process for audio recording data and directly transcribing quotes into the deductive analytic matrix was used for both modalities, and the same process of iterative review and analysis across all cases within each modality was used to generate the final themes. Data collectors received two days of training before conducting the interviews in September 2023.

Comparison domains

We gathered data on six domains of richness. We then collated data on the time taken to complete both sets of 31 interviews and their associated costs, following the approach set out in our protocol.[20]

1. Interview duration: We measured the duration of each interview in minutes from the start of the consenting process until the researcher concluded the interview e.g. by thanking the participant for answering all of their questions. In line with previous studies discussed above, this metric was used as a proxy for richness, based on the assumption that longer interviews capture richer data than shorter interviews. Note that we did not use interviewer dominance measures this is only possible with typed transcripts, and our approach is based around direct-from-audio entry of verbatim quotes.
2. Matrix wordcount: We counted the total number of words entered into the analytic matrix for each set of interviews. These were verbatim quotes directly transcribed from the audio by the data collectors. In line with previous research, we assumed assume that a higher wordcount was associated with richer data.
3. Total number of themes: We counted the total number of unique themes for barriers and solutions that were reported across all interviews with each modality. We assumed that the modality that captured the largest number of unique themes was capturing richer data. From an operational standpoint, our underlying study is primarily concerned with generating potential solutions that will improve equitable access, so the number of unique solutions that emerged from each set of interviews is a particularly important metric.
4. Number of themes reported by each participant: We also reported the range and mean number of unique themes (barriers and solutions) identified by each participant for each modality. This was to hedge against a situation where one modality generated a greater number of themes than the other, but only because of one or two prolific interviews.
5. Interviewer subjective rating of richness: After all of the interviews were complete, each of the six data collectors were asked to provide a single global summary rating of the perceived richness obtained from all in-person and all telephone interviews. Following the approach used by previous researchers, we used a simple Likert scale: low = 1, moderate = 2, high = 3.
6. Interviewer subjective rating of rapport: We supplemented the subjective rating of richness with a second question that asked data collectors to provide a global summary rating of the perceived ease of building rapport across all in-person and all telephone interviews. Again, we used a simple Likert scale: low = 1, moderate = 2, high = 3.

7. Time taken to plan and complete all interviews: We documented the total amount of time taken to plan and complete all interviews in each modality to the nearest half-day. This was recorded by the Kenyan research manager in charge of scheduling, supervision, and logistics for the local research activities.
8. Costs: Working with a health economist, we recorded costs from the payer's perspective. Both modalities use the same sampling and analytic approach, so we only compared costs that were unique to each approach i.e. those associated with data collection. For telephone interviews these included airtime and staff daily salaries multiplied by the number of days required to complete data collection, starting with the first phone call to recruit the first participant, and ending with the conclusion of the final interview.

   For in-person interviews we included the costs of printing consent forms, transport for researchers, transport reimbursement offered to participants; payments for local Community Health Promoters and sub-county health officials to assist with setting up the interviews (mobilisation/sensitisation), and staff daily salaries multiplied by the number of days taken for data collection.

   The costs of voice recorders were not included in the comparison because they were used for both sets of interviews. Similarly, the same two-day training covered skills required for both interview modalities so this was not included in the comparison. We did not compare overhead costs unless they differed for the modalities. The local research manager also recorded any unforeseen additional costs associated with each modality.

Statistical approach

We used sign tests for the paired interviewer ratings. For the unpaired mean testing comparisons we used histograms to check the data for normality and then used T-tests or Mann-Whitney-U tests, as appropriate, to provide evidence as to whether the two modalities differed across the domains.

Triangulation of themes

Finally, we compared the barriers and solutions that emerged from both modalities. We identified themes that were identified in both sets of interviews (agreement); themes that emerged from one set of interviews but not the other (silence); and any areas of dissonance i.e. where themes from one set conflicted with those from the other.

Ethics

Ethical approval was granted by the Kenya Medical Research Institute (KEMRI), the Kenyan National Commission For Science, Technology & Innovation (NACOSTI), and the London School of Hygiene & Tropical Medicine research ethics committee. Each participant provided informed consent.

Findings

For our comparison we used 31 telephone interviews and 31 in-person interviews that were conducted by our team of six researchers in September 2023 across four sites in Meru County. Table 1 summarises our main findings.

Table 1: Performance characteristics of each modality

Comparison domain	Metric	Modality		p	Ratio
		In-person	Telephone		
Data richness	Mean interview duration in minutes and seconds (range)	10.20 (4.19 - 15.20)	8.30 (3.10 - 30.10)	0.005	1.11
	Analytic matrix wordcount – barriers	4,453	2,674	N/A	1.67
	Analytic matrix wordcount – solutions	2,638	2,094	N/A	1.26
	Total number of barriers identified	15	14	N/A	1.07
	Total number of solutions identified	22	22	N/A	1.00
	Mean number of barriers mentioned by each participant (range)	1.94 (0-4)	1.58 (0-3)	0.142	1.23
	Mean number of solutions mentioned by each participant (range)	2.23 (0-5)	1.61 (0-4)	0.029	1.39
	Interviewer global rating of richness (1-3)	3.0	2.0	0.014	1.5
	Interviewer global rating of ease of building rapport (1-3)	3.0	2.0	0.014	1.5
Time requirement	Time taken to organise and complete all interviews	5 days	3 days	N/A	1.67
Costs	Cost to complete all interviews	USD 668.29	USD 375.71	N/A	1.78

Richness

The average in-person interview lasted 110 seconds longer than the average telephone interview (P=0.05) and generated 33% more words in the analytic matrix. On average, face-to-face interviews identified a greater number of barriers(p=0.14) and solutions (0.03), however the entire in-person interview set only identified one additional barrier and the same number of unique solutions as telephone interviews. All six data collectors were unanimous in their ratings of data richness and ease of building rapport, rating in-person interviews as 'high' and telephone interviews as 'moderate' for both measures (p=0.01).

Time requirements

It took two days to prepare for the in-person interviews and then three days to complete them. Preparation time included phoning potential participants to invite them to participate, and then scheduling meeting times and places, and organising transport and local logistics. This included working with local Community Health Promoters (CHPs) and sub-county health officials to sensitise and locate interviewees. This is a vital element in building trust and legitimising our work with participants: the CHPs visited each person to discuss the project and answer any questions, and then supported the researchers to connect them with the interviewees in the field.

Costs

Telephone interviews required three days of our data collectors' time, plus the airtime used to complete the calls. Higher airtime costs for the telephone modality reflects the fact that phone calls were used for recruitment, consenting, and data collection, whereas the in-person approach only used calls for recruitment. Spending on data collectors' salaries was the same for the in-person interviews – which were also completed in three days - however this modality incurred a number of additional costs. We paid two local county officials to assist with scheduling the in-person interviews, and for sensitization and mobilisation on the days of the interviews. We paid nine Community Health Promoters to build trust, explain the project, and physically locate interviewees. We printed physical consent forms, reimbursed travel to a convenient interview location for our interviewees and paid to transport our data collectors to the same location. Whilst the VIP programme operates across the entire county, at the time that our study was running the programme was operating in Meru town, meaning that all of the interviews were conducted within 15-30 minutes away from our offices. As such, we estimate that the transport costs for data collectors could easily rise by a factor of ten or more for in-person interviews conducted in other parts of the county.

Table 2: Cost of telephone and physical interviews in USD

Line item	In-person	Telephone
Salaries for two sub-county health officials to schedule in-person interviews	50.10	N/A
Payments to nine Community Health Promoters for sensitization and mobilization activities	103.32	N/A
Printing consent forms	23.29	N/A
Transport for data collectors	50.10	N/A
Transport reimbursement for interviewees	97.06	N/A
Airtime	12.52	37.57
Data collector salaries to complete the interviews	338.15	338.15
Total	**674.55**	**375.73**

1 USD = 159.691 KES

Triangulation of themes

Table 3 presents the 21 unique barriers that were identified across all 62 interviews. There was agreement between in-person and telephone modalities on nine of these barriers (42.3%). There was silence on the remaining 12 (57.7%) with each modality identifying six unique barriers that did not emerge from the other set of interviews. We found no evidence of thematic dissonance.

Table 3: Thematic overlap across in-person and telephone modalities: barriers

Barriers	Number of interviews where this barrier was raised	
	In-person	Telephone
Conflicting work engagement	14	15
Long queue	11	9
Other conflicting engagement	7	3
Transport costs	7	1
Clinic not open at stated times	4	0
Fear	3	0
Perceived cost of eye drops/spectacles	2	2
Distance to the clinic	2	6
Insufficient numbers of staff	2	2

Lack of clear information on clinic opening times	2	0
Lack of clear information on services available	2	0
Insufficient counselling at the point of referral	1	0
Lack of clear information on the clinic appointment date	1	0
Opportunity costs from loss of wages/income	1	2
Sought services elsewhere	1	2
Forgot	0	3
Did not receive the SMS reminder message	0	2
Assumption that their eye problem wouldn't be addressed	0	1
Dislike of crowded places	0	1
Male health seeking behaviour	0	1
Mixed genders in the queue	0	1

Table 4 presents the 25 unique solutions that were identified across all 62 interviews. There was agreement between in-person and telephone modalities on 22 of these barriers (88.0%). There was silence on the remaining three (12.0%) with each modality identifying three unique barriers that did not emerge from the other set of interviews. We found no evidence of thematic dissonance.

Table 4: Thematic overlap across in-person and telephone modalities: solutions

Solutions	Number of interviews where this barrier was raised	
	In-person	Telephone
Hold the clinics on additional days	10	9
Add more staff to each clinic	9	4
Hold the clinics in different locations	6	4
Add a greater number of clinics	6	5
Add more drugs and essential supplies	4	2
Introduce phone call reminders	4	2
Explain the costs and services available	3	0
Extend clinic opening hours	3	2
Specify the clinic dates and times	3	0
Provide a door-to-door service	2	1
Provide transport fare	2	1
Provide transport to the clinic	2	1
Issue public reminders	2	1
Schedule fewer people to attend each clinic every day	2	2
Use SMS reminders	2	2
Have sperate clinic queues for men, women, young & elderly	2	1
Improve staff punctuality	2	1
Hold "mop-up" clinics for those who miss their appointment	1	3

Explain clinic importance at point of referral	1	1
Pay people to attend	1	1
Subsidise treatment	1	0
Hold weekend outreach clinics	1	3
Allow people to choose their appointment day	0	2
Provide specific appointment slots	0	1
Refer non-attenders to the next available clinic via SMS	0	1

Discussion

In this study we examined the quality, costs and time-requirements of in-person vs telephone modes, based on 62 interviews conducted with young adults who had not been able to access eye care services in Meru, Kenya. Even with serendipitously low transport costs, in-person interviews were almost twice as expensive as telephone interviews and took 1.7 times longer to complete. They delivered longer interviews with more words transcribed into the analytic matrix and more themes identified per interview. Our data collectors universally ascribed higher ratings of richness and ease of building rapport to in-person interviews. However, across both modalities, exactly the same number of unique solutions were identified.

Our findings align with the wider literature. Irvine et al. found that telephone interviews tended to be shorter than in-person interviews, although their study only included 11 interviews in total.[15] Novick's review of the literature found evidence that telephone interviews are generally less expensive and shorter than in-person interviews.[9] In their retrospective mode-effect analysis of 300 interviews, Johnson et al. found that in-person interviews produced longer transcripts and more word-dense field notes, but generated the same themes as telephone and videocall-based interviews.[16] Interestingly, subjective interviewer ratings were also similar across the approaches. Krouwel and colleagues also compared in-person interviews to those conducted using video-calling software. They found that in-person interviews generated more data but the overall number of themes derived from each approach was similar.[17] Vogl's triangulation of the themes that emerged from two sets of interviews with 56 children found negligible differences.[13] Finally, in his systematic review comparing telephone and in-person approaches, Rahman concludes that both telephone and in-person modalities can generate comparably rich data, with telephone interviews tending to be less time consuming and less expensive.[10]

Given that empirical mode comparisons consistently find that remote interviews are able to generate similar qualitive themes at lower costs and in shorter time periods than in-person interviews, irrespective of research question and population studied, Rahman has argued that the in-person

modality should only be used if the specific research question demands it.[10] The relationship between depth of detail, number of themes, and agreement between themes is intriguing. Participants tend to provide much more detail about a given phenomena during in-person interviews, as indicated by longer transcripts, interview durations, and analytic matrix wordcounts. However, this additional detail rarely translates into identification of novel codes or themes when compared to remote approaches.

There were differences in the themes that emerged from both sets of interviews. Whilst the differences between the solutions was fairly minor, several of the barriers that were raised during the telephone interviews were potentially more candid than those derived from in-person interviews. A form of social desirability bias might have been at play, with interviewees feeling more comfortable disclosing potentially embarrassing or taboo issues when the interviewer was not physically sat in front of them.[21,22] Some of the barriers that emerged exclusively from the phone interviews included forgetting about the appointment, assuming that the service would not meet their needs, and perceiving the mixing of men and women in a single queue as 'shameful'.

In terms of strengths and limitations, whereas most research in this field tends to employ one or two metrics, our study compared eight different dimensions of performance, including proxies for richness (duration and wordcount), mean and aggregate themes, and subjective interviewer ratings, supplemented with an assessment of costs and time requirements. We conducted a relatively large number of interviews on a topic that is central to global efforts to extend Universal Health Coverage as part of the Sustainable Development Goals.[23–25]

Our sample size was based on a post-hoc saturation analysis, but the decision to compare 31 interviews with each modality rather than 30 vs 30 was essentially arbitrary. The generalisability of our findings is limited by our relatively focused research question and the homogeneity of our population (younger adults in Meru who were found to have an eye problem during screening but did not manage to access further care). Ultimately, whilst our study presents multiple measures we are not able to definitely say which approach is best, as there is no single 'right' way to balance differences in richness, costs, and time requirements.

Previous research has documented that the impact of qualitative research findings on real-world programmes is influenced by the timeliness of the findings,[26,27] and our broader embedded qualitative work places a premium on rapidly identifying barriers and potential solutions to improve equitable access to care within a live, ongoing screening programme. Given our focus on identifying solutions and service modifications that can be rapidly tested, the lack of dissonance between the modes,

lower costs, lower time requirements, and additional researcher safety benefits associated with telephone interviews means that we are very likely to continue using this approach.

Conclusions

Our set of 31 telephone interviews was completed in less time and at less expense than the 31 in-person interviews. Whilst the in-person modality generated longer interviews and more data, the ultimate number of themes that derived from both sets was nearly identical. For our purposes, telephone interviews offer clear operational advantages with no meaningful reduction in data quality.

Declarations

Conflict of interest: The authors declare no competing interests.

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Author contributions: LA conceived the study with SK. LA and SK performed the data collection and analyses. LA wrote the initial draft. SK and MT provided additional written content. JT provided health economics input and reviewed the manuscript. DM provided statistical input and reviewed the manuscript. AB reviewed the protocol and provided additional methodological comments. All authors reviewed and approved the final version of the manuscript.

Ethical approval: The study was granted ethical approval by KEMRI scientific and ethics review unit on November 30th 2022, NACOSTI on 12th January 2023, and the LSHTM ethics committee on 5th May 2023.

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Appendix 5: Botswana's adaptive RCT protocol

Reference

Allen LN, Ratshaa B, Macleod D, Bolster N, Burton M, Kim M, Bastawrous A, Ho-Foster A, Chroston H, Nkomazana O. Protocol for an automated, pragmatic, embedded, adaptive randomised controlled trial: behavioural economics-informed mobile phone-based reminder messages to improve clinic attendance in a Botswanan school-based vision screening programme. Trials. 2022 Aug 15;23(1):656.

Trials

STUDY PROTOCOL

Open Access

Protocol for an automated, pragmatic, embedded, adaptive randomised controlled trial: behavioural economics-informed mobile phone-based reminder messages to improve clinic attendance in a Botswanan school-based vision screening programme

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Abstract

Background: Clinic non-attendance rates are high across the African continent. Emerging evidence suggests that phone-based reminder messages could make a small but important contribution to reducing non-attendance. We will use behavioural economics principles to develop an SMS and voice reminder message to improve attendance rates in a school-based eye screening programme in Botswana.

Methods: We will test a new theory-informed SMS and voice reminder message in a national school-based eye screening programme in Botswana. The control will be the standard SMS message used to remind parents/guardians to bring their child for ophthalmic assessment. All messages will be sent twice. The primary outcome is attendance for ophthalmic assessment. We will use an automated adaptive approach, starting with a 1:1 allocation ratio.

Discussion: As far as we are aware, only one other study has used behavioural economics to inform the development of reminder messages to be deployed in an African healthcare setting. Our study will use an adaptive trial design, embedded in a national screening programme. Our approach can be used to trial other forms of reminder message in the future.

Trial registration: ISRCTN 96528723. Registered on 5 January 2022.

Keywords: Behavioural economics, Reminder messages, mHealth, Health services research, Adaptive RCT

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Administrative information

Note: the numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers. The order of the items has been modified to group similar items (see http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/).

Title {1}	Protocol for an automated, pragmatic, embedded, adaptive randomised controlled trial: behavioural economics-informed mobile phone-based reminder messages to improve clinic attendance in a Botswanan schools-based vision screening programme
Trial registration {2a and 2b}.	ISRCTN96528723
Protocol version {3}	Version 1. January 2022.
Funding {4}	This work was supported by the National Institute for Health Research (NIHR) (using the UK's Official Development Assistance (ODA) Funding) and Wellcome [grant reference 215633/Z/19/Z] under the NIHR-Wellcome Partnership for Global Health Research.
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Name and contact information for the trial sponsor {5b}	**London School of Hygiene & Tropical Medicine** For further information regarding the sponsorship conditions, please contact the Research Governance and Integrity Office: London School of Hygiene & Tropical Medicine Keppel Street London WC1E 7HT Tel: +44 207 927 2626 Email: RGIO@lshtm.ac.uk
Role of sponsor {5c}	Delegated responsibilities will be assigned locally. The study funders will not have any role in- or ultimate authority over the study design; collection, management, analysis, and interpretation of data; writing of the report; or the decision to submit the report for publication.

Introduction

Background and rationale {6a}

Many health programmes experience large mismatches between those identified with a clinical need and those who attend services. A recent international systematic review of 'no-show' appointments across all medical specialities in primary and secondary care estimated that 23% of clinic appointments are not attended, with the highest rate observed in the African continent (43%) [1]. Complex supply and demand factors govern access to health services [2], and systematically marginalised populations are often the least likely to receive care [3, 4].

As mobile phone penetration has risen, there has been increasing interest in the use of phone-based reminder messages to reduce these missed appointments. Systematic reviews from 2011 [5], 2013 [6], 2016 [7], 2018 [8], and 2019 [9] have found that SMS and voice message reminders can improve clinic attendance by 50–100% depending on service, population and setting. In Linde and colleague's systematic review of African RCTs, their pooled analysis found that SMS reminders doubled appointment attendance compared with no SMS (odds ratio 2.03; 95% confidence interval 1.40 to 2.95; $I^2 = 85\%$) [9]. Robotham and colleagues' 2016 review found that two or more notifications increased attendance by as much as 19% over and above sending one notification, and voice notifications may offer slight improvements over text notifications for increasing attendance [7].

SMS and voice messages function as behavioural 'brief interventions', and a number of studies have used behavioural economics principles to guide the wording of these messages in order to optimise their impact [10, 11]. Senderey and colleagues used a set of established cognitive biases to develop the content of eight different clinic reminder messages [12] and Huf and colleagues used a similar approach in developing four different messages to boost clinic attendance in the UK [13]. Whilst both studies showed improvements in clinic attendance rates, neither provided the rationale for why these specific biases were selected. In Linde and colleagues' 2019 systematic review of 31 African RCTs using phone-based messages [9], only one study reported using behavioural theories to develop the content of their reminder message: Erwin and colleagues successfully boosted cervical cancer screening rates among women in Tanzania [14], basing their SMS reminder content on the Health Belief Model [15]. They also reported using a motivational tone—found to be more effective than an informational tone [16]—and pre-tested the SMS content validity and cultural sensitivity of the message with programme staff and laypeople.

One area that currently experiences very high rates of missed appointments—with substantial societal and

economic costs—is community-based vision screening. Approximately 1.1 billion people (over 10% of the global population) currently live with a form of easily correctable visual impairment [17, 18]. Two very cheap and simple interventions—spectacles and cataract operations—could eliminate over 90% of all visual impairment worldwide [17]. Provision of these services has risen exponentially in recent decades; however, effective coverage rates are disappointingly low and exhibit marked socioeconomic gradients at the international and intranational levels [17]. Women and marginalised groups bear a disproportionate burden of visual impairment, and often face structural social barriers that prevent them from accessing care—as noted in the recent UN Resolution on Vision [19].

Recognising the human, social, and economic drag exerted by cataracts and uncorrected refractive error, many low- and middle-income country (LMIC) governments are ramping up their vision screening programmes. Donor funding is rising in tandem, partly driven by the advent of phone-based screening platforms like Peek Acuity [20, 21] that have made it possible to rapidly screen entire regions with very modest resource requirements.

Screening programmes based on the Peek digital platform are currently operating in seven LMICs. The Botswanan Ministry of Health (MoH) has committed to use Peek software to screen all school children in government schools over 3 years beginning in Summer 2022 [22]. The Peek platform records basic sociodemographic data, visual acuity, referral status, and attendance status for each child. Every time a child is referred a series of three SMS messages are sent to the mobile phone number registered by their parent/guardian (see Table 1). The current SMS message was not developed with reference to behavioural economics principles. According to internal data from Peek screening programmes in other countries and pilot data in Botswana, attendance rates are currently around 50%, i.e. only half of those identified as needing ophthalmic assessment present to services.

We aim to develop two behavioural economics-informed reminder messages; an SMS and a pre-recorded voice message to be used in the new Botswana MoH schools-based vision screening programme, and tested using an embedded, pragmatic, adaptive RCT design.

Objectives {7}

Our objectives are to test a behavioural economics-informed SMS reminder message and a pre-recorded voice message that will be sent to the parents/guardians of school children who have been identified as having a visual impairment and referred to clinic. We hypothesise that these messages will be associated with a higher attendance rate than the current standard SMS reminder that is sent to all referred patients' parents/guardians.

Trial design {8}

This is an automated, adaptive, parallel, four-arm, embedded, pragmatic RCT. We will start by testing the two SMS reminder messages head-to-head with an initial 1:1 allocation ratio, and then introduce the voice messages after a period of six weeks. We will use a Bayesian adaptive trial algorithm to perform adaptive allocation as the trial progresses.

Methods: participants, interventions and outcomes

Study setting {9}

The Botswana National Comprehensive School Eye Health Program ('Pono Yame').

Eligibility criteria {10}

Reminder messages will be sent to the registered mobile phone numbers of parents/guardians of children who test positive at screening and are referred on to clinic in the Pono Yame MoH/Peek Vision school screening programme in 2022. Provision of a mobile number is a pre-condition of entry into the screening programme, although parents/guardians are able to supply the number of a friend or relative so in practice this stipulation does not exclude any children.

Reminders will be sent in English and Setswana; spoken by >96% of the local population. The screening programme routinely collects data on preferred language, and reminders will be sent in the preferred tongue. Those who list any language other than English of Setswana will receive the reminder in both Setswana and English. The reminder will also be sent in both languages to those where data on language is not available for any reason. We will perform a secondary analysis that excludes these participants, but they will be included in the primary analysis.

Who will take informed consent? {26a}

The interventions represent minor modifications to existing routine processes and present negligible risk to participants. Obtaining consent would introduce burdens to the participant that are greater than the intervention itself. As such, we will not seek informed consent. This approach has been approved by the LSHTM and University of Botswana ethics committees, and follows the precedent set by three previous RCTs testing SMS reminder messages [12, 13, 23].

Table 1 Control and intervention reminder messages

Control: Standard SMS reminder message
Setswana
Go [name],one wa tlhatlhobiwa matlho mme ga fitlhelwa ona le bothata jwa matlho. Ka jalo, tla ko [location] ka di [date] go tlhatlhobiwa.O kopiwa go tla le karata ya gago ya botsogo.
English
Dear [name],you were examined and found to have an eye problem. Kindly report to [location] on [date] for assessment. Please come with your clinic card.
Intervention: New SMS reminder message
Setswana
Go motsadi: Re lemogile ngwana wa gago [child's name] fa ana le bothata jwa matlho. Se, se ka ama tiro ya gagwe ya sekolo.Tswee-tswee, tsisa [child's name] ko sekolong ka [location and time] o tla tlhatlhobiwa matlho a sa duele Se, se direlwa ngwana mongwe le mongwe mo sekolong yoo nang le bothata jwa matlho Re ka leboga go le bona ka [day and time]. Kea leboga [Leina la ngaka]
English
Dear parent, we have found that your child [child's name] has an eye problem. This may affect [his / her] schoolwork.
Please bring [child's name] to [location] at [time], [day, date]. We will be doing a free medical check-up for all the children with eye problems in the school.
We look forward to seeing [child's name] on [day and time].
Many thanks, Dr [name], Ministry of Health

Intervention: New voice reminder message
Setswana
Dumelang: Ke bidiwa ngaka Dineo, go tswa ko lephateng la botsogo. Ngwana wa gago [leina la ngwna] o tlhatlhobilwe matlho mo bogaufing, mme a fitlhelwa a na le bothata jwa matlho. Fa a ka seka a alafiwa , go ka ama tiro ya gagwe ya sekolo. Setlhopha sa rona sa botsogo, se tlaa bo se le ko sekolong sa ga [leina la ngwana] ka [letsatsi le nako].
Tswee.tswee tsisa ngwana wa gago go tlhatlhobiwa go sena dituelo. Se, se direlwa ngwana mongwe le mongwe yoo nang le bothata jwa matlho. Kea leboga [Leina la ngaka]
English
Hello, my name is Dr [name] from the Ministry of Health.
Your child [child's name] recently had [his/her] eyes checked at school and was found to have an eye problem. If this is not corrected, it could affect their schoolwork. Our medical team will be at [location] on [date/time]. Please bring your child to get a free medical assessment. This is offered to all children with eye problems.
We look forward to seeing you and your child on [date/time]
Many thanks, Dr [name].

Additional consent provisions for collection and use of participant data and biological specimens {26b}

All parents/guardians are verbally informed that their children will partake in the Pono Yame vision screening programme. They are also asked to provide written opt-out consent for the use of their children's sociodemographic data for research and sharing purposes. Care will not be compromised in any way for those participants whose parents do not provide consent.

Interventions

Explanation for the choice of comparators {6b}

The standard SMS message presented in Table 1 is routinely sent to the registered mobile phone of parents/guardians of children referred on for refractive services in all Peek programmes. This is the control arm.

Intervention description {11a}

Process of developing the intervention SMS and voice reminder messages

We aimed to use an established framework to identify a theory-informed set of behaviour change principles to guide the development of our reminder messages. We elected to use Dolan and colleagues' *MINDSPACE* framework [24], developed in conjunction with the Institute for Government. This framework brings together insights from behavioural economics research that can be used to develop brief healthcare interventions (Table 2). The framework has been endorsed by the Behavioural Science and Public Health Network [25], the London School of Economics Behavioral Economics Playbook for behaviour change [10] and the Health Foundation in their guidance on behavioural insights in health care [11].

Whilst SMS and voice messages can include messenger, incentives, norms, defaults, salience, emotional appeals, commitments, and ego, they are less able to 'prime' recipients using subconscious cues. In addition to these principles, we also looked to the specific guidance on sending effective phone messages to reduce clinic non-attendance produced by Public Health England in 2020, based on their review of the international literature [26]. Their key messages are summarised below:

- Messages should be clear, brief and well-formatted, with essential information only.
- Use line breaks to make the message easier to read.
- Personalise the text messages to include the recipient's name if local systems allow.

Table 2 The 'MINDSPACE' framework and application for phone-based reminder messages

Principles	Application
Messenger	People are heavily influenced by the authority and credibility of the person sending the message, so the reminder messages should be signed-off by a trusted official/professional.
Incentives	People are more sensitive to losses than gains, so the reminders should frame non-attendance as a loss.
Norms	People want to fit in and are strongly influenced by the actions of others, so the reminders should signal that attendance is the norm.
Defaults	People tend to 'go with the flow' and use pre-set options, so attendance should be the default option in the reminders.
Salience	People are drawn to things that are novel and appear relevant to them, so the reminders should be personalised and stress the novelty of the opportunity.
Priming	Peoples' decisions are commonly influenced by subconscious cues in their environment. We cannot influence this via phone-message.
Affect	Peoples' decisions are often based on emotional associations rather than facts, so the reminders should seek to make emotive arguments for attendance.
Commitments	People seek to be consistent with public promises and reciprocate acts, so the reminders should aim to elicit a commitment to attend and stress the social expectation of attendance.
Ego	People act in ways that support the impression of a positive self-image, so the reminders should reinforce the message that attendance is consistent with recipients' positive self-perceptions.

- Keep messages to 480 characters (3 standard text messages) in length.
- Include the date, time, and location of the appointment, as well as any special instructions, and contact phone number (if different to the number the text message is sent from).
- Write out the day of the week and the month in dates. For example, 'Monday 23 March.'
- GP endorsement can encourage people to take screening more seriously.

One researcher (LA) drafted an initial SMS that included all of the eight relevant MINDSPACE behavioural economics elements and adhered to PHE guidance (Fig. 1). We convened a workshop to refine the SMS and develop a pre-recorded voice message with an African economist and representatives from the University of Botswana, and Peek Vision's Botswana office. Further iterations were made following a robust refinement process (Additional file 1: Appendix 1) that included input from laypeople, and professional translation and back-translation. The final messages are presented in Table 1.

We will use four arms as outlined below. Each SMS will be sent two times; on the day of referral and on the day before the appointment.

Initially, we will only test arms 1 and 2 (the control and intervention SMS messages). We plan to introduce the voice message arms after 6 weeks. This is because we are interested in introducing new arms at later stages in the screening programme and want to observe how the allocation algorithm handles the introduction of new arms part-way through testing established interventions.

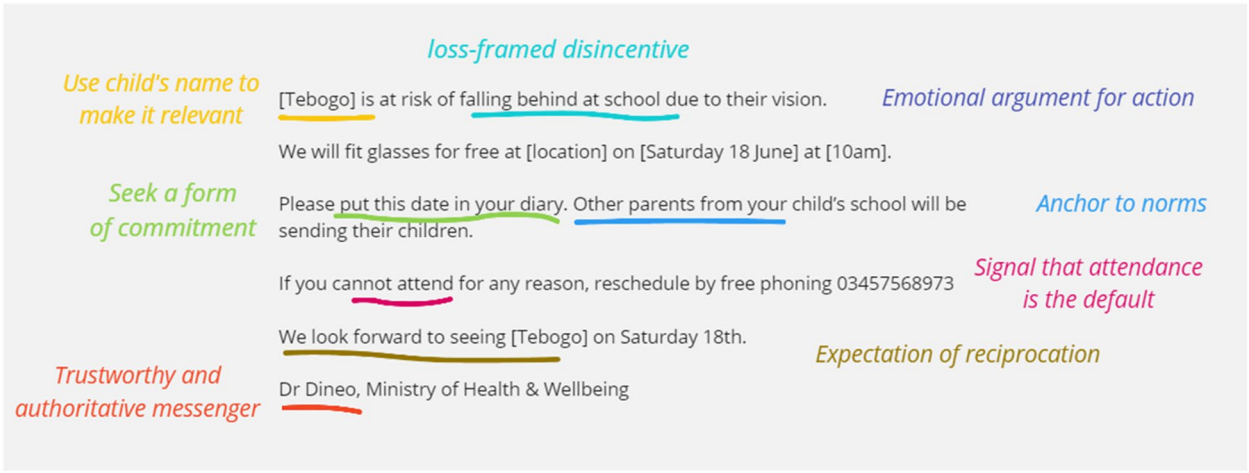


Fig. 1 First draft SMS reminder. Note: 'Tebogo' and 'Dr Dineo' are not real names

- Arm 1 (Control): Standard SMS reminder messages.
- Arm 2: New SMS reminder messages.
- Arm 3: Standard SMS reminder messages plus the pre-recorded voice reminder
- Arm 4: New SMS reminder messages plus the pre-recorded voice reminder

Criteria for discontinuing or modifying allocated interventions {11b}

Due to the low-risk nature of the interventions, there will not be any formal option to discontinue or modify the reminder messages.

Strategies to improve adherence to interventions {11c}

There are no relevant strategies to improve adherence. This is a pragmatic intention-to-treat study, and we will not collect data on whether messages were actually read or listened to by the intended recipients. A potential limitation of this study is that we cannot ensure that the message is actually delivered to- and read by the correct person. To an extent, this is true of all forms of phone-based reminder messages, as it is of paper reminder letters or notes sent by post, or home with children.

Relevant concomitant care permitted or prohibited during the trial {11d}

No other reminder messages will be sent from the Peek platform during the trial.

Provisions for post-trial care {30}

As this is a negligible risk trial, no provisions will be made for post-trial care.

Outcomes {12}

All children who are screened and found to need further assessment and treatment (e.g. refractive services) will be given an appointment, approximately 1 week later, at a specified field 'triage and treatment' clinic or at a specialist ophthalmic hospital clinic. The primary outcome is attendance at this pre-specified appointment on the appointment date (yes/no).

The Peek software retains a record of every referred child. When children attend for these appointments, they are checked in using Peek software. This automatically updates their attendance status. Attendance data will be automatically reviewed by an algorithm every 24 h. The great advantage of the Peek-based screening programme is that is a closed data system with complete, unified data records for every person screened, their referral status and their attendance status. No additional data collection activities are required.

- *Primary outcome*: attendance at clinic on invited date. This is a binary outcome measure (yes/no). We will compare mean outcome rates between arms.
- *Secondary outcome*: days elapsed between appointment date and attendance. This is because children may miss their appointed day but attend at a later date. We will compare mean number of days elapsed between each arm.
- *Subgroup analyses*: attendance by age, sex, urban/rural residence, distance to clinic, ethnicity, guardianship, religion, language, household composition, migrant status, parental occupation, housing, assets and income.

Participant timeline {13}

This automated adaptive trial will run continually for three working months (i.e. pausing during the school holidays when screening does not happen), recruiting participants until sufficient evidence has been gathered to reject the null (by triggering a stopping rule). Enrolment is planned to commence in quarter 3 2022. We intend to start with two SMS arms and add in voice messaging once the trial is underway. This is because we want to observe how the automated allocation system handles the introduction of new arms.

Sample size {14}

Approximately 1000 children will be screened every day. Based on previous programmes, we expect approximately 160 of these children to be identified as requiring referral for further assessment and treatment. All of these children's parents/guardians would receive the standard SMS reminders in a standard programme.

The adaptive allocation method that we are using does not use a pre-specified a sample size. Instead, the study will run until one of two criteria is met:

- There is a >95% probability that one arm is best.
- There is a >95% probability that the difference between the arms remaining in the study is <1%.

Depending on the effect of the interventions, one of the stopping criteria might be met after a few days; however, it could also take years before reaching a definitive conclusion. We will set a 3-month limit for this current study due to resource constraints.

Recruitment {15}

Community sensitisation is being led by the Ministry of Health and Ministry of Education. This includes TV and radio coverage explaining the Pono Yame screening programme. Our field coordinator will visit each region

and work with schools to ensure that they are set up to enrol as many children as possible. Every referred child's data will be included in the primary analysis. Subgroup analyses will only be permitted for children whose parents have consented for their sociodemographic data to be used for research purposes. This is a separate consenting process led by Peek.

Assignment of interventions: allocation

Sequence generation, concealment and implementation {16a, 16b, 16c}

Participants will initially be randomly allocated into two arms using computer-generated blocks of 12. As allocation and intervention delivery (sending SMS messages) is fully automated, there is no need for any of the human investigators to know participant allocation status. Once the first participants attend refractive services, the algorithm will begin adjusting the allocation ratio to favour the best-performing arms. There is no need for the investigators to see allocation status at this stage either. The data safety monitoring committee will be fully unmasked to allocation status and all outcome data and will have the power to stop the trial or suspend any arm.

Assignment of interventions: blinding

Who will be blinded {17a}

Trial participants will not be blinded. Programme implementers will check in participants when they attend clinic using Peek Capture. The software will automatically record the date and the time elapsed since referral. The adaptive algorithm will analyse attendance rates between arms according to pre-defined rules. Screening programme staff and data analysts will be blinded to assignment status. A small team of unblinded human statisticians will monitor the algorithm's performance. They will double-check the algorithm's working every 24 h during the trial and will repeat the final analysis comparing each arm. They will have the power to stop the trial, but they will not influence allocation.

Procedure for unblinding if needed {17b}

There is no procedure for unblinding.

Data collection and management

Plans for assessment and collection of outcomes {18a}

Referral status, attendance status and days elapsed since referral will be collected using the Peek Capture system on Android devices. Every time a participant is referred and every time they attend at clinic, they are checked in using an android device operating Peek Capture software. Additional data on sociodemographic characteristics will be collected when participants initially present to the screening programme.

Plans to promote participant retention and complete follow-up {18b}

As the intervention is an SMS sent automatically by the programme, there is no scope for deviation. Similarly 'loss to follow-up' is the reciprocal for our primary outcome (attendance on appointed day).

Data management {19}

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 will be 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 centres which are state of the art, utilising innovative architectural and engineering approaches. Routine manual data cleaning will be conducted periodically by Peek administrators. Internal software guardrails will pick up simple errors.

Data collected can be monitored using Peek Admin; it tracks the Programme progress, provides insights and helps ensure no one is left behind. Data exported from Peek Admin will be pseudo-anonymised removing names and any other key identifiers, only the least amount of data will be shared, and where possible it will be fully anonymised and aggregated for research purposes.

At the analysis stage, data will be sent via a secure file transfer, using an encrypted zip file to LSHTM researchers to perform statistical testing. The zip file will be saved on the protected LSHTM server and only authorised named project staff will be given access. Passwords will be sent separately. Further details can be found in the Data Management Plan (Additional file 1: Appendix 2).

Confidentiality {27}

Peek routinely collects sociodemographic information from each child who is referred on for refractive services including age, sex, location, ethnicity, religion, parents' occupation, parents' education, housing characteristics and asset ownership. This information will be held on a Peek-managed server hosted in a Virtual Private Cloud (VPC) utilising the Amazon Web Services (AWS) Cloud. Peek also seeks consent to use this data for research purposes.

Sociodemographic data on participants who have provided consent will be shared with the statistical analysis team at LSHTM for subgroup analysis. All team members who will access these data will have undertaken information security training. We will use encrypted data transfer and avoid cloud services outside the EU. 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. All data arising from this project will be stored securely for 10 years. Further information is provided in the data management plan (Additional file 1: Appendix 2).

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

Not applicable. We will not be using biological specimens.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

This study will use Thompson sampling a Bayesian approach to identify the best arm. This is a Bayesian algorithm widely used to learn about arms and optimise decision making [27] Every 24 h, the probability of each arm being the best arm overall will be estimated, using Monte-Carlo simulations to get the posterior probability estimates. As there is no evidence available on how the messages would perform relative to another, a regularising prior of Beta(100,000) (i.e. centred at p=0.5 with a 90% credible interval of 0.44–0.56) will be used to avoid overfitting extreme data in the early phase of the trial. It is expected that about 1,000 children will enrol every day, and the observed data will begin to dominate the prior within the first couple of days. Each arm will have a probability of being best between 0 and 100%, and the sum of all two probabilities will equal 100%. These probabilities will be compared to the stopping rules as to whether the trial should stop or continue into the next day. If the trial is to continue, the proportion allocated to each arm for the next day will be updated to be proportional to the estimated probabilities. We will conduct all analyses using the runif and rbeta functions in R (R Foundation for Statistical Computing, Vienna, Austria). Figure 2 illustrates participant flow and operation of the algorithm.

Interim analyses {21b}

This is an automated adaptive trial. Our algorithm will review the attendance data every 24 h and perform statistical testing. Two stopping rules will be applied during these daily interim analyses:

1. There is a >95% probability that one arm is best.
2. There is a >95% probability that the difference between the arms remaining in the study is <1%.

If neither of these rules have been satisfied, then the trial (i.e. enrolment) will continue until three months of active screening have elapsed. The Bayesian algorithm will adjust the allocation ratio based on the performance of each arm with respect to the updated posterior probability that each is associated with attendance (Fig. 3).

Methods for additional analyses (e.g. subgroup analyses) {20b}

Internal data from a pilot site suggests that around 10% of children who attend the 'triage and treatment' clinic

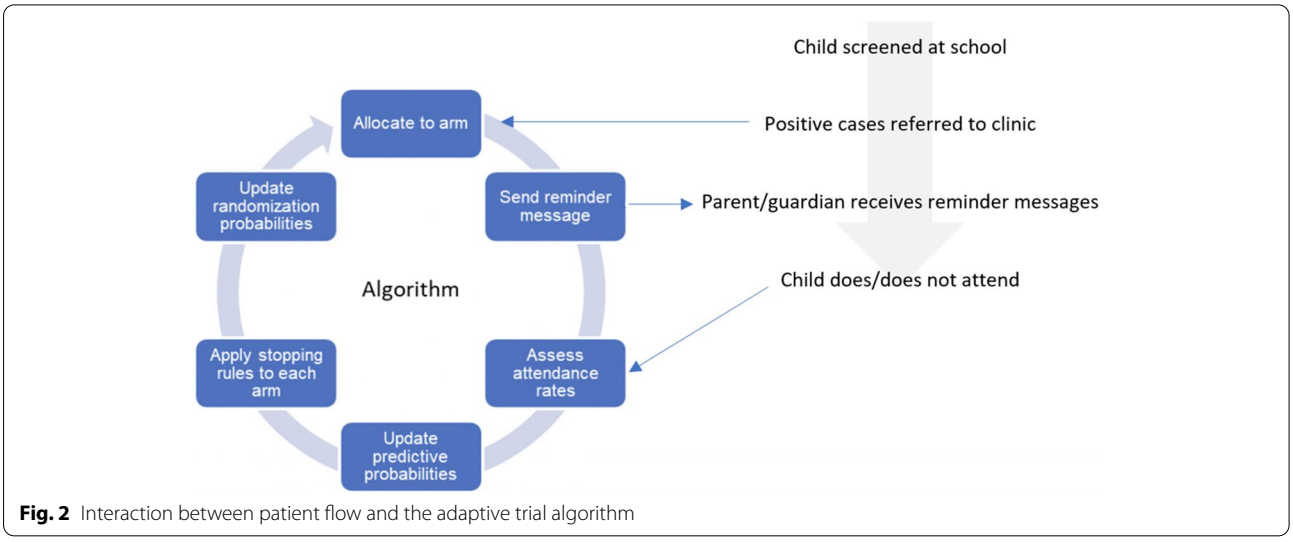


Fig. 2 Interaction between patient flow and the adaptive trial algorithm

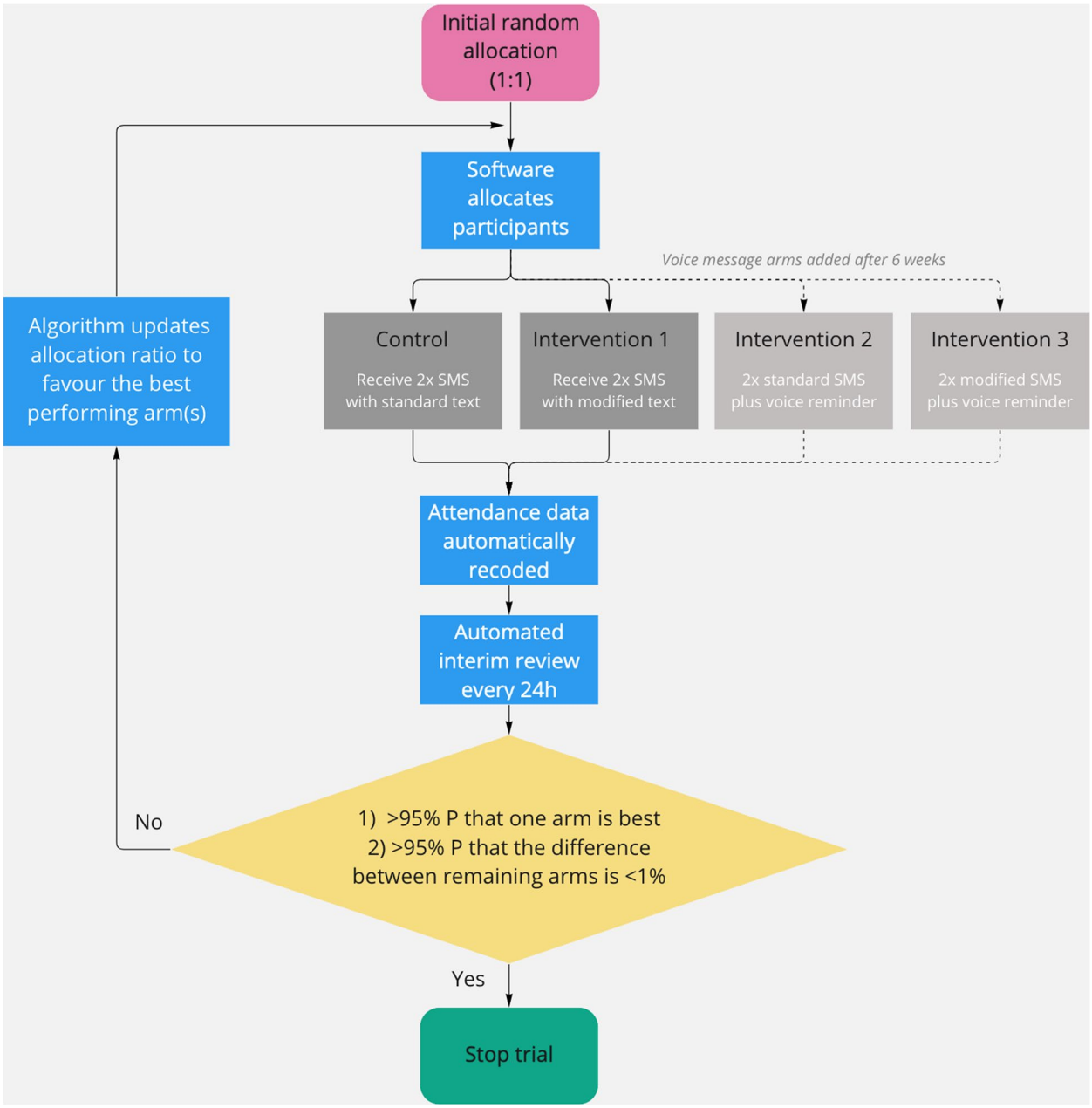


Fig. 3 Allocation flow diagram

will subsequently be identified as having an eye need that requires further specialist ophthalmological assessment in a hospital clinic. These children will be referred from the 'triage and treatment' clinic to the local hospital. This subgroup will also receive either the intervention or control reminder messages. Again, the outcome will be attendance on appointed date.

Once the trial is complete, we will perform retrospective subgroup analyses to explore whether attendance within each group was associated with sociodemographic variables. We use multivariable logistic regression to assess whether each sociodemographic variable is associated with attendance. We note that this is an exploratory analysis, providing hypotheses that can be tested in subsequent studies.

We will perform a secondary analysis that excludes participants whose preferred language is neither Setswana nor English.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

The primary analysis only requires trial arm and the outcome (attendance) to be recorded. The trial arm should be recorded automatically as part of the Peek coding, and if it was missing it would be due to a bug in the coding. If this occurred, there is no statistical method that could be used to recover that data so any records with trial arm missing would not be included in the updating of the probability that an arm is best. We will check the code every 24 h to ensure that it is running as expected and correct any errors that we find immediately. The outcome cannot be missing, as a participant is set as 'not attended' until the point where they are updated as having 'attended'.

Plans to give access to the full protocol, participant-level data and statistical code {31c}

The full protocol is available from the corresponding author. Statistical code will be made freely available online using GitHub. In line with the UK concordat on open research data (2016), anonymised participant-level data from this trial will be made available to bona fide research groups (evidenced via curriculum vitae 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.

Patient and public involvement

Laypeople were involved in checking the wording of the intervention messages and suggesting refinements that better conveyed their underlying meaning.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {5d}

Trial coordinating centre:

- Dr Luke Allen, Co-Principle Investigator and trial manager, LSHTM
- Hannah Chroston, lead administrator, LSHTM
- Bakgaki Ratshaa, trial coordinator, University of Botswana

Trial management group

- Prof Andrew Bastawrous, chief investigator
- Prof Oathokwa Nkomazana, co-PI
- Dr Luke Allen, co-PI
- Prof Matthew Burton, methods advisor
- Dr David Macleod, lead statistician
- Dr Nigel Bolster, Peek integration
- Min Kim, statistician
- Dr Ari Ho-Foster

Dr Michael Gichangi, methods advisor
Data management team

- Dr Luke Allen, co-PI
- Dr David Macleod, lead statistician
- Dr Nigel Bolster, Peek integration
- Min Kim, statistician

Composition of the data monitoring committee, its role and reporting structure {21a}

An independent Data and Safety Monitoring Board (DSMB) will be appointed by the trial steering committee. The DSMB will have three members, all independent of the running of the trial with relevant clinical and epidemiological experience.

The DSMB will confirm their specific meeting arrangements. It is proposed that the DSMB would meet prior to the beginning of the trial (Q2 2022), one third of the way through, and at the end, to assess the safety of the trial procedures. The DSMB will agree the way it will monitor the data, what it requires from the investigators in this respect and will communicate this to the PIs. All data can be interrogated remotely in real time.

The DSMB may visit the study coordination centre to assess data management, record keeping and other important activities. The DSMB will determine the manner in which it will monitor the data, what it requires from the investigators in this respect and will communicate this to the PIs.

Adverse event reporting and harms {22}

Definitions

Term	Definition
Adverse event (AE)	Any untoward medical occurrence in a patient or study participant
Serious adverse event (SAE)	A serious event is 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.

Reporting procedures

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 AEs.

Responsible personnel

Chief Investigator (CI)

- The CI has overall responsibility for the conduct of the study and the ongoing safety and evaluation of any IMPs 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.

Principal Investigators (PI)

- The PIs have responsibility for the research performed at the local site, handling and management of investigational medical products, 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.

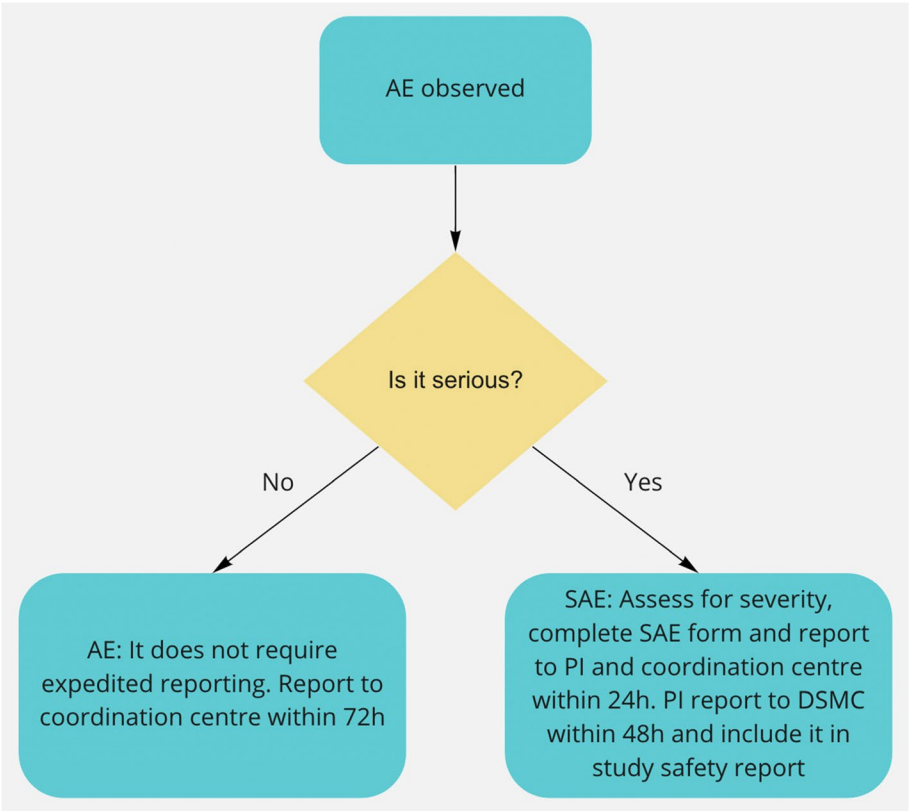
Non-serious AEs All non-serious AEs will be reported to the study coordination centre and recorded in a dedicated AE log within 72 h. The entry must state the patient ID, date and time of AE, nature and relation to the intervention, if any. The AE should also be reported to the data and safety monitoring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

Serious AEs Serious adverse events (SAEs) will be reported to the PI and study coordination centre within 24 h of the local site being made aware of the event. The PI will report the event to the data safety monitoring committee within 48 h 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 h 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.



Contact details for reporting SAEs

Please send SAE forms to: luke.allen@lshtm.ac.uk or nkomazanao@UB.AC.BW using the title 'SAE'

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

Tel: +267 355 0000

Frequency and plans for auditing trial conduct {23}

The study may be subject audit by the London School of Hygiene & Tropical Medicine under their remit as sponsor, the Study Coordination Centre and other regulatory bodies to ensure adherence to Good Clinical Practice.

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

Any important protocol modifications will be reported to the co-investigators, research committees, the trial registry and—where appropriate—journals and regulators via email.

Dissemination plans {31a}

Scientific results will be published in Open Access in peer-reviewed journals and presented at relevant international conferences. All publications and presentations relating to the study will be authorised by the Trial Management Group. The first publication of the trial results will be in the name of the Trial Management Group members. Members of the Data and Safety Monitoring

Board will be listed and contributors will be cited by name if published in a journal where this does not conflict with the journal's policy. Authorship of any parallel studies initiated outside of the Trial Management Group will be according to the individuals involved in the project but must acknowledge the contribution of the Trial Management Group and the Trial Coordinating Centre.

Discussion

This study is embedded in the national Pono Yame school-based vision screening programme. As such, any delays to the launch of the programme will delay the start of the trial. As far as we are aware, only one other study has used behavioural economics to inform the development of reminder messages to be deployed in an African healthcare setting. Our study will use an adaptive trial design, embedded in a national screening programme. Our approach can be used to trial other forms of reminder message in the future, including tweaks to the messages that are sent and varying message content according to the demographic characteristics of the recipient.

Trial status

This is protocol version 1.2 (14 June 2022). Recruitment has not yet commenced but is planned for Q3 2022.

Abbreviations

DSMC: Data and Safety Monitoring Committee; LSHTM: London School of Hygiene and Tropical Medicine; RCT: Randomised controlled trial; WHO: World Health Organization.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-022-06519-y.

Additional file 1.

Authors' contributions {31b}

LA is co-PI. He led the protocol, co-designed the study, and drafted the manuscript. ON is co-PI. She conceived and co-designed the study and revised and approved the manuscript. AB is the chief investigator; he conceived the study, led the initial funding proposal, and revised and approved the manuscript. DM is the lead statistician. He conceived and co-designed the study, revised and approved the manuscript. NB conceived and co-designed the study, revised and approved the manuscript, and integrated the code into the Peek software. MK conceived and co-designed the study, revised and approved the manuscript, and developed the code. MB conceived and co-designed the study, revised and approved the manuscript. BR developed the intervention and revised and approved the manuscript. AH-F co-designed the study and read and approved the final manuscript. HC revised and approved the final manuscript. All author(s) read and approved the final manuscript.

Funding {4}

'This work was supported by the National Institute for Health Research (NIHR) (using the UK's Official Development Assistance (ODA) Funding) and Wellcome [grant reference 215633/Z/19/Z] under the NIHR-Wellcome Partnership for Global Health Research. The views expressed are those of the authors and not necessarily those of Wellcome, the NIHR or the Department of Health and Social Care'.

Availability of data and materials {29}

Any participants' identifiable personal data collected following informed consent by the Trial Coordinating Centre will be stored in a secure Peek Vision server (See Data Management Plan for more details on the purpose and type of data collected, and the security of the Peek Vision server). Confidentiality protected in accordance with the Data Protection Act 2018 and the General Data Protection Act. Patient-level data will be pseudo-anonymised removing names and any other key identifiers before it is shared. Only the least amount of data will be shared, and where possible it will be fully anonymised and aggregated.

All published findings will be at anonymous aggregate subpopulation level. 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 Management Plan (Additional file 1: Appendix 2), 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.

Peek Vision has a signed data sharing agreement with the Ministry of Botswana that governs the use of patient data collected and used in Peek Vision screening programmes. 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.

Declarations

Ethics approval and consent to participate {24}

The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions. The study will comply fully with the Botswana Data Protection Act of 2018.

In line with previous phone-based reminder message RCTs, this study tests a negligible risk intervention and will not seek informed consent from participants. The Study Coordination Centre has already received approval from the LSHTM Research Ethics Committee (Ref 26480). The Coordination Centre will also seek approval from the University of Botswana Research Ethics Board (Office of Research and Development), and the study will not commence until approval has been obtained.

Consent for publication {32}

Not applicable.

Competing interests {28}

AB and NB are employees of Peek Vision. MJB is a Trustee of The Peek Vision Foundation. AB is CEO of The Peek Vision Foundation and Peek Vision Ltd and receives salary support from Peek Vision. The other authors declare that they have no competing interests.

Author details

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Published online: 15 August 2022

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Publisher's Note

Appendix 6: KEMRI Ethics approval for the Gather study

In Search of Better Health

KENYA MEDICAL RESEARCH INSTITUTE

OFFICE OF THE DIRECTOR RESEARCH & DEVELOPMENT

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KEMRI/RES/7/3/1 **November 30, 2022**

TO: **SARAH KARANJA,**
DR. MICHAEL GICHANGI,
PROF. ANDREW BASTAWROUS,
PRINCIPAL INVESTIGATORS.

THROUGH: **THE DEPUTY DIRECTOR, CPHR,**
NAIROBI.

Dear PIs

RE: **PROTOCOL NO. KEMRI/SERU/CPHR/44/06/2022/4571 *(RESUBMISSION OF INITIAL SUBMISSION)*: SOCIO-ECONOMIC AND DEMOGRAPHIC CHARACTERISTICS ASSOCIATED WITH NON-CLINIC ATTENDANCE AMONG PARTICIPANTS SCREENED IN A COMMUNITY AND SCHOOL EYE SCREENING PROGRAMME: PROTOCOL FOR EMBEDDED, PRAGMATIC, CROSS-SECCTIONAL EQUITY ANALYSES IN KENYA *(VERSION 2 DATED 25 OCTOBER 2022)***

Reference is made to your letter dated November 14, 2022. The KEMRI Scientific and Ethics Review Unit (SERU) acknowledges receipt of the revised study documents on November 15, 2022;

1. Cover letter
2. Letter from SERU
3. Point by point response to the comments
4. Protocol with track changes
5. Clean version of the protocol
6. Questionnaire with the proposed additional questions highlighted in yellow
7. Revised assent and consent forms
8. Translated assent and consent forms
9. Translation certificate
10. Ethics certificates for Dr. Rono, Prof. Burton and Dr. Bolster.

This is to inform you that the issues raised during the 328th Committee B meeting of the KEMRI Scientific and Ethics Review Unit (SERU) held on **October 19, 2022** have been adequately addressed.

Consequently, the study is **granted approval** for implementation effective this day, **November 30, 2022** for a period of **one (1) year**. Please note that authorization to conduct this study will automatically expire on **November 29, 2023.** If you plan to continue with data collection or analysis beyond this date, please submit an application for continuation approval to SERU by **October 18, 2023.**

Please note that only approved documents including (informed consents, study instruments, Material Transfer Agreement) will be used. You are required to submit any proposed changes to this study to SERU for review and the changes should not be initiated until written approval from SERU is received. Any unanticipated problems resulting from the implementation of this study should be brought to the attention of SERU and you should advise SERU when the study is completed or discontinued.
Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://oris.nacosti.go.ke and also obtain other clearances needed

Yours faithfully,

REDACTED

ENOCK KEBENEI,
THE ACTING HEAD,
KEMRI SCIENTIFIC AND ETHICS REVIEW UNIT

Appendix 7: LSHTM ethics approval for the Gather study

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
United Kingdom
Switchboard: +44 (0)20 7636 8636

www.lshtm.ac.uk

Observational / Interventions Research Ethics Committee

Dr Luke Allen
LSHTM

5 September 2023

Dear DrLuke

Study Title: Sociodemographic Characteristics of Community Eye Screening Participants: a cross sectional equity analysis

LSHTM Ethics Ref: 26541 - 2

Thank you for your application for the above amendment to the existing ethically approved study and submitting revised documentation. The amendment application has been considered by the Observational Committee.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above amendment to research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval for the amendment having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Other	Adult in-person consent wording_v2_tracked	28/07/2023	2
Other	Consent form with impartial witness_v2_tracked	28/07/2023	2

After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

An annual report should be submitted to the committee using an Annual Report form on the anniversary of the approval of the study during the lifetime of the study.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: http://leo.lshtm.ac.uk

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,

REDACTED

Professor David Leon and Professor Clare Gilbert
Co-Chairs

ethics@lshtm.ac.uk
http://www.lshtm.ac.uk/ethics/

Appendix 8: KEMRI ethics approval for the Engage study

In Search of Better Health

KENYA MEDICAL RESEARCH INSTITUTE

OFFICE OF THE DIRECTOR RESEARCH & DEVELOPMENT

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0722 205 901, 0733 400 003

P.O. Box 54840-00200, Nairobi
Email: ddrt@kemri.go.ke
Website: www.kemri.go.ke

KEMRI/RD/22 **August 09, 2023**

TO: **PROFESSOR ANDREW BASTAWROUS & DR. MICHAEL GICHANGI,**
PRINCIPAL INVESTIGATORS

THROUGH: **DEPUTY DIRECTOR, CPHR,**
NAIROBI.

Dear PIs,

RE: **PROTOCOL NO. SERU 4765 (*RESUBMISSION OF INITIAL SUBMISSION*): ELICITING BARRIERS AND SOLUTIONS TO EYE CLINIC NON-ATTENDANCE IN BOTSWANA, INDIA, KENYA AND NEPAL: A MULTI-PHASED MIXED METHODS STUDY *(VERSION 3 DATED 24TH JULY, 2023)***

Reference is made to your letter dated July 24, 2023. The KEMRI Scientific and Ethics Review Unit (SERU) acknowledges receipt of the revised documents on July 25, 2023.

This is to inform you that the Committee notes that the following issues raised by SERU Expedited Review Team KEMRI Scientific Ethics Review Unit (SERU) have been adequately addressed.

Consequently, the study is **granted approval** for implementation effective this day, **August 9, 2023** for a period of **one (1) year**. Please note that authorization to conduct this study will automatically expire on **August 08, 2024.** If you plan to continue with data collection or analysis beyond this date, please submit an application for continuation approval to SERU by **June 28, 2024.**

Please note that only approved documents including (informed consents, study instruments, Material Transfer Agreement) will be used. You are required to submit any proposed changes to this study to SERU for review and the changes should not be initiated until written approval from SERU is received. Any unanticipated problems resulting from the implementation of this study should be brought to the attention of SERU and you should advise SERU when the study is completed or discontinued.

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://oris.nacosti.go.ke and also obtain other clearances needed.

Yours faithfully,

REDACTED

ENOCK KEBENEI,
THE ACTING HEAD,
KEMRI SCIENTIFIC AND ETHICS REVIEW UNIT

Appendix 9: LSHTM ethics approval for the Engage study

London School of Hygiene & Tropical Medicine
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www.lshtm.ac.uk

Observational / Interventions Research Ethics Committee

Dr Luke Allen

LSHTM

5 May 2023

Dear Luke

Study Title: Eliciting barriers to attending eye clinics and identifying potential solutions in the context of community-based eye screening programmes in Botswana, India, Kenya and Nepal: a mixed methods study pr

LSHTM Ethics Ref: 28415

Thank you for responding to the Interventions Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the RGIO.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Investigator CV	Andrew Bastawrous CV	14/12/2022	1
Investigator CV	Luke Allen CV November 2022	14/12/2022	1
Other	Research_Ethics_online_training_certificate	14/12/2022	1
Other	Andrew ethics training cert	14/12/2022	1
Investigator CV	CV 2021- Prof. Nkomazana	16/03/2023	1
Investigator CV	SAILESH KUMAR MISHRA CV	16/03/2023	1
Other	Oathokwa research ethics certificate	16/03/2023	1
Other	Sailesh Kumar Mishra research ethics certificate	16/03/2023	1
Other	Good Clinical Practice certificate Luke Allen 2021	16/03/2023	1
Other	A.Bastawrous__GCP Certificate_15.07.20	16/03/2023	1
Other	Elicitation consent form	16/03/2023	1
Information Sheet	Elicitation telephone interview script + consent	16/03/2023	1
Information Sheet	Elicitation FGD PIL	16/03/2023	1
Information Sheet	In-person elicitation interview PIL	16/03/2023	1
Information Sheet	Call script invite for in-person interview	16/03/2023	1
Protocol / Proposal	Elicitation protocol March 16th	16/03/2023	1
Investigator CV	Gichangi CV	16/03/2023	1

Document Type	File Name	Date	Version
Other	Gichangi research ethics certificate	16/03/2023	1
Information Sheet	Online PIL Bots PV survey	16/03/2023	1
Sponsor Letter	Elicitation RGIO Sponsor Confirmation	16/03/2023	1
Covering Letter	Response to LSHTM ethics request for clarification	04/05/2023	1
Protocol / Proposal	Elicitation protocol revision_May 4_tracked	04/05/2023	2

After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

An annual report should be submitted to the committee using an Annual Report form on the anniversary of the approval of the study during the lifetime of the study.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: http://leo.lshtm.ac.uk

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,

Professor David Leon and Professor Clare Gilbert
Co-Chairs

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http://www.lshtm.ac.uk/ethics/

Appendix 10: KEMRI ethics approval for the initial RCT

In Search of Better Health

KENYA MEDICAL RESEARCH INSTITUTE

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Website: www.kemri.go.ke

KEMRI/RD/22 **March 27, 2024**

TO: **SARAH KARANJA & ANDREW BASTAROUS,**
PRINCIPAL INVESTIGATOR.

THROUGH: **THE DEPUTY DIRECTOR, CPHR,**
NAIROBI.

Dear P. Is,

RE: **PROTOCOL NO. KEMRI/SERU/CPHR/XXX/4919 (*RESUBMISSION II OF INITIAL SUBMISSION*): ASSESSING THE EFFECT OF ENHANCED PATIENT COUNSELLING AND TEXT REMINDERS ON ACCESS TO COMMUNITY-BASED EYE SERVICES IN MERU COUNTY, KENYA: A RANDOMIZED CONTROLLED TRIAL USING BAYESIAN STOPPING RULES**

Reference is made to your letter dated March 13, 2024. The KEMRI Scientific and Ethics Review Unit (SERU) acknowledges receipt of the revised study documents on March 18,2024.

This is to inform you that the issues raised during the 344th Committee A meeting of the KEMRI Scientific and Ethics Review Unit (SERU) held on **February 13, 2024** have been adequately addressed.

Consequently, the study is **granted approval** for implementation effective this day, **March 27, 2024,** through to **March 26, 2025**. Please note that authorization to conduct this study will automatically expire on **March 26, 2025**. If you plan to continue with data collection or analysis beyond this date, please submit an application for continuation approval to SERU by **February 13, 2023**.

You are required to submit any proposed changes to this study to SERU for review and the changes should not be initiated until written approval from SERU is received. Please note that any unanticipated problems resulting from the implementation of this study should be brought to the attention of SERU and you should advise SERU when the study is completed or discontinued.

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://oris.nacosti.go.ke and also obtain other clearances needed.

Yours faithfully,

REDACTED

ENOCK KEBENEI,
THE ACTING HEAD,
KEMRI SCIENTIFIC AND ETHICS REVIEW UNIT

Appendix 11: LSHTM ethics approval for the adaptive platform trial

London School of Hygiene & Tropical Medicine
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Observational / Interventions Research Ethics Committee

Dr Luke Allen

LSHTM

10 January 2024

Dear Luke

Study Title: Protocol for an adaptive platform trial of intended service user-derived interventions to equitably reduce non-attendance in eye screening programmes in Botswana, India, Kenya & Nepal

LSHTM Ethics Ref: 29549

Thank you for responding to the Interventions Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Other	Luke Allen Research_Ethics_online_training_certificate	04/03/2021	1
Other	citi hipaa_Motlhatlhedi	02/06/2021	1
Other	Gichangi research ethics certificate	05/07/2021	1
Other	Andrew Bastawrous Research Ethics certificate	28/07/2021	1
Other	Module 1_Training Certificate_Motlhatlhedi	10/03/2023	1
Other	Module 1_Training Certificate_Motlhatlhedi	10/03/2023	1
Other	Shalinder Research certificate	01/06/2023	1
Other	Shalinder Research certificate	01/06/2023	1
Investigator CV	Luke Allen CV June 2023	01/06/2023	1
Investigator CV	Andrew Bastawrous CV	21/06/2023	1
Investigator CV	Gichangi CV	21/06/2023	1
Investigator CV	SAILESH KUMAR MISHRA CV	21/06/2023	1
Investigator CV	Shalinder CV	21/06/2023	1
Other	Module 1_Training Certificate	16/07/2023	1
Other	Module 1_Training Certificate_Mishra	16/07/2023	1
Sponsor Letter	2023-KEP-981_Prov sponsor letter (global policy only)_31.07.23	31/07/2023	1

Document Type	File Name	Date	Version
Other	Luke Allen_Good Clinical Practice certificate_2023-12-07	07/12/2023	1
Other	Module 1 (2023)_Certificate of completion for module 1 (2023)	12/12/2023	1
Information Sheet	Informed consent and PIL Template	12/12/2023	1
Investigator CV	Keneilwe Motlhatlhedi CV	13/12/2023	1
Other	Andrew Bastawrous GCP certificate 13.12.2023	13/12/2023	1
Other	DSMB Charter	13/12/2023	1
Other	Gichange_GCP certificate 16.12.2023	18/12/2023	1
Covering Letter	Platform_trial_letter_of_support_Carpenter	20/12/2023	1
Protocol / Proposal	Platform Trial Protocol v2 (1)	20/12/2023	2
Covering Letter	APT_Response to LSHTM ethics request for clarification	20/12/2023	1
Information Sheet	Informed consent and PIL Template_v2_Jan 2024	04/01/2024	2
Covering Letter	Responses to IRB Comments_APT_v2_Jan 2024	04/01/2024	2

After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

An annual report should be submitted to the committee using an Annual Report form on the anniversary of the approval of the study during the lifetime of the study.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: http://leo.lshtm.ac.uk

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,

REDACTED

Professor David Leon and Professor Clare Gilbert
Co-Chairs

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Improving health worldwide

Appendix 12: LSHTM ethics approval for the initial RCT

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Observational / Interventions Research Ethics Committee

Dr Luke Allen

LSHTM

6 February 2024

Dear DrLuke Allen

Study Title: Protocol for an adaptive platform trial of intended service user-derived interventions to equitably reduce non-attendance in eye screening programmes in Botswana, India, Kenya & Nepal

LSHTM Ethics Ref: 29549 - 1

Thank you for your application for the above amendment to the existing ethically approved study and submitting revised documentation The amendment application has been considered by the Interventions Committee via Chair's Action.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above amendment to research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval for the amendment having been received, where relevant.

Approved documents

The final list of documents reviewed and approved is as follows:

Document Type	File Name	Date	Version
Other	2024-24-01_Kenyan PIL & consent form_RCT	24/01/2024	1
Covering Letter	cover letter LEO	25/01/2024	1
Other	Platform Trial Protocol v2_tracked	25/01/2024	2
Other	APT Appendix_Kenya_counselling intervention	02/02/2024	1
Other	2024-KEP-1049_Prov sponsor letter (global policy only)_final_01.02.2024	02/02/2024	1

After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

An annual report should be submitted to the committee using an Annual Report form on the anniversary of the approval of the study during the lifetime of the study.

At the end of the study, the CI or delegate must notify the committee using the End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: http://leo.lshtm.ac.uk.

Further information is available at: www.lshtm.ac.uk/ethics.

Yours sincerely,

REDACTED

Professor David Leon and Professor Clare Gilbert
Co-Chairs

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http://www.lshtm.ac.uk/ethics/

Improving health worldwide