Increasing Access to Eye Care using Mobile Phone-based Interventions.

The development, validation and implementation of Peek to optimise human resources and lower barriers to access for those most in need

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Declaration

I, Dr. Hillary Kipkemboi Rono, confirm 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.

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Abstract

Background

A combination of limited access to eye services and low numbers of eye care providers in low and middle income (LMIC) populations results in high prevalence of avoidable visual impairment.

Aim

To develop and evaluate a demonstration model of community volunteers and teachers using a novel mobile phone-based technology (Peek) in communities and schools, respectively, to identify and refer those with referable eye conditions and increase adherence to services so as to reduce avoidable visual impairment.

Methods

This thesis comprises: (1) a three-year retrospective review of utilisation of hospital eye care services; (2) a cluster randomized trial (C-RCT) to determine the effectiveness of using of the mobile phone based, Peek School Eye Health System (Peek SEH) to increase identification and referral adherence to hospital of school pupils with visual impairment; (3) the development and validation of a smartphone based community screening decision-support algorithm (Peek Community Screening App) that enables Community Volunteers (CVs) to make referral decisions about patients with eye problems in the community; and (4) a second single masked C-RCT where the Peek Community Screening App was integrated into an mHealth system, Peek Community Eye Health system (Peek CEH) for integrating eye health screening in communities with primary and secondary health care facilities in Kenya to increase access and to optimise health system utilisation.

Results

For the **first** study, the retrospective analysis of records showed an average annual attendance rate increase from 60.9 to 79.2 per 10,000 population, incidence rate ratio (IRR)

1.30 (95% confidence interval (CI) 1.26–1.35) between 2013 and 2015. Also 61.0% of consultations in the three-year period were for primary eye conditions (allergic or other conjunctivitis or normal eyes) which could potentially be managed by primary eye care (PEC) and only 8.3% were for the three leading causes of vision loss in this population (cataract, glaucoma and refractive errors).

In the **second** study, Peek SEH was validated by comparing the results of Peek Acuity test and the Snellen Tumbling-E card when performed by teachers against a reference standard backlit EDTRS LogMAR visual acuity test chart, when performed by trained ophthalmic workers. Sensitivities were similar (77% [95% CI 64·8–86·5] vs 75% [63·1–85·2]). In the C-RCT, the Peek SEH intervention, comprising of Peek Acuity test, sight simulation referral cards, and short message service [SMS] reminders, was compared to standard Tumbling E card vision test and paper referral letters. The proportion of pupils identified as having visual impairment who attended their hospital referral was higher in the intervention group (285 [54%] of 531) than in the standard group (82 [22%] of 366; odds ratio 7·35 [95% CI 3·49–15·47]; p<0·0001). This result informed the design of a school project that subsequently screened a further 168,820 children, identified 6,696 (4.0%) with VI and achieved 93% treatment coverage.

In the **third** study, the sensitivity of community volunteer referral decisions using the “Peek Community Screening App” as compared to decisions made by the reference Ophthalmic Clinical Officer was 91.0%, (95% CI 87.7% - 93.7%) and Specificity was 78.1%, (95% CI 71.6% - 83.6%).

The **fourth** study, compared the Peek CEH (comprising Peek Community Screening app, short message service [SMS] reminders and door to door screening), delivered by CVs against current care (periodic health centre-based outreach clinics with onward referral). The intervention was associated with increased utilization to PEC services at four weeks from sensitization. The mean attendance was 14.3% vs. 5.2%, risk difference 9.1% (95%CI:

6.9-11.3%); p<0.00001. Overall, 76% of participants were treated at PEC level. About 11% of hospital consultations were for primary eye conditions and 56% for cataract, glaucoma and refractive errors (compared to 63% and 8% respectively in the hospital utilisation study, in the first study).

Conclusion

This study provides strong evidence that integration of Peek interventions in to the health system can increase access to eye care, whilst making more appropriate use of limited eye care resources.

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Acknowledgement

Figure 0.1: The study team

The journey toward the completion of this PhD thesis has been both interesting and challenging. It would not have been possible without the contributions of many individuals both in the UK and Kenya to whom I am extremely grateful. The work presented in this thesis has been a team effort.

"If You want to go fast, go alone. if you want to go far, go together."
African proverb

I am sincerely grateful to all those who helped me to make this PhD a success. The specific contributions of these individuals are highlighted in appendix 1.

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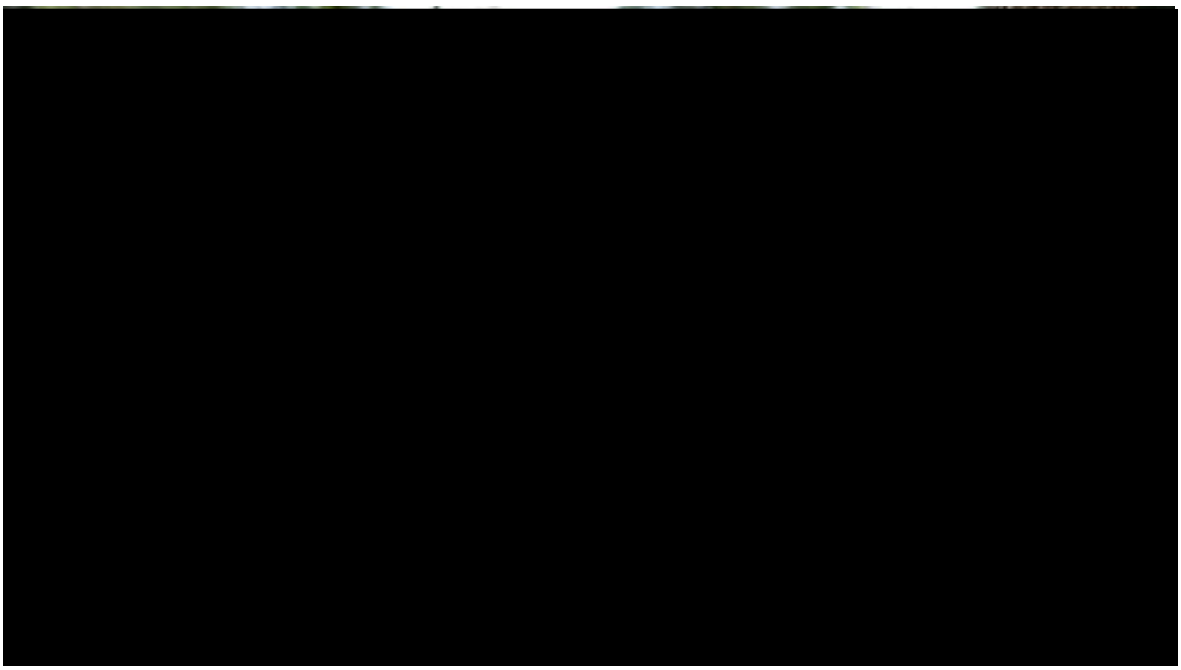


Figure 0.2: A community volunteer preparing to measure someone's visual acuity.

List of Abbreviations

C-RCT	Community cluster randomized controlled trial
CHEWs	Community Health Extension Workers
CU	Community Unit
CVs	Community Volunteers
DALYs	Disability adjusted life years
DR	Diabetic Retinopathy
DSMB	Data Safety and Monitoring Board
ECD	Early Childhood Development
GCP	Good Clinical Practise
HMIS	Health Management Information Systems
ICEH	International Centre for Eye Health
ICO	International Council of Ophthalmologist
IMCI	Integrated Management of Childhood Illnesses
IREC	Institutional Research and Ethics Committee
LMICs	Low and middle-income countries
LSHTM	London School of Hygiene & Tropical Medicine
mHealth	Mobile Health
MSVI	Moderate or severe vision impairment
NGOs	Non- Governmental Organizations
OEU	Operation Eye Sight Universal
PACTR	Pan African Clinical Trials Registry
PEC	Primary Eye Care
Peek SEH	Peek School Eye Health
Peek CEH	Peek Community Eye Health
PHC	Primary Health Care
PMTCT	Prevention of Mother-To-Child Transmission

RAAB	Rapid Assessment of Avoidable Blindness
SDA	Safe Delivery App
SMS	Short Text Message
SSA	sub-Saharan Africa
USA	United States of America
VI	Visual Impairment
WHO	World Health Organization
<	Less than

Chapter 1: Introduction and Background Literature Review

Figure 1.1: Visual impairment has profound implications for the effected individual and their family

Global Blindness & Visual Impairment

Globally, it is estimated that 253 million people have visual impairment (VI), (visual acuity in the better eye <6/18), 36 million of whom are blind (visual acuity in the better eye <3/60).[1] About 80% of the impairment is avoidable.[2] Approximately 90% of those who are living with VI are in low and middle-income countries (LMICs),[3] predominantly in Asia and Africa.[4] According to a systematic review and meta-analysis from survey data on global causes of blindness and distance vision impairment 1990–2020, 36 million people were estimated to be blind, 216.6 million people had moderate or severe vision impairment (MSVI),[5] and 188.5 million had mild visual impairment, globally, in 2015.[1]

Although there was a remarkable reduction in prevalence of blindness and MSVI between 1990 and 2015, the number of blind people and those with MSVI increased from 30·6 million to 36 million and from 159.9 million people to 216.6 million respectively over the same period.[6] [7] This increase has been attributed to global population growth and an ageing population which has led to a relative increase in the number of older adults (50 years and above) who are at a higher risk of vision impairment.[4] Based on current trends and estimates, it is projected that 38.5 million people will be blind and 237 million people with MSVI by 2020, globally.[5]

Blindness & Visual Impairment in sub-Saharan Africa (SSA)

Results from 11 population-based studies in Africa suggest that there are 26 million people living with visual impairment, of whom almost 6 million are blind.[8] According to 2010 estimates, about 4.8 million people are blind (14.8% of global blindness) and 16.6 million people have MSVI (17.1% of global burden) in sub-Saharan Africa (SSA).[9] This was a 16% increase in the number of blind people from 4.1 million in 1990 to 4.8 million in 2010 and a 28% increase in the number of people with MSVI from 13 million to 16.6 million over the same period. This increase has been attributed to the 66% increase in the SSA population between 1990 and 2010 and improved life expectancy.[9] Over the same period, the prevalence of blindness decreased by 32% from 1.9% in 1990 to 1.3% in 2010 and moderate to severe visual

impairment decreased by 25%, owing to major improvements in eye care and prevention brought about by technology and global initiatives such as VISION 2020.[10]

In sub-Saharan Africa specifically, the reported prevalence of blindness varies from 0.1% in Uganda to 9.0% in Eritrea, while the prevalence of visual impairment ranges from 1.6% to 17.1%, respectively.[11] The number of people with visual impairment or blindness varied depending on the region, West Africa had the highest number of people with 2.1 million blind and 7.2 million MSVI followed by East Africa with 2.1 million blind and 7.1 million MSVI. Central Africa and Southern Africa had the lowest prevalence of blindness and MSVI, at 0.28 million blind; and 1.4 million MSVI and 0.29 million blind and 0.94 million MSVI respectively.[9] The prevalence of blindness and MSVI is higher among women than men. A higher prevalence of blindness and MSVI has been reported in the older adults (50 years and above) due to the risks associated with older age.[6]

Blindness & Visual Impairment in Kenya

In Kenya, approximately 676,640 people were blind or visually impaired, of whom about 315 000 were blind in 2014.[12] The prevalence of blindness varies by region, Table 1.[13-17] According to a series of eight regional eye surveys conducted in Kenya in 1990, as part of the Kenya Rural Blindness Prevention Project, approximately 0.7% of rural Kenyans were blind (visual acuity <3/60 in the better eye), and another 2.5% had significant visual impairment (visual acuity of <6/18 in the better eye).[16]

Over the past two decades, a number of population-based surveys have been conducted in Kenya. According to a recent morbidity survey conducted in Mbeere District, 15.5% of those examined were found to have eye problem in at least one eye.[18] In another part of the country, a Rapid Assessment of Preventable Blindness (RAAB) survey conducted in Kericho District in 2007 reported a 2% estimated prevalence of blindness and 7.1% prevalence of vision impairment, table 1.[19]

Table 1. Prevalence of Blindness and visual impairment in Kenya

Region	Author (year published)	Age Examined	Sample size	Prevalence of blindness (95% CI)	Prevalence of VI (95% CI)
Multiple sites	Whitfield[16] (1990)	All	1800	0.7%	2.5%
Nairobi (slums)	Ndegwa[15] (2006)	All	1438	0.6% (0.21 - 1.0)	6.2% (4.95,7.15)
Nakuru	Mathenge[13] (2007)	≥ 50	3503	2.0% (1.5-2.4)	5.8% (4.8, 6.8)
Embu	Karimurio[14] (2007)	≥ 50	3376	2.0% (1.5 -2.5)	Not stated
Nakuru	Mathenge[17] 2012	≥ 50	4414	1.6% (1.2-2.1)	8.1% (7.2%–9.2)
Mombasa	Wachira[20] (2011)	≥ 50	3124	2.5% (1.9– 3.0)	13.0%

Prevalence of blindness by gender is variable. Some studies report a higher prevalence in females,[21] while others found no gender difference.[13] The excess burden in women appears to arise from a lack of access to surgical eye services instead of a biological predisposition.[22] [23] Other studies suggest that being male is a risk factor for blindness.[17]

Blindness increases with increasing age, Figure 1.2. This is largely driven by age-related cataracts, the leading cause of blindness worldwide.[13,17]

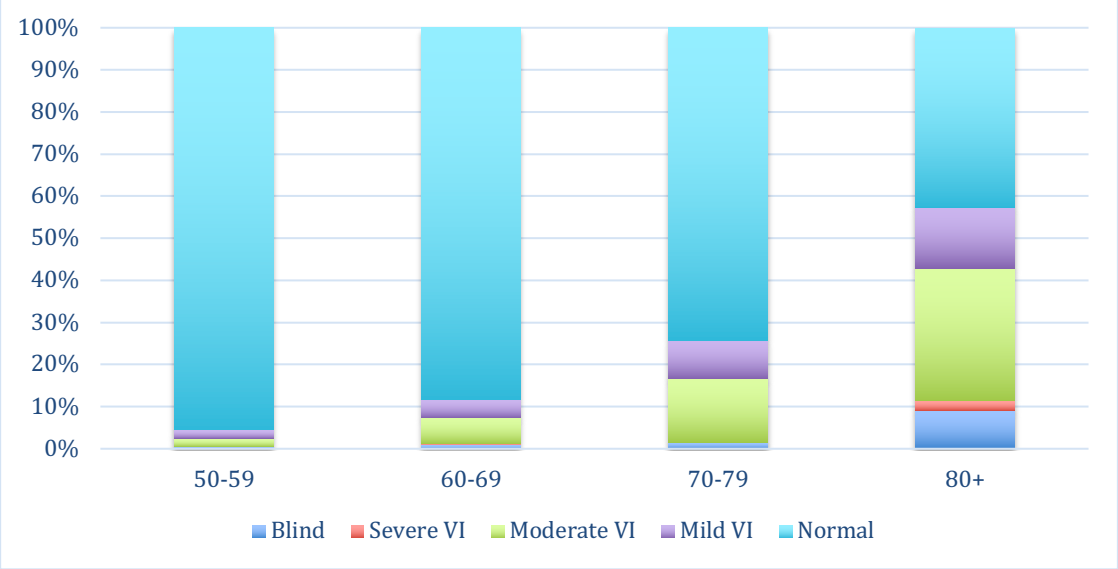


Figure 1.2: Prevalence of Visual Impairment in Nakuru, Kenya

(Reproduced from RAAB in Kenya, Mathenge et al.[13])

Causes and risk factors

Globally the leading causes of visual impairment are uncorrected refractive error (116·3 million), cataract (52·6 million), age-related macular degeneration (8·4 million), glaucoma (4·0 million) and diabetic retinopathy (2·6 million) while the major causes of blindness are cataract (12·6 million), uncorrected refractive error (7·4 million) and glaucoma (2·9 million).[5] Cataract and uncorrected refractive error contributed to 55% of blindness and 77% of vision impairment in adults aged 50 years and above in 2015.[5]

These causes vary according to regions and countries.[9,24 25,26] In sub-Saharan African (SSA) countries, cataracts, uncorrected refractive error and trachoma are the most common causes compared to macular degeneration and refractive error in the Americas and Western Europe, Table 2.

Table 2. Causes of blindness (visual acuity <3/60) in selected regions of the world

Region	Cataract (%)	Uncorrected Refractive error (%)	Macular degeneration (%)	Glaucoma (%)	Diabetic retinopathy (%)	Trachoma (%)	Reference
World	51	3	5	8	1	3	Pascolini *et al* [8]
East Asia	28.1	13.7	6.9	5.4	1.1	2.0	Wong *et al*[25]
Sub Saharan Africa	35.0	13.2	6.3	4.4	2.8	5.2	Kovin *et al*[9]
North America	12.7	14.1	16.4	10.7	3.9	0	Bourne *et al*[24]
Western Europe	13.8	14.0	16.1	10.6	4.2	0	Bourne [24]
North Africa and Middle east	18.7	13.1	10.3	9.6	3.5	2.6	Khairallah *et al* [26]
Kenya	35.7	5.7	7.1	8.5	-	18.5	Whitfield *et al*[16]

In SSA, The leading causes of moderate or severe vision impairment in those aged 50 years and older are uncorrected refractive error followed by cataract and age-related macular degeneration.[6] The major causes of blindness reported in 2010 were cataract 35%,

other/unidentified causes 33.1%, refractive error 13.2%, age-related macular degeneration 6.3%, trachoma 5.2%, glaucoma 4.4% and diabetic retinopathy 2.8%.[9]

In Kenya, the leading causes of blindness in people over 50 years were: Cataracts, 39-59%; Posterior Segment Diseases, 17-28 %; Glaucoma, 6-15%; and uncorrected aphakia 0-6.1% while causes of severe visual impairment were: Cataracts, 55-61%; Posterior segment diseases, 7-22%; and Uncorrected Refractive Error, 7-13 %. [13 20 18] About 20% of blindness is preventable and 55% treatable.

In a follow up longitudinal study conducted in 2014 to assess the incidence and risk factors of vision impairment and blindness among adults aged 50 years and above in Kenya, the incidence of blindness and vision impairment was reported to be 2.2 per 1000 people per year and 20.9 per 1000 people per year, respectively.[27] Trachoma, the second most common cause of blindness is localised to the northern and southern parts Rift Valley,[28] compared to other causes which are more widespread.[14-16] In trachoma endemic areas, the prevalence of active trachoma ranges from 6.4% to 42.3% while that of potentially blinding trachoma (trichiasis), ranges from 1.0 % to 8.7%. [29-31]

Diabetes is an emerging challenge arising from urbanization and lifestyle change.[32] The prevalence of diabetes mellitus is 3.3%.[33] The prevalence of diabetic retinopathy amongst diabetics ranges between 18.35 and 49.8%.[32] Other diseases of the retina and vitreous (Posterior eye diseases) are now important causes of blindness,[14,17] with the prevalence of macular degeneration being 11.2%.[34] This emerging challenge requires the health system to change and adapt. The incidence of visual impairment, diabetes and related retinal changes in Kenya is on the increase according to the findings of the Nakuru cohort study, Table 3.[35]

Table 3: Incidence of blindness, visual impairment, Diabetes and Diabetic Retinopathy

Incidence of	Incident cases / At risk cases	Six-year cumulative incidence (N / per 1000 of population, 95% CI)
Bilateral blindness	29 / 2140	15.1 (10.4 – 21.7)
Bilateral Visual Impairment	234 / 1983	119.4 (103.1 - 137.9)
Unilateral blindness	111 / 1984	54.6 (43.7- 68.0)
Unilateral Visual Impairment	390 /1721	228.0 (206.0 – 251.6)
Diabetes Mellitus (in patients with no diabetes at baseline)	123 / 2056	61.0 (50.3 - 73.7)
Diabetic Retinopathy (in patients without diabetes at baseline)	20 / 1421	15.8 (9.5 - 26.2)
Diabetic Retinopathy (in patients with diabetes but no retinopathy at baseline)	11 / 44	224.7 (116.9 - 388.2)

Source: Reproduced from the Nakuru Eye Disease Cohort Study, Bastawrous.[35]

Reasons for high burden of Visual impairment

The reasons for a high burden of visual impairment include poverty and a lack of access to eye services.[36] Patient factors such as lack of awareness, fear of the outcome,[37] older age; male gender and presence of diabetes increases the risk of blindness.[17] Health system related factors such as the low number of available of eye workers,[38] varied productivity of the eye workers, higher indirect and direct costs, [39,40] and the distribution of the available work force which is currently concentrated in urban areas.[41] In addition there are "provider" factors such as poor quality services arising from a shortage of trained eye care workers,[42] [37]

Many people in the world live in rural areas and have poor health including visual impairment arising in part, from limited access to general and eye health services.[43] An inverse relationship

between need and provision of eye care services exists, especially in sub-Saharan Africa, meaning that there are fewer services available where the need is greatest, such as in rural areas.[44] The main challenges are a lack of eye care manpower, poor infrastructure development and lack or poor service delivery.[45] The effect of these challenges in LMICs is suboptimal access and utilization of eye care services. Identifying barriers that hinder access and utilization of eye care services is therefore key in overcoming the burden of avoidable blindness and visual impairment.[46]

Limited access to eye health services from poor infrastructural development could arise from lack of social infrastructure such as electricity, water, access to information and communication technology, schools for children, less opportunities for professional development, and poor prospects for part-time private practice for health workers, this in turn does not attract eye health workers to rural areas. [47] [48]

The eye health work force is still a major challenge in most countries in SSA. Only a few countries in sub-Saharan Africa have reached the World Health Organisation (WHO) suggested ophthalmic cadre minimum targets to meet the population needs.[49] The recommended WHO minimum ratio is 230 per 100,000 population for any cadre.[50] In some countries, the few eye health workers that are available are concentrated in urban cities/counties compared with rural counties, hence creating further inequalities in access to eye health.[49,51] The current challenge may persist because the numbers of eyecare staff is not only low, but according to survey by International Council of Ophthalmologist (ICO), the current rate of training may not achieve WHO target soon. There is therefore a call for other innovative ways of delivering eye care to be explored.[42] The low number of eye health work force and the limited access to infrastructure need to deliver eye care limit the eye services to be offered to the population.

Access to eye care and factors affecting utilization of eye care services

Access in this context is defined as the opportunity or ability to obtain the health services that one needs without the risk of financial impoverishment.[52] A review of utilization of eye services showed that, only about 25% of those who need eye care globally actually utilize eye services.[53] This is an indication that utilization of eye care services in most countries is low owing to a number of factors that affect the availability, accessibility and affordability of these services. These factors are classified into 'demand' related or patient related (the health seeking behaviour of the population) and 'supply' or providers related (eye services provision and availability) factors.

Demand or patient factors especially in Africa include lack of knowledge of the services, lack of knowledge of the possible impact of an eye disease and lack of knowledge on where to seek the services, table 4. Demographic, personal, social and cultural factors have also been found to influence or act as barriers to access and utilization of eye care services.[54]

Table 4: Proportion accessing eye care services and barriers to utilizations in Africa

Country	Proportion accessing eye services *	Barriers	Author (year published)
Ghana	60%	• Other social engagements and competing priorities • Ability to perform daily task despite having the eye condition, • High cost of services and transport • Distance to eye care facility • Lack of knowledge on the eye care services and • Lack of knowledge on where treatment available	Akowuah *et al* [55] (2017)
Nigeria	38%	• No felt need • High cost of services, • Other financial constraints, • lack of or limited availability of eye care services, • Long waiting time at the eye facilities • younger age group	Ibeneche *et al* [56] (2018)
Nigeria	32%	• Lack of felt need for eye care services • cost of treatment • Lack of patient escort to hospital • Other social engagements • cultural beliefs discouraging seeking eye care	Ebeigbe *et al* [57] (2014)
Kenya	93 %[#]	• No perceived need • lack of money • Did not know where to seek eye care services • other social engagements	Kimani *et al* [58] (2008)
Kenya	17%[#]	• Lack of money • Lack of awareness where to seek services • Eye problem was not a perceived need	Ndegwa et al.[59] (2005)

*self-reported proportion with eye problems who utilized eye services.

[#] The study was done in the same area but at different times. The Ndegwa et al 2005 study on accessing eye services for an eye problem was done before an eye unit was introduced and 3 years later Kimani et al conducted a follow-up study on the same.

Few studies have explored the barriers to the provision of eye care services which affect the availability; and subsequent access and utilization of these services. In Australia, a study on the utilization of eye care services found differences in patterns of utilization of eye care services between rural and urban areas, despite similar prevalence of eye disease in both areas, and associated it to availability of eye care services.[60]

In developing countries, where the number of care providers are limited, the eye services available, especially in the rural areas, are not enough to meet the need. For example, in a

study of the perceived barriers to the provision of clinical low-vision services among ophthalmologists in Nigeria, unavailability of low-vision devices, lack of adequate training in low-vision care, and limited number of specialists were cited as the main factors hindering provision of low-vision services in the country.[61] In Zambia, the limited number of spectacles manufacturing workshops and eye surgery theatres per unit of population have been cited as the barriers encountered in accessing eye care services in rural areas. Higher access and utilization of eye care services reported in urban areas due to availability of private eye care facilities. [62]

Poverty is a critical social determinant of VI, and in turn VI leads to further poverty.[63] For instance, as a result of low socioeconomic status, patients have no insurance, yet they may have to incur high transport costs to the hospital, which limits the use of services.[64] They are also likely to have low education, low awareness of the eye conditions and of the services available, and fear of adverse outcomes from treatment. [65] [37]

Additional barriers might include negative attitudes towards services and difficult communication between providers and patients.[66] Studies in LMICs, have shown that the need for eye services is high and people often travel long distances to access these services.[67] Communities with inadequate or inaccessible eye care facilities tend to seek other alternatives of eye care services, including self-medication, which may further contribute to VI and blindness.[68]

Social attitudes and cultural beliefs may also act as barriers to using available services, such as the belief that blindness is a normal and non-reversible part of the aging process hence no treatment is sought.[69] A review on barriers to utilization of eye care services found that women were more careful about their eye health than men, suggesting gender influence service utilization.[54] Gender disparities in accessing eye health care services was identified for eye trauma and cataract in studies from Tanzania where females had difficulty in accessing services.[70,71] In such communities, men decide on most matters affecting the family including

those related to seeking health services.[72] This was observed in one study on access to cataract surgical services from Tanzania where women needed to seek permission from their husbands before going to hospital and out of fear of being a burden to the family, they frequently opted live with the adversity and did not access services.[71]

Strategies to improve access to eye care services

To address the burden of eye diseases it is necessary to radically improve access of the population to quality eye health services. The World Health Organization (WHO) and partners have developed a global initiative to eliminate avoidable blindness by the year 2020. The '*Universal eye health: global eye health action plan 2014–2019'* aims to reduce avoidable visual impairment as a global public health problem by promoting universal access to comprehensive eye care services that are integrated into health systems.[2]

The three main factors that contribute to the high prevalence of VI, particularly in rural and remote areas, are non-availability, non-accessibility and non-affordability of eye care services.[54] The strategies therefore include increasing human resources for eye care, infrastructure development, improving service delivery and coordination, at all levels of health care.[45]

Improving service delivery and coordination

WHO advocates for a well-coordinated and systematic eye care system with each level of health care performing specific roles such as management of cataracts and refractive errors at secondary care and identification with limited care at primary care level to reduce avoidable blindness.[73] At primary eye care (PEC), frontline activities (such as promotive and preventive) providing limited care and identifying disease before it becomes a serious medical issue are done and is delivered at the community level.[74] Secondary level provides treatment of common blinding conditions such as cataracts and refractive errors and act as referral points for PEC

while tertiary level provides specialized eye treatment of less prevalent visually impairing conditions that are more complex to manage.[73]

Improving primary eye care and Outreach eye care programs

Delivery of primary eye care can be broadly categorized in to two models based on their working operations, it may be either through fixed facilities and human resources or mobile services from a secondary care team.[75] The effectiveness of PEC fixed facility delivery model by fulltime, integrated, health workers is inconclusive partly due to a lack of agreement in the definition and varied eye health skills of the health workers.[76] The outreach model on the other hand is more effective at providing short term access to eye care especially in rural areas. [77] The long-term, more sustainable goal is to integrate eye services into fixed primary health care (PHC) as a continuum of health service provision.[78] Service improvement that includes provision of affordable or free spectacles, eye drops and eye consultations should ideally be provided. This may be achieved through eliminating user fees for example by having in place the provision of health insurance to cater for the cost of eye services.[79]

In developing countries, a high proportion of healthcare is provided in urban areas; outreach programs are designed to promote access to eye services by communities in remote communities.[39 80] Services provided in outreach include surgery, screening and refraction with provision of eyeglasses. The success of outreach requires understanding of health inequities, community expectations and government policies.[80,81] Forming partnerships with Non-Governmental Organizations (NGOs) to improve access to eye care by taking eye services closer to the communities through 'outreach' services, an essential step towards provision of accessible and affordable eye services.[80,82] Recently outreach service provisions in India have incorporated electronic transfer of health-related data from outreach clinics to base hospitals with some success.[83] This provides an opportunity for a combined outreach model, which incorporates triage and referral aided by mobile technology, and has not been tried.

Availability of human resources for eye health

To improve on in the human resources, several strategies and policy changes have been explored with some success such as deployment of staff to rural areas, task shifting and integration of services into primary health care and improved supervision of health care staff.[79] In areas with few eye health workers, task shifting using guiding clinical decisions have been used.

Task shifting

Task shifting involves the redistribution of tasks among health workforce teams, to improve efficiency among available human resources.[16,82] The success of task-shifting in eye care has been variable. The factors affecting its success include lack of clear definitions for the scope of practice and the skills required for Primary Eye Care (PEC) workers to work optimally; changing government policies, patients preferences, expectations and competing responsibilities of the nurses involved in PEC.[84,85] In trachoma programs, task shifting has been used extensively in some countries for the delivery of trichiasis surgery. However, this has at least in some regions been limited by low productivity and high attrition rates of workers trained in PEC.[86] Improved productivity is associated with regular supportive supervision, provision of equipment and focused training.[87] Other factors are development of appropriate infrastructure, advocacy, and having clear management and referral guidelines of patients.[88] Integrated task shifting with guided decision-making has been used successfully to reduce childhood mortality in Africa.[89]

Clinical algorithms / Decision Trees

Effective task shifting with clear referral criteria and management plans has been delivered through algorithms especially in the integrated management of childhood diseases at primary level (IMCI)[89,90]. The process began with validation of algorithms and later adoption into clinical practice. During validation, classification of childhood illness by a health worker using IMCI algorithm compared favorably to the diagnosis and classification by physicians; sufficient to justify its use in clinical practice. [91,92] In Fiji, PHC workers used algorithms to improve case

identification of childhood skin diseases. The sensitivity of the algorithms was 98.7% (95%CI 95.5-99.9) when compared to physicians diagnosis.[93]

In eye care, decision trees/algorithms have been developed, mostly outside Africa, Table 5. Most of the algorithms focused on identifying the diagnosis and treatment at a secondary level and although some were validated the sample sizes of each study was small.[94-96]

The World Health Organization (WHO) has developed and validated algorithms to be used by primary health care workers to assess patients with eye conditions and improve decision making PHC level.[97] Digitalization of the algorithms could make them portable and usable in PHC.

Personal factors

in some instances, even when services are available, accessible and affordable, there are other barriers that might prevent people from using them. These personal factors include poverty, lack of knowledge about the services, where to seek eye care, the possible effects of an eye disease, and whom to consult to manage eye diseases.[98] To improve this situation there is a need for eye health education and information on available services as well as a review of the cost of services to ensure that services are available and affordable for all. [58]

Table 5. Available eye health algorithms, purpose and the target user groups

Country	Purpose of algorithms/ Decision tree	Target group	Accuracy of algorithm (sensitivity)	References
Scotland	Diagnosis of causes of Red eyes	Optometrist, General health practitioners	28/39 (72%)	Timlim *et al* [94]
Scotland	Diagnosis of causes of Vision loss	Optometrist, General health practitioners	57/68 (84%)	Goudie *et al* [96]
Scotland	Diplopia	Optometrist, General health practitioners	37/45 (82%)	Butler *et al* [95]
Ohio USA	Diagnosis and causes of red eyes	Optometry, General practitioners	Not indicated	Cronau *et al*[99]
USA, New York	Diagnosis of causes of Swollen eye lids	Primary Health Care workers	Not indicated	Papier et al [100]
UK (International centre for eye heath - ICEH)	Management decision to Eye injuries	Primary Health Care workers	Not indicated	Ansumana et al [101]
WHO, Rwanda	Aid management decisions to common eye conditions	Primary Health Care workers	Not indicated	World Health Organization.[97]
South Africa (Brien Holden Vision Institute Foundation)	Diagnosis of eye conditions in primary and aid management decisions	Primary Health Care workers	Not indicated	ICEE Sight[102]

mHealth

Mobile health (mHealth) is the use of mobile and wireless technologies to support the achievement of health objectives.[103] It involves the utilization of short messaging service (SMS), wireless data transmission, voice calling, and smartphone applications towards the realization of these objectives.[104] The advent of smartphones, new technology that combines mobile communication and computation in a handheld device, has facilitated mobile computing at the point of care.[105] Mobile health interventions to support communication between health

care providers and patients through short messaging services (SMS) appointment reminders has been shown to be beneficial suggesting its use could be considered in the provision of health care.[106]

Over the last decade, there has been a rapid evolution of mobile phone technology and its integration into clinical practice globally. This has been contributed to partly by improved infrastructure and technologies which have made connectivity to rural and remote areas feasible. Increased awareness of digital technologies, growing acceptance of remote monitoring tools, and growth of unmet healthcare demand leading to growth of the mHealth market.[107] Distribution platforms such as Google Play have also made mobile applications readily available, sometimes at no cost.[108] Mobile phone coverage is growing to universality while mobile devices are advancing to sophisticated hand held computers.[109] Mobile telephone penetration and technology has also expanded due to availability of mobile devices, including the growing access to affordable smartphones and better quality network connectivity, providing a potential to increase access to health services without the previously required infrastructure.[110]

A survey by the WHO among 114 member countries showed that 83% were offering at least one type of mHealth service.[103] As of 2012, there were 83 documented mobile applications: 57 applications were for healthcare professionals focusing on disease diagnosis; 11 applications for medical or nursing students focusing on medical education; and 15 applications for patients.[105] There has been a huge increase in the past four years in terms of availability and usage of smartphone applications for eye care. The commonest applications are References, Calculators and Vision Tests.[111,112] There continues however to be a shortage of clinically proven applications.

Acceptance of mobile technology, especially in the finance sector has increased mobile money transfer penetration to 61.8% and improved mobile pentration.[113] This suggests there is an opportunity to develop and scale mobile based health intervention. Further, availability of local

innovation tech hubs, which provide support responsive to local needs and collaboration opportunities for innovators and digital entrepreneurs have grown in some African countries such as Kenya.[108]

The factors that influence acceptance and use of any technology include; cost, privacy implications and usability factors, expected benefits of technology, perceived need for technology, availability of alternative technology and social influences from family, friends and professional caregivers.[114]

mHealth in Africa

Africa is in a transition characterised by increasing burden of diseases, and health system challenges arising from globalisation and urbanisation.[115] The health system challenges included shortages of health workers, lack of access to essential medicines, limited capacity of national health management information systems (HMIS) to generate, analyse and disseminate information for use in decision-making, inadequate health financing and poor service delivery. [116] Combining task shifting with mHealth could address some of the barriers by taking advantage of high mobile phone coverage. Encouragingly, mHealth interventions seeking to improve patient communication, promote access to health services, clinical diagnosis, and treatment adherence, and manage chronic diseases is becoming accepted.[117] It has also shown initial promise in emergency and disaster response, helping standardize, store, analyse, and share patient information. [118]

The use of connected diagnostics and symptom-reporting mobile applications, combined with standardized electronic collection of epidemiological and clinical data, has great potential to enhance the efficiency and speed of management of both epidemic and endemic infections, including the management of referrals where appropriate.[119] This was put into perspective during disease surveillance of Ebola and Zika outbreaks where it was used to track, analyse, and share data quickly and effectively.[120] Further, real-time reporting of diagnostic test results

can enhance disease surveillance through the geo-spatial mapping of infections via geo-tagged test results, [121] or social network and internet search analysis, thereby providing new tools for assimilation into outbreak control.[122] Other uses of mHealth technology include patient education, support and motivation, drug supply-chain and stock management, patient education and awareness, emergency and disease surveillance and intervention monitoring and data collection/transfer and reporting. [117,123]

Although many mHealth initiatives in Africa are still in the development and pilot phases, a growing number of applications have been implemented.[117,118] Currently, a majority are focused on the use of established mobile technologies, such as text messages and calls, to connect healthcare workers and patients to each other and to test results.[118] [123,124] [117] Text messages have been found to be effective for communicating information in a health-care context and have been well accepted by users. Research also indicates that text messages could serve as a powerful tool for behaviour change both in developed and developing countries.[125] [126]

According to a systematic review on the impact of mHealth interventions, a consistent improvement on healthcare appointments' attendance rates has been demonstrated when using text messages and/or phone call reminders compared to no reminders or postal reminders.[127] Similar findings were reported in another systematic review which reported that text message-based interventions increased adherence to antiretroviral therapy (ART) and smoking cessation although there was no significant effect on the number of cancelled appointments and adherence to clinic attendance between using SMS reminders versus other reminders .[128]

mHealth Interventions and various Health Conditions

A recent systematic review of peer-reviewed literature on mHealth projects in Africa, between 2003 and 2013, found 44 studies on mHealth projects in Africa. Most of these are on HIV,

malaria, tuberculosis, diabetes and antenatal care.[129] Until recently, mHealth interventions for managing disability conditions such as hearing and visual impairment were less common, especially in Africa. However, this is now changing with the evolution of smart-phone based diagnostic tests such as the smartphone-automated pure-tone audiometry (hearTest™) and speech-in-noise testing (digits-in-noise test) used to detect and monitor hearing loss using minimally trained personnel.[130]

mHealth interventions in the management of HIV

improving adherence to referrals using text messages

In a randomised controlled trial conducted in Kenya to investigate the effect of short message service (SMS) text messaging on post-operative clinic attendance, a modest improvement in attendance at the 7-day post-operative clinic visit following adult male circumcision compared to a control condition with standard care.[131] In another study conducted in Kenya, automated text message reminders sent at a daily or weekly frequency were found to be useful in improving HIV medication adherence.[132] In this study, weekly reminders seemed to be the most effective in improving adherence compared to daily reminders and no reminders. Further, short reminders to take medications only were found to be more effective than long reminders that provided reminders and additional support to patients. Similar results were reported in the WelTel Kenya1 study, a multisite randomised clinical trial designed to promote antiretroviral (ARV) medication adherence among HIV-infected adults using weekly SMS text messages, followed by phone calls to patients who failed to respond within 48 hours. [133] This shows that a simple and cheap intervention such as automated reminders for HIV patients on antiretroviral therapy can significantly increase adherence, and mobile phones might be effective tools to improve patient outcomes, especially in resource-limited settings.

Interventions for diagnosis support and Linkage to health facilities

Some mHealth interventions have combined the use of text messages with portable diagnostic devices that connect, and report results automatically in a bid to streamline disease

management. A good example of this is SmartLink, a health app designed to provide HIV-related laboratory results, information, support, and appointment reminders to engage and link patients to care. [134] A multisite randomized controlled trial study conducted in South Africa on the ability of SmartLink to improve linkage to care for HIV-positive smartphone owners found evidence that app-linked information and prompting can lead to increased linkage to care compared to standard care, especially among young people aged 18 to 30 year. [134]

Improving health information system and reporting

In Kenya, a mobile phone-based Prevention of Mother-To-Child Transmission (PMTCT) cascade analysis tool mPCAT was used to provide facility-based health workers with a quick summary of the number of patients and percentage drop-off at each step of care cascade, as well as how many women-infant pairs would be retained if a step was optimized. [135] The app gives frontline health workers and facility managers an immediate, direct, and tangible way to use their clinical documentation and routinely reported data for decision making for their own clinical practice and facility-level improvements.

Intervention to motivate and behaviour change in the adolescences

Closely related to the mobile based applications are smartphone games which have become increasingly popular as part of mHealth interventions, especially those targeting young people. A good example of this is “Tumaini”, a narrative-based interactive smartphone-based game designed to help prevent HIV among children aged 11 to 14 years by delaying first sex and increasing condom use at first sex. [136] According to a randomized feasibility study conducted in Western Kenya to assess its acceptability, the intervention was found to be acceptable both to adolescents and their parents and that of the study methods used to pilot-test the intervention.[136]

mHealth intervention in management of Malaria

In Malawi, text-message reminders to health workers were found to provide a platform to improve understanding of treatment guidelines and case management decision-making skills, although there was no evidence on the effect on actual adherence to case management guidelines for malaria and other diseases guidelines. [137] This shows that, although technology can help address structural barriers and facilitate improved clinical practice, it does not replace the need for human interaction, for example through targeted supervision or two-way technology communication, which are essential components of a successful intervention.

Interventions to report medicine stock outs and improve adherence to medication

Adherence to medication and treatment

Apart from the use of SMS-based messaging systems to improve patient follow-up and adherence to medication and treatment, a number of mHealth interventions have made use of software applications to improve the delivery of health services. A good example of this is SIMpill, a pill dispensing system that embeds a SIM card in a small pill bottle, which registers and sends an SMS text to a central server each time the bottle is opened.[118] Each text message is assigned a unique identification code which is linked to the patient's mobile phone number and has a time-stamp to show when it is sent. If the central server does not receive text messages before a certain pre-specified time, a reminder text is automatically sent to the patient's mobile phone and an alert is also sent to the healthcare provider who can follow up directly with the patient. [118]

According to a pilot study conducted in South Africa to assess the effectiveness of SIMpill, adherence rates of between 86-92% with treatment success rates of 94% were reported after using SIMpill for 10months, up from 22–60%.[138] A similar but less expensive system, SIMmed which requires patients to dial into a central server using their phones each time they take their medications showed compliance rates of up to 90%, but health outcomes such as treatment

success rates have not yet been studied. [138]

Reporting Pharmacy stockouts

Still in Malawi, SMS-based communication and professional networking was found to improve support to community health workers working in rural areas of Malawi. [139] In this study, the health workers reported using SMS to report medical supply shortages, obtain or communicate general information, and report patients with emergencies. Communication via SMS took an average of nine minutes, whereas health workers in areas without SMS generally had to report any issues in person and this took an average of 24 hrs. Further, the health workers who were using SMS-based interventions as part of their day-to-day work claimed that they had gained more respect and confidence from the communities that they served and had to make fewer referrals to district hospitals since they could handle more problems on their own. [139] Similar findings were reported in Ghana, where mHealth interventions targeting health providers and rural women were found to have the potential to reduce barriers to equitable access to maternal and child healthcare services in rural settings. [140]

Intervention to promote safe delivery and neonatal care

Apart from promoting adherence to treatment, a number of mHealth interventions have been designed as tools to provide health workers' access to health information, decision making, and/or logistical support. Safe Delivery App (SDA) is one such app which provides animated clinical instruction videos in basic emergency obstetric and neonatal care with the aim of improving knowledge and skills of health workers located in the periphery of the health system in order to improve quality of care and potentially save the lives of mothers and new-born babies. A qualitative study conducted within five districts in West Wollega Zone of Ethiopia to explore users' experiences with using the SDA and their perceived ability to conduct safe deliveries found that the health workers perceive the SDA as having improved their ability to manage complications during childbirth and have gained increased recognition and trust from the communities. [141]

Interventions delivered by mobile phone for Eye care

In eye care, innovative technologies are emerging to test visual acuity easily and objectively, correct refractive errors inexpensively, capture retinal images with portable tools, train cataract surgeons using simulators and share or access ophthalmic advice remotely. These advancements have enabled non-specialised ophthalmic practitioners to provide low-cost, high impact eye care in resource-limited regions around the world.[142] For instance, tele-ophthalmology using portable retinal imaging technology, mobile phone and Internet connectivity has been found to improve access to diabetic retinopathy (DR) screening services in Sub-Saharan African countries where the burden of diabetes is increasing and there is limited access to eye care services and specialists. [143] [144]

Peek Acuity, a smartphone-based visual acuity test which enables health workers to test eyes easily and affordably using a smart-phone in the community and refer those who need further care appropriately was designed to address this gap and overcome the barriers of limited access associated with traditional ophthalmic testing methods.[145] Clinically validated in 2014, this app has been found to produce accurate and repeatable acuity measurements comparable to the conventional methods for visual acuity testing. [146] The test uses the touchscreen interface to record participant's responses without the user needing to see the screen. This makes the test both faster, objective and easy to use by both healthcare and non-healthcare professionals such as teachers.

Similarly, non-clinicians using Peek Retina for the detection of optic nerve abnormalities were able to capture quality optic nerve images that were comparable to those obtained from a standard desktop retinal camera operated by trained eye care personnel.[147] It was further shown to be an acceptable tool to patients, care givers and stakeholders.[145]

A referral app, Vula, connects primary health workers, especially those in remote areas, with specialists in hospitals through technology. This app allows health workers to capture basic patient information, take photographs, do a basic eye test, capture a brief medical history and send all this directly to a specialist over a dedicated messaging platform for diagnosis.[148] However, this app has not been clinically validated or certified.

PhD Conceptual framework

Overall, several mHealth interventions have been designed to improve health service delivery, client health outcomes and for health research. Interventions for patients includes those that aim to improve chronic disease management, medication adherence, appointment attendance, or change health behavior.[149] [150,151] Depending on the purpose of the intervention and health outcome, mHealth interventions have been designed for use by researchers, healthcare professionals, patients, or the general population. A conceptual framework for mHealth intervention classification was developed by Free et al, figure 1.3.[152]

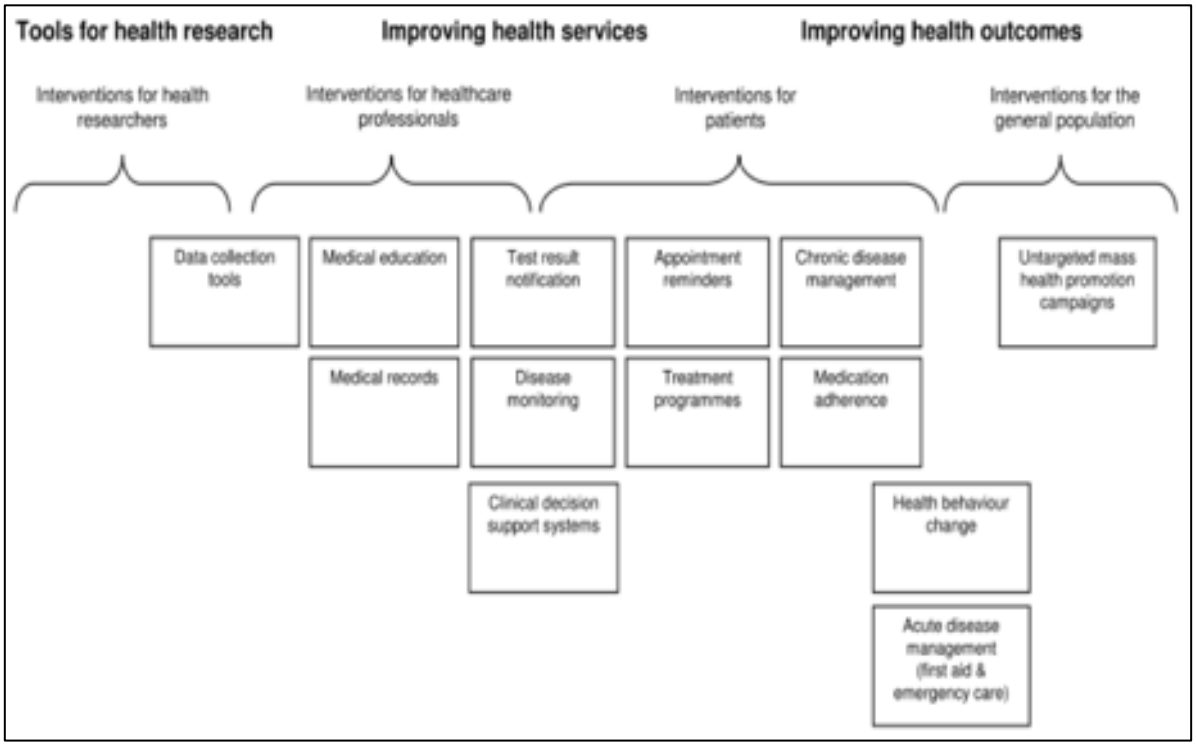


Figure 1.3: The conceptual framework used for mobile electronic intervention classification

Source: *The effectiveness of M-health technologies for improving health and health*[152]

The two domains relevant to this PhD are those focusing on improving health services and research related to eye care. The interventions thus include patient appointment reminders; clinical decisions support system for the general healthcare professionals and data collections tools to support research and health care professionals.

Rationale

Africa is undergoing a health transition owing to the rapidly increasing population and urbanization.[115] Health needs remain unmet for many. For example, only 58% of people in sub-Saharan Africa have access to safe water supplies.[116] In relation to visual impairment, about 15% of the world's population lives in Africa and contributes about 5.9 of the 36 million (15.4%) blindness.[153] Access to eye care remains a challenge owing to the huge shortage of human resources for eye health in both the public and private sectors, particularly in rural areas.[49] The majority of the ophthalmic personnel available, including ophthalmologists, optometrists, ophthalmic clinical officers and ophthalmic nurses among other cadres, are largely concentrated in urban areas while a majority of the people in need of the services live in rural areas.[51] [44] This has created a disconnect between the "need" and the "service providers". [44]

With today's knowledge and technology, cost-effective interventions that can help reduce the disease burden in Africa, including eliminating the unnecessary burden related to avoidable blindness are available.[142] However, low coverage and lack of access to healthcare services remains a major challenge due to the weak health systems. As a result, millions of people in Africa remain at risk of vision loss due to the lack of basic eye care services. [154]

One way to address these challenges is through the integration of mHealth interventions to improve access and delivery of healthcare service to those in need, especially in the rural areas.[149] In resource-limited settings, where health services may be lacking or overwhelmed, mHealth interventions are particularly useful in bringing health services closer to the community where the need is.[118] Taking diagnostics outside the formal health facility setting and linking the output of testing into the appropriate referral pathways of clinical and preventative care that can be delivered in the community could yield more cost-effective and

user-friendly healthcare.[117,155] In principle, these interventions are likely to increase the accessibility and affordability of healthcare services for those in need.

With the increasing mobile phone penetration in Africa, mobile health technology has provided new innovative approaches of delivering eye care without the previously required infrastructure.[142] In limited-resource settings, and with the critical shortage of health professionals, mHealth interventions have been increasingly adopted and have shown promise for improving the delivery of health care services.[156] However, although there are a number of mobile applications available for vision testing in Africa, very few had undergone validation or certification.

Fundamental to clinical practice is the concept of evidence-based medicine, and as such clinical decisions need to be guided by the scientific literature. Therefore, while mobile phone technology continues to improve in Africa, there is a need for research to fully understand the potential of mHealth technology, and its integration into health care, and more specifically in eye care.

Theory of change

Peek harnesses the portability and connectivity of mobile devices with the ability to undertake a comprehensive eye examination at school or in the community close to patients.[157] It also enables task shifting by allowing non-eye care specialists to conduct large-scale vision screening, identify patients requiring specialist review and connect them to the local services thereby making efficient use of the limited resources available. The Peek diagnostic apps and associated system could improve the accuracy of management decisions in the primary setting and reduce the pressure on the main hospital. Based on the three domains described earlier,[128] the Peek package for this trial includes a decision support algorithm to make a referral decision, a data capture system with referral notifications and an in-built SMS reminder system.

It is expected the intervention will increase the access to planned specialist assessment and hence early treatment of eye ailments, figure 1.4. The Peek intervention would enable health workers to make accurate management decisions and refer those who need further assessment, increasing the overall number in the population accessing basic eye care services without over burdening the overstretched capacity at secondary care level by managing more patients in the primary health care level and expediting referral to secondary care earlier for patients with preventable sight loss.

Those referred to the secondary care services will be captured in the system and the hospital services will be notified of participants who are referred using a hospital based “Reception App”. Automated reminder SMSs was be sent to non-attenders on the need for attending referral and for follow-up.

Figure 1.4: Role of the interventions in the reduction of the prevalence of Visual Impairment

Sources : *(Developed from the concept of change by the primes study[158])*

Hypothesis and Research aims

Hypothesis

We hypothesized that the integration of Peek Solutions into the local health care system will increase the uptake to appropriate eye care services.

Aims

The main aim is to develop, describe and evaluate a demonstration model of community volunteers and teachers using Peek in communities and schools, respectively, to identify referable eye conditions, refer those with eye problems for treatment and monitor adherence so as to reduce avoidable visual impairment in the population.

The specific aims are:

1. Determine the current utilisation of eye health services in Trans Nzoia County.
2. Develop and validate smartphone diagnostic algorithms for use in school eye health programmes
3. Describe the process of adoption and scaleup from a trial to an integrated school eye health programme
4. Develop and validate algorithms for door to door community screening (Peek community Screening) for use in eye care by Community volunteers to identify and refer people with eye problems
5. To evaluate whether using Peek Community eye health system can lead to increased uptake of eye care and appropriate use of services.

Study Setting

The study was conducted in Trans Nzoia County in Kenya (Figures 1.5 and 1.6). Trans Nzoia County in Western Kenya has a population of 818,757 people (2009 census) of which 407 172 (49.7%) were male. Children aged 0-14-year olds constitute 47% of the population, figure 1.7.[159] There were 173,719 households, with an average of five people per household. About 669,347 (81.8%) of 818,757 have no internet access.[160]

There are 734,293 people aged 3 years or older of which 329,764 (44.9%) were in school, 302,083 (41.1%) had left school while 88,592 (12.1%) have never attended school.[161] Also there are 761 Early Childhood Development (ECD) centres, 525 primary schools, 169 secondary schools (151 public and 18 private), 14 polytechnics and 4 university campuses in the county. Each primary school has an average pupil population of 400 - 500 children.[162]

There are 61 government health facilities (6 hospitals, 12-health centers, 43 dispensaries) and 76 health facilities owned privately or by faith based organizations.[163] The studies included in this PhD thesis were conducted in government run health facilities.

Figure 1.5: Kenya and Trans Nzoia county

Source : google maps[164]

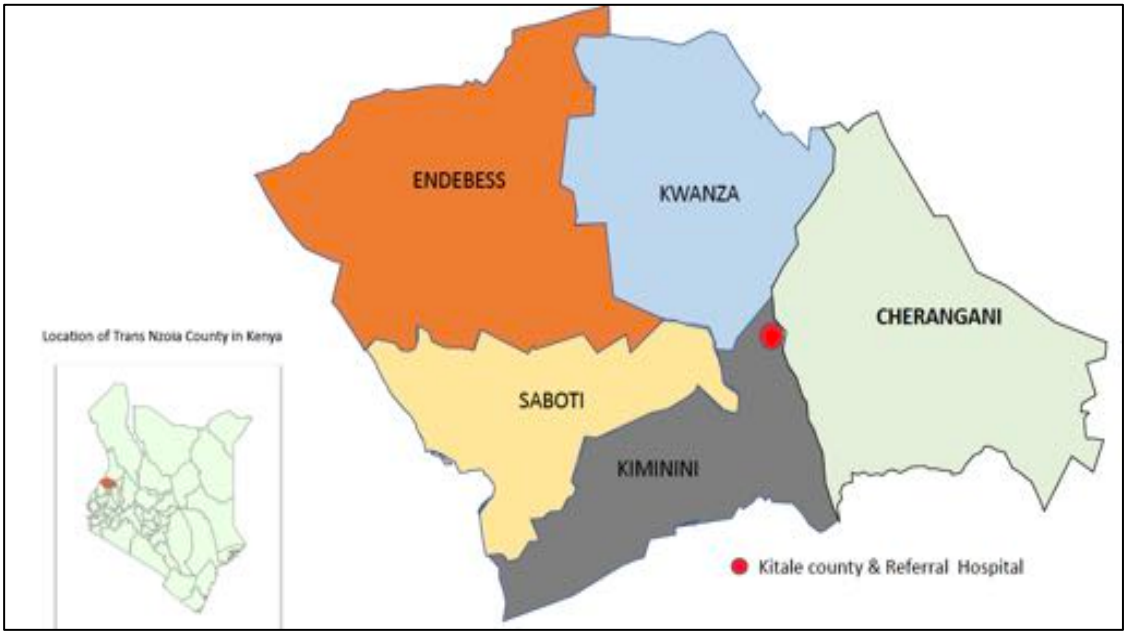


Figure 1.6: Location of Trans Nzoia County in Kenya and the sub counties in relation and Kitale County & Referral hospital

Source: *Modified from a report by Kenya National Bureau of statistics et al.*[165]

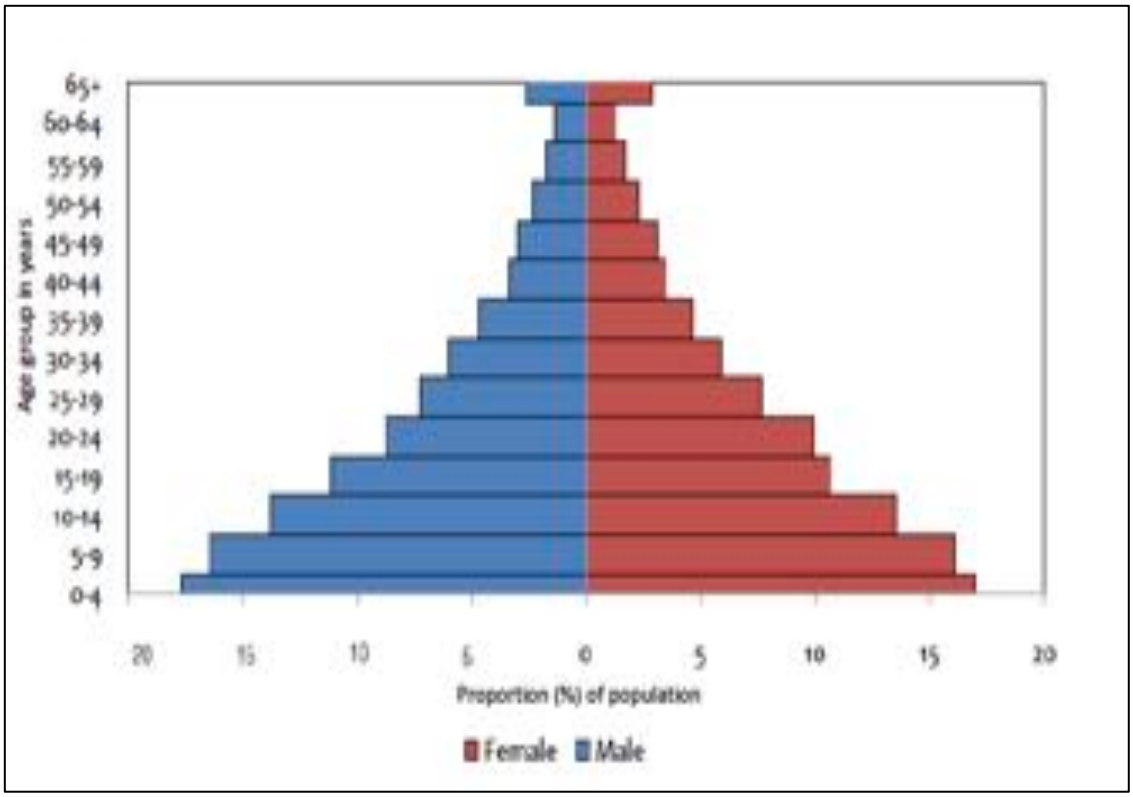


Figure 1.7: The Population structure of Trans Nzoia County

source: Exploring Kenya's Inequalities: Pulling apart or pooling together? Trans Nzoia County. [165]

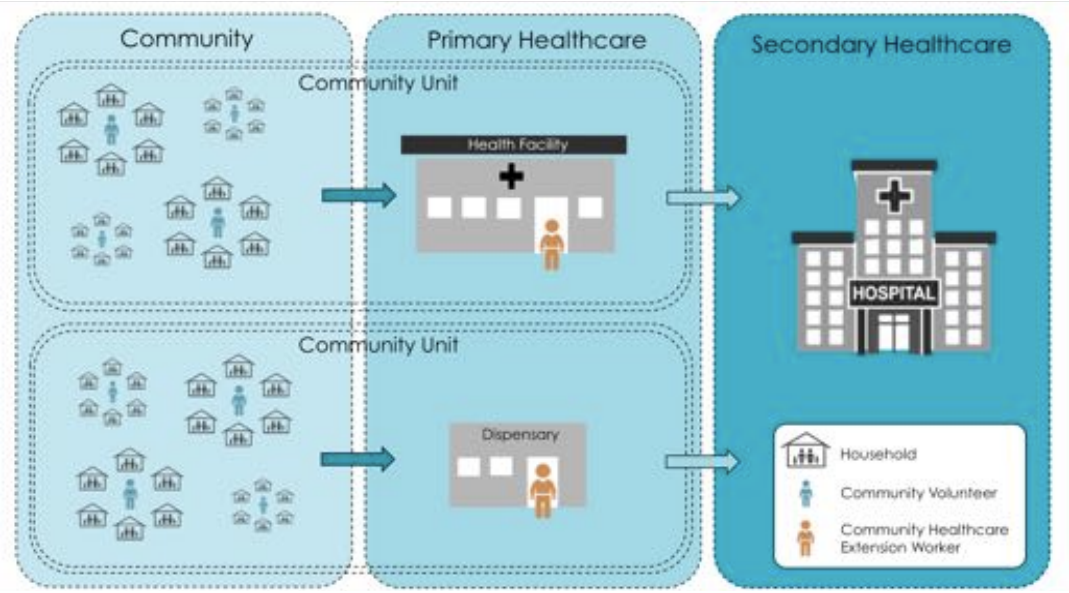
Kenya Health service structure:

There are two levels of health service delivery, National and County (regional) governments, Table 6.[166] The national government is responsible for national hospitals, policy formulation and quality standards, while the County Governments are responsible for delivery of health care.[167] The communities are empowered to identify their own health priorities and find solutions, while the government's role is to facilitate the provision of quality services.[167] Most eye clinics / hospitals are at level 5 and 6 of the health system.

Table 6: The structure of the Kenyan health system

Government responsible	Levels of Health services	Human resources	Population served
National Government	Level 6: National and Tertiary hospitals	Specialists + level 5 staff + trainees	20,000,000-25,000,000
County Governments	Level 5: County referral Hospitals	Consultants specialists, Internship trainees and Level 4 staff	500,000 - 1,000,000
	Level 4: Sub-County Hospitals	Medical officers + level 3 staff	100,000 - 200,000
	Level 3: Health Centres	Clinical offices, Registered nurses, public health officers, lab technicians, community health extension workers (CHEW)	20,000- 40,000
	Level 2: Dispensaries	Enrolled Nurses, Public Health technicians, 1 CHEW = 50 CVs	5000 - 10000
	Level 1: Community	Community Volunteers (CV), 1 CV = 20 households, 1 House hold = 5 - 6 people	100

Health centers and dispensaries are the first contact of the community with the health system. A dispensary or health centre together with the community it serves is defined as a **Community unit,** (figure 1.8).



Courtesy: Andrew Bastawrous

Figure 1.8: Organization of County health system and referral pathway

The Community Health Extension Workers (CHEWs) at the health centre or dispensary train, support and supervise the community volunteers (CVs). CVs are community members selected by the community to represent them on issues of health.[168] Their roles include health promotion and participating in meetings organised by the CHEWs and the Community Health Committee.

A Community Unit (CU) is composed of 20 to 50 CVs attached to a dispensary or health Centre, in which one or two CHEWs are based, and serves a population of 5,000 - 10,000 people. The CU has a Community Health Committee with defined roles and governance responsibilities.[168] The community volunteers form a vital link between the health care delivery system and the community.

In Trans Nzoia County, there are 137 health facilities with 1,251 workers, and 85 out of the 180 CUs have been formed (as of August 2018).[169,170] The health worker to 100,000 population ratio is 5.4 for doctors, 9.6 for allied medical worker (clinical officers) and 47 for nurses.[163] This is half than the recommended WHO ratio of 230 per 100,000 population for any cadre.[50] Eye services are offered at Kitale Eye Unit and through outreach services (provided by eye care

staff from Kitale) to other health facilities. Screening and treatment of eye conditions (Triage) is offered at most health facilities. The challenges encountered include those related to the health system in general: few health facilities, high cost services, and few health workers.[163] Challenges for setting up outreach-screening include: impassable roads, lack of electricity, and lack of data for planning.

Eye care system

Kitale Eye Unit is the only eye unit in the county and is located at the main county hospital in Kitale (figure 1.9). The Unit provides secondary eye services daily at the central unit and through mobile outreach services at peripheral health centres. The unit staff also provide supportive supervision and training for the Health workers within these other facilities.[171] The unit has one ophthalmologist, four ophthalmic clinical officers and eight nurses (two working outside the eye unit). Each consultation visit costs about one USA dollar while eye drops or surgery are subsidised but paid separately. Spectacles are not provided at the hospital.

Figure 1.9: Kitale Eye Unit, Kenya

The local eye health system is under resourced and the majority of the population has limited access to eye care services, particularly vulnerable groups such as the elderly, females and those of low education or low socioeconomic status. From routine data, many patients who attend eye clinics in Kitale have conditions that could be managed at primary health care facilities, hence overcrowding the central eye clinics that should be used mainly by patients who need to be managed at that level. The limited number of eye care providers are required to attend to all patients who present to the eye hospital. This heavy workload is a source of stress on the health care system, eye care workers frequently burnout leading to poor quality of services being offered.

This PhD project was designed to enable integration into the health system with the health personnel in each of those levels' being enabled to perform activities that would lead to realization of the aims of the study. The CVs and teachers in the community were supported to make accurate management decisions and refer those who need further assessment, while at primary health care level triage and referral was provided to increase the overall number in the population accessing basic eye care services without over burdening the overstretched capacity at secondary care level, figure 1.10.

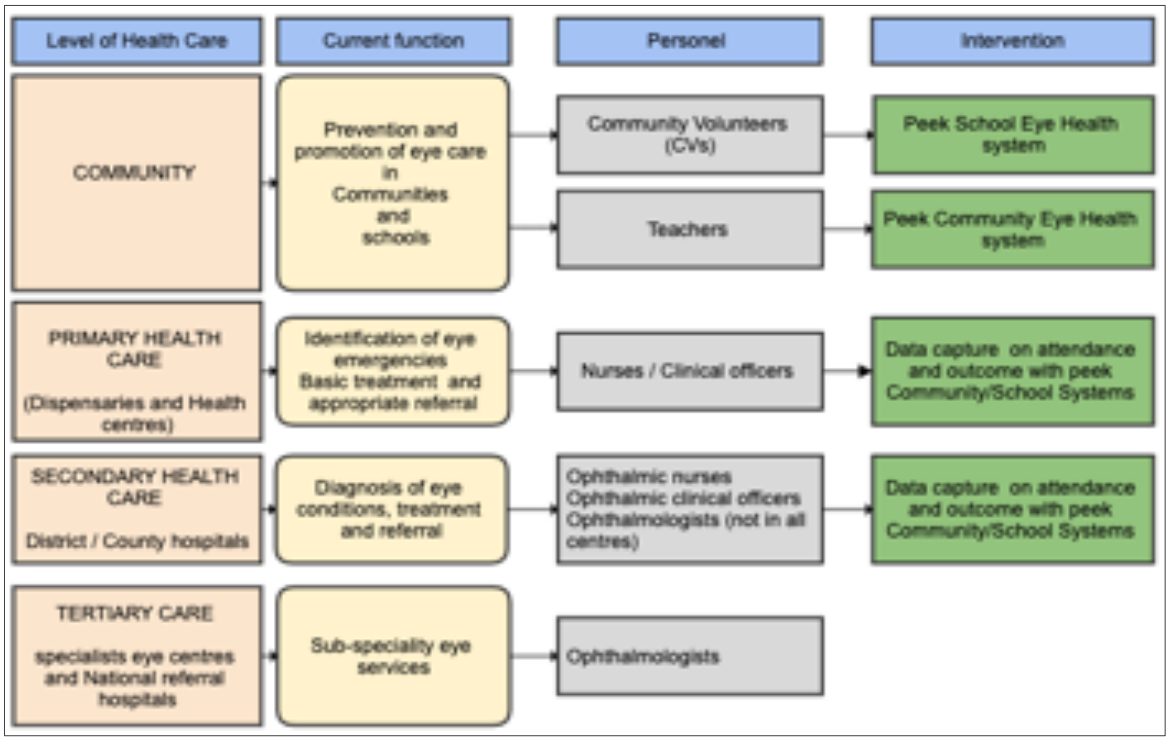


Figure 1.10: Level of health care & current functions, health workers and Peek interventions

Thesis structure

This PhD thesis is in the "research papers" format and contains eight chapters including this chapter on the background and addressing the objectives of the thesis. The thesis contains three published papers, two under peer review as well as two being submitted for peer-review and publication. The sequence of papers follows a logical sequence starting with a literature review (this chapter) and progressing to analysis of the current situation, the intervention development, trial protocol followed by the trial results. Some papers were written simultaneously while others had longer peer-review processes, meaning that the papers were published in a slightly different order than as presented. The contribution of others to these publications and the thesis are stated in the acknowledgment and research paper cover sheets for each chapter.

Chapter 1 presents an introduction to the thesis as well as relevant background literature, on magnitude and trends of visual impairment, risk factors, mHealth interventions and behaviour change theory, aims and objectives and thesis outline.

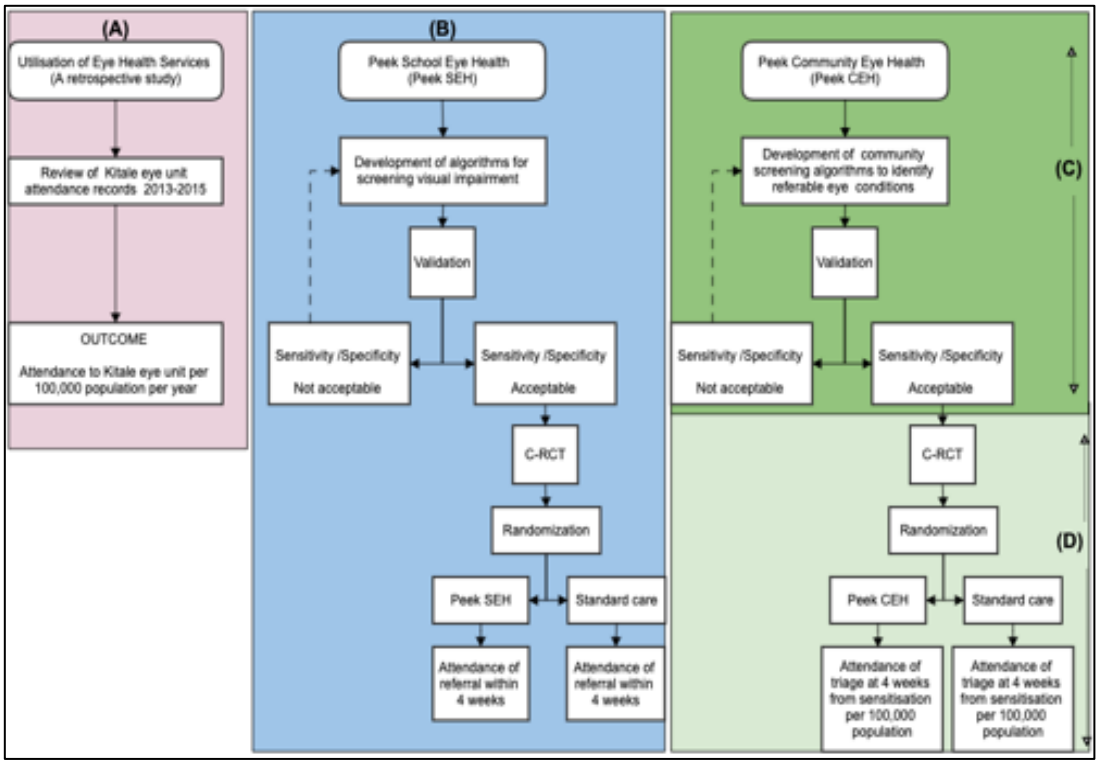


Figure 1.11: Study designs for some research papers in the PhD Thesis

Chapter 2 is a research paper on the utilization of eye services in the study area before the intervention. At the time [Dates, 2013-15] there were minimal or no primary eye care services with most eye care provided at the secondary centre, Kitale Eye Unit. The paper is a retrospective review of records on utilization of eye services at Kitale Eye Unit between 2013 to 2015, figure 1.11A. Information from the hospital database was used to assess attendance while the 2009 census reports provided population data for specific areas, age and gender, that was used for direct comparisons. This paper provides an outline of the utilization of eye services by age and gender and the eye conditions and provides key baseline information for comparison post intervention. The article is Open Access and distributed under the terms of the Creative Commons Attribution 4.0

International License which permits unrestricted use, distribution and reproduction in any medium, appendix 2.

Citation: Hillary, K., Macleod, D., Bastawrous, A., Wanjala, E., Gichangi, M., & Burton, M. J. (2019). Utilization of Secondary Eye Care Services in Western Kenya. International journal of environmental research and public health, 16(18), 3371.

Chapter 3 is a published research paper describing the validation, implementation and results of the system level intervention in school children. This paper has two parts; the first part comprises the development and validation process and the results of the validation of the mHealth interventions when used by school teachers, figure1.11B. Here results obtained from teachers using the smartphone Peek Acuity app are compared to those from by the clinical officer using the reference standard EDTRS chart. The second part of the paper describes the methods and the results of a cluster randomised controlled trial with a primary outcome of increasing adherence to the hospital services for children identified with VI.

I presented the results at the 9th General Assembly of the International Agency International prevention of blindness in Durban, South Africa in 2016 and previously at The Royal College of Ophthalmologist Annual Congress, UK in 2015. The results of this paper were used to develop and scale up a screening program described in chapter 4. The paper is an open

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citation: Rono HK, Bastawrous A, Macleod D, et al. Smartphone-based screening for visual impairment in Kenyan school children: a cluster randomised controlled trial. The Lancet Global Health 2018; 6(8): e924-e32.

Chapter 4 presents the process of practical steps to scale up a programme from the research. The three phases of the PRIME framework (formative, implementation and scale up phases) are described how there are interlinked factors influencing the process. The Peek School Screening programs as a model is acceptable and effective in screening for visual impairment in this population. This program was declared the best innovative programme in the Africa by the African Union at the 2018 All African Public Service Innovation Awards (AAPSIA 2018) at a ceremony held in Addis Ababa, Ethiopia.

Chapter 5 is a research paper under peer review as of September 2019**.** It outlines the development process and the results of validation of the Peek Community Screening App (that support non eye care workers to make referral decisions on patients) over a number of iterations, where the algorithm was altered to improve its performance, before settling on a final algorithm deemed acceptable to be used in community screening. The paper highlights the validation process, where the results of the app when use by community volunteers were compared with those from an experience ophthalmic worker using standard outreach equipment, figure 1.11C. The paper highlights the potential for mHealth in supporting task-shifting especially in areas with scare eye health workers.

Chapter 6 is a published trial protocol research paper outlining the details on the study design, intervention, study hypothesis, sample size calculation, outcome measures and effect measures of the randomised community trial that is described in chapter 7, figure 1.11D. The

Citation: Rono H, Bastawrous A, Macleod D, Wanjala E, Gichuhi S, Burton M. Peek Community Eye Health - mHealth system to increase access and efficiency of eye health services in Trans Nzoia County, Kenya: study protocol for a cluster randomised controlled trial. Trials 2019; 20(1): 502.

Chapter 7 is a research paper prepared for submission that presents the results of a community cluster randomised controlled trial described in chapter 6 that was designed to investigate the effects of the mHealth interventions in a health system. The main outcome was attendance of primary eye care facilities (dispensary and health centres) for triage at weeks from sensitization. This chapter contains analyses of primary and secondary outcomes with an aim of understanding the effect of intervention on overall uptake of eye services and by gender and age. it also contains quantitative analysis barriers that determine utilization of secondary eye services and the eye conditions among patients seen at triage and hospital. This paper is being submitted for peer-review and preliminary data was presented at the Commonwealth Eye Health Consortium research meeting in London, March 2019.

Chapter 8 is the presentation of the summaries of the main findings of the thesis, its overall strengths and limitations. The implications the findings in relation to other studies in the eye care and interventions are discussed and finally, recommendations for practice and further research explained.

Ethics

The ethical principles of the Helsinki declaration and Principles of good clinical practise were followed. I completed the e-learning courses on Good Clinical Practice course at the London School of Hygiene & Tropical Medicine in December 2017 and also the web-based course on protecting Human Research Participants at the National Institute of Health (NIH) in June 2014, appendix 5

Ethical approval was obtained from the London School of Hygiene & Tropical Medicine Medical (LSHTM) Ethics Committee and Institutional Research and Ethics Committee (IREC) of Moi University, Eldoret, Kenya. When there was a delay in field work due to elections, re-elections and health worker strikes an approval for extension of research period was granted.

- Utilization of eye services in western Kenya, retrospective study: Kenya (IREC /2016/40), appendix 6; LSHTM (number 10509) appendix 7.
- School eye health system approvals: LSHTM (8835), appendix 8; Kenya (IREC 001359) appendix 9 and ratification of extension of the study period (IREC 0001258), appendix 10.
- A scale up process from research to scaled up project; case study of the school eye health project. The upscaling process was now routine practices outside research setting, therefore ethical approval was not required, appendix11.
- Development and validation of community screening system approvals: Kenya (IREC 001644) appendix 12 and ratification of extension of the study period (IREC 0001258), appendix 13; LSHTM (10508) appendix 14
- Community cluster randomised controlled trial (C-RCT): Kenya (IREC 3025) appendix 15; LSHTM (14633), appendix 16.

Both the school and community cluster randomised trials are registered with the Pan African Clinical Trials Registry (PACTR), numbers PACTR201503001049236 and PACTR201807329096632 respectively. (appendix 17 & 18 respectively)

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Chapter 2. Utilization of Secondary Eye Care Services in western Kenya

Figure 2.1: Ophthalmologists examining a patient on slip lamp

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RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS.

SECTION A – Student Details

Student	Hillary Kipkemboi Rono
Principal Supervisor	Dr. Andrew Bastawrous
Thesis Title	Increasing Access to Eye Care using Mobile Phone-based Interventions. The development, validation and implementation of Peek to optimise human resources and lower barriers to access for those most in need

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 Environmental Research and Public Health. citataion Rono MMed, H.K., et al., Utilization of Secondary Eye Care Services in Western Kenya. International Journal of Environmental Research and Public Health, 2019. 16(18): p. 3371		
When was the work published?	Received: 23rd July 2019 Accepted: 7th September, 2019 Published 12th September, 2019		
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?*	**Yes**	Was the work subject to academic peer review?	**Yes**

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SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	N/A
Please list the paper's authors in the intended authorship order:	
Stage of publication	Choose an item.

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)	Together with my senior colleagues I designed the study, prepared the protocol, led the data collection. Conducted initial data analysis and wrote the first draft of the paper with edits from supervisors and co-authors

Student Signature: [redacted] **Date:** 08.10.2019

Supervisor Signature: [redacted] **Date:** 09.10.2019

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Article

Utilization of Secondary Eye Care Services in Western Kenya

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Abstract: Background: Eye care provision is currently insufficient to meet the population's eye health needs in Kenya. Many people remain unnecessarily visually impaired or at risk of becoming so due to treatable or preventable conditions. A lack of access and awareness of services are key barriers, in large part due to their being too few eye care providers in the health system for this unmet need. **Methods:** A hospital-based, retrospective analysis of patients who attended Kitale eye unit, Trans Nzoia County, Kenya from 1st January 2013 to 31st December 2015. Age and sex standardized hospital attendance rates by residence, age group, and sex were calculated for Trans Nzoia county and each subcounty. The changing trends in attendance rates were estimated by calculating the difference between base year and last year. Incidence rate ratios for attendance for each age-group, sex, and residence were estimated using a multivariable regression model. **Results:** 20,695 patients from the county were seen in Kitale Eye Unit in 2013, 2014 and 2015. In that period, 8.3% had either uncorrected refractive error, cataracts or glaucoma, the priority VISION2020 diseases, and 61.0% had allergic or other conjunctivitis or normal eyes, which could potentially be managed at primary eye care. During the study period, overall average annual attendance rate increased from 609 to 792 per 100, 000 population, incidence rate ratio (IRR) 1.30 (95% confidence interval (CI) 1.26–1.35). Attendance rates increased more in females than males (34.7% vs. 25.1%, respectively), IRR 1.07 (1.04–1.10). Attendance rates increased with increasing age, (highest among the elderly compared to the young). We found that in extreme age groups (>75 years and <15years) females were less likely to attend than males and there was reduced utilization from those based furthest from the hospital. **Conclusion:** Specialist eye services are heavily utilized by people with conditions that could be managed at the primary health care level. Barriers to accessing eye services were distance and gender, especially among the most vulnerable groups (young and the elderly). Integration of primary and secondary eye care services could lower barriers to essential eye care services to the population whilst lowering pressure on the limited specialist services by ensuring more appropriate utilization.

Keywords: eye problems; eye health services; eye care utilization; routine hospital records; visual impairment and blindness

1. Background

About 36 million people are blind worldwide (visual acuity in the better eye < 3/60) and another 217 million are severely or moderately visually impaired (visual acuity in the better eye < 6/18) [1]. There is notable variation in the distribution of both blindness and Visual Impairment (VI) by region and gender. About 90% of people with blindness and VI live in low and middle-income countries (LMICs) such as Kenya [2]. Results from 11 population-based studies in sub-Saharan Africa suggest about 26 million people are visually impaired of whom, almost 6 million are blind [3]. The main causes of VI are uncorrected refractive errors (42%) and cataract (33%); both of these cause avoidable VI [3]. Recent studies have shown that the prevalence of VI is decreasing. However, women have a higher prevalence of blindness than men [4]. Despite the reduction in the prevalence of blindness, the number of people with VI has risen due to an increase in population and improved life expectancy [1].

There are multiple reasons for the high prevalence of VI in LMICs. Most of these relate to poverty and barriers to access and utilization of eye care services [5]. Poverty is a critical social determinant of VI, and in turn VI leads to further poverty [6]. For instance, as a result of low socioeconomic status, patients have no insurance, yet they may have to incur high transport costs to the hospital, which limits the use of services [7]. They are also likely to have low education, low awareness of the eye conditions, low awareness of the services available, and fear of adverse outcomes from treatment [8,9]. Additional barriers might include negative attitudes towards services and difficult communication between providers and patients [10]. Studies in LMICs, have shown that the need for eye services is high and people often travel long distances to access these services [11]. Communities with inadequate or inaccessible eye care facilities tend to seek other alternatives of eye care services, including self-medication, which may further contribute to VI and blindness [12].

Health system barriers include insufficient availability of services, shortages of health workers trained in eye care, inadequate skills of health workers and poor-quality eye care services [13]. An inverse relationship between need and provision of eye care services exists, especially in sub-Saharan Africa, meaning that there are fewer services available where the need is greatest, such as in rural areas [14]. The effect of these challenges in LMICs is suboptimal access and utilization of eye care services. Identifying barriers that hinder access and utilization of eye care services is therefore key in overcoming the burden of avoidable blindness [15].

The World Health Organization (WHO) recommends improving access and utilization of health services and monitoring equity as part of universal health coverage (UHC) [16]. Some of the interventions to improve access to eye care services in the literature include peer education, deployment of staff to rural areas, task shifting and integration of services, supervision of health staff, eliminating user fees and provision of health insurance [17]. However, the interventions should be selected based on identified gaps, which are likely to be context-specific.

Few studies have however quantified the current utilization of eye services especially in Africa, therefore there is need to assess utilization of eye services so as to plan for efficient interventions and utilization. In this paper we report on the utilization of eye services in Trans Nzoia county, a county with an estimated population of 818,757 people in 2009 with one government-run secondary eye care unit, and three privately owned eye clinics. This evidence is useful for effective planning of services to reduce the burden of avoidable blindness.

2. Methods

A hospital-based, retrospective analysis of patients who attended Kitale eye unit, Trans Nzoia County, Kenya from 1st January 2013 to 31st December 2015 was conducted between June and October 2016. The study period was representative of standard practice as there were minimal non-surgical outreach services to the community from the hospital or other partners in this 36-month period; the eye unit at Kitale was operating optimally and it coincided with the final three years prior to devolution of Health services to the County governments in which considerable disruption to services was experienced.

Trans Nzoia County is located 400 km West of Nairobi, Kenya. According to the 2009 census, Trans Nzoia County had a population of 818,757 people of which 49.7% were male, with an annual growth rate of 3.0% [18]. About 50.1% of the population live on less than one USA dollar per day, and 18.2% work for pay (employed) [19]. The county is subdivided in to five sub-counties, Figure 1: Kiminini (190,912), Cherangani (195,173), Saboti (174,956), Kwanza (166,524) and Endebess (91,192) [18]. To provide some indication of how far patients have to travel from each subcounty, the mean distance to Kitale hospital from health facilities in each county was calculated. Distance between the primary health facility and Kitale was estimated from Google-maps [20]. The mean distance and standard deviation (SD) of health facilities in the sub-counties to Kitale from the nearest to furthest are: Kwanza 14.9 kms (8.0), Kiminini 16.1 kms (7.4), Saboti 16.2 kms (9.6) Cherangani 18.2 kms (7.4) and Endebess, 29.9 kms (3.9).

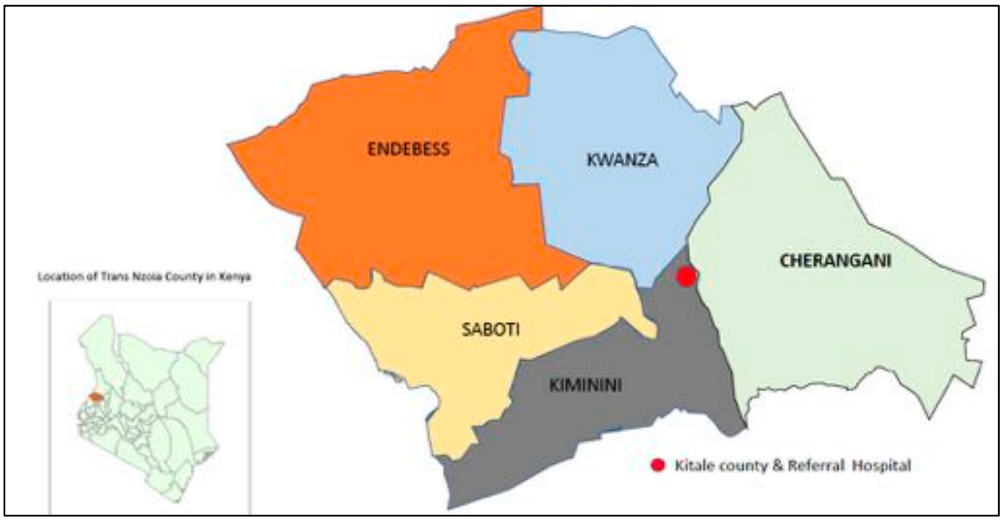

Figure 1. Location of Trans Nzoia County in Kenya and the sub-counties in relation and Kitale County & Referral hospital.

Modified from a report by Kenya National Bureau of statistics et al. [19].

There are 146 health facilities of which 61 (41.8%) are government public facilities (6 hospitals, 12-health centers, 43 dispensaries), 22 (15.1%) are Faith-based/not for profit and 63 (43.2%) are private [21]. The doctor to population ratio is 5.4 per 100,000; Allied medical worker (clinical officers) is 9.6 per 100,000 and the nurse population ratio is 47 per 100,000 people. This is lower than the recommended WHO ratio of 230 per 100,000 population for any cadre [22]. Kitale Eye Unit is the only public eye unit in the county that provides secondary eye services daily at the central unit, training, and periodic services through mobile outreach at peripheral health centres [23]. The unit has one ophthalmologist, four ophthalmic clinical officers and eight nurses (two working outside the eye unit). Each consultation visit costs about one USA dollar while eye drops or surgery are subsidised but paid separately. Spectacles are not provided at the hospital.

Ethical approval was obtained from the London School of Hygiene & Tropical Medicine Medical Ethics Committee (Ref 10509) and Institutional Research and Ethics Committee (IREC) in Eldoret, Kenya (IREC/2016/40). Permission was sought from the hospital to use the secondary data. The study adhered to the Declaration of the Helsinki.

We obtained data from Kitale's hospital database and the 2009 census report. All new patients who attended the Kitale eye hospital from 1st January 2013 to 31st December 2015 were included. We accessed the hospital attendance and morbidity Database (Med-boss) and extracted data for patients who attended Kitale County Hospital for consultations related to eye conditions for the 36-month period. Information extracted included age, gender, residence, date of first attendance, number of subsequent visits to the eye unit, diagnosis and visual acuity. Identifying information such as patient's

names and hospital numbers were deleted and a unique study number was assigned. Diagnosis was recorded based on the disease codes for routine reporting of eye diseases to the Ministry of Health, Kenya but reclassified using ICD10 classification [24]. The diagnosis recorded at first visit was used. Incomplete data such as those without location of residence, age or sex were excluded during analysis.

Records of the health facilities and their catchment locations was obtained from the department of health in the county. The 2009 populations and census report were used to obtain the populations for Trans Nzoia and the sub-counties by age group and sex. An annual growth rate of 3% was assumed and that was applied uniformly across age groups, in order to estimate the population for the period 2013–2015.

Best presenting visual acuity (vision in the better eye) was used to assess visual status. Blindness was defined as Visual acuity (VA) < 3/60 in the better eye with available spectacle correction. Severe visual impairment was VA ≥ 3/60 to < 6/60, moderate visual impairment was VA ≥ 6/60 to < 6/24, mild visual impairment was VA ≥ 6/24 to < 6/12 and normal VA was ≥ 6/12. We compared visual acuity in males and females using an ordinal logistic regression model, adjusted for age, location and year.

We estimated the rate of attendance to the eye unit at the hospital per 100,000 population for the years 2013–2015. This was done overall for Trans Nzoia and also stratified by subcounty, age group, and sex. The rate was estimated by dividing the number attending the hospital during the year by the estimated population. The rates of attendance for individual diagnoses were also estimated.

The trends in standardized attendance rates for the corresponding time periods were expressed as the annual average percent change (AAPC).

Analysis using the Poisson regression model was conducted using the standardized attendance rates as the dependent variable and the year of attendance to hospital as the independent variable. A Poisson regression model was conducted to evaluate the determinants of attendance adjusted for age, gender, residence and year of occurrence.

3. Results

3.1. Demographic Characteristics

A total of 24,776 patient records were extracted from hospital records on patients' attending Kitale hospital for eye-related problems in the period 1st January 2013 to 31st December 2015. Of these 4081 (16.5%) patients were from outside Trans Nzoia county and therefore excluded, leaving 20,695 patients for analysis.

Attendance to the Kitale general hospital in 2013 was 80,797, higher than the 57,127 in 2014 and 48,158 in 2015. In the eye department, attendance in 2013 was 5613 patients, fewer than in the subsequent two years (2014: 7336; 2015: 7746). Overall slightly more were women (52.4%) than Males, and about a third of patients were less than 15 years old. The mean age was 27.7 (SD 22.2), range (0–111) years. The subcounty where most patients came from was Kiminini (34.6% of all patients) whereas only 3.7% of patients originated from Endebess, the most remote of the five sub-counties, Table 1.

Table 1. Characteristics of Patients attending Kitale eye unit between 2013 to 2015 (*N* = 20,695).

Characteristic	*N* (20,695)	%
Year of attendance (*N* missing = 0)		
2013	5613	27.1%
2014	7336	35.5%
2015	7746	37.4%
Subcounty (*N* missing = 0)		
Cherangani	4111	19.9%
Endebess	761	3.7%
Kiminini	7178	34.6%
Kwanza	3755	18.1%
Saboti	4890	23.6%

Table 1. *Cont.*

Characteristic	N (20,695)	%
Age group (N missing = 1)		
<15	7389	35.7%
15–29	5496	26.6%
30–44	3016	14.6%
45–59	2258	10.9%
60–74	1645	8.0%
75+	890	4.3%
Sex (N missing = 839)		
Female	10,403	52.4%
Male	9453	47.6%

3.2. Visual Status of All Participants Attending Kitale Eye

Visual status of 17,912 patients were available. Information on vision from 2783 patients mainly children less than eight years old were not available because it was not measured. The majority of the patients had normal vision and were less than 30 years old, Figure 2. Visual impairment and blindness was common among those older than 45 years and increased with age. There was no evidence of a (OR 0.96, 95% CI 0.86–1.08, $p = 0.521$) difference in visual acuity between males and females.

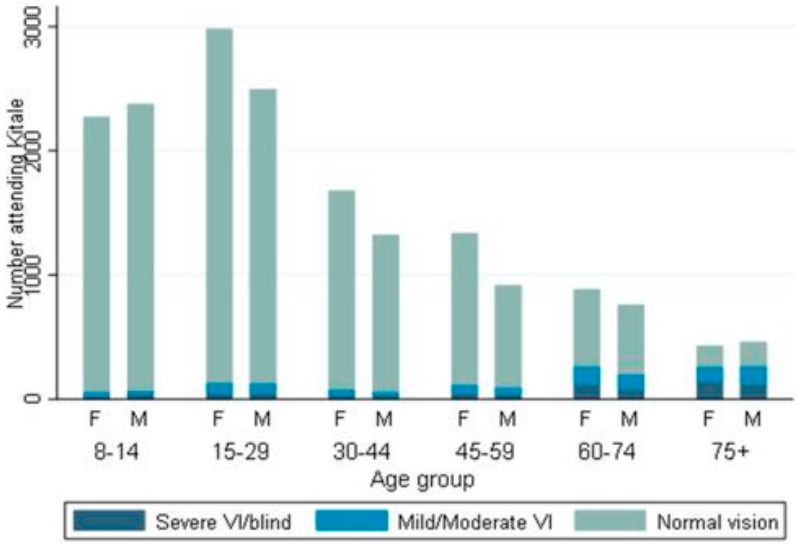

Figure 2. Visual status of patients attending Kitale Eye Unit between 2013 to 2015 stratified by age group and gender (M = male, F = female), ($N = 17912$).

3.3. Attendance Rates

Overall, the annual attendance rate to Kitale eye unit increased by 30% over time, from 609 per 100,000 of the population attending in 2013 up to 792 per 100,000 in 2015. There was strong evidence ($p < 0.001$) that the rate of attendance differed by subcounty, with Endebess (the furthest from hospital) having the lowest attendance rate over the 3-year period and Kiminini (the nearest to the hospital) the highest, Figure 3A. In fact, the rate of attendance among individuals from Kiminini was estimated to be 4.5 times that of individuals from Endebess (controlling for age, sex and year), Table 2. There was also evidence ($p < 0.001$) that older aged groups had higher utilization of the eye unit services, Table 2, an increased attendance rate, and also the older age groups also showed the greatest increase in attendance across the three years, Figure 3B and Table 2. Overall, there was evidence that women attended at a higher rate than men, but the estimated increase was quite small (IRR 1.07, 95% CI 1.04–1.10, $p < 0.001$). There appeared to be little difference in 2013 but this gap widened in subsequent years, Figure 3C and Table 2.

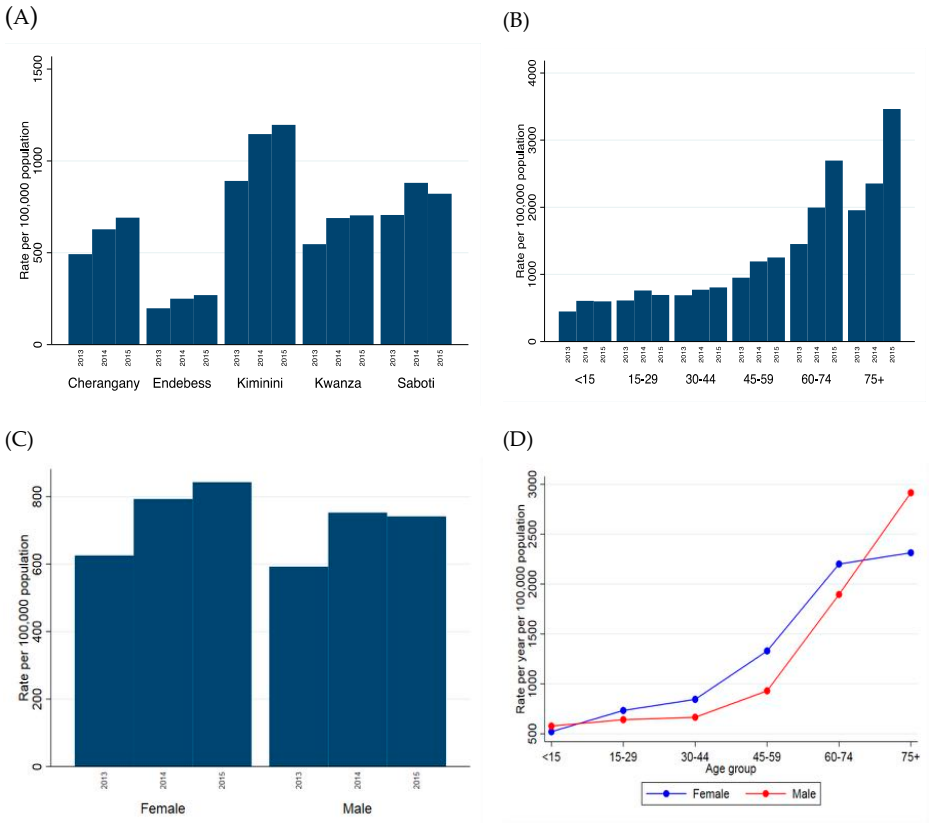

Figure 3. Attendance rates by (**A**) subcounty, (**B**) age group and (**C**) sex, across the three years. (**D**) shows the rate of attendance across age groups, stratified by age (attendance rate is the mean across the three years).

Table 2. Attendance rates to Kitale eye unit for eye consultations, by year, subcounty, sex, and age in Trans Nzoia Kenya.

Characteristic		Attendance Per 100,000 of the Population			% Change 2013 to 2015	Incidence Rate Ratio IRR(CI) *	*p*-Value
		2013	**2014**	**2015**			
Year	2013	609.1	-	-		Baseline	
	2014	-	772.9	-	30.1%	1.27 (1.23–1.31)	<0.001
	2015	-	-	792.3		1.30 (1.26–1.35)	
Subcounty	Cherangani	492.6	627.2	690.8	40.3%	Baseline	
	Endebess	197.8	249.7	270.0	36.5%	0.40 (0.37–0.43)	
	Kiminini	890.8	1146.3	1196.3	34.3%	1.78 (1.72–1.85)	<0.001
	Kwanza	546.9	689.0	704.1	28.7%	1.07 (1.02–1.12)	
	Saboti	705.4	880.6	820.9	16.4%	1.33 (1.27–1.38)	
Sex **	Male	592.4	752.7	741.4	25.1%	Baseline	<0.001
	Female	625.6	792.8	842.7	34.7%	1.07 (1.04–1.10)	
Age group	<15	447.7	605.1	597.0	33.4%	Baseline	
	15–29	612.8	759.9	693.9	13.2%	1.25 (1.21–1.29)	
	30–44	688.8	772.6	805.7	17.0%	1.37 (1.32–1.43)	
	45–59	951.3	1193.8	1252.8	31.7%	2.06 (1.96–2.16)	<0.001
	60–74	1451.9	1996.0	2697.0	85.8%	3.74 (3.54–3.94)	
	75+ years	1954.6	2354.5	3463.0	77.2%	4.71 (4.39–5.05)	

* All IRR estimates adjusted for year, subcounty, sex and age group; ** 839 individuals were missing sex. It was assumed that 50% of the missing were male and 50% female.

It was noticed that the differences observed between men and women varied with age, and a test for interaction resulted in strong evidence of this ($p < 0.0001$). Although overall women attended at a higher rate than men, this difference was most prominent from the ages 30–74. Among those aged under 15 and those 75 and over, men had a higher estimated rate of attendance than women, Figure 3D and Table 3.

Table 3. Stratum specific Incidence Rate Ratios (IRR) for age and sex.

Strata	Exposure	Incidence Rate Ratio IRR (95% CI)	*p*-Value
	Sex (Male is baseline)		
<15	Female	0.90 (0.86–0.94)	<0.001
15–29	Female	1.14 (1.08–1.20)	<0.001
30–44	Female	1.26 (1.18–1.36)	<0.001
45–59	Female	1.42 (1.31–1.55)	<0.001
60–74	Female	1.16 (1.05–1.28)	0.003
75+	Female	0.79 (0.69–0.90)	0.001
Female	<15	Baseline	<0.001
	15–29	1.41 (1.34–1.48)	
	30–44	1.62 (1.53–1.72)	
	45–59	2.55 (2.39–2.72)	
	60–74	4.24 (3.93–4.56)	
	75+	4.46 (4.03–4.92)	
Male	<15	Baseline	<0.001
	15–29	1.11 (1.05–1.17)	
	30–44	1.15 (1.08–1.22)	
	45–59	1.61 (1.50–1.73)	
	60–74	3.29 (3.04–3.55)	
	75+	5.05 (4.59–5.57)	

* *p*-value for interaction is <0.0001.

3.4. Attendance Rate and the Type of Eye Problem

Over the three-year period just over 61% of people attending Kitale hospital for eye problems had conditions (allergic/other conjunctivitis or no eye problem found) considered suitable for management at the primary health care level, Table 4. Of the remaining conditions, the most common were eye injury (6.1%), post-surgical follow-ups (4.5%), refractive error/presbyopia (4.0%) and cataract (3.6%). The problems that showed the greatest increase in attendance rate were uveitis, glaucoma and post-surgical follow up for cataracts and glaucoma, all of which more than doubled between 2013 and 2015. There were decreases observed in the rate of attendance for people with no issues found and refractive error/presbyopia, especially between 2014 and 2015. The possible reasons are explained in the discussion.

Out of the 5793 school-age children (5–15 years), the proportion who had conditions suitable for management at the primary health care level is even higher, at 78.8% (allergic conjunctivitis 65.4%, normal 8.1% and other types of conjunctivitis 5.3%).

Table 4. Trends and percentage change in attendance rates to Kitale Eye Unit (standardized to population for respective year) by eye conditions in Trans Nzoia County.

Diagnosis	Total Attending 2013–2015 (%)	Attendance Rate Per 100,000 Population			
		2013	2014	2015	% Change 2013 to 2015
Normal	1895 (9.2%)	95.9	76.8	28.8	−69.9%
Cataract	747 (3.6%)	19.1	25.9	33.2	74.1%
Refractive errors & Presbyopia	820 (4.0%)	36.5	36.0	14.5	−60.2%
Glaucoma	150 (0.7%)	3.4	3.5	8.8	161.5%
Allergic conjunctivitis	9245 (44.7%)	268.1	338.1	364.7	36.0%
Conjunctivitis-other	1459 (7.1%)	42.4	57.1	53.8	26.8%
Corneal diseases	354 (1.7%)	10.4	10.7	16.0	53.2%
Retinal diseases	708 (3.4%)	18.9	26.0	29.4	55.5%
Eye injury and FB in eye	1271 (6.1%)	32.9	39.0	61.2	86.0%
Uveitis	444 (2.2%)	8.0	15.4	22.9	185.3%
Conjunctival growths	695 (3.4%)	17.3	24.2	31.3	81.4%
Chalazion and other lid swellings	358 (1.7%)	8.5	13.7	15.3	81.3%
Lid inflammations	67 (0.3%)	2.0	2.2	2.9	46.6%
Others	1548 (7.5%)	24.7	79.0	58.3	135.6%
Post-surgical follow-up	934 (4.5%)	21.1	25.2	51.2	143.4%

4. Discussions

The World Health Assembly has adopted a key resolution on Universal Health Coverage (UHC). Member states commit to provide access to necessary health services for the whole population, leaving no one behind [25]. Routine health information collected by eye health facilities or hospital reports within the national or regional health information system can provide a data source to monitor progress towards UHC [26]. To our knowledge, this is the first study to use routine hospital data to assess the utilization of eye services in Sub Sahara Africa. It has demonstrated the potential of such data in assessing equity, planning and monitoring eye health services delivery.

This study was conducted in a county where most people live in rural communities and experience high inequality (poverty and unemployment) [19]. There was a decrease in attendance to the general hospital, probably due improvement of peripheral health facilities to handle most healthcare cases. In the same period, there was a gradual increase in the utilization of secondary eye care service from 609 per 100,000 population in 2013 to 792 by 2015, with higher utilization in children and women. When we compared the demographic characteristic of those who attended hospital to the population, we found higher attendance rates among residents who lived closer to the hospital, women and older people. Although, at both ends of the age range (vulnerable populations), male attend more than females. The increase did not overload the system because an additional ophthalmic nurse was posted to the unit to support increased workload.

The higher absolute numbers attending among children was expected. This is in line with the structure of the Kenyan population (47.2% are <15 years) [19]. The attendance rates appear to be skewed in favor of male children, suggesting that male children could be more susceptible to eye ailments or preferential health-seeking behavior. The differences in health-seeking in gender has not been fully explained, but could arise from household power dynamics and prevailing social norms where men have authority in family decisions [12]. A review on barriers to utilization of eye care services found that women were more careful about their eye health than men, suggesting gender influence service utilization [27]. Gender disparities in accessing eye health care services were identified for eye trauma and cataract in studies from Tanzania where females had difficulty in accessing services [28,29]. In such communities, men decide on most matters affecting the family including those related to seeking health services [30]. This was observed in one study on access to cataract surgical services from Tanzania where women needed to seek permission from their husbands before going to hospital and out of fear of being a burden to the family, they opt live with the adversity [29].

We observed an inverse relationship in age distribution among those who attended hospital and the incidence of attendance by age. Cumulatively, there were more young people who attended hospital, Table 1, but when compared to stratum population, utilization increases with increasing age Figure 3B. We also found that the proportion of people with visual impairment (mild visual impairment and blind) increased with age and was more pronounced after the age of 45 years, Figure 2. The rise in the age stratum utilization can be explained by the various changes in the eye that occur with age and affect Visual function, such as complaints of glare in cases of nuclear sclerosis, presbyopia or reduced contrast sensitivity from progressive media opacities [31]. Other studies reported similar findings and attributed the increase to the higher prevalence of diabetes, hypertension, cataract, and related maculopathy that increase with age [32]. Higher absolute numbers of younger people attending is due to the pyramidal structure of this population [18].

We found that less than 1% of the people in Trans Nzoia had eye problems and presented for treatment at Kitale hospital. This was lower than findings of a community survey in Mbeere in Kenya, which found that 15.5% of the population reported at least one eye problem during six months prior to survey and had about 4.4% of the same population sought treatment from eye practitioners (health worker, doctor or optician) [33]. From our study we could not estimate the prevalence of the ocular morbidity in the population, however assuming that the population in Mbeere were similar then the current utilization does not meet current need. If Trans Nzoia county had a population of 1 million people, about 155,000 would be expected to have an eye problem of which less than 10,000 are currently accessing services from eye practitioners. The findings, therefore, suggest that a large proportion of people with eyecare needs are not reached; improving access to eye services is required. From this study, we could not establish where patients with eye problems sought treatment. However, a community survey on utilization of health services in other parts of Kenya, showed that patients who did not seek health services at the hospital largely resorted to self-medication by buying non-prescription drugs [12]. This finding might suggest that those with eye problems could be using alternative services. Another reason for low utilization is affordability of eye services [27], especially those from the low socioeconomic status. From this study, more than half of the population live on less than one USA dollar a day, which is equivalent to the cost of the consultation fee needed to access eye services at the hospital. When other hospital costs (eyedrops and surgery) are added, the cost of services become unaffordable for most people. Studies have reported that higher direct costs reduced the uptake of cataract surgery [34,35]. These costs increase further when indirect expenses such as transport and living costs of patients and those accompanying them to hospitals are included [36]. Most patients, therefore, may not be able to afford services, particularly those coming from rural areas [37].

Our study suggests greater distance to health facilities hinders access to eye health services among people in Trans Nzoia county. This finding is consistent with other studies from LMICs, which asked patients about barriers to attending health care services [8,12,38]. Distance not only affects access to health care by increasing indirect costs, but also determines the availability of transport [7]. In some other LMICs patients have been known to bypass local eye health services and go to tertiary services or wait for outreach eye services [39]. We do not think that this was the case here, because there were infrequent outreach services conducted in the main town and none in the rural areas. Besides, most parts of the Endebess subcounty is forested with Kitale being the nearest facility offering eye services. Since about 48.1% of residence in Endebess depend on subsistence agriculture compared to 30.5% in Trans Nzoia County and 32.7% in Kenya [19], it is possible that seasonal availability rather than lack of funds to be spent on health could be a factor because most residences grow maize, which takes up to nine months to mature. Also, few people (3.8% Endebess compared to 8.3% for Trans Nzoia County) have no work [19].

Diseases of the conjunctiva (allergic conjunctivitis and vernal keratoconjunctivitis) were the most common problem. This finding is similar to other studies in Kenya which have reported allergic conjunctivitis to be the most common problem [33,40]. We found that 61% of the people utilizing eye services had eye conditions (allergic conjunctivitis, other conjunctivitis, and no eye health problem) that

could have been managed in primary health facilities (dispensaries and health centres), particularly among the school going age group. According to Kenya's strategic plan for eye care, secondary care eye facilities are equipped to manage Vision 2020 priority diseases (cataracts, glaucoma, corneal diseases, and refractive errors) that are responsible for the majority of visual impairment [41]. We found that only 8.3% of the patients seen at the hospital had these priority conditions (cataracts, glaucoma or refractive errors) suggesting a mismatch in the utilization of available capacity. The decline in utilization of eye services by people with refractive errors could have been due to lack of spectacles at the eye unit resulting in the patients seeking the services from other eye care providers. Encouragingly, during these three years, there was increasing utilization of eye services at Kitale by people with potentially blinding conditions such as those with diabetic retinopathy and those on post-surgical follow-up for cataracts. There was also a reduction in people without any eye problem (normal). This may have been attributed to improved accuracy of referrals following refresher training of health workers at the health posts (dispensaries and health centres) on how to identify and refer eye people with problems that took place from September 2013 to June 2014, and funded by Operation Eyesight Universal (OEU) and Seeing is Believing. Monthly Continuous Medical Education sessions provided by eyecare workers may have contributed [42]. Studies from the region identified skills of the general health workers in Primary Eye Care (PEC) to be low (about 8.2% were able to measure visual acuity) [43], however short training, supervision and continuous medical education for the PEC workers could improve their skills leading to better utilization of available eye services [44]. Training and deployment of middle level eye care workers (ophthalmic nurses and ophthalmic clinical officers) to primary eye care facilities could also improve management of these eye conditions. In some countries, this carder provides the bulk of eye care (including preventive, diagnostic and referral services) especially in rural areas [45].

Overall, secondary eye care services in Kitale were utilized by people closer to the hospital and by many people with conditions that could have been managed at the primary care level. This can result in over loading the limited central eye care services and further increasing the barriers to those with priority eye conditions. This data suggests a need to rethink the structure and mode of delivery of eye care services. There is potential for greater task shifting and integration of simpler services into primary health care [17]. To overcome the barrier presented by distance to the health facility there is a role for deploying eye care staff to provide regular outreach services, integrated with the standing primary health services further developing both capacity at the primary level in tandem with providing ad hoc secondary services [39,46].

Limitations of the Study

We had incomplete or missing records. We assumed linear population growth, as provided for in the census to extrapolate the population size for subsequent years but this estimate may not be accurate. The study did not capture information on the non-users of public health services or those who are treated elsewhere.

5. Conclusions

In conclusion, secondary eye services in Kitale Eye Unit, Trans Nzoia were heavily utilized by people with conditions that could be managed at in a primary care setting. Barriers to accessing services were distance and gender especially among the most vulnerable groups (young and the elderly). We recommend, that the eye health services be redesigned to increase access to community and primary level services, thereby reducing inappropriate utilization of secondary level services and reducing the barriers to access to increased secondary service capacity with a particular focus on equitable access for the young, old and those living at greater distances from secondary level care. Further population-based studies to assess ocular morbidity and the barriers to eye service in the community; as well as changing trends in utilization of eye services are recommended. Similarly, qualitative studies to explore the barriers to utilization of the services.

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3. Smartphone-based screening for visual impairment in Kenyan school children: a cluster randomised controlled trial

Figure 3.1: A teacher screener explaining screening process to a pupil in a school

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RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS.

SECTION A – Student Details

Student	Hillary Kipkemboi Rono
Principal Supervisor	Dr. Andrew Bastawrous
Thesis Title	Increasing Access to Eye Care using Mobile Phone-based Interventions. The development, validation and implementation of Peek to optimise human resources and lower barriers to access for those most in need

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?	Lancet Global Health. Citation Rono, H.K., et al., Smartphone-based screening for visual impairment in Kenyan school children: a cluster randomised controlled trial. The Lancet Global Health, 2018. 6(8): p. e924-e932		
When was the work published?	30th July, 2018		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion			
Have you retained the copyright for the work?*	**Yes**	Was the work subject to academic peer review?	**Yes**

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SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	N/A
Please list the paper's authors in the intended authorship order:	
Stage of publication	Choose an item.

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)	Together with my senior colleagues I designed the study, prepared the protocol and submited for ethical approval registration, led the project, data collection, initial analysis of the data and wrote the first draft of the paper with edits from supervisors and co-authors.

Student Signature: [redacted] **Date:** 08.10.2019

Supervisor Signature: [redacted] **Date:** 09.10.2019

Smartphone-based screening for visual impairment in Kenyan school children: a cluster randomised controlled trial

Hillary K Rono, Andrew Bastawrous, David Macleod, Emmanuel Wanjala, Gian Luca Di Tanna, Helen A Weiss, Matthew J Burton

Summary

Background Childhood visual impairment is a major public health concern that requires effective screening and early intervention. We investigated the effectiveness of Peek school eye health, a smartphone-based sight test and referral system (comprising Peek Acuity test, sight simulation referral cards, and short message service [SMS] reminders), versus standard care (Snellen's Tumbling-E card and written referral).

Methods We initially compared the performance of both the Snellen Tumbling-E card and the Peek Acuity test to a standard backlit EDTRS LogMAR visual acuity test chart. We did a cluster randomised controlled trial to compare the Peek school eye health system with standard school screening care, delivered by school teachers. Schools in Trans Nzoia County, Kenya, were eligible if they did not have an active screening programme already in place. Schools were randomly allocated (1:1) to either the Peek school eye health screening and referral programmes (Peek group) or the standard care screening and referral programme (standard group). In both groups, teachers tested vision of children in years 1–8. Pupils with visual impairment (defined as vision less than 6/12 in either eye) were referred to hospital for treatment. Referred children from the standard group received a written hospital referral letter. Participants and their teachers in the Peek group were shown their simulated sight on a smartphone and given a printout of this simulation with the same hospital details as the standard referral letter to present to their parent or guardian. They also received regular SMS reminders to attend the hospital. The primary outcome was the proportion of referred children who reported to hospital within 8 weeks of referral. Primary analysis was by intention to treat, with the intervention effect estimated using odds ratios. This trial is registered with Pan African Clinical Trial Registry, number PACTR201503001049236.

Findings Sensitivity was similar for the Peek test and the standard test (77% [95% CI 64·8–86·5] *vs* 75% [63·1–85·2]). Specificity was lower for the Peek test than the standard test (91% [95% CI 89·3–92·1] *vs* 97·4% [96·6-98·1]). Trial recruitment occurred between March 2, 2015, and March 13, 2015. Of the 295 eligible public primary schools in Trans Nzoia County, 50 schools were randomly selected and assigned to either the Peek group (n=25) or the standard group (n=25). 10 579 children were assessed for visual impairment in the Peek group and 10 284 children in the standard group. Visual impairment was identified in 531 (5%) of 10 579 children in the Peek group and 366 (4%) of 10 284 children in the standard care group. The proportion of pupils identified as having visual impairment who attended their hospital referral was significantly higher in the Peek group (285 [54%] of 531) than in the standard group (82 [22%] of 366; odds ratio 7·35 [95% CI 3·49–15·47]; p<0·0001).

Interpretation The Peek school eye health system increased adherence to hospital referral for visual impairment assessment compared with the standard approach among school children. This indicates the potential of this technology package to improve uptake of services and provide real-time visibility of health service delivery to help target resources.

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Introduction

Worldwide, an estimated 19 million children have visual impairment (defined as Snellen visual acuity of <6/12 [or <20/40] in the better-seeing eye). Visual impairment can have a profound effect on child development, quality of life, educational attainment, and economic productivity.[1,2] The leading cause of visual impairment in children is uncorrected refractive error, affecting approximately 12 million children, which can be easily corrected with spectacles.[3] Many school children are held back by poor sight for lack of this simple intervention. Most children with visual impairment live in low-income countries.[4] In Kenya, for example, the estimated prevalence of visual impairment among school children (6–20 years) ranges from 4·8% to 5·6%.[5,6] In Asian populations, estimates range from 6·4% to 22·3%.[7,8]

Addressing childhood blindness and visual impairment is a major priority for VISION2020, a global programme fighting avoidable blindness led by WHO and the International Agency for Prevention of Blindness.[9] To reduce childhood visual impairment, the programme promotes vision screening of all children who go to

Research in context

Evidence before this study

A systematic review of mobile health (mHealth) applications for vision testing identified numerous available applications; however, very few had undergone validation or certification. mHealth systems have shown promise for improving health-care delivery although no trials of mHealth interventions to improve eye health have been published.

Added value of this study

This study showed both the feasibility of effective task-shifting to teachers using the Peek school eye health system to identify and refer children with sight problems and substantially increased adherence to referral (within 8 weeks of screening) of those identified by establishing a closed-loop between screeners (teachers) and the service provider (hospital).

Implications of all the available evidence

Poor vision has negative social, health, educational, and economic consequences. Early identification and treatment of eye conditions reduces the prevalence of visual impairment. Our results have shown that the Peek school eye health system, when used by teachers, is effective for identification and referral, as well as providing live health system data with evidence of barriers to service delivery. The lessons learned from this trial have been adopted and scaled up in Kenya by the Ministries of Health and Education to a countywide programme, serving 200 000 children. Additionally, this programme has been replicated and further developed in India and Botswana, which is taking it to a national scale.

school and promotes integration of vision screening into school health programmes by 2020. Vision testing to identify children with correctable visual impairment enables interventions to be offered early, before educational and social progress is adversely affected.[10]

Vision screening of children in Kenya is guided by school policies.[11] In areas with active programmes, trained hospital-based clinical officers and ophthalmic nurses usually carry out the screening in schools. This procedure requires eye-care workers to leave their usual workplace (hospital eye clinics), thus reducing the availability of these services. In a pilot school-screening programme in Trans Nzoia County, Kenya, we trained school teachers to identify children with visual impairment using a Snellen Tumbling-E card. Children passed or failed at two predefined threshold levels: 6/60 (20/200) and 6/12 (20/40), in either eye. A hospital referral was made for children failing at either level by sending a letter to the child's parent or guardian explaining the need to access care. However, only a few children attended this hospital referral. Multiple barriers to care include communication failure between pupils or schools and parents or carers, as well as between schools or carers and hospitals, the inaccessibility of services, direct and indirect costs, myths related to treatment, and fear.[12]

Access to a connected mobile device in sub-Saharan Africa has increased dramatically in recent years, from 1% in 2002 to around 75% in 2016.[13,14] This increase in use is resulting in profound improvements in communication and commerce, and opens new opportunities for health care. Use of mobile health (mHealth) interventions to support communication between providers and patients through short messaging services (SMS) can promote access to health care.[15] Previously, we developed and tested a smartphone application for Tumbling-E visual acuity testing (Peek Acuity app) to measure visual acuity in adults in Kenya. This test was accurate and repeatable, and acceptable to patients, examiners, and stakeholders.[16,17] We have now integrated this app into an mHealth system for vision screening among school children. The aims of this study were to validate the Peek school eye health system and to assess the effect of this system on the referral rate of children with visual impairment compared with the standard visual screening system currently used in Kenya.

Methods

Study design and participants

We first did a validation study to confirm that the teachers could be trained to carry out vision screening. We compared the performance of both the Snellen Tumbling-E card and the Peek Acuity test with a standard backlit EDTRS LogMAR Tumbling-E visual chart (Precision Vision, Woodstock, IL, USA) in measuring visual acuity in children. The order of the assessments was random. This validation study was carried out in three schools not involved in the subsequent trial.

We then did a single-masked, parallel-group, cluster randomised controlled trial in 50 primary schools in Trans Nzoia County, Kenya. Clusters were individual schools with no active visual screening programme in place. School children were tested for visual impairment by teachers who were trained to use either the standard school screening system Snellen Tumbling-E card and paper referral) or the Peek school eye health system. CONSORT guidelines for reporting cluster randomised trials were followed.[18]

All pupils attending years 1–8 in the selected schools were eligible for inclusion. Children were provided with information and consent forms to give to parents or guardians who were then requested to give written informed consent for teachers to test eye sight before enrolment. Children were excluded if they were unwilling or unable to give verbal consent, or if their parents or guardians did not provide consent.

The study was approved by the Moi University Institutional Research and Ethics Committee, Kenya and the London School of Hygiene & Tropical Medicine Ethics Committee, UK. Permission was also granted by Trans Nzoia Education and Health authorities, Kenya. The study adhered to the principles of the Declaration of Helsinki on Ethics.

Randomisation and masking

Schools were randomly assigned (1:1) to either the Peek school eye health system (Peek group) or the standard school screening system (standard group). Geocoordinates of all eligible schools were obtained. To minimise imbalance in geographical location between the two groups, a statistician used a minimisation-based algorithm in R based on the geographical location (six zones, each covering 60 degrees of a circle around Kitale hospital) of the schools and their distance from the hospital, using random permuted blocks.[19,20] Using this balance algorithm, we obtained a set of optimal allocations and sampled the final distribution of allocations from this set of optimal allocations.

We could not mask the study team providing training, or mask participants and teachers to the screening method being used. The primary outcome data were collected by one hospital clerk who was masked to the screening method used. On arrival at the hospital, the child's parent or guardian presented a referral slip, which was identical for each group. Children who attended the hospital appointment in the Peek group were also marked as attended in the hospital app by a different clerk to those who received them at reception, to maintain masking of the primary outcome data collection.

Procedures

We selected 25 teachers, who had previously been trained to use the standard system as part of the pilot school-screening programme, on the basis of their availability and activity during the pilot. We trained them for 1 week on how to operate a smartphone and how to screen and refer using both methods (Peek and standard). We allocated teachers and transported them to schools, where they did not work, in a manner that ensured a teacher screened at two schools each, one from each group. The teachers screened the children class by class. We classified children in years 1–3 as lower primary school and those in years 4–8 as upper primary school. We recorded age, sex, and education level for each child in the study. For those who screened positive (ie, could not see 6/12 in either eye), we collected additional information for contact and follow-up purposes: child's name, parent's name, primary language, and contact number.

In schools allocated to the standard group, the teacher tested the children's sight for each eye separately. The eye not being tested was covered with an occluder. The child was shown a Tumbling-E vision screening card (figure 1A) at a distance of 3 m. This card has a row of five letter Es, in four different orientations. The size of the letters at this test distance corresponds to a visual acuity of 6/12. The child passed the 6/12 threshold test if they correctly identified the direction of four of the five letter Es. If they failed at 6/12, they were shown the 6/60 card, which has larger letter Es, and again passed if four of five were correctly identified. The result was recorded for each eye separately as: can see 6/12, cannot see 6/12 but sees 6/60, or cannot see 6/60. Children who could not see 6/12 in either eye were referred to Kitale hospital. The paper referral form was completed in triplicate: one copy given to the child, advising the parent to take the child to hospital, one copy to the head teacher, and one copy sent directly to the hospital.

In schools allocated to the Peek school eye health system, the teacher used the Peek Acuity vision screening app on a smartphone (Samsung Galaxy S3) at 2 m. Each eye was tested separately, with the fellow eye covered with an occluder. A series of up to five Tumbling-E optotypes equivalent in size to Snellen 6/12 (20/40, LogMar 0.3) were presented randomly in one of four orientations (figure 1B). The child pointed in the direction they perceived the arms of the letter E to be pointing, and the teacher used the phone's touch screen to swipe in the same direction to enter the child's response, without looking at the phone's screen. One optotype was presented at a time. The test automatically concluded when the threshold number of passes (four of five) or fails (two of five) at the 6/12 optotype size was reached.[16] If the child failed the 6/12 level, the app automatically presented a 6/60 sized optotype and the test was repeated to determine whether or not 6/60 (20/200, LogMAR 1.0) could be seen. At the end of the test, if the child failed the 6/12 level in either eye (ie, screened positive), the app prompted the collection of referral details (patient's or guardian's name, local language, and mobile phone number) and generated a referral to the hospital. A child who screened positive was given a printed referral photo card with their name, hospital contact details, and opening times to take home. The card included a split image with one half blurred to the same degree as the child's visual impairment (figure 1C). When connected to the internet, the app sends this referral details to a cloud-based server, which automatically generated a personalised SMS that was then sent to the child's parent or guardian with advice on the outcome of the eye assessment and instructions for referral in the chosen local language (figure 1D). A contact person (usually the head teacher for schools) also received an SMS with a list of children found to be visually impaired, needing referral. The messages were resent at intervals of 2 weeks until the child attended the hospital or for a maximum of 8 weeks. A referral was also automatically sent to the hospital where a database of referred children was kept accessible through a hospital reception app.

The follow-up period of this trial was 8 weeks. On presentation to the eye department at Kitale hospital for

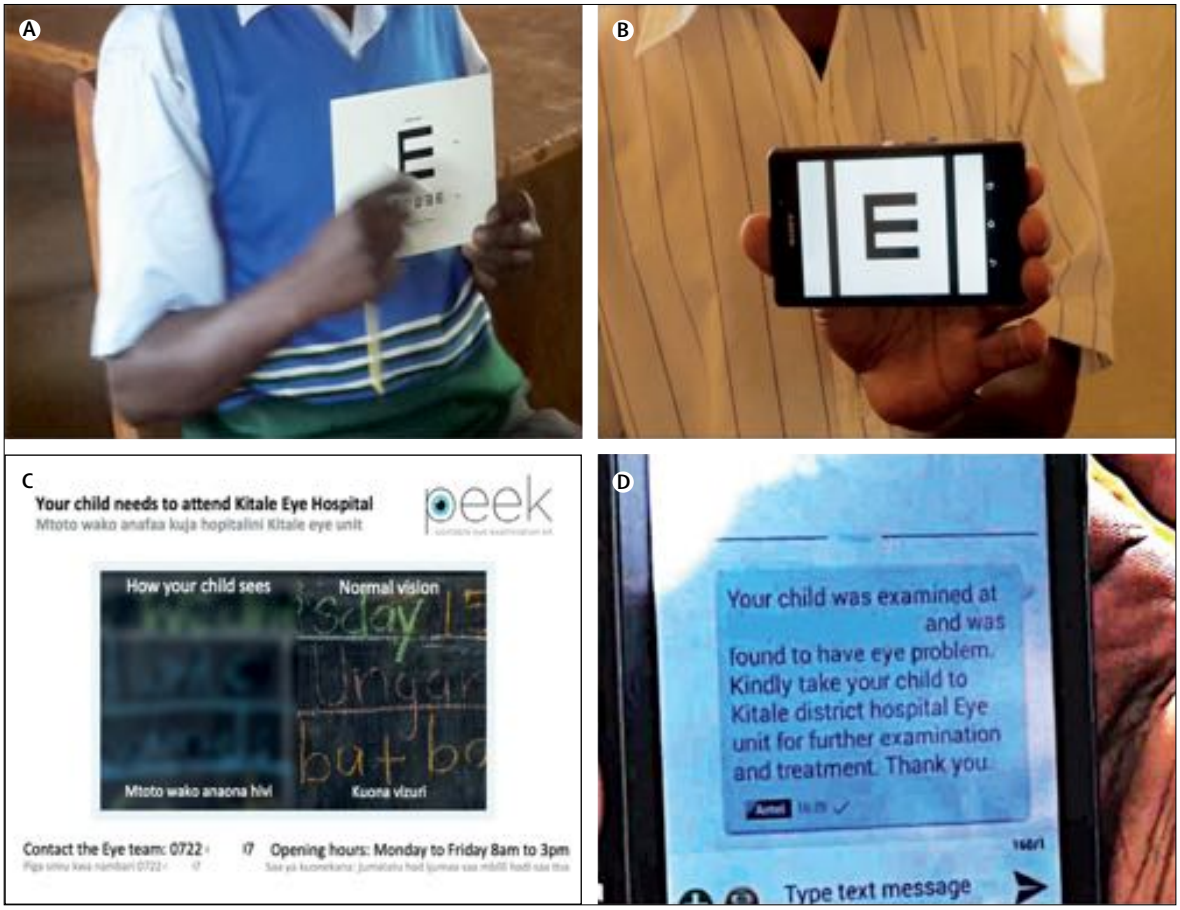

Figure 1: **Vision screening methods used in school children**
(A) Standard screening with a Tumbling-E card. (B) Peek Acuity screening app used on a smartphone. (C) Peek referral card showing the vision of the child and the referral instructions. (D) Parent receiving an SMS message with instructions after screening. SMS=short message service.

assessment, a clerk recorded the attendance of the referred child. The clinical team assessed the child to determine the level of vision, cause of visual impairment, and any treatment needed. Interventions included provision of eye drops, spectacles, or surgery. The team assessed visual acuity using a 6 m Snellen chart and classified the cause of vision loss on the basis of common treatable or preventable causes.[21] All children with visual impairment received free treatment at hospital.

Outcomes

The primary outcome, which was centrally assessed, was the proportion of referred participants who attended the Kitale hospital eye department within 8 weeks of referral. The main secondary outcome was the time taken by children with visual impairment to reach hospital. We also report the level of vision measured in hospital and the causes of visual impairment identified.

Statistical analysis

We calculated the sample size assuming a visual impairment prevalence of 4·8% (<6/18 in better eye) and average school size of 542 pupils (about 25 visually impaired children per school).[5] Assuming a design effect of 1·24 (ie, intraclass correlation coefficient 0·01) at least 21 schools were required in each group to provide 80% power to detect a difference of 10% (60% in the Peek group *vs* 50% in the standard group) in overall hospital attendance within 8 weeks. However, to ensure enough power would be retained to detect this difference if some schools dropped out of the study, we selected a final sample of 50 schools (25 in each group), providing 88% power to detect this difference if all schools participated.

For the initial validation study, we defined a child as visually impaired if they had at least one eye classed as having vision worse than 6/12 (or worse than 0·3 when using LogMAR). Using ETDRS LogMAR as the reference test, and the previous definition of visual impairment as the outcome, we estimated the sensitivity, specificity, positive predictive value, and negative predictive value for Peek and Tumbling-E cards.

The analysis was by intention to treat. For the primary outcome analysis, we used mixed effect logistic regression

	Number of children who failed 6/12* test in at least one eye (N=1862)	Sensitivity	Specificity	Positive predictive value	Negative predictive value
LogMAR†	65 (4%)	..	..	..	..
Standard‡	95 (5%)	75·4% (63·1–85·2)	97·4% (96·6–98·1)	51·6% (41·1–62·0)	99·1% (98·5–99·5)
Peek‡	216 (12%)	76·9% (64·8–86·5)	90·8% (89·3–92·1)	23·1% (17·7–29·4)	99·1% (98·5–99·5)

Data are n (%) or % (95% CI). *LogMAR value 0·3. †Test done by ophthalmic clinical officer. ‡Test done by teacher.

Table 1: **Performance of each test of visual impairment in the validation study**

to estimate the odds ratio (OR), comparing the odds of attendance within 8 weeks of referral between the control (standard) and intervention (Peek) groups, first unadjusted and then, in case of any imbalance between demographics in the two groups, adjusted for age, sex, education level, and distance to hospital.

We generated Kaplan-Meier (K-M) survival curves to illustrate the difference in time-to-attendance between the two groups. We assessed the difference in time-to-attendance with hazard ratios (HRs) estimated by Cox regression, with a shared frailty at school level, first unadjusted and then adjusted for age, sex, education level, and distance to hospital. We checked Schoenfeld residuals and did a test of proportionality of hazards to identify if the assumption of proportional hazards was valid.[22] In the case of the proportional hazards assumption being violated, we estimated HRs for narrower time bands, within which the proportional hazard assumption holds. We assessed the relationship between level of vision and diagnosis at hospital descriptively. We used STATA version 13 (STATA Corp, TX, USA) for the analysis.

The trial was registered with the Pan African Clinical Trial Registry, number PACTR201503001049236.

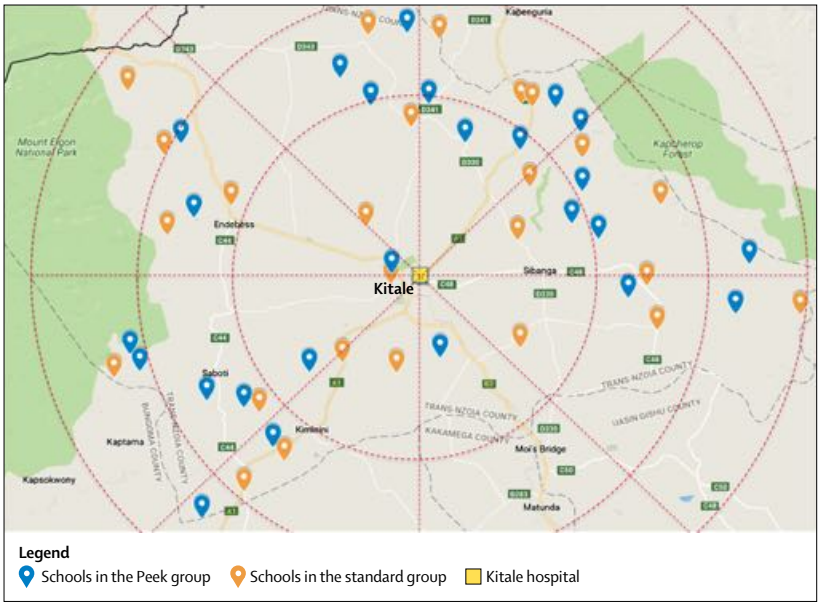

Figure 2: **Location of primary schools in each study group in Trans Nzoia County, in relation to Kitale hospital, Kenya**

Role of the funding source

The funders of the study had no role in the study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

In the validation study, we tested the visual acuity of 1862 children using Peek Acuity, the standard Tumbling-E card, and ETDRS LogMAR (the reference test). Prevalence of visual impairment, as measured by ETDRS LogMAR (at least one eye with <6/12 vision), was 4% (n=65). Peek correctly identified 50 of 65 children as visually impaired (sensitivity 76·9% [95% CI 64·8–86·5]) and standard E-cards detected 49 of 65 children (sensitivity 75·4% [63·1-85·2]) (table 1). 12 (80%) of 15 children with visual impairment not identified by Peek had a LogMAR score in their worse eye of less than 0·3 and better than or equal to 0·4. With standard E cards, 15 (94%) of 16 children fell within this region of mild visual impairment, suggesting that it was mostly children with milder visual impairment that were missed by Peek and E cards. The specificity of Peek was lower (91%) than that of standard E cards (97%). Peek had a lower positive predictive value (23% [95% CI 17·7–29·4]) than the E card (52% [95% CI 41·1–62·0]) due to Peek's lower specificity (table 1).

Trial recruitment occurred between March 2, 2015, and March 13, 2015. The final 8-week follow-up period finished on May 8, 2015. Of the 320 public primary schools, 25 were excluded as they already had active school screening programmes. Of the remaining 295 eligible schools, 50 were randomly selected and 25 were allocated to each group (figure 2). The mean distances between the schools in which screening took place and the hospital, and school sizes were similar in each group (table 2). All 27 316 potentially eligible children attending the 50 schools were invited for vision screening. Parental consent and child's assent were granted for 22 934 (84·0%) children (78·8% in the standard group and 89·6% in the Peek group), of whom 20 863 (91·0%) were assessed during a 2-week period (figure 3).

	Peek group	Standard group
Number of schools	25	25
Mean number of children per school, n (range)	423 (223–1135)	411 (270–1037)
Mean distance from school to Kitale hospital, km (range)	21·1 (1·9–50·6)	19·0 (1·8–37·6)
Number of children examined	10 579	10 284
Male sex	5303 (50%)	4953 (48%)
Mean age, years (SD)	11·2 (2·8)	11·4 (2·7)
Lower primary years 1–3	3744 (35%)	3236 (32%)
Upper primary years 4–8	6835 (65%)	7048 (69%)

Data are n (%), unless otherwise specified.

Table 2: **Baseline characteristics of the schools and study participants**

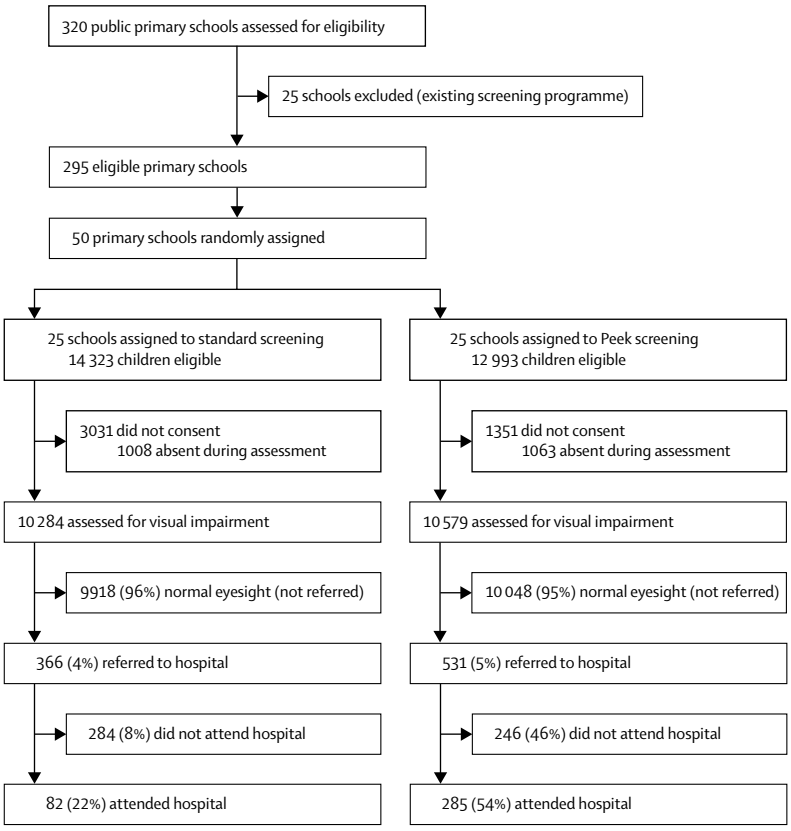

Figure 3: **Trial profile**

	Peek group	Standard group
Children with visual impairment on screening referred to hospital*		
Number of children	531 (5%)	366 (4%)
Male sex	226 (43%)	153 (42%)
Mean age, years (SD)	11·5 (3·0)	11·7 (2·8)
Lower primary years 1–3	179 (34%)	94 (26%)
Upper primary years 4–8	352 (66%)	272 (74%)
Children with visual impairment on screening who presented at hospital*		
Number of children	285 (54%)	82 (22%)
Male sex	130 (46%)	35 (43%)
Mean age, years (SD)	11·6 (2·9)	11·5 (2·6)
Lower primary years 1–3	88 (31%)	16 (20%)
Upper primary years 4–8	197 (69%)	66 (72%)
Children who could not see 6/12 in either eye in hospital visual acuity test		
Number of children	68 (25%) 276†	37 (47%) 78‡

Data are n (%), unless otherwise specified. *Visual impairment defined as vision less than 6/12 in either eye. †Vision from nine children was not recorded. ‡Vision from four children was not recorded.

Table 3: **Proportion of children with visual impairment and proportion who presented to hospital (primary outcome)**

In this study, 531 (5%) of 10 579 children in the Peek group and 366 (4%) of 10 284 children in the standard group failed the screening test. Of these 897 referred children, 379 (42%) children were boys, with a mean age of 11·6 years (2·9), and 273 (30%) children were in lower primary; characteristics were similar between groups (table 3).

Of the 366 children referred from the standard group, 82 (22%) presented to the hospital during the 8-week follow-up period compared with 285 (54%) of 531 children referred from the Peek group. After adjusting for school clustering, children referred with the Peek school eye health system were more likely to attend hospital within 8 weeks than children referred with the standard screening system (OR 7·35 [95% CI 3·49–15·47]; p<0·0001). When distance from the hospital, age, education level, and sex were also adjusted for, the estimated effect was similar (adjusted OR 8·27 [95% CI 3·77–18·1]; p<0·0001).

The rate of hospital attendance among those who screened positive for visual impairment was significantly higher in the Peek group than the standard group (HR 2·56 [95% CI 1·43–4·56]; p=0·0001; figure 4; table 4). However, because hazards were not proportional (p<0·0001), the time was split into weekly sections and HR was estimated for each week (table 4). This HR estimation was only possible for the first 4 weeks of follow-up because after this time no children arrived to hospital from the standard group. We did not find an intervention effect in week 1 (HR 1·03 [95% CI 0·54–1·98]; p=0·92). However, in week 2, evidence suggests that children referred using Peek had an increased attendance rate, with an estimated HR of 4·63 (95% CI 2·15–9·95; p=0·0001). Stronger intervention effects were seen in weeks 3 (HR 5·01 [95% CI 2·00–12·52]; p=0·0006) and 4 (HR 11·51 [2·41–54·93]; p=0·002).

Of the children referred from schools in the standard group, 37 (47%) of 78 children were confirmed to have visual impairment (four had missing visual acuity data) compared with 68 (25%) of 276 children referred from schools in the Peek group (nine had missing visual acuity data; table 5). A higher proportion of false

positives were identified among children screened using Peek than among those screened using the standard screening (p<0·0001). However, the absolute number of confirmed visually impaired children was higher in the Peek group (n=68) than the standard group (n=37). Most of the children referred who were not found to have visual impairment in the clinic had a diagnosis of allergic conjunctivitis (139 [67%] of 208 children in the Peek group and 32 [78%] of 41 children in the standard group; table 5). All children who had visually significant refractive error (<6/12) were offered free spectacles and three children had cataract surgery.

Discussion

Early identification and management of visual impairment in children is important to enable participation in education and society.[10] We showed that an integrated system comprising a smartphone-based visual acuity test (Peek Acuity), a printed referral card illustrating the degree of visual impairment, and SMS reminders (ie, the Peek school eye health system) significantly improved the overall hospital attendance rate among children referred compared with the standard system. In this first trial, to assess the use of smartphones for vision screening and referral, we found the test can be effectively delivered by school teachers.

The rate of hospital attendance was initially similar in both groups. However, in the standard group attendance slowed after the first week before stopping completely after 4 weeks. The initial similar attendance in both groups might have been due to early responders who seek medical attention faster. Hospital attendance was better maintained in the Peek group. As the Peek system is an intervention package involving both repeated SMS and a special referral card illustrating visual impairment, which elements led to the increased attendance is unknown. The reminder messages appeared to have no additional effect on attendance after the first two reminders were sent (figure 4).

In the validation study, we found the sensitivity of Peek and the standard E-cards in detecting visual acuity of less than 6/12 to be about 75% when used by school teachers compared with about 100% for ETDRS LogMAR chart used by a clinician. Most of the false negative individuals had an EDTRS LogMAR visual acuity close to the threshold level. The negative predictive values of both tests were very high.

The specificity and positive predictive value were lower for Peek than the standard system, resulting in more children being referred who were not subsequently found to have visual impairment. However, many of them were noted to have an ocular condition. A low positive predictive value could overburden the health system with unnecessary referrals and costs, resulting in increased pressure on limited eye-care services.[12] These false positive results might have arisen for a number of reasons: subtle variation in the smartphone screen angle, reflections off the screen or variation, and increased glare from a bright screen in the presence of inflammatory eye conditions, such as allergic conjunctivitis.[23]

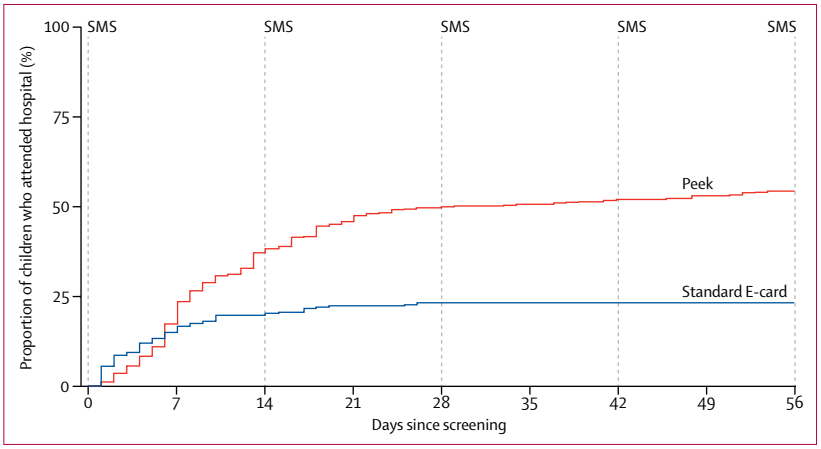

Figure 4: **Kaplan-Meier analysis of time from screening to attendance at the hospital ophthalmology clinic**
SMS=short message service.

	Peek group	Standard group	Hazard ratio (95% CI)	p value
Week 1	91 (17%)	54 (15%)	1·03 (0·54–1·98)	0·9232
Week 2	105 (37%)	17 (19%)	4·63 (2·15–9·95)	0·0001
Week 3	46 (46%)	9 (22%)	5·01 (2·00–12·52)	0·0006
Week 4	20 (49%)	2 (22%)	11·51 (2·41–54·93)	0·0022
Week 5	5 (50%)	0 (22%)	..	..
Week 6	6 (51%)	0 (22%)	..	..
Week 7	6 (53%)	0 (22%)	..	..
Week 8	6 (54%)	0 (22%)	..	..

Data are number of children (cumulative %), unless otherwise specified.

Table 4: **Children who attended hospital after initial referral during each week of the trial**

To reduce the false positive rate, we propose additional testing strategies. This involves retesting the vision of all children who initially screened positive. A referral is only triggered if the child fails to meet the threshold acuity on the repeat test. If a child fails the first test and then passes the second test, a third screening test is delivered (maximum three tests per eye). Referral is triggered on confirmation of two of three failed tests. An alternative approach, currently being tested, involves extension of the number of optotypes shown to confirm the acuity level. Additionally, a set number of children who pass the screening test will be prompted by the examiner to deliver a repeat test to enable monitoring of false negative rates.

This trial suggests that, for every 10 000 children screened with standard methods, 80 of those are expected to be referred to attend the hospital clinic—38 with visual impairment and 42 without. With the Peek system, 269 children are expected to attend hospital—66 with visual impairment and 203 without. Therefore, with use of the first iteration of the Peek school eye health system an anticipated additional 28 visually impaired children

	Peek group	Standard group
Visual acuity among children attending hospital		
Children in each group	276*	78†
6/12 or better in both eyes	208 (75%)	41 (52%)
Worse than 6/12 in either eye (visual impairment confirmed)	68 (25%)	37 (47%)
Visual acuity in the worst seeing eye of children without visual impairment in hospital		
Children in each group	208	41
6/5	3 (1%)	0
6/6	107 (51%)	23 (56%)
6/9	66 (32%)	13 (32%)
6/12	32 (15%)	5 (12%)
Diagnosis among children without visual impairment in hospital		
Children in each group	208	41
Normal eyes	7 (3%)	1 (2%)
Allergic conjunctivitis, including vernal kerato-conjunctivitis	139 (67%)	32 (78%)
Refractive error	21 (10%)	4 (10%)
Others	5 (2%)	0
Not stated	36 (17%)	4 (10%)
Visual acuity in the worst seeing eye of children with visual impairment (in either eye) in hospital		
Children in each group	68	37
6/18	19 (28%)	14 (38%)
6/24	13 (19%)	7 (19%)
6/36	8 (12%)	4 (11%)
6/60	9 (13%)	3 (8%)
5/60 or worse	19 (28%)	9 (24%)
Diagnosis among children with visual impairment (in either eye) in hospital		
Children in each group	68	37
Allergic conjunctivitis, including vernal kerato-conjunctivitis	6 (9%)	3 (8%)
Refractive error	31 (46%)	26 (70%)
Corneal scars	4 (6%)	2 (5%)
Globe abnormalities	9 (13%)	3 (8%)
Cataracts	2 (3%)	1 (3%)
Others	8 (12%)	1 (3%)
Not stated	8 (12%)	1 (3%)

Data are n (%). *Vision from nine children was not recorded. †Vision from four children was not recorded.

Table 5: **Visual acuity status and diagnosis of children who screened positive for visual impairment who then attended the hospital**

will present to the clinic for assessment and treatment for every 10 000 children screened. This comes at a cost of an extra 161 children without visual impairment presenting on the basis of the methods used in this trial.

Measurements of visual acuity in children attending hospital were done with a Snellen chart several days or weeks after their initial assessment; therefore, visual acuity could have fluctuated, accounting for some of the differences. Short-term to medium-term test-retest variation in visual acuity has been reported previously.[24,25] Visual acuity is usually delivered as a continuous test from large to small angles of resolution. However, decisions for referral are made based on a threshold from that continuous test—eg, <6/12. For practical reasons, given the volume of children being screened and the need for a referral decision rather than an acuity score being the primary driver, a threshold acuity test is appropriate for screening. Most acuity tests have a one line tolerance (ie, limits of agreement) and thus delivering a threshold test is likely to result in under or over referrals of those whose true acuity falls above or below the threshold.

Of note is that most of these false positives for visual impairment were found to have some ocular pathology, most frequently allergic eye disease, which is particularly common in this population. The risk of overburdening the health system might be reduced by the delivery of triage services in or close to the school to review all children who screened positive and to manage minor eye ailments, and, where capacity allows, the assessment and delivery of refractive services referring only those who require further hospital-based treatment onwards to secondary care. A direct-to-hospital or additional triage step both require balancing outreach service capacity with health service demands for that population.

A major limitation of the current system is the low specificity of the threshold testing algorithm. In our previous study in adults,[26] we found a substantially higher specificity for severe visual impairment using a full visual acuity as opposed to a threshold acuity testing algorithm, suggesting that modifications to the testing algorithm could improve this result. A two-staged Peek school eye health system that provides screening in the school and triage services delivered in or close to the school could optimise the benefits of its use while minimising the potential overload of the health system. This system has subsequently been refined based on findings from this trial and is being deployed to support comprehensive child eye health services to all public primary schools in Trans Nzoia County (n=340) in partnership with the Ministries of Health and Education. The triage system for refractive services recommendation has been developed into an iteration of the system that was successfully deployed in Botswana and is now being prepared for a nationwide scale-up. Further research is needed to systematically assess the barriers to accessing child eye health services and to develop and test contextually relevant measures to improve on these barriers as shown in the Peek school eye health system trial in progress in India.[27]

In conclusion, the Peek school eye health system resulted in a substantial increase in the proportion of children who attended the hospital clinic for assessment after screening positive for visual impairment and provided real-time visibility to the health system. This outcome indicates the potential value of this technology in improving uptake of services and encouraging improvement in delivery through identification of areas with potential bottlenecks in the care pathway (such as regions with the highest

number of children who have not attended the hospital). The Peek Acuity screening algorithm used in this trial was less specific than the Tumbling-E card in identifying children with visual impairment. Additionally, ongoing work is required to further refine the testing algorithm, maintaining sensitivity while improving specificity without substantially increasing the testing time and systematically reducing barriers to patient care across the entire patient care pathway.

Contributors

HKR and AB searched the medical literature. HKR, AB, and MJB conceived and designed the study. HKR, EW, and GLDT collected data. HKR, DM, and HAW did the statistical analysis. HKR, AB, GLDT, DM, HAW, and MJB interpreted the data. HKR drafted the manuscript, and all authors critically revised the manuscript for important intellectual content. AB and MJB obtained funding for the study. EW provided administrative, technical, and material support. AB and MJB supervised the study.

Declaration of interests

The Peek Vision Foundation (09919543) is a registered charity in England and Wales (1165960), 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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Chapter 4. From research to scaling-up programs: case study of Peek school eye health program in Trans-Nzoia county, Kenya

Figure 4.1: Children preparing for visual Eye screening

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RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS.

SECTION A – Student Details

Student	Hillary Kipkemboi Rono
Principal Supervisor	Dr. Andrew Bastawrous
Thesis Title	Increasing Access to Eye Care using Mobile Phone-based Interventions. The development, validation and implementation of Peek to optimise human resources and lower barriers to access for those most in need

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?			
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SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	The Journal of Ophthalmology of Eastern, Central and Southern Africa (JOECSA),
Please list the paper's authors in the intended authorship order:	Hillary K Rono Nyawira Mwangi Alice Mwangi Emmanuel Wanjala Juliet Khachesanga Michael Gichangi Cosmas Bunywera Andrew Bastawrous Matthew J Burton

Stage of publication	**Undergoing revision**

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)	Together with my senior colleagues I designed the study. I led the project implementation, coordinating partners and data collection. I wrote the first draft of the paper with edits from supervisors and co-authors

Student Signature: [redacted] **Date:** 08.10.2019

Supervisor Signature: [redacted] **Date:** 09.10.2019

From research to scaling-up programs: case study of Peek school eye health program in Trans-Nzoia county, Kenya

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Abstract

There are barriers to accessing eye health services by children especially in low and middle-income countries (LMIC), where the prevalence of visual impairment is highest. We report the process of scaling up the Peek school screening program that was initially tested in a randomized clinical trial in Trans-Nzoia county, Kenya.

The initial steps involved forming an advisory group that possessed expertise in technical, technological, managerial, and program management. The team used the PRIME framework to develop a theory of change on how the intervention would work at scale-up. The team led the project implementation through the three phases of the PRIME framework (formative, implementation and scale up phases).

In this paper we report on this process and influencing factors. We conclude that it is feasible to translate research to scaled-up programs in LMICs. Important tools in this process include stakeholder mapping and engagement. The Peek school screening model is acceptable and effective in screening for visual impairment in this population.

Introduction

The World Health Organization (WHO) advocates for increasing access and utilization of health services as the means of achieving universal health coverage (UHC).[1] However, there are barriers to accessing eye health services for children, especially in low and middle-income countries (LMIC), where the burden of visual impairment is highest.[2] About 19 million children are blind or have low vision (Visual Impairment) worldwide (defined as Snellen visual acuity of <6/12 (or <20/40) in the better-seeing eye).[3] Most visual impairment (VI) is preventable or treatable.[4] About 12 million children, have VI due to uncorrected refractive error, which can be corrected by spectacles.[5] Many school children have poor sight, for lack of this simple intervention. In Kenya, prevalence estimates of VI among school children (aged 6 to 20 years) range from 4.0 % to 5.6%.[6,7,8] Vision impairment and blindness results in negative impact on child development, quality of life, education prospects, and economic productivty.[5,6]

Elimination of childhood VI, through vision screening of all school-going children and integration into health programmes has been prioritised by the World Health Organization (WHO) and the International Agency for Prevention of Blindness (IAPB).[9],[10] The success of such school-based interventions largely depends on effective communication between health services and schools, the willingness of schools to schedule adequate time for screening and the good collaborations between teachers and parents.[11] The strategies that seem to promote uptake of screening services are delivery of services at or closer to schools, promoting education programs that create awareness and use of text messages.[12] Some barriers to the success of such programs are high direct and indirect costs to accessing services, lack of human resources to screen and treat children, lack of awareness about the available eye services and myths about causes and impact of seeking

eye care.[11],[13] Delivery of vision screening and provision of treatment for eye conditions at or closer to the school coupled with text message reminders show encouraging trends.[8] [12]

The recent increase in access to a connected mobile device especially in sub-Saharan Africa (SSA) has improved communication and commerce, and also created new opportunities for health care.[14] [15] There are many applications (apps) that use mobile health (mHealth) interventions to support communication between providers and patients.[16] One such app is a smartphone Tumbling-E visual acuity testing application (Peek Acuity), used to measure visual acuity in older adults in Kenya.[17] Studies in Kenya showed that the Peek Acuity app was accurate and repeatable among patients 50 years or older, and acceptable to patients, examiners and stakeholders.[19, 18] In a recent cluster trial where dedicated teacher screeners used the Peek Acuity app to identify visual impairment in randomized school children, It was found that dedicated teacher screeners could reliably screen for visual impairment, and the proportion of pupils identified having VI who attended their hospital referral increased by more than twofold. [8]

Following the success of this trial in Trans Nzoia county involving 50 schools, we scaled up this new method of screening to cover all public primary schools in the county. Trans Nzoia county has 426 primary schools (both private and public) with a total enrolment of 236,837 children, a pupil to teacher ratio of 39.6:1.[19] The vision screening of the school children in the county was guided by Kenyan school policies.[20] However there is paucity of published literature on the process of implementing innovative interventions, particularly school-based interventions in low resource settings.

We adopted the 'Programme for Improving Mental health care (PRIME)' theory of change (ToC) as an approach to develop and integrate eye healthcare plans into the health system.[21] The overall goal was to design a programme that explicitly states the theory of

how the programme would achieve its impact, by describing steps along the causal pathway that would guide the evaluation of the programme later.[22] The development of the theory of change was based on the principle of health system strengthening, working with other partners, priority eye health conditions and reducing inequities in service provision.[23] The framework emphasises the importance of working with the existing structures, such as healthcare coordination and stewardship, health facilities and the community.[24]

In this paper we describe the process of using a theory of change to implement this program in Trans-Nzoia. This resulted in improved adherences to referrals following screening from an initial 54% in the same region,[8] to 93%.[25] We leveraged on an initial situation analysis in the primary schools and the programmatic experience of the partners. The initial development of the framework was done by a team who included an Ophthalmologist from the Ministry of Health, a representative from Peek and partner NGO (OEU) and a teacher.

Methods

We designed a Peek school health intervention to screen children for visual impairment, using the opportunity provided by the Peek innovation. This intervention was tested through a cluster randomized clinical trial, where 50 schools were recruited and allocated to an intervention (Peek, n=25) arm and a control (standard practice, n=25) arm. The ethics review board of Moi Teaching and Referral hospital and London School of Hygiene & Tropical medicine (LSHTM) provided ethics approval. The intervention was effective and scale up was recommended.[8]

For the scale up, we adopted the approach used in the Program for improving mental health (PRIME) model.[24] This model recommends a three-phased approach to implementation of interventions (formative phase, implementation phase and scale up phase). An advisory committee of five members was selected to lead the project through the three phases, and report to the county government. Primary schools in the county were recruited through engagement with the Ministry of Education. All the children in each school were screened for visual impairment by a teacher trained to use the Peek app. Children with VI were referred to Kitale County Referral hospital for further evaluation and treatment. Table 1 highlights the recommended areas of focus in each of these phases.

Table 1: Areas of focus within the PRIME model

Formative phase	**Implementation phase**	**Scale up phase**
Formation of a committee of actors Situation analysis Identification of gaps Develop theory of change Setting objectives Resource mapping Beneficiaries mapping Costing the intervention Resource planning Stakeholder identification and definition of roles	Funding acquisition Technology acquisition Capacity building of the health system Stakeholder engagement Mobilization of actors Official launch of the project Training Piloting Screening Treatment Documentation	Incremental scale up Targets setting Monitoring targets and trends Facilitators and enablers Distractions Evaluation Team dynamics

Results

We present the results for each of the three phases separately.

Formative phase

The formative phase took about 12 months. In early 2015, the advisory committee was formed, consisting of the lead author (ophthalmologist), the county officer of health, a teacher, Peek (design and technology support partner) and an international NGO partner, Operation Eyesight Universal (OEU). These members met bi-monthly on average, and each was responsible for various tasks in between the meetings.

We performed an initial situational analysis of eye care pathway for children and identified the following gaps: (1) Children were erratically being screened for visual impairment (2) The screening was conducted by a small number of eye health workers, further compromising the quality of their hospital work during screening. (3) There was poor record keeping on who accesses the care. (4) The county department of health was not aware of how much to budget for eye care suppliers and medications. We also found the following strengths: (1) there was an eye health work force to provide treatment; (2) the community had high access to mobile phones; (3) good collaboration existed between the government and NGO sector.

Using the theory of change we identified how the scaled-up intervention might work (Figure 1). Thereafter we set the project objectives, mapped the available resources, and engaged state and non-state stakeholders through a series of meetings. We mapped the roles of each of the stakeholders (Table 2).

The initial memorandum of understanding was signed between the county and the implementing partner (OEU) and the hospital. Further agreement was made between OEU and The Peek Vision Foundation. We also applied for funding from Seeing is Believing (for logistics) and Peek (for data processing and software), which we received in 2016.

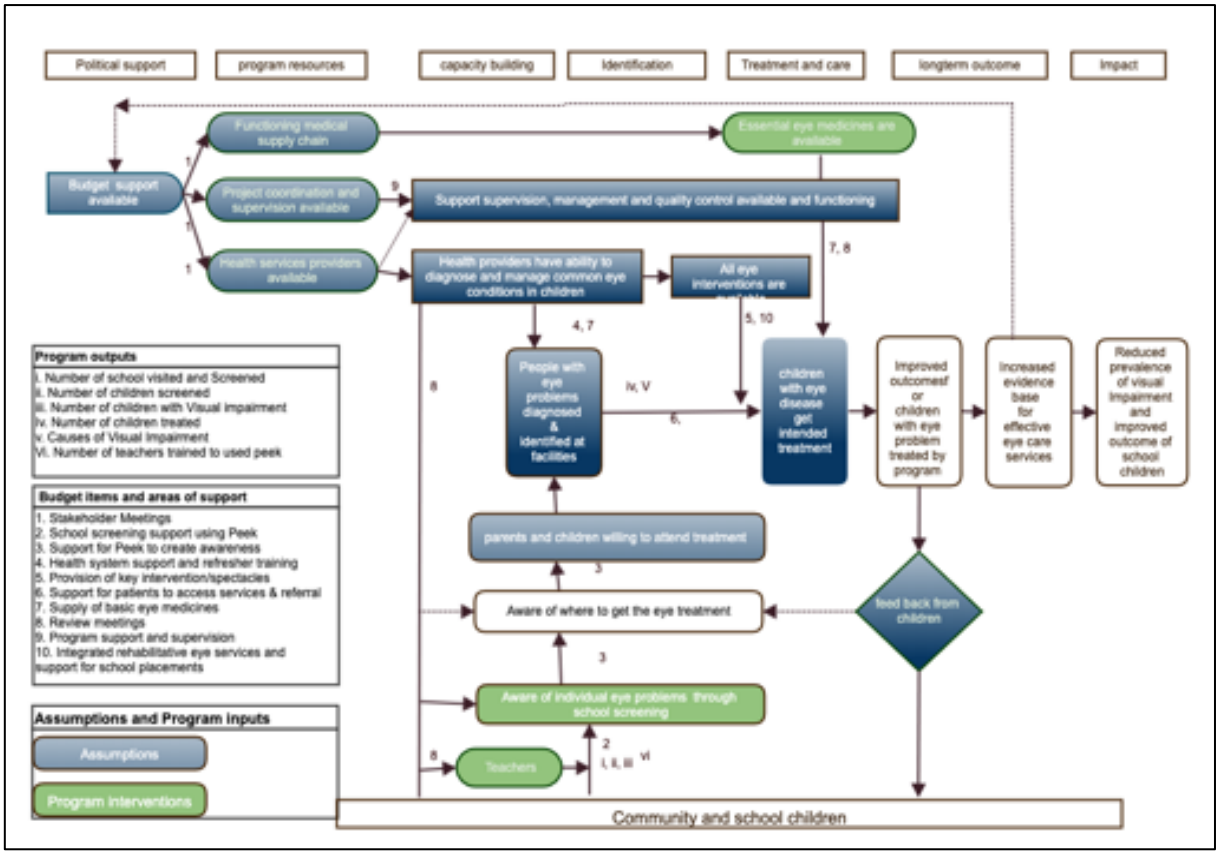

Figure 1: Theory of change for the scale up of the school eye health programme.

Adapted from the PRIME theory of change for mental health.[24,26]

Table 2: Partners and their role in school eye health project

Partner	Role
Ministry of Health	Overall facilitation of the project and provision of eye medicines
Ministry of Health- Ophthalmic Services Unit	Provide policy guide
Kitale County Referral & teaching Hospital	Release staff for screening; provide hospital fee waiver for children referred to the hospital; provide treatment for children found with eye conditions during screening
County government	Address political determinants, support community mobilization, leadership and administrative support for the project
Ministry of Education	Provide permission to screen school children in the county schools
Teachers Service Commission	Release teachers to participate in screening
Primary Schools	Facilitate screening
Head teacher	Release teachers for screening; follow up children who are referred
Operation Eyesight Universal	Support project coordination, procure any shortfall of consumables and manage the program funds
Peek	Provide technical support, mobile phones and cloud hosting for the project
London School of Hygiene & Tropical Medicine (LSHTM)	Provided technical guidance for the research phase and continued guidance
Standard Chartered Bank	Funding through the SIB project.
Media	Community sensitization
Parents and communities	Support children to receive the intervention
Eye care workers	Attend to children presenting at the hospital

Implementation phase

This phase took about 12 months. Project implementation began with extensive mobilization of the actors and beneficiaries through print media, radio and television. We also had a consensus meeting with national and county level policy-makers (Ministry of Health, Ministry of Education and Teachers Service Commission). Following consensus, the advisory teams appointed a project implementations team consisting of the ophthalmologist, Information technology specialist (to work with Peek) and three teachers to coordinate implementation. This team met weekly to coordinate the implementation activities.

An official launch of the project was conducted at a primary school in Nairobi, supported by Standard Chartered Bank. However, continuous sensitization through the media and through video seminars was continued during the entire implementation phase so as to sustain project awareness. We identified local leaders to be champions for the project. Thereafter the project was set up (service points, screening schedules and data management facilities) and the required equipment (mobile phones) were procured. 25 dedicated teacher screeners and 11 eye health workers were trained to facilitate implementation of the intervention.

Pilot implementation was conducted to assess project feasibility in terms of access, usability of tools, technology systems and training programs. 16 schools located near the Kitale hospital participated in the pilot. The first screening was conducted in June 2016. All the 25 dedicated teacher screeners (12 male and 13 female) were trained and participated in the screening of 8,000 children in this pilot. Children with VI were referred to Kitale hospital. This showed that Peek in the hands of teachers is an effective method of identifying children with visual impairment, even in a program setting.

Scale up phase

In the scale up phase we targeted all county schools. The project team met quarterly to monitor the progress, identify the facilitators and barriers to implementation and to review the theory of change. One of the challenges experienced in this phase was attrition of teachers. Of the initial 25 dedicated teacher screeners (12 male and 13 female) who were trained, only 15 were active during the entire scale up phase. The reasons for attrition were: teacher transfers (3), exit to attend further training (2), lack of permission from head teachers (2), promoted and therefore more responsibilities (2) and death (1). The screeners who were more likely to be lost were those in the early career phase (less than 5 years teaching experience) and those who had multiple professional or personal commitments. In response to this attrition, we had to train more teachers during the scale-up phase.

During the scale up, schools also reported that they had additional new activities being implemented concurrently, thus crowding the school calendar. This included examinations, sports events and other activities. There were also new school policies that limited activities outside of teaching and learning during the last quarter of the year. For this reason, schools limited the screening activities to only specific periods, mainly January to July every year. There were new officials deployed at the Ministry of Education in the county so we had to conduct regular re-sensitization. All stake holders however, remained engaged throughout the process.

The other challenges that we faced were: (1) occasional delay in supply of medicines, though the county government increased the county budget for eye drops during this project; (2) frequent technology updates; (3) maintaining team motivation; (4) industrial strikes by health workers interfered with the smooth running of the project. We addressed

these challenges through constant communication with and support from the stakeholders, partners, technical experts and the project team.

We did a mid-term evaluation to assess progress. We found that (1) screening using smartphones (Peek) was accepted by pupils, parents, teachers and other stakeholders; (2) some children with VI had not accessed treatment due to lack of transport to the hospital; (3) the eye hospital was closed over the weekend, when children are not in school. The main success factors for the project were support from the national and county government; appropriate stakeholder engagement and participation, and the ease of use of Peek.

The end term evaluation was conducted by an independent consultant. During the three phases, 6,696 (3.97%) out of 168,820 pupils screened in the project were identified as having eye problems and referred to the eye clinic. About 6,200 out of 6,696 (92.6%) presented to triage centre or Kitale eye clinic for treatment.[25] The causes of morbidity in 2,523 children for whom we found complete data are shown in table 3. Overall, screening was initially slow, followed by a linear activity growth phase before a plateau phase later when the project was near completion. Most children were screened in the first half of the year (months 0 - 6,12 - 18 and 24 - 30), compared to the second half of the year, except at the inception phase, figure 2.

Table 3: Causes of Morbidity among the children referred for treatment. (N=2,523)

Eye Condition	n	%
Allergic conjunctivitis	1,675	66.39
Normal	338	13.4
Refractive errors	184	7.29
Conjunctivitis-other	96	3.80
Other causes	89	3.53
Corneal diseases	37	1.47
Undetermined cause of Low vision & blindness	36	1.43
Cataract	27	1.07
Retinal diseases	17	0.67
Chalazion & lid swellings	8	0.32
Lid inflammations	6	0.24
Eye injury & FB in eye	4	0.16
Conjunctival growths	3	0.12
Uveitis	2	0.08
Glaucoma	1	0.04

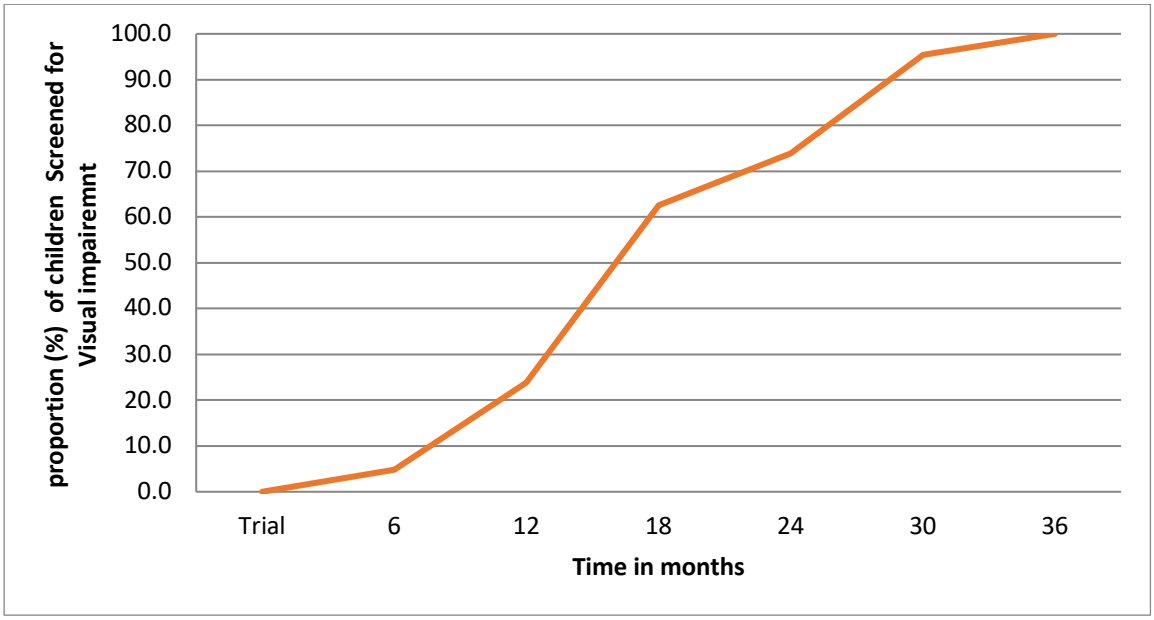

Figure 2: Proportion of children screened at each phase of implementation of school screening in Trans Nzoia County

The evaluation report, showed that: (1) the challenge of shortage of skilled eye health workers to conduct school screening could be overcome by task-shifting to trained teachers; (2) Peek technology could enhance time-efficiency in screening; (3) existing eye health services could be overrun by a large number of referrals from schools; (4) involvement of teachers in planning, implementation, follow-up and coordination of school screening is key to success; (5) community members (parents) with eye problems also presented for treatment during school screening and treatment; (6) two health information systems were used, the Peek screening system was independently used to identify and refer children for triage and the outcome of triage was recorded using the national health system.

We shared the results of evaluation with the stakeholders such as County Department of Health, Ministry of Education, funders and teachers. We agreed to further disseminate results through other forums such as conferences and publications. We also discussed the need to integrate the screening outputs such as the number and diagnoses of children who received treatment into the Health Information Management Systems so that the information generated by the project is all-inclusive and routinely collected and easily available.

Lessons learnt

Some of the lessons learnt during the three phases include:

1) PRIME model and the theory of change can be adapted for eye care
2) Systematic progress through the three stages of the PRIME model is crucial to the success of the project
3) Dedicated teacher screeners are effective in screening children for visual impairment
4) Stakeholder handling is important – roles must be explicit and communication must be constant. Early communication and engagement when there is a change in policy.

5) Selection of screening teams - the ideal members are agile and easily adaptable to the community.
6) Potential interruptions must be anticipated and dealt with, such as delays in the supply chain for medicines
7) Updating the technology is a constant requirement as technology is dynamic
8) Mid-term and end-term project evaluation helps to identify gaps and solutions.
9) Partnership with stakeholders can help deliver sustainable solutions

Discussion

We have presented the process we followed in setting up the school screening program using Peek and going from a trial to a program. This is the first study to document the setting up of smartphone supported school screening project and implementation by government actors and agencies. We reached more schools than had been initially envisaged. Through this program we have been able to screen over 168,000 school children for visual impairment and we have identified the leading causes of ocular morbidity in this population.

Our study was informed by the PRIME model. We found this model to be useful in visual impairment, just as it was useful in mental health. This might be because both fields meet the following conditions, particularly in low resource settings: they are accorded low priority, they need to be detected in the community, they require innovative tools for detection, the patient and the families need to be supported to take up the intervention.[24] Although the main actors in the schools' eye health project were implementors from government departments and agencies with funding from non-government organization, the process of adoption was similar. This suggests that PRIME framework can be used in eye health so long as there is willingness to adopt and to continuously improve.

We found that the intervention was successful, and that it worked as intended. However, we learnt important lessons about how to scale up programs. Other projects have reported similar findings, however most of the published literature is not from the African setting. The advisory committee had a cornerstone role in the success of the program, and we found that all the members were committed and highly skilled in their roles. Their technical and managerial skills were particularly important for the program; hence we recommend identifying the important skills that would be needed for the program to be implemented.

We had a team of five, which worked well for us, but a larger team might reduce the workload on individual members especially during the intensive formative stage.

There were developments and improvements in the technology that occurred during implementation that necessitated upgrade. The improvements needed stopping screening and more training for the teams. These disruptions had the potential of causing discomfort among the various stakeholders due to delay in meeting the set goals but were reduced due the clear program outputs and a monitoring framework agreed at the start of the project. Similarly changes in government policies on screening that could affect school screening, were anticipated and communicated early during stake holders meeting. This therefore reinforces the importance of frequent and open communication to facilitate early planning and tackling of emerging issues.

The intervention had high acceptability among the stakeholders and users. Several factors may have contributed to this. One is the existing trust in technology in the country, arising from the success of similar venture in financial sector, the m-Pesa money transfer app. There was also marked ownership of the process by the county lead, by the governor, and other stakeholders. This strong collaboration between government actors and non-government actors also provided impetus to the implementers. [11]

We learnt that strong governance with strong local leadership and commitment is needed to deliver and sustain the scale-up. Moreover, having local participants to champion of the process was very powerful. The engagement based on stakeholders' experiences and skill sets enabled the design of the equitable eye health program.

Mid-term evaluation identified lack of transport and the unavailability of eye services at weekends as important barriers. We introduced provision of triage at a hub school instead of children traveling to the main hospital, based on experiences of implementing the program in Botswana.[27] This reduced the distanced traveled by children and hence, improved adherences to attending their referrals following screening from 54% initially in the same region,[8] to the 92.6% that was finally achieved.[25]

We found that mapping of key stakeholders, defining their roles and engaging them throughout the project cycle are all critical for acceptance, support, integration and sustainability.[23] Integration of school screening activities into the broader health system with available and functional referral pathways, treatment and follow-up mechanism is a prerequisite to ensure delivery of eye care for the patient.[24] Regular engagement of parents as key stakeholder through school and parents' forums was essential for acceptance and taking children for treatment and should be considered for similar projects.

Alignment of the project goals and objectives with government policies enhances acceptability of the project and makes integration into mainstream government structure easy. For instance, aligning the Kenya Peek School Screening project with the Universal Health Coverage agenda, which is currently a priority for the Kenyan government attracted attention of government officials to the project, creating an opportunity for better understanding of the relevance to the health agenda.[1,28]

Keeping stakeholders engaged throughout a program is critical but often challenging. All the stakeholders remained engaged with the project perhaps because we had a shared plan, and frequent communication. Accountability was maintained by having partners represented in the advisory committee and providing them with quarterly written reports.

However, the choice of stakeholders is also important; we engaged stakeholders who had a high level of interest and power, and their roles were clearly defined.[29]

Although the phases are presented as sequential steps in the framework, we found a lot of overlap between them. Thus, we had to carry on planning, stakeholder engagement and training even beyond the formative stage. The screening itself had a slow start and then picked up. Programs should anticipate this and plan sufficient time for the project.

Each of the phases has unique challenges and it is helpful for future programs to anticipate them. The formative stage was intensive as there were many unknowns especially involving technology. It may have helped to have a demonstration of the technology, role play and discussion of the process involving all the stakeholders during the planning phase. To overcome the uncertainties of the formative phase, it is important for the core team to meet very frequently with stakeholders, and to include role play and demonstration to familiarize them with the new technology or new roles. We also had to conduct sensitization and training even during the scale up phase, hence it is important to plan a budget with these possibilities in mind. Program implementers may also consider planning for an extra workforce at the beginning to avoid delays or the need to recruit additional workforce to respond to these needs. It is also important to carefully consider the selection criteria for the workforce, so as to recruit those who are more likely to stay on the program.

Conclusion

Our experience provides a proof of concept that Peek school screening model can be applied to low resource settings. Its implementation is feasible, given the commitment of the stakeholders. The PRIME model is useful for program implementers because it gave a framework for action and monitor progress. Finally, in translating research to a scale-up

program it is important to consider the context (social cultural political and technological), the actors (role of different stakeholders) and process in each of the phase. This finding may be generalized to areas with similar context.

Future studies might investigate costs and cost-effectiveness of such programs and avenues of reducing the false referrals. We plan to replicate this methodology in other counties in Kenya and in other countries.

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Chapter 5. The development and validation of smartphone guided algorithms for use by Community Volunteers to screen and refer people with eye problems in Trans Nzoia County, Kenya

Figure 5-1: Translating decision matrix in to a digital guided form operated on Android

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RESEARCH PAPER COVER SHEET

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SECTION A – Student Details

Student	Hillary Kipkemboi Rono
Principal Supervisor	Dr. Andrew Bastawrous
Thesis Title	Increasing Access to Eye Care using Mobile Phone-based Interventions. The development, validation and implementation of Peek to optimise human resources and lower barriers to access for those most in need

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?			
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SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	Journal of Medical Internet Research (JMIR) - mHealth and uHealth
Please list the paper's authors in the intended authorship order:	Hillary Rono Andrew Bastawrous David Macleod Cosmas Bunywera Ronald Mamboleo Emmanuel Wanjala Matthew Burton
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)	Together with my senior colleagues I designed the study, prepared the protocol and submited for ethical approval, led the project, data collection, initial analysis of the data and wrote the first draft of the paper with edits from supervisors and co-authors

Student Signature: [redacted] **Date:** 08.10.2019

Supervisor Signature: [redacted] **Date:** 09.10.2019

The development and validation of smartphone guided algorithms for use by Community Volunteers to screen and refer people with eye problems in Trans Nzoia County, Kenya

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Abstract

Background: Eye care provision is currently insufficient to meet the requirement for eye care services. Many people remain unnecessarily visually impaired or at risk of becoming so due to treatable or preventable eye conditions. A lack of access and awareness of services are key barriers, in large part due to their being too few eye care providers in the health system for the unmet need. We hypothesized that by utilising novel smartphone-based clinical algorithms it is possible to task-shift eye screening to community volunteers (CVs) to accurately identify and refer patients to primary eye care services.

Methods: We compared CVs referral decisions using smartphone based clinical algorithms (*Peek Community Screening App*) to those by an experienced Ophthalmic Clinical officer (OCO), the reference standard. The same participants were assessed by a trained CV using the App and by an OCO using standard outreach equipment. The outcome was the proportion of all decisions that were correct when compared to the OCO's results. All decisions about referral were used to calculate sensitivity, specificity, and predictive values (positive and negative). An iterative design approach was used to reach the required sensitivity and specificity. The final iteration sample size was 516 participants.

Results: The required sensitivity and specificity was of the Peek Community Screening was reached after seven iterations. In the seventh iteration the OCO identified referable eye problems in 378/574 (65.9 %) participants. CVs correctly identified 344/378 (sensitivity 91.0%, 95% CI 87.7% - 93.7%) of these and also correctly identified 153/196 (specificity 78.1%, 95% CI 71.6% - 83.6%) as not having a referable eye problem. The positive predictive value was 88.9%, (95% CI 85.3%-91.8%) and the negative predictive value was 81.8%, (95% CI 75.5%-87.1%).

Conclusion: CVs can accurately use the Peek Community Screening App to identify and refer people with eye problems. An iterative design process is necessary to ensure validity in the local context.

Key words

Visual impairment; eye problems; clinical algorithms; mobile phone; screening; eye-care workers; mHealth; sensitivity; specificity

Background

It is estimated that 216.6 million people globally are visually impaired (visual acuity in the better eye <6/18) and 36 million are blind (visual acuity in the better eye <3/60).[1] About 90% live in low and middle-income countries (LMICs).[2] In sub-Saharan Africa about 26 million people are visually impaired and almost 6 million are blind.[3]

The high prevalence of visual impairment (VI) is attributed to poverty and lack of access to eye services;[4] shortages of health workers trained in eye care; [5] and lack of awareness of the eye conditions they have.[6] Few countries in sub-Saharan Africa have reached the World Health Organization (WHO) suggested ophthalmic cadre minimum targets of one ophthalmologist for 250,000 people to meet the surgical need of population to meet the population needs. [7, 8] Some countries especially in Africa have trained mid-level personnel including ophthalmic nurses and ophthalmic clinical officers (OCOs) to share key tasks and to compensate for the lack of ophthalmologists.[9, 10] In those countries, they provide the bulk of eye care (including preventive, diagnostic and referral services) in most rural and remote areas. [11] Generally the few available eye health workers are concentrated in urban areas, further increasing inequalities in access to eye health care.[7, 12] For example, in Trans Nzoia, a rural county in Kenya, with a population of 818,757, [13] the doctor to population ratio is 5.4 per 100,000 and the nurse population ratio is 47 per 100,000 people.[14] This is lower than the recommended WHO minimum ratio of 230 per 100,000 population for any cadre.[15]

An important strategy to improve access to eye care is task shifting, with redistribution of tasks within the health workforce, through clear referral criteria and management plans.[16] For example, guided task shifting through clinical algorithms defined as a text (flow chart) representing clinical decisions for guiding patient care [17]) are a core part of the Integrated Management of Childhood Illness (IMCI).[18] IMCI algorithms are effective in identifying pneumonia, gastroenteritis, measles, malaria and malnutrition, however, eye conditions were not included.[19] Clinical algorithms have also been developed for use in eye care, although

the accuracy of these algorithms has been variable. These include the “Edinburgh Red Eye Diagnostic Algorithm” to determine the correct ophthalmic diagnosis in a hospital by non-eye care nurses, [20] and the “Edinburgh Visual Loss Algorithm” to assess the cause of visual loss by clinicians with no experience in ophthalmology.[21] Recently, the World Health Organization (WHO) developed and published clinical algorithms for primary health care (PHC) workers in Africa to assess patients with eye conditions, if proved acceptable these algorithms could improve decision making at the PHC level. [22]

Mobile health (mHealth) defined as the use of mobile and wireless technologies to support the achievement of health objectives is increasing and gaining acceptance.[23, 24] There are a growing number of mHealth interventions for eye care. These include Peek Acuity, a smartphone/tablet application for measuring visual acuity,[25] A trial in primary schools in Kenya demonstrated teachers could use Peek Acuity to detect visual impairment (visual acuity $\leq$ 6/12) in school children who were age 6 years or older. [26] This provided evidence that mHealth solutions could enable task-shifting and improved access to eye health services.

In this study we describe the process of developing and testing the “Peek Community Screening App”. A smartphone-based referral decision support algorithm designed to guide users to identify eye problems which need referral using common eye signs and symptoms. To our knowledge this is the first smart phone-based algorithm to aid referral of patients with eye problems from the community to primary eye care.

The target system users were community volunteers (CV) -individuals who live in the community and are selected by the community to represent them on issues of health.[27] Their roles include health promotion, referring cases to the nearest health facility, visiting homes to determine health status and communication with household members. [28, 29] They receive a short defined informal training that is relevant to their work.

Most studies have used ophthalmologists as the reference standard.[20-22, 30] We chose OCOs because the majority work in rural areas (context where the app is used), are the first contact between people with eye problems and have the relevant experience to make diagnoses and treatment decisions using available equipment in outreach settings, figue1.

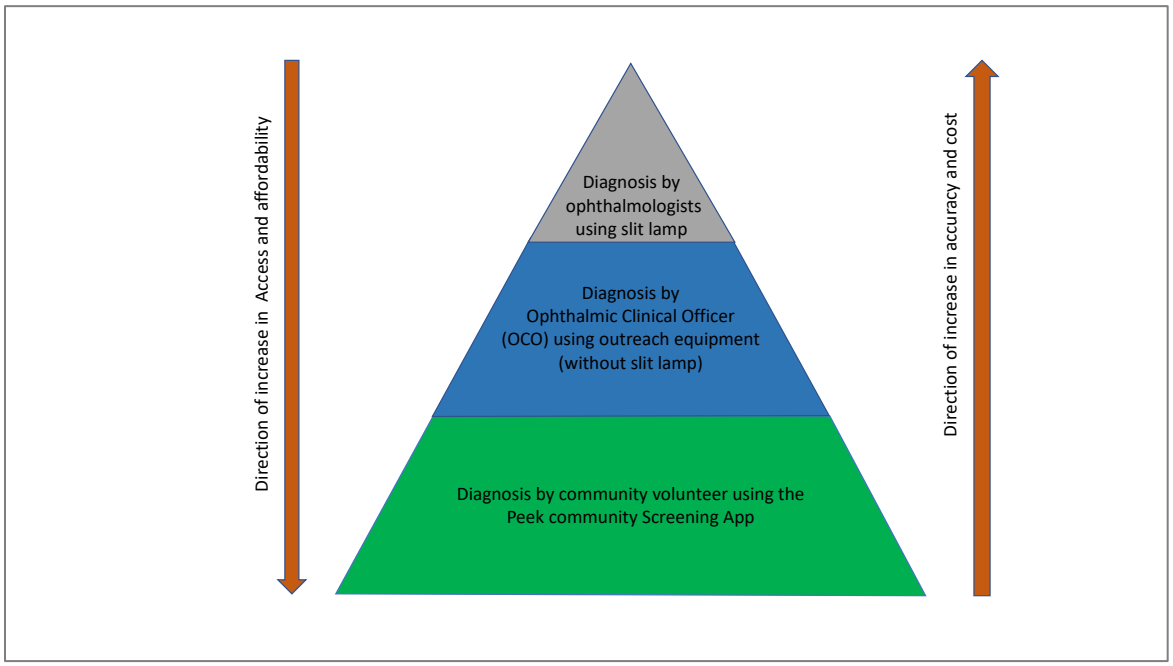

Figure 1: Conceptual framework for the various methods used to identify eye problems

Source: Modified from theoretical frame work used to train Community Volunteers to identify stroke.[31]

This paper outlines the development process and the results of Peek Community Screening App over a number of iterations, where the algorithm was altered to improve its performance, before settling on a final algorithm to be taken forward. We describe in detail the results for the final algorithm.

Methods

Ethics Approval

Approval was granted by the London school of Hygiene & Tropical Medicine Ethics Committee, UK and the Institutional Research and Ethics Committee (IREC) in Moi University, Eldoret Kenya. The study adhered to provisions of the Helsinki Declaration. Written informed consent was obtained from all participants.

Development and Pre-Validation Testing

We initially adopted the signs and symptoms used in a study that predicted eye conditions requiring referral in Rwanda, Madagascar and Malawi, [30] and incorporated the process used in developing WHO clinical algorithms for primary health care (PHC) as a starting point for the design of our algorithms.[22] We adapted them to the environment and context for Trans Nzoia County for which the algorithms were to be used. The factors considered in making referral decisions were: age, the presence of signs and symptoms of common eye problems and visual acuity. Initially decision trees were drawn on paper and tested informally on small numbers of individuals in a hospital setting. In early tests we observed low specificity and incrementally changed the algorithm based on the observed results and clinical knowledge of the study authors.

From this formative work, we then developed guided questions and assessments for the CVs in order for them to be able to make referral decisions. Using the potential responses to the questions, we developed a workflow and decision matrix that were then translated in to a digital guided form operated on Android smartphones or tablets. The decision matrix (algorithms) were coded into a prototype App the 'Peek Community Screening App' in collaboration with Peek Vision (London, UK) for use by the community volunteers.

We adopted a two phase (hospital and community) pre-validation process to ensure that the final algorithm was accurate, relevant and acceptable in this setting and also to prepare the

team adequately before the formal validation study.[32] Based on the clinical experience of the authors, we set the sensitivity of the algorithm to be no less than 90% and specificity above 75%. We selected and trained the CVs before commencing the pre-validation in the community setting.

Four Community Volunteers (CVs) were purposefully selected from a pool of practising CVs. A three-day training of CVs, on how to use the Peek Community Screening App to identify and refer participants with eye problems was conducted by two authors. Written guides, role-plays and supervised practice sessions using consenting patients from the eye department were used for teaching purposes. Two CVs discontinued the training due to personal reasons while the remaining two CVs conducted all the validations.

To assess the consistency of CVs using the App, the same patients were independently examined by the lead author and by the two remaining CVs, all using the Peek Community Screening App to make an automated referral decision. We compared the referral decisions of the CVs to the lead author using the same app on the same participants. Interrater agreement was assessed using the Kappa statistic. A Kappa value of 0.41 to 0.60 indicated moderate, 0.61 to 0.80 fair, and 0.81 or more indicated a good agreement. [33]

We first tested the App and refined its algorithm in a hospital setting where people with a variety of eye conditions were available. We examined both the patients and their escorts (without eye problems). The purpose was to assess if the algorithm was able to identify referable eye conditions, and to refine the procedures that would be followed by CVs during screening.

Following the initial hospital-based testing, we transferred the testing and refinement of the algorithms to a community setting where they would eventually be used in practice. The aim was to assess the usability of the App in identifying people with eye problems; and to determine whether the target sensitivity and specificity thresholds could be met.

Interim analysis was conducted after two field tests to determine whether the target sensitivity and specificity had been achieved. For this, we compared referral decisions of the CVs using the App to that of the ophthalmologist as reference standard. If the target sensitivity and specificity were both not met, data on the decision trees were assessed to determine which specific inputs (questions, measures or dependencies) needed to be amended and made such amendments using our clinical knowledge. The changes were implemented in software and the validation process repeated until the sensitivity and specificity targets were met. The accepted end point was determined to be either the targets being met or when all practical combinations had been exhausted.

Validation Study

Study design and setting

The validation study was conducted during outreach clinics in selected communities of Trans Nzoia County, Kenya. Most outreach clinics were conducted after church services to provide a broadly representative sample from the community. All consenting participants presenting to outreach centres (irrespective of the type of illness) were eligible to participate. These participants were examined by same Community Volunteers (who had participated in the pre-testing), using the 'Peek Community Screening App' and by one experienced Ophthalmic Clinical officer (OCOs), the reference standard, using standard outreach equipment. Their referral decisions (refer or not) were compared. The study was coordinated by a team from the Kitale Eye Unit.

Index test: Referral decisions by CVs using Peek Community Screening App

In the final test algorithm users were prompted to ask the following screening questions to the parents or guardian with a child, "Does the child have any problem with their eyes today?" or directly to participant themselves, "Do you have any discomfort or pain in your eyes today?" and "Do you have a problem with your sight when seeing far or near objects?". If the participant was six years or older, the App prompts the user to test distance visual acuity using Peek

Acuity App and assess near visual acuity for all people aged 40 years and older assessed at 33 cm using the RADNER reading chart.[34] The distance visual acuity of each eye was measured separately and recorded automatically using the Peek Acuity App.[35] If the distance visual acuity was less than 6/12 in either eye; or there was the presence of any self-reported eye pain or discomfort; difficulty seeing distant or near objects; or not able see N8 on near vision assessment for those aged 40 years or older, the participant was referred. Any eye problem in children (≤6 years) as reported by parents or caretakers triggered a referral, Figure 2.

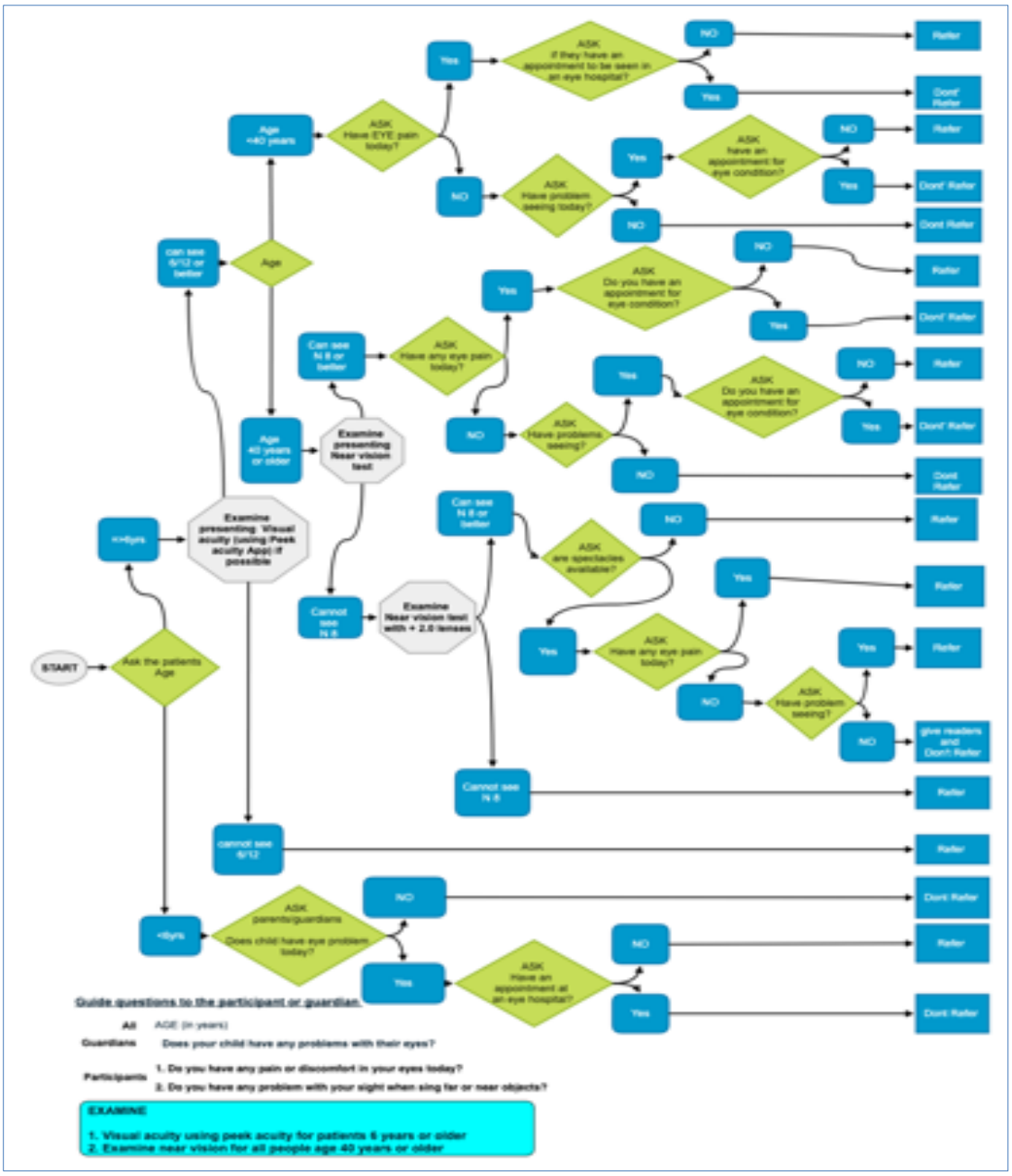

Figure 2: The questions and decisions matrix used in the Peek community-screening app to generate a referral decision

Reference standard: Referral decisions by OCO using standard outreach equipment

The reference standard was the referral decision by one ophthalmic clinical officer with 14 years' experience in ophthalmology using standard equipment for outreach. He was familiar with local customs in the setting. The outreach equipment included a Snellen 6-metre vision chart to asses distance vision, RADNER reading chart for near vision, a torch, magnifying loop, i-care contact tonometer, direct ophthalmoscope, retinoscope, trial lens set and fluorescein stains. Standard slit lamp was not used for assessment because it is not the norm to conduct a slit lamp assessment during outreach in this setting.

Study Procedures

Consecutive participants were examined for eye problems by the CVs using the app and then by the OCO using standard outreach equipment. The CVs followed the assessment guide and examined visual acuity using the embedded Peek Acuity vision test or near vision using a card when indicated. They entered the participant's responses in the Peek Community Screening App, where a referral decision was generated automatically. Their decisions were also automatically recorded and uploaded to a dedicated cloud server once internet connectivity was available.

After the CVs examination, the OCO masked to the decision of the CV, took a detailed history and examination from the same participants. Specific information on eye pain, eye discomfort (itching, irritation), tenderness or eye discharge was collected; vision was assessed as outlined above. A magnifying loupe and torch were used to assess the colour of the conjunctiva, the appearance of the pupil, the alignment of the participants' eyes, the presence of eye discharge and any lid abnormalities. Direct ophthalmoscopy was used to assess the lens, vitreous and retina. When indicated the cornea was assessed using fluorescein and blue for corneal ulcers or abrasions. Intraocular pressure was measured using the i-care tonometer. A retinoscope and trial lenses were used to assess refractive errors

A differential diagnosis for each eye was made for the purpose of management. Recording of the diagnosis followed the Kenyan Ministry of Health classification where the eye could be "normal" (no eye pathology) or any of the following diagnoses; cataract, corneal scars, conjunctivitis, keratitis, uveitis, retinal disease, eyelid disease, presbyopia, other refractive error, foreign body, eye growths, eye injury and "other". The OCO selected the applicable diagnosis. All patients were treated as per the OCO's plan. The OCO recorded their decision and treatment plan on a pre-coded data collection form.

Analysis

The primary outcome was the sensitivity and specificity of the CV assessment using the Peek Community Screening App for appropriate referral decisions, compared to the OCO's recommendation for referral. The minimum target sensitivity was 90% and specificity 75%. Positive and negative predictive values were also estimated. Logistic regression was used to identify whether there was any association between correct decisions being made by CVs and the participants' age and sex. This was done by using CV's referral decisions as the outcome variable and age/sex as exposures, and the analysis was performed separately among those classed as requiring referral or not requiring referral by the reference standard.

We calculated that a sample size of 517 participants was required in order to estimate a sensitivity to a precision of +/- 5%, assuming a sensitivity of 90% and that 30% of participants require referral. So, we aimed to recruit this number for the final iteration of the validation.

Data for CVs was downloaded from Peek's dedicated servers in Excel format, exported to STATA, cleaned and analysed. Information from the OCO pre-coded questionnaire were entered into an Excel database (Microsoft, Seattle, USA), cleaned and exported to STATA. Data was analysed using STATA, version 15.0, (Stata Corp. LP, College Station, TX, United States of America).[36] Age was rounded up to the nearest one year and the diagnosis was

reclassified using the International Statistical Classification of Diseases and Related Health Problems- ICD 10. [37]

Results

This study was conducted between November 2016 and May 2018.

Interrater agreement of the CVs

During training of the CVs, automated referral decisions were generated by the app for 59 participants which were used to assess interrater agreement between the reference assessor (lead author) and the CVs. The reference assessor found that 44/59 (74.6%) of the participants required referral compared to 49/59 (83.0%) and 50/59 (84.8%) by CV1 and CV2, respectively. There was 84.8% agreement for referral decisions between the reference assessor and CV1 and 86.4% for CV2; with a moderate κ of 0.55 and 0.58, respectively.

Pre-validation of Peek Community Screening app

One iteration in the hospital and Five iterations were tested in the community before arriving at the final version (iteration seven) which was used for validation study. The changes introduced at each iteration stage and the test performance of the versions are shown in Table 1.

Table 1: Sensitivity and specificity of Peek community screening app and the changes introduced at each iteration during validation.

Setting, Iteration and changes introduced	OCO Decision	CV Decision using 'Peek screening App'			Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
HOSPITAL SETTING								
Iteration 1 (enriched sample)		**Refer**	**Don't refer**	**Total**				
Ask for presence of any eye problem (No time limit)	**Refer**	117	1	118	99.2 % (95.4-100)	52.4% (29.8-74.3)	92.1% (86.0-96.2)	91.7 % (61.5-99.8)
Distance VA testing not mandatory for someone with eye problem	**Don't refer**	10	11	21				
	Total	127	12	139				
COMMUNITY SETTINGS								
Iteration 2 (enriched community sample)		**Refer**	**Don't refer**	**Total**				
Same question above, in outreach setting with self-selected patients	**Refer**	250	3	253	98.8% (96.6-99.8)	66% (51.7-8.5)	93.3% (89.6-96.0)	92.1% (78.6-98.3)
Ask for presence of any eye problem (No time limit)	**Don't refer**	18	35	53				
Distance VA testing not mandatory for someone with eye problem	**Total**	268	38	306				
Iteration 3		**Refer**	**Don't refer**	**Total**				
Introduced mandatory VA testing	**Refer**	110	3	113	97.3 % (92.4-99.4)	17.8% (10.5-27.3)	59.8% (52.3-66.9)	84.2 % (60.4-96.6)
Ask for presence of any eye problem (No time limit)	**Don't refer**	74	16	90				
Mandatory distance VA testing	**Total**	184	19	203				
Iteration 4		**Refer**	**Don't refer**	**Total**				
Limited the duration of eye problem to 1 day (today)	**Refer**	182	50	232	78.4 % (72.6-83.6)	75.6 (67.3-82.7)	85 % (79.6-89.5)	66.4 % (58.3-74.0)
Ask for presence of eye problem today?	**Don't refer**	32	99	131				
Mandatory distance VA testing	**Total**	214	149	363				
Iteration 5		**Refer**	**Don't refer**	**Total**				
Introduced eye pain instead of eye problem limited to 1 day	**Refer**	144	28	172	83.7 % (77.3-88.9)	61.2% (52.5-69.3)	72.7% (66-78.8)	75.2% (66.2-82.9)
Mandatory distance VA testing	**Don't refer**	54	85	139				
Asked - Any pain in your eyes today?	**Total**	198	113	311				
Asked - Any problem with seeing far or near objects today?								
Iteration 6		**Refer**	**Don't refer**	**Total**				
Introduced eye discomfort	**Refer**	342	36	378	90.5% (87.1-93.2)	63.3% (57.3-69.0)	77.0% (72.8-80.9)	83.0% (77.3-87.8)
Mandatory distance VA testing	**Don't refer**	102	176	278				
Asked - Any eye pain or discomfort today?	**Total**	444	212	656				

Asked - Any problem with seeing far or near objects today?								
Iteration 7 – FINAL ALGORITHM		**Refer**	**Don't refer**	**Total**				
Mandatory distance VA testing & near vision for those aged 40+	**Refer**	344	34	378	91.0% (87.7-93.7)	78.1% (71.6-83.6)	88.9% (85.3-91.8)	81.8% (75.5-87.1)
Asked - Any eye pain or discomfort today?	**Don't refer**	43	153	196				
Asked - Any problem with seeing far or near objects today?	**Total**	387	187	574				

Legend: CV – community volunteer, NPV- Negative Predictive Value, PPV - Positive predictive value

Validation Study of the final Peek Community Screening App

We included 574 (who had complete OCOC and CV examination and outcome data) out of the potential 607 eligible participants in the analysis of the performance of the seventh iteration of the Peek community Screening App, Figure 3.

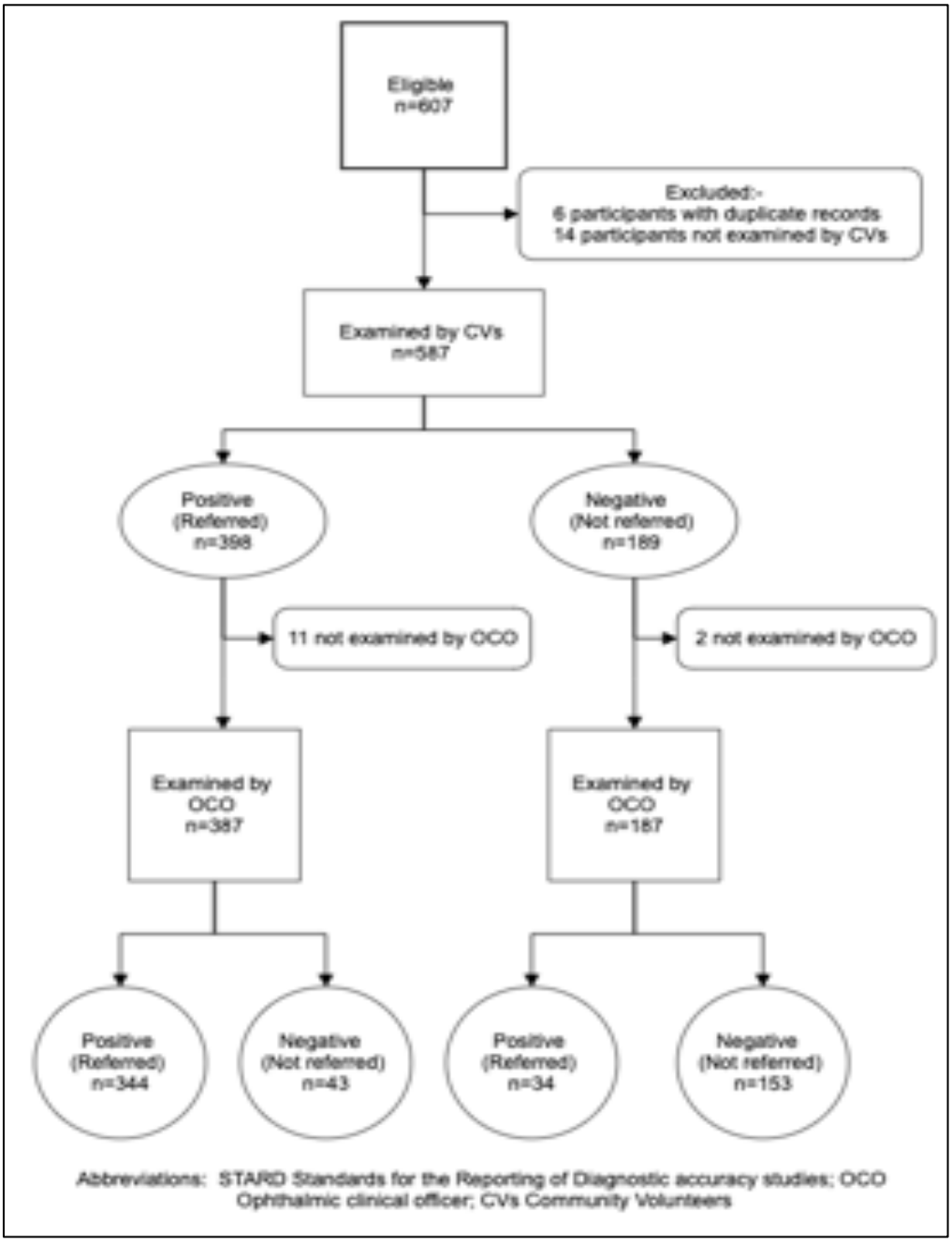

Figure 3: A STARD flow chart for study participants

The demographic characteristics of this group are shown in Tables 2.

Table 2: Age, Sex and visual status of all study participants, those referred by OCO using standard equipment and by CVs using Peek Community Screening App.

Characteristics	Total number N=574[a]		Referred by OCO N=378 [b]		Referred using Peek N=387 [b]	
	n	%	n	%	n	%
Sex						
Male	213	37.1	135	63.4	140	65.7
Female	361	62.9	243	67.3	247	68.4
Age group						
<15	252	43.9	128	50.8	141	55.0
15-29	100	17.4	53	53.0	55	55.0
30-44	80	13.9	57	71.3	53	66.3
45-59	76	13.2	75	98.7	72	94.7
60-74	52	9.1	51	98.1	52	100
75+	14	2.4	14	100	14	100
Visual Acuity (reference)						
Children (vision not assessed)	82	14.3	41	50	40	48.8
6/6 - 6/12	411	71.6	256	62.3	268	65.2
6/18 - 6/60	59	10.3	59	100	57	96.6
< 6/60	22	3.8	22	100	22	100

[a] The distribution of the characteristics the study participants.

[b] Proportions within each characteristic group that were referred by the OCO or CVs using Peek.

Eye problems that needed referral were diagnosed by the OCO (reference standard) in 378/574 (65.9 %) of the participants. CVs using Peek Community Screening App correctly identified 344/378 (sensitivity 91.0%, 95% CI 87.7% - 93.7%) as having referable eye conditions and 153/196 (specificity 78.1%, 95% CI 71.6% - 83.6%) as not. The positive

predictive value was 88.9%, (95% CI 85.3%-91.8%) and the negative predictive value was 81.8%, (95% CI 75.5%-87.1%).

The accuracy of algorithm varied depending on whether question alone or objectively assessed vision was used. If we used distance visual acuity and assessed near vision for those aged 40 years or older alone, without asking any of the questions about eye pain or discomfort or the question about disturbance in vision, the sensitivity dropped to 42.1% (95% CI 37.0% - 47.2%) and specificity was 98.5% (95% CI 95.6% - 99.7%).

If we asked about symptoms of eye pain / discomfort and disturbance in vision, with no eye examinations the sensitivity would be 87.6% (95% CI 83.8% - 90.7%) and specificity of 79.1% (95% CI 72.7% - 84.6%). If the strategy was to refer anyone aged 40 years or older (irrespective of visual acuity of self-reported issues) and those aged under 40 who self-reported either vision problems or eye pain/discomfort then the estimated sensitivity would be 91.5% (95% CI 88.3% - 94.1%) and a specificity of 77% (95% CI 70.5% - 82.7%)

Out of the 196 participants not referred by the OCO (without eye conditions), CVs using the app incorrectly referred (false positives) 43/196 (21.9%). There was no evidence found that being incorrectly referred was associated with sex (OR 0.70, 0.35-1.35, p=0.31) or age (OR 1.00, 0.97-1.03, p=0.86).

Further analysis of these incorrect referrals by CVs (false positives) showed that the reasons they had been referred were: 3/43 (7.0%) could not see 6/12 (had visual impairment); 1/43 (2.3%) had both visual impairment and self-reported eye pain or discomfort; 19/43 (44.2%) had self-reported difficulty seeing distant or near objects only; 16/43 (37.2%) had eye pain or discomfort only; and 4 (9.2%) complained of both eye pain or discomfort and difficulty seeing distant or near objects. None were due to the near vision assessment.

Similarly, out of 378 participants who were referred by the OCO (had eye problems), CVs correctly referred 344/378 (91.0%). There was evidence (p=0.003) of a difference in the odds

of the CV using the app referring participants by age, with the odds of being referred (if referral was required according to reference standard) higher in those aged 40 or older compared to those under 40 (OR 4.38, 95% CI 1.66 – 11.59), this was driven by the very high referral rate in the over 40s, with the vast majority being referred both by the OCO and the CV using the app. There was no evidence (p=0.28) of a difference by sex (OR 1.47, 95% CI 0.72 – 3.00). Most (25/34, 73.6%) of the participants classified as false negatives had conjunctivitis (allergic and other), Table 3.

Table 3: Clinical diagnosis of the participants referred by OCO and referral decisions by CHV using the Peek Community Screening App

Summary of Diagnosis	Referral decision by CV using Peek Community Screening App			
	Referred		Not referred (false negatives)	
	Number	%	Number	%
Cataracts	29	8.5	0	0
Presbyopia	56	16.3	2	5.9
Glaucoma	1	2.9	1	0.5
Refractive Errors	64	18.6	2	5.9
Allergic Conjunctivitis	117	34.0	16	47.1
Other Conjunctivitis	44	12.8	9	26.5
Corneal disease	2	0.6	0	0
Retinal Disease	5	1.5	0	0
Eye Injury and FB	1	0.3	0	0
Uveitis	1	0.3	0	0
Pterygium conjunctival swellings	10	2.9	0	0
Chalazion and lid swellings	2	0.3	0	0
Others:	12	3.5	4	11.8
Total	344	100	34	100

Discussion

We iteratively developed and validated smartphone-based algorithms used by community volunteers to identify and refer people with eye conditions for services from the community. The standard against which the algorithm was designed and validated were the referral decisions of a trained ophthalmic worker on the same participants.

We pre-determined in the study design the acceptable sensitivity and specificity levels to ensure adequate sensitivity to detect people with referable eye conditions in the community and also specific enough not to overburden the system. This was determined as a sensitivity of not less than 90% and specificity not less than 75%.

We found 65.9% of the participants enrolled in this study had a referable eye condition based on the examination using standard outreach equipment. This was higher than the prevalence of ocular morbidity found in other studies in Kenya and Rwanda, where the prevalence was 15.2% and 34%, respectively.[38, 39] This is likely to be due to differences in the study populations and case definitions used by the studies. We conducted most validation rounds after church when most people could attend an eye check, to get a representative sample of the community, however this may not be an unbiased sample. The case definition for the earlier ocular morbidity study in Kenya excluded minor eye conditions such as pinguecula, which we included.[39] In the Rwanda national survey only moderate to severe eye symptoms were included but in our study all symptoms irrespective of severity were considered.[38]

We found that community volunteers (CVs) could use the App, with moderate inter-observer agreement between them and the study ophthalmologist. The accuracy (sensitivity and specificity) of the algorithm was affected by prior duration of the symptoms, the commonality of symptoms and signs across different eye diseases and the number of signs and symptoms used to generate algorithm. Sensitivity of the algorithm decreased (from 97.3% to 78.4%) with a corresponding increase in specificity (17.8 % to 78.6%) when the duration of any eye symptoms was limited to one day from any duration [“Do you have any eye problem today?”]. There was a simultaneous increase in specificity (from 61.2% to 63.3%) and in sensitivity (from

83.7% to 90.5%) when presence of pain was expanded to include eye discomfort. Finally, introduction of near vision assessment improved the specificity (from 63.3% to 78.1%). It appears that if more signs and symptoms were included in the development of that algorithm the accuracy could be improved, but the decision to include additional elements had to be balanced with the extra cost of equipment to be used and the level of education and subsequent training requirement of CVs. Overall the algorithm had to be accurate, acceptable affordable and reproducible.

Trained CVs could use the final algorithm to accurately identify and refer people with eye problems (sensitivity 91.0%) and also those without eye disease (specificity 78.1%) in the community. We observed that that subjective questions were likely to cause greater variation in responses and hence performance of the algorithm.

For example, analysis of the referral criteria used in the algorithm show that, self-reported symptoms contributed more to the sensitivity of the algorithm than objective measurement of vision. If we didn't ask any of the questions on eye pain or discomfort and the one on disturbance in vision, our sensitivity would drop to 42.1%, this would result in missing 219 out of 378 determined to need referral instead of the 34 we miss now. In fact, it would be a far better screening test to not do any eye tests at all and just ask for symptoms of eye pain or discomfort and disturbance in vision. This would give us a sensitivity of 87.6% and specificity of 79.1%. If we just asked the two questions and age, then referred anyone over 40 or who answered yes to either question we get an estimated sensitivity of 91.5% and specificity of 77.0%. The findings suggest that if we excluded the objective measurement, we would not achieve an acceptable algorithm, unless if we referred everyone older than 40 years. A population-based study in Tanzania found the prevalence of presbyopia among people aged 40 years or older to be 61.7%,[40] implying that by referring everyone over 40 years we could overload the system with false referrals. This concurs with our observation in which participants aged 40 years or older were more likely to be referred by a CV and not by the OCO (false positives).

Similarly, the same self-reported symptoms of eye pain or discomfort and self-reported poor sight contributed to inaccurate decisions from the algorithm. About 81.4 % of false positive referrals using the app were from participants self-reporting to have eye discomfort or poor eyesight. Whereas, only 7% of false positives were due to inaccurate vision assessment. The findings suggest the need for training of the CVs to have skills in basic history taking and examinations. To reduce these false positive referrals, more clinical practise during training could improve their skills in assessing patients with eye problems. Some studies on performance of CHVs,[41] suggest a thorough initial training with supportive supervision to improve agreement between assessors. This implies that successful training could aim at certifying CVs who attained minimum agreement (moderate to almost perfect agreement with the reference assessor) before screening the community for eye problems. A further suggestion would be to retrain or even discontinue CVs who do not achieve the desired agreement, and include a systematic way to provide continuous assessment on referral appropriateness to maintain post-training standards.

We found that the participants who were referred by the OCO but not by the CV (false negatives), mostly (73.6%) had ocular surface inflammatory conditions such as allergic conjunctivitis, presbyopia (5.9%) or refractive errors (5.9%) (Table 3). We found that most participants with allergic conjunctivitis were correctly referred, suggesting that those identified as false negatives, may have had mild symptoms. This could have resulted from self-reported symptoms that were selectively mentioned to the CV but not the OCO. Although we did not analyse the severity of allergic conjunctivitis to conclusively classify them as false negatives, other studies have found that some patients who presented with red eyes and allergic conjunctivitis for outpatient consultations had less severe conjunctivitis that could be transient or managed at primary point of contact.[42, 43]

The findings therefore suggest the need for a deeper understanding and analysis of allergic eye conditions according to severity. There are suggestions to improve the sensitivity of current algorithm: the first approach is to introduce an assessment for red eyes into the algorithm with

integrated images of different types of red eyes to aid in the classification of severity. The second approach is up scaling screeners' knowledge to distinguishing normal and allergic eye disease. The ideal CVs should therefore have the skill set to identify visual impairment, referable and non-referable allergy; and Identification and management of presbyopia. This could however require policy change to implement in practice.

Finally, it may be possible to recalibrate the referral criteria for visual impairment based on the capacity of the services, restricting the threshold of referral to a level that generates referrals of those with more severe visual impairment and lowering this threshold over time as capacity increases to ensure the health system is not overburdened.

As demonstrated, there are multiple factors that affect the performance and acceptance of a guided screening algorithm, these include the subjective and objective inputs in the decision tree. Objective threshold tests such as acuity lead to a binary output (pass or fail) whereas subjective assessments such as self-perception of vision loss has a spectrum of outputs that requires a binary threshold to be derived in order to progress through the decision tree. Every iteration requires significant time and resource making optimisation challenging in practice, there is a potential for utilizing web-based A / B testing techniques currently being used in digital marketing to optimise algorithms more rapidly. [44]

There are limitations to be considered in this study. The study was conducted after church services and could have excluded those who didn't attend church. Moreover, those who participated may have had a perceived eye problem, which could have resulted in higher prevalence of referable eye conditions and hence higher predictive values. There could also be diagnostic uncertainty in the reference standard in this study where an OCO used simple outreach equipment without a slit lamp. The OCOs used as the reference are not available in other health systems and therefore the results may be not generalizable to those setting.

The Peek Community Screening App meets the minimum predetermined criteria. The next step is to incorporate the algorithm into a screening system to asses performance in a health

system, to identify people with eye problems and link them to primary and secondary centres. We anticipate that more people with eye health needs will be able access the appropriate level of eye services. More validation studies conducted in different settings and improvement to the existing algorithm may be required. Further research on the performance of the algorithms is needed for specific ages groups (aged 15 years or less, 15-40 years and those 40 year and older). If acceptable standards are met it could be of value in both determining the population demand for eye services in population-based studies as well as being a validated methodology for increasing access to appropriate services in integrated eye health programmes.

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Authors' contributions

Literature search: HR AB

Study conception, design and Methodology: HR AB DM MJB

Data collection: CB HR RM

Statistical analysis: HR DM

Drafting the manuscript: HR

Critical revision of the manuscript for important intellectual content: All authors

Obtained funding: AB MJB

Administrative, technical or material support: EW CB

Study supervision: AB MJB

Competing interests

The Peek Vision Foundation (09919543) is a registered charity in England and Wales (1165960) with a wholly owned trading subsidiary, Peek Vision Ltd (09937174). Professor Matthew Burton is a Trustee of The Peek Vision Foundation and Dr Andrew Bastawrous is CEO of The Peek Vision Foundation and Peek Vision Ltd. HR is an advisor to Peek Vision Ltd. All other authors declare no conflict of interest. This submission has not been published anywhere previously and is not simultaneously being considered for any other publication.

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6. Peek Community Eye Health – mHealth system to increase access and efficiency of eye health services in Trans Nzoia County, Kenya: study protocol for a cluster randomised controlled trial

Figure 6.1: A community volunteer assessing visual acuity during household screening using Peek Community Eye Health system

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SECTION A – Student Details

Student	Hillary Kipkemboi Rono
Principal Supervisor	Dr. Andrew Bastawrous
Thesis Title	Increasing Access to Eye Care using Mobile Phone-based Interventions. The development, validation and implementation of Peek to optimise human resources and lower barriers to access for those most in need

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

SECTION B – Paper already published

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SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	N/A
Please list the paper's authors in the intended authorship order:	
Stage of publication	Choose an item.

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)	Together with my senior colleagues I designed the study, prepared the protocol and submited for ethical approval, led the project and wrote the first draft of the paper with edits from supervisors and co-authors

Student Signature: [redacted] **Date:** 08.10.2019

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Trials

STUDY PROTOCOL Open Access

Peek Community Eye Health - mHealth system to increase access and efficiency of eye health services in Trans Nzoia County, Kenya: study protocol for a cluster randomised controlled trial

Hillary Rono[1,2*], Andrew Bastawrous[1,4], David Macleod[1], Emmanuel Wanjala[2], Stephen Gichuhi[3] and Matthew Burton[1]

Abstract

Background: Globally, eye care provision is currently insufficient to meet the requirement for eye care services. Lack of access and awareness are key barriers to specialist services; in addition, specialist services are over-utilised by people with conditions that could be managed in the community or primary care. In combination, these lead to a large unmet need for eye health provision.
We have developed a validated smartphone-based screening algorithm (Peek Community Screening App). The application (App) is part of the Peek Community Eye Health system (Peek CEH) that enables Community Volunteers (CV) to make referral decisions about patients with eye problems. It generates referrals, automated short messages service (SMS) notifications to patients or guardians and has a program dashboard for visualising service delivery.
We hypothesise that a greater proportion of people with eye problems will be identified using the Peek CEH system and that there will be increased uptake of referrals, compared to those identified and referred using the current community screening approaches.

Study design: A single masked, cluster randomised controlled trial design will be used. The unit of randomisation will be the 'community unit', defined as a dispensary or health centre with its catchment population. The community units will be allocated to receive either the intervention (Peek CEH system) or the current care (periodic health centre-based outreach clinics with onward referral for further treatment). In both arms, a triage clinic will be held at the link health facility four weeks from sensitisation, where attendance will be ascertained. During triage, participants will be assessed and treated and, if necessary, referred onwards to Kitale Eye Unit.

Discussion: We aim to evaluate a M-health system (Peek CEH) geared towards reducing avoidable blindness through early identification and improved adherence to referral for those with eye problems and reducing demand at secondary care for conditions that can be managed effectively at primary care level.

(Continued on next page)

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(Continued from previous page)
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Keywords: Eye problems, Visual impairement, Access, Primary eye care, Community Eye Health system, Community volunteers, Peek community screening App, Cluster randomised controlled trial

Background

Globally, it is estimated that 253 million people have visual impairment (VI; visual acuity in the better eye < 6/18), 36 million of whom are blind (visual acuity in the better eye < 3/60) [1]. About 80% of the impairment is avoidable [2]. Approximately 90% of those who are living with VI are in low- and middle-income countries [3]. Although the prevalence of moderate or severe vision impairment in adults aged ≥ 50 years is higher in South and Southeast Asia, North Africa, and the Middle East [4], sub-Saharan Africa (SSA) has the greatest gap between need (blindness VI) and available eye services [5]. In Kenya, the prevalence of blindness is high; it is in the range of 0.6–2.0%, depending on the region [6–10]. There are only 115 ophthalmologists for a population of 49 million. Moreover, their distribution is very uneven, in the range of 0–17 per 1 million population across the various counties [11].

The causes of blindness vary according to regions and countries [12–15]. Globally, the leading causes of VI are uncorrected refractive error and cataract, while cataract and glaucoma are the leading causes of blindness [2, 16]. Other causes of blindness include diabetes, macular degeneration, and other posterior eye diseases [7, 10, 17].

The reasons for a high burden of VI include poverty and a lack of access to eye services [18]. Patient factors such as lack of awareness, fear of treatment outcomes, increasing age, female gender, and presence of diabetes increase the risk of blindness [10, 19]. Health system-related factors include low numbers of eye workers, variable productivity, high indirect and direct costs, and the mal-distribution of the work force, which currently favours major urban areas [20–23]. In addition, there are 'provider' factors, such as poor-quality services arising from a shortage of trained staff and infrastructure [19, 24]. There is a large disparity between the need for eye services and availability of eye care workers [5].

To improve access to eye health services, especially in rural areas, outreach programs designed to promote access to eye services by communities in remote regions have been used [22, 25]. They provide short-term access to eye services for patients; however, the long-term goal is to integrate eye services into primary healthcare (PHC) as a continuum of health service provision [26, 27]. Redistribution of tasks among health workforce teams, to improve efficiency among available human resources, have also been used with variable success [9, 28]. Effective task shifting with clear referral criteria and management plans has been successfully delivered through algorithms such as the Integrated Management of Childhood Illness (IMCI) at primary level [29, 30]. In eye care, decision trees and algorithms have been developed, mostly outside Africa, and focused on identifying the diagnosis and treatment at a secondary level [31–33]. The World Health Organization (WHO) recently developed similar algorithms and training manual for use at the PHC facilities in Africa [34]. To our knowledge, there are no digital algorithms to identify and refer people from communities.

Rationale

There is a clear need for improved access to eye health services for populations in many regions of the world. Availability of mobile phone technology and its usage in healthcare, including eye care, is increasing rapidly [35, 36]. One such example is Peek acuity, which has developed applications (Apps) for measuring visual acuity [37]. One study in Kenya showed that the Peek Visual Acuity App was a repeatable, accurate and reliable measure of visual acuity in adults [38]. This App was found to be acceptable to patients, care givers and stakeholders [39]. Another study among school-going children compared the performance of teachers using the Peek Acuity App to assess children's vision to a clinician assessing the same children using as standard backlit EDTRS LogMAR visual acuity test chart found a sensitivity of 77% (95% confidence interval [CI] = 64.8–86.5) and specificity of 91% (95% CI = 89.3–92.1) [40]. We initially developed and validated the 'Peek community screening App' that allows referral decisions to be made precisely and reliably across all ages for the trial. Results from the validation of this App showed that community volunteers (CV) could accurately make referral decisions (manuscript in preparation).

A recent systematic review showed that mobile health (m-Health) interventions that support communication between healthcare providers and patients through short messaging service (SMS) appointment reminders are beneficial [41]. Similarly, outreach service provision in India incorporated the electronic transfer of health-related data from outreach clinics to base hospitals with some success [42]. This provides an opportunity for a combined outreach model, which incorporates triage and referrals aided by mobile technology.

We recently conducted a cluster randomised controlled trial in primary schools in Kenya using the Peek School Eye Health system. The system uses the Peek

Acuity App to detect VI in school children. For those that then screen positive and who require further assessment or follow-up, it generates automated text messages to parents/guardians and contact teachers, as well as real-time notifications to hospital services. We found that teachers could reliably screen for VI. Uptake of referrals to eye care providers was substantially higher in the Peek intervention arm of this school trial [40]. This trial provided evidence that m-Health solutions could be used to improve access to eye health services.

In this new trial, the Peek Community Eye Health (Peek CEH) system will be compared to the current standard approach of periodic health centre-based outreach clinics. The system uses the 'Peek Community Screening App', which is a smartphone-guided algorithm for supporting 'Peek Users' to identify and refer people with visual impairment and other eye problems in the community. Peek Users are CVs who are trained specifically in how to use Peek. They travel to multiple communities to perform their duties. During community outreach, they work with the local CVs to identify and refer patients needing ophthalmic attention. Although treatment will be provided at no cost, it is assumed that: (1) all patients trust the health system; (2) eye health workers have the capacity and able to manage all conditions; and (3) relevant treatment modalities will be available.

Objectives

The objective of this cluster randomised trial is to test the hypothesis that the Peek CEH system can increase access to eye services through: (1) increased identification of people with impaired vision and eye problems in the community; (2) increased uptake of a referral within four weeks by patients with identified an eye problem; and (3) more appropriate utilisation of primary and secondary care services at each health system level.

Methodology

This protocol is structured in accordance with the Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT) 2013 Checklist [43] (see Additional file 1).

Trial design and overview

This trial is a single-masked, parallel-group, cluster randomised controlled trial. Thirty-six community units with their health facilities (dispensary or health centres) will be randomly selected to receive either the intervention (community screening using the Peek screening system) or the current standard of care (periodic health centre-based outreach clinics). The health workers involved in the study will be trained to ensure standardised screening. Participants who provide consent will be enrolled to the arm to which their cluster is randomised.

In the Peek arm, all households in the cluster will be visited in turn. Consenting individuals will have their visual acuity tested using the Peek visual acuity screening application on a smartphone. All participants with reduced visual acuity or reporting another eye problem will be referred to the linked PHC for assessment and management. Those requiring treatment not available from the PHC facility will be referred onwards to Kitale Eye Unit (KEU). In the control arm, communities will be notified about the periodic eye health outreach clinic that will be held in the local health centre. People attending this service will be assessed and, if necessary, referred onwards to KEU.

The participants will be followed up for eight weeks after referral from the community. The primary outcome will be the number of people per 10,000 population (rate) attending triage at a local health facility (PHC) with any confirmed eye conditions (true-positive cases determined at triage by hospital outreach team) following a referral or by self-referral within four weeks from the time of sensitisation. The secondary outcome will be the proportion of people referred from the PHC triage attending their referrals at KEU within four weeks of being referred. A participant (standard or Peek) who attends the hospital appointment within four weeks will be considered an 'attender' while anyone who is referred but does not attend within the same time is a 'non-attender'.

Participant timeline and study flow chart

The study flow chart and participant timeline are presented in Fig. 1 and Table 1, respectively.

Participants, interventions and outcomes

Study setting

The trial will be conducted in community units that are served by government-run dispensaries and health centres in Trans Nzoia County in northern Kenya. Trans Nzoia County has a population of 818,757 people (2009 census) of which 407,172 (49.7%) were male [44]. It is organised into five sub-counties. There were 173,719 households, with an average of five people per household. The large majority have no Internet access (669, 347, 81.8%) [45]. There are 61 government facilities (six hospitals, 12 health centres, 43 dispensaries) and 76 facilities owned privately or by faith-based organisations [46]. Eye services are offered at KEU and through outreach services, provided by eye care staff from KEU to other health facilities. Screening and treatment of eye conditions (triage) is offered during outreach. The trial will be coordinated from Kitale Hospital by a team consisting of a programme manager, administrator, ophthalmic nurses, field workers and an ophthalmologist.

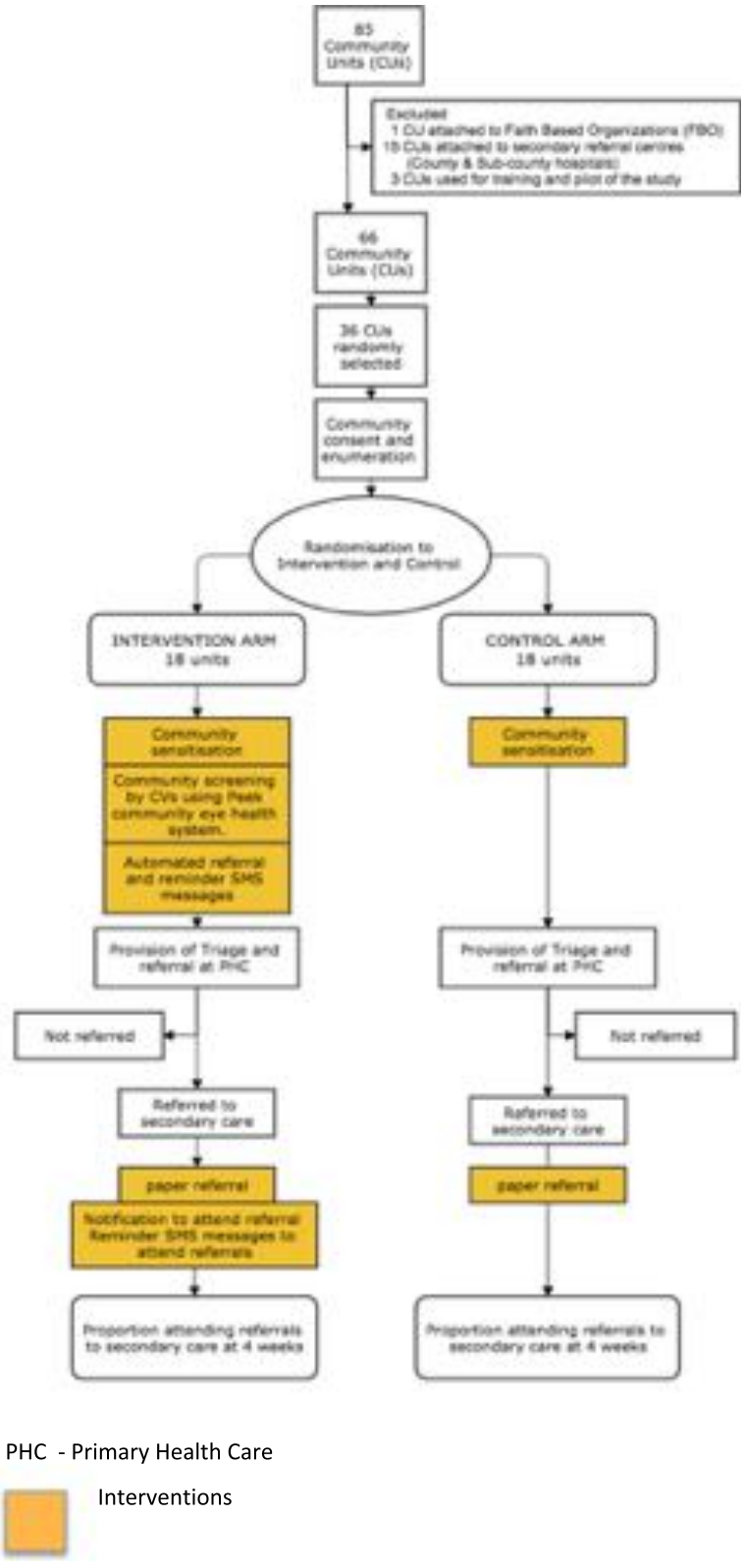


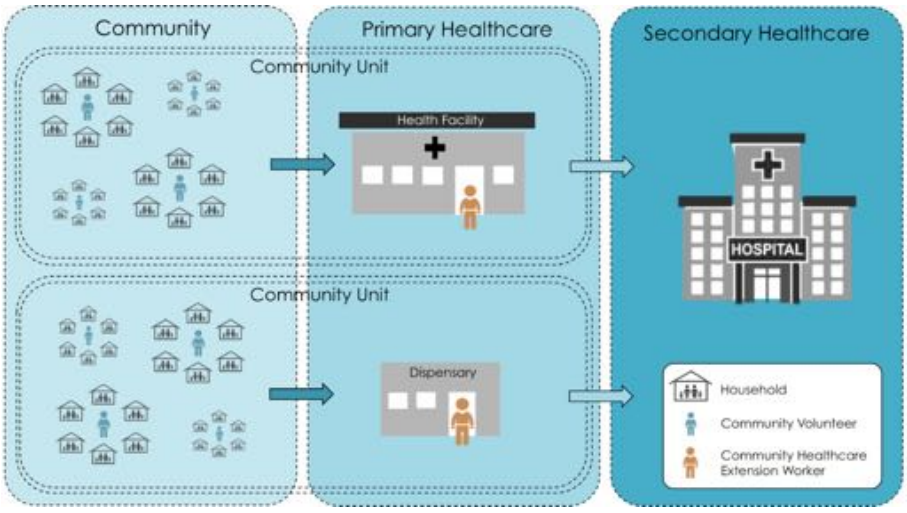
Fig. 1 Trial design outline: randomisation, interventions and flow of participants

Table 1 Project timeline

	Study period											
	Enrolment		Allocation	Post allocation								Close-out
Week	− 2	− 1	0	1	2	3	4	5	6	7	8	9
Preparation												
Training of field workers	X	X										
Approvals: Trans Nzoia health department and head of health facilities	X											
Community enumeration and obtaining consent	X	X										
Allocation of community units			X									
Interventions												
Community sensitisation				X								
Peek package (community screening, automatic reminder short text messaging)					X	X	X					
Standard care				X								
Triage treatment camp								X				
Peek referral reminders to attend Kitale Eye Unit (automatic reminder short text messaging)								X	X	X	X	X
Assessment												
Attendance (uptake) of referrals								X	X	X	X	X

Cluster definition

The unit of randomisation for this trial will be Community Units (CU). These are defined as a dispensary or health centre together with the community they serve (Fig. 2). A typical CU comprises a population of 5000–10,000 people. It has a dispensary or health centre, staffed by one or two Community Health Extension Workers (CHEWs). Associated with each CU, there are usually 20–50 CVs [47]. The CHEWs based at the health centre or dispensary train, support and supervise the CVs. To date, 85 CUs have been established and personnel trained in this county [46]. CUs were chosen because it represents the future shape of healthcare in Kenya; they are distributed throughout the county and have a good referral network that provides linkages between community and health system. The CUs with untrained



Courtesy: Andrew Bastawrous

Fig. 2 Community units, levels of healthcare and referral pathway (prepared by Andrew Bastawrous)

personnel provide a buffer zone that will minimise contamination.

Cluster eligibility criteria

A list of all health facilities with their geo-coordinates as well as corresponding CUs and catchment population will be obtained from the Trans Nzoia County Department of Health. The location of each hospital will be determined using Google Maps. Health facilities without CUs, those with existing screening programs and the communities directly served by KEU will be excluded. We will also exclude all the non-government health facility-associated CUs. From the remaining 66 CUs, a total of 36 CUs will be randomly selected for the study. A restricted cluster random sampling technique (described below) will be applied to allocate the selected CUs to the Peek intervention (18 CUs) or the standard care group (18 CUs). The restriction will be based on the distance and location of the CU's heath facility relative to KEU.

Participant eligibility criteria

All people who consent to participate and present in the community unit area during the study period will be included. People who are unwilling to give consent or who have had an eye condition treated at hospital within two weeks before the beginning of the study will be excluded.

Interventions

A comparison of the two arms is shown in Table 2 and Fig. 1. Before the beginning of the trial, households in each of the clusters in both arms will be visited by the field team to explain the study, obtain consent (see Additional file 2) and enumerate the residents. Parents/guardians will provide consent for children. At the beginning of the trial, in both arms, there will be posters and verbal notices (churches and schools) advertising the forthcoming outreach clinic for eye checks, encouraging people with eye problems to self-report to the clinic on a specific date when the team will visit.

Peek CEH intervention arm In each cluster, a small mobile team of a 'Peek User' (CVs trained specifically on how to use the Peek Community Screening App and who travel to multiple communities to perform their duties) and local CV will visit each household. The CV, a person from that same community, will guide the Peek User around the village. After reconfirming consent, people who are resident in the household at the time of the visit will have a vision assessment. The visual acuity of each eye will be measured separately using the Peek Acuity App [38]. This smartphone application presents a series of E-optotypes in one of four orientations, selected at random. The test algorithm prompts the following screening questions to the parents or guardian with a child ('*Does the child have any problem with their eyes*

Table 2 Comparison of the interventions in the two arms of the trial

	Intervention arm	Control arm
Consent and enumeration	Yes	Yes
Community sensitisation	Posters and announcement in churches and schools	Posters and announcement in churches and schools
Community screening	Vision assessed at household level using Peek E- acuity by field worker	No vision assessment at household level
	Screening decision using Peek Screening App	No screening
	Personalised text and weekly reminder messages for participants/carers in the relevant local language to attend appointments	No text message
Referral from community to PHC (triage centre)	Self-referring participants and referrals by CV using Peek system?	Self-referring participants
	Automatic referral through Peek system	No referrals
Provision of triage	Trained team composed of ophthalmic clinical officer, ophthalmic nurses and two field workers	Trained team composed of ophthalmic clinical officer, ophthalmic nurses and two field workers
Referral from triage centre to secondary care	Paper referral	Paper referral
	Automatic referral through Peek system and weekly reminder SMS	
Assessment of primary outcome	Same for both arms (trained field worker)	Same for both arms (trained field worker)
Assessment of referrals	Ophthalmic clinical officer	Ophthalmic clinical officer

today?') or directly to participant themselves ('*Do you have any discomfort or pain in your eyes today?*' and '*Do you have a problem with your sight when seeing far or near objects?*'). If the participant is aged ≥ 6 years, the App prompts for distant visuals acuity assessment using Peek Acuity App and assessment of near visual acuity for all people aged ≥ 40 years. Near vision will be assessed at 40 cm using the RADNER reading chart [48]. They will be referred to the PHC for subsequent assessment by the visiting time if: the visual acuity is < 6/12 in either eye; there is any self-reported eye pain or discomfort; there is difficulty seeing distant or near objects; or they are not able see N8 on near vision assessment. Household members absent during the first visit will be asked to join the examination team at the next household or next day.

Those who have reduced visual acuity on screening or report an eye problem will be referred to a health post for triage on a specific date when the KEU team visit. The system will generate several SMS text messages: (1) to the patient and family associate asking them to present to the health facility on a specific day (set to be within four weeks); (2) the CV will receive an SMS list of patients from their community that have been referred; and (3) the CHEW responsible for that CU will similarly receive the same list of referred patients. A weekly reminder SMS will be sent to the patient for them to attend their referral appointment with the last reminder being one day before the appointment.

On the pre-advertised date, a team from KEU will be based at the CU's dispensary. The participants referred from the household screening because of reduced vision or a specific eye problem will be reminded to attend. They will assess the presenting patients using the current standard procedure (Snellen chart visual acuity, magnifying loop, refraction and direct ophthalmoscopy when indicated). They will provide simple treatments or refer patients to KEU for further assessment as indicated. A pre-numbered paper referral letter will be given to the patient to present at KEU. The referral slip has their study number, name and triage centre, and telephone number, and indicates that assessment and treatment will be provided at no cost. It is expected that they will report to KEU within four weeks from being referred.

Immediately after referral from the PHC, an SMS will be sent to the patient and the family associate asking them to present to KEU. A weekly reminder SMS will be sent for those who have not attended their referral to KEU. An SMS with a list of patients who have not attended their referral will be sent to the CHEW responsible for the PHC.

Standard of care (control) arm In the control arm, there will be no active Peek screening in the community; however, potential participants with eye problems at the community will be notified through community sensitisation (posters and local announcements) that if they have an eye problem to present themselves to the health facility for the triage clinic on a specified date. On that advertised date, the team from KEU will conduct an outreach clinic within the CU, which will be identical to the ones in the Peek arm described above. If an individual needs to be referred to KEU, they will be given an identical referral letter to the ones used in the Peek arm. Each letter will have a unique code number to link the patient referral record to their KEU attendance.

Outcomes

Primary outcome The primary outcome is the number of people per 10,000 population (rate) attending triage at a local health facility (PHC) with any confirmed eye conditions (true positives) following a CV referral or by self-referral, within four weeks from the time of sensitisation. The rate will be based on baseline enumeration census for each CU. The true positives will be determined at triage by the hospital outreach team.

Secondary outcomes The secondary otucomes are: (1) the number of people per 10,000 (rate) attending the triage post without any eye condition (false positives) as determined by the eye team; (2) the number of people per 10,000 population (rate) attending KEU within four weeks after being referred from PHC; (3) the proportion of participants referred from the PHC who attend the referral at KEU within four weeks of being referred from a PHC; and (4) the time taken by a participant referred from PHC to attend KEU.

Sample size

The sample size of 36 clusters was determined using the Hayes formula for rates in unmatched cluster randomised trials [49]. In Trans Nzoia County, a typical health facility has a catchment population of 5000 people [46]. During previous community outreaches to these health facilities, about 50–100 new patients attended. This translates to an average rate of 15 per 1000 population [50]. Assuming an intraclass correlation coefficient of 0.001, desired power of 90% and significance level of 5%, a sample of 36 CUs (18 in each arm) would be sufficient to detect a difference of 0.5%, from 1.5% in the control arm to 2.0% in the intervention arm (a 33% relative change) in overall attendance rates.

Assignment of interventions

Allocation There are 66 potentially eligible CUs in the county (see above). We will select 36 CUs for inclusion in the trial. In order to ensure balance between the arms,

restricted randomisation will be used. A list of the 66 CUs with their sub-county, distance from Kitale and direction from Kitale (categorised into four quadrants, North, South, East and West) will be compiled and used during randomisation. A statistician, who will not participate in recruitment, will generate a random allocation sequence. Randomisation will consider the direction, cluster size and distance from the hospital. The following restrictions will be used in the randomisation:

- each arm must include at least two CUs from each sub-county;
- each arm must include at least two CUs from each direction of North, South, East and West;
- the ratio between number of CUs in each arm from each direction must be in the range of 0.67–1.5;
- the difference in mean health centre distance from Kitale in each of the arms should not be > 4 km; and
- there should not be more than one CU per link health facility.

A list of 10,000 valid permutations will be generated and checked that there are no clear deviations in randomness (e.g. pairs of health centres that occur within the same arm considerably more/less often than would be expected by chance). One of these 10,000 permutations will be computer-selected at random. A list of CUs allocated to the control group, intervention group and those not involved will be prepared.

In health facilities where there are larger catchment populations and served by more than one CU, one of the CUs will be randomly selected along with its population unit, so that the size of the clusters studied is around 5000.

Masking

It will not be possible to mask the participants or the health workers from the intervention to which they are allocated; however, the study statistician, hospital registration clerk and clinician assessing outcomes will be masked. The data clerk will be masked to the intervention arm because all the patients will present with paper referral. The clinician assessing secondary outcomes will not participate in patient recruitment or assessing attendance and all patients will be given similar assessment questionnaires. The statistician will not participate in patient recruitment.

Data collection, management and analysis

Data collection In both arms, we will use electronic data capture and management using dedicated Peek software with built-in consistency checks. In both arms, this will include the enumeration data, the triage data in the health centre/dispensary and the outcome data collected in the KEU. In addition, the household screening data will also be captured electronically for the Peek arm during the study period and in the control arm following the study when the team will screen all the control clusters. Field workers will be provided with tablets for data entry. Information will be backed up regularly.

During triage assessment at the health centre/dispensary, trained field workers will verify that the participant comes from the catchment population. From each eligible participant, date of attendance, name, age, gender and own or parents' mobile phone number, whether referred using the Peek system or self-referral, the diagnosis and treatment plan (treated or referred) will be obtained. At KEU, all referred patient will be marked as attended upon presentation and record the date of visit, diagnosis and outcome of the visit.

Data management

Data will be entered directly onto smartphones by trained field workers and uploaded to a secure server once connected to the Internet before being exported into Stata for analysis. The database will be encrypted and password-protected. At the end of the study, the data will be archived at LSHTM.

Data analyses The trial will be reported using the 2010 CONSORT guidelines, with the cluster RCT extension [51]. Analysis will be by intention to treat. Socio-demographic characteristics of participants at baseline will be tabulated by arm: age; sex; residence; and distance from hospitals (categorised distances). The distributions of these variables by intervention arm will be compared to assess whether there is imbalance at baseline in these potential confounding factors.

Analysis of the primary outcome

The proportion of individuals attending triage within each cluster will be calculated, by dividing the number attending triage and having a confirmed eye condition by the cluster population, which will be determined by the baseline enumeration census in both arms (true-positive attendance rate). A t-test will be performed on these cluster-level rates providing an estimate of the rate difference (with a 95% CI) between the two arms and a P value in order to assess the strength of evidence against the null hypothesis that the rate is equal in the two arms [52]. The two study arms should be balanced in terms of confounders due to the restricted randomisation process so the primary analysis will be unadjusted.

Analysis of secondary outcomes

The proportion attending triage but having no eye condition (false-positive attendance rate) will be estimated

in a similar manner to the above in both arms, with a rate difference estimated, along with its 95% CI.

In order to estimate the effect of the intervention on the attendance rate of true positives at KEU the approach will be identical to the cluster-level analysis of the primary outcome. The numerator of each cluster is the number of individuals attending KEU following a referral from triage and the denominator is the cluster population. Again, a t-test will be used to assess the evidence as to whether the rate differs between arms and the analysis will again be unadjusted.

The difference in the proportion of patients referred from the PHC to the KEU who attend their referral within four weeks, by arm, will be tested using a random effects logistic regression, with attendance at KEU as the outcome, trial arm as the primary exposure and cluster as a random effect to account for within cluster correlation. Due to the fact that the characteristics of the patients referred in each arm may be different (due to the potential upstream impact of the intervention), this analysis will be adjusted for sex, age group and distance from KEU.

The impact of the intervention on time-to-attendance will be investigated, using Kaplan–Meier plots for each arm to compare attendance of referral. The hazard ratio will be estimated using Cox regression, again adjusted for sex and age group, to assess whether patients referred in the intervention arm attended their referrals sooner than those in the control arm..

We will assess possible effect modification of sex, age and distance from KEU. In the cluster-level analyses, the approach recommended by Cheung et al. [53], will be used for age and sex, where the rate in each group within each cluster will be estimated, then the difference in this rates in each group found, before finally performing a t-test on these differences by arm. In order to identify if the distance from KEU is an effect modifier, since it is a cluster-level covariate, this can be done by performing a linear regression on the cluster level rates and include distance and trial arm as exposures with an interaction term between them. For the individual-level analyses, an interaction term will be included with trial arm for each of the potential effect modifiers (age, sex, distance from KEU).

Monitoring

Data monitoring

The study presents minimal risk and we do not anticipate significant adverse events. Therefore, a data and safety monitoring committee was not considered necessary; however, an audit will be done by the London School of Hygiene and Tropical Medicine (LSHTM), the Trial Sponsor, if it is deemed necessary. No interim analysis is planned due to the relatively short duration of the study.

Harm

The tests being done are in routine clinical use in Kenya and internationally. There are no anticipated harms from this non-invasive assessment process in either arm. Assessment in the community will take 5 min per person. Experienced certified ophthalmic clinical officers will provide treatment for all participants with eye problems, under the supervision of an ophthalmologist.

Protocol amendments

There have been no protocol amendments since the initial application. Amendments to the protocol are not currently anticipated; however, if they are required they will be submitted to the two committees mentioned above.

Consent

Trained field workers will obtain written informed consent from all participants. Where an individual is unable to read, the information will be read to them and their consent documented by thumbprint, in the presence of an independent witness. Consent for children will be obtained from parents or guardians accompanying them. A copy of the information sheet will be given to each participant. Verbal assent will also be obtained from children before being examined.

Confidentiality

Data will be anonymised before analysis and long-term storage by the removal of personal identifying information. The Peek database will be encrypted and password-protected with access only granted to staff involved in the study. Data with identifiable information will be secured within a locked project office at KEU, with limited access to only authorised staff.

Access to data

Investigators at LSTHM and Kitale Hospital will have access to the final trial dataset. An agreement exists on data sharing and intellectual property. All the data will be archived at LSHTM after the study is completed.

Post-trial care

Given that the trial is being conducted by KEU, it is integrated into existing health systems through which the patients will be managed. The control arm clusters will have the same screening service as the intervention arm after the end of the trial.

Dissemination

Summary of the findings will be provided for local stakeholders, Ministry of Health and participating institutions. Publications will be submitted to peer-reviewed journals (open access) and presentations made at regional and

international conferences and meetings in Kenya and the United Kingdon.

Discussion

This trial is designed to evaluate whether the Peek Screening system in the community increases access to eye services at PHC within four weeks for patients with eye problems, as well as to assess whether the same system increases uptake of referrals of people identified with eye problems from PHC to secondary care within four weeks.

One identified limitation of the study would be the number of people who will be screened and referred but have no eye problems (false positives) and may potentially overload the health system. Through the trial, we shall analyse the potential limitations with a view of understanding and providing potential solutions in the future.

The WHO and International Agency for Prevention of Blindeness (IAPB) have set a target of eliminating avoidable blindness by 2020 through early identification and treatement. This study aims to evaluate a system to reduce the prevalence of people with VI through early identification and referral from the community for those with ophthalmic ailments. The system will potentially increase access and uptake of eye services through screening and referral by CVs, for those with eye problems. Through the system, we shall be able to track the process of screening and referral of patients with a view of identifying gaps in the health system and advise policy makers on potential solutions. The results will therefore be relevant and contribute towards realising this goal.

Trial status

At the time of submission, recruitment was ongoing. Recruitment started on 26 November 2018 and is expected to be completed on 09 April 2019. It was registered by Pan African Trials Registry on 8 June 2018.

Additional files

Additional file 1: Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT) 2013 Checklist. (DOC 122 kb)

Additional file 2: Informed consent materials. (DOCX 112 kb)

Abbreviations

App: Application; CEH: Community Eye Health; CHEWs: Community health extension workers; CU: Community unit; CV: Community volunteer; IAPB: Internatinal Agency for Prevention of Blindeness; IMCI: Integrated Management of Childhood; KEU: Kitale Eye Unit; LSHTM: London School of Hygiene and Tropical Medicine; m-health: Mobile health; PACTR: Pan African Clinical Trials Registry; Peek: Portable eye examination kit; PHC: Primary healthcare; SMS: Short messaging services; SSA: Sub-Saharan Africa; VI: Visual impairment; WHO: World Health Organization

Acknowledgements

International Centre for Eye Health, Peek vision ltd, Operation Eye sight Universal, Kitale county hospital staff, Kenya. London School of Hygiene & Tropical Medicine sponsors the study.

Trial status

At the time of the submission, recruitment was ongoing. The protocol version 1 of 20/3/2018 was registered by Pan African Trials Registry on 08.06.2018. Recruitment started on 26.11.2018 and is expected to be completed on 09.04.2019.

Sponsor

London School of Hygiene & Tropical Medicine is the main research sponsor for this study. For further information regarding the sponsorship conditions, please contact the Research Governance and Integrity Office:
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Authors' contributions

Literature search: HR AB. Study conception and design: HR AB MB. Data collection: HR EW SG. Statistical analysis: HR DM. Drafting the manuscript: HR. Critical revision of the manuscript for important intellectual content: All authors. Obtained funding: AB MB. Administrative, technical or material support: EW. Study supervision: AB MB SG. All authors read and approved the final manuscript.

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This protocol has undergone peer review. The funders and trial sponsor have no role in data collection, analysis, and interpretation of data, decision to submit the protocol for publication and in preparation of manuscript.

Availability of data and materials

Not applicable.

Ethics approval and consent to participate

This protocol has been approved by the London School of Hygiene & Tropical Medicine Ethics Committee (reference 14633) and Institutional Research and Ethics Committee (IREC) of Moi University (number 0003025). It is registered with the Pan African Trials Registry number 201807329096632. Local administrative permission has also been provided by Ministry of Health officials and the heads of the selected health facilities involved in the study. Written informed consent wil be obtained from all participants. Parents or guardians will provide consent for their child and verbal assent also will be obtained from the children.

Consent for publication

Not applicable.

Competing interests

The Peek Vision Foundation (09919543) is a registered charity in England and Wales (1165960) with a wholly owned trading subsidiary, Peek Vision Ltd. (09937174). Professor Matthew Burton is a Trustee of The Peek Vision Foundation and Dr. Andrew Bastawrous is Chief Excecutive Officer (CEO) of The Peek Vision Foundation and Peek Vision Ltd. HR is an advisor to Peek Vision Ltd.
All other authors have no proprietary or commercial interest in any of the materials discussed in this article. This submission has not been published anywhere previously and is not simultaneously being considered for any other publication.

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Publisher's Note

7. Increasing access to eye health services in Kenya using an mHealth system: a Cluster randomised controlled trial.

Figure 7.1: Increases attendance to health posts by patients seeking eye care services during outreach.

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RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS.

SECTION A – Student Details

Student	Hillary Kipkemboi Rono
Principal Supervisor	Dr. Andrew Bastawrous
Thesis Title	Increasing Access to Eye Care using Mobile Phone-based Interventions. The development, validation and implementation of Peek to optimise human resources and lower barriers to access for those most in need

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?			
When was the work published?			
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion			
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:	Hillary Rono Andrew Bastawrous David Macleod Ronald Mamboleo Cosmas Bunywera Emmanuel Wanjala Stephen Gichuhi Matthew Burton
Stage of publication	**Not yet 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)	Together with my senior colleagues I designed the study, prepared the protocol and submited for ethical approval and registration, led the project, data collection, initial analysis of the data and wrote the first draft of the paper with edits from supervisors and co-authors

Student Signature: [redacted] **Date:** 08.10.2019

Supervisor Signature: [redacted] **Date:** 09.10.2019

Increasing access to eye health services in Kenya using an mHealth system: a Cluster randomised controlled trial.

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Trial registration The Pan African Clinical Trials Registry (PACTR), 201807329096632.

Abstract

Background

A combination of limited access to eye services and low numbers of eye care providers in low and middle-income (LMIC) populations results in high prevalence of avoidable vision impairment. Poverty, lack of awareness and longer distance are key barriers to access these services. We investigated the effectiveness of the Peek Community Eye Health system (Peek CEH), a smartphone-based referral system comprising decision support algorithms (Peek Community Screening app), short message service (SMS) reminders and real-time system level reporting.

Methods

We conducted a single masked cluster randomised controlled trial. All participants in a 'community unit' defined as a dispensary or health centre with its catchment population were eligible. Community units were randomly allocated (1:1) to receive either the Peek CEH and referral (intervention group) or the current standard with periodic health centre-based outreach clinics and onward referral (control group). Participants in the intervention group were assessed in their houses by screeners and those referred were asked to present for triage. They also received regular SMS reminders. In both groups, community sensitization was done followed by a triage clinic at the link health facility four weeks from sensitisation. During triage, participants in both groups were assessed and treated and, if necessary, were given a referral letter to Kitale Eye Unit, participants in intervention arm received further SMS reminders. The primary outcome was the number of people per 10,000 population (rate) with eye conditions attending triage at four weeks of sensitization. Primary analysis was by intention to treat, with the intervention effect estimated using a t-test performed on cluster-level rates. This trial is registered with Pan African Clinical Trial Registry, number PACTR 201807329096632.

Results

Trial recruitment occurred between November 26, 2018, and June 7, 2019. We randomly selected 36 out of the 66 eligible CUs; these were then randomised to either the intervention group (68,348 participants) or the control group (60,243 participants). 9,387 (13.7%) participants from intervention group and 3,070 (5.1%) from the control group attended triage. The mean attendance by participants with eye problems was 5.2% in the control arm compared to 14.3% in the intervention, risk difference 9.1% (95%CI: 6.9-11.3%); p <0.00001. The mean hospital attendance was 0.8% for the intervention group vs. 0.3% in the control, risk difference 0.5% (95%CI:0.25-0.73%); p=0.0002. Hospital utilization (secondary care) rates by the catchment population remained consistent with normal annual levels, however a major change in the proportion of appropriate utilization was seen with a decrease from 63% to 13% with primary eye care conditions (most managed at triage) and an increase from 8% to 56% with priority vision impairing eye conditions.

Interpretation

The Peek Community Eye Health system increased primary care or hospital attendance for people with eye problems compared with the standard approach in communities. This indicates the potential of this technology package to improve uptake of eye services and guide task shifting of case identification to help target resources.

Funding

The Queen Elizabeth Diamond Jubilee Trust. MJB is supported by the Wellcome Trust (207472/Z/17/Z)

Background

Globally, about 253 million people have vision impairment (VI), (visual acuity in the better seeing eye <6/18), of which 36 million are blind (visual acuity in the better eye <3/60).[1] An estimated 89% of those who are living with VI are in low and middle-income countries (LMICs) and about 80% of the impairment is avoidable.[2] Worldwide, the main causes of VI are uncorrected refractive errors (42%) and cataract (33%); both of these being preventable and reversible VI.[3]

Some of the reasons for a high prevalence of VI are poverty; [4] lack of awareness and fear of treatment outcomes, [5,6] low numbers of eye workers, and the mal-distribution of the workforce which currently favours major urban areas, [7,8] and "Provider" related factors such as poor quality services arising from a shortage of trained staff and infrastructure.[6,9] In addition, the limited available services are being utilized by people with conditions that could be managed at other levels of health care, creating further pressures on service providers and reducing equity and access to eye health.[10]

A major priority for VISION2020, the global initiative to eliminate avoidable blindness, is to reduce VI through equitable access to eye services and appropriate management of the conditions.[11] The World Health Organization (WHO) advocates for a well-coordinated and systematic eye care system with each level of health care performing specific roles such as management of cataracts and refractive errors at secondary care, [12] and identification with limited care at the primary care level.[13] Delivery of primary eye care can be broadly categorised in to two models based on their working operations, it may be either through fixed facilities and human resources or mobile services from a secondary care team. [14] The latter outreach model is more effective at providing short term access to eye care especially in rural areas.[22] [15] The long-term, more sustainable goal though is to integrate eye services into fixed primary health care (PHC) as a continuum of health service provision.[16]

An outreach from secondary eye care to fixed government run facilities model was used in this trial.

Mobile health (m-Health) interventions that support communication between health care providers and patients such as through short messaging services (SMS) appointment reminders is beneficial in improving adherence. [17] Others have reliably been used to identify VI enabling patients to recognise the need for eyecare.[18,19] These interventions can increase system efficiency by reducing workload and making more efficient use of the limited human resources currently available through task-shifting,[20] minimise errors associated with paper reporting and prevent stock-outs through the increased automation of inventory and supply-chain management systems.[21,22] Additionally, phone-based decision trees can assist less-well-trained users in decision making and can be helpful in diagnosis, monitoring or for data-gathering more generally.[21]

Previously we conducted a cluster randomised controlled trial in primary schools in Kenya using the Peek School Eye Health system to detect vision impairment in school children by task-shifting detection to teachers using a vision testing smartphone application. We found that teachers could reliably screen for vision impairment and the uptake of referrals to hospital was almost more than twice among those who received the intervention, suggesting that mHealth solutions could be used to improve access to eye health services.[23]

Prior to commencing this trial, we developed and validated the "Peek Community Screening App," (PCS app) a decision support algorithm, including the previously validated visual acuity test, [18] that allows referral decisions by community volunteers to be made precisely and reliably across all ages for the trial (manuscript in submission). We have now integrated this app into an mHealth system for eye health screening in communities.

The aim of this study was to assess the effect of the Peek Community Eye Health system on increasing access to eye services through increased identification of people with eye

problems in the community; increased uptake of a referral within four weeks by those with an identified eye problem; and more appropriate utilisation of primary and secondary care services at each health system level.

Methods

Trial Design and Participants

The methodology for this trial of the Peek Community Eye Health - mHealth system has previously been described in detail and is summarised here.[24]

We conducted a single-masked, parallel-group, cluster randomised controlled trial in 36 community units in Trans Nzoia County, Kenya. CONSORT guidelines for reporting cluster randomised trials were followed.[25] Clusters were community units (CU), defined as a dispensary or health centre together with the community they serve. A typical CU has a population of 5,000 to 10,000 people, although some may be smaller.[26,27] Community members self-presenting with eye problems or those identified by trained community screeners using the Peek Community Screening app (PCS app) were asked to present for assessment and treatment of basic eye conditions (triage) on a specified date at the linked primary health facility. Those with conditions requiring secondary level assessment and treatment, such as cataract or refractive errors, that could not be managed at triage were referred to the secondary eye care unity, Kitale Eye Hospital.

We conducted a baseline census in selected community units before allocation to the study arms to determine the population size per cluster. Residence, age and sex were recorded. All people present in the community unit during the study were eligible for inclusion. Written informed consent from all participants was obtained before enrolment, parents or guardians consented for children. Participants were excluded if they did not provide consent. The study adhered to the principles of the Declaration of Helsinki on Ethics. It was approved by the Moi University Institutional Research and Ethics Committee, Kenya and the London School of Hygiene & Tropical Medicine Ethics Committee, UK. Permission was also granted by department of Health Trans Nzoia County, Kenya.

Randomisation and masking

Community units were randomly assigned (1:1) to either the Peek Community Eye Health System (intervention) or the current standard (control group), with restricted randomization used to ensure balance between the arms in terms of distance from KEU, direction from KEU and subcounty. This has been described previously but briefly, one million potential allocations of CUs to arms were generated and a subset of 10,000 of those that met the restriction criteria were selected at random.[24] These were checked to ensure no pair of CUs were in the same arm more or less often than would be expected by chance, then one of these allocations was selected at random using a computer program.

Neither the study participants nor the screening team could be masked. The study statistician, hospital registration clerk and clinicians assessing outcomes were masked. All the primary outcome data on attendance to triage was entered into a dedicated cloud-based system developed by Peek which generated unique identifier numbers. The number was recorded on clinical forms before triage. Secondary data was collected by one hospital clerk who was masked to the intervention. On arrival at the hospital, the participants presented a referral slip, which was identical for each group. Using the unique number provided at triage they were all marked as attended in the hospital app so as to maintain masking of the secondary outcome data collection.

Procedures

We selected and trained 18 Peek Screeners (Community Volunteers (CVs) trained specifically on how to use the Peek Community Screening App and who travelled to multiple communities to perform their duties) for two weeks on how to operate a smartphone and how to identify and refer participants using the app.

In both arms, we sent posters and verbal notices (to churches and school) four weeks in advance of the date of triage clinic, encouraging people with eye problems to self-report to the clinic on a specific date and location for an eye check-up.

In the communities assigned to the intervention, we provided transport to Peek screeners to the community for screening. A local CV, (a person from that same community) was paired with a screener. The Peek users and local CV visited households to screen participants for eye problems. After reconfirming consent, screeners used the PSC app to identify people with eye problems. The test algorithm prompted screening questions to participants or the parents or guardian of a child. The App prompts for distant visual acuity assessment using the embedded Peek Acuity App for children older than five years; and assessment of near visual acuity for all people aged 40 years and older using the RADNER reading chart at 40cm and the result recorded in the app.[28] Distance visual acuity of each eye was tested separately, with the fellow eye covered with the palm of the hand and near vision tested binocularly (both eyes together).[18] We recorded age and gender for each participant. Participants absent during the house visit were asked to join the examination team at the next household or the next day at another location within the same cluster.

For those who screened positive (visual acuity less than 6/12 [20/40] in either eye; or presence of any self-reported eye pain or discomfort; self-reported difficulty seeing distant or near objects; or not able see N8 on near vision assessment for those aged 40 years or older), the app prompted the collection of additional information for contact and follow-up purposes: name, guardians / parent's name if a child, primary language, and contact telephone number and generated a referral to the link facility. They were also asked to attend the triage clinic on the pre-advertised date. When connected to the internet, the app sends these referral details to a cloud-based server, which automatically generated a personalised SMS to the participant or associate with advice on the outcome of the eye assessment and instructions for referral date and location in the chosen language. Weekly reminder messages were sent with the last one being one day prior to the appointment date. A referral was also automatically sent to the hospital where a database of referred participants was kept.

On the chosen date, a team from Kitale Eye Unit (KEU) provided triage at the CU's dispensary. Patients were assessed using the current standard outreach procedures and equipment (Snellen chart visual acuity, magnifying loop, refraction and direct ophthalmoscopy when indicated). They were either treated on site or referred to KEU for further assessment as indicated.

Intervention at triage included provisions of reading spectacles, eye drops and removal of foreign bodies. When referred, a pre-numbered referral slip with their study number, name, date, reason for referral and triage centre was provided to participants in both arms. For the intervention arm, immediately after referral from the PHC, an SMS was sent to the patient or guardian asking them to present to KEU. SMS was also sent to the hospital where the participant was referred to. A weekly reminder SMS were sent to those who had not yet attended their referral to the hospital for up to 4 weeks from the primary health centre assessment.

In the control arm, there was no active Peek screening in the community, potential participants with eye problems were notified through community sensitization (posters and local announcements), to present themselves to the specified health facility for the triage clinic on a pre-advertised date. On that advertised date the team from KEU conducted the outreach clinic within the CU, following procedures identical to the ones in the intervention arm described above. When referral was needed, patients were given an identical referral letter to the ones used in the intervention arm. They did not receive reminder SMSs. Each letter had a unique code number to link the patient referral record to their KEU attendance.

The follow-up period was 4 weeks from being referred from triage. On arrival at the KEU for assessment, a clerk recorded the attendance of the referred participant. The hospital's clinical team assessed the patient to identify the nature of the ailment and the treatment needed. Interventions included provision of eye drops, spectacles, or surgery. The team assessed visual acuity using a 6-meter Snellen chart. The cause of referral was recorded

based on the disease codes for routine reporting of eye diseases to the Ministry of Health, Kenya and reclassified using the ICD10 classification.[29] Vision impairment was defined as not able to see 6/12 in either eye. Distance between the primary health facility and Kitale eye was estimated from Google-maps.[30] All patients (control and intervention arms) received free treatment at the hospital.

Outcomes

The primary outcome, determined by the hospital team, was the number of people per 10,000 of population (rate) attending triage at a local health facility (PHC) with a confirmed eye condition (true positive), at 4 weeks from the time of initial sensitization. The secondary outcomes were (1) the number of people per 10,000 population (rate) attending the triage post without any eye condition (false positives) and (2) number of people attending KEU within four weeks after being referred from PHC. We also report the proportion of participants and the time taken by a participant referred from the PHC to attend the referral at KEU as well as diagnosis at triage and KEU giving us the appropriateness of the referral.

Statistical analysis

We calculated the sample size assuming an average rate of 150 new patients with eye problems per 10 ,000 population,[31] based on previous attendance at outreach clinics in the region and an average population of a community unit of 5,000 people (about 75 people with eye problem per CU).[26] Therefore, using the Hayes formula for rates in unmatched cluster-randomised trials,[32] and assuming an intraclass correlation coefficient of 0.001, at least 36 CUs (18 each group) was sufficient to provide 90% power to detect a difference of 0.5%, from 1.5% in the control arm to 2.0% in the intervention arm (a 33% relative change) in overall attendance rates from the community to the primary facility at 4 weeks (the primary outcome).

The analysis was by intention to treat and the primary analysis was performed at the cluster level. We calculated the proportion of individuals attending triage within each cluster, by dividing the number attending triage with confirmed eye condition by the cluster population, determined by the baseline enumeration census (true positive attendance rate). A t-test was performed on the cluster-level proportions to provide an estimate of the rate difference (with a 95% confidence interval) between the two arms and a p-value in order to assess the strength of evidence against the null hypothesis that the rate is equal in the two arms.[33] We tested whether this effect was modified by any of sex, age and distance from KEU. For distance, since it was a cluster-level covariate we performed a linear regression on the cluster level rates and included distance and trial arm as exposures with an interaction term between them. For age and sex, we used the approach recommended by Cheung et al, [34] for testing for effect modification of individual level covariates in a cluster-level analysis. Where evidence of effect modification was observed, stratum specific estimates were presented. The proportion attending triage but have no eye condition (false positive attendance rate) was estimated in a similar manner to the above in both arms.

We also estimated the effect of the intervention on the attendance rate of true positive referrals from primary care to secondary care at KEU using same approach of the cluster-level analysis of the primary outcome. The numerator of each cluster was the number of individuals attending KEU following a referral from triage and the denominator is the cluster population.

Among those referred to KEU, we tested whether there was a difference in the odds of attending KEU within 28 days of referral between arms using a logistic regression model, adjusted for age, sex and distance to KEU and cluster included as a random effect. We also investigated whether time to attendance at KEU post-referral was different in the two arms, first visually using Kaplan-Meier plots then tested formally using Cox regression, again adjusted for age, sex and distance from KEU.

Data on participants' visual acuity and diagnosis of eye problems at both triage and at KEU was tabulated. We used STATA version 15 (STATA Corp, TX, USA) for the analysis.[35]

There was potential contamination in the control arm where 9 out of 18 clusters erroneously received SMS reminder messages that should only have been delivered to the intervention arm after referral from triage. We therefore repeated the analyses involving hospital attendance, separating out the clusters into three groups - 1) Control - Did not receive hospital reminder SMS, 2) Control - received hospital appointment reminder SMS, 3) Intervention - to assess the effect, if any, of contamination on the intervention.

The trial was registered with the Pan African Clinical Trial Registry (PACTR), number 201807329096632.

Role of the funding source

The funders had no role in the study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

The Trial recruitment was conducted between November 26, 2018, and June 7, 2019 in Trans Nzoia County, Kenya. The final follow-up period at the hospital after triage ended on June 7th, 2019. Of the 85 eligible community units, 19 were excluded as they were attached to private or secondary heath facilities. Of the remaining 66 eligible CUs, 36 were randomly selected and 18 were allocated to each group (figure1).

Demographic characteristics

Overall 128,591 people were enumerated, 68,348 (53.2%) were from the 18 intervention communities. The intervention communities tended to be a little larger on average with a mean cluster size of 3,797 (range 2,139 - 6,526) compared to 3,346 (range 2,190 - 5,607) in the control group. The mean distance from community unit to Kitale hospital was 18.3 kilometres (range 5 – 36 km) for the communities in the interventions arm compared to 19.8 km (range 5-32 km) in the control. Overall 50.6% of those enumerated were female and 44.9% were aged less than 15 years, with no difference by age or sex between study arms, table 1. Consent was granted by 128,322 (99.8%) out of 128 591 potential participants. Those without consent were not screened but would able to attend triage if they had any eye problem. We therefore used the enumerated population as the denominator for estimating proportions.

Out of 68,174 participants in the intervention arm who consented, 27,692 (40.6%) were screened during house screening. The mean cluster coverage was 42.8% (range 21.8% – 92.4%). The main reason for low coverage was participants being absent during screening. Out of the participants screened, 15,299 (55.2%), were referred for eye problems, out of which 6,045 (39.5%) presented for triage, figure 1.

Table 1: The demographic characteristics of eligible population, and participants who attended triage and Hospital by study arm in the trial

	Intervention						Control					
characteristics	**Enumerated**		**Attended Triage**		**Attended Hospital**		**Enumerated**		**Attended Triage**		**Attended Hospital**	
	n	%*	n	%†	n	%†	n	%*	n	%†	n	%†
All population	68,348		9,387	13.7	552	0.8	60,243		3,070	5.1	210	0.4
Age group												
<15	30,317	44.9	1,843	6.1	56	0.2	26,755	44.9	743	2.8	26	0.1
15-29	18,102	26.8	1,203	6.6	98	0.5	15,705	26.4	445	2.8	38	0.2
30-44	9,387	13.9	1,640	17.5	97	1.0	8,604	14.5	473	5.5	34	0.4
45-59	5,561	8.3	2,360	42.4	116	2.1	5,066	8.5	730	14.4	47	0.9
60-74	3,162	4.7	1,677	53.0	120	3.8	2,629	4.4	456	17.3	46	1.7
75+yrs.	975	1.4	664	68.1	65	6.7	785	1.3	223	28.4	19	2.4
Mean age (years), standard deviation (SD)	22.4 (18.7)		41.6 (23.2)		46.1(23.0)		22.4 (18.5)		38.9 (24.1)		44.8 (23.1)	
Sex												
Female	34,629	50.7	5706	16.5	301	0.9	30,405	50.5	1759	5.8	107	0.4
Male	33,719	49.3	3681	10.9	251	0.7	29,838	49.5	1311	4.4	103	0.3

* Denominator is all enumerated within the trial arm

† Denominator is those enumerated within the category of age or sex in the trial arm

Figure 1: The flow of participants through the trial

Triage attendance

In total, 12,457 participants attended triage; 9,387 (75.4%) from communities in the intervention arm and 3,070 (24.6%) from the control arm, table 1. Of these 11,862 (95.2%) were diagnosed by a clinician as having some form of eye problem. The proportion of the population (as enumerated) attending triage and who had an eye problem in the control communities ranged from 0.8% up to 9.0% compared with a range from 8.3% to 20.9% in the intervention communities, table 2 & figure 2A.

Table 2: Attendance rates by trial arm for (1) the community Triage clinic and (2) the hospital eye department clinic.

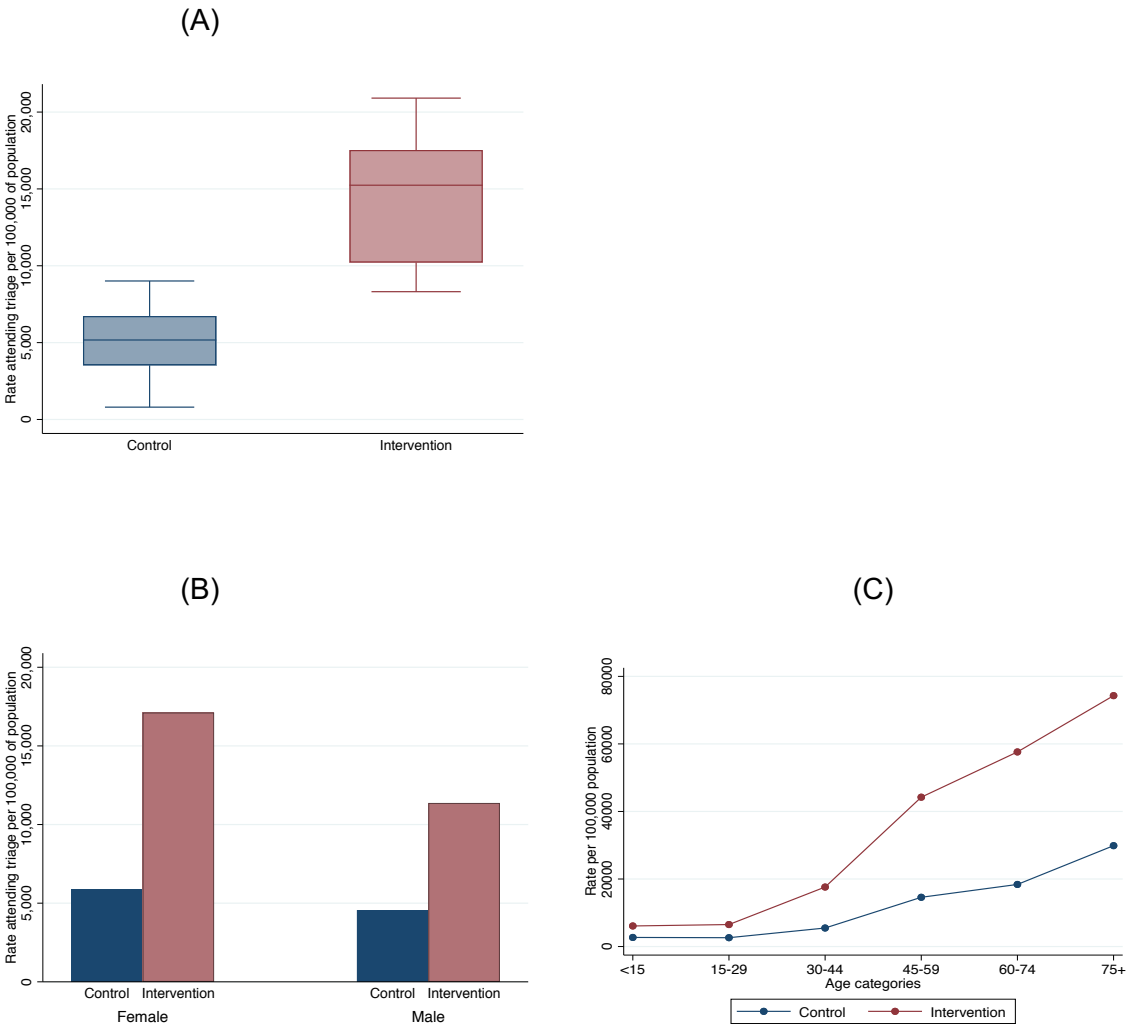
Characteristic		Proportion of those enumerated attending			p-value*	p-value#
		Control arm n, (95% CI)	Intervention arm n, (95% CI)	Risk difference n, (95% CI)		
(1) Community triage clinic						
Overall		5.2% (4.2 -6.3)	14.3% (12.3-16.3)	9.1% (6.9%-11.2%)	<0.0001	N/A
Sex	Female	5.9% (4.6%-7.1%)	17.1% (14.6%-19.6%)	11.3% (8.6%-13.9%)	<0.0001	<0.0001
	Male	4.6% (3.6-5.5%)	11.4% (9.8%-12.9%)	6.8% (8.6%-5.1%)	<0.0001	
Age group	<15	2.7% (2.1-3.3%)	6.1% (4.8%-7.4%)	3.4% (2.1%-4.7%)	<0.0001	<0.0001
	15-29	2.6% (2.1%-3.2%)	6.5% (5.3%-7.7%)	3.9% (2.6%-5.2%)	<0.0001	
	30-44	5.5% (4.3%-6.7%)	17.6% (15.0%-20.2%)	12.2% (9.3%-14.9%)	<0.0001	
	45-59	14.6% (11.7%-17.5%)	44.2% (38.4%-50.1%)	29.6% (23.4%-35.9%)	<0.0001	
	60-74	18.4% (13.5%-23.3%)	57.6% (46.6%-68.6%)	39.2% (27.6%-50.8%)	<0.0001	
	75+	29.9% (22.8%-37.0%)	74.3% (58.7%-89.9%)	44.4% (27.9%-60.9%)	<0.0001	
(2) Hospital eye department clinic						
Overall		0.4% (0.3%-0.5%)	0.9% (0.7%-1.2%)	0.5% (0.3%-0.8%)	0.0001	N/A
Sex	Female	0.4% (0.3%-0.5%)	1.0% (0.7%-1.3%)	0.6% (0.3%-0.9%)	0.0001	0.0315
	Male	0.4% (0.3%-0.5%)	0.8% (0.6%-1.0%)	0.4% (0.2%-0.7%)	0.0015	
Age group	<15	0.1% (0.1%-0.2%)	0.2% (0.1%-0.3%)	0.1% (0.0%-0.2%)	0.0364	0.0004
	15-29	0.3% (0.1%-0.4%)	0.6% (0.4%-0.8%)	0.4% (0.1%-0.6%)	0.0019	
	30-44	0.4% (0.2%-0.6%)	1.1% (0.7%-1.5%)	0.7% (0.2%-1.2%)	0.0038	
	45-59	0.9% (0.6%-1.3%)	2.2% (1.5%-2.8%)	1.2% (0.5%-1.9%)	0.0015	
	60-74	2.0% (1.2%-2.7%)	4.5% (2.9%-6.2%)	2.6% (0.8%-4.3%)	0.0052	
	75+	2.5% (1.6%-3.5%)	7.8% (4.3%-11.2%)	5.2% (1.8%-8.7%)	0.0041	

CI – Confidence Interval,

* - P- value for risk difference

- p-value for interaction

Figure 2: (A) Distribution of cluster attendance rates by participant with confirmed eye problems, by trial arm, (B) Mean attendance rate by sex and trial arm, (C) Mean attendance rate by age category and trial arm



Very strong evidence (p<0.0001) was found of a higher rate of attendance of individuals with eye problems in the intervention arm compared to the control arm, with an estimated mean attendance of 5.2% in the control arm compared to 14.3% in the intervention arm resulting in an estimated risk difference of 9.1% (95%CI: 6.9-11.3%).

We also found strong evidence (p<0.0001) that effect of intervention differed between males and females, with the increase in the attendance rate found to be greater among females. The risk difference was estimated to be 11.3% (95% CI: 8.6 – 13.9%) in females compared with 6.8% (95% CI: 5.1 – 8.6%) in males, figure 2B.

Strong evidence (p<0.0001) was also found of effect modification by age, table 2 & figure 2C. The estimated risk difference was 3.4% (95% CI: 2.1 – 4.7%) among those aged under 15 increasing with each age category up to an estimated risk difference of 44.4% (95% CI: 27.9 – 60.9%) in those aged over 75. There was no evidence found (p=0.8917) of effect modification by distance.

Triage attendance by participants without eye problems (False positives)

Out of the 12,457 participants who presented for triage, 595 (4.8%) had no eye problems (false positives). In the intervention arm 442/9,387 (4.7%) participants had no eye problems compared to 153/3,070 (5.0%) in the control arm. Among those reporting to triage, there was no evidence of a difference in the proportion without eye problems in the study arms (OR 0.94, [95%CI 0.78 - 1.14]; p= 0.519). We did however find strong evidence (p=0.0001) that the proportion of the population attending triage without any eye problem, similar to overall attendance, was higher in the intervention communities. The mean attendance was 0.72% in the intervention communities compared to 0.26 % in the control. The estimated risk difference was 0.46% (95%CI: 0.24-0.67%).

Hospital attendance

The proportion of individuals referred to the Kitale Eye Unit (KEU) within each arm was broadly similar, with 713/3,070 (23.2%) referred in the control arm and 2,263/9,387 (24.1%) referred from the intervention arm. Of the 2,976 participants referred to Kitale Eye Unit (KEU) six were missing follow up data. Out of the 2,970 participants with follow up data, 762 (25.7%) attended hospital with 671 (22.6%) arriving within 28 days. The proportion of the population (as enumerated) referred from triage and attending hospital in the control communities ranged from 0.08% up to 0.9% compared with a range from 0.2% to 1.7 % in the intervention communities.

The estimated proportion of the population (as enumerated) attending hospital after referral from triage within 28 days was 0.8% in the intervention communities compared to 0.3% in the control. This provided strong evidence (p=0.0002) of a difference in the attendance between intervention communities and the control communities, with an estimated risk difference of 0.5% (95%CI: 0.25-0.73%).

There was strong evidence (p=0.0086) that the intervention effect on attendance to hospital after triage referral differed between males and females, with the increase in the attendance rate found to be greater among females. The risk difference was estimated to be 0.6% (95% CI: 0.3 – 0.9%) in females compared to 0.3 % (95% CI: 0.1 – 0.6%) in males, table 2.

We found strong evidence (p=0.0004) that the effect of intervention on attendance to hospital was greater among older participants. The risk difference ranged from 0.3% (95% CI: 0.1 – 0.4%) in those less than 15 years old up to 3.7% (95% CI: 0.2 – 7.3%) in those aged 75 and above, table 2. Again, no evidence (p=0.879) of effect modification by distance from the hospital was found.

The median time to hospital attendance was 16 days (IQR 9-22) with a mean of 17.9 days. Of the 711 participants referred from the control arm, 181 (25.5%) presented to the hospital within 28 days compared to 490/2,259 (21.7%) in the intervention arm.

After adjusting for clustering of community units, distance from the hospital, whether they were categorised as visually impaired at triage, age and sex the evidence of a difference in odds of attending hospital within 28 days was very weak (p=0.145) with the observed odds of attendance lower in the intervention arm than in the control (adjusted OR 0·77 [95% CI 0.54 – 1.10]).

We found evidence that the following groups were more likely to attend hospital among participants referred from triage: - males were more likely to attend than women; younger age groups than older; those with poor vision identified at triage than those who didn't; and those living closer to the hospital than those more distant, table 3.

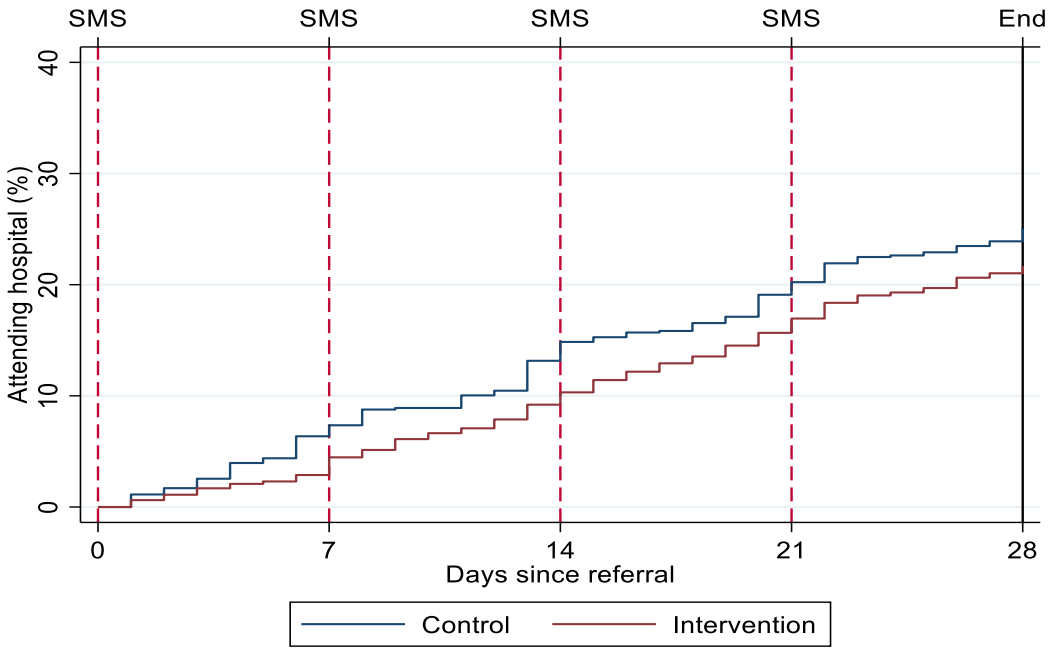
The rate of hospital attendance (hazards) among those who were referred at triage for eye problems was estimated to be lower in the intervention group than the standard group, with an adjusted hazard ratio of 0.80 [95% CI 0.59 – 1.08]; p=0·137), Figure 4A.

Table 3: The proportion of participants referred from Triage who arrive at Kitale eye unit within 28 days of being referred.

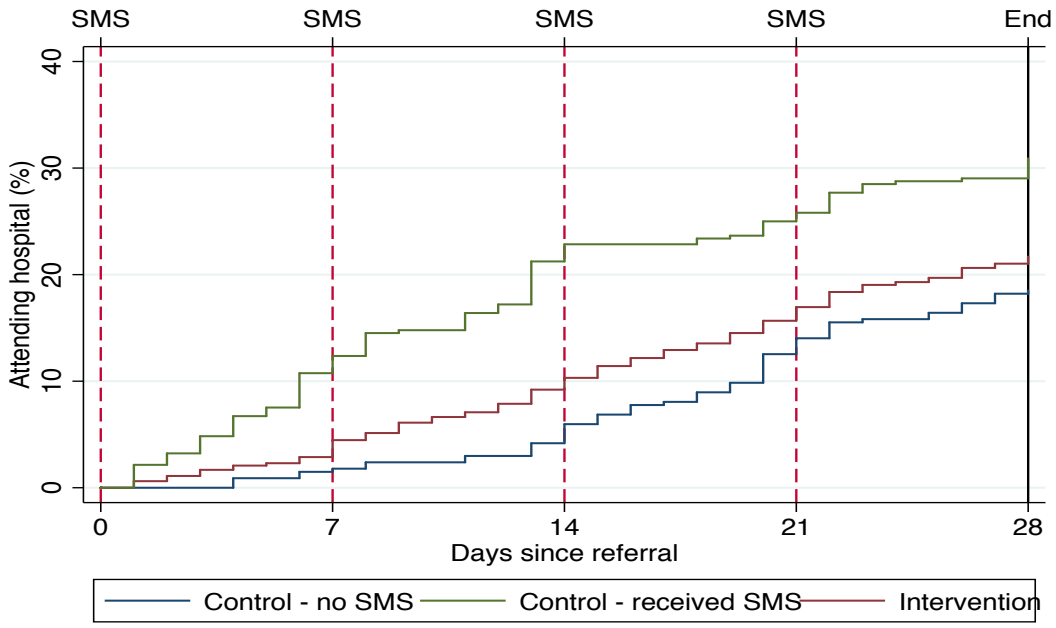
	Number referred	Number and proportion that Attended hospital				
	N	n	%	Adjusted OR	95% CI	pooled p-value
Intervention						
Control	711	190	26.7	1		0.145
Intervention	2259	499	22.1	0.77	0.54 - 1.10	
Age group (years)						
<15	298	76	11.0	1		
15-29	514	124	18.0	1.03	0.73 - 1.45	
30-44	494	123	17.8	1.06	0.75 - 1.50	0.0065
45-59	665	147	21.3	0.82	0.59 - 1.15	
60-74	592	148	21.5	0.89	0.63 - 1.25	
75+yrs.	407	71	10.3	0.56	0.38 - 0.83	
sex						
Male	1207	319	26.4	1.40	1.17 - 1.68	0.0003
Female	1763	370	21.0	1		
Visual status at Triage						
6/12 or better in both eyes	1084	230	21.2	1		
Worse than 6/12 in either eye (visual impairment)	1886	459	24.3	1.28	1.05 - 1.56	0.0162
Distance to the Hospital in Kilometers (kms)						
10 kms or less	448	125	27.9	1		
11kms – 20 kms	1574	382	24.3	0.84	0.53 - 1.36	0.0369
20 or more kms	948	182	19.2	0.56	0.34 - 0.92	

Figure 3: Kaplan-Meier analysis of time from Triage referral to attendance at the hospital eye clinic, among all participants (A) and stratified by those who erroneously received SMs, (B).

(A)



(B)



Eye conditions in participants attending triage and hospital

Overall, 68.2 % of the 12,457 participants seen at triage had either allergic/other conjunctivitis, presbyopia or no problem found with their eyes, conditions considered suitable for management at this primary health care level. Of the remaining conditions, the most common were cataracts (10.9%), refractive errors (10.6%) and retinal diseases (2.4%). Overall 9,481 (76.1%) out of 12,457 participants were treated at triage.

There were 762 participants who attended hospital, however only 719 participants were treated as 43 participants checked into the hospital but left before being attended to. Of these 719, 55.5% had either cataracts, glaucoma or refractive error considered suitable for management at secondary (hospital) level. The other conditions were allergic conjunctivitis (10.3%), retinal diseases (7.4%) and conjunctival growths (5.7%), table 4.

Table 4: Diagnosis of the participants who attended Triage and Hospital appointments in Trans Nzoia county, Kenya.

Venue of diagnosis	**Triage**		**Hospital**	
	n/12,457		**n/ 719***	
Eye conditions	**n**	**%**	**n**	**%**
Allergic conjunctivitis	3,359	27.0	74	10.3
Presbyopia	3,327	26.7	31	4.3
Other Conjunctivitis	1,212	9.7	11	1.5
Cataracts	1,362	10.9	188	26.2
Refractive errors	1,326	10.6	203	28.2
Normal	594	4.8	8	1.1
Retinal diseases	291	2.4	53	7.4
Conjunctival growths	222	1.8	41	5.7
Corneal diseases	180	1.5	15	2.1
Glaucoma	78	0.6	8	1.1
Eye injury & FB in eye	40	0.3	5	0.7
Chalazion & lid swellings	42	0.3	18	2.5
Uveitis	24	0.2	5	0.7
Lid inflammations	18	0.1	0	0
Others	382	3.1	59	8.2

* 43 participants checked into the hospital but left before being attended

Potential contamination

In error, 9 out of the 18 clusters in the control arm received SMS reminder messages. Comparing the odds of attendance at 28 days across the three groups (control - no SMS, control - with SMS and intervention) there was some weak evidence (p=0.0575) of a difference in the odds of attendance within 28 days of referral. After adjustment for clustering in the community, age, sex, vision status and distance, the estimated odds of attendance in the intervention group was very similar to the odds in the control with no SMS group (OR 1.04, 95%CI 0.66-1.63, p=0.868), but the odds of attendance in the control arm clusters where reminder SMS were sent were estimated to be a bit higher (OR 1.68, 95%CI 1.00-2.83, p=0.050) than in the control group who did not receive messages. This is consistent with what is observed in the time to attendance analysis, with a hazard ratio of 1.11 (95%CI 0.75-1.65, p=0.589) estimated when comparing the intervention arm to the control clusters who did not receive messages, and a hazard ratio of 1.72 (95%CI 1.10-2.69, p=0.017) comparing the control clusters that received messages with those that did not, figure 4B.

This “contamination” of the control group could also have led to a dilution of the effect of the intervention on the overall population proportion that attended KEU. By treating these three groups separately it was estimated that the attendance among the population (as enumerated) in the control group without messages was 0.3% (95%CI 0.1-0.6%), the control group with messages was estimated at 0.5% (95%CI 0.2-0.7%) and in the intervention arm it was 0.9% (0.7-1.1%). The evidence of a difference between the two control groups was very weak (risk difference 0.2%, 95%CI -0.2%-0.5%, p=0.379), but there was evidence that the attendance in the intervention arm was higher than in each of the control groups (risk difference vs control without messages 0.6%, 95%CI 0.3-0.9%, p=0.0003; risk difference vs control with messages 0.5%, 95%CI 0.1-0.8%, p=0.0055).

Discussion

Elimination of avoidable blindness from causes such as cataracts, refractive errors and glaucoma are prioritized by the World Health Organization. [11] The current barriers to achieving this goal include insufficient eye health workers;[36] limited awareness of eye health in the general population, including where to access services; [6] and high-demand on specialist secondary services for eye health conditions that could be managed in a primary care setting.[37] [10]

Utilization of eye care services was comparable in the control group (5.2%) that received community sensitization only compared to other studies in the country which found 4.8% as having sort treatment following sensitization,[38] suggesting that sensitization is an effective means of increasing utilization of available services. This trial showed that an integrated system comprising a smartphone-based decisions support algorithm to identify eye problems (PCS app) and SMS reminders (the Peek Community Eye Health System) as well as sensitization significantly improved the overall triage (PEC) and hospital attendance rate among people with eye problems compared with standard processes. This suggests that the intervention is effective in increasing access, which is likely to be due to the accurate identification of people with eye problems as well as making available the timing and location of appointments by SMS, thus helping patients to adhere to their appointment.

The findings of this trial also suggest that, for every 10,000 people sensitized and screened using the Peek Community Eye Health System, 1,502 presented for triage. Of these, 1,430 had confirmed eye problems and 72 did not; 92 attended hospital following referral from triage. In contrast, the standard methods, for every 10,000 people sensitized, 546 presented at the triage clinic; 520 with confirmed eye problem and 26 without; and 39 attended hospital following referral from triage. This therefore means that with the use of Peek CEH system

an anticipated additional 910 people with confirmed eye problems will present to triage for treatment and 53 to the hospital for every 10 000 people. However, an extra 46 people will present to triage without eye problems. Based on the results of the study, the use of Peek CEH system leads to increased attendance at both primary facilities (for triage) and at the secondary level facility.

This study highlights the complementary roles of the different levels of the health system in the management of eye conditions. For example, a previous study on the utilization of secondary eye services in the region,[10] found an annual utilization rate of 79 per 10,000 population, with 61% of patients seen having allergic/other conjunctivitis or normal eyes, which could be managed at the primary eye care level and only 8.3% having VISION2020 priority eye conditions (cataract, Refractive errors, glaucoma).

In this trial we found a similar hospital utilization rate (80 per 10,000 population), but a change in the proportion of presenting eye conditions, with 11.4% having a condition suitable for primary care management and 55.5% having (cataract, Refractive errors, glaucoma) considered suitable for management at secondary (hospital) level. This result indicates that despite the intervention increasing the overall attendance for those who need eye services, the overall numbers did not increase at the secondary unit work load because most patients (76%) were managed at triage with few requiring referrals. As a result, more people received attention for primary eye care conditions in a community setting, there was a reduction of people with simpler conditions coming to secondary unit, and an increase in people with more complex conditions accessing secondary level services.

WHO advocates for a well-coordinated eye care system with each level of health care performing specific roles such as management of cataracts and refractive errors in secondary care [12] and basic eye care provision at the primary care setting.[13] Our findings suggest that depending on the capacity of the eye health workforce, it may be possible to shift management of some eye condition to primary eye care, leaving greater capacity at

the secondary level to handle more complex eye conditions warranting specialist services, in line with WHO recommendations.[12]

One of the challenges found in previous studies on the use of smartphones to identify visual impairment was a higher proportion of false positives.[23] In this study there was no difference in the proportion of false positives in the two arms in this study (4.7% intervention vs 5.0% in control) although the absolute number of people without eye problems was higher in the intervention group due to an overall increase in the number of people who attended triage. The trial further demonstrated that non eye-care workers using smartphone decision supported algorithms can correctly identify and refer patients with eye problems. This suggests that this is an acceptable and effective task-shifting method in this context and provides an opportunity to enhance the role of community health workers and primary care workers in supporting the delivery of eye care services in areas of need.

We found that the intervention increased the utilization of eye services both at primary (triage) and secondary (Hospital) services, more so in females than males and across all ages. Previous studies in the same region found that secondary services were less utilized by the young and older women,[10] our finding suggests that the intervention could improve equity in eye care especially among women and those aged 45 years or older because visual impairment is prevalent in this age group.[1] Improvement in uptake could be due to increased awareness of the existing eye services, [39] knowledge about who and where to consult for management of eye complaints, a lack of which were identified as barriers in other studies. [40]

We found that barriers that hindered utilization are mainly between the primary to secondary level of health care. Coverage of screening in the community was relatively low (41%) suggesting provider challenges while factors associated with poor adherence to primary services (Triage) were not established in this study. Despite these challenges more of the older people which is perhaps the group with greatest need attended triage. About three-

quarters of those who were referred did not attend their secondary referrals suggesting there were barriers to accessing secondary services. Barriers included: female gender, longer distances to the health facilities, older ages groups and those without any visual impairment as barriers to utilizing secondary eye services. Other barriers that were not assessed include poverty, costs, or fear of treatment outcomes.[4-6] Our finding suggests that the influence of gender depends on the level of health care where the outcome was assessed. When services are closer access by females is higher, however when accessing secondary services other considerations may arise. This includes prevailing social norms where men have authority in family decisions.[41] for example, in some communities women needed to seek permission from their husbands before going to hospital and out of fear of being a burden to the family, they opt to live with the adversity rather than seek treatment.[42] It may also be due to other competing priorities deemed of greater importance than seeking eye care.

The trial also indicates that the presence of visual impairment corresponded to increased utilization of secondary eye care services, suggesting that people in the community may choose to wait until they have VI before seeking help. This might arise because eye problems are not seen as a priority or as life-threatening, or because prior to the intervention people had low awareness of eye care services. We would expect higher utilization among older people given vision impairment increases with age.[43] However, in this trial utilisation by people 75 years and older was lower than younger age groups, perhaps suggesting that there may be a number barriers to accessing care, such as the belief in some societies that blindness is viewed as an inevitable accompaniment of growing old hence there is no need to seek treatment,[44] or it could be due to a lack of family support or escorts to accompany the patient to eye care services.[45]

This trial has a number of strengths. We conducted a full enumeration of the target population to accurately define the study population. The trial was integrated into the existing health system, which informs potential future adoption and scale-up possible.[23] The

trial also represents the first community cluster RCT of an mHealth intervention to increase access to eye care services. The primary outcome measure of attendance was objective and robust.

Limitations to note were that during the study, there was industrial action between 1st and 28th February 2019 by nurses throughout County that could have discouraged hospital or triage attendance by some participants, due to uncertainty about the availability of health services. However, attendance rates did not appear to be lower during the period when there was industrial action. The trial activities were not affected. There was an intervention error in the control arm which involved residents of half the clusters receiving SMS reminders. When we performed stratified multivariate analysis, we observed that more participants in the 'contaminated group' attended the hospital appointment and came faster than those who received no SMS or those who did receive one in the intervention group. It seems to be an effect of the first two messages but subsequent ones have reduced effect. Studies on SMS-marketing have reported saturation effects which differed by gender.[46] This observation suggests that either patient's perception that they should have received the treatment they needed in the primary care setting, and so an onward referral leads to reduced trust in the health system or perhaps the novelty of the message wears off. Finally, multiple SMS may have introduced some intervention fatigue. A future study could explore single message vs multiple messages and bespoke counselling. Cost-effectiveness was not assessed, which is relevant for resource-constrained contexts. Future studies will include cost-effectiveness of this intervention, barriers to uptake of adherence of secondary care and new mHealth enabled hypothesis driven health system optimisation techniques that make it possible to determine the programmatic effect of interventions such as messaging frequency and content.

Recommendations

The model is scalable provided other key elements being present such as capacity of the primary health system to handle extra referrals, the skill set of PEC workers to make a diagnosis, the accuracy of a screening tool in the specific setting and the resources to do so. We recommend that care providers at primary health care facilities be trained and equipped to provide these services. A scaling approach could be to increase resources or stagger the rate of screening to match the existing resources. If it were to be scaled in areas with low primary level skill set, an adapted outreach model can be used where secondary level health workers are deployed periodically in outreach at the primary level whilst concurrently providing training to permanent staff to transition from secondary to primary outreach to a feeder model from primary to secondary.

Conclusion

This trial has provided strong evidence that integration of community, primary and secondary health services using the Peek Community Eye Health system both increased access to vital services to the population by ensuring individuals are seen at the appropriate level of the health system whilst also ensuring that service providers time is utilised effectively and efficiently.

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8. Discussion and Conclusion

Figure 8-1: Ophthalmic workers examining a patient

8. Discussion and conclusion

The findings from each research component of this thesis have been discussed in each of the respective papers in Chapters 2-7. This chapter (8) provides a summary of the key findings, the strengths, limitations and the implications of the findings for policy and practice and for suggested areas of future research.

The aim of this thesis was to develop, describe and evaluate a demonstration model of community volunteers (CVs) and teachers using Peek systems in communities and schools respectively to identify people with referable eye conditions, refer those with eye problems for treatment and evaluate a follow-up system so as to reduce avoidable visual impairment in Trans Nzoia, Kenya.

Overall, the primary eye care services were not well developed nor integrated with the community or secondary eye services. Secondary eye services were underutilized; but when utilized it was predominantly by people with eye conditions that could be managed in primary eye care. The findings in this thesis demonstrated that non eye care workers could use Peek systems to identify and refer people with eye problems and that these mHealth interventions integrated into the community, primary and secondary services, improving access to care, adherence to referrals and utilization of the appropriate level of services.

Principle findings

Findings from the literature review in Chapter 1 suggested a lack of proven mHealth interventions for eye care. We established that current eye care provision is currently insufficient to meet the minimum requirement for eye care services.[1] Many people remain unnecessarily visually impaired or at risk of becoming so due to treatable or preventable eye conditions.[2] A lack of access and awareness of services are key barriers,[3,4] partly due to too few eye care providers in the health system for the unmet need.[5] One of the strategies

to improve access to eye care involves redistribution of tasks among health workforce teams, to improve efficiency among available human resources.[6] Effective task shifting through clear referral criteria and management plans has been delivered through clinical algorithms as was demonstrated in the integrated management of childhood illnesses (IMCI).[7] Clinical algorithms have also been developed for use in eye care, however they have infrequently been validated or where they have, the accuracy has been variable.[8,9] A recent systematic review showed that mobile health (mHealth) interventions that support communication between healthcare providers and patients through short messaging service (SMS) appointment reminders are effective and beneficial in the provision of health care.[10] Although mHealth is gaining acceptance in the healthcare community,[11] the majority of mHealth interventions, especially in Africa, have been focused on managing HIV, tuberculosis and malaria,[12] and none in eye care. A need has been identified for developing such interventions for eye care.

The first objective of the thesis was to determine the current utilization of hospital eye care services in the catchment population. To achieve the objective, a retrospective review of hospitals records of new patients seen in Kitale Eye Unit between 2013 and 2015 to assess the utilization of eye services in the context of Trans Nzoia County was done (Chapter 2). In this period, 20,695 hospital visits from the catchment population were recorded in the three-year period. Of these, only 8.3% had either uncorrected refractive error, cataracts or glaucoma, the priority VISION 2020 diseases, and 61.0% had allergic or other forms of conjunctivitis (or they had normal eyes), which could potentially be managed at primary eye care. The overall average annual attendance rate increased from 609 to 792 per 100, 000 population, incidence rate ratio (IRR) 1.30 (95% confidence interval (CI) 1.26–1.35) over the three-year period. There was evidence that attendance rates increased more in females than males (34.7% vs. 25.1%, respectively), IRR 1.07 (1.04–1.10). Attendance rates also increased with increasing age, (highest among the elderly compared to the young). We found that in extreme age groups (>75 years and <15years) females were less likely to

attend than males and there was reduced utilization from those based furthest from the hospital.

Overall, specialist eye services are heavily utilized by people with conditions that could be managed at the primary health care level. Barriers to accessing eye services were distance and gender, especially among the most vulnerable groups (young and the elderly). This suggests that eye care services could be integrated into primary health care services to lower barriers to essential eye care services whilst lowering pressure on the limited specialist services based at the secondary level.

The second objective was to develop, validate and evaluate a smartphone based diagnostic algorithm for use in School eye health programmes (Peek School Eye Health). In developing and validating the intervention the results on the performance of both the Snellen Tumbling-E card and the Peek Acuity test when performed by teachers was compared to a reference standard backlit EDTRS LogMAR visual acuity test chart when performed by trained ophthalmic workers.

To evaluate the intervention further, a cluster randomised controlled trial to compare the Peek SEH (comprising of Peek Acuity test, sight simulation referral cards, and short message service [SMS] reminders) with standard school screening care (Snellen Tumbling-E card and written referral), delivered by school teachers was conducted. From the findings in Chapter 3, the sensitivity was similar for the Peek test and the standard test (77% [95% CI 64·8–86·5] vs 75% [63·1–85·2]). Specificity was however lower for the Peek test than the standard test (91% [95% CI 89·3–92·1] vs 97·4% [96·6-98·1]). From these results it was determined that teachers could therefore use the Peek School Eye Health system (Peek SEH) to identify and refer children with visual impairment. In the RCT, visual impairment was identified in 531 (5%) of 10,579 children in the Peek group and 366 (4%) of 10,284 children in the standard care group. The proportion of pupils identified as having visual impairment who attended their hospital referral was evidently higher in the Peek group (285

[54%] of 531) than in the standard group (82 [22%] of 366; odds ratio 7·35 [95% CI 3·49–15·47]; p<0·0001). We concluded that the Peek SEH using Peek Acuity can be effectively conducted by school teachers thereby leaving eye care workers to focus on providing specialised treatment.

There was concern over lower specificity and positive predictive value for Peek SEH than the standard system, which could result in more children being referred who were not subsequently found to have visual impairment and could overburden the health system with unnecessary referrals. Many of those without VI were noted to have an ocular condition, most frequently allergic eye disease, which is particularly common in this population and benefited from hospital referral for treatment. The findings demonstrated the potential of the Peek school eye health system enabling task shifting of identifying visual impairment to teachers and in improving uptake of eye services by school children.

The results of the trial were used to set up a region wide school screening program to screen all children in public primary schools in Trans Nzoia County. The process of scaling up (translating the trial into practice) was the third objective of the thesis. As described in Chapter 4, there are multiple factors that interact and must be considered before the scale-up of projects from research. These include, the context (social cultural political and technological), the actors (role of different stakeholders) and the process in each of the phases. A strong governance system with strong local leadership and commitment is needed to deliver and sustain the scale-up, and local participants should be engaged to be champions of the process. Defining stakeholders' roles and engaging them throughout the project cycle was found to be critical for acceptance, support, integration and sustainability. Integration of school screening activities into the broader health system with available and functional referral pathways, treatment and follow-up mechanisms are a prerequisite to ensure a complete closed-loop (identification and treatment) for the patient. Regular engagement of parents as key stakeholders through school and parents' forums was essential for acceptance and taking children for treatment and should be considered for

similar projects. Other important stakeholders were Ministries of Health and Education who provided oversight, teachers, eye care workers and non-governmental organizations who provided funding financial and in-kind support as well as on the ground human resources. Through the collaborative process the school project screened over 168,820 children of which 6,696 (4.0%) had visual impairment and through continuous improvements and stakeholder involvement achieved 93% treatment coverage, up from 54% in the intervention described in Chapter 3.

Using the same principles used in the school eye heath system, a “Peek Community Screening App (Peek CS)” was developed and validated. Peek CS is a smartphone-based decision support algorithm that allows referral decisions by community volunteers (CVs) to be made precisely and reliably and was developed and validated through an extensive and iterative process. In line with the fourth objective of developing and validating algorithms for door to door community screening to identify and refer people with eye problems. In the validation (Chapter 5), CVs referral decisions using Peek CS were compared to those by an experienced Ophthalmic Clinical officer (OCO), the reference standard. The Sensitivity was 91.0%, (95% CI 87.7% - 93.7%) and Specificity was 78.1%, (95% CI 71.6% - 83.6%). The positive predictive value was 88.9%, (95% CI 85.3%-91.8%) and the negative predictive value was 81.8%, (95% CI 75.5%-87.1%). This suggests that trained community volunteers can effectively use the app to identify and refer people with eye problems. As part of the iterative design, we found that subjective questions in the algorithm were likely to cause the greatest variation in responses and hence affect the performance of the algorithm.

This app met the minimum predetermined criteria and was subsequently integrated into an mHealth system, Peek Community Eye Health system (Peek CEH) for vision screening in communities linked to primary eye care facilities. The effectiveness of the system, which was the fifth objective of the thesis, was evaluated in a cluster randomised trial in which the methods are described in Chapters 6 and the results in Chapter 7. A single masked cluster

randomised controlled trial was used to compare the Peek CEH (comprising Peek Community Screening app, short message service [SMS] reminders and real-time programme data), delivered by Community volunteers against current care (periodic health centre-based outreach clinics with onward referral). The primary outcome was the number of people per 10,000 population with confirmed eye conditions attending triage at primary care facilities.

Overall, 9,387/ 68,348 (13.7%) participants from the intervention group and 3,070/ 60,243 (5.1%) in the control group attended triage. The study found that Peek CES improved adherence to both triage and hospital attendance among people with eye problems in the community compared with the standard system. The mean attendance to triage by participants with eye problems was 5.2% in the control arm compared to 14.3% in the intervention arm, risk difference 9.1% (95%CI: 6.9-11.3%); p <0.00001. This effect of the intervention was found to differ by gender with a higher attendance rate among females than in males. The majority (76.1%) of beneficiaries were treated at the primary level and of those requiring referral for specialist hospital services only 13% (previously 61%) were for primary eye conditions and 56% (previously 8%) were for cataract, glaucoma and refractive errors. This shows that, by establishing primary eye care services and integrating these in to community based activities and secondary care services, governments can shift the management of some eye conditions to primary care facilities thereby leaving the secondary facilities to deal with only major cases instead of overburdening them with unnecessary referrals which can be managed at the PEC level.

The Peek Community Eye Health system increased primary care or hospital attendance for people with eye problems compared with the standard approach in communities. This indicates the potential of this technology package to improve uptake of eye services, create gender equity and guide task shifting of case identification to help target resources. This trial is the first mHealth intervention to support uptake of eye services and it provides evidence that integration of Peek School and Community eye health systems could increase

access to eye care services, increase adherence to referrals and support more appropriate utilisation of services.

Reflections on the findings

The effectiveness of these mHealth interventions in improving the attendance adds to previous evidence of improved adherences to hospital appointments following mHealth interventions that supported communication between health care providers and patients through short messaging services (SMS).[13,14] The success of our interventions were multifactorial. First, the interventions themselves but also because there was good collaboration between the leadership of the County Government, the hospital and the trust of the community in the health systems where they access eye services. In our study, acceptance and adoption by both participants and policy makers may have been contributed to by the previous exposure and success of M-Pesa, the mobile phone money transfer platform in Kenya. The acceptance of mobile technology, especially finance has increased mobile money transfer penetration to 61.8%.[15] The trust by the community and their leaders in health workers has been built over time due to previous interactions and could have also contributed towards the success. Therefore, implementing future programs that replicate the findings demonstrated here may require building relationships and trust ahead of time and investing in managing the expectations of the community.

The trial demonstrated that non eye-care workers (teachers and community volunteers) using smartphone decision supported algorithms can correctly identify and refer patients with eye problems. The screening and identifications of people in the community is dependent on the interactions between the teachers and pupils; and the CVs with the community. They establish rapport before screening, then use the technology to aid in screening. The calibre and manner of screeners used in the programs is important, they need to be carefully selected before training is done. Screeners who were respected but not previously exposed to smartphone use took longer to train than those who were

previously exposed because they could navigate the phone Apps easily. We observed the local knowledge of volunteers and their interactions was essential in selecting a team that were respected and willing to learn. It is essential to invest in a local management team to manage the recruitment based on the set criteria.

Despite multiple reminders, only 54% of the school going children in the trial in Chapter 3 attended the hospital and only about 25% in the community trial attended hospital (Chapter 7), suggesting major barriers to adherence still exist. During the scaling up of the school eye health project in Chapter 4, the approach was changed from children travelling to hospitals to offering treatment near schools enabling management of non-complex issues and further referring just those that needed attending to in a hospital setting (e.g. surgical needs), the uptake from referral increased to 93% using this model. Also, during the community trial, attendance was higher for females at primary eye care centres than at the hospital. This seem to suggest that establishing primary eye care centres or providing services closer to the community rather than asking the population to attend the hospital for all eye related issues might be the key to improving access. The mHealth technology is a tool to supports people navigate the process efficiently rather than being the standalone solution of utilization. SMS reminders are important in communication between health workers and patients; however, we still don't know how many reminders should be sent before patients reaches SMS fatigue or determine that no action will be forthcoming. The mHealth system made it possible to identify the specific individuals and assess risk factors at a population level for those who were not accessing services, thus driving programme design towards reducing these barriers in a data driven manner as demonstrated in the scale-up of the school programme as well as planned initiatives to translate the community trial in to practice.

Strengths and Limitations

Strengths

This work has several overall strengths. To my knowledge, this thesis describes the first trials of interventions delivered through smartphone technology to support eye care. It was conducted in a low- and middle-income country where there is huge need for eye serves and few eye care workers, therefore the results have potential to be applied for public health benefit.

The trials were embedded in the schools and health system and therefore making the path to adoptions and scale up clear. The measure of the primary outcome (attendance) was objective and hence reduced risk measurement bias.

The studies included in the thesis were conducted in the same area, Trans Nzoia County therefore results from the baseline assessment of utilizations of eye services could be compared with outcome after the interventions.

Similarly, the trials involved a large sample size hence providing narrow confidence intervals around the outcomes. The enumeration of the target populations enabled direct comparison of the denominator (total possible population) and characteristics of the population including determinants of coverage and adherence.

Limitations

The work has limitations that have been discussed in the individual Chapters 2 -7. An overall limitation is the generalisability of this study to other setting due to the wide variation in health systems and regulations. The study population was representative of participants

seeking eye care, the prevalence of eye conditions and populations dynamics might be different in other locations therefore the process might have to be adapted for the settings.

The definition of visual impairment in this study is also a limitation — we used only distant visual acuity and did not assess near vision in school screening. There is agreement on the importance of assessment of near vison in children particularly when they are struggling with reading, because it could affect reading and learning.[16] A study from Norway showed 4% of the children aged 7-15 years had hyperopia compared to 17% with myopia,[17] suggesting that children with reading difficulties are left out and the magnitude of VI could be underestimated as well as missed in screening programmes that utilise only distance vision tests as per current global guidelines. This omission in most programs could be the focus of programs being medical, preventing amblyopia rather than educational, preventing learning difficulties,[18] and also the current inadequacy of the near-point visual acuity measurements using the reading cards or charts.[16]

Another limitation of this thesis is the lack of a cost-effectiveness analysis for the community trial. The cost of delivering the intervention includes use of the platform, costs for messages, screeners time, devices (smartphones and computers), human resources, treatment and patients' cost of travel.

A cost-effectiveness analysis of Peek school eye health was undertaken as part of a master's project at LSHTM. A cost-utility analysis was performed using a decision analytical model which synthesized data from the school RCT in chapter 3 to compare the costs and effects of screening with Peek versus screening with Tumbling E. The outcomes were disability adjusted life years (DALYs) averted and costs were estimated from both a health service and a societal perspective. The results from the un published data showed that Peek SEH was cost-effective at twice the Gross Domestic Product (GDP) per capita of Kenya. Analysis was based on the benefits derived from refractive error without considering the those for other referred eye conditions (unpublished data MSc thesis 2015). Similar analysis is planned for the Peek CEH, where a sensitivity analysis will consider patient and

provider perspectives and uncertainties with respect to effectiveness. Information on the cost-effectiveness of the intervention is likely to be useful for governments, service providers and funders when considering implementation of such interventions.

There was low screening coverage specifically for the community RCT (chapter 7) because many participants were not found at home during house to house screening and thus suggests mixed modes of community screening may be required to cater for those who are at work, for example, work-based screening and screening clusters at community meeting points (e.g. churches) as well as offering multiple dates for screening (as opposed to the single opportunity available in the trial presented here) and screening on weekends or evenings after work.

Implications to practice

Findings from this thesis have potential implications for service delivery and have been described in Chapters 3, 4 and 7.

Overall, the findings from this trial and scale up process suggest that the intervention comprising active case finding, referral with reminder messages to attend hospital appointments could be delivered as demonstrated in the trials. It has also shown that it is feasible to introduce mHealth interventions in LMICs. The process of setting up similar intervention in school been has been described in Chapter 4 however, further adaptations and understanding the context is recommended prior to implementing similar interventions in other settings.

The adoption process may be slow and hence this finding will be shared with implementors (eye health workers), NGO partners and the key leaders at the ministries of Health and the County Governments. Specifically, the summary findings will be shared with stakeholders

during the deliberations of the national strategic planning meetings with a view to adoption and use in other areas of Kenya.

Evidence from this trial showed improved adherence hospital referrals and increased access and more appropriate utilization of eye services. The Ministry of Health could consider such interventions as routine practice to improve referral services, and utilization of eye care services in schools and especially in hard to reach populations. This could be facilitated by the fast-growing coverage, high penetration of smart phones and improved capabilities of the phones.[19]

The model is scalable provided other key elements being present such as capacity of the primary health system to handle extra referrals, the skill set of primary eye care workers to make a diagnosis, the accuracy of a screening tool in the specific setting and the resources to do so. Health care providers at primary health care facilities should be trained and equipped to provide these services. As described in Chapter 4, one scaling approach could be to increase resources or stagger the rate of screening to match the existing resources. If it were to be scaled in areas with low primary level skill set, an adapted outreach model can be used where secondary level health workers are deployed periodically in outreach at the primary level whilst concurrently providing training to permanent staff to transition from a secondary to primary outreach model to a feeder model from primary to secondary.

Before deciding on the approach to use in scaling up such interventions, it is important to first understand the eye health services situation in the country or region where the intervention will be implemented. This entails understanding the need through needs analysis, environmental analysis to identify potential risks, threats and opportunities that might affect the interventions implementation, stakeholder mapping to identify all the key stakeholders who should be informed or engaged in the process and comprehensive eye health service analysis.[20]

This process can be done using various tools such as the eye care service assessment tool (ECSAT) which allows planners and decision makers to collect data and information on the provision of eye care at the country and district level with a focus on the six areas of the WHO framework for strengthening health systems;[21] and identify gaps in the eye care provision in order to strengthen access to comprehensive, high quality and integrated eye care services. This tool also helps in the implementation of evidence-based interventions through periodic data collection which is useful in assessing the impact of interventions and identifying trends and emerging needs. It might be essential to identify the tasks that can be delegated to others leaving more complex tasks to health workers.

Despites the interventions improving adherence to hospital appointments, there is a potential for causing poor services from increased patient numbers seeking eye services with low number of eyes-health workers and lack of funds to cater for consequential extra management and treatment cost. The governments and partners may have to find innovative ways to raise extra funds to meet the new demand. This includes promoting health insurance or exploring non-monetary incentives to stimulating quality improvement in general eye practices and out-of-hours services provision. Service providers would need to consider the cost-implications of implementing the intervention, balanced against potential benefits such as increased uptake of eye services and the gain to the economy from avoided blind years and increased productivity.[22] Although cost analysis were not part of the thesis it is an important element to be considered before adopting a program.

Implications for policy

The World Health Assembly has adopted a key resolution on Universal Health Coverage (UHC).[23] Member states commit to provide access to necessary health services for the whole population, “leaving no one behind”.[24] The trials provide strong evidence of increased access to eye care, particularly for women and vulnerable groups, whilst making more appropriate use of limited eye care resources. Therefore, a change in policy to adopt

mHealth integration in to the health system as part of routine practise could contribute to UHC in Kenya. Routine health information collected by eye health facilities or hospital reports within the national or regional health information system can provide a data source to monitor progress towards UHC.[25] The findings in Chapter 2 of this thesis on the use routine hospital data to assess the utilization of eye services demonstrates the potential of using such routine data in assessing equity, planning and monitoring eye health services delivery.

These findings have far reaching implications for policy regarding planning the establishment of primary and secondary health care facilities in different locations based on utilization level and the subsequent proper and efficient management of established facilities in order to encourage health seeking behaviour of the population. Although the findings in Chapters 3 and 7 have shown that Peek is a scalable intervention, there is a need to have it included in national plans and strategies in order to maximize its impact in strengthening health systems for eye care provision. An example is policies or plans on task shifting, which should specify the task to be delegated. Further, alignment of the project goals and objectives with government policies is important as it enhances acceptability of the project and makes integration into mainstream government structure easier. For instance, aligning the Kenya Peek School Screening project with universal health coverage agenda,[23] and the National school eye health policy [26] which is currently a priority for the Kenyan government.

Lastly, scaling up of mHealth interventions should be done in a stepwise manner to minimize the potential risks to the health system. These risks include availability of medication, capacity and readiness of hospitals to handle referrals and availability of human resources throughout the health system. It is also important to consider regulations and the policy on the role of hospitals in patient data sharing and securing their privacy which is guaranteed in the Kenya constitution.[27]

Recommendations for further research

The results of the following research endeavour will be useful to further strengthen eye care services using Peek:

Analysis of existing research data

1. Assessment of the Cost effectiveness of the Peek Community eye health system (Peek CEH)

   Aim to utilise the findings of the Peek CEH RCT to conduct a cost-effectiveness analysis of screening and referral using the intervention compared to the current care.

   Methods A cost-utility analysis to compare the costs and effects of screening with Peek CEH versus screening current standard. The outcomes will be expressed in disability adjusted life years (DALYs) averted and costs estimated from both a health service and a societal perspective.

   A sensitivity analysis will be conducted and a cost-effectiveness plane and a cost-effectiveness acceptability curve will be produced.

2. Pattern of Visual impairment

   Objective: To assess the magnitude and causes of visual impairment and blindness among patients attending primary eye care centres.

   Methods – Descriptive analysis of data already available from the community trial.

3. Assessment of barriers to assessing secondary services.

   Objective: To investigate why about 76% of those referred for secondary services did not attend, despite weekly reminders.

Methods – qualitative study to explore the barriers and potential solutions. Interviews with those who did not attend (have barriers) and those who attended hospital (overcame barriers).

New study projects

4. Investigate the effect of single message and multiple SMS reminders with additional counselling on attendance to hospital

   As described in Chapter 7 following potential contamination, it was observed that the first two messages seemed to have effect but subsequent ones have reduced effect. It was hypothesized that multiple SMS may have introduced some intervention fatigue to some participants and discouraged their compliance. A study could explore the potential for a single message vs multiple messages and bespoke counselling. Industry A/B testing methods could be deployed to test various message content and frequencies

   Objective: To explore the effects of messages (notification and a reminders) and SMS reminder frequency on adherence to hospital referrals with additional of counselling at primary eye care.

   Method: A factorial randomised controlled trial

5. Development and validations of smartphone-based algorithms to aid screening

   There are multiple factors that affect the performance and acceptance of a smartphone guided screening algorithm, as described in Chapter 4, these include the objectively assessed inputs such as acuity and subjective assessments such as self-perception of vision loss or eye problems. The subjective assessment creates variability in accuracy and limits it use in other areas. Expansion of the algorithm to include more objective signs such as shape, size and colour of eye is hypothesised to increase identification of those with eye health morbidity.

Objective: to explore further development and refinement of Peek community screening app to improve its accuracy based on more objective signs and less subjective symptoms.

Methods: Validation study

6. Development and validation of smartphone-based algorithms to aid in primary health care workers in management of eye conditions.

   The World Health Organization (WHO) developed and published clinical algorithms for primary health care (PHC) workers in Africa to assess patients with eye conditions,[28] the algorithms need to be digitalised and validated for smartphones. Some of the work was initiated as part of PhD but incomplete and could potentially be continued.

7. Routine assessment of community needs and utilization of eye services.

   Currently utilised rapid survey methods provides estimates of the visual impairment related need in the population but not the proportion of populations utilizing eye health resources. It is hypothesised that incorporation of such indicators would critical data for health service planning.

   Objective: Explore the potential of standardising the reporting of utilization of eye care services and incorporating such methods during assessments of the community eye health needs.

Conclusion

This study utilized robust methods to develop and evaluate whether community volunteers and teachers can effectively use a novel mobile phone-based technology (Peek) in communities and schools respectively, to identify people with referable eye conditions, referring those with eye problems for treatment and to also monitor adherence to services so as to reduce avoidable visual impairment in the population. The results provide strong evidence that integration of Peek mHealth interventions in to the health system can increase access to eye care services, particularly for the most vulnerable groups, whilst making more appropriate use of limited eye care resources. These findings have important implications for policy, practice and research in LMICs, where there is currently low access to services and a growing burden of visual impairment.

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Appendices

Appendices

Appendix 1: List of people contributed to the work presented in this thesis

Person	Position	Contribution
Abraham Bwambok	Ophthalmic Clinical Officer	Provision of triage
Andrew Bastawrous	Senior Lecturer, LSHTM	PhD supervisor, field project funding, study design, analysis, write-up and review of manuscripts
Benard Simiyu	Lead Community health volunteer	coordination of community health volunteers, mapping out clusters, facilitating community entry by the screening team
Benedictor Milimu	Screener	Data collection as a screener in the community screening Trial
Billy Otieno	Screener	Data collection as a screener in the community screening Trial
Bridgit Nambuchi	Hospital Receptionist	Receiving of patients from triage and directing them in the hospital recording their details into capture
Caroline Rombosia	Field Support	Management of patients flow and order during triage
Centrine Wanyonyi	Screener	Data collection as a screener in the community screening Trial
Chemtai Kirui	Screener	Data collection as a screener in the community screening Trial
Cheruiyot Langat	Ophthalmic Clinical Officer	Provision of triage
Christopher Biko	Screener	Data collection as a screener in the community screening Trial
Cosmas Bunywera	Research coordinator,	Recruited field workers, coordinated field work, overall planning
Daisy Muyesu	Teacher screener	Data collection by screening school children
David Macleod	Statistician, LSHTM	Data analysis and review of manuscript
Dennis Likalia	Screener	Data collection as a screener in the community screening Trial
Dorcas Simatwa	Records officer	Organizing of all research related records at hospital
Edwin Nyabuto	Screener	Data collection as a screener in the community screening Trial

Emmanuel Wanjala	Hospital medical superintendent	Research coordination and review of manuscripts
Everlyne Chepkorir	Office manager/ Data entry	office administration and data entry
Gavine Juma	Data entry and Book keeping	Data entry payment of field workers
Grace Mwangi	Ophthalmic Nurse	Coordinating the treatment team, proving treatment
Gyreth Muyuka	Screener	Data collection as a screener in the community screening Trial
Hellen Nyongesa	Teacher screener	Data collection by screening school children
Ian Kiprop	Screener	Data collection as a screener in the community screening Trial
Jane	Teacher screener	Data collection by screening school children
John Shery	Technology support and data entry	Ensure smartphones are charged, and the screening apps are updated and configured. Training and support to screeners
Ken Juma	Screener	Data collection as a screener in the community screening Trial
Kennedy Nyabwondo	Teacher screener	Data collection by screening school children
Kevin Kingi	Screener	Data collection as a screener in the community screening Trial
Kibet Korir	Ophthalmic Clinical Officer	Provision of triage
Komen William	Ophthalmic Nurse	Provision of triage
Lennox Juma	Screener	Data collection as a screener in the community screening Trial
Levin Mwania	Assistant Research coordinator	Coordinated field work, overall planning
Lily Kimetto	Optometrist	Refraction of school children
Lorna Tuitei	Screener	Data collection as a screener in the community screening Trial
Lydia Agesa	Teacher coordinator and screener	Planning, coordination of schools, data collection during school Screening
Margaret Opaa	Ophthalmic Nurse	Provision of triage
Mariam Wafula	Screener	Data collection as a screener in the community screening Trial
MaryJuliet Khachesanga	Teacher coordinator	Liaison with ministry of education, Consenting in schools and data collection
Matthew Burton	Professor, LSHTM	PhD supervisor, project funding, study design, analysis, write-up and review of manuscripts

Maureen Mutende	Screener	Data collection as a screener in the community screening Trial
Mercy Miliza	Technology support and data entry	Ensure smartphones are charged, and the screening apps are updated and configured. Training and support to screeners
Mercy Tanui	Screener	Data collection as a screener in the community screening Trial
Mercy Wanyonyi	Ophthalmic Nurse	Provision of triage
Monica Nyambura	Optometrist	Refraction of participants in the community trial
Moureen Etyany	Optometrist	Refraction of school children
Nicholas Mageto	Screener	Data collection as a screener in the community screening Trial
Nobert Musundi	Public Health Officer, Trans Nzoia County	Coordinating training of community volunteers and Community extension Health workers
Nolega Amani	Field Support	Management of patients flow and order during Triage
Nyongesa Kizito	Teacher screener	Data collection by screening school children
Phanice Temko	Ophthalmic Clinical Officer	Provision of triage
Protas Nyongesa	Screener	Data collection as a screener in the community screening Trial
Rodah Kipyegon	Ophthalmic Nurse	Provision of triage
Rodgers Okumu	Data Entry	Data entry
Rodgers Sitati	Teacher screener	Data collection by screening school children
Ronald Mamboleo	Ophthalmic clinical officer, Research data collection	Reference standard, conducted treatment of all participants
Ruth Sikolia	Teacher screener	Data collection by screening school children
Samuel Kuria	Teacher screener	Data collection by screening school children
Sandra Chepchirchir	Field coordinator	Coordination of community enumeration and consenting, coordinator of data collection
Shadrack Chebet	Ophthalmic Clinical Officer	Treatment of study patients in the Hospital
Sheilah Achieng	Screener	Data collection as a screener in the community screening Trial
Silas Lumbasi	Screener	Data collection as a screener in the community screening Trial
Stephen Gichuhi	Senior Lecturer, University of Nairobi	Study design and review of manuscripts
Susan Anyolo	Teacher coordinator and screener	Planning, coordination of schools, data collection during school Screening
Swafi Hamisi	Driver	Driving of all the teams

Vincent Serem	Field coordinator	Coordination of community enumeration and consenting, coordinator of data collection
Wilberforce Nyukuri	Teacher screener	Data collection by screening school children
William Kemei	Ophthalmic Clinical Officer	Treatment of study patients in the Hospital
Willy Bett	Community strategy coordinator	Providing insights to Community screening, and contact with community units
Zipporah Wambulwa	Screener	Data collection as a screener in the community screening Trial

Appendix 2: Permissions to include the article Utilization of Secondary Eye Care Services in Western Kenya

Begin forwarded message:

From: "Kristin.Xie" <kristin.xie@mdpi.com>

Subject: Re: Permissions to include the article "Utilization of Secondary Eye Care Services in Western Kenya" in my PhD thesis

Date: 23 September 2019 at 03:58:29 BST

To: HILLARY RONO <hkrono75@gmail.com>

Dear Dr. Rono,

Apologies for the late reply. You can reference your articles without additional permissions. **So, it is OK for you to use it as in the thesis.**

Best Regards,

Ms. Kristin Xie

Assistant Editor

On 2019/9/21 22:37, HILLARY RONO wrote:

Dear Kristine

I am the author of the above ref https://doi.org/10.3390/ijerph16183371. I would like to use this article as one of the chapters in the PHD thesis. I was checking whether I will need either permissions or it is OK for me to use it as in the thesis.

Regards

Hillary Rono

Appendix 3: Permission from co -authors for Smartphone-based screening for visual impairment in Kenyan school children: a cluster randomised controlled trial

From: David Macleod <david.macleod@lshtm.ac.uk>
Subject: RE: Inclusion of the publication in PhD thesis
Date: 23 September 2019 at 10:16:42 BST
To: Hillary Rono <rono@peekvision.org>

Of course, no problem

Cheers
Dave

From: Gian Luca Di Tanna <glditanna@gmail.com>
Subject: Re: Inclusion of the publication in PhD thesis
Date: 22 September 2019 at 23:55:36 BST

Sure! Good luck and keep us updated on how it goes!

Thanks,
Gian Luca

From: Helen Weiss <Helen.Weiss@lshtm.ac.uk>
Subject: RE: Inclusion of the publication in PhD thesis
Date: 21 September 2019 at 16:27:37 BST
To: Matthew Burton <Matthew.Burton@lshtm.ac.uk>, wanjala emmanuel <eswanjalah@yahoo.com>
Cc: Hillary Rono <rono@peekvision.org>, Andrew Bastawrous <andrew@peekvision.org>, Gian Luca Di Tanna <glditanna@gmail.com>, David Macleod <david.macleod@lshtm.ac.uk>

Yes of course – best of luck with the thesis!
h

From: Matthew Burton <Matthew.Burton@lshtm.ac.uk>
Subject: Re: Inclusion of the publication in PhD thesis
Date: 21 September 2019 at 16:19:40 BST
Of course

Prof. Matthew Burton

From: wanjala emmanuel <eswanjalah@yahoo.com>
Subject: Re: Inclusion of the publication in PhD thesis
Date: 21 September 2019 at 16:08:13 BST
To: Hillary Rono <rono@peekvision.org>, Andrew Bastawrous <

I'm in agreement that you process it towards the same ,thesis success.

Sent from Yahoo Mail for iPhone

-----Original Message-----
From: Hillary Rono <rono@peekvision.org>
Sent: 21 September 2019 16:04
To: Andrew Bastawrous <andrew@peekvision.org>; Matthew Burton <Matthew.Burton@lshtm.ac.uk>; Gian Luca Di Tanna <glditanna@gmail.com>; Helen Weiss <Helen.Weiss@lshtm.ac.uk>; eswanjalah@yahoo.com; David Macleod <david.macleod@lshtm.ac.uk>
Subject: Inclusion of the publication in PhD thesis

Dear co-authors,

I'm writing to see if you would be happy for me to use the article " Smartphone-based screening for visual impairment in Kenyan school children: a cluster randomised controlled trial" published by the Lance global Health in 2018 as a chapter of my PhD thesis.

Regard

Hillary Rono

Appendix 4: Permission for Peek Community Eye Health - mHealth system to increase access and efficiency of eye health services in Trans Nzoia County, Kenya: study protocol for a cluster randomised controlled trial

From: "customercare@copyright.com" <customercare@copyright.com>
Subject: Case #00885247 - Permission to use the article as part of phD thesis [ref:_00D30oeGz._5000c1tqcZh:ref]
Date: 25 September 2019 at 21:56:56 BST
To: "hkrono75@gmail.com" <hkrono75@gmail.com>

Dear Hillary Rono,

Thank you for contacting Copyright Clearance Center (CCC). I sincerely apologize for the delayed reply. Here at CCC, **we grant copyright permission on behalf of publishers and rightsholders** who list their titles with us.

I see the article *Peek Community Eye Health - mHealth system to increase access and efficiency of eye health services in Trans Nzoia County, Kenya: study protocol for a cluster randomised controlled trial* is covered under a creative commons license. You can view the terms by click on this link http://creativecommons.org/licenses/by/4.0/???????. If you do not believe this fits your need, you will want to contact Springer directly at Journalpermissions@springernature.com.

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---------- Original Message ----------

From: HILLARY RONO [hkrono75@gmail.com]

Sent: 9/19/2019 7:04 PM

To: customercare@copyright.com

Subject: Permission to use the article as part of phD thesis

Dear Sir / madam,

I am the author of the artcilecle published bu the Trials "Peek Community Eye Health - mHealth system to increase access and efficiency of eye health services in Trans Nzoia County, Kenya: study protocol for a cluster randomised controlled trial" by Hillary Rono, et al in the Trials volume 20, Article number: 502 (2019) . https://doi.org/10.1186/s13063-019-3615-x.

I am doing PHD by publication and would like to use this article as one of the chapters in the PHD. i look toward to your permissions

Rono

ref:_00D30oeGz._5000c1tqcZh:ref

Appendix 5: Evidence of completion of Good Clinical Practice course (A) and web-based course on Protecting Human Research Participants (B)

(A)

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

This is to certify that

Hillary Rono

successfully completed the

Good Clinical Practice

December 2, 2017

GCP Assessment (R2) Grade: 87.50 %

An e-learning course comprising of modules covering:

- Introduction to Good Clinical Practice
- Roles and Responsibilities – Key players
- Informed Consent
- Essential documents
- Data Management
- Monitoring, Auditing and Inspections
- Investigational Medicinal Products
- Safety Reporting
- End of Study and Archiving

Provided by
London School of Hygiene & Tropical Medicine

This ICH E6 (R2) GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma Inc. as necessary to enable mutual recognition of GCP training among trial sponsors

London School of Hygiene & Tropical Medicine, Keppel Street, London WC1E 7HT

(B)

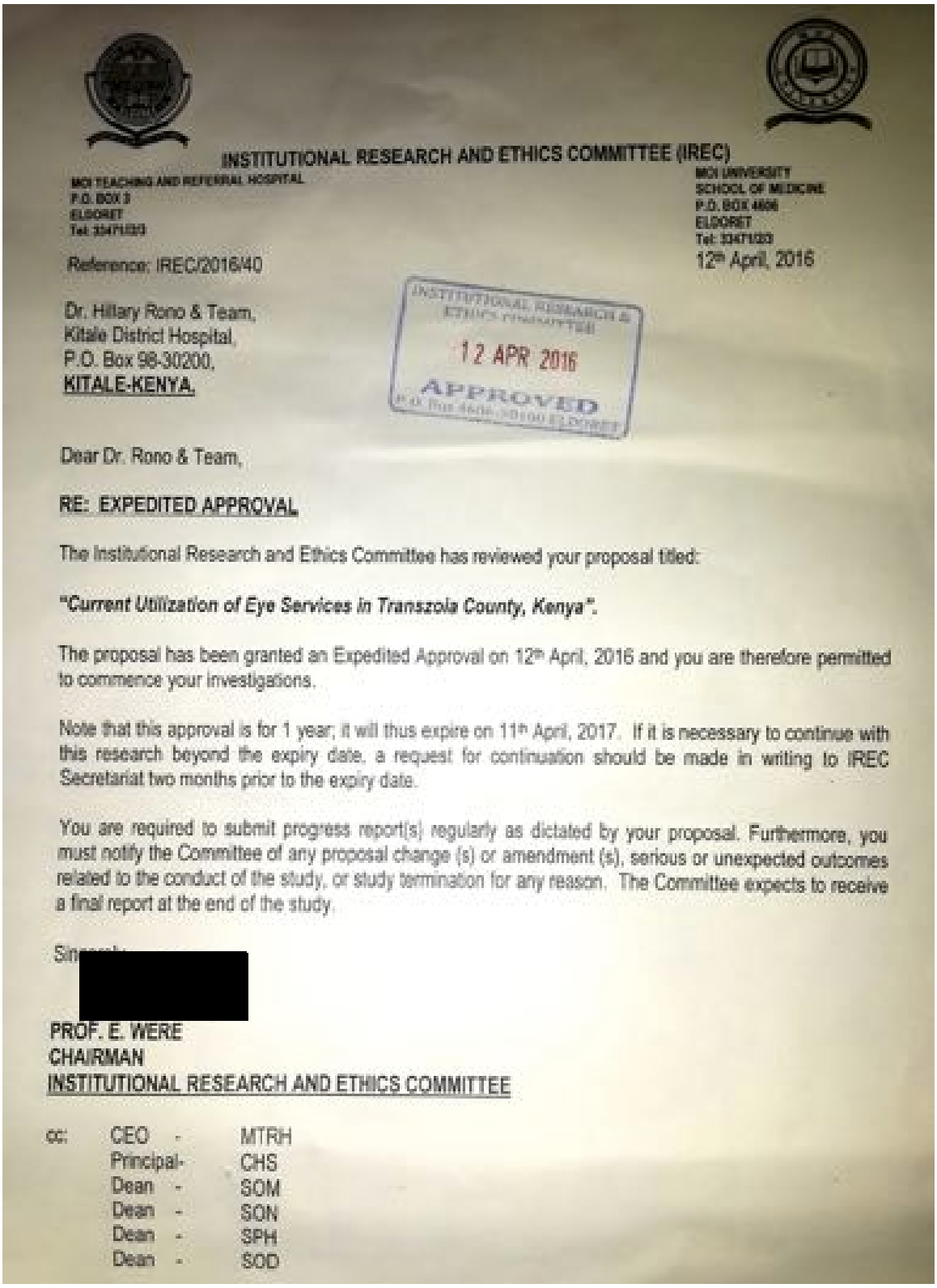
Certificate of Completion

The National Institutes of Health (NIH) Office of Extramural Research certifies that **Hillary Rono** successfully completed the NIH Web-based training course "Protecting Human Research Participants".

Date of completion: 06/20/2014

Certification Number: 12309

Appendix 6: Evidence of ethical approval in Kenyan for the Retrospective analysis of utilization of eye.



INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/33

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET
Tel: 33471/33

Reference: IREC/2016/40

12th April, 2016

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
12 APR 2016
APPROVED
P.O Box 4606 - 30100 ELDORET

Dr. Hillary Rono & Team,
Kitale District Hospital,
P.O. Box 98-30200,
KITALE-KENYA.

Dear Dr. Rono & Team,

RE: EXPEDITED APPROVAL

The Institutional Research and Ethics Committee has reviewed your proposal titled:

"Current Utilization of Eye Services in Transzola County, Kenya".

The proposal has been granted an Expedited Approval on 12th April, 2016 and you are therefore permitted to commence your investigations.

Note that this approval is for 1 year; it will thus expire on 11th April, 2017. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

[redacted]

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc: CEO - MTRH
Principal- CHS
Dean - SOM
Dean - SON
Dean - SPH
Dean - SOD

Appendix 7: Evidence of ethical approval from LSHTM for the Retrospective analysis of utilization of eye.

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
United Kingdom
Switchboard: +44 (0)20 7636 8636

www.lshtm.ac.uk

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

Observational / Interventional Research Ethics Committee

Dr Andrew Bastawrous
LSHTM

15 June 2016

Dear Andrew

Study Title: Retrospective analysis of Eye Hospital Data in Kitale, Kenya

LSHTM Ethics Ref: 10509

Thank you for responding to the Observational 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
Investigator CV	Matthew Burton - CV - CEA	03/11/2014	1
Investigator CV	CV R0560_ FEB _2016	01/03/2016	1
Investigator CV	CV_Andrew Bastawrous_JULY2014	01/03/2016	1
Protocol / Proposal	16.2.7 Current utilization of eye services 16.2. 7_HR	07/03/2016	1
Local Approval	approved_ current utilization of eye services in tuuuuuu	12/04/2016	1
Covering Letter	LSHTM responses 27.5.16	27/05/2016	1
Covering Letter	London ethics response 8.6.16	08/06/2016	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.

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://ies.lshtm.ac.uk

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,

[redacted]

Professor John (Jill) Parker
Chair

Appendix 8: Evidence of ethical approval by LSHTM for the School Eye Health study

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
United Kingdom
Switchboard: +44 (0)20 7636 8636

www.lshtm.ac.uk

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

Observational / Interventions Research Ethics Committee

Dr. Andrew Bastawrous
Clinical Research Fellow
Department of Clinical Research (DRD)
LSHTM

7 January 2014

Dear Andrew

Study Title: Smartphone vision testing of school children in Tranzoia county Kenya: A randomized Controlled Trial

LSHTM Ethics Ref: 8033

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.

The documents reviewed were:

Document Type	File Name	Date	Version
Investigator CV	cv_template_ethics_bastawrous.docx	08/11/2013	1
Investigator CV	cv_template_ethics_RJRono.docx	08/11/2013	1
Investigator CV	Matthew Burton Ethics CV.docx	08/11/2013	1
Sponsor Letter	Sponsor Letter Q645 1.pdf	01/12/2013	1
Protocol / Proposal	PeekCRCTKenya2. PROTOCOL.docx	01/12/2013	1.1
Information Sheet	Peek_Kenya_InfoSh02_Info and consent.docx	01/12/2013	1.1
Covering Letter	Cover Letter Ethics Ref 8033	23/12/2013	1
Protocol / Proposal	PeekCRCTKenya2. PROTOCOL_V2.0	23/12/2013	2.0

Provisional opinion

The Chair would be content to give a favourable ethical opinion of the research, subject to receiving a complete response to the request for further information set out below.

Further information or clarification required

- There appears to be no information about local approval - please could you provide this

When submitting your response to the Committee, please submit a revised copy of the application form through the ethics online applications website: http://ethics.lshtm.ac.uk

Please list the changes and requested clarifications in a covering letter to the Committee. Please send any revised documentation, where appropriate underlining or otherwise highlighting the changes you have made and giving revised version numbers and dates as well as making any necessary changes to the application form. For further instructions, on the Help section on the website, please refer to the section on 'Provisional Approvals - submitting responses to queries raised by the committee'.

Yours sincerely,

[redacted]

Professor John Dill Porter
Chair

ethics@lshtm.ac.uk
http://www.lshtm.ac.uk/ethics/

Improving health worldwide

Appendix 9: Evidence of ethical approval in Kenya for the School Eye Health study

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471020

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET

Reference: IREC/2015/08
Approval Number: 0001359

23rd February, 2015

Dr. Hillary Rono,
Kitale District Hospital,
P.O. Box 98-30200,
KITALE-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
23 FEB 2015
APPROVED
P. O. Box 4606-30100 ELDORET

Dear Dr. Rono,

RE: FORMAL APPROVAL

The Institutional Research and Ethics Committee has reviewed your research proposal titled:-

"Smartphone Vision Testing of School Children in Transzoia County, Kenya: Randomized Controlled Trial."

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 1359*** on 23rd February, 2015. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 22nd February, 2016. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

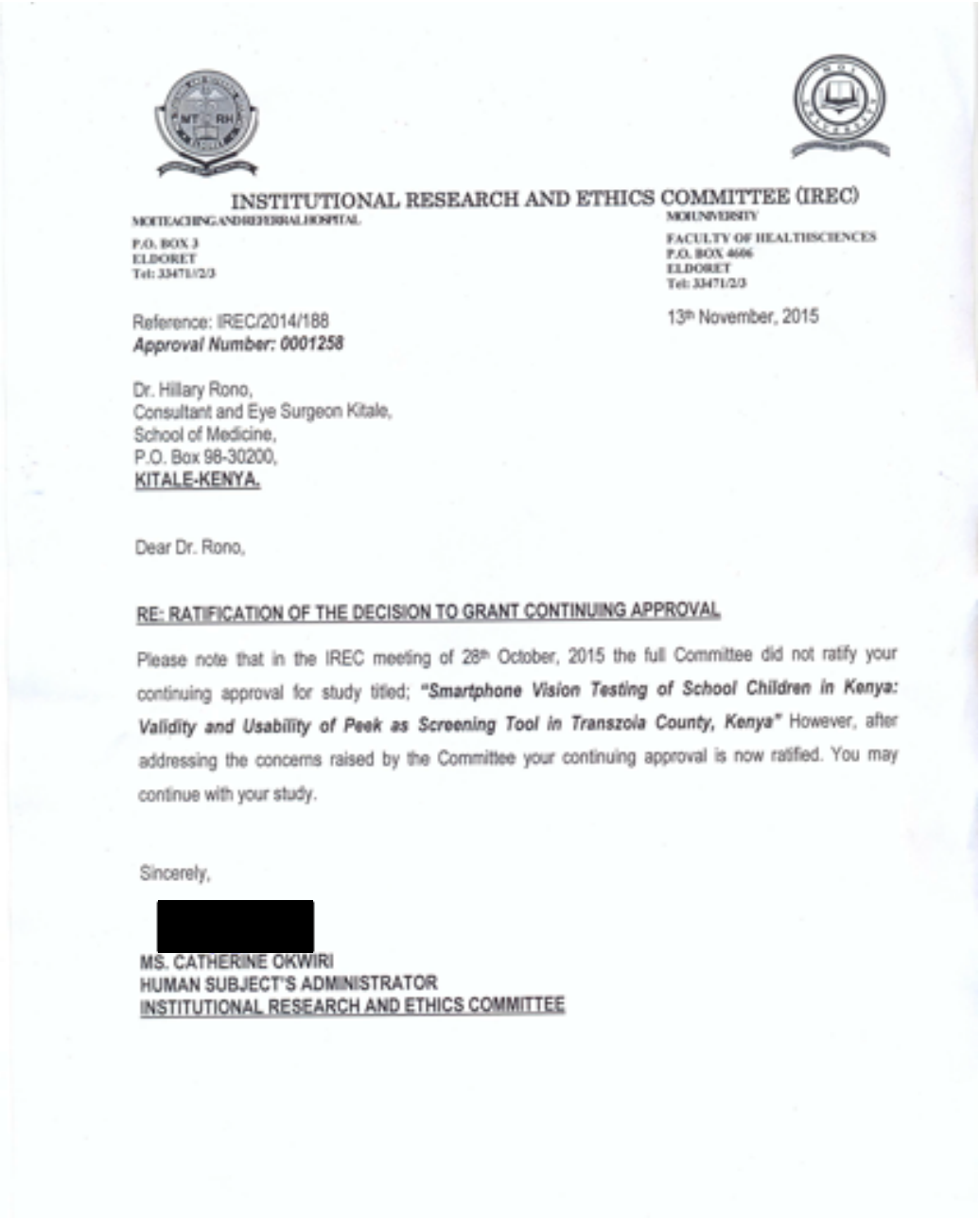
Sincerely,

[redacted]

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc Director - MTRH Dean - SOP Dean - SOM
Principal - CHS Dean - SON Dean - SOD

Appendix 10: Evidence for extension Kenya ethical approval for the School Eye Health study



INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
FACULTY OF HEALTHSCIENCES
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference: IREC/2014/188
Approval Number: 0001258

13th November, 2015

Dr. Hillary Rono,
Consultant and Eye Surgeon Kitale,
School of Medicine,
P.O. Box 98-30200,
KITALE-KENYA.

Dear Dr. Rono,

RE: RATIFICATION OF THE DECISION TO GRANT CONTINUING APPROVAL

Please note that in the IREC meeting of 28th October, 2015 the full Committee did not ratify your continuing approval for study titled; ***"Smartphone Vision Testing of School Children in Kenya: Validity and Usability of Peek as Screening Tool in Transzoia County, Kenya"*** However, after addressing the concerns raised by the Committee your continuing approval is now ratified. You may continue with your study.

Sincerely,

[redacted]

MS. CATHERINE OKWIRI
HUMAN SUBJECT'S ADMINISTRATOR
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

Appendix 11: Evidence of communication with on the need for ethical approval for the research paper on scaling up school screening using smartphones

From: Ethics <ethics@lshtm.ac.uk>
Subject: RE: ethical review for data
Date: 14 June 2019 at 15:55:44 BST
To: HILLARY RONO <hkrono75@gmail.com>
Cc: "andrew.bastawrous@gmail.com" <andrew.bastawrous@gmail.com>, Matthew Burton <Matthew.Burton@lshtm.ac.uk>

Hi,

If the process is now outside of research conditions, and so is standard of care, **you won't need to submit for ethical approval** as the ethics committee currently only review research projects.

Just as a reminder, if the study has finished, and was originally reviewed by LSHTM, please submit your end of study form if you haven't done so already.

Best wishes,
Rebecca

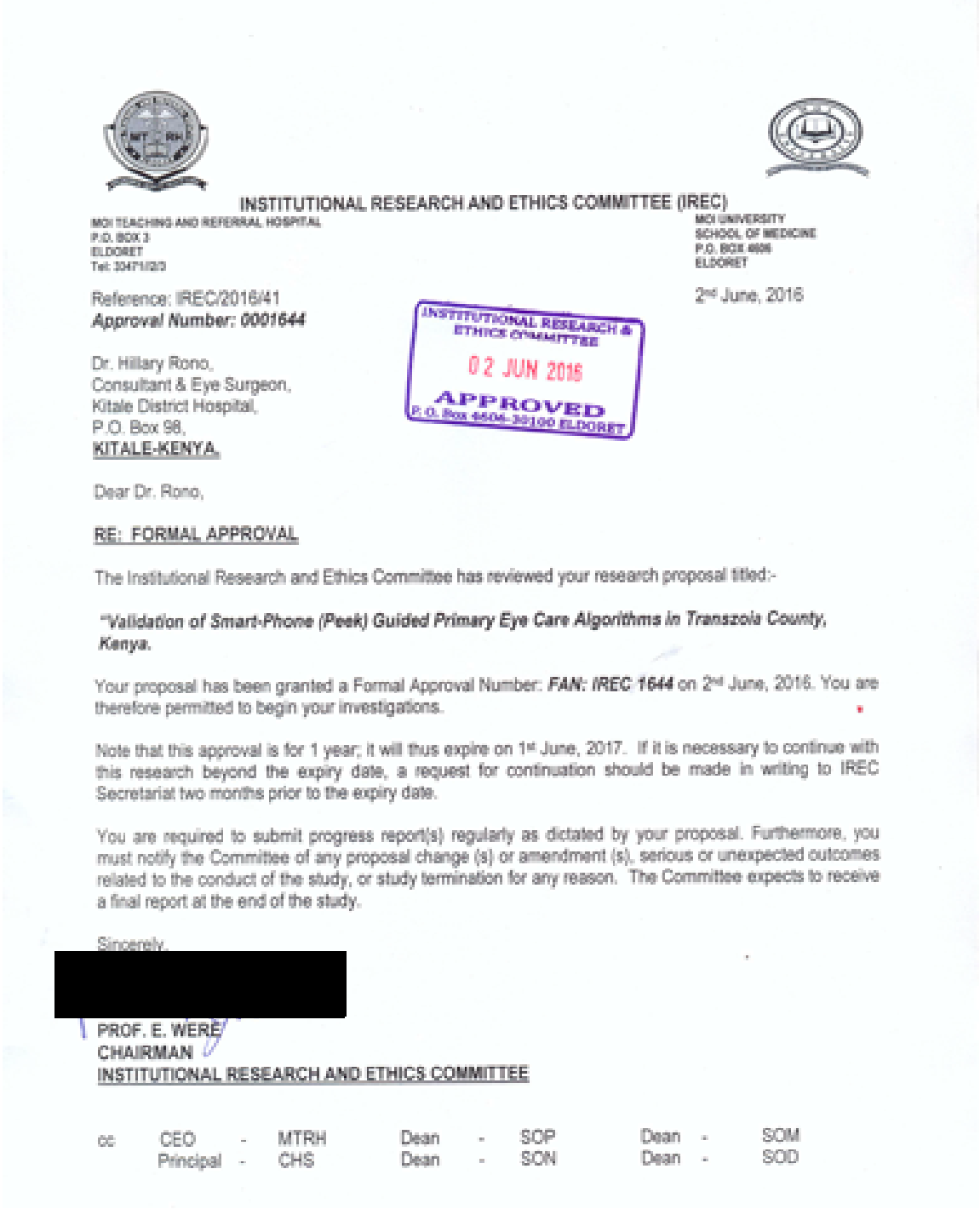
_____
Ethics Admin | London School of Hygiene & Tropical Medicine
Room LG36, Keppel Street, London WC1E 7HT, United Kingdom | E-mail: ethics@lshtm.ac.uk | Tel: +44 (0)20 7927 2221

LEO: LSHTM Ethics Online: http://leo.lshtm.ac.uk

-----Original Message-----
From: HILLARY RONO <hkrono75@gmail.com>
Sent: 12 June 2019 16:49
To: Ethics <ethics@lshtm.ac.uk>
Cc: andrew.bastawrous@gmail.com; Matthew Burton <Matthew.Burton@lshtm.ac.uk>
Subject: ethical review for data

Dear Rebecca,
We have been conducting a study on the use of smart phones to identify children / and other community members with eye problems and refer appropriately to health services.
Following the completion of one of the studies, the ministry of health decided to scale up the intervention outside research conditions. I have been involved in the process and would like to report on the the process of this calling up. Would this require ethical review before we write and publish information on the process?
Rono

Appendix 12: Evidence of ethical approval in Kenya for development and validations of community algorithms



INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET

Reference: IREC/2016/41
Approval Number: 0001644

2nd June, 2016

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
02 JUN 2016
APPROVED
P. O. Box 4606-30100 ELDORET

Dr. Hillary Rono,
Consultant & Eye Surgeon,
Kitale District Hospital,
P.O. Box 98,
KITALE-KENYA.

Dear Dr. Rono,

RE: FORMAL APPROVAL

The Institutional Research and Ethics Committee has reviewed your research proposal titled:-

"Validation of Smart-Phone (Peek) Guided Primary Eye Care Algorithms in Transzoia County, Kenya.

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 1644*** on 2nd June, 2016. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 1st June, 2017. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

[redacted]

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc: CEO - MTRH; Dean - SOP; Dean - SOM
Principal - CHS; Dean - SON; Dean - SOD

Appendix 13: Evidence of Extension of Kenyan approvals for the development and validations of community algorithms

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference: IREC/2016/41
Approval Number: 0001644

2nd June, 2017

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
02 JUN 2017
APPROVED
P.O. Box 4606-30100 ELDORET

Dr. Hillary Rono,
Consultant & Eye Surgeon,
Kitale District Hospital,
P.O. Box 98-30200,
KITALE, KENYA.

Dear Dr. Rono,

RE: CONTINUING APPROVAL

The Institutional Research and Ethics Committee has reviewed your request for continuing approval to your study titled:-

"Validation of Smart-Phone (Peek) Guided Primary Eye Care Algorithms in Trans Nzoia County, Kenya ".

Your proposal has been granted a Continuing Approval with effect from 2nd June, 2017. You are therefore permitted to continue with your study.

Note that this approval is for 1 year; it will thus expire on 1st June, 2018. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely

[redacted]

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc: CEO - MTRH
Principal - CHS
Dean - SOM
Dean - SPH
Dean - SOD

Appendix 14: Evidence of ethical approvals by LSHTM for the development and validations of community algorithms

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
United Kingdom
Switchboard: +44 (0)20 7636 8636
www.lshtm.ac.uk

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

Observational / Interventional Research Ethics Committee

Dr Andrew Bastawrous
LSHTM

31 March 2016

Dear Andrew,

Study Title: Validation of smart-phone (Peek) guided primary eye care algorithms in Trans Nzoia County, Kenya

LSHTM ethics ref: 10560

Thank you for your application for the above research, which has now 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 research on the basis described in the application form, protocol and supporting documentation, 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	Matthew Burton Ethics CV - Peek	25/02/2016	1
Investigator CV	cv_template_ethics_ andrew	25/02/2016	1
Investigator CV	cv_template_ethics_phase1 project_KONO	25/02/2016	1
Protocol / Proposal	26 2 16 Validation of peek community algorithms_HR	26/02/2016	1
Information Sheet	Information Sheet and Consent Form version 1	26/02/2016	1
Protocol / Proposal	Validation of PeekScreening & PeekTriage - Protocol v1 - 26FEB2016	26/02/2016	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.

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://lnv.lshtm.ac.uk

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,

[redacted]

Professor John Dil Porter
Chair

ethics@lshtm.ac.uk

Appendix 15: Evidence ethical approval in Kenya for the Community Eye Health study

MU/MTRH-INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471020

MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET

Reference: IREC/2018/68
Approval Number: 0003025

31st May, 2018

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
31 MAY 2018
APPROVED
P. O. Box 4606-30100 ELDORET

Dr. Hillary Rono & Team
P.O. Box 98–30200,
ELDORET-KENYA.

Dear Dr. Rono,

RE: FORMAL APPROVAL

The MU/MTRH- Institutional Research and Ethics Committee has reviewed your research proposal titled: -

"Community Screening and Referral for Eye Problems Using Smartphone Based Algorithms in Trans- Nzoia County, Kenya: A Cluster Randomised Controlled Trial".

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 3025*** on 31st May, 2018. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; hence will expire on 30th May, 2019. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date. You will be required to submit progress report(s) on application for continuation, at the end of the study and any other times as may be recommended by the Committee.

Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. You will also be required to seek further clearance from any other regulatory body/authority that may be appropriate and applicable to the conduct of this study.

Sincerely,

[redacted]

DR. S. NYABERA
DEPUTY-CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc: CEO - MTRH; Dean - SOP; Dean - SOM
Principal - CHS; Dean - SON; Dean - SOD

Appendix 16: Evidence for ethical approval by LSHTM for the Community Eye Health study

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
United Kingdom
Switchboard: +44 (0)20 7636 8636
www.lshtm.ac.uk

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

Observational / Interventional Research Ethics Committee

Dr Hillary Rono
LSHTM

9 May 2018

Dear Hillary ,

Study Title: Community screening and referral for eye problems using smartphone based algorithms in Trans Nzoia County, Kenya: a cluster randomized controlled trial.

LSHTM ethics ref: 14633

Thank you for your application for the above research, which has now been considered by the Interventional Committee.

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, 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	ETHICS Certificate of Completion	20/08/2014	version 1
Investigator CV	CV_Andrew Bastawrous_September 2017	07/09/2017	1.1
Other	GCP_GCP Certificate_rone	02/12/2017	1
Investigator CV	Matthew Burton - Short CV - 2018	28/02/2018	1
Investigator CV	CV RONO_ FEB_2018	06/03/2018	1
Safety Information	peek acuity technical summary	07/03/2018	1
Safety Information	User Requirement Specification	07/03/2018	1
Sponsor Letter	2018-IDEP-081_Sponsor confirmation_14-03-18	14/03/2018	1
Protocol / Proposal	1. Protocol - v1 - 20MAR2018	20/03/2018	1
Protocol / Proposal	3. Data collection forms - v1 - 20MAR2018	20/03/2018	1
Information Sheet	2. Participant Information and Consent Form - v1 - 20MAR2018	20/03/2018	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 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://ethics.lshtm.ac.uk

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,

[redacted]

Appendix 17: Evidence for the registration of the school eye health trial in the Pan African Clinical Trial Registry

SOUTH AFRICAN COCHRANE CENTRE

31 March 2015

To Whom It May Concern:

RE: Smartphone vision testing of school children in Transzoia county, Kenya. A randomized controlled Trial.

As project manager for the Pan African Clinical Trial Registry (www.pactr.org) database, it is my pleasure to inform you that your application to our registry has been accepted. Your unique identification number for the registry is **PACTR201503001049236**

Please be advised that you are responsible for updating your trial, or for informing us of changes to your trial.

Additionally, please provide us with copies of your ethical clearance letters as we must have these on file (via email, post or fax) at your earliest convenience if you have not already done so.

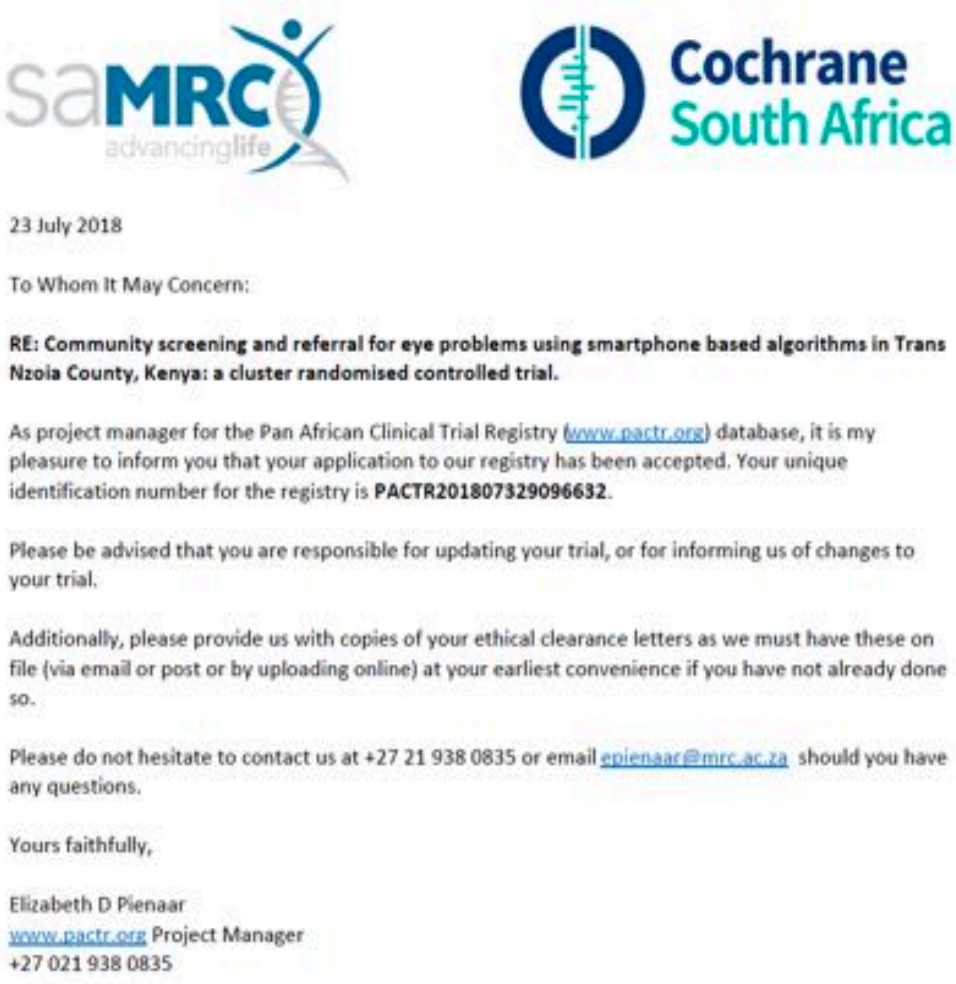
Please do not hesitate to contact us at +27 21 938 0835 or email epienaar@mrc.ac.za should you have any questions.

Yours faithfully,

Elizabeth D Pienaar
www.pactr.org Project Manager
+27 021 938 0835

PACTR

Appendix 18: Evidence for the registration of the Community eye health trial in the Pan African Clinical Trial Registry



23 July 2018

To Whom It May Concern:

RE: Community screening and referral for eye problems using smartphone based algorithms in Trans Nzoia County, Kenya: a cluster randomised controlled trial.

As project manager for the Pan African Clinical Trial Registry (www.pactr.org) database, it is my pleasure to inform you that your application to our registry has been accepted. Your unique identification number for the registry is **PACTR201807329096632**.

Please be advised that you are responsible for updating your trial, or for informing us of changes to your trial.

Additionally, please provide us with copies of your ethical clearance letters as we must have these on file (via email or post or by uploading online) at your earliest convenience if you have not already done so.

Please do not hesitate to contact us at +27 21 938 0835 or email epienaar@mrc.ac.za should you have any questions.

Yours faithfully,

Elizabeth D Pienaar
www.pactr.org Project Manager
+27 021 938 0835